Australian Government

Department of Health

Therapeutic Goods Administration

Guidance 2: Fees and charges for prescription medicines

Previously ARGPM Appendix 2: Fees and

Version 1.1, September 2014

TGA Health Safety Regulation

Check the TGA website for up-to-date guidance

The most up-to-date information about prescription medicine registration in Australia is on the TGA website <http://www.tga.gov.au>. Now that guidance is presented in a series of web pages, updates are likely to be more common than in the past. If you subscribe to the TGA guidelines email alert service, you will be emailed every time the TGA web guidance is updated.

TGA web pages are dated, and can be printed.

A PDF format is being provided during the transition between the former version of the ARGPM (Australian Regulatory Guidelines for Prescription Medicines) and the new web format. Please note that information in the PDF should not be relied upon to be up-to-date.

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <http://www.tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Office of Medicines Authorisation	12/07/2013
V1.1	Addition of link to guidance on orphan drug designations	Office of Medicines Authorisation	09/09/2014

Contents

This guidance:

- outlines the types of fees for services that apply to the registration of prescription medicines, and the variation of existing registrations
- provides an overview of the various types of applications to do with prescription medicines
- explains when payments are required for the various types of applications to register prescription medicines or to vary information on the Australian Register of Therapeutic Goods (ARTG) about prescription medicines
- describes the provisions in the Therapeutic Goods Regulations 1990 (the Regulations) for waiving or reducing fees and charges, and provides information about refunds
- explains what annual charges are.

2.1 Background to fees and charges

The TGA operates on a cost-recovery basis by charging fees for services and collecting annual charges Schedule 9 of the Regulations outlines the range of fees for services that the TGA provides. Each fee in Schedule 9 reflects the cost of providing that service to an applicant.

The Regulations allow the TGA to waive or reduce the fees payable for certain services in limited circumstances. These involve applications for registration of orphan drugs, and for the registration and variation of prescription medicines in response to a public health emergency.

Annual charges are a tax imposed on users of the regulatory scheme.

The Therapeutic Goods (Charges) Regulations 1990 list the charges that apply to prescription medicines, payable every year by a sponsor to maintain that entry in the ARTG.

2.2 When to make an application under sections 23 or section 9D of the Act

Broadly, the prescription medicine fees relate to:

- application fees and evaluation fees for entering prescription medicines in the ARTG under s. 23 of the *Therapeutic Goods Act 1989* (the Act)
- application fees and evaluation fees to vary the registration details of existing ARTG entries under s. 9D of the Act
- other miscellaneous matters, such as:
  - applications to obtain consent to supply prescription medicines that do not comply with certain aspects of an applicable standard under ss. 14/14A of the Act, and
  - fees for providing advice to the Pharmaceutical Benefits Program.

2.2.1 What section of the Act to apply under?

Whether an application should be submitted under s. 23 or a request made under s. 9D of the Act depends on whether:

- a sponsor wishes to market (import, export, manufacture or supply) a prescription medicine that the sponsor has not entered in the ARTG, or whether
- a sponsor whose prescription medicine is already entered in the ARTG wishes to make changes to information about this prescription medicine or make changes to their prescription medicines of a kind that is described in s. 9D of the Act.

2.2.2 What is a submission?

A submission refers to one or more simultaneous applications of the same kind with the same active ingredient, lodged by the same sponsor. For example, multiple applications lodged by an applicant simultaneously for a new chemical entity under item 4(a) of Part 2, Schedule 9 would constitute a submission. A simultaneous or concurrent application from, or on behalf of, another applicant is a separate submission.

Both application and evaluation fees are payable on a 'per submission' basis.

Subclauses 1(2) and 1(3) of Part 1, Schedule 9 of the Regulations describe what constitutes a submission for particular kinds of applications (these subclauses apply to applications concerning prescription medicines referred to in paragraph (a) of item 2A and items 2B, 2C, 2CA and 4 of Part 2 of Schedule 9).

2.3 When to pay application and evaluation fees for prescription medicines

Application fees cover the administrative costs associated with an application.

Evaluation fees cover the cost of assessing the supporting information in an application.

For some applications for variation of an ARTG entry, the applicant only pays an evaluation fee, which includes the fee for administrative costs.

For the TGA to process an application the required fees must be paid at the time they become due and payable. This time depends on the application type.

Table 1: Fees at a glance - summary of s. 23 application types, timeframes and item numbers from Schedule 9 (Table 1) and Table 2: Fees at a glance - summary of s. 9D request types, timeframes and item numbers from Schedule 9 (Table 2) set out how each application type is processed by the TGA.

2.3.1 Applications under section 23 of the Act via the prescription medicines registration process

Applications lodged under the prescription medicines registration process are set out in Table 1.

The following payment provisions are prescribed for prescription medicines registration process applications by Schedule 9 of the Regulations and ss. 23(2)(a) and 24(1) of the Act:

- an application fee equivalent to 20 per cent of the total fees must be paid when the pre-submission planning form is submitted.
- the evaluation fee equivalent to 80 per cent of the total fees must be paid once the applicant has been notified of the TGA's acceptance of the submission and advised of the amount of the evaluation fee.

The TGA issues invoices to cover these payments.

If the evaluation is not paid within two months of an applicant being notified of the acceptance of its submission and of the amount of the evaluation fee, the application will lapse in accordance with s. 24(2)(a) of the Act.

2.3.2 Applications under section 23 of the Act for an additional trade name

The following payment provisions are prescribed by ss. 23(2)(a) and 24(1) of the Act for applications to register an additional trade name for an existing registration:

- an application fee equivalent to 20 per cent of the total fees must be paid upon lodgement of the application.
- the remaining evaluation fee equivalent to 80 per cent of the total fees should be paid (if not already paid) when the applicant has been notified of the TGA's acceptance of the application.

The TGA issues invoices for the evaluation fees only. The evaluation fee must be paid within two months of its due date or the application will lapse.

2.3.2.1 Applications under section 23 of the Act for minor variations (quality related change and self assessable change)

Application or evaluation fees equivalent to 100 per cent of the total fees are payable upon lodgement of the application.

Processing or assessing an application does not commence until the required fees are paid. Refer to Table 1.

2.3.3 Requests under section 9D3 of the Act via the prescription medicines registration process

Requests lodged under the prescription medicines registration process are set out in Table 2.

The following payment provisions are prescribed for prescription medicines registration process applications by Schedule 9 of the Regulations and s9D7 of the Act:

- an application fee equivalent to 20 per cent of the total fees must be paid when the pre-submission planning form is submitted.
- the remaining evaluation fee equivalent to 80 per cent of the total fees should be paid when the applicant has been notified of the TGA's acceptance of the submission.

The TGA issues invoices to cover these payments.

2.3.3.1 Other requests under 9D of the Act

Application or evaluation fees equivalent to 100 per cent of the total fees are payable upon lodgement of the request.

Processing or assessing a request does not commence until the required fees are paid. Refer to Table 2.

2.4 Fees for prescription medicine applications made under section 23 of the Act

Table 1 summarises the fee item numbers from Schedule 9 of the Regulations (covering both application fees and evaluation fees) payable by applicants for each of the application types lodged under s. 23.

Applicants should consult these item numbers in Schedule 9 of the Regulations when lodging an application, because the fees vary from year to year.

Each of these fee categories is discussed in further detail in subsequent sections.

Table 1: Fees at a glance - summary of s. 23 application types, timeframes and item numbers from Schedule 9 of the Regulations

Application type[a]	Application fee - item number	Evaluation fee - item number	Processed under prescription medicines registration process
New chemical entity	2(ba)	4(a)	Yes
Extension of indications	2(bd)	4(b)	Yes
New generic medicine	2(bg)	4(c)	Yes
Additional trade name	2(bh)	4(d)	No
Major variation	2(bi)	4(g)	Yes
Minor variation	2(bj)	4(h)	Yes (if clinical, nonclinical or bioequivalence data are required)
Minor variation (quality-related change)	2(bj)	4(h)	No (no clinical, nonclinical or bioequivalence data are required) Quality only data submitted
Minor variation (self-assessable request)	2(a)	Nil	No (if submitted as a self-assessable request)

[a] Multiple applications are allowable as a 'submission' under Part 1 of Schedule 9.

Information about fee categories for prescription medicines used as an ancillary medical component of a device is available on the TGA website.

2.4.1 New chemical entity

This fee category relates to an application under s. 23 to enter a new chemical entity (fee items 2(ba) and 4(a)) in the ARTG. Part 1 of Schedule 9 to the Regulations defines a new chemical.

For the purpose of application fees, a similar biological medicine product (SBMP) is a new chemical entity as defined under Schedule 9 of the Regulations. These are biological substances that differ from the reference product because SBMPs:

- have a different molecular structure, or
- are derived from a source material of a different nature, or
- are derived from a different manufacturing process.

If the applicant can demonstrate that a new isomer, mixture of isomers, complex, derivative or salt of a registered drug substance does not change the pharmacokinetics, pharmacodynamics or toxicity of the moiety in a way that could change the safety and efficacy profile, the new medicine may be considered to be essentially similar to the registered drug substance, and the fee level would be for a generic product rather than a new chemical entity.

In these circumstances, it must also satisfy the other requirements for a new generic medicine.

2.4.2 Extension of indications for prescription medicines

Indications in relation to therapeutic goods are defined in s. 3(1) of the Act as the specific therapeutic uses of the goods. This fee category relates to an application under s. 23 to change the indications of an already registered medicine (fee items 2(bd) and 4(b)).

This fee category does not relate to applications for **removal** of indications made as 'safety-related' requests under ss. 9D(2) (see ss. 9D(2A), which has the effect of allowing this kind of application to be made under s. 9D, rather than s. 23, of the Act).

An application to extend the indications of a generic medicine to include a new indication is an extension of the indications, regardless of whether the reference product has that indication or not, and must be made under s. 23 of the Act. Alternatively, the applicant can apply for a new generic medicine with the new indications.

2.4.2.1 Generic medicine

This fee category relates to an application under s. 23 to register a generic medicine (fee items 2(bg) and 4(c)) for entry in the ARTG. Part 1 of Schedule 9 to the Regulations defines a generic medicine.

Note

Fees for generic medicines do not apply to SMBPs and new biotechnology products.

According to s. 25A of the Act, the Secretary cannot use 'protected information' relating to other medicines lodged by another sponsor to register a generic medicine. Protected information is information about an active ingredient included in a medicine that was first registered less than five years earlier, and is information about the active ingredient that is

not in the public domain. A generic version of such a drug substance would require assessment as a new chemical entity.

2.4.3 Additional trade name

This fee category relates to applications under s. 23 to register an additional trade name as a separate entry in the ARTG based on an existing registration (fee items 2(bh) and 4(d)). A trade name is defined in r. 2 as the commercial name:

- given to goods of that kind by the manufacturer, and
- under which the goods are supplied.

The fee for an additional trade name only applies to applications in which an applicant has already registered a medicine under one trade name and is seeking to register the same medicine under another trade name. Applications involving a second applicant – that is, where the original applicant is seeking to register the medicine under another trade name on behalf of another applicant, or where a second applicant is seeking to register the medicine under another trade name – are applications for a new generic medicine.

Note

There is a separate process to applying for a change to the trade name.

2.4.4 Major variation

This fee category relates to applications under s. 23 to approve a major variation to an already registered medicine (fee items 2(bi) and 4(g)). The nature of the variation produces a separate and distinct good under s. 16 of the Act. Part 1 of Schedule 9 to the Regulations defines a major variation.

Strength is the quantitative composition in terms of drug substance. The strength represents the amount of drug substance in the pharmaceutical form, which can be defined per unit dose or as a concentration. The concentration can be stated per unit of mass (250 mg/g) or per unit of volume (2 mg/mL), or as a percentage (5 per cent).

For the purpose of this guidance, some examples are as follows:

- for single-dose preparations, the strength is defined as the amount of drug substance per unit dose
- for multidose preparations, the strength is defined as the concentration, expressed as the amount of drug substance per mL, per puff, per drop, per kg or per m2, as appropriate
- for powder for reconstitution (powder for oral solution or suspension, powder for solution for injection, etc.)
  - single-dose preparations – the strength is defined as the quantity per container
  - multidose preparations – the strength is defined as the concentration after dissolution or suspension (reconstitution) to the volume and liquid recommended
- for concentrates for solutions (for injection or for infusion), single-dose preparations, the strength is defined as the quantity per container

- for transdermal patches, the strength is defined as the amount of active substance released from the patch in 24 hours.

Changes to the absolute amount of a drug substance may result in a new strength (as described above) and an application under s. 23 of the Act, or may be considered a variation under s. 9D of the Act. Examples of applications types that would result in a new strength or a variation are given in Annex 1.

A change in the intended patient group refers to any application that:

- alters the number of patients using a medicine; or
- modifies the category of patients using a medicine; but
- is not an extension of the indications or other major variation; and
- is not a safety-related notification; and
- is not an application for deletion of an indication.

Examples are an application to delete a contraindication or precaution, and some changes to the clinical trials section of the product information (PI).

2.4.5 Minor variation

This fee category relates to applications under s. 23 to approve a minor variation that results in a separate and distinct good under s. 16 of the Act (fee items 2(bj) and 4(h)). Part 1 of Schedule 9 to the Regulations defines a minor variation.

An application for a change in trade name can be considered a minor variation.

Minor variations can be lodged under the prescription medicines registration process (timeframe of 255 or 175 days, depending on the category of application) or outside the prescription medicines registration process (timeframe of 45 days), depending on the type of data required for the change. Under r. 16G, the following requirements apply to applications lodged outside the prescription medicines registration process:

- the applicant must hold a registration for the good containing the same active ingredient(s) in the same dosage form and strength
- the application must be of a kind that does not require the evaluation of clinical, nonclinical or bioequivalence data (e.g. applications for a replacement trade name).

Related information and guidance

- Minor variations to registered prescription medicines: chemical entities
- Minor variations to registered prescription medicines: biological medicines

2.5 Fees for requests to vary an ARTG entry for prescription medicines under section 9D of the Act

Table 2 summarises the fee item numbers from Schedule 9 of the Regulations payable by applicants for each of the request types lodged under s. 9D. Applicants should consult these item numbers in Schedule 9 of the Regulations when lodging a request, as these fees vary from year to year.

Table 2: Fees at a glance – summary of s. 9D request types, timeframes and item numbers from Schedule 9 of the Regulations

Request type	Application fee - item number	Evaluation fee - item number	Processed under prescription medicines registration process
9D(1): correction of ARTG entry	2A(a)	Nil	No
9D(2): safety-related request	2A(a)	Nil	No
9D(2): safety-related request with data	Nil	2CA	No
9D(3): self-assessable request	2A(a)	Nil	No
9D(3): quality-related change with data	Nil	2B	No
9D(3): change to ARTG entry with clinical/nonclinical/bioequivalence data	2AC	2C	Yes

[a] Multiple applications are allowable as a 'submission' under Part 1 of Schedule 9.

2.5.1 Requests for variations without data (item 2A(a) of Schedule 9 of the Regulations)

The application and evaluation fees that apply to this category of requests to vary information in the ARTG under s. 9D of the Act cover simultaneous requests for variations of a minor nature:

- with the same drug substance,
- that are submitted by the same applicant, and
- do not require evaluation of data.

The submission involves a minor variation or variations under one or more of ss. 9D(1), 9D(2) or 9D(3) of the Act. Requests of this type only attract one payment, provided that the variations contain the same drug substance and are appropriately identified for simultaneous lodgement by the applicant.

2.5.1.1 Variation request under subsection 9D(1) of the Act

This fee category (fee item 2A(a)) covers variations to correct or complete information that was inadvertently recorded incorrectly or omitted in the ARTG entry, including the PI.

In some cases, errors in quality-related specifications may need to be corrected. For example;

- correcting typographical errors in quantities of excipients,
- correcting grammatical errors in the records held about a product, or
- adding a manufacturing step for a licensed manufacturer that was inadvertently omitted.

2.5.1.2 Variation request under subsection 9D(2) of the Act

This fee category (fee item 2A(a)) covers safety-related requests to vary an entry in the ARTG. A safety-related request is one where the variation has one of two possible outcomes:

- to reduce the class of persons for whom the goods are suitable; or
- to have the effect of adding a warning or precaution.

2.5.1.3 Variation request under subsection 9D(3) of the Act

This fee category (fee item 2A(a)) covers variations that are not safety related (i.e. do not meet the criteria for a safety-related request under subs. 9D(2)), provided that the variation:

- does not reduce the quality, safety or efficacy of the product, and
- does not create a separate and distinct good.

Variations made under ss. 9D(3) often relate to the quality of registered prescription medicines. Minor editorial changes to the PI are also included in this fee category.

Subsection 9D(3) applications submitted under this fee category will be accepted in accordance with the TGA guidance Minor variations to registered prescription medicines: chemical entities and Minor variations to registered prescription medicines: biological medicines.

Where an application under ss. 9D(3) requires evaluation of quality data only, item 2B applies (see 'Quality-related variations (chemistry, quality control and manufacturing information)').

Where an application under s. 9D(3) requires evaluation of nonclinical, clinical or bioequivalence data, items 2AC and 2C apply (see 'Requests to change the PI that requires evaluation').

2.5.2 Quality-related variations (chemistry, quality control and manufacturing information)

This fee category (fee item 2B) relates to a request under s. 9D(3) covered by any of the changes described in r. 16F(1) of the Regulations. The kinds of changes covered by this fee category are variations to:

- the specifications for the drug substance, medicine or excipients; or
- the method of manufacture of the drug substance; or
- the manufacturing procedure for the medicine; or

- the site of manufacture of the drug substance or the medicine; or
- the shelf life; or
- the storage conditions; or
- the product label; or
- any other particular that is not mentioned in subs. 16(1) of the Act.

Consistent with r. 16F(2)(b), applicants can only submit this type of request if it does not require the evaluation of clinical, nonclinical or bioequivalence data.

2.5.3 Safety-related request to change product information requiring evaluation of clinical data

This fee category (fee item 2CA) relates to variations under ss. 9D(2) of the Act.

These are applications that require evaluation of data to make safety-related changes to the PI. That is, the variations reduce the class of persons for whom the goods are suitable, or have the effect of adding a warning or precaution.

Related information and guidance

- Minor variations to registered prescription medicines: chemical entities
- Minor variations to registered prescription medicines: biological medicines

2.5.3.1 Requests to change the PI that requires evaluation

This fee category (fee items 2AC and 2C) relates to requests to change the PI that require evaluation of clinical, nonclinical and/or bioequivalence data, where r. 16D applies (i.e. evaluation completed within either 255 or 175 days).

Applications under this fee category must be submitted via the prescription medicines registration process.

2.6 Other fees that apply to prescription medicines

2.6.1 Testing and providing advice requested from the Pharmaceutical Benefits Program

The fee category (fee item 18 in Schedule 9 of the Regulations) covers the testing and provision of advice, requested from the Pharmaceutical Benefits Program, before listing on the Pharmaceutical Benefits Listing Program.

2.6.2 Requesting consent under section 14 for goods that do not comply with a standard

Under s. 14 and s. 14A of the Act, sponsors may seek consent from the Secretary to import, supply or export therapeutic goods that do not comply with applicable standards.

Item 1A of Schedule 9 of the Regulations specifies the application fee for processing an application for consent under s. 14 of the Act.

2.7 When evaluation fees are waived or reduced for prescription medicines

Application and evaluation fees can be waived or reduced under the following circumstances, as prescribed by the Regulations.

2.7.1 Orphan drugs

If a product has been designated as an orphan drug in accordance with r. 16J, then pursuant to subregulation 45(12)(c), the application and evaluation fees for an application submitted under s. 23 of the Act will be waived.

However, full fees will apply to all variations to an orphan drug (i.e. applications submitted under s. 9D). Designation as an orphan drug must occur before any application to register the product is lodged.

2.7.2 Supply of medicines in response to a public health emergency

In accordance with subregulation 45(4AA), the Regulations provide the Secretary (or delegate), in limited circumstances, with the discretion to waive or reduce an evaluation fee prescribed in Schedule 9 in relation to goods of a kind mentioned in Part 1 of Schedule 10 to address an actual public health emergency.

In determining whether to waive or reduce the evaluation fee under subregulation 45(4AA), the Secretary (or delegate) must consider that:

a. supply of the goods in Australia is necessary because of a public health emergency; and

b. the waiver or reduction is necessary to enable the goods to be supplied in Australia; and

c. the Secretary has information relating to the goods that allows the evaluation procedure to be abridged.

In any request under subregulation 45(4AA), the applicant must address all three elements for the Secretary (or delegate) to appropriately consider the request. The applicant will still be required to pay the full application fee. Applicants who believe that they qualify for this provision should contact the TGA.

2.8 When application fees are refunded for prescription medicines

2.8.1 Refund of application fees for incorrect or ineffective submissions

The Act contains no provisions to refund application fees to applicants after the application has been received by the TGA. Applicants should therefore take care before submitting applications to avoid the loss of application fees. The TGA retains application fees even if:

- the application is withdrawn before it has been accepted
- the application is deemed ineffective by the TGA.

2.8.2 Refund of evaluation fees for effective submissions

For applications submitted via the prescription medicines registration process under ss. 9D(3) or s. 23 of the Act, the TGA must complete the evaluation within the timeframes set out in rr. 16C and 16D, respectively.

If the evaluation exceeds this timeframe, the TGA must refund 25 per cent of the evaluation fee to the applicant, as specified in s. 24D of the Act and r. 43AA. Please note that these provisions only relate to the evaluation fee and not the application fee. The full application fee will be retained by the TGA.

There is no reduction in evaluation fee for other applications that exceed the statutory timeframe prescribed in rr. 16F and 16G.

However, for a minor variation to which r. 16F or r. 16G applies, the delegate will be deemed to have approved the application if the application exceeds the statutory timeframe.

2.9 Annual charges for prescription medicines

An annual charge is payable for maintaining registration in the ARTG. There are two levels of annual charges, based on whether the medicine is of biological or nonbiological origin. A list of charges can be found in the *Therapeutic Goods (Charges) Regulations 1990*.

A sponsor can seek exemption from the liability to pay an annual charge for an entry in the ARTG if the therapeutic good qualifies for *'low value'* turnover (LVT).

Note

Where a number of prescription medicines are 'grouped' under a grouping order in accordance with ss. 16(2) of the Act, only one relevant annual charge is payable by a sponsor for the purposes of maintaining all that sponsor's medicines registered in the ARTG that are included in the same grouping order - ss. 4(1A) of the *Therapeutic Goods (Charges) Act 1989*

Annex 1: Examples of applications resulting in a new strength or a variation

Examples			Strength (for classification of category of application only)	New Strength or Variation
Solid - Single-dose				
1. Tablets	*from* *to*	100 mg 500 mg	100 mg 500 mg	New strength (Major variation)
2. Granules (sachet)	*from* *to*	1 g 2 g	1 g 2 g	New strength (Major variation)
Solid - Multi-dose				
3. Granules (bottle)	*from* *to*	100 mg/5 g (spoon) 500 mg/5 g	20 mg/g 100 mg/g	New strength (Major variation)
	from *to*	500 g bottle (of 100 mg/g) 1000 g bottle (of 100 mg/g)	100 mg/g 100 mg/g	Variation (New pack size)
Solid - Fixed combinations/combination packs				
4. Tablets (fixed combination)	*from* *to*	5 mg X + 10 mg Y 10 mg X + 20 mg Y	5 mg + 10 mg 10 mg + 20 mg	New strength (Major variation)
	from *to*	5 mg X + 10 mg Y 5 mg X + 20 mg Y	5 mg + 10 mg 5 mg + 20 mg	New strength (Major variation)
Semi-solid - Multi-dose				
5. Gel	*from* *to*	20 mg/g 100 mg/g	20 mg/g 100 mg/g	New strength (Major variation)
	from *to*	20 g jar (of 100 mg/g) 30 g jar (of 100 mg/g)	100 mg/g 100 mg/g	Variation (New pack size)

Examples			Strength (for classification of category of application only)	New Strength or Variation
Powder for oral solution/suspension - Single-dose				
6. Powder for oral solution (sachet)	*from* *to*	100 mg (to 2 mL) 200 mg (to 2 mL)	100 mg 200 mg	New strength (Major variation)
	from *to*	100 mg (to 2 mL) 200 mg (to 4 mL)	100 mg 200 mg	New strength (Major variation)
Powder for oral solution/suspension - Multi-dose				
7. Powder for oral suspension (bottle)	*from* *to*	10 g (to 200 mL) 20 g (to 200 mL)	50 mg/mL 100 mg/mL	**New strength (Major variation)**
	from *to*	10 g (to 200 mL) 20 g (to 400 mL)	50 mg/mL 50 mg/mL	**Variation (New pack size)**
Liquid ready-to-use - Single-dose				
8. Oral solution (sachet)	*from* *to*	100 mg/5 mL 200 mg/5 mL	100 mg 200 mg	New strength (Major variation)
	from *to*	100 mg/5 mL 200 mg/10 mL	100 mg 200 mg	New strength (Major variation)
Liquid ready-to-use - Multi-dose				
9. Oral solution (bottle)	*from* *to*	500 mg/50 mL 1000 mg/50 mL	10 mg/mL 20 mg/mL	New strength (Major variation)
	from *to*	500 mg/50 mL 1000 mg/100 mL	10 mg/mL 10 mg/mL	Variation (New pack size)

Examples			Strength (for classification of category of application only)	New Strength or Variation
Liquid ready-to-use - Single-dose				
10. Solution for injection (example, pre-filled syringe)	*from* *to*	100 mg/1 mL 200 mg/1 mL	100 mg 200 mg	New strength (Major variation)
	from *to*	100 mg/1 mL 200 mg/2 mL	100 mg 200 mg	New strength (Major variation)
	from *to*	100 mg/1 mL 100 mg/0.5 mL	100 mg 100 mg	Variation (New formulation)
Liquid ready-to-use - Multi-dose				
11. Solution for injection (example, hospital pharmacy bulk pack)	*from* *to*	500 mg/50 mL 1000 mg/50 mL	10 mg/mL 20 mg/mL	New strength (Major variation)
	from *to*	500 mg/10 mL 1000 mg/20 mL	50 mg/mL 50 mg/mL	Variation (New pack size)
Powder for reconstitution				
12. Powder for solution for injection	*from* *to*	100 mg (to 2 mL) 200 mg (to 2 mL)	100 mg 200 mg	New strength (Major variation)
	from *to*	100 mg (to 2 mL) 200 mg (to 4 mL)	100 mg 200 mg	New strength (Major variation)
Cutaneous Semi-solid - Multi-dose				
13. Cream	*from* *to*	20 mg/g 100 mg/g (sachet)	20 mg/g 100 mg/g	New strength (Major variation)
	from *to*	20 mg/g 40 mg/2g (sachet)	20 mg/g 20 mg/g	Variation

Examples			Strength (for classification of category of application only)	New Strength or Variation
	from *to*	20 g tube (of 100 mg/g) 30 g tube (of 100 mg/g)	100 mg/g 100 mg/g	Variation (New pack size)
Eye preparations, liquid ready-to-use - Single-dose				
14. Eye drops, Solution	*from* *to*	10 mg/0.5 mL 20 mg/0.5 mL	10 mg 20 mg	New strength (Major variation)
Eye preparations, liquid ready-to-use - Multi-dose				
15. Eye drops, Solution	*from* *to*	50 mg/5 mL 100 mg/5 mL	10 mg/mL 20 mg/mL	New strength (Major variation)
	from *to*	50 mg/ 5 mL 100 mg/ 10 mL	10 mg/mL 10 mg/mL	Variation (New pack size)
Transdermal patch				
16. Transdermal patch	*from* *to*	2 mg 3 mg	25 µg/ 24 h 30 µg/ 24 h	New strength (Major variation)
	from *to*	2 mg 2.5 mg	25 µg/ 24 h 25 µg/ 24 h	Variation
Liquid ready-to-use - Multi-dose				
17. Pressurised inhalation solution	*from* *to*	5 mg/ puff 10 mg/ puff	5 mg/ puff 10 mg/ puff	New strength (Major variation)
	from *to*	60 puffs 100 puffs per container (of 5 mg/ puff)	5mg/ puff 5mg/ puff	Variation (Cat 3 - new pack size)
Powder - Single-dose				
18. Inhalation powder, hard capsule	*from* *to*	1 mg 2 mg	1 mg/ puff 2 mg/ puff	New strength (Major variation)

Examples			Strength (for classification of category of application only)	New Strength or Variation
Powder - Multi-dose				
19. Inhalation powder	*from* *to*	6 mg/ puff 12 mg/ puff	6 mg/ puff 12 mg/ puff	New strength (Major variation)
	from *to*	60 puffs 100 puffs per container (of 6 mg/ puff)	6mg/ puff 6mg/ puff	Variation (New pack size)
(Semi)-solid, liquid ready-to-use - Single-dose				
20. Suppository	*from* *to*	100 mg 200 mg	100 mg 200 mg	New strength (Major variation)
(Semi)-solid, liquid ready-to-use - Multi-dose				
21. Vaginal cream	*from* *to*	20 mg/g 100 mg/g	20 mg/g 100 mg/g	New strength (Major variation)
	from *to*	20 g tube (of 100 mg/g) 30 g tube (of 100 mg/g)	100 mg/g 100 mg/g	Variation (New pack size)

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Reference/Publication #