







Technical Alert

TGA Advisory Committee Roles and Outputs

Dear Member,

The TGA has communicated a revised process that aims to bring greater consistency and clarity to the roles of the TGA's statutory advisory committees.

1. The role of the TGA's statutory advisory committees:

A statement to clarify the role of the TGA's statutory advisory committees in the context of the TGA's regulatory decision making process (Transparency Review Recommendation 8), has recently been developed and is available publically via the TGA website here.

2. The public release of committee meeting information:

Given that information about advice provided by a committee may not become publically available until sometime after a committee has provided that advice, and to achieve a timely, consistent and transparent approach to the publication of TGA committee meeting information, from 2013 a statement that broadly canvasses the matters considered by the committees at each meeting will be made publically available. It is important to note that this new approach replaces all current committee publishing processes.

This statement will include general information about the role of the committee in the TGA's regulatory decision making process, and an overview of the matters referred to the committee. This will <u>not</u> include information about any advice provided, but rather a snapshot of the number, class and type of therapeutic goods considered, without disclosing specific information (such as an indication or the actual product or sponsor), and other associated matters including for example consideration of any public consultations.

Where a subcommittee exists, the parent committee can refer to the work of the subcommittee in the meeting statement. A separate meeting statement for subcommittees is not required, but may be produced where TGA management considers it appropriate.

It is important to note that the responsibility of any regulatory decision being made publically available rests with the TGA. In this context, the broader issue of publishing TGA decisions (which should incorporate committee advice where relevant) will be progressed by other projects being undertaken as part of the Blueprint.

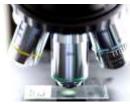
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3. Complementary activity

The TGA is also undertaking a related activity to ensure consistency in the way advice is commissioned from each of the statutory advisory committees. Further information in relation to this activity will be communicated as it becomes available.

The TGA has discussed these changes with members of the Advisory Committee on Complementary Medicines (ACCM), with particular reference to the change to the current procedure for publication of extracted ratified minutes of ACCM meetings.