

**ICMRA COVID-19 Vaccines Pharmacovigilance Network (VPN)**

Meeting #20 - Tuesday 3 August, 2021

New Zealand (UTC+13)	AEDT (UTC+11)	Japan and Korea (UTC+9)	India (UTC+5:30)	Europe (UTC+1)	UK and Ireland (UTC)	Canada and USA (UTC-5)
11:00 PM	9:00 PM	8:00 PM	4:30 PM	1:00 PM	12:00 Noon	7:00 AM

**Meeting report - DRAFT**

31 members attended from across 15 regulatory agencies in: Australia (TGA), Canada (HC); Europe (EMA); India (CDSCO); Ireland (HPRA), Israel (MOH); Japan (MHLW/PMDA), Korea (MFDS), New Zealand (Medsafe), Saudi Arabia (SFDA), Singapore (HSA), Spain (AEMPS); Switzerland (Swissmedic), United Kingdom (MHRA), United States of America (US FDA), and World Health Organisation (WHO).

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**Summary:**

Round table discussion of emerging safety profiles and highlights of public communications s22

s22 s33 s33 s22

s22

. AEMPS said menstrual disorders currently has media and public attention. s22

## Record of Discussion

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### 3. Emerging Safety Profiles and highlights of public communications

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**Spain (AEMPS):**

- Menstrual disorders and COVID-19 vaccines have been a hot topic in Spain and there is still a lot of media and public attention on this.
- **MHRA** noted the UK press were also interested in this topic, but no signal had emerged.

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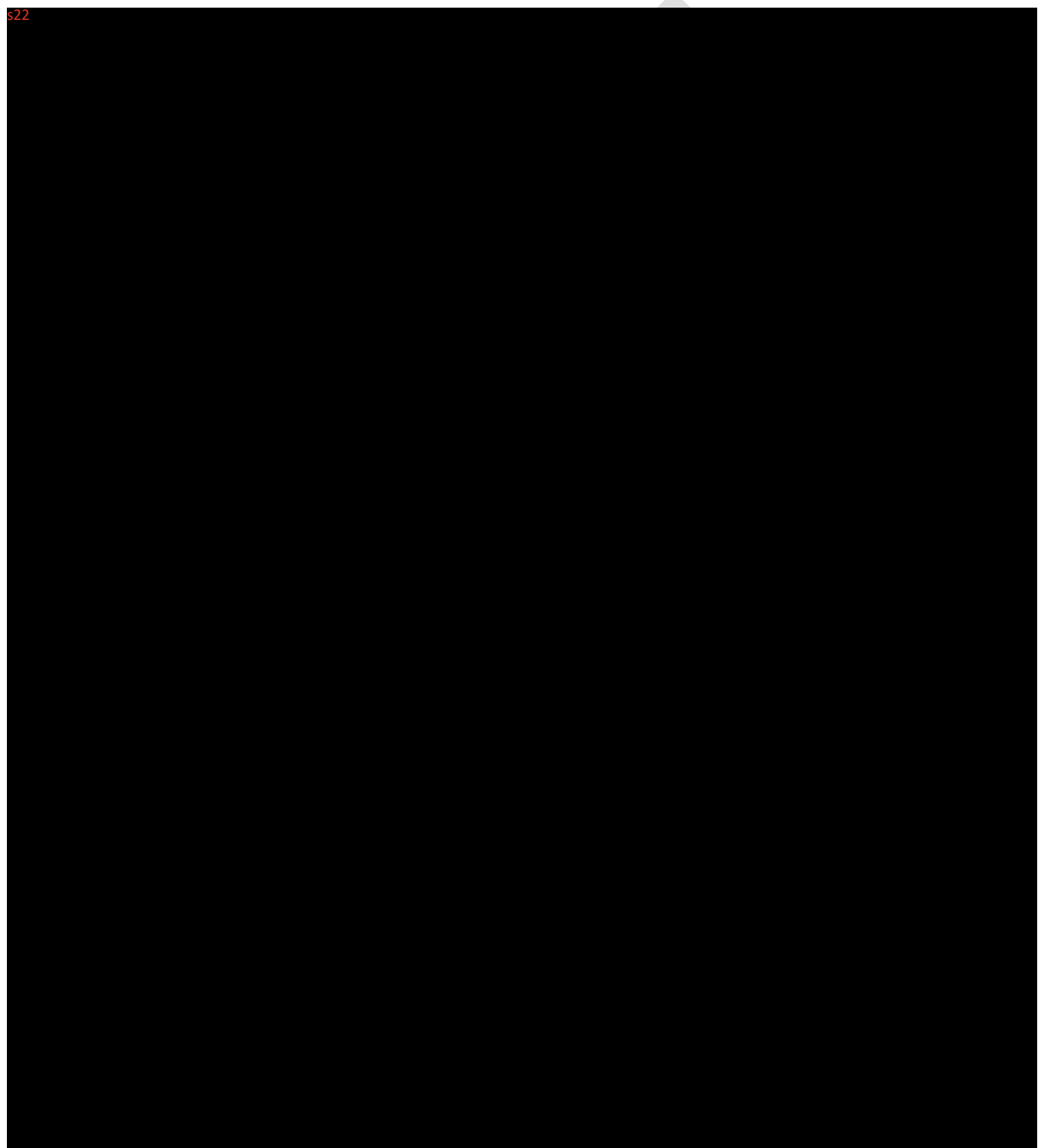


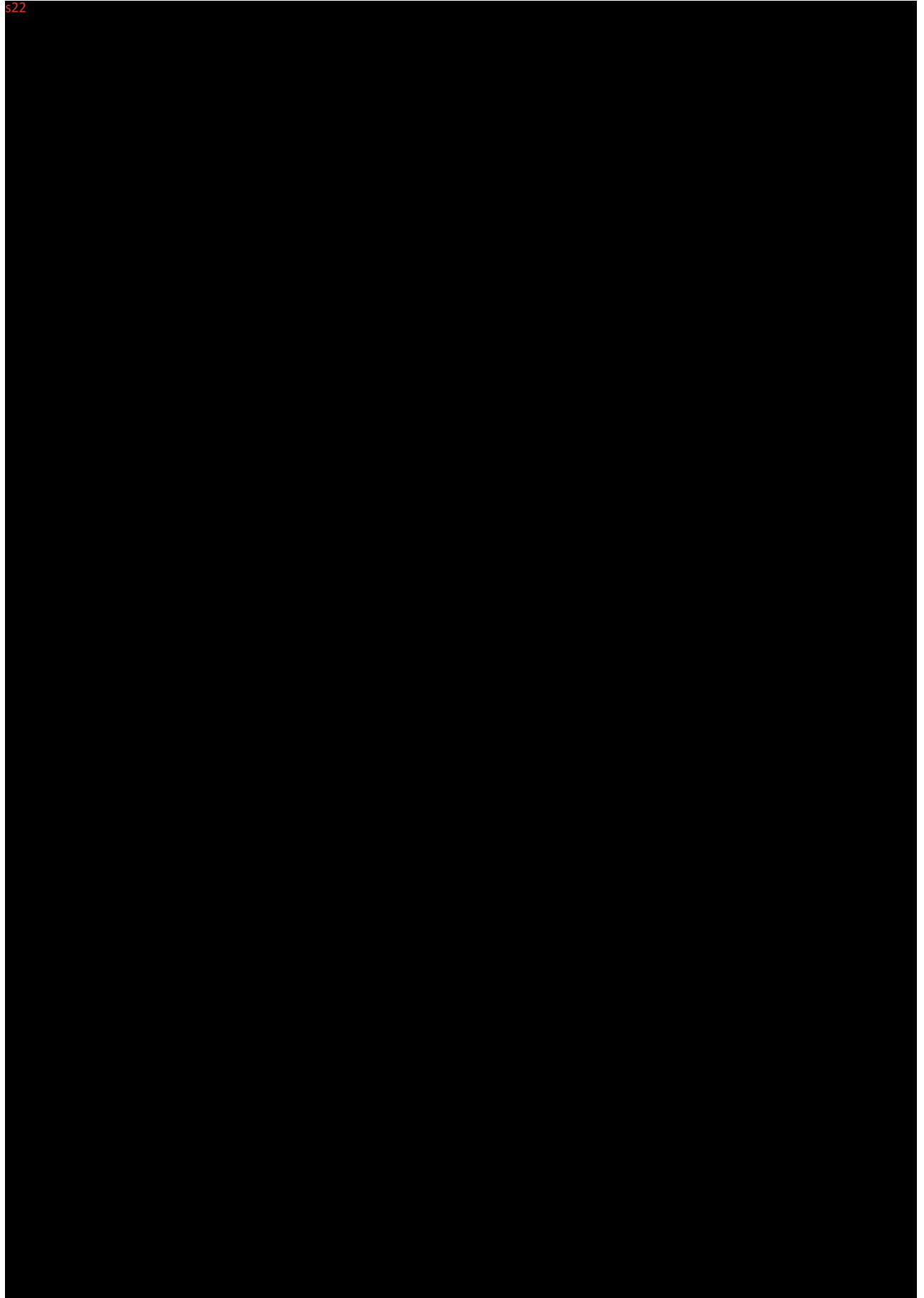
Ireland (HPRA):

- s22

. There is interest around menstrual disorders with a few cases of post-menopausal bleeding reported.

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**Australian Government**  
**Department of Health**

**Surveillance and Targeted Review  
Stream (STRS) – Targeted Investigation  
Process (TIP) for vaccines**

**Medicines and Vaccines Investigation  
and Surveillance Section**

TRIM reference:

[D21-2947788](#)

**Vaxzevria (previously COVID-19 Vaccine AstraZeneca) ChAdOx1-S and Comirnaty (BNT162b2[mRNA]) COVID-19 vaccine and menstrual disorders.**

<b>Evaluator</b>	s22
<b>Date and Time completed</b>	20/08/2021 2:00 PM

**Summary**

This issue was identified in a disproportionality analysis (DPAR) run on data for the period March-June 2021, where the vaccine event pairs Comirnaty (BNT162b2) [mRNA] COVID-19 vaccine (PF) and several of the MedDRA preferred terms (PT) that describe menstrual bleeding disorders and Vaxzevria (previously COVID-19 Vaccine AstraZeneca) ChAdOx1-S (AZ) and postmenopausal haemorrhage flagged.

Menstrual irregularities occur in an estimated 14% to 25% of women of childbearing age. During the reproductive years, vaginal bleeding may be abnormal when menstrual periods are too heavy or too light, last too long, occur too often, or are irregular. Any vaginal bleeding that occurs before puberty or after menopause is considered abnormal until proven otherwise. Many things can cause irregular periods including: changing contraceptive methods; medications including antihypertensives, antiepileptics; lifestyle, including stress, extreme changes to weight, excessive exercise; polycystic ovary syndrome; hyperthyroidism or hypothyroidism; thickening of or polyps on the uterine lining; and uterine fibroids or malignancy.

There are 149 reports of menstrual disorders following AZ and 298 following PF in the TGA's Adverse Event Management System (AEMS) up to 7 August 2021. No fatal outcomes have been reported.

The reporting rate for females of all ages for AZ is 3.48 per 100,000 doses and for PF it's 7.13 per 100,000 doses. The reporting rate for premenopausal women for AZ is 19.4 per 100,000 doses and for PF it's 8.74 per 100,000. The reporting rate for menopausal and postmenopausal women for AZ is 1.43 per 100,000 doses and for PF it's 2.21 per 100,000 doses.

A published study by Li, Chen et al that investigated if SARS-CoV-2 had an effect on ovarian reserve, sex hormones and menstruation of women of child-bearing age concluded that of the 237 patients with confirmed COVID-19 studied, nearly one-fifth of patients exhibited menstrual volume decrease or cycle prolongation, and that these changes were transient in nature.

Although there have been media articles in response to reports of menstrual disorders following COVID-19 vaccination, there is a lack of research literature, including published case studies, to support a causal association at this time.

This issue has been raised by international regulators in TGA's regular meetings with its international regulatory counterparts. The UK Medicines and Healthcare products Regulatory Agency (MHRA) is reviewing reports of suspected side effects menstrual disorders (period problems) and unexpected vaginal bleeding following vaccination against COVID-19 in the UK. These reports are also being reviewed by the independent

<p>experts of the Commission on Human Medicines' (CHM) COVID-19 Vaccines Benefit Risk Expert Working Group (EWG) and the Medicines for Women's Health Expert Advisory Group (MWHEAG). The rigorous evaluation completed to date does not support a link between changes to menstrual periods and related symptoms and COVID-19 vaccines.</p> <p>The European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) has requested that sponsors for all COVID-19 vaccines approved in the European Union provide further data as part of the monthly summary safety reports. The PRAC will review all available evidence, including reports of suspected adverse events and scientific literature, and will continue monitoring the issue.</p> <p>The most recent Sponsor Monthly Safety Summary Report (MSSR) for AZ analysing data from 1 June to 30 June 2021 includes a cumulative review of menstrual disorders which concluded that the majority of the reports were not medically confirmed and that the qualitative review of the 106 serious, medically confirmed cases of menstrual disorders (out of a total of 8115 case reports) did not suggest a causal association between the AZ vaccine and menstrual disorders.</p> <p>The MSSR for PF analysing data from 1 June to 30 June 2021 does not review menstrual disorders but notes that menstrual disorders are under review for inclusion in PSUR #1 as requested by EMA. The PSUR is due to the TGA in September 2021.</p> <p>Menstrual disorders are not described in the Australian or international Product Information (PI) for AZ or PF.</p> <p>It is the recommendation of this review that the TGA continue to monitor menstrual disorders and the COVID-19 vaccinations through routine pharmacovigilance processes, including the review of the PF PSUR which is due to the TGA in September 2021, environmental scanning of published literature and the findings from other regulators.</p>
<b>Delegates' Comment</b>
<p><b>The Delegate endorses the recommendations outline (unchanged) at the Mavis / Vera update on 23 August 2021</b></p>
<b>Recommendations</b>
<p><b>It is the recommendation of this review that the TGA continue routine pharmacovigilance monitoring.</b></p> <p><b>The TGA will monitor the reviews currently being undertaken by the MHRA and the EMA PRAC.</b></p> <p><b>The TGA will review the information to be provided in the PF PSUR which is due to the TGA in September 2021.</b></p>
<b>Priority</b>
<b>Medium</b>

**DISCLAIMER: The purpose of this report is to provide a targeted assessment (at a point in time) of the described vaccine-event pair to assist with triage of workflow. It does not constitute a full evaluation nor a regulatory decision.**

## 1. List of abbreviations

Abbreviation	Meaning
ACCESS	Australia-Canada-Singapore-Switzerland-United Kingdom (consortium)
ADR/AE	Adverse Drug Reaction / Adverse Event
AEFI	Adverse Event Following Immunisation
AEMS	Adverse Event Management System
AESI	Adverse Event of Special Interest
AIR	Australian Immunisation Register
ARTG	Australian Register of Therapeutic Goods
ATAGI	Australian Technical Advisory Group on Immunisation
ATC	Anatomical Therapeutic Chemical (classification system)
AZ	VAXZEVRIA (previously COVID-19 Vaccine AstraZeneca (ChAdOx1-S))
CMI	Consumer Medicine Information
COVID-19	Coronavirus disease 2019
DHCPL	Dear Healthcare Professional Letter
EMA	European Medicines Agency (European Union)
FDA	Food and Drug Administration (United States)
GACVS	Global Advisory Committee on Vaccine Safety
IC	Information Component
ICMRA	International Coalition of Medicines Regulatory Authorities
IPMST	International Post Market Surveillance Teleconference
MaVIS	Medicines and Vaccines Investigation and Surveillance
MedDRA	Medical Dictionary for Regulatory Activities
MHRA	Medicines and Healthcare Products Regulatory Agency (United Kingdom)
MSSR	Monthly Safety Summary Report
MSU	Medicines Safety Update
NCIRS	National Centre for Immunisation Research and Surveillance
O/E	Observed vs. Expected (analysis)

PF	COMIRNATY (BNT162b2 [mRNA]) COVID-19 Vaccine Pfizer
PI	Product Information
PRAC	Pharmacovigilance Risk Assessment Committee
PRR	Proportional Reporting Ratio
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
RMP	Risk Management Plan
ROS	Regulatory Outcomes Stream
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SPC/SmPC	Summary of Product Characteristics
STRS	Surveillance and Targeted Review Stream
TIP	Targeted Investigation Process
VSIG	Vaccine Safety Investigation Group
WHO-UMC	World Health Organisation – Uppsala Monitoring Centre

## 2. Vaccine information

Indication(s)	<p>VAXZEVRIA (previously COVID-19 Vaccine AstraZeneca (ChAdOx1-S)) (AZ): Provisional approval for active immunisation of individual <math>\geq 18</math> years old for the prevention of COVID-19 caused by SARS-CoV-2.</p> <p>COMIRNATY (BNT162b2 [mRNA]) COVID-19 Vaccine Pfizer (PF): Provisional approval for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older.</p>
Vaccine roll-out status	<p>COVID-19 vaccine, information on eligible groups throughout each phase of the roll-out is located here: <a href="https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/getting-vaccinated-for-covid-19/when-will-i-get-a-covid-19-vaccine#eligibility-for-the-covid19-vaccine">https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/getting-vaccinated-for-covid-19/when-will-i-get-a-covid-19-vaccine#eligibility-for-the-covid19-vaccine</a></p> <p><b>Information available on 13 August 2021:</b></p> <p><u>Eligibility for the Pfizer COVID-19 vaccine</u></p> <p>You are eligible for the Pfizer vaccine if you are 40 to 59 years of age.</p> <p>You are also eligible for the Pfizer vaccine if you are <a href="#">aged 16 to 39</a> and you are:</p> <ul style="list-style-type: none"> <li>• an Aboriginal and Torres Strait Islander person aged 16 and over</li> <li>• an NDIS participant or unpaid or informal carers of NDIS participants of any age</li> <li>• pregnant</li> <li>• a quarantine or border worker</li> <li>• a health care worker</li> <li>• and aged care or disability care resident or worker</li> <li>• a person with an underlying medical condition or significant disability</li> <li>• a critical or high-risk worker including defence, police, fire, emergency services and meat processing</li> </ul>

	<ul style="list-style-type: none"> <li>• a person with an Australian Border Force <a href="#">outwards travel exemption</a> in an eligible category</li> <li>• a temporary visa holder who is currently in Australia and has been approved for return travel to Australia through the travel exemption process.</li> </ul> <p>The evaluator notes that the Australian Government announced on 19 August 2021 that all people 16 years and older will be eligible to receive the Pfizer vaccine from 30 August 2021.</p> <p><u>Eligibility for the AstraZeneca COVID-19 vaccine</u></p> <p>You are eligible for the AstraZeneca vaccine if you are aged 60 years or older. If you are aged 18-59 years of age, you can choose to receive the AstraZeneca vaccine:</p> <ul style="list-style-type: none"> <li>• following an appropriate assessment of suitability by a qualified health professional; and</li> <li>• if you provide verbal or written consent.</li> </ul> <p>Some states and territories will amend their eligibility based on their COVID-19 situation and vaccine supply and uptake.</p> <p>The ATAGI COVID-19 vaccine clinical guidance 2021 version 6.0 was last updated on 30 July 2021 [TRIM <a href="#">D21-2928516</a>]  <a href="http://www.health.gov.au/resources/publications/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021">www.health.gov.au/resources/publications/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021</a></p> <p>Comirnaty is preferred over COVID-19 Vaccine AstraZeneca in people aged &lt; 60 years. This is based on the higher risk and observed severity of thrombosis and thrombocytopenia syndrome (TTS) in people &lt; 60 years compared to those ≥ 60. However, COVID-19 Vaccine AstraZeneca can be used in adults aged &lt; 60 years if Comirnaty if the person has made an informed decision based on an understanding of the risks and benefits. In outbreak settings, adults &lt;60 years of age should strongly consider COVID-19 Vaccine AstraZeneca if they are unable to access Comirnaty.</p> <p>Comirnaty is also the recommended vaccine for pregnant women. Pregnant women who have already received a first dose of COVID-19 Vaccine AstraZeneca can receive either Comirnaty or COVID-19 Vaccine AstraZeneca for their second dose, although Comirnaty is preferred.</p> <p>Comirnaty is recommended for children aged 12-15 years with medical conditions that increase their risk of severe illness; all Aboriginal and Torres Strait Islander children aged 12-15 and all children aged 12-15 years in remote communities as part of outreach vaccination programs.</p>
<b>Mechanism of action</b>	<p>VAXZEVRIA (previously COVID-19 Vaccine AstraZeneca (ChAdOx1-S)) is a recombinant replication-defective chimpanzee adenovirus ChAdOx1, carrying a gene encoding the SARS-CoV-2 spike (S) surface glycoprotein. Following administration, the S glycoprotein is expressed locally, stimulating neutralising antibody and cellular immune responses.</p> <p>COMIRNATY (BNT162b2 [mRNA]) COVID-19 Vaccine Pfizer comprises a nucleoside-modified messenger RNA (mRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2. The RNA is encapsulated in lipid nanoparticles (LNPs), which enables entry into host cells, expression of the S protein, and elicitation of both antibody and cellular immune responses.</p>



### 3. Adverse event information

Signal Source	This issue was identified in a disproportionality analysis (DPAR) run on data for the period March-June 2021, where the vaccine event pairs COMIRNATY and several of the MedDRA preferred terms (PTs) that describe menstrual bleeding disorders and VAXZEVRIA (previously COVID-19 Vaccine AstraZeneca) and Postmenopausal Haemorrhage flagged and was referred for a Targeted Review on 5 August 2021. [TRIM <a href="#">D21-2951314</a> ].																												
AESI status	Menstrual bleeding disorders are not currently listed as adverse events of special interest.  The current AESI list for COVID-19 is located at TRIM <a href="#">D20-3595626</a> .																												
AEFI	<p>Menstrual irregularities occur in an estimated 14% to 25% of women of childbearing age<sup>1</sup>. During the reproductive years, vaginal bleeding may be abnormal when menstrual periods are too heavy or too light, last too long, occur too often, or are irregular. Any vaginal bleeding that occurs before puberty or after menopause is considered abnormal until proven otherwise. Many things can cause irregular periods including:</p> <ul style="list-style-type: none"><li>• Changing contraceptive methods</li><li>• Medications including antihypertensives, antiepileptics</li><li>• Lifestyle, including stress, extreme changes to weight, excessive exercise,</li><li>• Polycystic ovary syndrome</li><li>• Hyperthyroidism or hypothyroidism</li><li>• Thickening of or polyps on the uterine lining</li><li>• Uterine fibroids or malignancy.</li></ul> <p>There are potentially more long terms risks to health depending on the particular menstrual disorder experienced. For example, untreated menorrhagia (heavy menstrual bleeding) affects about one in five women and is a common problem in the 30-50 year age group<sup>2</sup>. It is a common cause of iron deficiency anaemia in females.<sup>3</sup> It negatively affects quality of life and is associated with financial loss, decreased productivity, poor health (including stress and anxiety), and increased use of health care resources<sup>4</sup>. The most common cause of postmenopausal bleeding is endometriosis, however 10% of women with postmenopausal bleeding will be found to have endometrial cancer. In these cases postmenopausal bleeding is an early warning sign that leads women to seek medical advice.<sup>5</sup></p>																												
Magnitude of signal	<p><u>TGA DPAR</u></p> <p>The MedDRA preferred terms (PT) for the PF and AZ vaccines flagged in the March to June 2021 DPAR which is filed at <a href="#">D21-2947984</a>:</p> <table><tr><th>Vaccine</th><th>PT</th><th>Number of cases</th><th>PRR</th><th>PRR LCI</th><th>IC</th><th>IC LCI</th></tr><tr><td>PF</td><td>Amenorrhoea</td><td>5</td><td>4.19</td><td>1.40</td><td>1.36</td><td>-0.20</td></tr><tr><td>PF</td><td>Dysmenorrhoea</td><td>13</td><td>7.54</td><td>3.50</td><td>1.93</td><td>0.99</td></tr><tr><td>PF</td><td>Heavy menstrual bleeding</td><td>26</td><td>4.67</td><td>2.86</td><td>1.65</td><td>0.99</td></tr></table>	Vaccine	PT	Number of cases	PRR	PRR LCI	IC	IC LCI	PF	Amenorrhoea	5	4.19	1.40	1.36	-0.20	PF	Dysmenorrhoea	13	7.54	3.50	1.93	0.99	PF	Heavy menstrual bleeding	26	4.67	2.86	1.65	0.99
Vaccine	PT	Number of cases	PRR	PRR LCI	IC	IC LCI																							
PF	Amenorrhoea	5	4.19	1.40	1.36	-0.20																							
PF	Dysmenorrhoea	13	7.54	3.50	1.93	0.99																							
PF	Heavy menstrual bleeding	26	4.67	2.86	1.65	0.99																							

<sup>1</sup> Whitaker, L., & Critchley, H. O. D. (2016). Abnormal uterine bleeding. *Best Practice & Research Clinical Obstetrics & Gynaecology*, 34, 54–65. Retrieved December 2, 2016, from <http://www.sciencedirect.com/science/article/pii/S1521693415002266> [TRIM [D21-2995095](#)]

<sup>2</sup> Jean Hailes Heavy Menstrual Bleeding – fact sheet – updated May 2019  
[https://assets.jeanhailes.org.au/heavy\\_menstrual\\_bleeding.pdf?ga=2.70192912.1846493863.1629424949-62988700.1628555415](https://assets.jeanhailes.org.au/heavy_menstrual_bleeding.pdf?ga=2.70192912.1846493863.1629424949-62988700.1628555415) [TRIM [D21-2998523](#)]

<sup>3</sup> Apgar BS, Kaufman AH, George-Nwogu U, Kittendorf A. Treatment of menorrhagia. *Am Fam Physician*. 2007 Jun 15;75(12):1813-9. PMID: 17619523. [TRIM [D21-2997473](#)]

<sup>4</sup> Wouk N, Helton M. Abnormal Uterine Bleeding in Premenopausal Women. *Am Fam Physician*. 2019 Apr 1;99(7):435-443. PMID: 30932448. [TRIM [D21-2997572](#)]

<sup>5</sup> Brand AH, The woman with postmenopausal bleeding. *Aust. Fam Physician*. 007 March Vol. 36, No. 3. [TRIM [D21-2999928](#)]

PF	Intermenstrual bleeding	14	21.12	7.61	2.41	1.51
PF	Menstrual disorder	28	7.81	4.61	2.04	1.41
PF	Menstruation delayed	3	11.32	1.89	1.169	-0.38
PF	Menstruation irregular	21	7.92	4.30	2.02	1.29
PF	Polymenorrhoea	12	18.11	6.38	2.33	1.35
AZ	Postmenopausal haemorrhage	9	13.21	2.85	1.53	0.39

Total TGA vaccine reporting rates of all Menstrual Disorder PTs for females of all ages up to 17 August 2021

Following a search on MedDRA a list of 18 preferred terms (PTs) were identified to describe a range of menstrual bleeding and menstrual cycle disorders [TRIM [D21-2984709](#)].

MedDRA Preferred Terms	Definitions – where needed
Heavy menstrual bleeding	Excessive menstrual blood loss which interferes with a woman's physical, social, emotional and/or material quality of life
Menometrorrhagia	Excessive uterine bleeding, both at the usual time of menstrual periods and at other irregular intervals
Polymenorrhagia	Excessive or frequent menstruation
Polymenorrhoea	Menstrual cycle that is shorter than 21 days
Menstrual discomfort	
Amenorrhoea	An abnormal absence of menstruation
Hypomenorrhoea	Decreased menstrual flow
Menstruation delayed	
Oligomenorrhoea	Irregular and inconsistent menstrual blood flow
Retrograde menstruation	Menstrual flow moves in the wrong direction
Premenstrual syndrome	Physical and emotional symptoms that some women experience in the lead up to menstruation.
Premenstrual pain	
Menstruation irregular	
Menstrual disorder	
Intermenstrual bleeding	Vaginal bleeding at any time during the menstrual cycle other than during normal menstruation.
Dysmenorrhoea	Painful, cramping sensation in the lower abdomen or back associated with menstrual periods
Abnormal uterine bleeding	
Postmenopausal haemorrhage	Vaginal bleeding after menstrual cycles have ceased due to menopause.

The number of doses is taken from the Australian Immunisation Register (AIR) which was pulled from QLIK on 18 August 2021 - data up to 17 August 2021 [TRIM: [D21-2989880](#)].

The number of AEFI reports received by the TGA and entered into the TGA's Adverse Event Management System (AEMS) was pulled from QLIK 18 August 2021 – data up to 17 August 2021 [TRIM: [D21-2989919](#)]

There are 149 reports of menstrual disorders following AZ and 298 following PF in the TGA's Adverse Event Management System (AEMS) up to 7 August 2021.

	Vaccine	Number of Doses	Number of Reports	Reporting Rate per 100,000 doses						
	AZ	4,280,361	149	3.48 per 100,000						
	PF	4,181,727	298	7.13 per 100,000						
<u>TGA reporting rates for females above and below 50 years of age.</u> The age range is used to show the potential differences between pre- and post- menopausal women reporting rates. The average age of menopause for women in Australia is 51-52 years <sup>6</sup> .										
	Vaccine	Age Range	Number of Doses*	Number of Reports**	Reporting Rate per 100,000 doses					
	AZ	<50 years	417,752	81	19.4 per 100,000					
		≥50 years	3,683,609	53	1.43 per 100,000					
	PF	<50 years	2,825,918	247	8.74 per 100,000					
≥50 years		1,355,806	30	2.21 per 100,000						
*excludes doses when the age was not provided – 3 doses of PZ										
** excludes reports when the age was not provided – 15 reports for AZ and 21reports for PZ										
No. of AEFI reports	A Qlik search was conducted on 17 August 2021 using the default bookmark, the tradenames PF and AZ, and the 18 PTs identified in the MedDRA search.									
	The search for PF vaccine identified 298 case reports. The PCDs for the PF vaccine [TRIM <a href="#">D21-2985322</a> ].									
	The search for the AZ vaccine identified 150 case reports. The PCDs for AZ vaccine [TRIM <a href="#">D21-2985370</a> ].									
	<u>A comparison of the numbers of PTs reported by vaccine. Note that more than one PT can be reported in each report</u>									
	Adverse Event PT		AZ vaccine		PF Vaccine					
	Menstrual disorder		60		170					
	Heavy Menstrual Bleeding		50		74					
	Menstruation Irregular		20		59					
	Intermenstrual bleeding		14		44					
	Dysmenorrhoea		12		31					
	Polymenorrhoea		6		17					
	Menstruation delayed		2		12					
	Postmenopausal haemorrhage		20		11					
	Amenorrhoea		3		7					
	Oligomenorrhoea		4		6					
	Hypomenorrhoea		-		2					
	Menstrual discomfort		1		1					
	Premenstrual pain		-		1					
	Abnormal uterine bleeding		1		-					
	Menometrorrhagia		1		-					
	Premenstrual syndrome		1							
<u>A comparison of the number of reports submitted by age group for each vaccine</u>										
	18-44 years		45-64		65-74		75 and above		Unknown	
Vaccine	AZ	Pfizer	AZ	Pfizer	AZ	Pfizer	AZ	Pfizer	AZ	Pfizer
Number of Reports	58	199	71	77	6	1	-	1	15	19
	39%	68%	47%	26%	4%	0.3%		0.3%	10%	6%

<sup>6</sup> Jean Hailes Menopause – fact sheet – updated September 2018

<https://www.jeanhailes.org.au/resources/menopause-fact-sheet> TRIM [D21-2989287](#)

**The management of events reported for the AZ and PF Vaccines**

Management of events reported	AZ Vaccine (150 reports)	PF vaccine (298 reports)
Hospital Admission	NIL	5 cases (1.7%)
ED	5 cases (3.3%)	10 cases (3.4%)
GP or Nurse	25 cases (16.7%)	64 cases (21.5%)
Advice from Helpline or Self	44 cases (29.3%)	87 cases (29.2%)
Not reported (unknown)	76 cases (50.7%)	138 cases (46.3%)

**The outcome of events reported for the AZ and PF vaccines**

Outcome reported at time of reporting	AZ Vaccine (150 reports)	PF vaccine (298 reports)
Recovered / resolved	37 cases (24.7%)	67 cases (22.5%)
Recovering / resolving	20 cases (13.3%)	27 cases (9.1%)
Not recovered / not resolved / ongoing	65 cases (43.3%)	145 cases (48.7%)
Resolved with sequelae	NIL	1 case (0.34%)
Unknown / Not reported	28 cases (18.7%)	58 cases (19.5%)
No fatal outcomes were reported with either vaccine		

**AEFI by dosage and vaccine administered**

More AEFIs were reported following the first dose of both vaccines. However, there are many reports where the dose number was not provided.

Doses	AZ Vaccine	PF Vaccine
First dose	82	108
Second dose	9	88
Unknown	59	102
Total	150	298

**Summary of AEFI reports**

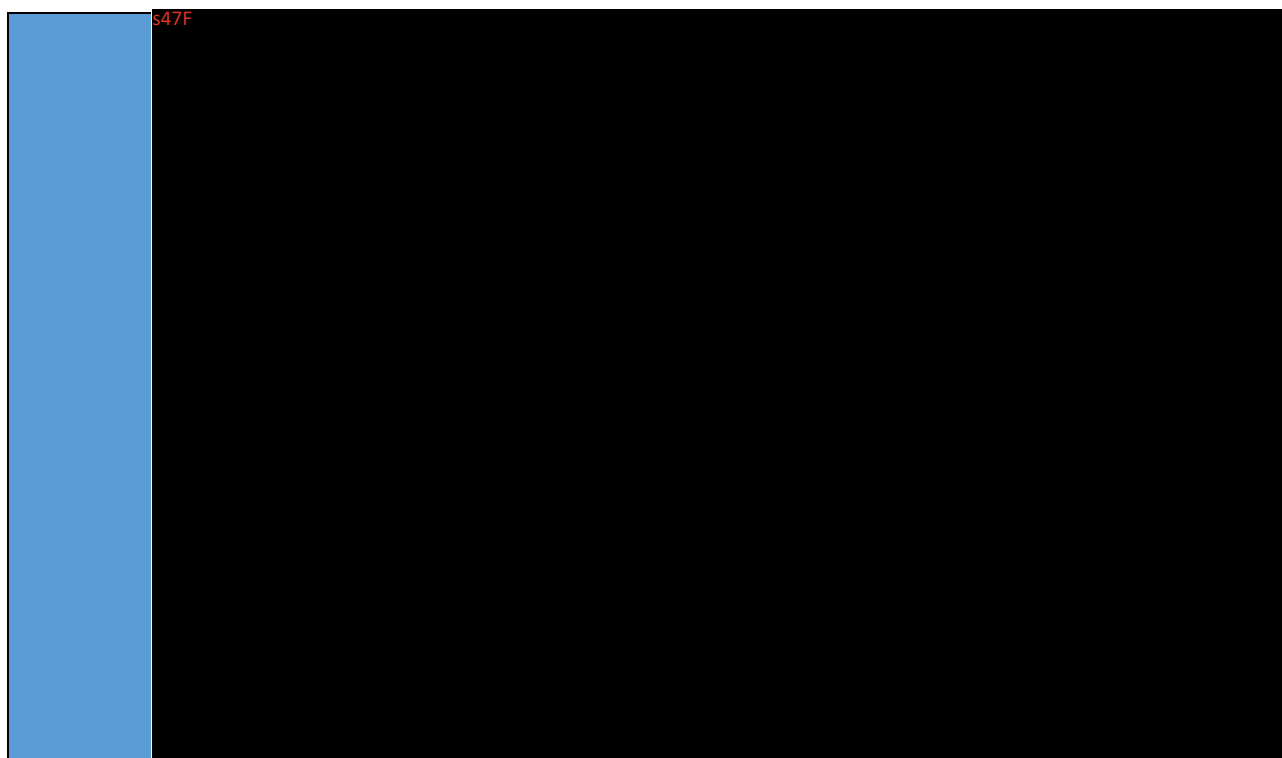
A total of 448 AEFI reports have been received by the TGA of which 150 are for the AZ vaccine and 298 are for the PF vaccine.

A high-level review of the reports was conducted due to the large number of reports identified in the QLIK search. 18 MedDRA PTs been used to identify relevant reports for this review which covers a very broad range of menstrual disorders with varying causalities that traverse a wide range of age groups. Many have the reports include more than one PT.

A more detailed review of the reports including recoding as necessary would potentially reduce the large number of reports coded as 'menstrual disorder' and provide a more accurate description of the AEFI.

The review of the five cases that reported hospitalisation with the PF vaccine identifies two cases of low platelets which, although potentially-vaccine related, belong in the Immune Thrombocytopenia (ITP)/ thrombocytopenia review. There was one report of a mass in the uterus (which 40 hours post-vaccination is unlikely related to the vaccine), and one report where the patient is experiencing more complex neurological symptoms.

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#### 4. Regulatory surveillance

Local, including:	Product Information (PI)
PI, Sponsor's PSUR/MSSR, and applicable clinical guidance	<p>The Australian Product Information (PI) – PF version: pfpcovii10721 was revised on 22 July 2021 [TRIM <a href="#">D21-2963561</a>]. Menstrual bleeding disorders are not described in the Australian PI.</p>
	<p>The Australian PI - AZ version: Doc ID-004490138 v6 was revised on 14 July 2021 [TRIM <a href="#">D21-2963623</a>]. Menstrual bleeding disorders are not described in the Australian PI.</p>
	<p>The Australian PI – Spikevax (Elasomeran) version 1.0 was approved on 9 August 2021 [TRIM <a href="#">D21-2980134</a>]. Menstrual bleeding disorders are not described in the Australian PI.</p>
	Applicable clinical guidance
	<p>The ATAGI COVID-19 vaccine clinical guidance 2021vesion 6.0 is located at: <a href="http://www.health.gov.au/resources/publications/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021">www.health.gov.au/resources/publications/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021</a></p> <p>The Guidance was last updated on 30 July 2021[TRIM <a href="#">D21-2963714</a>]. Menstrual bleeding disorders in relation to COVID-19 vaccines is not referenced in the Clinical Guidance document.</p>
	Sponsor's PSUR/MSSR
	<p>The AZ MSSR 1 June to 30 June 2021 [TRIM <a href="#">D21-2963765</a>].</p> <p>As requested by PRAC, a cumulative review of menstrual disorders is presented with a cut-off date of 28 June 2021. Since the medical concept of menstrual disorders covers a wide range of disorders, it was not considered feasible to establish the background rate and therefore observed versus expected analysis was not undertaken. The review concluded that the majority of the reports were not medically confirmed and that the qualitative review of the 106 serious, medically confirmed cases of menstrual disorders (out of a total of 8115 case reports) did not suggest a causal association between the AZ vaccine and menstrual disorders.</p>

	<p>The PF MSSR 1 June 20 30 June 2021 [TRIM <a href="#">D21-2964022</a>].</p> <p>The MSSR does not specifically review menstrual disorders but notes that Menstrual disorders are under review for inclusion in PSUR #1 as requested by EMA. This is due to the TGA in September 2021.</p>
US FDA	<b>Label</b>
	<p>The FDA's Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Emergency Use Authorization (EUA) of the Pfizer-Biontech Covid-19 Vaccine to prevent Coronavirus Disease 2019 (Covid-19) was revised on 25 June 2021 and is filed at <a href="#">D21-2964394</a>. Menstrual bleeding disorders are not listed in the FDA's Fact Sheet.</p> <p>The FDA's Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Emergency Use Authorization (EUA) of the Moderna Covid-19 Vaccine to prevent Coronavirus Disease 2019 (Covid-19) was revised on 24 June 2021 and is filed at <a href="#">D21-2982271</a></p>
	<b>Advisory Committee on Immunisation Practices (ACIP) CDC</b>
	<p>The Advisory Committee on Immunisation Practices (ACIP) CDC information does not include references to menstrual bleeding disorders in relation to COVID-19 vaccines.</p>
US National Institutes of Health (NIH)	<p>In May 2021, the <i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development (NICHD) released a notice of special interest for researchers to compare the menstruation experiences of vaccinated and unvaccinated people. NICHD will support research focused on menstruation before and after vaccination, how the vaccine affects menstruation, and the influence of other factors, such as stress, on these menstrual changes. The due date for the publication of the research is not provided in the announcement.[TRIM <a href="#">D21-2992159</a>].</p>
EU EMA	<b>Summary of Product Characteristics (SmPC)</b>
	<p>The Eu SmPC for Vaxzevria (AZ) was last revised on 19 July 2021 [TRIM <a href="#">D21-2979651</a>]. Menstrual bleeding disorders are not referenced in this document.</p> <p>The EU SmPC for Comirnaty (PF) was last updated 11 August 2021 (TRIM <a href="#">D21-2979887</a>). Menstrual bleeding disorders are not referenced in this document.</p> <p>The EuSmPC for Spikevax (previously COVID-19 vaccine Moderna) was last revised on 11 August 2021 [TRIM <a href="#">D21-2979768</a>]. Menstrual bleeding disorders are not referenced in this document.</p>
	<b>Pharmacovigilance Risk Assessment Committee (PRAC)</b>
	<p>Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 5 August 2021[TRIM <a href="#">D21-2979939</a>].</p> <p>The PRAC discussed reported cases of menstrual disorders occurring after vaccination against COVID-19.</p> <p>No causal association between COVID-19 vaccines and menstrual disorders has been established so far.</p> <p>Menstrual disorders are very common and can occur without an underlying medical condition. Causes can range from stress and tiredness to underlying medical conditions, such as fibroids and endometriosis. Women experiencing unexpected vaginal bleeding (e.g. in postmenopausal women) or who are concerned about prolonged or severe menstrual disturbances may want to seek medical advice.</p> <p>The marketing authorisation holders for all COVID-19 vaccines approved in the EU have been asked to provide further data as part of the monthly summary</p>

	safety reports. The PRAC will review all available evidence, including reports of suspected adverse events and scientific literature and will continue monitoring the issue.
UK MHRA	<b>Summary of Product Characteristics (SPC)</b>
	The UK SPC for Vaxzevria COVID-19 Vaccine (AZ) was last updated on 15 July 2021 [TRIM <a href="#">D21-2980077</a> ]. Menstrual bleeding disorders are not referenced in this document.
	The UK SPC for Comirnaty (PF) was last updated on 11 August 2021 [TRIM <a href="#">D21-2980291</a> ]. Menstrual bleeding disorders are not referenced in this document.
	The UK SPC for Moderna was last update on 10 August 2021. [TRIM <a href="#">D21-2980217</a> ]. Menstrual bleeding disorders are not referenced in this document
	<b>Yellow Card reporting / Relevant regulatory action</b>
	The MHRA Coronavirus vaccine – weekly summary of Yellow Card reporting was updated on 13 August 2021 and covers the period 9 December 2021 to 4 August 2021 [TRIM <a href="#">D21-2980345</a> ].
	The weekly report includes a report: <b>Menstrual disorders (period problems) and unexpected vaginal bleeding</b>
	<p>The MHRA is reviewing reports of suspected side effects menstrual disorders (period problems) and unexpected vaginal bleeding following vaccination against COVID-19 in the UK. These reports are also being reviewed by the independent experts of the Commission on Human Medicines' COVID-19 Vaccines Benefit Risk Expert Working Group and the Medicines for Women's Health Expert Advisory Group. The rigorous evaluation completed to date does not support a link between changes to menstrual periods and related symptoms and COVID-19 vaccines.</p> <p>A total of 30,304 reactions relating to a variety of menstrual disorders have been reported after all three of the COVID-19 vaccines including heavier than usual periods, delayed periods and unexpected vaginal bleeding. This is following approximately 44.8 million COVID-19 vaccine doses administered to women up to 4 August 2021. The number of reports of menstrual disorders and vaginal bleeding is low in relation to both the number of people who have received COVID-19 vaccines to date and how common menstrual disorders are generally.</p> <p>The menstrual changes reported are mostly transient in nature. There is no evidence to suggest that COVID-19 vaccines will affect fertility and your ability to have children.</p> <p>Whilst uncomfortable or distressing, period problems are extremely common and stressful life events can disrupt menstrual periods. Changes to the menstrual cycle have also been reported following infection with COVID-19 and in people affected by long-COVID. General advice about period problems and/or unexpected vaginal bleeding is available from the NHS website. It is important that anyone experiencing changes to their periods that are unusual for them, persist over time, or has any new vaginal bleeding after the menopause, following COVID-19 vaccination, should contact their doctor. Anyone presenting with menstrual disorders and/or unexpected vaginal bleeding following COVID-19 vaccination should be treated according to clinical guidelines for these conditions, as usual.</p> <p>The MHRA continues to closely review reports of suspected side effects of menstrual disorders and unexpected vaginal bleeding.</p> <p>On the 16 August 2021, the MHRA published <i>COVID-19 vaccines: updates for August 2021</i> which provides information relating to COVID-19 vaccines that has</p>



	<p>been published since the July 2021 issue of Drug Safety Update [TRIM <a href="#">D21-2982304</a>].</p> <p>The update includes information about the Review of reports involving menstrual disorders and unexpected vaginal bleeding.</p> <p><i>The MHRA is reviewing, with expert advice, reports of suspected side effects of menstrual disorders and unexpected vaginal bleeding following vaccination against COVID-19 in the UK.</i></p> <p><i>The rigorous evaluation completed to date does not support a link between changes to menstrual periods and related symptoms and COVID-19 vaccines. The number of reports of menstrual disorders and vaginal bleeding is low in relation to both the number of people who have received COVID-19 vaccines to date and how common menstrual disorders are generally. Details are included in the summary of Yellow Card reporting for the COVID-19 vaccines.</i></p> <p><i>The menstrual changes reported are mostly transient in nature. There is no evidence to suggest that COVID-19 vaccines will affect fertility and the ability to have children.</i></p> <p><i>It is important that anyone experiencing changes to their periods that are unusual for them, persist over time, or has any new vaginal bleeding after the menopause, following COVID-19 vaccination, should contact their doctor. Anyone presenting with menstrual disorders and/or unexpected vaginal bleeding following COVID-19 vaccination should be treated according to clinical guidelines for these conditions, as usual.</i></p> <p><i>The MHRA continues to closely review reports of suspected side effects of menstrual disorders and unexpected vaginal bleeding. As with any suspected side effects from the COVID-19 vaccines, please continue to report via the Yellow Card scheme. You can also encourage your patients to do the same.</i></p>
Health Canada	<p><b>Product Monograph</b></p> <p>The Health Canada Product Monograph for the Astrazeneca COVID-19 vaccine was last revised on 13 August 2021 [TRIM <a href="#">D21-2980410</a>]. Menstrual bleeding disorders are not referenced in this document.</p> <p>The Health Canada Product Monograph for the Pfizer-Biontech COVID-19 Vaccine (PF) was last revised on 4 August 2021 [TRIM <a href="#">D21-2980451</a>]. Menstrual bleeding disorders are not referenced in this document.</p> <p>The Health Canada Product Monograph for the COVID-19 vaccine Moderna was last revised on 30 June 2021 [TRIM <a href="#">D21-2980494</a>]. Menstrual bleeding disorders are not referenced in this document.</p> <p><b>Relevant regulatory action</b></p> <p>The Reported side effects following COVID-19 vaccination in Canada weekly report was last updated on 13 August 2021 with data up to and including 6 August 2021 [TRIM <a href="#">D21-2980509</a>]. Menstrual bleeding disorders are not referenced in this document.</p>
NZ Medsafe	<p><b>Datasheet</b></p> <p>The New Zealand Data Sheet for the COVID-19 Vaccine AstraZeneca was approved on 29 July 2021 [TRIM <a href="#">D21-2980556</a>]. Menstrual bleeding disorders are not referenced in this document.</p> <p>The New Zealand Data Sheet for the Comirnaty COVID-19 Vaccines was revised on 28 July 2021 [TRIM <a href="#">D21-2980574</a>]. Menstrual bleeding disorders are not referenced in this document.</p>



	Relevant regulatory action
Other international regulators (via ICMRA PV Network and ACCESS)	<p>The New Zealand Adverse Events following immunisation with COVID-19 vaccines: Safety Report was published on 11 August 2021 and includes data up to 24 July 2021 [TRIM <a href="#">D21-2980640</a>]. Menstrual disorders are listed as a safety signal that Medsafe will continue to monitor.</p> <p>At the International Coalition of Medicines Regulatory Authorities (ICMRA) COVID-19 Vaccines Pharmacovigilance Network (VPN) 3 August 2021 Meeting, Menstrual disorders and COVID-19 vaccines was briefly discussed [TRIM <a href="#">D21-2982753</a>].</p> <ul style="list-style-type: none"> <li>• The Spanish Agency of Medicines and Medical Products (AEMPS) reported that Menstrual disorders and COVID-19 vaccines have been a hot topic in Spain and that there was still a lot of media and public attention on this.</li> <li>• The MHRA noted that the UK press was interested in this topic, but no signal had emerged.</li> <li>• The Health Products Regulatory Authority (Ireland) reported that there is interest around menstrual disorders with a few cases of post-menopausal bleeding reported.</li> </ul> <p><u>GAVI, the Vaccine Alliance</u> On 11 June 2021, the GAVI published an article <i>Do COVID-19 vaccines affect menstruation and fertility?</i><sup>7</sup> The author notes that changes in menstrual cycles following COVID-19 vaccination have mainly been reported through social media and that there hasn't been any scientific study to understand the validity of these reports. The author refers to the UK's Yellow Card reporting system, that is encouraging women to report any changes in menstruation there to aid future research studies on a possible causal relationship. The author provides potential biological plausibility for menstrual changes following COVID-19 vaccination.</p>

## 5. Other information

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<sup>7</sup> Joi P. Do COVID-19 vaccines affect menstruation and fertility? 2021 June 11. <https://www.gavi.org/vaccineswork/do-covid-19-vaccines-affect-menstruation-and-fertility> [TRIM [D21-2998193](#)]

<b>Literature</b>	<p>A PubMed search for COVID-19 disease and menstrual disorders / abnormalities / irregularities identified the following article:</p> <p>Li, Chen et al <sup>8</sup>conducted a small study to identify if SARS-CoV-2 has an effect on ovarian reserve, sex hormones and menstruation of women of child-bearing age. Of the 237 patient's with confirmed COVID-19, the study concluded that nearly one-fifth of patients exhibited menstrual volume decrease or cycle prolongation and that these changes were transient in nature.</p> <p>A PubMed search for COVID-19 vaccines and menstrual disorders / abnormalities / irregularities did not identify any research articles.</p> <p>Although there have been media articles in response to reports of menstrual disorders following COVID-19 vaccination, there is a lack of research literature including published case studies to support a causal association at this time.</p>
<b>Biological plausibility</b>	<p>The HPV (human papillomavirus) vaccine and the flu vaccine have been reported to affect menstrual cycles temporarily but there is no evidence that these affect fertility. Immune cells are at work in the creating and then breaking down the lining of the uterus that happens during menstruation; vaccines produce inflammatory molecules called cytokines and interferons that stimulate immune cells, including potentially in the uterus. This might cause the lining to shed sooner or more intensively than usual, causing changes to the menstrual cycle.<sup>9</sup></p>

<sup>8</sup> Li K, Chen G, Hou H, et al. Analysis of sex hormones and menstruation in COVID-19 women of child-bearing age. *Reprod Biomed Online*. 2021;42(1):260-267. doi:10.1016/j.rbmo.2020.09.020 [TRIM [D21-2983370](#)]

<sup>9</sup> Joi P. Do COVID-19 vaccines affect menstruation and fertility? 2021 June 11.

<https://www.gavi.org/vaccineswork/do-covid-19-vaccines-affect-menstruation-and-fertility> [TRIM [D21-2998193](#)]

## 6. Conclusion

<b>Conclusion</b>	<p>Several of the MedDRA Preferred Terms for Menstrual disorders flagged in DPAR for PF and Postmenopausal Haemorrhage flagged for AZ. The high-level review of the case reports indicate that the information provided in the case narrative was limited for many of the reports, including the outcome of the reported AEFI. Specifically whether the menstrual disorder self-corrected in the months following the report.</p> <p>Although there have been media articles in response to reports of menstrual disorders following COVID-19 vaccination, there is a lack of research literature including published case studies to support a causal association at this time.</p> <p>The most recent Sponsor's MSSR for PF notes that Menstrual disorders are under review for inclusion in the PSUR #1 as requested by EMA. This report is due to the TGA in September 2021.</p> <p>The EMA PRAC and the UK MHRA have both reported that they are reviewing reports of menstrual disorders following COVID-19 vaccination.</p> <p>It is the recommendation of this review that the TGA continue to monitor menstrual disorders and the COVID-19 vaccinations through routine pharmacovigilance processes, including the review of the PF PSUR which is due to the TGA in September 2021, environmental scanning of published literature and the findings from other regulators.</p>	
<b>Proposed action</b>	<p><input type="checkbox"/> <b>Refer to Stream B – MAVIS Evaluation Stream</b></p> <p><input type="checkbox"/> <b>Refer to Stream C – Regulatory Outcomes Stream (ROS)</b></p> <p><input checked="" type="checkbox"/> <b>Routine monitoring</b></p>	
<b>Instructions for Stream B, MAVIS Evaluation Stream (if applicable)</b>	<p>N/A</p>	
<b>Instructions for Stream C, ROS (if applicable)</b>	<b>Proposed regulatory action</b>	
	<input type="checkbox"/> PI/CMI update	<input type="checkbox"/> Recall
	<input type="checkbox"/> Safety alert	<input type="checkbox"/> IPMST topic
	<input type="checkbox"/> Medicines Safety Update (MSU)	<input type="checkbox"/> Pregnancy Category update
	<input type="checkbox"/> DHCP Letter	<input type="checkbox"/> External/Internal liaison (specify)
	<input type="checkbox"/> RMP update	<input type="checkbox"/> Other (specify)
	<b>Statement on validity/public health impact</b>	
	<p>N/A</p>	
	<b>Specific instructions for selected regulatory action(s)</b>	
	<p>N/A</p>	

**References**

Whitaker, L., & Critchley, H. O. D. (2016). Abnormal uterine bleeding. *Best Practice & Research Clinical Obstetrics & Gynaecology*, 34, 54–65. Retrieved December 2, 2016, from <http://www.sciencedirect.com/science/article/pii/S1521693415002266> [TRIM [D21-2995095](#)]

Jean Hailes Heavy Menstrual Bleeding – fact sheet – updated May 2019  
[https://assets.jeanhailes.org.au/heavy\\_menstrual\\_bleeding.pdf?ga=2.70192912.1846493863.1629424949-62988700.1628555415](https://assets.jeanhailes.org.au/heavy_menstrual_bleeding.pdf?ga=2.70192912.1846493863.1629424949-62988700.1628555415) [TRIM [D21-2998523](#)]

Apgar BS, Kaufman AH, George-Nwogu U, Kittendorf A. Treatment of menorrhagia. *Am Fam Physician*. 2007 Jun 15;75(12):1813-9. PMID: 17619523. [TRIM [D21-2997473](#)]

Wouk N, Helton M. Abnormal Uterine Bleeding in Premenopausal Women. *Am Fam Physician*. 2019 Apr 1;99(7):435-443. PMID: 30932448. [TRIM [D21-2997572](#)]

Brand AH, The woman with postmenopausal bleeding. *Aust. Fam Physician*. 007 March Vol. 36, No. 3. [TRIM [D21-2999928](#)]

Jean Hailes Menopause – fact sheet – updated September 2018  
<https://www.jeanhailes.org.au/resources/menopause-fact-sheet> TRIM [D21-2989287](#)

Joi P. Do COVID-19 vaccines affect menstruation and fertility? 2021 June 11.  
<https://www.gavi.org/vaccineswork/do-covid-19-vaccines-affect-menstruation-and-fertility> [TRIM [D21-2998193](#)]

Li K, Chen G, Hou H, et al. Analysis of sex hormones and menstruation in COVID-19 women of child-bearing age. *Reprod Biomed Online*. 2021;42(1):260-267. doi:10.1016/j.rbmo.2020.09.020 [TRIM [D21-2983370](#)]

**Template version history**

*The purpose of this section is to record any amendments made to the TIP template for vaccines. This section can be removed following completion of signal review.*

Version	TRIM Reference	Description of change	Author/s	Effective date
1.0	D21-2850188	Original template	MAVIS STRS	15/07/2021

## Doses



### Vaccination Details

Vaccination Date

GenderAge when vaccinatedState

### Doses Delivered by Age

Over 65	AZ	COMIRN	Total
<b>Totals</b>	<b>4280361</b>	<b>4181727</b>	<b>8462085</b>
0 - 64 yrs	1760567	3827231	5587798
65+ yrs	2519794	354493	2874287
Age not given	0	3	0

### Doses Delivered by Age

Over 50	AZ	COMIRN	Total
<b>Totals</b>	<b>4280361</b>	<b>4181727</b>	<b>8462085</b>
0 - 49 yrs	417752	2825918	3243670
50+ yrs	3862609	1355806	5218415
Age not given	0	3	0

☰

AEMS

AnalysisStory

🔖

📄 Duplicate

AEMS Dashboard

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Study Type  
2 of 4

Case Decision  
Accepted

Characterisation  
2 of 4

Reaction Term  
18 of 24828

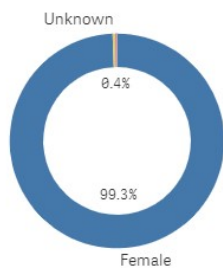
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Selections

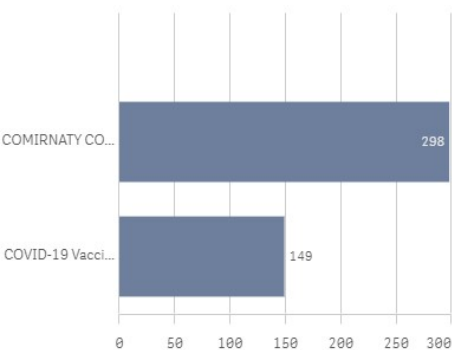
Insights

## AEMS Dashboard

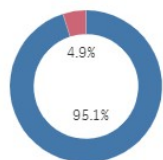
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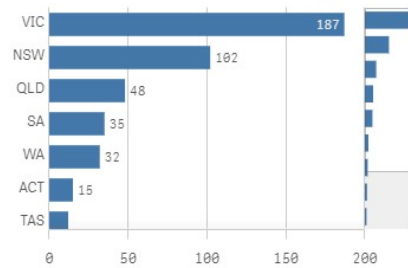
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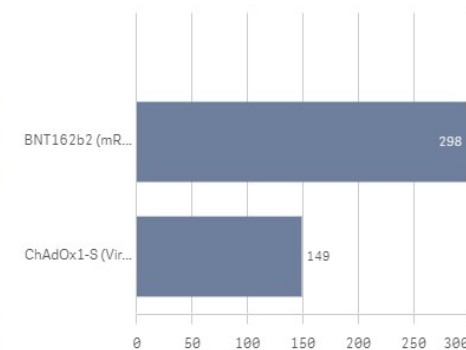
Seriousness



State



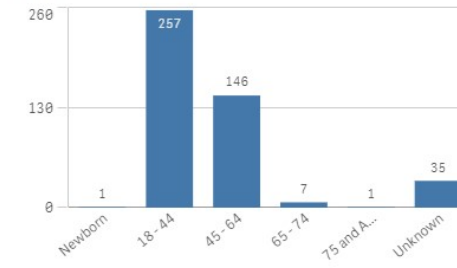
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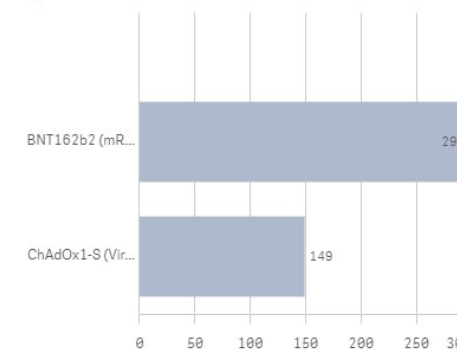
Case Report Date 2021



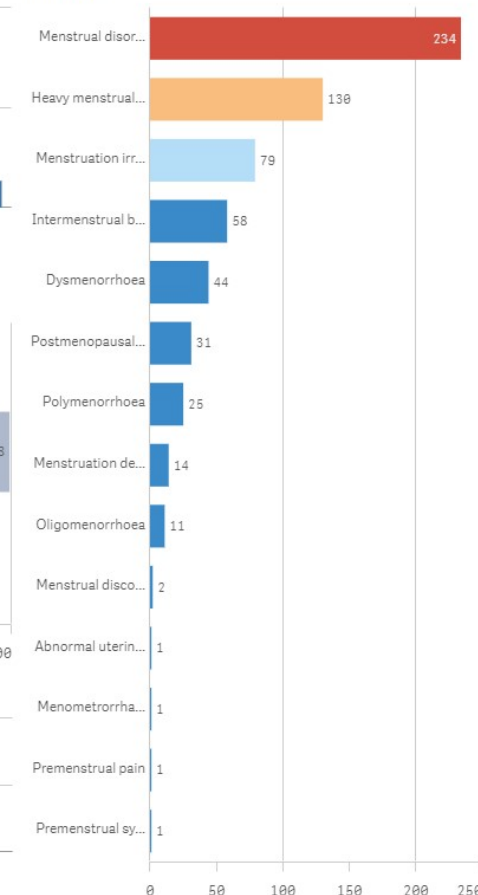
Age



Ingredient



Reaction



Case Number Count

447

Report Date

Trade Name

Generic Name

Ingredient Name

Reaction Term

Characterisation

Product Type

Report Type

Case Decision

Case Decision Reason

Sole Suspect

Is Serious Case

Reaction Outcome

Age

Sender Type

...



**Australian Government**  
**Department of Health**  
**Therapeutic Goods Administration**

## Public Case Details

### Filter(s):

Study Type: Unknown, Other studies

Case Decision: Accepted

Characterisation: Suspect, Interacting

Trade Name: COMIRNATY COVID-19 vaccine

Reaction Term: Amenorrhoea, Dysmenorrhoea, Heavy menstrual bleeding, Intermenstrual bleeding, Menstrual discomfort, Menstrual disorder, Menstruation delayed, Menstruation irregular, Oligomenorrhoea, Polymenorrhoea, Postmenopausal haemorrhage, Premenstrual pain, Abnormal uterine bleeding, Polymenorrhagia, Retrograde menstruation.

**Number of cases in this report:** 298.

17 August 2021

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**Limitations of the data**

This document contains information from reports of adverse events that the TGA has received in relation to therapeutic goods. It does not contain all known information, and an assessment of the safety of a medicine cannot be made based on this information.

**Causality**

- The reports received by the TGA contain suspected associations that reflect the observations of an individual reporter. The reporter may be a health professional, a sponsor, or a member of the public.
- Adverse events are suspected of being related to a therapeutic good, but this relationship is usually not certain - the symptom may be related to the underlying illness or to other factors.
- There might be no relationship between the adverse event and the medicine - it may be a coincidence that the adverse event occurred when the medicine was taken.

**Case ID: AU-TGA-0000526168****Case Details**

Report Date: 25/03/2021  
 Modified on: 28/03/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	§47F			§47F
Pelvic pain				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	§47F

**Case ID: AU-TGA-0000531339****Case Details**

Report Date: 05/04/2021  
 Modified on: 09/04/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 34  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000537604****Case Details**

Report Date: 14/04/2021  
 Modified on: 19/04/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 30  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Fatigue				<span style="color: red;">§47F</span>
Headache				
Injection site reaction	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	
Menstrual disorder				
Oropharyngeal pain				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000542182****Case Details**

Report Date: 22/04/2021  
 Modified on: 28/04/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 35  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chills	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Injection site reaction				
Menstruation irregular				
Migraine				
Nausea				
Pain in extremity				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>

Indication:	
Action Taken:	

**Case ID: AU-TGA-0000542781****Case Details**

Report Date: 23/04/2021  
 Modified on: 04/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age:  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular				<span style="color: red;">s47F</span>
Myalgia	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000544602****Case Details**

Report Date: 28/04/2021  
 Modified on: 02/05/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 26  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000547473****Case Details**

Report Date: 04/05/2021  
 Modified on: 07/05/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 35  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Amenorrhoea	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Arthralgia				
Chills				
Headache				
Lethargy				
Myalgia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose form: INJECTION
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000548497****Case Details**

Report Date: 06/05/2021  
 Modified on: 08/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 25  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Other health professional

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Contusion	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Dysgeusia				
Intermenstrual bleeding				
Mouth haemorrhage				
Nausea				
Vomiting				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular

Treatment details:	Started:	s47F	
Indication:			
Action Taken:			

**Case ID: AU-TGA-0000549748****Case Details**

Report Date: 08/05/2021  
 Modified on: 14/05/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 30  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain				<span style="color: red;">§47F</span>
Headache				
Menstrual disorder	<span style="color: red;">§47F</span>			

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	<span style="color: red;">§47F</span>

**Case ID: AU-TGA-0000550731****Case Details**

Report Date: 10/05/2021  
 Modified on: 15/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: s47  
F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

s47  
F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Amenorrhoea	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>		<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	
Hot flush	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>			

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000550974****Case Details**

Report Date: 11/05/2021  
 Modified on: 21/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 30  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Amenorrhoea	<span style="color: red;">s47F</span> <span style="background-color: black; color: red;">[REDACTED]</span>		<span style="color: red;">s47F</span> <span style="background-color: black; color: red;">[REDACTED]</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span> <span style="background-color: black; color: red;">[REDACTED]</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000551254****Case Details**

Report Date: 11/05/2021  
 Modified on: 21/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 34  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Myalgia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000551280****Case Details**

Report Date: 11/05/2021  
 Modified on: 12/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 29  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dizziness				<span style="color: red;">s47F</span>
Heavy menstrual bleeding				
Malaise				
Muscular weakness				
Pain in extremity			<span style="color: red;">s47F</span>	
Pyrexia				
Vomiting				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000552136****Case Details**

Report Date: 13/05/2021  
 Modified on: 18/05/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 35  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000552220****Case Details**

Report Date: 13/05/2021  
 Modified on: 20/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Not Specified  
 Age: 31  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Autoscopy				<span style="color: red;">s47F</span>
Heavy menstrual bleeding	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000552622****Case Details**

Report Date: 13/05/2021  
 Modified on: 20/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age:  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Physician

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>		<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000552765****Case Details**

Report Date: 14/05/2021  
 Modified on: 18/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 33  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Breast tenderness	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Dyspnoea				
Fatigue				
Headache			<span style="color: red;">s47F</span>	
Intermenstrual bleeding				
Myalgia				
Nausea				
Pyrexia				
Tachycardia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000553870****Case Details**

Report Date: 17/05/2021  
 Modified on: 18/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 37  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	
Menstrual disorder				
Menstruation irregular				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000554840****Case Details**

Report Date: 18/05/2021  
 Modified on: 26/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 40  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Nausea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000554867****Case Details**

Report Date: 18/05/2021  
 Modified on: 22/05/2021  
 Causality: Causality possible  
 Serious ICSR: S47  
F

**Patient Details:**

Sex: Female  
 Age: 29  
 State: S47F  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Oligomenorrhoea			<span style="color: red;">S47F</span> <span style="background-color: black; color: red;">F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000555465****Case Details**

Report Date: 20/05/2021  
 Modified on: 21/05/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 38  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding				<span style="color: red;">§47F</span>
Menstruation irregular				
Vaginal haemorrhage	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000557080****Case Details**

Report Date: 23/05/2021  
 Modified on: 01/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 40  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation delayed	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000559283****Case Details**

Report Date: 27/05/2021  
 Modified on: 05/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 48  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000559505****Case Details**

Report Date: 27/05/2021  
 Modified on: 02/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 33  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chills				<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Ear pain				
Headache				
Heavy menstrual bleeding				
Lethargy				
Myalgia				
Nasal congestion				
Pyrexia			<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000560233****Case Details**

Report Date: 28/05/2021  
 Modified on: 02/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 38  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea				§47F
Heavy menstrual bleeding	§47F			
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000560632****Case Details**

Report Date: 31/05/2021  
 Modified on: 02/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 31  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dizziness				<span style="color: red;">§47F</span>
Menstruation irregular				
Palpitations	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000560794****Case Details**

Report Date: 31/05/2021  
 Modified on: 01/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 32  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Heavy menstrual bleeding				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000561846****Case Details**

Report Date: 01/06/2021  
 Modified on: 03/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia				<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Back pain				
Contusion				
Dizziness				
Fatigue				
Headache	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>			
Myalgia				
Nausea				
Polymenorrhoea				
Rash				
Vision blurred				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000561853****Case Details**

Report Date: 01/06/2021  
 Modified on: 04/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 42  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Polymenorrhoea	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000562244****Case Details**

Report Date: 02/06/2021  
 Modified on: 03/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age:  
 State: §47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000562767****Case Details**

Report Date: 03/06/2021  
 Modified on: 04/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 26  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	
Intermenstrual bleeding				
Thrombosis				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000563538****Case Details**

Report Date: 04/06/2021  
 Modified on: 05/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 49  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Oligomenorrhoea	s47F	s47F		s47F

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000563698****Case Details**

Report Date: 04/06/2021  
 Modified on: 07/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 26  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Thrombosis				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000563910****Case Details**

Report Date: 04/06/2021  
 Modified on: 09/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000563942****Case Details**

Report Date: 04/06/2021  
 Modified on: 09/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 36  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	§47F	§47F		§47F

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

§47F	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	§47F



**Case ID: AU-TGA-0000564005****Case Details**

Report Date: 05/06/2021  
 Modified on: 09/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000564036****Case Details**

Report Date: 05/06/2021  
 Modified on: 09/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 49  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000564125****Case Details**

Report Date: 05/06/2021  
 Modified on: 09/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Thrombosis				<span style="color: red;">§47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000564127****Case Details**

Report Date: 05/06/2021  
 Modified on: 09/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Diarrhoea				<span style="color: red;">§47F</span>
Menstrual disorder	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>
Nausea				<span style="color: red;">§47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000564573****Case Details**

Report Date: 07/06/2021  
 Modified on: 10/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 20  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Injection site reaction	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>		<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	
Menstruation delayed				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000564594****Case Details**

Report Date: 07/06/2021  
 Modified on: 08/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 21  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Heavy menstrual bleeding				
Menstruation irregular			<span style="color: red;">§47F</span>	
Nausea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000564821****Case Details**

Report Date: 07/06/2021  
 Modified on: 10/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 44  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	s47F		s47F	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: s47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000565032****Case Details**

Report Date: 08/06/2021  
 Modified on: 11/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 44  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Headache	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	
Lethargy				
Menstrual disorder		<span style="color: red;">§47F</span>		

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000565254****Case Details**

Report Date: 08/06/2021  
 Modified on: 11/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 27  
 State: s47  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder				<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Migraine	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>			
Nausea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000565413****Case Details**

Report Date: 08/06/2021  
 Modified on: 11/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 40  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea				<span style="color: red;">s47F</span>
Heavy menstrual bleeding				
Menstruation irregular	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000565421****Case Details**

Report Date: 08/06/2021  
 Modified on: 11/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age:  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia				<span style="background-color: black; color: red;">s47F</span>
Dysmenorrhoea				
Fatigue				
Menstruation irregular	<span style="background-color: black; color: red;">s47F</span>			
Myalgia				
Pyrexia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="background-color: black; color: red;">s47F</span>
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: §47F [REDACTED]
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000565530****Case Details**

Report Date: 08/06/2021  
 Modified on: 11/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 28  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea				<span style="color: red;">§47F</span>
Heavy menstrual bleeding	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000566217****Case Details**

Report Date: 09/06/2021  
 Modified on: 15/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age:  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000566632****Case Details**

Report Date: 10/06/2021  
Modified on: 14/06/2021  
Causality: Causality possible  
Serious ICSR: S47  
F

**Patient Details:**

Sex: Female  
Age: 36  
State: S47F  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
Centre

**Reporter Details:**

Qualification: Consumer or other non  
health professional

**Case narrative:**S47F

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Anxiety				s47F
Arthralgia				
Confusional state				
Headache				
Hypoaesthesia				
Lymphadenopathy	s47F		s47F	
Malaise				
Menstruation irregular				
Nausea				
Nausea				
Oropharyngeal pain				
Paraesthesia				
Pyrexia				
Rash				
Vomiting				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: s47F
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000567844****Case Details**

Report Date: 13/06/2021  
 Modified on: 19/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 44  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000567895****Case Details**

Report Date: 14/06/2021  
 Modified on: 21/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 46  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Decreased appetite	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	
Dysmenorrhoea				
Fatigue				
Nausea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>

Indication:	
Action Taken:	

**Case ID: AU-TGA-0000568360****Case Details**

Report Date: 14/06/2021  
 Modified on: 16/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 53  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	§47F	§47F		§47F
Menstruation irregular				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000568712****Case Details**

Report Date: 15/06/2021  
 Modified on: 17/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain				<span style="color: red;">s47F</span>
Arthralgia				
Headache				
Heavy menstrual bleeding	<span style="color: red;">s47F</span>			
Injection site pain	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	
Myalgia				
Nausea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: §47F [REDACTED]
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000569010****Case Details**

Report Date: 15/06/2021  
 Modified on: 19/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 25  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Physician

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000569348****Case Details**

Report Date: 16/06/2021  
 Modified on: 23/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47  
F

**Patient Details:**

Sex: Female  
 Age: 62  
 State: §47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Postmenopausal haemorrhage				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000569426****Case Details**

Report Date: 16/06/2021  
 Modified on: 17/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47  
F

**Patient Details:**

Sex: Female  
 Age: 32  
 State: §47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea				<span style="color: red;">§47F</span> <div></div>
Fatigue				
Headache	<span style="color: red;">§47F</span> <div></div>	<span style="color: red;">§47F</span> <div></div>		
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span> <div></div>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000570563****Case Details**

Report Date: 17/06/2021  
 Modified on: 24/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 31  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**
s47  
F
**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder			<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000570578****Case Details**

Report Date: 17/06/2021  
 Modified on: 23/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 44  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding			<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000571280****Case Details**

Report Date: 18/06/2021  
 Modified on: 19/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 26  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chest discomfort				<span style="color: red;">s47F</span>
Chest pain				
Dyspnoea	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	
Fatigue				
Menstruation delayed				
Nausea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F [REDACTED]
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000571526****Case Details**

Report Date: 19/06/2021  
 Modified on: 26/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 32  
 State: s47  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">s47F</span> <div style="background-color: black; height: 15px; width: 100%;"></div>	<span style="color: red;">s47F</span> <div style="background-color: black; height: 15px; width: 100%;"></div>		<span style="color: red;">s47F</span> <div style="background-color: black; height: 40px; width: 100%;"></div>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000571609****Case Details**

Report Date: 20/06/2021  
 Modified on: 26/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chills	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	
Menstrual disorder				
Myalgia				
Rash				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000571614****Case Details**

Report Date: 20/06/2021  
 Modified on: 26/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 49  
 State: s47  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Injection site pain	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="background-color: black; color: red;">F</span>	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="background-color: black; color: red;">F</span>
Injection site reaction				
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000571719****Case Details**

Report Date: 20/06/2021  
 Modified on: 26/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 22  
 State: s47  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Herpes simplex reactivation	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>		<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	
Polymenorrhoea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000571760****Case Details**

Report Date: 20/06/2021  
 Modified on: 26/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Injection site pain	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	
Menstrual disorder				
Uterine contractions abnormal				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

(2) IBUPROFEN - CODEINE PHOSPHATE (codeine phosphate hemihydrate; Ibuprofen) - Concomitant	
Dosage information:	

Treatment details:	
Indication:	
Action Taken:	Not applicable

s47F	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	Not applicable

**Case ID: AU-TGA-0000572165****Case Details**

Report Date: 21/06/2021  
 Modified on: 26/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 36  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Other health professional

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>		<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	
Neuralgia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000572193****Case Details**

Report Date: 21/06/2021  
 Modified on: 29/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 29  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Other health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Amenorrhoea	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	
Dysmenorrhoea				
Headache				
Injection site reaction				
Lethargy				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000572571****Case Details**

Report Date: 22/06/2021  
 Modified on: 28/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 65  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Postmenopausal haemorrhage	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000572576****Case Details**

Report Date: 22/06/2021  
 Modified on: 28/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 53  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Polymenorrhoea		<span style="color: red;">s47F</span>		

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000572578****Case Details**

Report Date: 22/06/2021  
 Modified on: 28/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 44  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000572594****Case Details**

Report Date: 22/06/2021  
 Modified on: 28/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>
Polymenorrhoea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000572605****Case Details**

Report Date: 22/06/2021  
 Modified on: 28/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 45  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Heavy menstrual bleeding		<span style="color: red;">s47F</span>		

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000572727****Case Details**

Report Date: 22/06/2021  
 Modified on: 28/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 38  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Polymenorrhoea	§47F	§47F		§47F

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000572810****Case Details**

Report Date: 22/06/2021  
 Modified on: 23/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 45  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chills				<span style="color: red;">§47F</span>
Fatigue				
Menstrual disorder	<span style="color: red;">§47F</span>			
Menstruation irregular				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000572855****Case Details**

Report Date: 22/06/2021  
 Modified on: 01/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 48  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Polymenorrhoea			<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000572915****Case Details**

Report Date: 22/06/2021  
 Modified on: 30/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 45  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Amenorrhoea			<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000572989****Case Details**

Report Date: 22/06/2021  
 Modified on: 01/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 36  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000573436****Case Details**

Report Date: 23/06/2021  
 Modified on: 29/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> , Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000573666****Case Details**

Report Date: 23/06/2021  
 Modified on: 01/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 28  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chills				<span style="color: red;">s47F</span>
Dehydration				
Dizziness				
Lethargy				
Menstruation irregular				
Myalgia				
Night sweats				
Pyrexia	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000573877****Case Details**

Report Date: 23/06/2021  
 Modified on: 30/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 44  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Decreased appetite	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Menstruation irregular		<span style="color: red;">§47F</span>		
Oral herpes				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: s47F
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: s47F
Indication:	
Action Taken:	

s47F	
Dosage information:	Route of Administration: s47F
Treatment details:	Started: s47F
Indication:	s47F
Action Taken:	

s47F	
Dosage information:	Route of Administration: s47F
Treatment details:	Started: s47F
Indication:	s47F
Action Taken:	

s47F	
Dosage information:	Route of Administration: s47F
Treatment details:	Started: s47F
Indication:	s47F
Action Taken:	

(6) DYMISTA 125/50 (Azelastine hydrochloride; fluticasone propionate) - Concomitant	
Dosage information:	Route of Administration: Inhalation
Treatment details:	Started: s47F
Indication:	s47F
Action Taken:	

s47F	
Dosage information:	Route of Administration: s47F
Treatment details:	Started: s47F
Indication:	s47F

Action Taken:	s47F
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s47F	
Dosage information:	Route of Administration: Oral
Treatment details:	Started: s47F
Indication:	s47F
Action Taken:	

(9) PANAFCORTELONE (Prednisolone) - Concomitant	
Dosage information:	Route of Administration: Oral
Treatment details:	Started: s47F
Indication:	s47F
Action Taken:	

s47F	
Dosage information:	Route of Administration: Subcutaneous
Treatment details:	Started: s47F
Indication:	s47F
Action Taken:	

(11) AMLODIPINE-VALSARTAN (Amlodipine; Valsartan) - Concomitant	
Dosage information:	Route of Administration: Oral
Treatment details:	Started: s47F
Indication:	s47F
Action Taken:	

**Case ID: AU-TGA-0000573976****Case Details**

Report Date: 24/06/2021  
 Modified on: 30/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 35  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal distension				s47F
Abdominal pain				
Chills	s47F		s47F	
Headache				
Limb discomfort				
Menstrual disorder				
Nausea				
Pyrexia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000574108****Case Details**

Report Date: 24/06/2021  
 Modified on: 11/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 29  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Menstrual disorder			<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

(2) FEMME-TAB ED 20/100 (ethinylestradiol; lactose monohydrate; Levonorgestrel) - Concomitant	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000574196****Case Details**

Report Date: 24/06/2021  
 Modified on: 30/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 45  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000574310****Case Details**

Report Date: 24/06/2021  
 Modified on: 08/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 34  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Injection site reaction	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Menstruation irregular				
Vertigo			<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000574363****Case Details**

Report Date: 24/06/2021  
 Modified on: 30/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 53  
 State: s47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Heavy menstrual bleeding				
Nausea				
Vomiting				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> , Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000574457****Case Details**

Report Date: 24/06/2021  
 Modified on: 06/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 36  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Injection site reaction	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Menstrual disorder				
Rhinorrhoea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000574624****Case Details**

Report Date: 24/06/2021  
 Modified on: 02/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: s47  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual discomfort	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="background-color: black; color: red;">F</span>		<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Polymenorrhoea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000574895****Case Details**

Report Date: 24/06/2021  
 Modified on: 08/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Fatigue				
Polymenorrhoea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000575050****Case Details**

Report Date: 24/06/2021  
 Modified on: 02/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Fatigue	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Headache				
Intermenstrual bleeding				
Pyrexia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000575316****Case Details**

Report Date: 25/06/2021  
 Modified on: 30/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 37  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chills	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Headache				
Hyperhidrosis				
Polymenorrhoea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000575658****Case Details**

Report Date: 25/06/2021  
 Modified on: 01/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 27  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	s47F			s47F

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000575676****Case Details**

Report Date: 25/06/2021  
 Modified on: 01/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 39  
 State: s47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding				<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000575752****Case Details**

Report Date: 26/06/2021  
 Modified on: 03/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 35  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000575768****Case Details**

Report Date: 26/06/2021  
 Modified on: 03/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

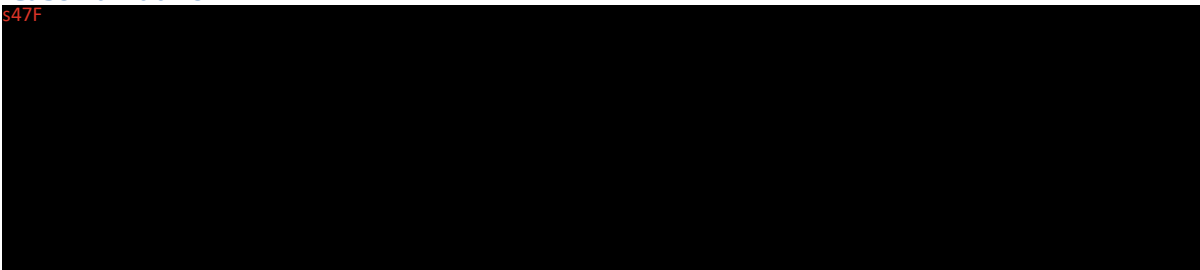
Sex: Female  
 Age: 27  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000576024****Case Details**

Report Date: 27/06/2021  
 Modified on: 03/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heart rate increased				<span style="color: red;">s47F</span>
Hyperhidrosis				
Menstrual disorder				
Pyrexia	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000576144****Case Details**

Report Date: 28/06/2021  
 Modified on: 05/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 45  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Polymenorrhoea	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000576196****Case Details**

Report Date: 28/06/2021  
 Modified on: 01/07/2021  
 Causality: Causality possible  
 Serious ICSR: S47F

**Patient Details:**

Sex: Female  
 Age: 45  
 State: S47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**S47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia				<span style="color: red;">S47F</span>
Headache				
Intermenstrual bleeding				
Local reaction				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000576231****Case Details**

Report Date: 28/06/2021  
 Modified on: 01/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 44  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	§47F	§47F		§47F
Heavy menstrual bleeding	§47F			

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000576615****Case Details**

Report Date: 28/06/2021  
 Modified on: 01/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Polymenorrhoea				<span style="color: red;">§47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000576761****Case Details**

Report Date: 29/06/2021  
 Modified on: 30/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 45  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000576947****Case Details**

Report Date: 29/06/2021  
 Modified on: 06/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 40  
 State: s47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding			s47F	
Immune thrombocytopenia	s47F			

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: s47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000577108****Case Details**

Report Date: 29/06/2021  
 Modified on: 09/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000577681****Case Details**

Report Date: 30/06/2021  
 Modified on: 06/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 46  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000577936****Case Details**

Report Date: 01/07/2021  
 Modified on: 03/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000578302****Case Details**

Report Date: 01/07/2021  
 Modified on: 05/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: s47  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	Not applicable

**Case ID: AU-TGA-0000578417****Case Details**

Report Date: 01/07/2021  
 Modified on: 03/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	§47F		§47F	§47F
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000579324****Case Details**

Report Date: 02/07/2021  
 Modified on: 14/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age:  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000579354****Case Details**

Report Date: 02/07/2021  
 Modified on: 05/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 35  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000579370****Case Details**

Report Date: 02/07/2021  
 Modified on: 05/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age:  
 State: s47  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chills				<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Fatigue				
Heavy menstrual bleeding				
Hypoaesthesia				
Nausea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

(2) SERTRALINE (Sertraline hydrochloride) - Concomitant	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	Dose not changed

**Case ID: AU-TGA-0000579409****Case Details**

Report Date: 03/07/2021  
 Modified on: 05/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 44  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Diarrhoea	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Intermenstrual bleeding			<span style="color: red;">§47F</span>	
Vomiting				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000579522****Case Details**

Report Date: 03/07/2021  
 Modified on: 06/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000579589****Case Details**

Report Date: 04/07/2021  
 Modified on: 06/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 42  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Fatigue	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Injection site pain				
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000579591****Case Details**

Report Date: 04/07/2021  
 Modified on: 08/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 64  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chills	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	
Headache				
Myalgia				
Postmenopausal haemorrhage				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

(2) IRBESARTAN (Irbesartan) - Concomitant

Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

(3) LIPITOR (Atorvastatin calcium) - Concomitant	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

(4) SYMBICORT TURBUHALER 200/6 (Budesonide; formoterol (eformoterol) fumarate dihydrate) - Concomitant	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000579615****Case Details**

Report Date: 04/07/2021  
 Modified on: 06/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: s47  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47  
F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="background-color: black; color: red;">F</span>		<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Menstruation delayed				<span style="background-color: black; color: red;">F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000579622****Case Details**

Report Date: 04/07/2021  
 Modified on: 06/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 26  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	<span style="color: red;">s47F</span>



**Case ID: AU-TGA-0000579631****Case Details**

Report Date: 04/07/2021  
 Modified on: 06/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: §47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Headache	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Hyperhidrosis				
Menopausal symptoms				
Myalgia				
Postmenopausal haemorrhage		<span style="color: red;">§47F</span>		
Pyrexia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">§47F</span> , Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000580053****Case Details**

Report Date: 05/07/2021  
 Modified on: 08/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 25  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular				<span style="color: red;">s47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	
Indication:	
Action Taken:	

(2) YAZ (Drospirenone; ethinylestradiol) - Concomitant	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000580068****Case Details**

Report Date: 05/07/2021  
 Modified on: 07/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 25  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000580253****Case Details**

Report Date: 05/07/2021  
 Modified on: 07/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 44  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding				<span style="color: red;">§47F</span>
Lethargy			<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000580255****Case Details**

Report Date: 05/07/2021  
 Modified on: 07/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Headache				<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Lethargy				
Lymphadenopathy			<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	
Menstruation irregular				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000580270****Case Details**

Report Date: 05/07/2021  
 Modified on: 06/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 38  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>		<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Menstrual disorder				<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000580499****Case Details**

Report Date: 06/07/2021  
 Modified on: 07/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Headache	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Injection site pain				
Lethargy				
Lymphadenopathy				
Menstrual disorder				
Myalgia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

(2) GONAL-F (Follitropin alfa) - Concomitant	
Dosage information:	Route of Administration: Subcutaneous
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	<span style="color: red;">s47F</span>
Action Taken:	<span style="color: red;">s47F</span>

**Case ID: AU-TGA-0000580583****Case Details**

Report Date: 06/07/2021  
 Modified on: 07/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: s47  
F  
 State: SA

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47  
F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Polymenorrhoea	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>			<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000580900****Case Details**

Report Date: 06/07/2021  
 Modified on: 08/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 34  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000580951****Case Details**

Report Date: 06/07/2021  
 Modified on: 14/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 35  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Fatigue			<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Headache				
Heavy menstrual bleeding				
Injection site reaction				
Polymenorrhoea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> , Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000581062****Case Details**

Report Date: 06/07/2021  
 Modified on: 14/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000581164****Case Details**

Report Date: 06/07/2021  
 Modified on: 07/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 42  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Headache			<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Heavy menstrual bleeding				
Lethargy				
Menstrual disorder				
Myalgia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000581471****Case Details**

Report Date: 07/07/2021  
 Modified on: 11/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 25  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	s47F		s47F	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: s47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000581698****Case Details**

Report Date: 07/07/2021  
 Modified on: 09/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 25  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chest discomfort	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>		<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Fatigue	<span style="background-color: black; color: red;">F</span>			<span style="background-color: black; color: red;">F</span>
Menstrual disorder	<span style="background-color: black; color: red;">F</span>			<span style="background-color: black; color: red;">F</span>
Nausea	<span style="background-color: black; color: red;">F</span>			<span style="background-color: black; color: red;">F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect

Dosage information:

Treatment details:	Started: 847F [REDACTED]
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000581718****Case Details**

Report Date: 07/07/2021  
 Modified on: 16/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 26  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation delayed			<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000581798****Case Details**

Report Date: 07/07/2021  
 Modified on: 20/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 21  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Other health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000581902****Case Details**

Report Date: 07/07/2021  
 Modified on: 09/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Diarrhoea	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Headache				
Injection site reaction				
Lethargy				
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000582154****Case Details**

Report Date: 08/07/2021  
 Modified on: 09/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Not Specified  
 Age:  
 State: Unknown

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000582228****Case Details**

Report Date: 08/07/2021  
 Modified on: 11/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 31  
 State: s47F  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47F</span> <span style="background-color: black; color: red;">F</span>			<span style="color: red;">s47F</span> <span style="background-color: black; color: red;">F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> <span style="background-color: black; color: red;">F</span> Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000582332****Case Details**

Report Date: 08/07/2021  
 Modified on: 09/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 31  
 State: s47  
F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Cold sweat				<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Feeling hot				
Menstruation irregular				
Pain in extremity				
Paraesthesia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect

Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000582469****Case Details**

Report Date: 08/07/2021  
 Modified on: 20/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 21  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Other health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000582591****Case Details**

Report Date: 08/07/2021  
 Modified on: 23/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 36  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000582600****Case Details**

Report Date: 08/07/2021  
 Modified on: 23/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 30  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Physician

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>		<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Dysmenorrhoea				
Haematuria				
Uterine haemorrhage				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000582608****Case Details**

Report Date: 08/07/2021  
 Modified on: 23/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 57  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000582957****Case Details**

Report Date: 09/07/2021  
 Modified on: 11/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 45  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000583115****Case Details**

Report Date: 09/07/2021  
 Modified on: 22/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 24  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Physician

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chills	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Menstruation irregular				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000583126****Case Details**

Report Date: 09/07/2021  
 Modified on: 24/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age:  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia				<span style="color: red;">s47F</span>
Back pain				
Dysmenorrhoea				
Headache				
Nausea				
Oropharyngeal pain				
Pain in extremity	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	
Rash pruritic				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000583190****Case Details**

Report Date: 09/07/2021  
 Modified on: 20/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 29  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Lymphadenopathy			<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Oligomenorrhoea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000583224****Case Details**

Report Date: 09/07/2021  
 Modified on: 20/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Breast tenderness				<span style="color: red;">s47F</span>
Chest discomfort				
Menstrual disorder				
Myalgia	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000583414****Case Details**

Report Date: 09/07/2021  
 Modified on: 21/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

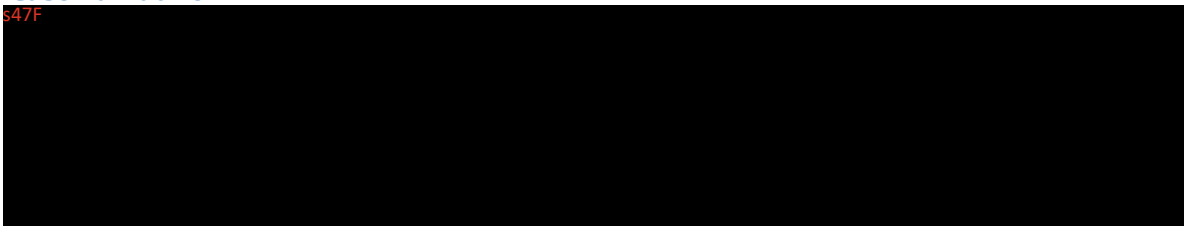
Sex: Female  
 Age: 46  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Other health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000583600****Case Details**

Report Date: 10/07/2021  
 Modified on: 13/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 44  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Diarrhoea	§47F		§47F	
Menstruation irregular				
Rhinorrhoea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: §47F , Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000583733****Case Details**

Report Date: 11/07/2021  
 Modified on: 13/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 38  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	
Polymenorrhoea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000584081****Case Details**

Report Date: 12/07/2021  
 Modified on: 14/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 52  
 State: s47  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Postmenopausal haemorrhage	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>			<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000584316****Case Details**

Report Date: 12/07/2021  
 Modified on: 22/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 44  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding			s47F	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: s47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000584382****Case Details**

Report Date: 12/07/2021  
 Modified on: 23/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 35  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000584403****Case Details**

Report Date: 12/07/2021  
 Modified on: 14/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age:  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Intermenstrual bleeding				
Menstruation irregular				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000584498****Case Details**

Report Date: 12/07/2021  
 Modified on: 24/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age:  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder				<span style="color: red;">§47F</span>
Menstruation irregular			<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000584826****Case Details**

Report Date: 13/07/2021  
 Modified on: 15/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 42  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation delayed	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000584832****Case Details**

Report Date: 13/07/2021  
 Modified on: 15/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 42  
 State: s47  
F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="background-color: black; color: red;">F</span>	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="background-color: black; color: red;">F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000585127****Case Details**

Report Date: 13/07/2021  
 Modified on: 24/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 32  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain				<span style="color: red;">s47F</span>
Arthralgia				
Headache				
Injection site reaction				
Lethargy				
Menstrual disorder				
Myalgia				
Pyrexia			<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000585223****Case Details**

Report Date: 13/07/2021  
 Modified on: 24/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 32  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder			<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000585251****Case Details**

Report Date: 13/07/2021  
 Modified on: 25/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 35  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia				<span style="color: red;">§47F</span>
Heavy menstrual bleeding				
Injection site reaction			<span style="color: red;">§47F</span>	
Lethargy				
Myalgia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000585314****Case Details**

Report Date: 13/07/2021  
 Modified on: 28/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 44  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain			<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Diarrhoea				
Headache				
Lethargy				
Menstruation irregular				
Nausea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000585347****Case Details**

Report Date: 13/07/2021  
 Modified on: 15/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 48  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding				<span style="color: red;">s47F</span>
Menstrual disorder	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		
Polymenorrhoea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000585385****Case Details**

Report Date: 13/07/2021  
 Modified on: 15/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 31  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Burning sensation				<span style="color: red;">s47F</span>
Fatigue				
Menstrual disorder	<span style="color: red;">s47F</span>			

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000585615****Case Details**

Report Date: 14/07/2021  
 Modified on: 16/07/2021  
 Causality: Causality possible  
 Serious ICSR: S47  
F

**Patient Details:**

Sex: Female  
 Age: 25  
 State: S47F  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular				<span style="color: red;">S47F</span> <span style="background-color: black; color: red;">F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

(2) ZOELY (estradiol hemihydrate; Nomegestrol acetate) - Concomitant	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	<span style="color: red;">S47F</span> <span style="background-color: black; color: red;">F</span>

**Case ID: AU-TGA-0000585628****Case Details**

Report Date: 14/07/2021  
 Modified on: 16/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="background-color: black; color: red;">§47F</span>			<span style="background-color: black; color: red;">§47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

(2) EFEXOR-XR (Venlafaxine hydrochloride) - Concomitant	
Dosage information:	Route of Administration: Oral
Treatment details:	
Indication:	<span style="background-color: black; color: red;">§47F</span>
Action Taken:	

(3) VOLTAREN (diclofenac potassium; Diclofenac sodium) - Concomitant	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	<span style="background-color: black; color: red;">§47F</span>

**Case ID: AU-TGA-0000585660****Case Details**

Report Date: 14/07/2021  
 Modified on: 16/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 49  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

N/a

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia				<span style="color: red;">§47F</span>
Breast pain				
Dysmenorrhoea	<span style="color: red;">§47F</span>			
Fatigue				
Lymph node pain	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		
Menstruation irregular				
Myalgia				
Pyrexia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

(2) LOVAN (Fluoxetine hydrochloride) - Concomitant	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	<span style="color: red;">§47F</span>

(3) MIRENA (Levonorgestrel) - Concomitant	
Dosage information:	

Treatment details:	
Indication:	
Action Taken:	s47F [REDACTED]

**Case ID: AU-TGA-0000585673****Case Details**

Report Date: 14/07/2021  
 Modified on: 16/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Fatigue				
Injection site reaction				
Menstrual disorder				
Vomiting			<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> , Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000585934****Case Details**

Report Date: 14/07/2021  
 Modified on: 19/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 58  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular				<span style="color: red;">s47F</span>
Vaginal haemorrhage	<span style="color: red;">s47F</span>			

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000586829****Case Details**

Report Date: 15/07/2021  
 Modified on: 06/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 42  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	§47F			§47F
Menstrual disorder			§47F	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000587046****Case Details**

Report Date: 15/07/2021  
 Modified on: 17/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 40  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Physician

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual disorder		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000587475****Case Details**

Report Date: 16/07/2021  
 Modified on: 30/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 56  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Other health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000588011****Case Details**

Report Date: 18/07/2021  
 Modified on: 20/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 29  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000588128****Case Details**

Report Date: 19/07/2021  
 Modified on: 20/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 42  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Headache	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000588131****Case Details**

Report Date: 19/07/2021  
 Modified on: 20/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 31  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Headache	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	
Heavy menstrual bleeding				
Injection site pain		<span style="color: red;">§47F</span>		
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	

Action Taken:	
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**Case ID: AU-TGA-0000588133****Case Details**

Report Date: 19/07/2021  
 Modified on: 20/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 45  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000588314****Case Details**

Report Date: 19/07/2021  
 Modified on: 30/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 35  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Axillary pain				<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Breast pain				
Dysmenorrhoea				
Headache				
Injection site reaction				
Lymphadenopathy	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>		<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Indication:	
Action Taken:	





**Case ID: AU-TGA-0000588566****Case Details**

Report Date: 19/07/2021  
 Modified on: 04/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 42  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Other health professional

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Amenorrhoea	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Breast pain				
Breast tenderness				
Intermenstrual bleeding				
Menstrual disorder				
Pregnancy test negative	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect

Dosage information: Dose form: INJECTION , Route of Administration: Intramuscular

Treatment details:	Started: s47F
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Stopped: s47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000588567****Case Details**

Report Date: 19/07/2021  
 Modified on: 04/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 27  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Other health professional

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>		<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	
Arthralgia				
Chills				
Headache				
Lethargy				
Menstruation irregular				
Myalgia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: §47F [REDACTED]
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000588571****Case Details**

Report Date: 19/07/2021  
 Modified on: 31/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 44  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea				<span style="color: red;">s47F</span>
Menstrual disorder	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000588624****Case Details**

Report Date: 19/07/2021  
 Modified on: 20/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 36  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Headache				
Heavy menstrual bleeding				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000588762****Case Details**

Report Date: 20/07/2021  
 Modified on: 21/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 36  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Contusion	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Heavy menstrual bleeding				
Menstrual disorder				
Petechiae				
Thrombocytopenia			<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000589016****Case Details**

Report Date: 20/07/2021  
 Modified on: 22/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 35  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Cough				s47F
Dyspnoea exertional				
Fatigue	s47F			
Haemoptysis				
Heavy menstrual bleeding				
Pyrexia				



**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000589524****Case Details**

Report Date: 20/07/2021  
 Modified on: 22/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 30  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Hypomenorrhoea	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000589587****Case Details**

Report Date: 21/07/2021  
 Modified on: 28/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47  
F

**Patient Details:**

Sex: Female  
 Age: 48  
 State: §47F  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Contusion	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Fatigue				
Fatigue			<span style="color: red;">§47F</span>	
Heavy menstrual bleeding				
Injection site pain			<span style="color: red;">§47F</span>	
Injection site pain				
Myalgia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: 647F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000589626****Case Details**

Report Date: 21/07/2021  
 Modified on: 24/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 25  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dizziness	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Fatigue				
Intermenstrual bleeding				
Nausea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000589795****Case Details**

Report Date: 21/07/2021  
 Modified on: 22/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47  
F

**Patient Details:**

Sex: Female  
 Age:  
 State: Unknown

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding			<span style="color: red;">§47F</span>	
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000589866****Case Details**

Report Date: 21/07/2021  
 Modified on: 23/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age:  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Injection site movement impairment				
Injection site pain			<span style="color: red;">s47F</span>	
Menstrual disorder				
Menstruation irregular				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000589985****Case Details**

Report Date: 21/07/2021  
Modified on: 22/07/2021  
Causality: Causality possible  
Serious ICSR: S47  
F

**Patient Details:**

Sex: Female  
Age: 38  
State: S47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
Centre

**Reporter Details:**

Qualification: Consumer or other non  
health professional

**Case narrative:**S47F  




**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dyspnoea	s47F		s47F	s47F
Fibrin D dimer increased				
Menstrual disorder				
Oxygen saturation decreased				
Palpitations	s47F		s47F	
Paraesthesia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: s47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000590242****Case Details**

Report Date: 22/07/2021  
 Modified on: 24/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 27  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000590244****Case Details**

Report Date: 22/07/2021  
 Modified on: 24/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 55  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chills	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Injection site pain				
Intermenstrual bleeding				
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000590395****Case Details**

Report Date: 22/07/2021  
 Modified on: 07/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 32  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dizziness	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Dyspnoea				
Fatigue			<span style="color: red;">s47F</span>	
Heart rate increased				
Menstrual disorder				
Menstruation irregular			<span style="color: red;">s47F</span>	
Palpitations				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> , Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000590447****Case Details**

Report Date: 22/07/2021  
 Modified on: 23/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstruation irregular				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> , Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000590508****Case Details**

Report Date: 22/07/2021  
 Modified on: 07/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age:  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Back pain				<span style="color: red;">s47F</span>
Diarrhoea				
Hyperhidrosis				
Injection site reaction	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	
Menstruation delayed				
Myalgia				
Pain in extremity				
Renal pain				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000590645****Case Details**

Report Date: 22/07/2021  
 Modified on: 11/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 21  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder			<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Oligomenorrhoea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000590658****Case Details**

Report Date: 22/07/2021  
 Modified on: 11/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age:  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000590707****Case Details**

Report Date: 22/07/2021  
 Modified on: 14/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 54  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Haemorrhage	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000590777****Case Details**

Report Date: 22/07/2021  
 Modified on: 25/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 24  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Menstruation irregular				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">§47F</span> , Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000590801****Case Details**

Report Date: 22/07/2021  
 Modified on: 25/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 46  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Malaise	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>
Menstrual disorder				
Menstruation irregular				
Muscular weakness		<span style="color: red;">§47F</span>		
Paraesthesia		<span style="color: red;">§47F</span>		
Urticaria				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">§47F</span> Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000590810****Case Details**

Report Date: 23/07/2021  
 Modified on: 25/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 33  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Premenstrual pain				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> , Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000591111****Case Details**

Report Date: 23/07/2021  
 Modified on: 11/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 30  
 State: s47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chest pain	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Chills				
Costochondritis				
Dyspnoea				
Headache				
Lethargy				
Menstrual disorder				
Nausea				
Pyrexia				
Sensitive skin				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000591222****Case Details**

Report Date: 23/07/2021  
 Modified on: 14/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 26  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Physician

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Haemoglobin decreased				<span style="color: red;">§47F</span>
Menstrual disorder				
Vaginal haemorrhage	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000591282****Case Details**

Report Date: 23/07/2021  
 Modified on: 10/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 32  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Injection site reaction				<span style="color: red;">§47F</span>
Menstruation irregular				
Myalgia			<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000591566****Case Details**

Report Date: 23/07/2021  
 Modified on: 25/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 23  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000591730****Case Details**

Report Date: 24/07/2021  
 Modified on: 25/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 33  
 State: s47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding				<span style="color: red;">s47F</span>
Menstrual disorder	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000591767****Case Details**

Report Date: 24/07/2021  
 Modified on: 27/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 31  
 State: §47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	§47F			§47F
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000591979****Case Details**

Report Date: 25/07/2021  
 Modified on: 27/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual disorder	<span style="color: red;">s47F</span>			

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000592050****Case Details**

Report Date: 26/07/2021  
 Modified on: 29/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Menstrual disorder				
Menstruation irregular			<span style="color: red;">s47F</span>	
Nausea			<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> , Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

(2) SYMBICORT (Budesonide; formoterol (eformoterol) fumarate dihydrate) - Concomitant	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000592153****Case Details**

Report Date: 26/07/2021  
 Modified on: 27/07/2021  
 Causality: Causality possible  
 Serious ICSR: S47F

**Patient Details:**

Sex: Female  
 Age:  
 State: Unknown

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

S47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Headache				<span style="color: red;">S47F</span>
Menstrual disorder				
Myalgia				
Pain in extremity				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">S47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000592218****Case Details**

Report Date: 26/07/2021  
 Modified on: 27/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 34  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000592270****Case Details**

Report Date: 26/07/2021  
 Modified on: 27/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 38  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>		<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000592282****Case Details**

Report Date: 26/07/2021  
 Modified on: 28/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: §47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Hypomenorrhoea	§47F	§47F		§47F
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000592339****Case Details**

Report Date: 26/07/2021  
 Modified on: 12/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 44  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Amenorrhoea	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000592414****Case Details**

Report Date: 26/07/2021  
 Modified on: 12/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 49  
 State: s47F  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder			<span style="color: red;">s47F</span> <span style="background-color: black; color: red;">F</span>	<span style="color: red;">s47F</span> <span style="background-color: black; color: red;">F</span>
Oligomenorrhoea				<span style="color: red;">s47F</span> <span style="background-color: black; color: red;">F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span> <span style="background-color: black; color: red;">F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000592450****Case Details**

Report Date: 26/07/2021  
 Modified on: 12/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea				§47F
Headache			§47F	
Heavy menstrual bleeding				
Lethargy				
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000592456****Case Details**

Report Date: 26/07/2021  
 Modified on: 15/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 42  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Physician

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder				<span style="color: red;">s47F</span>
Postmenopausal haemorrhage	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000592457****Case Details**

Report Date: 26/07/2021  
 Modified on: 13/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

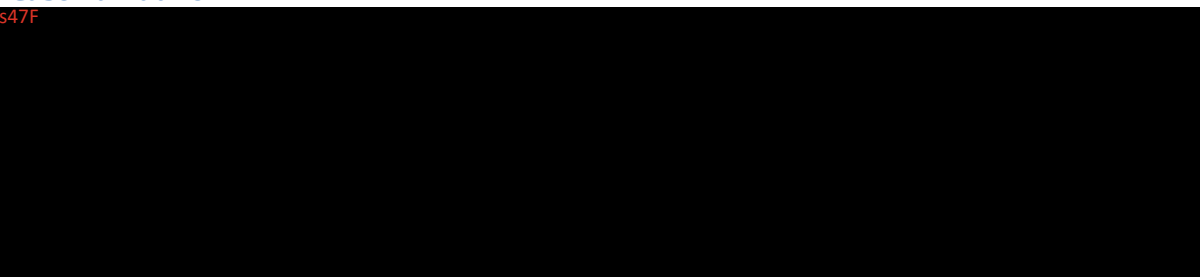
Sex: Female  
 Age: 42  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000592574****Case Details**

Report Date: 26/07/2021  
 Modified on: 28/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 39  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	Not applicable

**Case ID: AU-TGA-0000592703****Case Details**

Report Date: 27/07/2021  
Modified on: 30/07/2021  
Causality: Causality possible  
Serious ICSR: s47  
F

**Sender Details:**

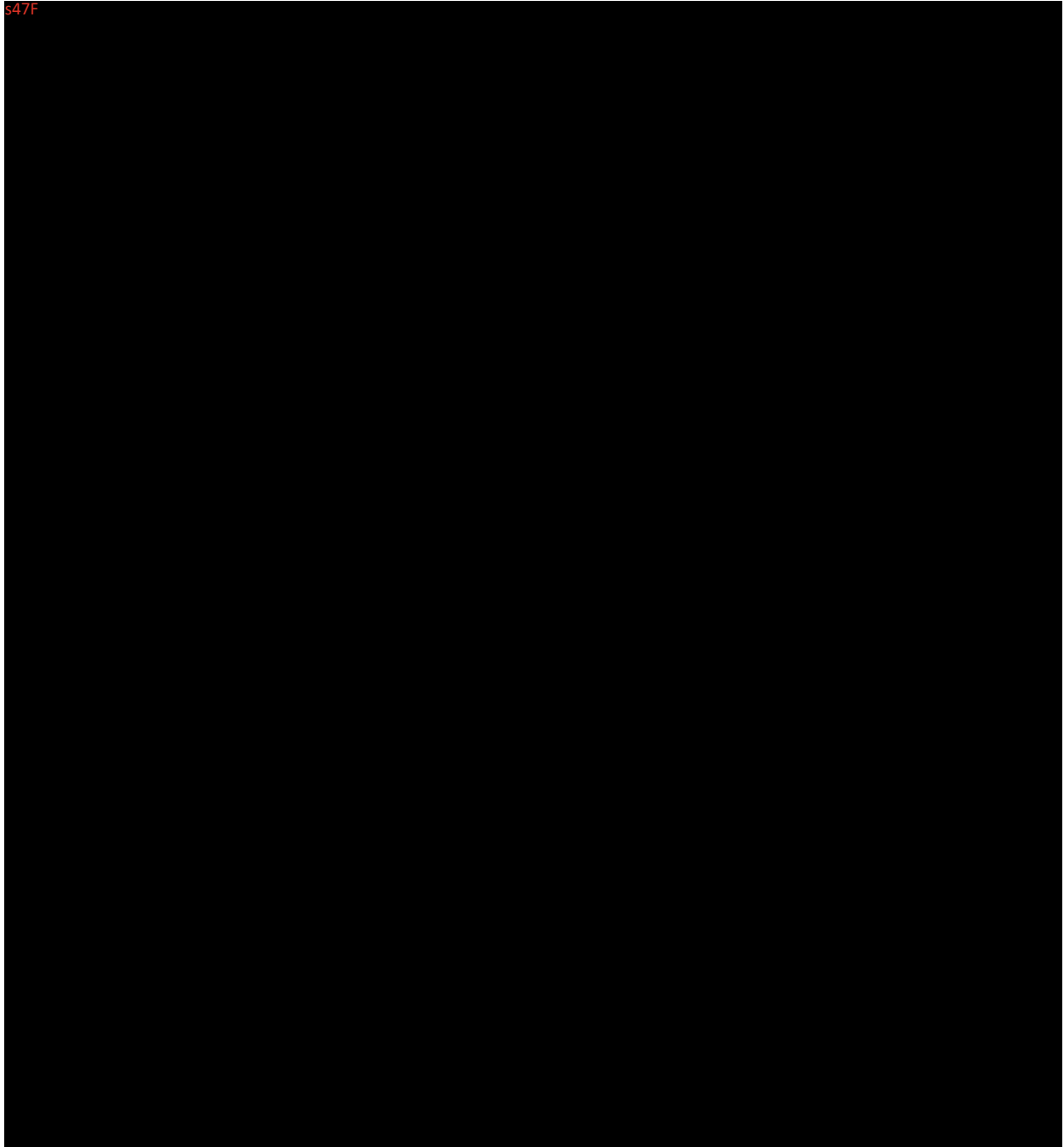
Sender type: Patient/Consumer

**Patient Details:**

Sex: Female  
Age: 38  
State: s47F

**Reporter Details:**

Qualification: Consumer or other non  
health professional

**Case narrative:**s47F

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Feeling abnormal	s47F			s47F
Headache			s47F	
Injection site reaction			s47F	
Insomnia				
Lethargy			s47F	
Menstruation irregular			s47F	
Mouth ulceration				
Neck pain				
Oropharyngeal pain				
Palpitations			s47F	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: s47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000592839****Case Details**

Report Date: 27/07/2021  
 Modified on: 15/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 29  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Axillary mass	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Headache			<span style="color: red;">§47F</span>	
Menstrual disorder				
Menstruation irregular				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000592842****Case Details**

Report Date: 27/07/2021  
 Modified on: 15/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 22  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Arthralgia				
Fatigue				
Headache				
Injection site reaction				
Intermenstrual bleeding				
Menstrual disorder				
Myalgia	<span style="color: red;">s47F</span>			
Pyrexia			<span style="color: red;">s47F</span>	
Vulvovaginal pain				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000593007****Case Details**

Report Date: 27/07/2021  
 Modified on: 15/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Fatigue	<span style="color: red;">s47</span>			<span style="color: red;">s47</span>
Headache				
Menstrual disorder				
Nausea				
Vaginal haemorrhage				
Vertigo				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000593123****Case Details**

Report Date: 27/07/2021  
 Modified on: 15/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 36  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding				<span style="color: red;">s47F</span>
Lymphadenopathy	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000593145****Case Details**

Report Date: 27/07/2021  
 Modified on: 15/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 51  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Physician

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Breast pain				<span style="color: red;">s47F</span>
Diarrhoea	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		
Dysmenorrhoea				
Dyspnoea				
Headache				
Heavy menstrual bleeding				
Injection site pain	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	
Menstrual disorder				
Menstruation irregular				
Nausea				
Palpitations				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000593194****Case Details**

Report Date: 27/07/2021  
 Modified on: 29/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 42  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia				<span style="color: red;">§47F</span>
Menstrual disorder	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000593200****Case Details**

Report Date: 27/07/2021  
 Modified on: 15/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 46  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Anxiety	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Dysgeusia				
Intrusive thoughts				
Menstrual disorder				
Menstruation delayed				
Pain in extremity				

Self-injurious ideation	§47F	§47F		§47F
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**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000593299****Case Details**

Report Date: 27/07/2021  
 Modified on: 16/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 46  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Epistaxis				<span style="color: red;">§47F</span>
Gingival bleeding				
Headache				
Injection site reaction			<span style="color: red;">§47F</span>	
Lethargy				
Menstrual disorder				
Postmenopausal haemorrhage				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000593304****Case Details**

Report Date: 27/07/2021  
 Modified on: 16/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 42  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Injection site reaction			<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Menstrual disorder				
Menstruation irregular				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000593598****Case Details**

Report Date: 28/07/2021  
 Modified on: 31/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 30  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Discomfort	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Dysmenorrhoea				
Headache		<span style="color: red;">s47F</span>		
Heavy menstrual bleeding				
Menstrual disorder				
Migraine				
Mobility decreased				
Pain		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect

Dosage information:	Dose: s47F [REDACTED] Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: s47F [REDACTED]
Indication:	
Action Taken:	

(2) VALDOXAN (Agomelatine) - Concomitant	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000593599****Case Details**

Report Date: 28/07/2021  
 Modified on: 31/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 46  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>
Menstruation irregular	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000593659****Case Details**

Report Date: 28/07/2021  
 Modified on: 30/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal distension				<span style="color: red;">s47F</span>
Abdominal pain	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		
Diarrhoea				
Dysmenorrhoea				
Dyspepsia				
Pelvic pain				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000593882****Case Details**

Report Date: 28/07/2021  
 Modified on: 16/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding				<span style="color: red;">§47F</span>
Heavy menstrual bleeding				
Menstrual disorder			<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000593885****Case Details**

Report Date: 28/07/2021  
 Modified on: 16/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: s47  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chills				<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Injection site reaction			<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	
Lymphadenopathy				
Menstrual disorder				
Menstruation delayed				
Myalgia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000593902****Case Details**

Report Date: 28/07/2021  
 Modified on: 16/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 49  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chills				<span style="color: red;">s47F</span>
Lethargy			<span style="color: red;">s47F</span>	
Menstrual disorder				
Menstruation delayed				
Myalgia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000594050****Case Details**

Report Date: 28/07/2021  
 Modified on: 16/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 42  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47F

[REDACTED]

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding			<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000594143****Case Details**

Report Date: 28/07/2021  
 Modified on: 30/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 46  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding				<span style="color: red;">s47F</span>
Menstrual disorder				
Menstruation irregular				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> , Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000594147****Case Details**

Report Date: 28/07/2021  
 Modified on: 30/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 76  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Menstrual disorder	<span style="color: red;">§47F</span>			

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000594368****Case Details**

Report Date: 29/07/2021  
 Modified on: 04/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 35  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Oropharyngeal discomfort				
Palpitations				
Urticaria				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000594498****Case Details**

Report Date: 29/07/2021  
 Modified on: 31/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>
Menstrual disorder				
Menstruation irregular				
Migraine				
Nausea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000594538****Case Details**

Report Date: 29/07/2021  
 Modified on: 31/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 38  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>
Menstrual disorder				
Night sweats	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000594677****Case Details**

Report Date: 29/07/2021  
 Modified on: 16/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 34  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder			<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Menstrual disorder				
Menstruation delayed				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000594728****Case Details**

Report Date: 29/07/2021  
 Modified on: 16/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain			<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Arthralgia				
Diarrhoea				
Dysmenorrhoea				
Headache				
Injection site reaction				
Lethargy				
Menstrual disorder				
Menstruation delayed				
Myalgia				
Nausea				
Pyrexia				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F [REDACTED]
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000594750****Case Details**

Report Date: 29/07/2021  
 Modified on: 16/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 49  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding				<span style="color: red;">s47F</span>
Menstrual disorder			<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000595023****Case Details**

Report Date: 30/07/2021  
 Modified on: 02/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 31  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000595233****Case Details**

Report Date: 30/07/2021  
 Modified on: 02/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 27  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000595511****Case Details**

Report Date: 30/07/2021  
 Modified on: 02/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 18  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000595565****Case Details**

Report Date: 31/07/2021  
 Modified on: 02/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 30  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	§47F		§47F	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000595580****Case Details**

Report Date: 31/07/2021  
Modified on: 02/08/2021  
Causality: Causality possible  
Serious ICSR: S47  
F

**Sender Details:**

Sender type: Patient/Consumer

**Patient Details:**

Sex: Female  
Age: 39  
State: S47F

**Reporter Details:**

Qualification: Consumer or other non  
health professional

**Case narrative:**S47F  


**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Headache	§47F		§47F	§47F
Injection site pain				
Menstrual disorder				
Muscular weakness	§47F		§47F	
Orthostatic hypotension				
Pain in extremity				
Vertigo	§47F		§47F	
Vestibular neuronitis				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000595587****Case Details**

Report Date: 31/07/2021  
 Modified on: 02/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding				<span style="color: red;">§47F</span>
Menstrual disorder	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000595711****Case Details**

Report Date: 01/08/2021  
 Modified on: 02/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Headache				<span style="color: red;">§47F</span>
Menstruation irregular	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		
Pain in extremity				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000595715****Case Details**

Report Date: 01/08/2021  
 Modified on: 02/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 49  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Hypersensitivity				
Rash				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000596012****Case Details**

Report Date: 02/08/2021  
 Modified on: 04/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 33  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	Not applicable

**Case ID: AU-TGA-0000596020****Case Details**

Report Date: 02/08/2021  
 Modified on: 04/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 38  
 State: s47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder				<span style="color: red;">s47F</span>
Menstruation irregular	<span style="color: red;">s47F</span>			

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	Not applicable

**Case ID: AU-TGA-0000596171****Case Details**

Report Date: 02/08/2021  
Modified on: 03/08/2021  
Causality: Causality possible  
Serious ICSR: <sup>S47</sup>  
F

**Patient Details:**

Sex: Female  
Age: 46  
State: <sup>S47F</sup>

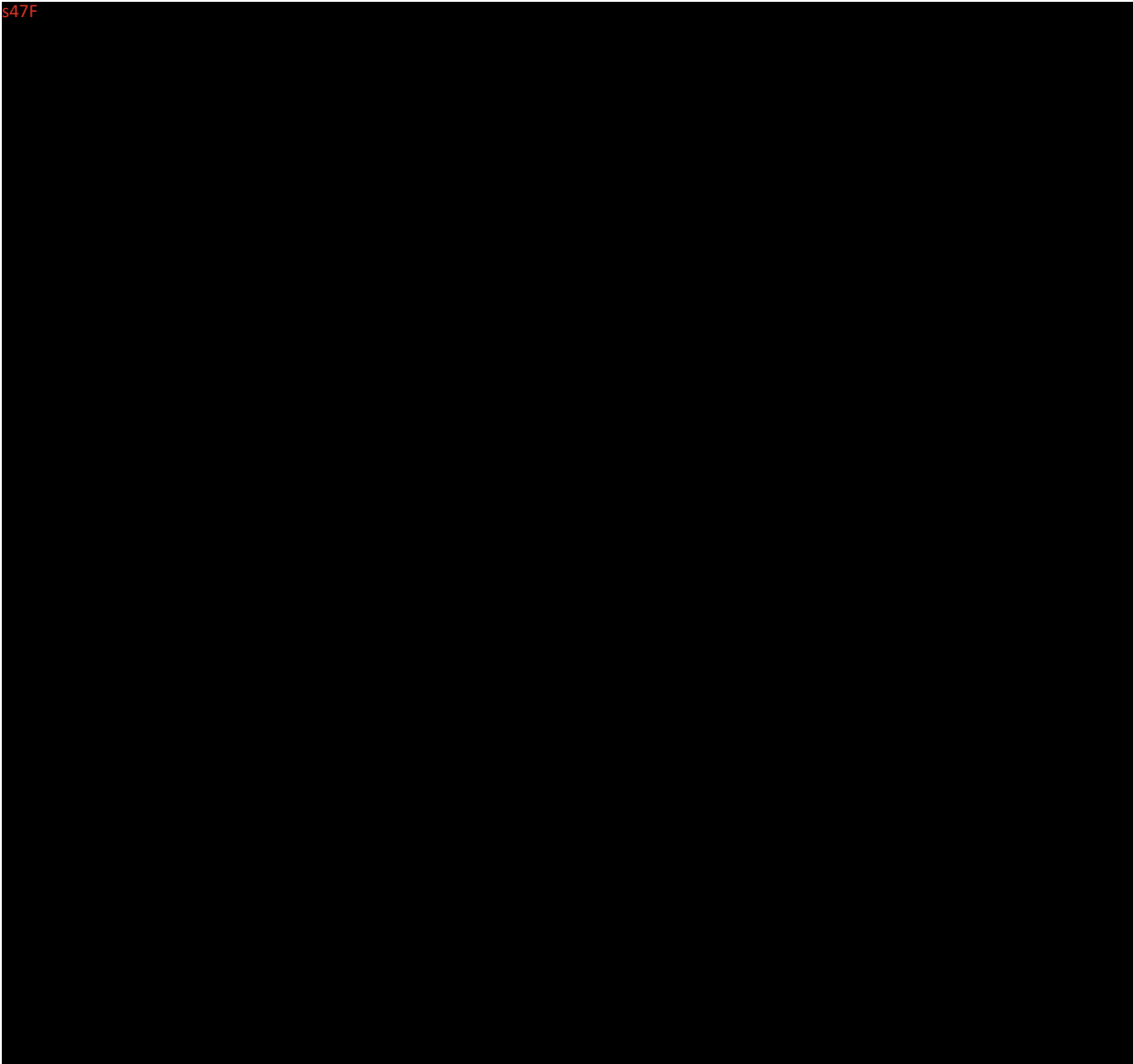
**Sender Details:**

Sender type: Regional Pharmacovigilance  
Centre

**Reporter Details:**

Qualification: Consumer or other non  
health professional

**Case narrative:**<sup>S47F</sup>



Reactions:

Preferred term	Onset date	End date	Management of Event	Outcome
Acne				<div>s47F</div>
Breast tenderness				
Menstrual disorder				
Pain				
Paraesthesia			<div>s47F</div>	
Weight increased				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: §47F [REDACTED]
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000596718****Case Details**

Report Date: 03/08/2021  
 Modified on: 04/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 39  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Polymenorrhoea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000596775****Case Details**

Report Date: 03/08/2021  
 Modified on: 04/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 53  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chills	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Injection site reaction		<span style="color: red;">§47F</span>		
Intermenstrual bleeding				
Myalgia				
Oropharyngeal pain				
Rhinorrhoea		<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	
Swollen tongue				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	

Action Taken:	
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**Case ID: AU-TGA-0000596857****Case Details**

Report Date: 03/08/2021  
 Modified on: 05/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47  
F

**Patient Details:**

Sex: Female  
 Age: 58  
 State: §47  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47  
F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder				<span style="color: red;">§47</span> <span style="background-color: black; color: red;">F</span>
Postmenopausal haemorrhage				<span style="color: red;">§47</span> <span style="background-color: black; color: red;">F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	Not applicable

**Case ID: AU-TGA-0000597027****Case Details**

Report Date: 03/08/2021  
 Modified on: 05/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 54  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	§47F	§47F		§47F
Menstrual disorder				
Myalgia	§47F	§47F		

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000597625****Case Details**

Report Date: 04/08/2021  
 Modified on: 05/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 54  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Menstrual disorder				
Presyncope				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000597653****Case Details**

Report Date: 04/08/2021  
 Modified on: 06/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 39  
 State: s47  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47  
F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>			<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000598024****Case Details**

Report Date: 05/08/2021  
 Modified on: 06/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 52  
 State: §47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Fatigue	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Menstrual disorder				
Pain in extremity	<span style="color: red;">§47F</span>			
Vaginal haemorrhage				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000598192****Case Details**

Report Date: 05/08/2021  
 Modified on: 06/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Fatigue				
Heavy menstrual bleeding				
Injection site pain				
Menstrual disorder				
Menstruation irregular				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F [REDACTED]
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F [REDACTED]
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000598230****Case Details**

Report Date: 05/08/2021  
 Modified on: 07/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Headache	§47F			§47F
Intermenstrual bleeding				
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

(2) CYMBALTA (Duloxetine hydrochloride) - Concomitant	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	§47F



**Case ID: AU-TGA-0000598480****Case Details**

Report Date: 05/08/2021  
 Modified on: 06/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 36  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Other health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000598674****Case Details**

Report Date: 06/08/2021  
 Modified on: 07/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 33  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dizziness	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Heavy menstrual bleeding		<span style="color: red;">§47F</span>		
Menstrual disorder				
Paraesthesia oral				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000598693****Case Details**

Report Date: 06/08/2021  
 Modified on: 07/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 48  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000598899****Case Details**

Report Date: 06/08/2021  
 Modified on: 07/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder			<span style="color: red;">s47F</span>	
Myocarditis				
Pericarditis	<span style="color: red;">s47F</span>			

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000599006****Case Details**

Report Date: 06/08/2021  
Modified on: 07/08/2021  
Causality: Causality possible  
Serious ICSR: s47F

**Patient Details:**

Sex: Female  
Age:  
State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chills	<span>s47F</span>			<span>s47F</span>
Heavy menstrual bleeding				
Injection site reaction				

Menstrual disorder				s47F
Pyrexia	s47F			

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: s47F
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: s47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000599015****Case Details**

Report Date: 06/08/2021  
 Modified on: 09/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 37  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	Not applicable

**Case ID: AU-TGA-0000599046****Case Details**

Report Date: 06/08/2021  
 Modified on: 09/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 54  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder				<span style="color: red;">§47F</span>
Postmenopausal haemorrhage	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000599057****Case Details**

Report Date: 06/08/2021  
 Modified on: 09/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 39  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000599171****Case Details**

Report Date: 07/08/2021  
 Modified on: 09/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 34  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Back pain	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	
Menstrual disorder	<span style="color: red;">§47F</span>			

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000599316****Case Details**

Report Date: 07/08/2021  
 Modified on: 09/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 46  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000599355****Case Details**

Report Date: 07/08/2021  
 Modified on: 10/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 32  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder			§47F	
Vaginal haemorrhage	§47F	§47F		

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000599361****Case Details**

Report Date: 07/08/2021  
 Modified on: 10/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 24  
 State: s47  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dizziness	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>			<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Menstrual disorder	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>		<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000599414****Case Details**

Report Date: 08/08/2021  
 Modified on: 10/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 32  
 State: s47  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**s47  
F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain upper	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Intermenstrual bleeding				
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	

Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000599453****Case Details**

Report Date: 08/08/2021  
 Modified on: 10/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 30  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000599507****Case Details**

Report Date: 08/08/2021  
 Modified on: 10/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 29  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Epistaxis	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual disorder				
Menstruation irregular	<span style="color: red;">s47F</span>			

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000599673****Case Details**

Report Date: 09/08/2021  
 Modified on: 10/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000599817****Case Details**

Report Date: 09/08/2021  
 Modified on: 11/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 51  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

(3) DESVENLAFAXINE (Desvenlafaxine) - Concomitant	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	<span style="color: red;">§47F</span>

(4) EUTROXSIG (levothyroxine sodium) - Concomitant	
Dosage information:	

Treatment details:	
Indication:	
Action Taken:	s47F [REDACTED]

**Case ID: AU-TGA-0000600039****Case Details**

Report Date: 09/08/2021  
 Modified on: 11/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age:  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000600702****Case Details**

Report Date: 10/08/2021  
 Modified on: 11/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 48  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Heavy menstrual bleeding				
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000600711****Case Details**

Report Date: 10/08/2021  
 Modified on: 11/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding				<span style="color: red;">s47F</span>
Intermenstrual bleeding				
Menstrual disorder	<span style="color: red;">s47F</span>			

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000601084****Case Details**

Report Date: 10/08/2021  
 Modified on: 12/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 48  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder			<span style="color: red;">s47F</span>	
Oligomenorrhoea	<span style="color: red;">s47F</span>			

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000601088****Case Details**

Report Date: 10/08/2021  
 Modified on: 12/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dizziness	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	
Postmenopausal haemorrhage				

**Drug information:**

(1) AMLODIPINE SANDOZ (Amlodipine) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	<span style="color: red;">§47F</span>

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

<span style="color: red;">§47F</span>	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	<span style="color: red;">§47F</span>

s47F	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	s47F

s47F	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	s47F

s47F	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	s47F

s47F	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	s47F

**Case ID: AU-TGA-0000601121****Case Details**

Report Date: 10/08/2021  
 Modified on: 12/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 42  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000601491****Case Details**

Report Date: 11/08/2021  
 Modified on: 12/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 51  
 State: s47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification: Physician

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Vaginal haemorrhage				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> , Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000601495****Case Details**

Report Date: 11/08/2021  
 Modified on: 14/08/2021  
 Causality: Causality possible  
 Serious ICSR: S47F

**Patient Details:**

Sex: Female  
 Age: 24  
 State: S47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding				<span style="color: red;">S47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000601559****Case Details**

Report Date: 11/08/2021  
 Modified on: 14/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 44  
 State: s47  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>	<span style="background-color: black; color: red;">F</span>		<span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Injection site pain				
Lethargy				
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47</span> <span style="background-color: black; color: red;">F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000601910****Case Details**

Report Date: 12/08/2021  
 Modified on: 13/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

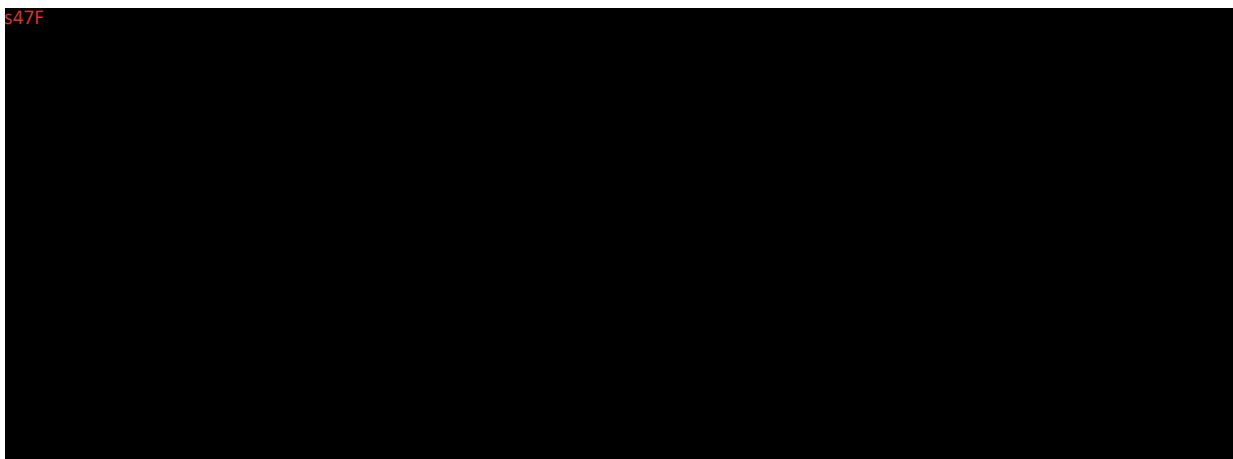
Sex: Female  
 Age:  
 State: Unknown

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder				<span style="color: red;">§47F</span>
Menstruation irregular				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000601970****Case Details**

Report Date: 12/08/2021  
 Modified on: 15/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 46  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder				<span style="color: red;">§47F</span>
Menstruation irregular	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

(2) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000601971****Case Details**

Report Date: 12/08/2021  
 Modified on: 15/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 57  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder				<span style="color: red;">§47F</span>
Postmenopausal haemorrhage	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000602088****Case Details**

Report Date: 12/08/2021  
 Modified on: 14/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Injection site pain	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Intermenstrual bleeding				
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000602557****Case Details**

Report Date: 12/08/2021  
 Modified on: 14/08/2021  
 Causality: Causality possible  
 Serious ICSR: S47  
F

**Patient Details:**

Sex: Female  
 Age: 28  
 State: S47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder			<span style="color: red;">S47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000602565****Case Details**

Report Date: 13/08/2021  
 Modified on: 15/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 37  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="background-color: black; color: red;">s47F</span>			<span style="background-color: black; color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

(2) ELIQUIS (Apixaban) - Concomitant	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	<span style="background-color: black; color: red;">s47F</span>

**Case ID: AU-TGA-0000602691****Case Details**

Report Date: 13/08/2021  
 Modified on: 14/08/2021  
 Causality: Causality possible  
 Serious ICSR: <sup>s47</sup>  
 F

**Patient Details:**

Sex: Female  
 Age: 31  
 State: <sup>s47</sup>

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<sup>s47</sup>		<sup>s47</sup>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <sup>s47</sup>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000602833****Case Details**

Report Date: 13/08/2021  
 Modified on: 15/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

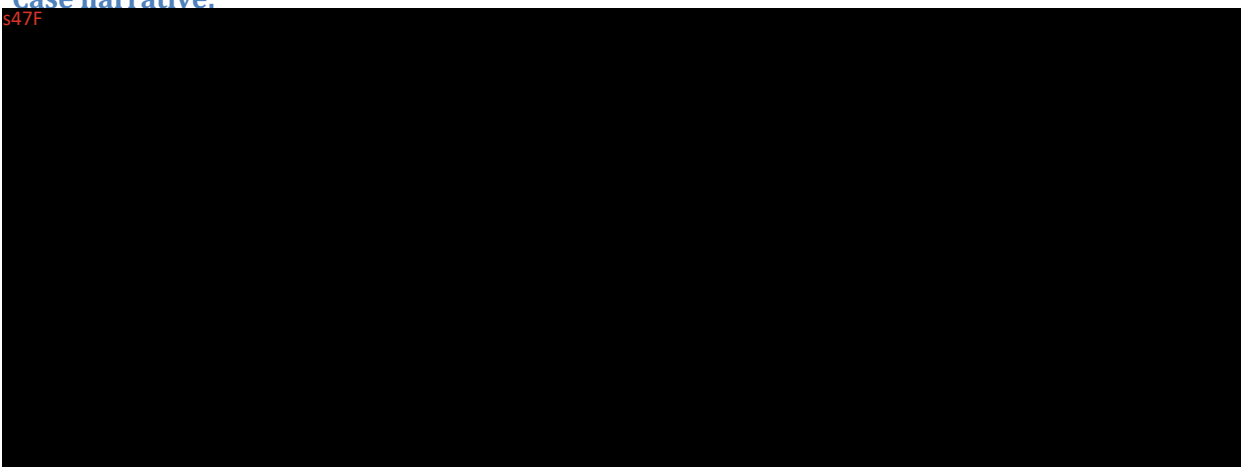
Sex: Female  
 Age: 27  
 State: s47  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Ageusia				<span style="color: red;">s47</span> <div style="background-color: black; width: 100%; height: 100%;"></div>
Dysgeusia	<span style="color: red;">s47</span> <div style="background-color: black; width: 100%; height: 100%;"></div>			
Heavy menstrual bleeding				
Menstrual disorder				
Paraesthesia oral				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000602991****Case Details**

Report Date: 13/08/2021  
Modified on: 14/08/2021  
Causality: Causality possible  
Serious ICSR: <sup>s47</sup>  
F

**Patient Details:**

Sex: Female  
Age: 38  
State: <sup>s47F</sup>

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**<sup>s47F</sup>  


s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dizziness	s47F		s47F	s47F
Dyspnoea				
Fibrin D dimer increased			s47F	
Heavy menstrual bleeding				
Injection site pain		s47F		
Menstrual disorder			s47F	
Menstruation irregular				
Pain				
Palpitations			s47F	



**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000603062****Case Details**

Report Date: 13/08/2021  
 Modified on: 15/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 32  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dyspepsia				<span style="color: red;">§47F</span>
Heavy menstrual bleeding	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		
Menstrual disorder				
Nausea				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000603335****Case Details**

Report Date: 13/08/2021  
 Modified on: 14/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 42  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000603654****Case Details**

Report Date: 14/08/2021  
 Modified on: 15/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 29  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="background-color: black; color: red;">s47F</span>	<span style="background-color: black; color: red;">s47F</span>		<span style="background-color: black; color: red;">s47F</span>
Menstrual disorder	<span style="background-color: black; color: red;">s47F</span>			

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000603662****Case Details**

Report Date: 14/08/2021  
 Modified on: 15/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 48  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual disorder	<span style="color: red;">s47F</span>			

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000603737****Case Details**

Report Date: 14/08/2021  
 Modified on: 16/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	s47F			s47F
Menstrual disorder				

**Drug information:**

(1) COMIRNATY COVID-19 VACCINE (BNT162b2 (mRNA)) - Suspect	
Dosage information:	
Treatment details:	Started: s47F
Indication:	
Action Taken:	



Australian Government

Department of Health

Therapeutic Goods Administration

## Public Case Details

### Filter(s):

Study Type: Unknown, Other studies

Case Decision: Accepted

Characterisation: Suspect, Interacting

Trade Name: COVID-19 Vaccine AstraZeneca

Reaction Term: Abnormal uterine bleeding, Amenorrhoea, Dysmenorrhoea, Heavy menstrual bleeding, Intermenstrual bleeding, Menometrorrhagia, Menstrual discomfort, Menstrual disorder, Menstruation delayed, Menstruation irregular, Oligomenorrhoea, Polymenorrhoea, Postmenopausal haemorrhage, Premenstrual syndrome, Polymenorrhagia, Premenstrual pain, Retrograde menstruation.

**Number of cases in this report:** 150.

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**Limitations of the data**

This document contains information from reports of adverse events that the TGA has received in relation to therapeutic goods. It does not contain all known information, and an assessment of the safety of a medicine cannot be made based on this information.

**Causality**

- The reports received by the TGA contain suspected associations that reflect the observations of an individual reporter. The reporter may be a health professional, a sponsor, or a member of the public.
- Adverse events are suspected of being related to a therapeutic good, but this relationship is usually not certain - the symptom may be related to the underlying illness or to other factors.
- There might be no relationship between the adverse event and the medicine - it may be a coincidence that the adverse event occurred when the medicine was taken.



**Case ID: AU-TGA-0000526133****Case Details**

Report Date: 25/03/2021  
 Modified on: 30/03/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 32  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Injection site pain	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	
Menstruation irregular				
Polymenorrhoea				
Premenstrual dysphoric disorder		<span style="color: red;">§47F</span>		
Pyrexia				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000529096****Case Details**

Report Date: 30/03/2021  
 Modified on: 07/04/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 32  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Physician

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Epistaxis	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Menstrual disorder				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000532786****Case Details**

Report Date: 06/04/2021  
 Modified on: 14/04/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age:  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Asthenia				<span style="color: red;">§47F</span>
Fatigue				
Headache	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	
Intermenstrual bleeding				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000533689****Case Details**

Report Date: 08/04/2021  
 Modified on: 14/04/2021  
 Causality: Causality possible  
 Serious ICSR: S47  
F

**Patient Details:**

Sex: Female  
 Age: 35  
 State: S47F  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**S47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia				<span style="color: red;">S47F</span> <span style="background-color: black; color: red;">F</span>
Chills				
Fatigue				
Headache				
Injection site reaction				
Myalgia				
Polymenorrhoea				
Pyrexia				
Rash				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect

Dosage information:

Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000534328****Case Details**

Report Date: 09/04/2021  
 Modified on: 13/04/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 26  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Chills		<span style="color: red;">§47F</span>		
Menstrual disorder				
Pyrexia		<span style="color: red;">§47F</span>		

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000535711****Case Details**

Report Date: 12/04/2021  
 Modified on: 16/04/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: §47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	§47F	§47F		§47F

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000536349****Case Details**

Report Date: 12/04/2021  
 Modified on: 15/04/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 23  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	§47F			§47F
Heavy menstrual bleeding				
Menstruation irregular				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose: §47F, Dose form: INJECTION
Treatment details:	
Indication:	
Action Taken:	

(2) VYVANSE (Lisdexamfetamine dimesilate) - Concomitant	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	§47F



**Case ID: AU-TGA-0000536910****Case Details**

Report Date: 13/04/2021  
 Modified on: 18/04/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 51  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Body temperature increased				<span style="color: red;">s47F</span>
Contusion				
Diarrhoea				
Dizziness				
Headache	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	
Lethargy				
Menstrual disorder				
Myalgia				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000536963****Case Details**

Report Date: 13/04/2021  
 Modified on: 17/04/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

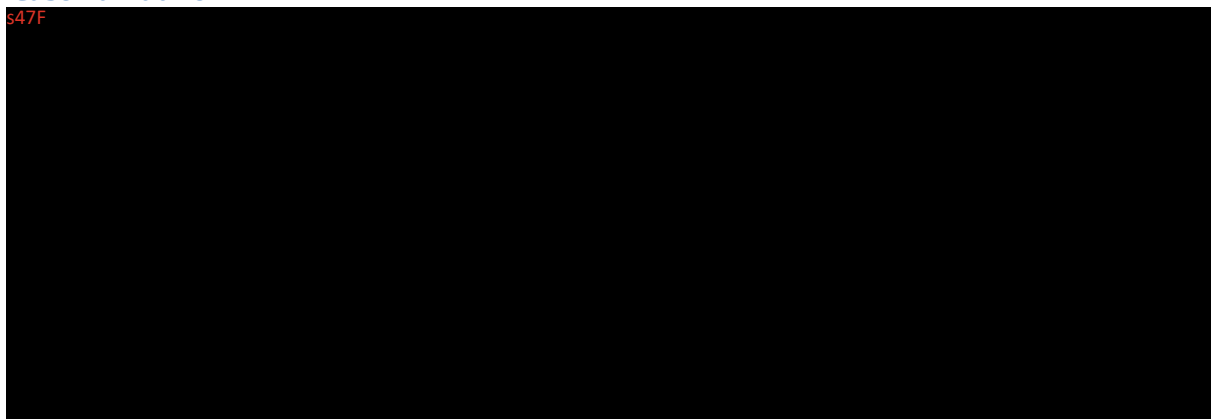
Sex: Female  
 Age: 29  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	Not applicable

**Case ID: AU-TGA-0000537578****Case Details**

Report Date: 14/04/2021  
 Modified on: 19/04/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000539124****Case Details**

Report Date: 16/04/2021  
 Modified on: 25/04/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age:  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Other health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea				<span style="color: red;">§47F</span>
Headache				
Injection site reaction	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	
Pyrexia				
Rash				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000539146****Case Details**

Report Date: 16/04/2021  
 Modified on: 21/04/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose form: INJECTION
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000539482****Case Details**

Report Date: 17/04/2021  
 Modified on: 11/05/2021  
 Causality: Causality possible  
 Serious ICSR: S47F

**Patient Details:**

Sex: Female  
 Age: 29  
 State: S47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

S47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder				<span style="color: red;">S47F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000539972****Case Details**

Report Date: 19/04/2021  
 Modified on: 03/05/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: §47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000540933****Case Details**

Report Date: 20/04/2021  
 Modified on: 23/04/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 44  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menometrorrhagia	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose: <span style="color: red;">§47F</span> , Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000541367****Case Details**

Report Date: 21/04/2021  
 Modified on: 23/04/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 28  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dizziness				<span style="color: red;">s47F</span>
Dizziness				
Feeling abnormal				
Heavy menstrual bleeding				
Lethargy				
Myalgia				
Vision blurred				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	

Indication:	
Action Taken:	

**Case ID: AU-TGA-0000541393****Case Details**

Report Date: 21/04/2021  
 Modified on: 24/04/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 48  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Epistaxis				
Headache				
Menstrual disorder				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000543618****Case Details**

Report Date: 26/04/2021  
 Modified on: 28/04/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age:  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Fatigue				
Headache	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	
Heavy menstrual bleeding				
Influenza like illness	<span style="color: red;">s47F</span>			
Myalgia	<span style="color: red;">s47F</span>			
Nausea	<span style="color: red;">s47F</span>			
Pain in extremity				
Pyrexia				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	

Action Taken:	
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**Case ID: AU-TGA-0000543619****Case Details**

Report Date: 26/04/2021  
 Modified on: 28/04/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 34  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Physician

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Heavy menstrual bleeding		<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000546051****Case Details**

Report Date: 30/04/2021  
Modified on: 10/05/2021  
Causality: Causality possible  
Serious ICSR: s47F

**Patient Details:**

Sex: Female  
Age: 39  
State: s47F

**Sender Details:**

Sender type: Pharmaceutical Company

**Reporter Details:**

Qualification: Other health professional

**Case narrative:**

s47F



s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia	s47F			s47F
Diarrhoea				
Exposure during pregnancy				
Injection site bruising				
Injection site erythema				
Joint stiffness				
Menstruation irregular				
Muscle abscess				
Pyrexia				
Salivary hypersecretion				
Swelling				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: s47F
Indication:	Vaccination
Action Taken:	Not applicable

**Case ID: AU-TGA-0000546207****Case Details**

Report Date: 30/04/2021  
 Modified on: 03/05/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 45  
 State: §47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Headache				
Injection site pain	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		
Insomnia				
Intermenstrual bleeding				
Nausea				
Pain in extremity				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000546375****Case Details**

Report Date: 01/05/2021  
 Modified on: 02/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chills	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>
Headache				
Injection site reaction				
Menstruation irregular				
Myalgia		<span style="color: red;">s47F</span>		

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000546427****Case Details**

Report Date: 01/05/2021  
 Modified on: 02/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age:  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Fatigue				<span style="color: red;">s47F</span>
Heavy menstrual bleeding	<span style="color: red;">s47F</span>			
Injection site pain				
Pyrexia				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000547062****Case Details**

Report Date: 03/05/2021  
 Modified on: 05/05/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 39  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding			<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Polymenorrhoea				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000547600****Case Details**

Report Date: 04/05/2021  
 Modified on: 06/05/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 27  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Physician

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Epistaxis	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Headache			<span style="color: red;">§47F</span>	
Heavy menstrual bleeding				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000547630****Case Details**

Report Date: 04/05/2021  
 Modified on: 06/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age:  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Headache				
Heavy menstrual bleeding				
Menstrual disorder				
Myalgia			<span style="color: red;">s47F</span>	

Oropharyngeal pain	§47F			§47F
Pyrexia				
Sensitive skin				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000548181****Case Details**

Report Date: 05/05/2021  
 Modified on: 13/05/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age:  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Physician

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dizziness	§47F		§47F	§47F
Dysmenorrhoea				
Feeling abnormal				
Headache				
Myalgia				
Nausea				
Palpitations				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Test and procedures:**

Test name	Test date	Normal range	Test result	Comment
			"	

**Case ID: AU-TGA-0000548857****Case Details**

Report Date: 06/05/2021  
 Modified on: 13/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age:  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000549277****Case Details**

Report Date: 07/05/2021  
 Modified on: 14/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 28  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding				<span style="color: red;">s47F</span>
Menstruation irregular	<span style="color: red;">s47F</span>			

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000549452****Case Details**

Report Date: 07/05/2021  
 Modified on: 12/05/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age:  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	§47F		§47F	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose form: INJECTION
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000549473****Case Details**

Report Date: 07/05/2021  
 Modified on: 09/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	s47F		s47F	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: s47F
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000550093****Case Details**

Report Date: 10/05/2021  
 Modified on: 12/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 36  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Feeling of body temperature change	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>
Injection site pain				
Menstrual disorder				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000550392****Case Details**

Report Date: 10/05/2021  
 Modified on: 16/05/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding			<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Menstrual disorder				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000550677****Case Details**

Report Date: 10/05/2021  
 Modified on: 11/05/2021  
 Causality: Causality possible  
 Serious ICSR: S47F

**Patient Details:**

Sex: Female  
 Age: 48  
 State: S47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**S47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Headache			<span style="color: red;">S47F</span>	<span style="color: red;">S47F</span>
Menstrual disorder				
Thrombocytopenia				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">S47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000551122****Case Details**

Report Date: 11/05/2021  
 Modified on: 19/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age:  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Oligomenorrhoea	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000551524****Case Details**

Report Date: 12/05/2021  
 Modified on: 28/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 46  
 State: s47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000552027****Case Details**

Report Date: 13/05/2021  
 Modified on: 18/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000552084****Case Details**

Report Date: 13/05/2021  
 Modified on: 14/05/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 55  
 State: §47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Contusion	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	
Epistaxis				
Menstrual disorder				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

(2) VAXIGRIP TETRA (Influenza virus haemagglutinin) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000553496****Case Details**

Report Date: 14/05/2021  
 Modified on: 18/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 34  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Eye pain				<span style="color: red;">s47F</span>
Headache			<span style="color: red;">s47F</span>	
Heavy menstrual bleeding				
Neck pain				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000555897****Case Details**

Report Date: 20/05/2021  
 Modified on: 21/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 69  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Postmenopausal haemorrhage	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000556083****Case Details**

Report Date: 20/05/2021  
 Modified on: 21/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 51  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain				<span style="color: red;">s47F</span>
Diarrhoea				
Dysmenorrhoea				
Epistaxis				
Injection site reaction			<span style="color: red;">s47F</span>	
Lethargy				
Myalgia				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000556248****Case Details**

Report Date: 21/05/2021  
 Modified on: 25/05/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 56  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Postmenopausal haemorrhage			<span style="color: red;">§47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000556444****Case Details**

Report Date: 21/05/2021  
 Modified on: 26/05/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 51  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dizziness	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Intermenstrual bleeding				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000557088****Case Details**

Report Date: 23/05/2021  
 Modified on: 01/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Amenorrhoea	§47F	§47F		§47F

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000557704****Case Details**

Report Date: 24/05/2021  
 Modified on: 29/05/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

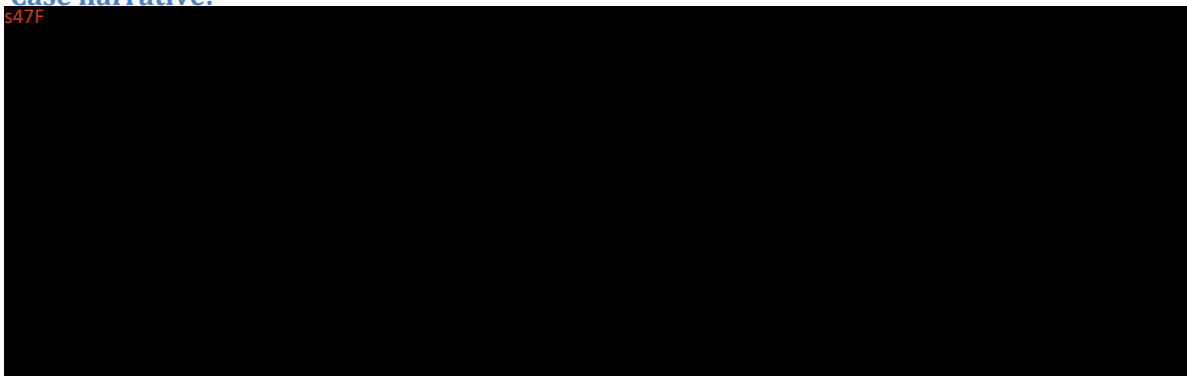
Sex: Female  
 Age:  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding			<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Menstruation irregular				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000560284****Case Details**

Report Date: 29/05/2021  
 Modified on: 31/05/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 48  
 State: s47F  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47F</span> <span style="background-color: black; color: red;">F</span>		<span style="color: red;">s47F</span> <span style="background-color: black; color: red;">F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000560541****Case Details**

Report Date: 30/05/2021  
 Modified on: 01/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 36  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	§47F			§47F

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000561053****Case Details**

Report Date: 31/05/2021  
 Modified on: 05/06/2021  
 Causality: Causality possible  
 Serious ICSR: S47  
F

**Patient Details:**

Sex: Female  
 Age: 28  
 State: S47F  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**S47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder				<span style="color: red;">S47F</span> <span style="background-color: black; color: red;">F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000562612****Case Details**

Report Date: 02/06/2021  
 Modified on: 04/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

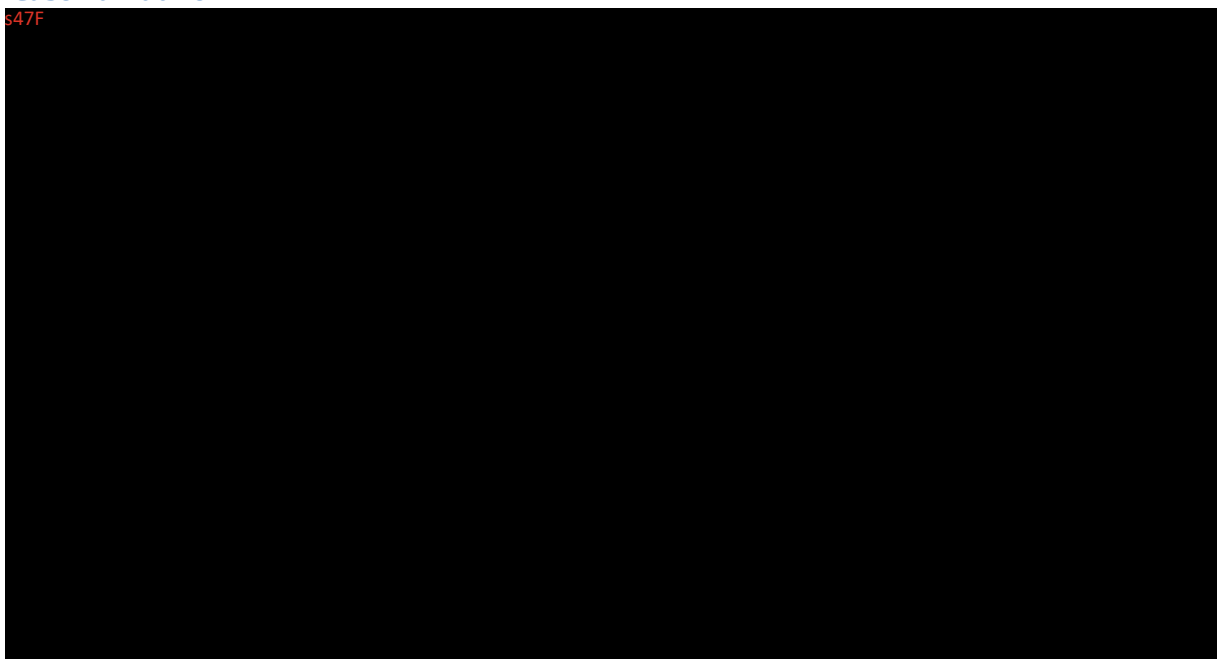
Sex: Female  
 Age: §47F  
 State: [REDACTED]

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Fibrin D dimer increased	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	
Heavy menstrual bleeding		<span style="color: red;">§47F</span>		

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000563480****Case Details**

Report Date: 04/06/2021  
 Modified on: 09/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 48  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chills	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	
Headache		<span style="color: red;">§47F</span>		
Heavy menstrual bleeding				
Myalgia		<span style="color: red;">§47F</span>		
Polymenorrhoea				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000564418****Case Details**

Report Date: 07/06/2021  
 Modified on: 11/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 53  
 State: s47F  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F  
F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding				<span style="color: red;">s47F</span> <span style="background-color: black; color: red;">F</span>
Influenza like illness				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000564575****Case Details**

Report Date: 07/06/2021  
 Modified on: 08/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 69  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000564902****Case Details**

Report Date: 07/06/2021  
 Modified on: 10/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age:  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain				s47F
Breast pain				
Menstrual disorder	s47F		s47F	
Vaccination site reaction				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: s47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000565356****Case Details**

Report Date: 08/06/2021  
 Modified on: 09/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 25  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000565522****Case Details**

Report Date: 08/06/2021  
 Modified on: 11/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 58  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Blindness	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Dysmenorrhoea				
Heavy menstrual bleeding				
Inflammation				
Injection site reaction			<span style="color: red;">s47F</span>	



Migraine	s47F			s47F
Visual impairment				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: s47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000565523****Case Details**

Report Date: 08/06/2021  
 Modified on: 11/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Adnexa uteri pain	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Headache				
Menstrual disorder				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000565525****Case Details**

Report Date: 08/06/2021  
 Modified on: 11/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age:  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000565959****Case Details**

Report Date: 09/06/2021  
 Modified on: 12/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: s47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	s47F		s47F	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: s47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000568069****Case Details**

Report Date: 14/06/2021  
 Modified on: 25/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 46  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain			<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Menstruation delayed				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000568607****Case Details**

Report Date: 15/06/2021  
 Modified on: 19/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 51  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000570585****Case Details**

Report Date: 17/06/2021  
 Modified on: 23/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 29  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000570715****Case Details**

Report Date: 17/06/2021  
 Modified on: 23/06/2021  
 Causality: Causality possible  
 Serious ICSR: S47F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: S47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abnormal uterine bleeding	S47F			S47F

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000570877****Case Details**

Report Date: 18/06/2021  
 Modified on: 23/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47  
F

**Patient Details:**

Sex: Female  
 Age: 36  
 State: s47F  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	<span style="color: red;">s47F</span> <span style="background-color: black; color: red;">F</span>			<span style="color: red;">s47F</span> <span style="background-color: black; color: red;">F</span>
Migraine				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000570951****Case Details**

Report Date: 18/06/2021  
 Modified on: 30/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 52  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Fatigue	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Influenza like illness				
Menstruation irregular		<span style="color: red;">§47F</span>		
Myalgia				
Pyrexia		<span style="color: red;">§47F</span>		

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000571436****Case Details**

Report Date: 19/06/2021  
 Modified on: 29/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 52  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Back pain	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Myalgia				
Postmenopausal haemorrhage		<span style="color: red;">s47F</span>		

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> , Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000571459****Case Details**

Report Date: 19/06/2021  
 Modified on: 29/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 61  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Postmenopausal haemorrhage	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose: <span style="color: red;">§47F</span> , Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000571500****Case Details**

Report Date: 19/06/2021  
 Modified on: 29/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 56  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Postmenopausal haemorrhage	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose: <span style="color: red;">§47F</span> , Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000571506****Case Details**

Report Date: 19/06/2021  
 Modified on: 29/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 30  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Headache	s47F	s47F		s47F
Menstruation irregular				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose: s47F, Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	
Indication:	
Action Taken:	

(2) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose: s47F, Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000571656****Case Details**

Report Date: 20/06/2021  
 Modified on: 26/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 41  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstruation irregular	§47F	§47F	§47F	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000572282****Case Details**

Report Date: 21/06/2021  
 Modified on: 30/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 58  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Premenstrual syndrome			<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Vaginal haemorrhage				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000572452****Case Details**

Report Date: 21/06/2021  
 Modified on: 29/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 53  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Postmenopausal haemorrhage		<span style="color: red;">§47F</span>		

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000572514****Case Details**

Report Date: 22/06/2021  
 Modified on: 28/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 52  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chills	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	
Fatigue				
Headache				
Myalgia				
Postmenopausal haemorrhage				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000572713****Case Details**

Report Date: 22/06/2021  
 Modified on: 23/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Blood test abnormal				<span style="color: red;">s47F</span>
Chest pain	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		
Chills				
Dyspepsia				
Headache		<span style="color: red;">s47F</span>		
Heavy menstrual bleeding				

Hot flush	s47F		s47F
Injection site reaction			

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect			
Dosage information:			
Treatment details:	Started:	s47F	
Indication:			
Action Taken:			

(2) GLUCOSAMINE (Glucosamine) - Concomitant			
Dosage information:			
Treatment details:			
Indication:			
Action Taken:	s47F		

(3) MAGNESIUM (magnesium) - Concomitant			
Dosage information:			
Treatment details:			
Indication:			
Action Taken:	s47F		

(4) NORTRIPTYLINE HYDROCHLORIDE (Nortriptyline hydrochloride) - Concomitant			
Dosage information:			
Treatment details:			
Indication:			
Action Taken:	s47F		

s47F			
Dosage information:			
Treatment details:			
Indication:			
Action Taken:	s47F		

(6) TURMERIC (Curcuma aromatica) - Concomitant			
Dosage information:			
Treatment details:			
Indication:			
Action Taken:	s47F		

s47F	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	s47F

**Case ID: AU-TGA-0000572794****Case Details**

Report Date: 22/06/2021  
 Modified on: 28/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 51  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	s47F			s47F

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000572918****Case Details**

Report Date: 22/06/2021  
 Modified on: 11/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 37  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Amenorrhoea			<span style="color: red;">§47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000573520****Case Details**

Report Date: 23/06/2021  
 Modified on: 26/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 45  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Physician

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000574193****Case Details**

Report Date: 24/06/2021  
 Modified on: 25/06/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 38  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal discomfort				<span style="color: red;">§47F</span>
Confusional state				
Fatigue				
Feeling abnormal				
Headache	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		
Nausea				
Polymenorrhoea				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000575078****Case Details**

Report Date: 24/06/2021  
 Modified on: 01/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Headache	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Mood altered				
Postmenopausal haemorrhage		<span style="color: red;">s47F</span>		
Uterine spasm				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000575197****Case Details**

Report Date: 25/06/2021  
 Modified on: 06/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 45  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Amenorrhoea	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	
Chills		<span style="color: red;">§47F</span>		
Headache				
Lethargy		<span style="color: red;">§47F</span>		
Myalgia				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000575291****Case Details**

Report Date: 25/06/2021  
 Modified on: 03/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 53  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Breast pain				s47F
Local reaction	s47F			
Postmenopausal haemorrhage				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000575569****Case Details**

Report Date: 25/06/2021  
 Modified on: 08/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 44  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Physician

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Extrasystoles				<span style="color: red;">§47F</span>
Heavy menstrual bleeding				
Oligomenorrhoea	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000575878****Case Details**

Report Date: 27/06/2021  
 Modified on: 02/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 45  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000576136****Case Details**

Report Date: 28/06/2021  
 Modified on: 02/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 52  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="background-color: black; color: red;">s47F</span>			<span style="background-color: black; color: red;">s47F</span>
Heavy menstrual bleeding				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

(2) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	Not applicable

**Case ID: AU-TGA-0000576271****Case Details**

Report Date: 28/06/2021  
 Modified on: 03/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 36  
 State: §47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	<span style="color: red;">§47F</span>

(2) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000576855****Case Details**

Report Date: 29/06/2021  
 Modified on: 30/06/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 49  
 State: s47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstruation delayed				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000577296****Case Details**

Report Date: 30/06/2021  
 Modified on: 02/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	s47F	s47F		s47F

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000577400****Case Details**

Report Date: 30/06/2021  
 Modified on: 04/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 46  
 State: s47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding				<span style="color: red;">s47F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000578180****Case Details**

Report Date: 01/07/2021  
 Modified on: 05/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 25  
 State: §47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Galactorrhoea				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

(2) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000578408****Case Details**

Report Date: 01/07/2021  
 Modified on: 03/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 37  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Headache			<span style="color: red;">s47F</span>	
Heavy menstrual bleeding				
Musculoskeletal stiffness	<span style="color: red;">s47F</span>			
Myalgia				
Pain in extremity				
Peripheral swelling				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

## Case ID: AU-TGA-0000578415

### Case Details

Report Date: 01/07/2021  
 Modified on: 11/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

### Patient Details:

Sex: Female  
 Age: 51  
 State: §47F

### Sender Details:

Sender type: Regional Pharmacovigilance  
 Centre

### Reporter Details:

Qualification: Consumer or other non  
 health professional

### Case narrative:

§47F

### Reactions:

Preferred term	Onset date	End date	Management of Event	Outcome
Lethargy	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Menstruation irregular				
Myalgia				

### Drug information:

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000578418****Case Details**

Report Date: 01/07/2021  
 Modified on: 03/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 54  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Headache				<span style="color: red;">s47F</span>
Injection site reaction	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	
Menstrual disorder				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000578467****Case Details**

Report Date: 01/07/2021  
 Modified on: 03/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 40  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Menstrual disorder				
Pain in extremity				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000578991****Case Details**

Report Date: 02/07/2021  
 Modified on: 05/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 26  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chest pain	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Intermenstrual bleeding		<span style="color: red;">§47F</span>		
Nausea				
Pain				
Pyrexia				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

(2) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	

Action Taken:	
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**Case ID: AU-TGA-0000579207****Case Details**

Report Date: 02/07/2021  
 Modified on: 16/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age:  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Postmenopausal haemorrhage	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000579251****Case Details**

Report Date: 02/07/2021  
 Modified on: 14/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 57  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Back pain				<span style="color: red;">s47F</span>
Postmenopausal haemorrhage			<span style="color: red;">s47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000579499****Case Details**

Report Date: 03/07/2021  
 Modified on: 05/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 54  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Influenza like illness	§47F			§47F
Intermenstrual bleeding			§47F	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: §47F
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000579644****Case Details**

Report Date: 04/07/2021  
 Modified on: 06/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 54  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Anaemia	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Asthenia				
Dizziness				
Dysgeusia				
Dyspnoea				
Fatigue				
Headache				
Heart rate increased		<span style="color: red;">§47F</span>		
Heavy menstrual bleeding				
Hypertension				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose: <span style="color: red;">§47F</span> , Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>

Indication:	
Action Taken:	



**Case ID: AU-TGA-0000579843****Case Details**

Report Date: 05/07/2021  
 Modified on: 06/07/2021  
 Causality: Causality possible  
 Serious ICSR: S47  
F

**Patient Details:**

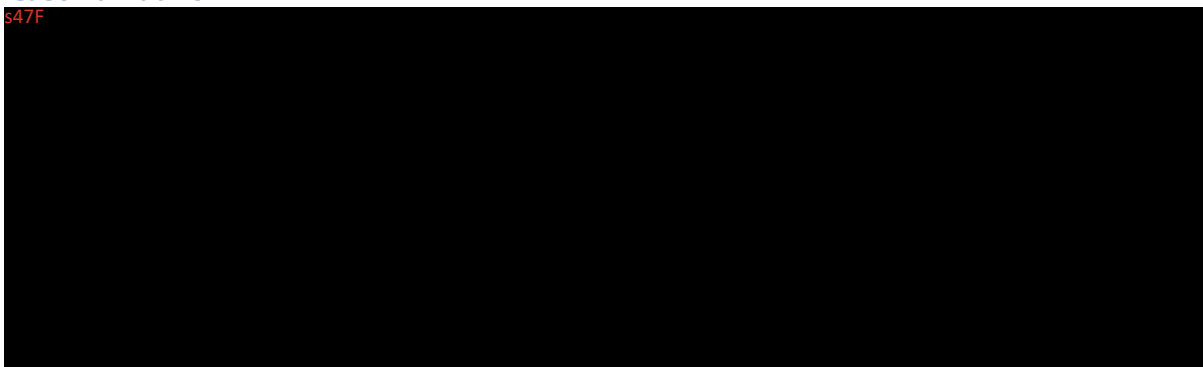
Sex: Female  
 Age: 46  
 State: S47F  
F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**S47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder				<span style="color: red;">S47F</span> <span style="background-color: black; color: red;">F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000580628****Case Details**

Report Date: 06/07/2021  
 Modified on: 13/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 65  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Deep vein thrombosis				<span style="color: red;">s47F</span>
Oligomenorrhoea				
Thrombophlebitis superficial	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect

Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000580940****Case Details**

Report Date: 06/07/2021  
 Modified on: 14/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 21  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000581031****Case Details**

Report Date: 06/07/2021  
 Modified on: 08/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 40  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Physician

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Varicose vein				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000581371****Case Details**

Report Date: 07/07/2021  
 Modified on: 09/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 51  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Breast cyst	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Influenza like illness				
Injection site pain				
Lymphadenopathy	<span style="color: red;">§47F</span>			
Menstrual disorder	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000581675****Case Details**

Report Date: 07/07/2021  
 Modified on: 09/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 47  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	s47F	s47F		s47F

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000581889****Case Details**

Report Date: 07/07/2021  
 Modified on: 16/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 27  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Other health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain upper	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Feeling abnormal				
Headache			<span style="color: red;">s47F</span>	



Injection site reaction	s47F			s47F
Lethargy				
Menstrual disorder				
Photophobia				
Pyrexia				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: s47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000581890****Case Details**

Report Date: 07/07/2021  
 Modified on: 16/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 48  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder				<span style="color: red;">§47F</span>
Vaginal haemorrhage			<span style="color: red;">§47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000583161****Case Details**

Report Date: 09/07/2021  
 Modified on: 11/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 57  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Cold sweat				<span style="color: red;">s47F</span>
Fatigue				
Headache				
Heavy menstrual bleeding				
Menstrual disorder				
Nausea				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect

Dosage information:

Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000583560****Case Details**

Report Date: 10/07/2021  
 Modified on: 13/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Epistaxis	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Heavy menstrual bleeding				
Injection site reaction	<span style="color: red;">s47F</span>			
Syncope				
Urticaria				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000584266****Case Details**

Report Date: 12/07/2021  
 Modified on: 24/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 51  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Postmenopausal haemorrhage			<span style="color: red;">s47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000584924****Case Details**

Report Date: 13/07/2021  
 Modified on: 15/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 49  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	
Menstrual disorder	<span style="color: red;">§47F</span>			

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000585967****Case Details**

Report Date: 14/07/2021  
 Modified on: 16/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 51  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Migraine				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>



Indication:	
Action Taken:	

**Case ID: AU-TGA-0000586530****Case Details**

Report Date: 15/07/2021  
 Modified on: 16/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 29  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000586599****Case Details**

Report Date: 15/07/2021  
 Modified on: 21/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 69  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder				<span style="color: red;">§47F</span>
Postmenopausal haemorrhage	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000587053****Case Details**

Report Date: 15/07/2021  
 Modified on: 28/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 51  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Physician

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Back pain	§47F		§47F	§47F
Menstrual disorder				
Pelvic pain				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000587343****Case Details**

Report Date: 16/07/2021  
 Modified on: 20/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 39  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Fatigue				
Myalgia				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000588395****Case Details**

Report Date: 19/07/2021  
 Modified on: 21/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 62  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Postmenopausal haemorrhage			<span style="color: red;">§47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose: <span style="color: red;">§47F</span> , Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000589130****Case Details**

Report Date: 20/07/2021  
 Modified on: 22/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 53  
 State: §47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dizziness	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Headache			<span style="color: red;">§47F</span>	
Heavy menstrual bleeding				
Menstrual disorder				
Visual impairment				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose: <span style="color: red;">§47F</span> , Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000589470****Case Details**

Report Date: 20/07/2021  
 Modified on: 22/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 31  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000590222****Case Details**

Report Date: 22/07/2021  
 Modified on: 24/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 34  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000590506****Case Details**

Report Date: 22/07/2021  
 Modified on: 07/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 54  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Dysmenorrhoea	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Malaise				
Nasopharyngitis				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000590901****Case Details**

Report Date: 23/07/2021  
 Modified on: 25/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 28  
 State: Unknown

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="background-color: black; color: red;">§47F</span>			<span style="background-color: black; color: red;">§47F</span>
Intermenstrual bleeding				
Menstrual disorder				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="background-color: black; color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000590902****Case Details**

Report Date: 23/07/2021  
 Modified on: 25/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia	s47F			s47F
Contusion				
Dyspnoea				
Intermenstrual bleeding				
Musculoskeletal chest pain				
Pain in extremity				
Pyrexia				
Swelling				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000591493****Case Details**

Report Date: 23/07/2021  
 Modified on: 11/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Other health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000592059****Case Details**

Report Date: 26/07/2021  
 Modified on: 29/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 48  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>
Bedridden				
Chills			<span style="color: red;">§47F</span>	
Fatigue				
Headache				
Insomnia				
Menstrual disorder				
Menstruation irregular				
Nausea		<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose: <span style="color: red;">§47F</span> , Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000592514****Case Details**

Report Date: 26/07/2021  
 Modified on: 27/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 33  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain				<span style="color: red;">s47F</span>
Arthralgia				
Chills				
Headache				
Injection site reaction			<span style="color: red;">s47F</span>	
Lethargy				
Menstrual disorder				
Myalgia				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000592556****Case Details**

Report Date: 26/07/2021  
 Modified on: 27/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

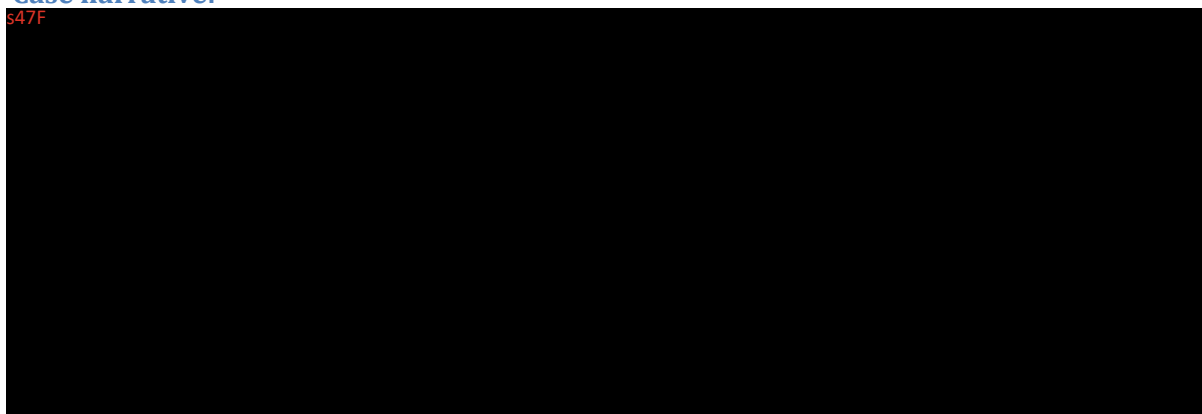
Sex: Female  
 Age: 52  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Headache	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Migraine				
Peripheral swelling			<span style="color: red;">s47F</span>	
Postmenopausal haemorrhage				
Tinnitus				
Vision blurred				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000592590****Case Details**

Report Date: 26/07/2021  
 Modified on: 30/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 39  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>
Dizziness				
Erythema		<span style="color: red;">§47F</span>		
Fatigue				
Feeling hot		<span style="color: red;">§47F</span>		
Flushing				
Hypoaesthesia oral				
Injection site reaction				
Menstrual disorder				
Menstruation irregular				
Paraesthesia		<span style="color: red;">§47F</span>		

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose: <span style="color: red;">§47F</span> , Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000592599****Case Details**

Report Date: 26/07/2021  
 Modified on: 28/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 53  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Lethargy	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual disorder				
Oligomenorrhoea				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000592732****Case Details**

Report Date: 27/07/2021  
 Modified on: 28/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age:  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Herpes zoster	<span style="background-color: black; color: red;">§47F</span>			<span style="background-color: black; color: red;">§47F</span>
Menstrual disorder				
Postmenopausal haemorrhage				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="background-color: black; color: red;">§47F</span>
Indication:	
Action Taken:	

(2) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="background-color: black; color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000593085****Case Details**

Report Date: 27/07/2021  
 Modified on: 29/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 68  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Postmenopausal haemorrhage	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000594390****Case Details**

Report Date: 29/07/2021  
 Modified on: 30/07/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 27  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000594505****Case Details**

Report Date: 29/07/2021  
 Modified on: 31/07/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 57  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder				§47F
Postmenopausal haemorrhage	§47F	§47F		

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000595252****Case Details**

Report Date: 30/07/2021  
 Modified on: 03/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 59  
 State: §47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Lethargy	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>
Menstruation irregular				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	

Action Taken:	
---------------	--



**Case ID: AU-TGA-0000595736****Case Details**

Report Date: 01/08/2021  
 Modified on: 03/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 33  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstruation irregular			<span style="color: red;">s47F</span>	
Pyrexia		<span style="color: red;">s47F</span>		

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose: <span style="color: red;">s47F</span> , Dose form: INJECTION, Route of Administration: Intramuscular
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000595994****Case Details**

Report Date: 02/08/2021  
 Modified on: 15/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 30  
 State: s47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual discomfort				
Menstrual disorder				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000596672****Case Details**

Report Date: 03/08/2021  
 Modified on: 04/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 27  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain				<span style="background-color: black; color: red;">s47F</span>
Chills				
Decreased appetite				
Delirium				
Diarrhoea				
Fatigue				
Headache				
Injection site reaction				
Menstrual disorder	<span style="background-color: black; color: red;">s47F</span>	<span style="background-color: black; color: red;">s47F</span>		
Myalgia				
Polymenorrhoea				
Pyrexia	<span style="background-color: black; color: red;">s47F</span>	<span style="background-color: black; color: red;">s47F</span>		
Vomiting				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000597615****Case Details**

Report Date: 04/08/2021  
 Modified on: 06/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 29  
 State: s47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000598316****Case Details**

Report Date: 05/08/2021  
 Modified on: 07/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 34  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	Not applicable

**Case ID: AU-TGA-0000598653****Case Details**

Report Date: 06/08/2021  
 Modified on: 07/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 50  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>	
Menstrual disorder	<span style="color: red;">§47F</span>			

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000599232****Case Details**

Report Date: 07/08/2021  
 Modified on: 09/08/2021  
 Causality: Causality possible  
 Serious ICSR: S47  
F

**Patient Details:**

Sex: Female  
 Age: 21  
 State: S47  
F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">S47</span> <span style="background-color: black; color: red;">F</span>			<span style="color: red;">S47</span> <span style="background-color: black; color: red;">F</span>
Menstrual disorder				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000599441****Case Details**

Report Date: 08/08/2021  
 Modified on: 10/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 45  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

s47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Intermenstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual disorder				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000599639****Case Details**

Report Date: 09/08/2021  
 Modified on: 10/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 48  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Arthralgia	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Fatigue			<span style="color: red;">§47F</span>	
Headache				
Heavy menstrual bleeding				
Hot flush			<span style="color: red;">§47F</span>	
Hyperhidrosis				
Hypoaesthesia				
Injection site pain				
Limb discomfort				
Menstrual disorder				
Nausea			<span style="color: red;">§47F</span>	

Paraesthesia	s47F		s47F
Rash			

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	Dose: s47F Dose form: INJECTION , Route of Administration: Intramuscular
Treatment details:	Started: s47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000599647****Case Details**

Report Date: 09/08/2021  
 Modified on: 10/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 31  
 State: s47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Headache	<span style="color: red;">s47F</span>		<span style="color: red;">s47F</span>	<span style="color: red;">s47F</span>
Influenza like illness				
Intermenstrual bleeding				
Malaise		<span style="color: red;">s47F</span>		
Menstrual disorder				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect

Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000600650****Case Details**

Report Date: 10/08/2021  
 Modified on: 12/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 39  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

Refer to the Reaction details

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">§47F</span>			<span style="color: red;">§47F</span>
Menstrual disorder				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000601045****Case Details**

Report Date: 10/08/2021  
 Modified on: 12/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 38  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chest pain	§47F			§47F
Decreased appetite				
Diarrhoea				
Dyspnoea				
Fibrin D dimer increased				
Headache				
Heart rate increased		§47F	§47F	
Liver function test increased				§47F
Malaise				
Menstrual disorder				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	



**Case ID: AU-TGA-0000601160****Case Details**

Report Date: 11/08/2021  
 Modified on: 12/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 43  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Heavy menstrual bleeding	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Menstrual disorder			<span style="color: red;">s47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000601886****Case Details**

Report Date: 12/08/2021  
 Modified on: 13/08/2021  
 Causality: Causality possible  
 Serious ICSR: s47F

**Patient Details:**

Sex: Female  
 Age: 21  
 State: s47F

**Sender Details:**

Sender type: Regional Pharmacovigilance  
 Centre

**Reporter Details:**

Qualification: Consumer or other non  
 health professional

**Case narrative:**s47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Contusion	<span style="color: red;">s47F</span>			<span style="color: red;">s47F</span>
Heavy menstrual bleeding				
Menstrual disorder				
Vulvovaginal pain			<span style="color: red;">s47F</span>	
Vulvovaginal swelling				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">s47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000601921****Case Details**

Report Date: 12/08/2021  
 Modified on: 14/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 32  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Abdominal pain upper	§47F	§47F	§47F	§47F
Menstrual disorder				
Menstruation irregular	§47F		§47F	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: §47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000602940****Case Details**

Report Date: 13/08/2021  
 Modified on: 15/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 68  
 State: §47F

**Sender Details:**

Sender type: Health Professional

**Reporter Details:**

Qualification:

**Case narrative:**

§47F

**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Postmenopausal haemorrhage				<span style="color: red;">§47F</span>
Vaginal haemorrhage	<span style="color: red;">§47F</span>	<span style="color: red;">§47F</span>		

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: <span style="color: red;">§47F</span>
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000604033****Case Details**

Report Date: 16/08/2021  
 Modified on: 16/08/2021  
 Causality: Causality possible  
 Serious ICSR: §47F

**Patient Details:**

Sex: Female  
 Age: 61  
 State: §47F

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification: Consumer or other non health professional

**Case narrative:**§47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Chest discomfort				<span style="color: red;">§47F</span>
Chills				
Diarrhoea	<span style="color: red;">§47F</span>		<span style="color: red;">§47F</span>	
Dizziness		<span style="color: red;">§47F</span>		

Headache	s47F	s47F	s47F	s47F
Hypoaesthesia				
Menstrual disorder				
Neck pain	s47F		s47F	s47F
Pain				
Postmenopausal haemorrhage				

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	Started: s47F
Indication:	
Action Taken:	

**Case ID: AU-TGA-0000604542****Case Details**

Report Date: 16/08/2021  
 Modified on: 16/08/2021  
 Causality: Causality possible  
 Serious ICSR: S47  
F

**Patient Details:**

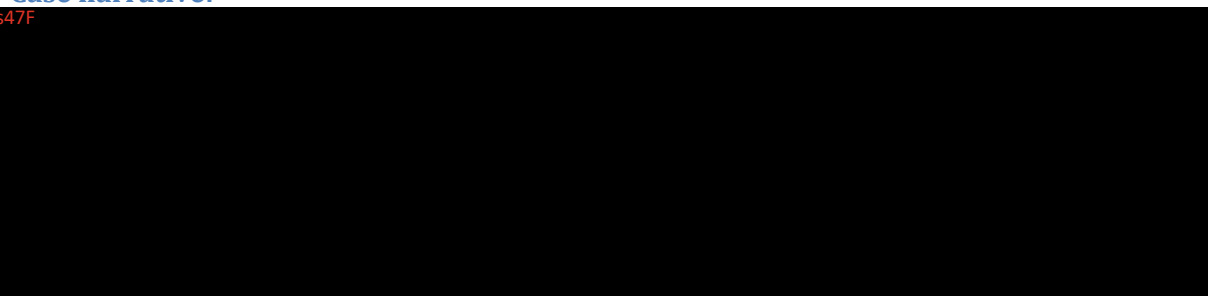
Sex: Female  
 Age: 34  
 State: Unknown

**Sender Details:**

Sender type: Patient/Consumer

**Reporter Details:**

Qualification:

**Case narrative:**S47F**Reactions:**

Preferred term	Onset date	End date	Management of Event	Outcome
Menstrual disorder			<span style="color: red;">S47F</span>	

**Drug information:**

(1) COVID-19 VACCINE ASTRAZENECA (ChAdOx1-S (Viral vector)) - Suspect	
Dosage information:	
Treatment details:	
Indication:	
Action Taken:	

## Mensrual Bleeding Disorder

8/17/2021 2:35:25 PM

MedDRA Code	English	Level	PT	HLT	HLGT	SOC	Primary SOC
10085423	Heavy menstrual bleeding	PT	Heavy menstrual bleeding	Menstruation with increased bleeding	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	Y
10027295	Menometrorrhagia	PT	Menometrorrhagia	Menstruation with increased bleeding	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	Y
10064050	Polymenorrhagia	PT	Polymenorrhagia	Menstruation with increased bleeding	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	Y
10036086	Polymenorrhoea	PT	Polymenorrhoea	Menstruation with increased bleeding	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	Y
10027342	Menstruation with increased bleeding	HLT		Menstruation with increased bleeding	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	
10027341	Menstruation with decreased bleeding	HLT		Menstruation with decreased bleeding	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	
10001928	Amenorrhoea	PT	Amenorrhoea	Menstruation with decreased bleeding	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	Y
10001928	Amenorrhoea	PT	Amenorrhoea	Female gonadal function disorders	Endocrine disorders of gonadal function	Endocrine disorders	N
10021033	Hypomenorrhoea	PT	Hypomenorrhoea	Menstruation with decreased bleeding	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	Y
10021033	Hypomenorrhoea	PT	Hypomenorrhoea	Female gonadal function disorders	Endocrine disorders of gonadal function	Endocrine disorders	N
10027336	Menstruation delayed	PT	Menstruation delayed	Menstruation with decreased bleeding	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	Y
10027336	Menstruation delayed	PT	Menstruation delayed	Female gonadal function disorders	Endocrine disorders of gonadal function	Endocrine disorders	N
10030295	Oligomenorrhoea	PT	Oligomenorrhoea	Menstruation with decreased bleeding	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	Y
10030295	Oligomenorrhoea	PT	Oligomenorrhoea	Female gonadal function disorders	Endocrine disorders of gonadal function	Endocrine disorders	N
10065951	Retrograde menstruation	PT	Retrograde menstruation	Menstruation and uterine bleeding NEC	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	Y
10036618	Premenstrual syndrome	PT	Premenstrual syndrome	Menstruation and uterine bleeding NEC	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	Y
10036618	Premenstrual syndrome	PT	Premenstrual syndrome	Emotional and mood disturbances NEC	Mood disorders and disturbances NEC	Psychiatric disorders	N
10065347	Premenstrual pain	PT	Premenstrual pain	Menstruation and uterine bleeding NEC	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	Y
10065347	Premenstrual pain	PT	Premenstrual pain	Pain and discomfort NEC	General system disorders NEC	General disorders and administration site conditions	N
10027339	Menstruation irregular	PT	Menstruation irregular	Menstruation and uterine bleeding NEC	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	Y
10027339	Menstruation irregular	PT	Menstruation irregular	Female gonadal function disorders	Endocrine disorders of gonadal function	Endocrine disorders	N
10027327	Menstrual disorder	PT	Menstrual disorder	Menstruation and uterine bleeding NEC	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	Y
10056344	Menstrual discomfort	PT	Menstrual discomfort	Menstruation and uterine bleeding NEC	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	Y
10022559	Intermenstrual bleeding	PT	Intermenstrual bleeding	Menstruation and uterine bleeding NEC	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	Y
10013935	Dysmenorrhoea	PT	Dysmenorrhoea	Menstruation and uterine bleeding NEC	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	Y
10085424	Abnormal uterine bleeding	PT	Abnormal uterine bleeding	Menstruation and uterine bleeding NEC	Menstrual cycle and uterine bleeding disorders	Reproductive system and breast disorders	Y
10055870	Postmenopausal haemorrhage	PT	Postmenopausal haemorrhage	Menopausal effects on the genitourinary tract	Menopause related conditions	Reproductive system and breast disorders	Y
10055870	Postmenopausal haemorrhage	PT	Postmenopausal haemorrhage	Reproductive system haemorrhages	Vascular haemorrhagic disorders	Vascular disorders	N



**From:** s22  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** PF DPAR March-June 2021 [SEC=OFFICIAL]  
**Date:** Thursday, 5 August 2021 4:05:56 PM  
**Attachments:** s22

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Hi s22

I've finally finished the PF COVID DPAR.

Comirnaty vaccine

- 84 rows, 15 possible signals ie one signal per 6 rows

Higher priority= 9 (though 8 once two are combined)

Lower priority= 6

s22

s22

s22

I've attached my updated summary document to replace the earlier one.

s22

s22

Comirnaty vaccine

- 84 rows, 15 possible signals ie one signal per 6 rows

Higher priority= 9 (though 8 once two are combined)

s22

s22

















s22

**9) Menstrual disorders:** has been added to share point site

Amenorrhoea PRR 4.19, 5 cases in total, period and sole suspected

Dysmenorrhea PRR 7.54, 13 cases in total and period, 12 sole suspect

Heavy menstrual bleeding PRR 4.67, 26 cases in total, period and sole suspect

Intermenstrual bleeding PRR 21.12, 14 cases in total, period and 13 sole suspect

Menstrual disorder PRR 7.82, 28 cases in total, period and 26 sole suspect

Menstruation delayed PRR 11.32, 3 cases in total, period and sole suspect

Menstruation irregular PRR 7.92, 21 cases in total and period, 19 sole suspect

Polymenorrhoea PRR 18.11, 12 cases in total, period and sole suspect

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International regulator intelligence

Has/ is being investigated by other regulators. Eg The MHRA is investigating reports of menstrual disorders (period problems) and unexpected vaginal bleeding following vaccination against COVID-19 in the UK. These reports are also being reviewed by the independent experts of the Commission on Human Medicines' COVID-19 Vaccines Benefit Risk Expert Working Group and the Medicines for Women's Health Expert Advisory Group.

A total of 27,510 reports of a variety of menstrual disorders have been reported after all three of the COVID-19 vaccines including heavier than usual periods, delayed periods and unexpected vaginal bleeding. This is following approximately 43.4 million COVID-19 vaccine doses administered to women up to 21 July 2021. The number of reports of menstrual disorders and vaginal bleeding is low in relation to both the number of females who have received COVID-19 vaccines to date and how common menstrual disorders are generally.

Menstrual disorders are very common (accounting for 12% of all referrals to gynaecology services) and can result from a variety of factors including undiagnosed underlying conditions such as fibroids and exposure to stress. There is some evidence for changes to the menstrual cycle following infection with COVID-19 and in women affected by long-COVID. The menstrual changes reported are mostly transient in nature and there is no evidence that short term changes in the menstrual cycle or administration of the COVID-19 vaccines are associated with negative effects on fertility.

Advice about period problems and/or unexpected vaginal bleeding is available at: [www.nhs.uk](http://www.nhs.uk) It is important that anyone experiencing menstrual disorders and/or unexpected vaginal bleeding seeks medical advice, and these events should be investigated in line with clinical guidance to understand the underlying cause. Any bleeding from the vagina after the menopause needs to be checked by a GP.

The MHRA continues to closely review reports of menstrual disorders and unexpected vaginal bleeding. [MHRA yellow card report 30 July 2021].

Recommendation

TIP covering both vaccines. TGA has already had media enquiries about this and prepared a response (s22 will have a copy). Disproportionate reporting for both vaccines to TGA (s33) and investigations by other regulators. A broader TIP has already been done for bleeding disorders, but one focussed on menstrual bleeding disorder is recommended.

Lower priority

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