AUSTRALIA – JAPAN FREE TRADE AGREEMENT
SUBMISSION FROM COCHLEAR LIMITED

1. BACKGROUND

Cochlear Limited is an Australian company who manufactures and sells implantable hearing systems to over 80 countries around the world. More than 80,000 recipients are now hearing as a direct result of accessing this technology. Our products including the Nucleus® cochlear implants and Baha® implantable bone conduction hearing systems are 'high-risk' medical devices that require approval for sale by relevant regulatory authorities e.g. Australian Therapeutic Goods Administration (TGA), US Food and Drug Administration (FDA) and Japanese Ministry of Health, Labour and Welfare (MHLW). A product license is granted once a device has been assessed to be of high quality, safe and effective for its intended purpose in the relevant population.

2. REGULATION OF MEDICAL DEVICES

Regulatory Authorities are government agencies who, for the purpose of safeguarding public health and ensuring honest and fair dealing between the regulated industry and consumers, enforce the law governing the sale and use of medical devices, medicines and other products. In Australia the law is defined by the Therapeutic Goods Act, 1989 and in Japan it is the Pharmaceutical Affairs Law. These laws are enforced through regulations.

Gaining approval for the safety and effectiveness of ones products, from the aforementioned regulators, is a critical step in bringing new medical devices to market and is becoming an increasingly significant cost to medical device companies selling their product in the Asia Pacific region.

Until recently many countries in Asia Pacific did not regulate the sale of medical devices. However, over the past few years, this scenario has rapidly changed and is moving towards each country having its own regulatory authority each with its own specific application and processing requirements. Naturally this has a significant impact on bringing product to market, a burden that could be reduced if there was harmonisation of regulations and approvals across the region, as is the case in Europe with the CE Mark.

3. IMPACT

Until recent years the Japanese MHLW has adopted a particularly stringent approach to the evaluation of medical devices for their quality, safety and performance. As a consequence, many products already approved by the US FDA and other regulators have spent several additional years being evaluated by the MHLW before product licenses are issued for their sale and use in Japan. Ironically, the result has been that the Japanese people have receiving medical devices that have already been obsolete in many other Western markets.

Cochlear's experience is no different from this. A product, the Nucleus® 24 Contour™ cochlear implant was launched in 2000 in the US with a commencement of the clinical trial and in Australia in 2001. This product was only approved by the MHLW in April 2006. Since 2000, Cochlear has introduced two new cochlear implant models that still are not available in Japan. As such Japanese people with a hearing impairment do not have access to current cochlear implant technology that is proving to deliver superior performance outcomes.

From a manufacturer's perspective the requirement becomes one of maintaining manufacturing lines specifically for products sold only in the Japanese market. The burden of this is not immaterial.

The Japanese MHLW has been aware of these 'unreasonable' product approval timelines and is to be commended for their participation in the Global Harmonisation Task Force (GHTF) and their implementation of significant changes to their regulatory framework. In 2005 Japan introduced a new regulatory framework that is more aligned to that of other key regulatory authorities. One key benefit of the new Pharmaceutical Affairs Law, is that for low risk devices, the MHLW will recognise third party assessments of companies' Quality Management Systems, however for the higher risk devices, no such mutual recognition is accepted. Full evaluation by the MHLW or PMDA is required.

Whilst the evaluation framework of these higher risk devices is now more aligned to that of other regulators, approval timelines are not expected to significantly reduce in the short-term as the review and evaluation of submissions continues to be impacted by:

- The extreme risk aversion of the reviewers, who are personally liable should an approved product not prove to be safe and effective
- Inadequate review resources in relation to the volume of product submissions
- Continual rotation of staff (to mitigate the risk of corruption) that impacts a development of knowledge and skills relating to different technologies. Our experience has been to encounter several rotations of staff during an individual submission.

Previously, Australia had in place a Memorandum of Understanding, recognising the TGA Quality Management System assessment. This meant that the Japanese regulators did not need to visit Cochlear and repeat an audit the Company's quality management system to the relevant ISO standard. It is not clear whether this Memorandum of Understanding remains valid under the new regulations.

4. RECOMMENDATIONS

As the key issue for medical device companies such as Cochlear is time to market, and the demonstrated willingness and inertia of the Japanese regulators to make appropriate changes the following recommendations are provided:

- MHLW / PMDA address limited resources allocated to the evaluation / review of product submissions
- Improve the skill level and knowledge of evaluators to support timely and effective reviews
- Explore options for granting approval based on third part conformity assessments of quality management systems.

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