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AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

# Response to the Therapeutic Goods Administration consultation on the Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia

**December 2021**

## Summary

The Australian Commission on Safety and Quality in HealthCare (the Commission) participated in the Therapeutic Goods Administration (TGA) preliminary consultation in regard to the potential benefits and limitations of mandatory reporting for adverse events related to medical devices early in 2021. The Commission was supportive of enablers which would support improved reporting of adverse events, by sponsors, health care professionals and patients, related to medical devices.

The Commission has wide-ranging and extensive experience with regard to the safety and quality implications of adverse events related to medical devices. Over an extended period, there have been a number of examples of work undertaken to investigate, advise on, respond to, and prevent these adverse events. More recently this experience has been in relation to devices such as transvaginal mesh, ventilators, and textured breast implants; each involving collaboration with the states and territories, and the TGA.

This submission, in response to the Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia Discussion Paper (the Discussion Paper), also supports action which will ultimately improve the safety and quality of health care provided to patients who are the recipients of various medical devices. The data received through improved reporting has the potential to prevent adverse events, and further improve patient care.

While the focus of the Discussion Paper is on reporting of adverse events by health service organisations, it is the Commission's view that continued complementary efforts also need to be undertaken to continue to improve reporting by both patients and health care professionals. The work undertaken by many organisations, including the Commission and TGA, in responding to the issues of adverse events resulting from the implantation of transvaginal mesh demonstrates the importance of continuing efforts to support each of these groups to report effectively. This is particularly the case where the impact of the medical device was not always recognised, or understood, by clinicians and patients for some time after the device was implanted.

In supporting a multi-pronged approach to improving medical device adverse event reporting, the Commission recognises the work undertaken to date, and sees opportunity for:

- initiatives to require reporting by private, public, and not-for-profit (NFP) providers of health care involving medical devices
- further consideration of supports for patients who want to report adverse events but still encounter barriers to doing so
- to initiate work to determine the most appropriate means to require health professionals to report adverse events, while not creating onerous reporting requirements
- consideration to the inclusion of electronic medicines management (EMM) systems as medical devices in the implementation of a robust system for mandatory reporting

- for medical devices and medicines in combination products, to be considered (and classified as ‘combination products’ - as both medicine and medical device with cross referencing between ARTG entries or having a separate classification. It is noted that this may cross-over with review of the National Medicines Policy)
- ensuring the use of a consistent and standardised system for classifying adverse events.

As the TGA is aware, during 2021, the Commission worked with TGA on issues relating to the safe and quality use of medical devices as they relate to the regulation of electronic medication management systems as medical devices and the regulation of medicines contained in medical devices. Work regarding the changes to the regulation of software-based products may also be of value in the implementation of mandatory reporting, in terms of implications for capturing critical information and reporting of suspected adverse events. The Commission is able to provide a range of publications and outcomes of the work undertaken in this regard, if this would be of assistance.

Through its formalised governance arrangements with the states and territories; networks across the private and not-for-profit sectors; experience with adverse event reporting of medicines; and the opportunity provided by the National Safety and Quality Health Service (NSQHS) Standards, the Commission is well placed to work with the TGA to identify the core elements of effective medical device adverse event reporting and develop the implementation strategy.

It is noted that the Commission’s submission includes the outcome of review across the Commission and also, due to recent organisational changes includes comments from the Diagnostic Imaging Accreditation Scheme Advisory Committee.

The Commission’s submission responds to the various dimensions and considerations contained in the Discussion Paper.

**Key Considerations**

The Commission remains supportive of mandatory reporting of medical device adverse events by sponsors, health professionals, health service organisations, and patients, as a means to reduce further harm and promote safe, quality delivery of health care involving medical devices. At this point, unintended consequences of mandatory reporting are not considered a substantial risk, but risk assessment and mitigation would be part of the feasibility and implementation planning.

It is acknowledged that a balanced approach to establishing a mandatory reporting approach is required, including the scope of the medical devices to be included in the system (possibly those with greatest potential to create harm, acknowledging that this is not always clear at the outset); definition of the nature of the adverse event; maximising the use of existing systems; and, timely reporting of critical information to health service organisations and clinicians to reduce, and potentially prevent, adverse events.

The NSQHS Standards provide a possible mechanism for the mandatory reporting of adverse events of medical devices to the TGA. As requirements already exist in the standards for reporting on adverse events with regard to medicines, an action could be included in the clinical governance standard, in the Patient Safety and Quality Systems,

to require notification of device failure. As indicated previously, this would require clear definitions on what devices were to be included in reporting and there was a clear and simple mechanism for submitting the information.

If this change were to be introduced through the NSQHS Standards, the requirements would apply to public and private sector hospitals, and day procedure services. Compliance with this action would occur during the independent assessment process, which occurs every 3 years. It is noted that, as the next edition of the NSQHS Standards is not due for released until 2027, an interim measure may need to be considered.

It is noted that the Discussion Paper includes reference to inclusion of aged care homes in the work undertaken by some overseas countries. As the nature of medical devices used in aged care homes may generally be considered to be potentially less harmful, inclusion of these categories of medical devices should be considered in the detailed planning stage.

It is acknowledged that the systems and infrastructure of larger health service organisations may be able to participate more readily in a mandatory reporting system and that individual health practitioners, such as general practitioners, may find additional reporting burdensome. While this aspect needs to be carefully considered, the value of inclusion of these providers in providing a more complete picture of adverse events has been seen to be very important in recent cases. As such, exemptions for this sector, and potentially some allied health professional, is not supported without further assessment of benefit and risk.

If the NSQHS Standards were to be considered for the mandatory reporting requirement, and this action was not considered relevant to a particular type of health service organisation, there are mechanisms for making the action ‘not applicable’, so that organisation would not be subject to any additional irrelevant compliance burden. In summary, accreditation in the acute sector is mandatory and provides 100 percent coverage of key groups responsible for using, inserting and replacing medical devices. The system is operational and there is a mechanism for ensuring compliance.

In terms of other frequent users of medical devices, where accreditation schemes exist, the same requirements could be included in national standards. For many of the primary and community care providers, the recently released National Safety and Quality Primary and Community Care (NSQPCH) Standards could also apply. It is important to note the difference with these standards is that they are voluntary and the NSQPCH Standards are not due to be updated until 2028. For general practices, the standards are developed by the RACGP.

In addition to the coverage able to be provided by the standards, the licencing role of the states and territories over the private sector is also a mechanism to be considered.

It is noted that participation in the DIAS scheme is only mandatory for imaging practices seeking access to Medicare rebates; while state and territory regulation is limited to devices utilising radiation, resulting in potential gaps in mandatory reporting. Overall, given the issues of this sector and the primary care sector, the option of amendment of the *Therapeutic Goods Act 1989* may also need to be considered as part of the mandatory requirement setting.

The Discussion Paper overviews the various systems currently collecting detailed information about serious adverse events to patients during clinical care. However, it is noted that a variety of categorisation of incidents may be in place, such as Incident Severity Rating (ISR), Harm Score (HS), or Severity Assessment Code (SAC) which are subject to detailed investigation and reporting. Similarly, there are a number of different IT systems which support reporting, and as such detailed mapping of taxonomy and systems interoperability is required.

It is understood that the TGA is also reviewing existing overseas reporting and taxonomy; the interface of systems; definitions; and the number of fields and use of free text, to be collected are some of the challenges in establishing this system.

In terms of the type of medical device-related adverse events to be reported, the majority of items proposed in the Discussion Paper are considered appropriate, including:

- Incidents resulting in death
- Incidents resulting in serious injury
- Near misses that could have resulted in death or serious injury
- Issues identified during routine maintenance where the device is fixed or replaced prior to use Incidents that occur outside of a hospital setting e.g. malfunction of an implant at some later time and potentially the patient presenting to a different health service, or primary practitioner.

The potential mandatory reporting system should therefore aim to use existing IT systems wherever possible, i.e. those in place in healthcare systems or across organisations to collect patient data, activity, the nature of the device (where included), and incident information. There would need to be appropriate consultation on the development of a minimum of data set – with limited of free text fields.

A move to mandatory will require significant mapping and interface functionality upgrades. The security and integrity of the interfaces will be a critical consideration.

It is agreed that also important that the systems introduced to report this data do not add additional and/or unreasonable burden to services and avoid, where possible, duplication of data entry and/or analysis.

The Discussion Paper's proposal for TGA to maintain, or enhance, access for online web submission to allow individuals (consumers or sole practitioners) to continue to report adverse events in an efficient manner, is supported.

While the information infrastructure is critical to the introduction of mandatory reporting, the broader systems implantation also need careful planning so that the training and support of those co- ordinating and reporting medical device-related adverse events to the national regulator will be imperative to accurate, timely and sustained reporting.

December 14th, 2021.