Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2012-2013, 17 & 19 October 2012

Question: E12-018

OUTCOME 1: Population Health

Topic: LICENSING AND SURVEILLANCE AUDITS

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Senator: Senator Fierravanti-Wells

Question:

Could you explain the process for licensing and for surveillance audits, including:

- The types of products that are involved;
- The actual number of products audited in a given year;
- The time frames, including the variety of those time frames (if there are audits and delays that can affect product sponsors and consumer safety, how do you deal with that?); and
- How long it is now taking?

Answer:

Overview of 'Licensing and surveillance inspections' and types of products involved

The Therapeutic Goods Administration (TGA) issues Manufacturing licences to Australian manufacturers of medicines and blood and tissues. Manufacturers of medical devices are not licensed, but receive a 'conformity assessment certificate'.

To gain a manufacturing licence, a manufacturer is inspected by the TGA for compliance with the code of Good Manufacturing Practice before actual manufacture takes place.

To gain a conformity assessment certificate, a medical device manufacturer would generally need to pass a 'Quality Management System' inspection against ISO Standard 13485.

Subsequent to licensing/certification, manufacturers must demonstrate continued compliance with the relevant standards through 'surveillance inspections', which occur at intervals of between 1 – 3 years depending on the risk profile of the manufacturer (inherent risk of the products manufactured coupled with the compliance history).

There are a number of ways offshore manufacturers are cleared to supply the Australian market. Clearance can be based on evidence of compliance provided to the TGA in the form of an inspection report from a trusted regulatory authority, such as the European Medicines Agency or the United States Food and Drug Administration. Where sufficient evidence does not exist, the TGA undertakes an inspection, as it would for a domestic manufacturer.

The actual number of products audited in a given year

Manufacturing licences/clearances are issued on a manufacturer by manufacturer basis, not on a product by product basis.

The time frames, including the variety of those time frames

All new applications for Australian manufacturing licences are automatically assigned a three month timeframe in which an inspection will be conducted. A six month timeframe is assigned for reinspection of existing Australian licence holders and all overseas manufacturers.

If there are audits and delays that can affect product sponsors and consumer safety, how do you deal with that?

Where consumer safety may be affected the *Therapeutic Goods Act* allows TGA to suspend or revoke a manufacturing licence which effectively prohibits further supply of product by that manufacturer. Minor delays in conducting surveillance audits of licensed manufacturers is unlikely to impact consumer safety. TGA uses other post-market tools such as laboratory testing and adverse event reporting to monitor products supplied in the marketplace to supplement manufacturing inspections.

How long it is now taking?

An inspection can vary from requiring one inspector for one day through to requiring several inspectors for a number of weeks. The inspection time depends on the complexity of the manufacturing operations.