Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2010-11, 20 October 2010

Question: E10-243

OUTCOME 1: Population Health

Topic: AUDITS OF CSL

Written Question on Notice

Senator Fierravanti-Wells asked:

a) Is the Government aware of any audits undertaken of CSL by the TGA? If so, please advise:
b) The dates of those audits?
c) What deficiencies were identified during those audits?
d) The extent of those audits – what was inspected, reviewed etc.
e) Did any relate to product safety issues?
f) Any corrective action required to remedy the deficiency?
g) The corrective action taken to remedy the deficiency?
h) Any product recall resulting from any deficiency?

Answer:

a) The TGA undertakes regular audits of CSL and other Australian manufacturers for compliance with internationally harmonised standards of Good Manufacturing Practice (GMP).

b) The TGA most recently audited CSL's vaccine manufacturing facilities located at 45 Poplar Road, Parkville Victoria on 12-13 May 2010 and 18, 21-23 June 2010.

c – g)

The audit process is designed to raise levels of compliance with manufacturing standards. The active cooperation of a manufacturer is vital to the investigation and assessment of facilities and manufacturing processes for compliance with GMP standards. The audit process is conducted in a confidential manner to facilitate the manufacturer's cooperation and to ensure that trade secrets and intellectual property attached to its manufacturing technologies, processes and products are safeguarded.

Consumer confidence in the quality of the medicines can be maintained in the knowledge that the TGA rigorously monitors the compliance of manufacturers with GMP standards and takes appropriate regulatory action where there is an unacceptable level of compliance or a failure to implement corrective actions. The TGA's regulatory approach to manufacturing compliance is outlined below.

Manufacturers of a therapeutic good in Australia are required to hold a manufacturing licence issued by the TGA. It is a condition of the licence that the manufacturer comply with GMP standards under the *Therapeutic Goods Act 1989*. Australia has adopted internationally harmonised manufacturing standards set out in the *Guide to Good Manufacturing Practice for Medicinal Products* produced by the Pharmaceutical Inspection Cooperation Scheme.

Good Manufacturing Practices are regulations, codes and guidelines which cover all aspects of manufacture of a therapeutic good including: a manufacturer's quality policy and procedures; supplier qualification and starting materials testing; suitability of premises and equipment; in-process and release testing of products; manufacturing and process validations; packaging, labelling and storage processes; cleaning, hygiene and air and water monitoring; staff training and hygiene; and the maintenance of documents and records. It is the manufacturer's responsibility to ensure that effective and efficient quality processes are in place and to comply with GMP.

Compliance with GMP is verified by periodic audits. A TGA audit will typically review a manufacturer's operating procedures, observe manufacturing processes, examine batch records and assess evidence supporting manufacturing process controls. Audits will also examine management procedures for change control and its investigations into product defects and complaints.

Should a manufacturing audit find a deviation from the code of GMP, the TGA writes to the manufacturer specifying where any non-compliance has been found, to enable the manufacturer to rectify any defects.

An audit report is issued to the manufacturer, usually within four weeks of completing the on site audit. The report outlines the scope of the audit, the controls and systems reviewed, and any deficiencies that require improvement. Where more serious matters are observed, the TGA will undertake an internal assessment prior to the issue of the report to determine if manufacturing can continue pending corrective action.

Manufacturers are required to respond to the audit report within 30 days. The response must detail the cause(s) of any deficiencies and provide evidence of corrective actions. It is expected that a manufacturer will implement corrections promptly and the TGA will assess the risk of continuing manufacture for supply should there be any delay.

Audits are concluded when all corrective actions have been made and GMP compliance is confirmed by letter to the manufacturer.

However, regulatory action will be initiated if the audit finds a critical deficiency, an unacceptable level of compliance, or a failure by the manufacturer to demonstrate the effectiveness of corrective actions. The TGA may impose an additional condition on or suspend or revoke a manufacturing licence, initiate a product recall, make changes to product registration and/or consumer information, and may pursue civil or criminal penalties for offences committed under the Act.

h) There has been no product recall arising from either TGA audits or US FDA inspection findings of CSL.