Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2011-2012, 19 October 2011

Question: E11-255

OUTCOME 1: Population Health

Topic: CSL MANUFACTURING

Written Question on Notice

Senator Xenophon asked:

In June this year, the Herald Sun also reported that the FDA had raised concerns regarding the CSL manufacturing plant in Melbourne: In the letter to CSL chief executive Brian McNamee the FDA said there are a "number of significant objectionable conditions relating to your facility's compliance with [current good manufacturing practice]" and criticised CSL's response to the convulsion scandal in children last year. And problems still persist at CSL's Australian manufacturing facilities, according to the FDA, which identified a number of ongoing issues during its March inspection including a failure of the company's quality control unit to fulfil its responsibility to "assure the identity, strength, quality, and purity of your monovalent influenza bulks and final drug products". A statement on the TGA's website says that the TGA was aware of these issues before the FDA investigation.

a) How long had the TGA been aware of these issues?

b) Had the TGA raised these concerns with any other regulatory bodies, either overseas or in Australia?

c) If so, when did this happen?

d) What steps had the TGA taken to work with CSL on improving these issues before the FDA raised concerns?

e) Why had no improvement occurred?

f) What is the TGA doing to improve these issues now?

g) What consequences will this incident have on Australian drug approvals in the US?

h) What impact will this have on the process of global regulatory harmonisation - will the FDA still trust Australian regulators?

Answer:

a) The Therapeutic Goods Administration (TGA) is unaware of a statement that claims that it was aware of the issues raised during Food and Drug Administration (FDA) audits prior to those audits taking place.

The matters that are referred to in the 'Warning Letter' issued in June 2011 and reported in various media arose from FDA audits in April 2010 and March 2011. The FDA has also audited CSL in 2008 and 2009.

The TGA was aware of the specifics of the FDA audits soon after those audits took place. The TGA and the FDA routinely share information about the outcomes of the audits that they undertake of companies that are of interest to both regulators. Hence, the FDA fully informs the TGA of its audits of companies in Australia like CSL and the TGA shares its information about its audits of companies based in the United States.

At the same time, the TGA has audited CSL at least annually for many years. During these audits, the TGA has made observations that broadly align with the observations that the FDA has made during its audits.

Auditing is a complex process and the audit process only provides a snapshot of the situation at a facility on the days that the audit is undertaken. Therefore, two regulators will never observe exactly the same deficiencies, but different observations will align with general themes. In these cases, the examples that the FDA has used aligns with previous and ongoing TGA observations that the company fails to investigate the systemic causes of unexpected deviations from the manufacturing process or the expected performance of their products.

b) The TGA has discussed its concerns with the FDA.

c) First discussions took place in May 2010, following the April FDA audit.

d) As explained under answer a) above, the TGA became aware of the specific issues raised by the FDA shortly after their audit.

e) Manufacturing compliance is an ongoing issue that requires close oversight by the relevant regulators. Improvement is a continuous process that requires the constant attention of both management of the company and the regulator.

The TGA has ensured that CSL has addressed the concerns identified by the TGA audits. This does not preclude new deficiencies arising, hence the need for an ongoing audit program.

f) The TGA is currently auditing the CSL Parkville facility monthly to ensure that the appropriate progress is being made on issues identified by both the TGA and the FDA. It is liaising closely with the FDA and providing regular updates on the matters that they have concerns about, as the FDA does for the TGA when it has particular concerns about US based manufacturers.

g) The FDA has not found any deficiencies that directly affect the safety of products marketed by CSL in either Australia or the United States. As a result, they have not issued a recall, nor suspended CSL's authorisation to supply the US market. Of particular note is that the FDA renewed CSL's authorisation to supply influenza vaccines to the US for the coming 2011/12 Northern Hemisphere influenza season.

This will not affect broader drug approvals in the US.

h) The close cooperation between the TGA and FDA over the audits of CSL is a good example of global regulatory cooperation and furthers the ongoing work of global regulatory harmonisation.