Senate Community Affairs References Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the Regulatory Standards for the Approval of Medical Devices
27 September 2011

Question no: 9

Topic: Overseas legal cases

Written Question on Notice

Senate Inquiry:

In Budget Estimates earlier this year, questions on notice were given by Senator Xenophon to the TGA in relation to overseas legal cases where De Puy executives had been found to be offering financial incentives (Refer p. 49 of Senate Community Affairs Committee Hansard, Budget Estimates, 31 May 2011).

In response to questions on notice, the TGA indicated it was not aware of either of these cases. Can the TGA provide the following information:

a) Does the TGA have any system or process set up to monitor overseas cases against medical/ pharmaceutical companies who also supply drugs/ devices etc to the Australian market? If not, why not?

b) If the TGA had been aware of these cases, would that knowledge have affected their dealings with De Puy in any way? If not, why not?

Answer:

a) The TGA does not specifically monitor overseas legal cases of this kind. This would be outside the remit of the TGA

b) The TGA's role under the *Therapeutic Goods Act 1989* relates to the manufacture, safety, quality, performance and timely availability of therapeutic goods supplied in or exported from Australia. Depending on the circumstances of particular cases, the TGA would consider whether there had been any breaches of the therapeutic goods legislation. To the extent that it relates to the relationship between a manufacturer and health care professionals, the conduct of the kind that is the subject of the cases cited is not likely to involve breaches of the TGA legislation, which is concerned with the safety, quality and performance of therapeutic goods.

Senate Community Affairs References Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the Regulatory Standards for the Approval of Medical Devices
27 September 2011

Question no:10

Topic: TGA company scrutiny

Written Question on Notice

Senate Inquiry:

Does the TGA consider that, if a company is found to have been acting inappropriately in other jurisdictions, the company would therefore merit closer scrutiny in Australia? If not, why not?

Answer:

If it appeared that the inappropriate company actions related to, or impacted on, the safety, quality or performance of a therapeutic good, then the TGA would undertake further action as appropriate to the matter.

Senate Community Affairs References Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the Regulatory Standards for the Approval of Medical Devices
27 September 2011

Question no: 11

Topic: TGA – scrutiny to information

Written Question on Notice

Senate Inquiry:

Given that the TGA relies on information provided to them by companies when approving devices for the Australian market, does the TGA apply greater scrutiny to information provided by these companies? If not, why not?

Answer:

Under the current Therapeutic Goods legislation, each application is considered on its own merits, in accordance with the criteria set out in the legislation, using an evidence-based approach.

Senate Community Affairs References Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the Regulatory Standards for the Approval of Medical Devices
27 September 2011

Question no: 12

Topic: Codes of Practice

Written Question on Notice

Senate Inquiry:

a) Can the TGA provide further information on what codes of practice cover the declarations of financial inducements offered to surgeons?

b) Are these codes legally binding?

Answer:

a) Industry and professional codes of practice do not fall within the remit of the TGA as set out in the Therapeutic Goods legislation. The promotion of therapeutic goods to health care professionals and to those that have responsibility for purchasing decisions is largely covered by industry and professional codes of practice.

b) This is not a matter on which the TGA can provide advice.

Senate Community Affairs References Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the Regulatory Standards for the Approval of Medical Devices
27 September 2011

Question no: 13

Topic: Inducements

Written Question on Notice

Senate Inquiry:

a) Does the TGA receive reports or declarations from surgeons or hospitals in relation to inducements?

b) Would the TGA find this information helpful when monitoring the activities of companies providing devices to Australian Market?

Answer:

a) No.

b) As noted in the answer to question on notice number 9, the TGA's role under the *Therapeutic Goods Act 1989* relates to the manufacture, safety, quality, performance and timely availability of therapeutic goods supplied in or exported from Australia. If activities of a company manufacturing devices for the Australian market were to impact on those matters it would be a matter for consideration.

Senate Community Affairs References Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the Regulatory Standards for the Approval of Medical Devices
27 September 2011

Question no: 14

Topic: Financial Inducements

Written Question on Notice

Senate Inquiry:

Does the TGA consider that financial inducements should be declared publicly, especially to patients being treated by surgeons or hospitals who have reduced such inducements?

Answer:

This is not a matter for the TGA.