



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA Update

Medical Devices & Product Quality

Tracey Duffy
First Assistant Secretary, Medical Devices & Product Quality Division, TGA
Association of Healthcare Supply and Procurement Officers Conference 2022

18 AUGUST 2022

TGA Health Safety
Regulation



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

This presentation will cover:

- Unique Device Identifier (UDI) for medical devices
- Patient information materials: patient implant cards (PICs) / patient information leaflets (PILs)
- Surgical Loan Kits
- Changes to assistive technology
- Changes to custom-made medical devices
- Recall reforms
- The impact of regulatory reforms in Australia and in the EU
- Pandemic impacts on approval and supply of therapeutic products



Australian Government

Department of Health and Aged Care

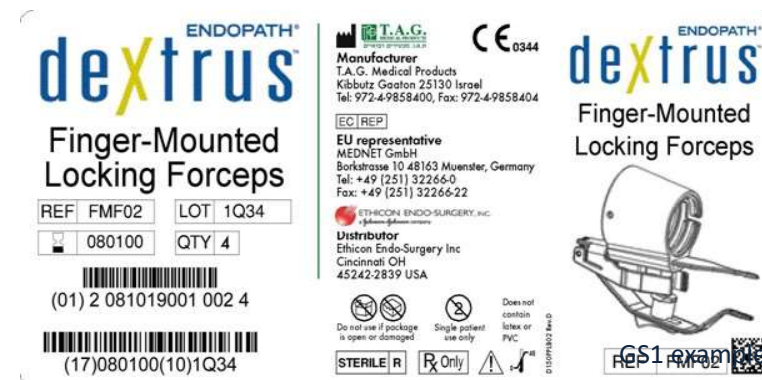
Therapeutic Goods Administration

Unique Device Identifier (UDI) for medical devices



The TGA is implementing UDIs for medical devices

- UDI is being implemented in many countries, including the USA, EU, UK, Canada, Japan
- When fully implemented every Australian device (unless exempted) will have a UDI on every level of packaging, and for some devices (that are reused) on the device itself
- Device manufacturers and sponsors will provide data about those devices to a new database, the TGA's Australian UDI database (AusUDID)
- Formats for the UDIs will include existing GS1 UDI standards
- Greater benefits will be realised if UDI is adopted in procurement, hospital, billing systems



GS1 example



What are the benefits (why is it important)?

Patients:	Faster and more accurate identification of patients who have devices that are included in a recall or safety action Help prevent recalled or expired products from being used in care process Enable accurate, real time details within digital health records
Recalls:	Prevent use of recalled products, and enhance surveillance activities
Healthcare:	More reliable and efficient system of tracking and tracing medical device issues
Point-of-Care:	Ensuring correct product is utilised and recording of data in Electronic Health Record and Patient Implant Cards
Research:	Comparative studies on product, treatment outcomes or patient care Automation of accurate product data into registries to support research and monitoring activities
Supply Chain:	Tracking use of Product, Lot Numbers and Expiry Easier identification of recalled products within inventory Enablement of consistency in data capture capability across all products supporting greater automation
Commerce:	Improving accuracy in transactional, analytical and contractual processes
Reimbursement:	Accurately identify devices for reimbursement requirements
Anti-Counterfeiting:	May enable additional preventative measures



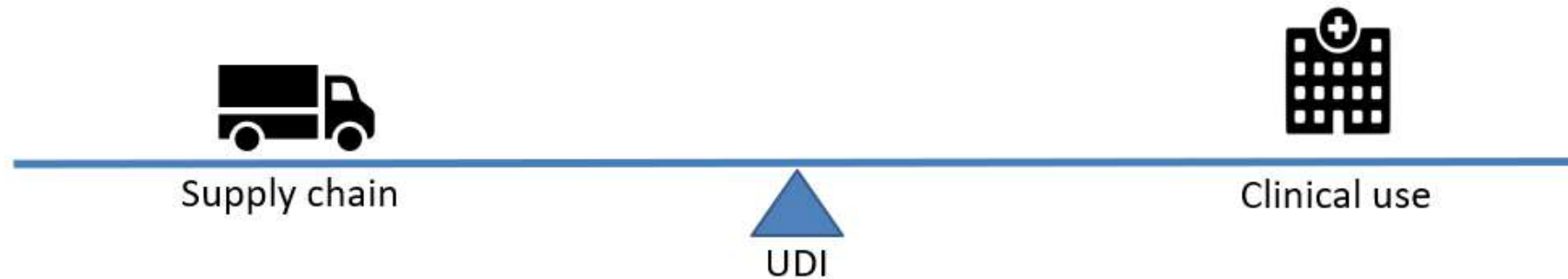
Patient Implant Card	
Name:	Rodney Goodpatient
Device:4700	Mosaic 305C227 Aortic stent
Manufacturer:	Medtronic
Serial number:	56998
At:	the Best Hospital
Address:	123 Healthy Street
Manufacturer:	Victoria



(00) 6 13994760692



Supply chain and Clinical use



- Ability to use UDI in Enterprise Resource Planning (ERP) and other systems
- Must work on conveyers
- UDI on multiple layers of packaging
- Different UDI standards
- Triggers – need for a new UDI-DI
- Changes to device data over time – from a supply chain perspective
- Supply-chain use of AIDC symbology vs other users
- Ability to scan and interpret different UDI carrier formats and standards
- Changes to device data over time – from a clinical perspective
- Incorporating device data into clinical device catalogues



Timing



Progress to date

- ✓ 'Sandpit' AusUDID released end June 2022 to continue to collaborate and co-design prior to planned January 2023 voluntary compliance
- ✓ Third consultation paper (on the regulatory framework) about to be published
- ✓ Approval and funding to build the Australian UDI database within a four year timeframe
- ✓ Legislation changed to allow for the TGA to collect UDI data
- ✓ Extensive consultation – including 'lessons learnt' and adoption challenges
- ✓ Working Groups established
- ✓ Successful connection of National Product Catalogue to the sandpit AusUDID for provision of UDI data by manufacturers and sponsors
- ✓ Monthly information webinars including invited guest speakers (such as from the UK Scan4Safety pilot, global manufacturers, issuing agencies)
- ✓ Planning started for adopting UDI in other TGA processes such as recalls and adverse events



For supply chain



- ✓ Supports a future of improved visibility and traceability of products throughout the supply chain
- ✓ Supports improved consignment management
- ✓ Enables greater automation and data capture, reducing errors and manual intervention in supply chain processes
- ✓ Greater inventory accuracy in real time
- ✓ Less reliance on manual processes to manage products
- ✓ Improved accuracy and timeliness where devices are used, enabling automation of ordering, reconciliation and reimbursement
- ✓ More accurate data capture to support improved analytics, especially in areas related to patient level costing, value based health and procurement



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Patient information materials:

Patient implant cards (PICs) / patient information leaflets (PILs)



Patient information materials

- October 2017 the Govt approved regulations to require patient information materials with implantable medical devices
 - Patient information leaflets to aid in patient informed consent
 - Patient implant cards for patients to have a record of what has been implanted
- Exemptions in line with the EU
- Staggered implementation approach
- Consent to supply non-compliant medical devices has been granted for many sponsors where the manufacturers are still implementing their final solutions

	Patient Information Leaflet (PIL)	Patient Implant Card (PIC)
Urogynaecological mesh		
New devices	1 Dec 2018	1 Dec 2018
Existing devices	1 Dec 2019	1 Dec 2019
Surgical mesh		
New devices	1 Dec 2018	1 Dec 2020
Existing devices	1 Dec 2021	1 Dec 2021
Implantable devices (other than those exempted)		
New devices	1 Dec 2018	1 Dec 2020
Existing devices	1 Dec 2021	1 Dec 2021



Consent to supply medical devices non-compliant with EPs



Welcome to the Regulatory and Compliance Portal.

Services



Devices
Compliance
(PMR)



Advertising
Compliance



Special Access
Scheme (SAS)

- In Dec 2021, modernised process from paper form to online form
- Applications made through TBS portal
- Multiple ARTG entries can be included in a single application if the application relates to non-compliance with the same EPs
- On 29 October 2021, amendment to legislation to allow reduced fees for applications relating to non-compliant patient information materials



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Surgical Loan Kits



Surgical Loan Kits

- **Regulations changed on 25 November 2021** to exempt Surgical Loan Kits from requiring ARTG inclusion
 - A ‘**Surgical Loan Kit**’:
 - only contains medical devices:
 - 2 or more reusable surgical instruments, implantable medical devices and any other medical device that is not reusable or an implantable medical device
 - used in a surgical procedure
 - supplied to Australian hospitals on loan/consignment
 - **Each medical device in the Surgical Loan Kit must be included in the ARTG** and the kit itself is subject to adverse events reporting
 - **Specific guidance is being developed** with stakeholders – publication later this year!





Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Changes to assistive technology



Excluded goods

- Some products are excluded from the therapeutic goods regulatory system ([Therapeutic Goods \(Excluded Goods\) Determination 2018](#)).
- This means they are not regulated by TGA
- Current exclusion:
 - household and personal aids, or furniture and utensils, for people with disabilities





Proposed changes for assistive technology

Proposed change:

- Assistive technology products intended by the manufacturer to maintain or improve functional capacity of persons with disability to undertake activities of daily living in settings other than health care settings.
- Must be:
 - Low risk (Class I, non-sterile, non-measuring)
 - would not pose a risk of harm that requires medical attention in circumstances where it malfunctions or deteriorates when used as intended

Example – devices that are not weight bearing (falls can cause significant injury)





Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Changes to custom-made medical devices



Custom-made medical devices



Originally defined
as all medical
devices designed
and manufactured
to suit a particular
individual



EXEMPT but not
EXCLUDED since
the introduction of
Regulations in 2002



Not required to be
included in the
Australian Register
of Therapeutic
Goods but had to
meet all other
regulatory
requirements



Usually:
- Low risk
(prescription
glasses, dental
splints, etc)
- Made by a trained
or accredited
professional



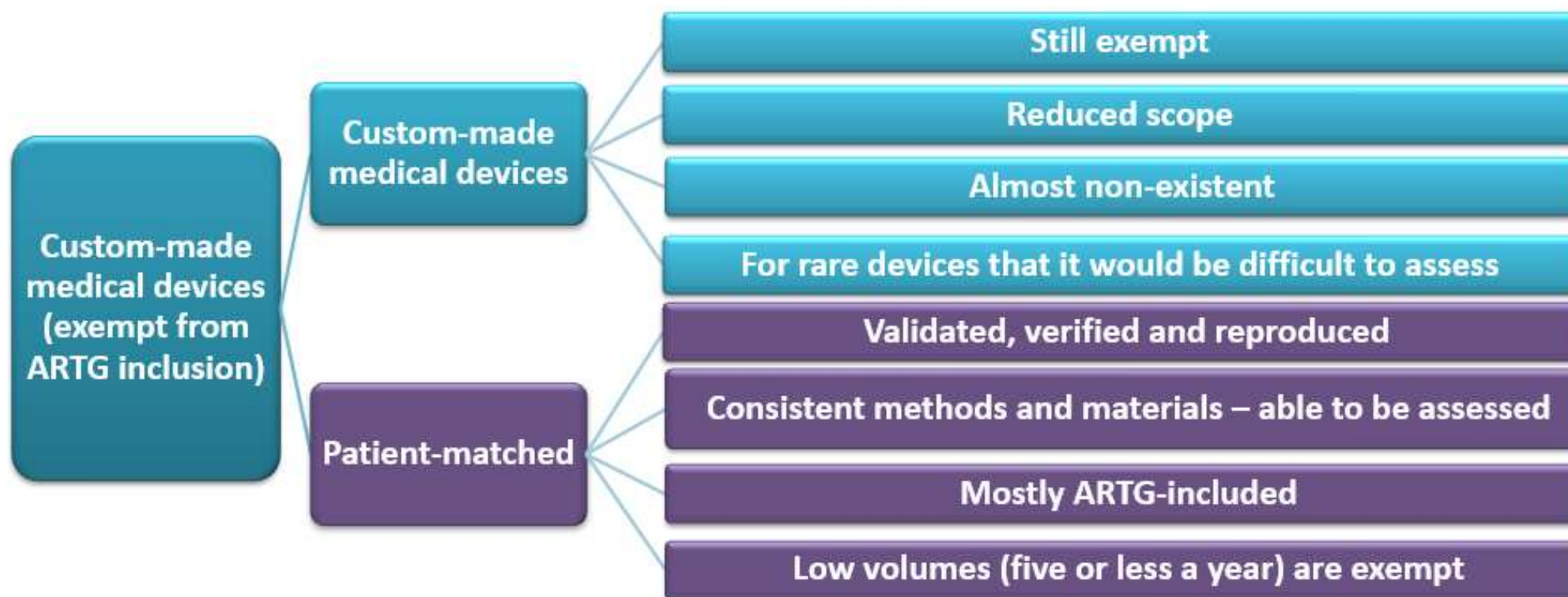
Why change?

- The rise of new technology presents new challenges
 - Higher risk custom-made medical devices (e.g. individualised high risk implants)
 - A new cohort of manufacturers entering the market (e.g. open source designs for medical devices can be made on domestic 3D printers)
- On 25 February 2021 a new framework for the regulation of personalised medical devices commenced





Changes to custom-made medical devices





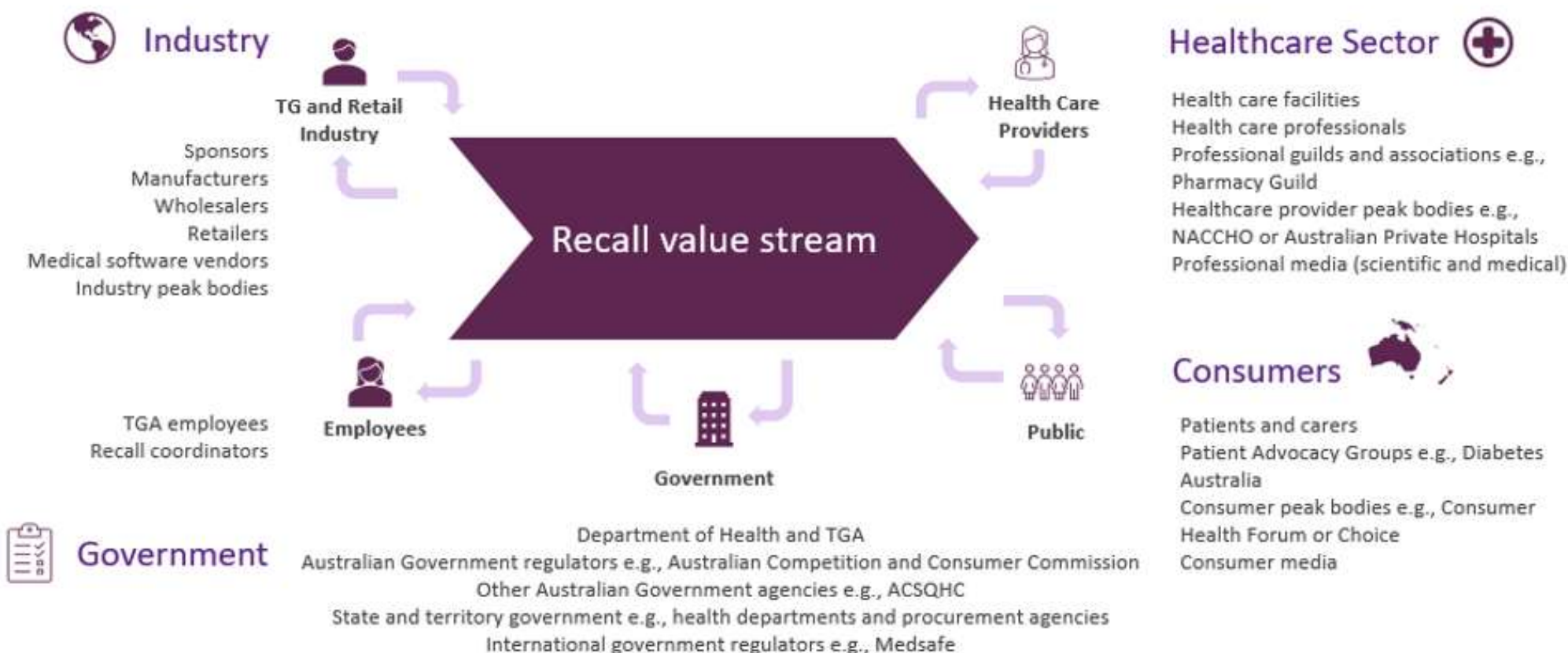
Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Recall reforms

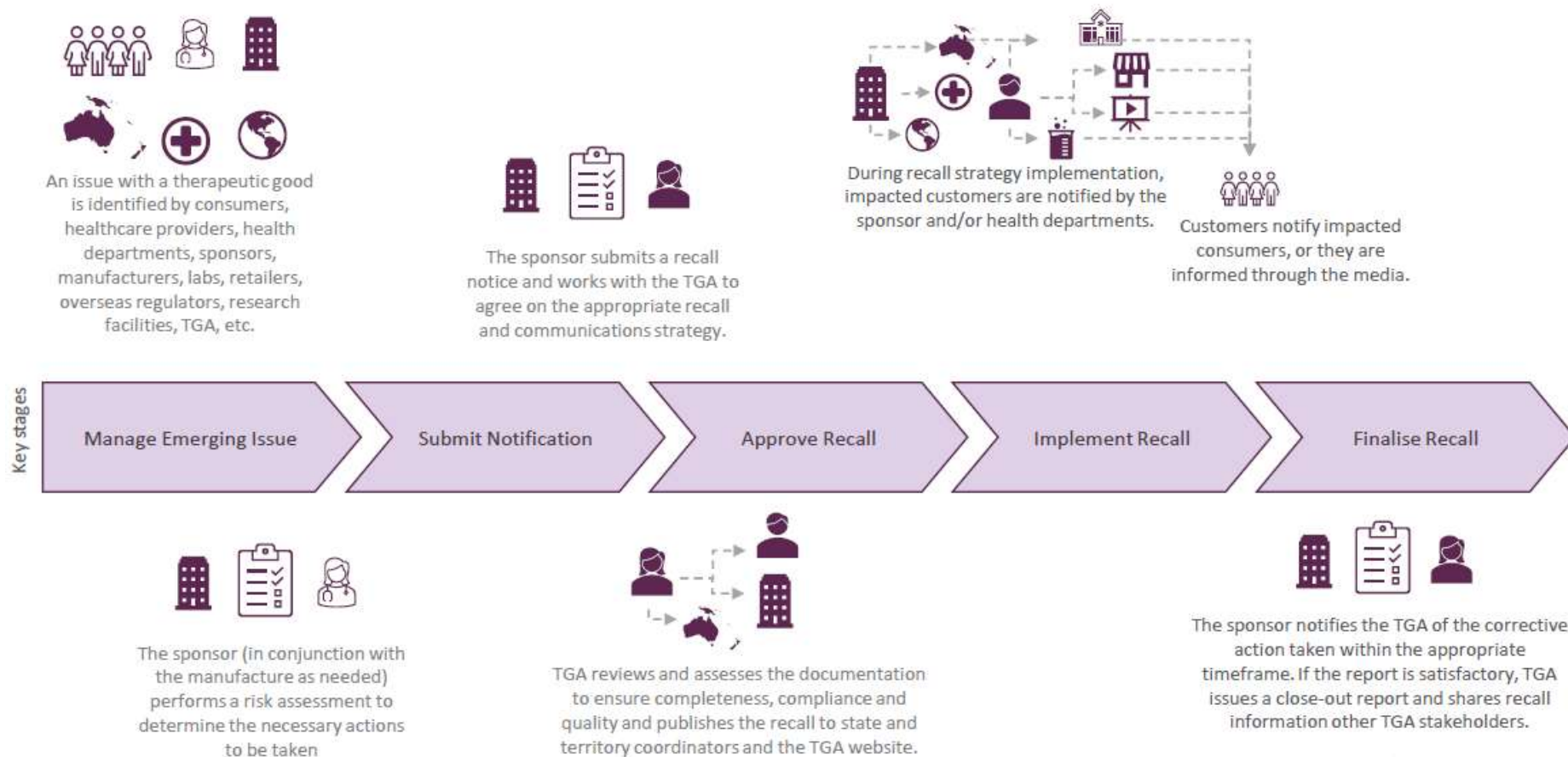


All recall stakeholders





The end-to-end recall process





Recall reforms

Themes already identified

- Information flow inefficiencies
- Difficulty at times identifying the precise product being recalled
- Duplication of effort
- Unclear roles and responsibilities
- Complexity of communication pathways across supply chains
- Difficulty reaching impacted customers
- Processes too manual
- Better education about recalls and recall terminology





Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Recall reforms

Next steps / what are we doing now?

- Recalls Data Model and Analytics
- Synthesising review recommendations & feedback from discovery activities
- Drafting Options Paper
- Standard Operating Procedures, Work Instructions and the QMS
- Robotic Process Automation (RPA)
- Recalls Education Material

**Stay tuned for the Options Paper ... we'll be in contact again.
Your views are very important to us!**





Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Impact of regulatory reforms in Australia and in the EU



New EU medical device regulation



- **Medical device regulation in the EU is in transition**
 - Manufacturers must have their products recertified under the EU Medical Device Regulations (MDR) by 26 May 2024
- **Most medical devices in Australia (not class I) are affected**
- **New EU requirements will result in product changes:**
 - Revised IFU and labels
 - Restricted intended purpose (e.g. intended patient population)
 - Some products may no longer be available
- **Some manufacturers are experiencing recertification delays**
- **The TGA is implementing a risk-based strategy**
 - to minimise burden and reduce impacts on supply
 - Online tools for sponsors with streamlined processes and reduced fees



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

New Australian regulatory requirements

- **Software as a Medical Device**
- Changes started from 25 February 2021
- clarified the boundary of regulated software products (including 'carve outs')
- new classification rules – some products have stronger regulatory scrutiny
- **Spinal implants**
- ARTG entries for Class IIb spinal fusion devices will list product names





New Australian regulatory requirements

Reclassification of some kinds of devices

Reform	Old classification	Revised classification
Active medical devices for therapy with diagnostic function	IIa or IIb	III
Spinal implantable medical devices	IIb	IIb or III
Devices used in direct contact with the heart, central circulatory system (CCS), or central nervous system	IIa	III
Medical devices that administer medicines or biologicals by inhalation	I or IIa	IIa or IIb
Active implantable medical devices (AIMD)	AIMD	III
Medical devices that are substances introduced into the body via body orifice or applied to the skin	I or IIa	IIa, IIb or III

A transition is in place for sponsors of existing products who lodged notifications with the TGA before 25 May 2022.



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Pandemic impacts on approval and supply of therapeutic products



Pandemic impacts on approval and supply of therapeutic products

General observations

- The pandemic remains challenging, but also seen by many as a huge opportunity
 - For some, it is the opportunity to do good and support Australia's pandemic response
 - For some, it is the opportunity to make money in a very short space of time
- Many entities are new to import and supply of medical devices and are unaware of the difference in a regulated market
- The inexperience and differing attitudes of applicants about safety and quality also puts Australians and Australian health workers at risk during a pandemic
- The TGA continues to manage the balance between timely approval versus public health and safety



Pandemic impacts

General observations

- The COVID-19 global pandemic has led to some very new ways that the TGA works with and supports these new comers to the regulatory environment:
 - received tens of thousands of enquiries and thousands of applications
 - increased its efforts in creating guidance, education at all levels, participated in many forums with industry and supply groups
 - frustration due to a long queues and some long wait times
 - products are therapeutic goods and consumer goods – there is high public, media and political interest



TGA media release following wrongdoing by a mask supplier



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Pandemic impact

- Government range of activities in relation to supporting and securing supply of critical goods including Office of Supply Chain Resilience
- Programs are delivered via multiple pathways by multiple Departments
- Communication and education critical for business to understand regulatory requirements early
- A high volume of noncompliance
 - Inappropriate advertising claims, including claims to treat COVID, or labelling goods as 'TGA approved'
 - Importation and supply of goods without market authorisation - held by Australian Border Force
 - Lack of evidence to support claims made about devices
 - Lack of procedures to maintain and obtain records about therapeutic goods



Pandemic impacts

Case study 1 - COVID-19 rapid antigen test (RAT)s

- Significant business opportunity means poor quality submissions - lead to a very high rate of rejections
 - Resource intensive and also meant other sponsor's applications sit in queues
- Emerging variants meant manufacturers needed to continue gathering data about RAT performance
- All approved devices are subject to day 1 post-market review to monitor their performance and activities
- Ongoing education of users and general public about what devices can / can't do
- Post market review and real world evidence





Pandemic impacts

Case study 2 – face masks and respirators

- Volume of face masks now over 2000 entries
- Post-market activity to review device safety and performance, including laboratory testing
- Revised computer assisted decision process from 1 Oct 2020 to undertake pre-market assessment as the review found the rate of compliance with regulatory requirements was low
- Extensive regulatory action including product cancellation and recall action where goods were found not to meet performance expectations
- Maintain discussion with State and Territories on supply and availability



TGA officer testing the particulate filtration efficiency of a N95 respirator



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

QUESTIONS?



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration