Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Advisory Committee on Complementary Medicines

Meeting Statement

1 MARCH 2013 - ACCM 13

Role of the Advisory Committee on Complementary Medicines (ACCM) in the TGA's regulatory decision making process

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

The TGA currently has nine 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 ACCM provides advice to the TGA on, amongst other things, matters relating to the inclusion, variation or retention of complementary medicines on the Australian Register of Therapeutic Goods.

The advice provided by the ACCM 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. While appropriate consideration will be given to such advice, it is important to note that neither the TGA nor a TGA delegate is obliged 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 one application before the TGA: this being a new substance for use in listed medicines (specifically whether submitted data are sufficient to establish safety).

The committee's advice has now been provided to the TGA for consideration as part of the TGA's regulatory decision making process.

Other matters considered

Complex substances and compliance with default standards

ACCM advice was sought on matters relating to the default standards recognised in the current therapeutic goods legislation.

The following background information related to this issue was provided to the committee.

Under the current Australian legislation, ingredients used in therapeutic goods must comply with the requirements of relevant monographs in the default standards; that is, monographs of the British Pharmacopoeia (BP), the United States Pharmacopoeia-National Formulary (USP) and the European Pharmacopoeia (Ph Eur).

Many ingredients that are manufactured from substances of natural origin are subjected to processing prior to their inclusion in medicine formulations. This is often undertaken to increase the concentration of constituents with which therapeutic claims are associated and can result in different 'grades' of material being available in the marketplace.

The monographs in the default standards recognise these deliberate variations by allowing wider than usual or open-ended limits for some constituents of the ingredient, for example, 'Not less than 60%' as a minimum assay amount. This is in contrast to single chemical entities where the limits are more restrictive, for example 'assay limits of 99.0-101.0%'.

The TGA is increasingly being asked to determine the status of ingredients for use in listed medicines that do not meet the requirements of an applicable monograph, ie. whether a 'non-compliant' substance should be considered a separate ingredient identified by a different name and hence not subject to the monograph.

The committee's advice was sought on whether complex substances of natural origin, that are the subject of a monograph in a default standard but do not comply with the requirements of that monograph, should be considered separate ingredients.

The committee discussion focused on the following:

- The process for drafting and updating existing monographs;
- The role of the regulator in these processes;
- Technological changes and the resultant need to update monographs;
- Comparison between the use of default standards and TGA compositional guidelines and the need for consistency in approach to drafting and maintaining currency of both these types of documents;
- The fact that if a substance is subject to a compendial monograph that is a default standard, but does not meet all of the requirements therein, then stakeholders can seek revision of the monograph using relevant processes;
- It was noted that a separate process is in place for stakeholders seeking revision of a TGA compositional guideline.

At the conclusion of the discussion, the committee endorsed the position outlined by the TGA, confirming

that, if a substance meets the definition of an ingredient in a monograph (in that it has the same source and undergoes processing as described in the pharmacopoeia), then it must comply with all of the requirements of the default standard. The committee noted that

requests can be made to pharmacopoeial commissions to revise the requirements of a monograph and that this is not the regulator's responsibility.

Regulatory reforms

For the benefit of new committee members, presentations were given on the current business processes of the Office of Complementary Medicines and members were also provided with an update on regulatory reforms affecting complementary medicines.

Next meeting

The next meeting of the ACCM is scheduled for 2 August 2013.

Further information

Meeting statements are made publicly available after each meeting.

For further information on the ACCM, please visit the ACCM web page or contact the ACCM Secretary: Jennifer Burnett by phone on 02 6232 8280 or email: accm@tga.cov.au