

From: s22
To: SAS; SAS
Cc: s22
Subject: SAS Report from Paradigm Biopharmaceuticals Ltd [SEC=No Protective Marking]
Date: Monday, 8 January 2018 2:29:21 PM
Attachments: [2018-01-08 SAS report template v1.0 Reporting Period 23Aug-31Dec2017.pdf](#)

Dear Sir or Madam:

Please find our SAS report attached.

We plan to send our next report around 30 June 2018.

If you have any questions please let me know,

Kind regards,

s22

[Redacted]

[Redacted]

Paradigm Biopharmaceuticals Ltd

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08 January 2018

Special Access Scheme
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia
By email: SAS@health.gov.au

Dear TGA

Re: Report on usage of pentosan polysulfate sodium (PPS) under the Special Access Scheme

Please find attached a report for usage of PPS 100 mg/mL injection under the Special Access Scheme for the period 23 August 2017 to 31 December 2017.

Paradigm has supplied PPS for use in 44 patients as shown in details on pages 2 - 5. No adverse reactions have been reported.

Please contact me if you would like further clarification.

Yours sincerely

s22

Paradigm Biopharmaceuticals Ltd

Email: s22

Usage of pentosan polysulfate sodium under the Special Access Scheme

Reporting period: 23 August 2017 to 31 December 2017

SAS approval number	Dosage regimen Dose/frequency/ duration)	Date commenced (DDMMYY)	Date completed (DDMMYY)	Number of ampoules issued	Number of ampoules returned	Adverse reactions reported (Y/N). If yes provide ADR number
section 22	2mg/kg for 3 weeks	17-Aug-17	04-Sep-17	20	Destroyed at clinic	No
	2mg/kg for 3 weeks	24-Aug-17	11-Sep-17	20	Destroyed at clinic	No
	2mg/kg for 3 weeks	22-Aug-17	08-Sep-17	20	Destroyed at clinic	No
	2mg/kg for 3 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Destroyed at clinic	No
	2mg/kg for 3 weeks	17-Nov-17	05-Dec-17	20	Destroyed at clinic	No
	2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	40	Awaiting destruction confirmation from clinic	No
	2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	40	Awaiting destruction confirmation from clinic	No
	2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No
	2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No
	2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	30	Awaiting destruction confirmation from clinic	No
	2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No

section 22

2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No
2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No
2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No
2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No
2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No
2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No
2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No
2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No
2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	30	Awaiting destruction confirmation from clinic	No
2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	30	Awaiting destruction confirmation from clinic	No
2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No
2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No
2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	30	Awaiting destruction confirmation from clinic	No

section 22

2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No
2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No
2mg/kg for 4 weeks	18-Dec-17	Still on treatment	20	Awaiting destruction confirmation from clinic	
2mg/kg for 4 weeks	18-Dec-17	Still on treatment	20	Awaiting destruction confirmation from clinic	
2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No
2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No
2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	20	Awaiting destruction confirmation from clinic	No
2mg/kg for 4 weeks	Awaiting data from clinic	Awaiting data from clinic	30	Awaiting destruction confirmation from clinic	No
2mg/kg for 6 weeks	23-Oct-17	16-Nov-17	30	Destroyed at clinic	No
2mg/kg for 6 weeks	07-Nov-17	24-Nov-17	30	Destroyed at clinic	No
2mg/kg for 6 weeks	06-Nov-17	23-Nov-17	20	Destroyed at clinic	No
2mg/kg for 6 weeks	18-Dec-17	Still on treatment	30		
2mg/kg for 6 weeks	28-Sep-17	23-Oct-17	40	Destroyed at clinic	No
2mg/kg for 6 weeks	30-Oct-17	24-Nov-17	40	Destroyed at clinic	No
2mg/kg for 6 weeks	Treatment commenced December 2017	Still on treatment	20		

section 22

2mg/kg for 6 weeks	Treatment commenced December 2017	Still on treatment	20		
2mg/kg for 6 weeks	27-Nov-17	Still on treatment	20		
2mg/kg for 6 weeks	24-Aug-17	25-Sep-17	20	Destroyed at clinic	No
2mg/kg for 6 weeks	Awaiting data from clinic	Awaiting data from clinic	40		
2mg/kg for 6 weeks	Commenced treatment in December 2017	Still on treatment	20		