



Advisory Committee on Prescription Medicines

Meeting Statement

Meeting 310, Thursday 2 and Friday 3 June 2016

Role of the Advisory Committee on Prescription Medicines in the TGA's regulatory decision making process

The ACPM is a statutory advisory committee established by the *Therapeutic Goods Regulations 1990*.

The TGA currently has eleven statutory advisory committees from which it can obtain independent expert advice on specific scientific and technical matters to aid the TGA's regulatory decision making and other regulatory processes. The ACPM provides advice to the TGA on, amongst other things, matters relating to the inclusion, variation or retention of prescription medicines on the Australian Register of Therapeutic Goods.

The advice provided by the ACPM is an important element in the undertaking of the regulatory functions of the TGA. However, it forms only part of the information that is available to, for instance, a TGA delegate making a regulatory decision under the *Therapeutic Goods Act 1989*. While appropriate consideration will be given to such advice, it is important to note that neither a TGA delegate nor the TGA is obliged to seek this advice in making a decision or to follow it.

It should also be noted that information about advice provided by the committee may not become publicly available for some time after a committee has provided that advice. The purpose of this Meeting Statement is to describe in general terms the matters considered by the committee at each meeting and for it to be available as soon as reasonably practical after the relevant meeting.

Overview of the therapeutic goods referred for advice

At this meeting, the committee's advice was sought on 17 applications before the TGA, including: five for new chemical entities; two for new biological entities; three seeking extensions of indications; one seeking a new dosage form; one seeking a new combination of active ingredients; one new generic medicine; one change in patient group; one change in strength; and two seeking multiple variation types requiring evaluation.

Pharmaceutical Sub-committee (PSC) update

Members noted the minutes from PSC meeting 169 held on 24 May 2016.

Update on the publication of matters where the Committee previously provided advice and a TGA decision has been made

An Australian Public Assessment Report (AusPAR) is compiled by the TGA after a delegate has made a decision relating to a submission for new prescription medicines and major changes to existing prescription medicines. It provides information about the evaluation of the submission and the considerations that led the TGA to approve or not approve the application.

The ACPM was advised the following applications, which were previously considered by the committee at meetings 296 through to 305, have resulted in the publication of an AusPAR.

Active	Application Type
Immunoglobulin normal	Type A - New chemical entity
Levothyroxine sodium	Type D - New generic medicine and Type F - Major variation (strength)
Efmoroctocog alfa (rhu)	Type A - New biological entity
Certolizumab pegol (rbe)	Type C - Extension of indications
Ibrutinib	Type A - New chemical entity
Dabigatran etexilate	Type C - Extension of indications
Liraglutide (rys)	Type C - Extension of indications
Ivermectin	Type C - Extension of indications
Human papillomavirus vaccine types 16 and 18 [recombinant, AS04 adjuvanted]	Type F - Major variation (dose)
Valganciclovir	Type F - Major variation (dosage)
Nintedanib esilate	Type A - New chemical entity
Arsenic trioxide	Type C - Extension of indications

For more information about AusPARs, see:<<https://www.tga.gov.au/australian-public-assessment-reports-prescription-medicines-auspars>>

To browse all AusPARs see: <<https://www.tga.gov.au/browse-auspars-active-ingredient>>

Further information

Meeting statements are made publicly available after each meeting.

For further information on the ACPM, please visit:

<<https://www.tga.gov.au/committee/advisory-committee-prescription-medicines-acpm>>

or contact the ACPM Secretary by phone on (02) 6232 8914 or email

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