Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2013 - 2014, 26 February 2014

Ref No: SQ14-000228

OUTCOME: 1 - Population Health

Topic: Therapeutic Goods Administration Blueprint Reforms

Type of Question: Written Question on Notice

Senator: McLucas Jan

Question:

a) Can the department provide an update on the implementation of the TGA blueprint reforms?
b) Page 44 of the Additional Portfolio Budget statements states the revised target for 2013/14 is 13 recommendations to be implemented. Will that be achieved? Can you please provide these 13 recommendations?

Answer:

a) An update on the implementation of reforms is provided in TGA reforms: A blueprint for TGA's future - Progress report as at 31 December 2013. It is available at http://www.tga.gov.au/about/tga-reforms-blueprint-progress-131231.htm As at 31 December 2013, thirty-two recommendations have been implemented. This includes four recommendations implemented in the period 1 July to 31 December 2013. A further nine recommendations were forecast for implementation by 30 June 2014. The remaining seven recommendations are forecast to be implemented by 31 December 2015.

b) Thirteen recommendations are forecast for delivery in 2013/14. Four of these recommendations were implemented by 31 December 2013. Three recommendations are on track for implementation by 30 June 2014. Six recommendations are being reviewed. This could impact on timeframe for implementation.

The four recommendations implemented are:

- Auditor-General's Report on Complementary Medicines Rec 4a – To improve compliance with the regulatory framework, the Australian National Audit Office (ANAO) recommends that the Therapeutic Goods Administration (TGA) use its random sampling review of listed medicines to develop risk profiles of sponsors and the most significant characteristics of medicines.
- Auditor-General's Report on Complementary Medicines Rec 4b – To improve compliance with the regulatory framework, the ANAO recommends that the TGA use the profiles to inform its program of post-market reviews.
- Auditor-General's Report on Complementary Medicines Rec 5b – The ANAO recommends that the TGA adopt a standard operating procedure for completing

investigations of advertising breaches, incorporating: provision of regular reports to the TGA executive on progress with investigations and trends in non-compliance.
- Transparency Review Rec 4 – Work transparently with other key providers of information to enhance the information available to the public consistent with the principles of the quality use of medicines.

An additional 3 recommendations are on track for implementation by 30 June 2014. They are:
- Transparency Review Rec 16 – The TGA actively promote the distribution of therapeutic goods safety information, and examine mechanisms for improving the timely communication of alerts and recalls, to health practitioners and to consumers.
- Transparency Review Rec 17 – The TGA explore mechanisms to maintain the currency of Consumer Medicines Information and Approved Product Information.
- Transparency Review Rec 19 – The TGA more effectively facilitate the recognition and reporting of adverse events by health practitioners and consumers, and promote the adverse event reporting system.

The implementation plans for the remaining six recommendations are being considered with the aim of minimising the costs of achieving regulatory objectives while promoting efficiency and effectiveness. The six recommendations are:
- Auditor-General's Report on Complementary Medicines Rec 2 – To improve the integrity of the self-assessment process for listing complementary medicines on the Australian Register of Therapeutic Goods, the ANAO recommends that Health seeks to finalise work on the 'coded indications' project so as to limit the use of inappropriate claims and indications on the ARTG.
- Informal Working Group on Complementary Medicines Rec 2a – Modify Electronic Listing Facility system to include restriction or elimination of access by sponsors to 'free text'.
- Informal Working Group on Complementary Medicines Rec 2b – Modify Electronic Listing Facility system to provide guidance and cautionary notes for sponsors using the Electronic Listing Facility, regarding the consequences of misleading and unsubstantiated claims.
- Informal Working Group on Complementary Medicines Rec 3 – Update 'Guidelines for levels and kinds of evidence' and include 'Guidelines for levels and kinds of evidence' in regulation.
- Informal Working Group on Complementary Medicines Rec 4 – Review current 'coded indications' project based on the document 'Guidelines for levels and kinds of evidence' and either restrict or eliminate access by sponsors to 'free text' in the Electronic Listing Facility.
- Medical Device Reforms – Proposal 4 – Publication of device product information on the TGA Website.