Senate Community Affairs References Committee Inquiry

The role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prothese (PIP) breast implants

Term of Reference ***(b) the procedures the TGA has in place to continuously monitor relevant information in relation to device manufacturers and sponsors, including the legal or approval issues both in Australia and overseas.***

Stryker supports the need for high quality, timely data on devices and their manufacturers/sponsors where that data is important to inform regulatory decisions. For example, it is important for TGA to be able to access available post market clinical data and correspond in a timely fashion with the manufacturers/sponsors regarding unexpected clinical performance, and be aware if devices are removed from registries in another country for quality or safety reasons. Other issues, such as manufacturers facing legal action for issues that may impact upon the safety or quality of devices (such as for providing false information on device performance), are also relevant to the TGA's role in regulating devices in Australia.

Stryker understands that there are a number of international agreements in place with other regulatory agencies to alert each other where there are quality and safety concerns about devices or where there are media reports about devices which may cause consumers some concern. Stryker agrees that it is important that TGA have access to relevant information in a timely manner to ensure that it can respond appropriately without delay. In particular, it is important that TGA is aware of any relevant information available publicly so that it can address consumer concerns.

It is important to also recognise that implant manufacturers, as a condition of registration, are obliged to enter all available clinical data into the Design History File of the product, and this DHF is available and reportable to TGA. Such clinical data would include any published data, data from known clinical trials, and data known from registries around the world, including the Australian National Joint Replacement Registry.

Stryker also notes that it is important that no commercial-in-confidence information is made publicly available. While Stryker supports the need to ensure any information relevant to safety issues is made available to the TGA, this needs to occur within the context of protection of other information which is sensitive from a commercial perspective. This ensures that innovation within the medical device sector is supported and that manufacturers have an incentive to develop new products which meet consumer needs.

However, Stryker emphasises the importance of Australia retaining sovereignty over its own regulatory decisions. The TGA is an experienced and well-respected regulatory agency which is focused on meeting the needs of the Australian community and which is answerable to the Minister for Health. This gives the TGA an accountability which is important to ensure that regulatory decisions are made in the best interests of our community. While the decisions made in other jurisdictions may be relevant to the Australian context there may also be differences in how information is used by TGA to inform regulatory decisions. This can be due to factors such as the needs and values of the community, broader aspects of our regulatory system, previous Australian experience of similar issues and differences in expert views on specific data.

Term of Reference ***(e) the procedures the TGA has in place to assess the risk to Australian patients if devices available in Australia are the subject of warnings or withdrawals overseas.***

As discussed above, Stryker believes that TGA should actively monitor regulatory decisions by other countries in relation to devices registered in Australia. TGA should have access to the information that informed those regulatory decisions in order to assess its relevance to Australian consumers. However, Stryker also highlights the need for Australia to retain its independence in relation to regulatory decisions to ensure that they reflect the needs of the Australian community.

Term of Reference ***(f) the procedures the TGA has in place to communicate device information (including withdrawal information) to the general public, with a focus on affected patients***.

Stryker supports the need to communicate device information to consumers, particularly when this is relevant to safety issues. In particular, it is important that recipients of a device are provided with information about any safety concerns relating to their device.

Stryker is aware that the 'gold standard' for tracking devices is a highly-compliant device registry, such as the National Joint Replacement Registry (NJRR) that records and tracks every device of its type implanted in Australia. This provides a valuable data source that could relate to device performance over time and also enables the timely communication of relevant information to consumers in the event of a problem arising with the device. Stryker supports the increased use of registries for devices as well improving the use of data already being collected by the NJRR. However, Stryker notes that device registries are extremely expensive to establish and maintain and that the costs of this need to be balanced with the risk profile of individual devices. Stryker also highlights the need for the cost of device registries to be shared by all relevant stakeholders, including government and consumers. Currently, the funding for the NJRR comes exclusively from industry which does not facilitate ownership or input from other users and raises the question of vestment. If the costs of registries continue to be imposed exclusively on industry, it may also create a barrier to innovation and the introduction of new products onto the Australian market. For lower risk products, Stryker urges the Government to consider other lower cost options for appropriate monitoring of device usage and targeting device information to affected patients without establishing a registry.

The methods by which TGA communicates device safety issues to the general public needs to be carefully reviewed. In line with the recently proposed TGA reforms, including the review of TGA transparency, the agency is considering a number of possible solutions. Among these is the consideration of providing product information on each medical device registered; listing adverse events reported with devices; and providing a complete list of all device recalls, not only those with high impact.

Transparency to the general public is both important and correct. Certainly the provision of product information is essential. However to display all adverse events and product recalls, they must be carefully reviewed and tempered for appropriateness. For example, listing of non-safety-related recalls (for an incorrect label perhaps) or a possibly surgeon-caused or non-device related adverse event, is unnecessary and indeed could lead to undue concern or panic for patients. Responsible transparency requires appropriate filters that assess the clinical and safety relevance of the information without leading to incorrect and disruptive assumptions.

Term of Reference ***(g) the ability of the TGA to undertake or commission research in relation to specific areas of concern regarding devices, such as metal-on-metal implants.***

Stryker supports evidence-based regulatory practices. Research plays an important role in informing regulatory decisions and Stryker believes that the research should reflect the level of risk associated with the device. For example, a higher risk implantable device (such as a knee prosthesis) should require a higher level of evidence than a lower risk non-implantable device (such as a compression stocking).

In most cases, clinically relevant research will be provided by the sponsor of the device as part of the application process and further research conducted in an ongoing fashion. For example, Stryker conducted extensive research on clinical wear on highly cross-linked polyethylene liners in the new generation X3™ orthopaedic implants. However, Stryker recognises that there may be a need for TGA to undertake or commission its own research on devices once they are on the market. This should involve consultation with sponsors, as appropriate, and in a timely fashion, to ensure that the research is informed by the most complete information about the devices.

Stryker supports a role for TGA in identifying the need for research on a particular issue, for example to investigate safety concerns for metal-on-metal implants. This is important so that all pertinent product manufacturers/sponsors contribute to ensure completeness of the research. Clearly, it would be important that the research was conducted according to accepted standards of transparency and independence. Stryker also believes that industry can play a role in advising TGA on research issues, for example, on possible methodologies and research designs given manufacturers' expertise in this area.