Lung Foundation Australia
when you can't breathe... nothing else matters®

Submission to TGA: Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia

Introduction:

Lung Foundation Australia is a consumer representative organisation that advocates for people with lung conditions. This includes advocating for patients to receive access to evidence-based diagnostic and treatment options. We acknowledge that access is a complex issue and is impacted by a number of variables including social, physical, environmental and economic factors.

Listed below are the questions posed through the public consultation process along with responses from Lung Foundation Australia.

Do you agree with our proposal to establish the UDI System in Australia, taking the International Medical Drug Regulators Forum (IMDRF) UDI Guidance (when it is finalised) as the basis for informing Australia's regulatory and legislative requirements?

It is difficult to comment with detail and clarity until the IMDRF UDI Guidance is finalised. It seems a reasonable approach to review the international UDI system as the basis for informing Australia's regulatory and legislative requirements.

The Australian UDI System will apply to all devices placed on the market except custom-made devices and certain other devices. For example, in Australia some products are regulated as devices while the same groups of products are not considered to be medical devices in some other jurisdictions. Also should UDI in Australia apply to Class I medical devices, particularly those other than Class Im (with measuring function) and/or Class Is (supplied sterile)? While it is highly desirable to align internationally, do you have proposals for possible exemptions for UDI requirements?

A determination is required to ensure that medical devices that are used daily with patients to support normal bodily functions and disease management are included in the UDI system. Devices that don't meet these criteria and/or have a low risk of defect causing adverse patient consequences should be excluded. Many of the low risk products are sold over the counter in pharmacy where the opportunity to track to individual patients is difficult. For example, devices that should include an UDI include:

- endobronchial valves which are implanted into the lungs
- Respiratory machines (e.g. Continuous positive airway pressure **(**CPAP) and Bilevel Positive Airway Pressure (BiPAP)), used to support normal airways and assist those with sleep apnoea
- airway clearance devices (as used in cystic fibrosis and neuromuscular disease), such as the 'cough assist' and nebulizers.

Some of these devices are very expensive, used for a long time and faulty manufacture would significant impact patient quality of life.

Other medical devices such as spacers should not carry an UDI as the risk is low and it is more difficult to track a specific product to an individual patient.

It is proposed to have the power to accredit one or more Issuing Agencies. What requirements should this accreditation be subject to?

Any issuing agency should have the expertise and capacity to deliver a coding system which conforms to international standards. This will be important to be effective in ensuring patient safety and other benefits offered through an UDI system.

Sponsors will be required to have an agreement with the device manufacturer to legally enter the required UDI information into the Australian Unique Device Identification Database (AusUDID) – what should be taken into account when making the legislative amendments to clarify these responsibilities? For example, where more than one sponsor has pre-market authorisation for the device?

Legislative amendments should outline that all manufacturers are responsible for entering UDI information into the AusUDID including how it is to be entered, specific data elements for entry and timeframes for entry.

It is proposed that the TGA establish and manage the AusUDID. Are there any concerns with this proposal? Are there alternative organisations that could establish and manage the AusUDID? What are the advantages and disadvantages of these alternatives?

It is important that the body to establish and manage the AusUDID is a federally regulated body with the capacity to manage the data elements included in the UDI system. The TGA are the regulatory body that assess medical devices for introduction into the Australian market and already administer the Australian Register of Therapeutic Goods (ARTG) entries associated with these devices. It would seem logical that this body would be the most appropriate to establish and manage the AusUDID. We are unaware of an alternate organisation that would be as well placed as the TGA to successfully undertake and deliver on this body of work.

What core data elements and other relevant information should be entered into AusUDID?

The set of data elements should be consistent with those agreed upon by the IMDRF.

How should we link the ARTG and the UDI database? What information should they share?

An UDI could be part of the ARTG entry.

Should different transitional arrangements be implemented for different classes and categories of devices? Is the alignment with EU transitional times appropriate?

A cost analysis should be undertaken to determine the feasibility of alignment with the EU transitional timeframes. The higher risk medical devices should be addressed as priority.

What impacts (including unintended impacts) do you anticipate for you and other stakeholders?

Potential benefits for patients include increased patient safety and speed of recall in circumstances where defects are identified. Another potential benefit is increased knowledge of product performance through contributions to information systems.

There is concerns, however, that there will be significant cost implications for compliance of sponsors of medical devices supplied in Australia with the implementation of the UDI system. This will be passed on to consumers which in turn increases cost to consumers and acts as a barrier to access. The benefits of implementation of the UDI system needs to be considered in relation to cost and access implications for consumers.

Are there any other issues and questions we need to consider when implementing this change?

In Summary

LFA does not object to the amendment of the Therapeutic Goods Act 1989 and the Therapeutic Goods (Medical Devices) Regulations 2002 (Medical Device Regulations) to include the legislative and regulatory powers allowing the TGA to establish a UDI system in Australia.