Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2014-2015, 2/3 June 2014

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OUTCOME: 7 – Health Infrastructure, Regulation, Safety & Quality.

Topic: ASR Hip Replacement Implants

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Senator: Xenophon, Nick

Question:

1) Did Europe test all of the 12 devices or did it only test one or two?

2) How does the TGA ensure that devices approved in other jurisdictions have gone through the appropriate processes and testing?

3) In Australia, problems with the device were raised by the NJRR as early as 2007. Did TGA have this information back in 2007?

4) Would the TGA still have considered this advice of the NJRR by the time DePuy in effect voluntarily withdrew the device from 2009?

Answer:

1) As a result of the similarity of arrangements applying to the regulation of medical devices between Australia and in Europe it is normal practice for TGA, prior to supply to the Australian, market to take into consideration medical device assessments performed by European assessment bodies for the purposes of European market approval. These assessment bodies are referred to as Notified Bodies.

   In the case of the ASR, the original components (which were Class IIb implants in Europe and Australia at that time) were included on the Australian Register of Therapeutic Goods (ARTG) on the basis of European Certification, issued by BSI. BSI is designated as a Notified Body by their European competent authority, the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom, to issue certificates to European legislative requirements. These requirements are very similar to the Australian requirements.

   TGA does not routinely receive information about testing of individual devices from European Notified Bodies. This is because, for the majority of devices supplied in Australia, the TGA accepts certificates issued by these bodies. In these cases there is no requirement for TGA to review the primary testing data.

Recognising the risk associated with joint replacement devices, both Europe and Australia have since reclassified hip, knee and shoulder joint replacement implant devices to Class III which involves a more detailed level of scrutiny prior to market approval.

2) A successful application for inclusion to the ARTG is required before a medical device can be marketed and supplied in Australia. This can only happen if the TGA is satisfied that the device has been appropriately classified and that evidence to support the safe and effective use of the device exists, appropriate to the risk classification.

   The majority of applications to include devices on the ARTG rely on existing certification from a European assessement body (refer Q1.).

   Legislation requires that all applications for high risk devices must be selected for audit by TGA.

   The audit assesses evidence that the device has been manufactured under a documented and sufficiently rigorous quality management system and is supported by clinical evidence that the benefits of the device outweigh any risks associated with its use, and that the device complies with any other relevant requirements.

3) & 4) Analysis by the TGA of data reported in the 2007 National Joint Replacement Registry (NJRR) annual report confirmed that the DePuy ASR resurfacing hip implant was associated with a higher than average revision rate. The data from the NJRR and the TGA's analysis was considered by TGA's independent expert advisory committee, the Orthopaedic Expert Working Group (OEWG). This group consists of orthopaedic surgeons and was set up by the TGA specifically to review NJRR annual reports and provide advice to the TGA on issues raised in the reports including revision rates and other performance issues. The OEWG considered that the likely reason for the observed higher than average revision rate for the ASR implant was the technical complexity of correctly siting the device during surgery. DePuy agreed to provide additional training to surgeons on the correct insertion technique. The OEWG endorsed this approach and also recommended ongoing monitoring through the NJRR to verify the effectiveness of additional training. These actions resulted in a large decline in the usage of the ASR implant in Australia over the next 18 month period.

   The October 2009 NJRR annual report revealed that the rate of hip revisions remained of concern. The TGA raised concerns with the sponsor regarding this ongoing, higher than anticipated revision rate and, consequently, DePuy elected to remove the ASR resurfacing hip implant from the Australian market in December 2009. A worldwide recall of the ASR implants followed in August 2010.

   The combination of data from the NJRR, appropriate expert advice from clinical experts on the OEWG, and effective communication between the TGA and the sponsor resulted in the ASR implant being withdrawn from the Australian market well before any other part of the world.