MED-EL: Comments Regarding the "Designation of Australian Conformity Assessment Bodies for Medical Devices"

Overall MED-EL views the proposal as a positive and important step towards enhancing the efficiency of medical device regulatory audits and providing timely access to technology in Australia, while at the same time ensuring the primary aim of safeguarding Australian public health. These proposed changes are a positive sign of progressing towards further harmonisation and collaboration with other markets.

In our view, it will be important to clearly define the differences between European and Australian requirements and to provide concrete guidance on what additional documentation will be required for Notified Bodies to review applications for Australian market approval. This will be particularly important to determine personnel needs by the Notified Body for Australian assessments and to determine appropriate costs and review times.

Regarding the question "TGA would continue to offer a full suite of conformity assessment functions. Is this important to you or your organization?", we would answer no. Where a system of using Notified Bodies is properly in place, there is no additional need for the TGA to fulfil this role. Instead, we feel that focus could be placed on ensuring adequate control of the Notified bodies and on resolving any disputes between manufacturers / applicants and Notified Bodies. On this note, we found that the document does not address the important topic of a complaints pathway / ombudsman. Currently, an appeals process is available which is addressed to the Minister for Health in relation to TGA's decisions concerning including (or not including) devices in the ARTG. Additionally, there are provisions for advertising-related complaints through the TGA and industry bodies. The private health insurance industry, for example, has an ombudsman. Therefore, please consider a complaints pathway and / or ombudsman in any system implemented.

Finally, one current disadvantage the European system of Notified Bodies from a manufacturer's perspective is the lack of regulation of costs. At present, manufacturers are permitted to change their Notified Body. However, this can be associated with enormous costs. Also, as well identified in this document, not all Notified Bodies are qualified to perform reviews of all products; in practice there are few choices of Notified Body. This produces a situation where Notified Bodies can increase costs to manufacturers as they see fit and manufacturers have little recourse. For this reason, it would be important to provide guidance on determining appropriate fees according to the services performed and on appropriate timeframes for prior announcement of fee increases.