Royal Australasian
College of Surgeons

11.10.22

250–290 Spring Street
East Melbourne VIC 3002 Australia
Telephone +61 3 9249 1200
www.surgeons.org
ABN 29 004 167 766

UDI Project
c/o Medical Devices Surveillance Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Email: udi@health.gov.au

Unique Device Identification (UDI) Consultation 3

Detailed considerations for implementing the proposed Australian medical device UDI regulatory framework

The Royal Australasian College of Surgeons' (RACS) is the leading advocate for surgical standards, professionalism and surgical education in Australia and New Zealand.

RACS' Fellows are among the primary users of devices which it is intended will carry Unique Device Identifiers (UDI).

RACS' vision is to advance surgery while embracing innovation, and a key element of its mission is to improve the quality of surgical care. RACS Health Policy & Advocacy Committee (HPAC) thus endorses the establishment of an Australian medical device UDI regulatory framework the primary objective of which is to improve patient safety and post market surveillance.

RACS HPAC agrees that once implemented a UDI regulatory framework should; enable easier and faster identification of patients who have been implanted with a device of concern; facilitate easier identification and removal of those devices from stocks, and; enable patients, consumers and health professionals to access information more easily about the devices that they use.

The questions examined in this consultation are for the most part not ones of specific concern to surgeons. Thus, rather than responding directly to the detailed questions set out in the consultation paper, RACS HPAC provides only the following general feedback regarding the development of an Australian UDI regulatory framework (as provided for by Question 11).

The Therapeutic Goods Administration and the Australian Government should encourage sponsors to develop consistent standards and UDIs where possible in both USA and the EU.

It is appropriate that UDIs be provided at the model level, but ideally UDIs should be grouped, like with like, to assist in making outcome comparisons.

A phased implementation approach that is aligned with other regulators is appropriate. The EU UDI implementation process is still in early stages, while the UDI implementation process in the USA only commenced in 2013. A phased approach will enable learnings from the EU and USA experiences, and enable better alignment with approaches taken in these jurisdictions.

It is appropriate that high risk and implantable medical devices be required to comply initially, prior to other classes of devices. The proposed mandatory compliance dates for Class III (1 July 2024) and Class II (1 July 2024 and 1 July 2025 for marketing) seem reasonable.

RACS HPAC has no specific thoughts on whether Class I devices should be included within the scope of the UDI regulatory framework.

The burden of reporting faults and compliance, as well as provision of informational material for patients must rest with sponsors and manufacturers.

Yours sincerely,

Prof Mark Frydenberg
Chair, Health Policy & Advocacy Committee