Australian
Private Hospitals
Association

Australian Medical Device Essential Principles – Part 2: Proposed alignment with the European Regulation

CONSULTATION SUBMISSION

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Introduction

Purpose

This document is intended to provide responses to the ongoing consultation by the Therapeutic Goods Administration on “Australian Medical Device Essential Principles – Part 2: Proposed alignment with the European Regulation”.

APHA Submission

SUBMISSION

The Australian Private Hospitals Association (APHA) welcomes the opportunity to provide feedback on the proposed alignment of Australian Medical Device (AMD) essential principles under schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) (TGA Regulations) with *EU Regulations 2017/745* on medical devices (MDR) and *2017/746* for in vitro diagnostic medical devices (IVDR) (EU Regulations).

The private hospital sector, while not expressly involved in the manufacture or development of medical devices, is at the forefront of the delivery of healthcare services and products to patients in Australia. Providing greater access to patients to advanced treatment options, supporting greater patient and clinician choice, and ensuring that patients receive care that is fit and appropriate towards realising good health outcomes form the cornerstones of private healthcare in Australia.

There is a strong case for greater integration between Australian and European markets for medical devices. This can help insulate the Australian healthcare system against domestic supply shortages, as has been observed with the ongoing shortfall in intravenous fluid bags. It can also support greater access to new and advanced technology being developed in EU countries. Global harmonisation of medical device regulations and standards can have positive impacts on the ability of healthcare systems, public or private, to pursue the objectives of better health, better treatments, and better rehabilitation. A lower regulatory burden for the approval of medical devices developed overseas to be sold in Australia can also lower costs of purchase for private hospitals at a time when viability is a significant concern.

However, care needs to be taken that regulation does not increase the burden on purchasers, prescribers and consumers of medical devices and that it lowers risk and costs, and results in better clinical outcomes.

APHA remains willing and able to engage with the department and work with other stakeholders to ensure that private hospitals can continue to deliver high value care to patients and support better public health outcomes.

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