South Australian Policy Advisory Committee on Technology

SAPACT Information Sheet on High-risk Medical Devices

This overview focuses on the classification of medical devices as an explanatory brief to the governance of medical devices and health technologies in SA Health. SAPACT evaluates health technologies which are considered high-risk and high-cost. High-risk products classified as TGA Class III or Active Implantable Medical Devices (AIMD) are within scope of evaluation of SAPACT. This inclusion criteria for evaluation of a health technology prior to use in SA Health has been established to ensure assessment of these products in the interest of patient safety. Further information regarding the role and scope of the SAPACT is available on the SAPACT website.

Therapeutics Goods Administration (TGA) Classification of Medical Devices

The TGA classifies medical devices and health technologies considered high-risk as Class III devices or AIMD. From 25 November 2021, active implantable devices will be required to be reclassified from Class AIMD to Class III, according to the *TGA Reclassification of Active Implantable Medical Devices: Guidance on the transitional arrangements and obligations (v1.0 April 2021)*.

The TGA considers the following when classifying a medical device:

- duration of use;
- placement and location of the device within the human body;
- intended use; and
- whether the device delivers a therapeutic agent (including medicine or ionising radiation) or undergoes chemical change within the human body.

Examples of class III devices are heart valves, major joint replacement implants, devices containing medicines or tissues, cells or substances of animal, biological or microbiological origin. Examples of AIMDs include the implantable pacemakers, defibrillators and nerve stimulators. The control(s) and/or monitor(s) which directly influence the performance of an active implantable medical device are also classified as AIMD.

Prior to approval to market and distribute medical devices in Australia, the TGA conducts assessments to evaluate product safety for intended use. The TGA evaluation assesses whether the new medical device demonstrates clinical safety and non-inferiority regarding clinical efficacy in the patient group intended for the use of the device. Consequently, the TGA mandates for medical device manufacturers to nominate the appropriate TGA Class prior to evaluation. More information regarding the TGA assessment process is available on the TGA website.

For more information

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