



Australian Government

Department of Health
Therapeutic Goods Administration

The Australian Therapeutic Goods Advisory Council

Meeting statement of 4 August 2015

Record of issues

The Australian Therapeutic Goods Advisory Council (the Council) met for the seventh time via teleconference at the Department of Health's facility in Symonston, on Tuesday, 4 August 2015.

The TGA provided an overview of the new Department of Health organisational structure. It was noted that, as part of the response to the Functional and Efficiency Review, a new Regulatory Service Group has been established. This brings together the Department's regulators; the Therapeutic Goods Administration, the Office of Gene Technology Regulator and the Office of Chemical Safety, which incorporates the National Industrial Chemicals Notification and Assessment Scheme and AgVet Chemicals assessment.

The Council was provided with an update on the TGA's Key Performance Indicators (KPIs) against the Regulatory Performance Framework. Members were thanked for the feedback they provided in March 2015. It was noted that the first report against the Regulator Performance Framework KPIs will cover the 2015-16 financial year and will be published in the second half of 2016.

A comprehensive overview of the first report from the Medicines and Medical Devices Review was provided to the Council. It was noted that the second report on regulatory frameworks for complementary medicine and the advertising of therapeutic goods has been provided to Government for consideration but is not yet publicly available. Stakeholder engagement forums were being held on the first report with industry, health professionals and consumer groups, and would focus on the early opportunities on reform.

Members discussed a range of topics in an open forum including de-prescribing, the availability of information on the stability of pharmaceuticals in storage facilities where there have been temperature excursions and mobile medical network applications in recognition of post-market monitoring.

For further information on the Council, please contact the Secretary:

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