Therapeutic Goods Administration Submission - NSW Health

Alignment with European medical device regulatory framework: Up-classification of surgical mesh, Patient implant cards

1. **Up-classification of surgical meshes**

   NSW Health supports the up-classification of surgical meshes to Class III. A higher classification will help increase safety and protect patients.

2. **Patient implant cards**

   NSW Health supports the provision of device information to patients. An approach that embeds this within existing systems is preferred. The My Health Record presents an opportunity to achieve this. With 5 million Australians currently using the My Health Record and plans to cover all Australians by December 2018, it is the ideal vehicle for recording such information. Recording of devices in My Health Record would overcome some of the practical difficulties inherent in using a physical card system for all devices such as administrative burden and work practice change for health staff as well as the risk of patients damaging or losing the card.

   However, not all devices present the same kind of risk or need for repeat engagement with the health system. For example, a mesh inserted for an umbilical hernia repair is different to a pacemaker that requires periodic testing and maintenance. For those devices where repeated engagement with the health system is required, a supplementary mechanism to support patients, such as a patient implant card, has a clearer role.

   NSW is concerned that a 3-year transition period for implementation of patient information about devices on the website of the TGA and manufacturers is too long. Sponsors should be able to provide relevant information about devices within a shorter period of time.