Unique Device Identification Webinar 18

Project checkpoint: update on what we know so far, future project plan, and what you can do to get involved

Gary Pascoe
UDI Project Lead
TGA

Jasmin Hyatt
UDI Support Team Manager TGA

Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past, present and emerging.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

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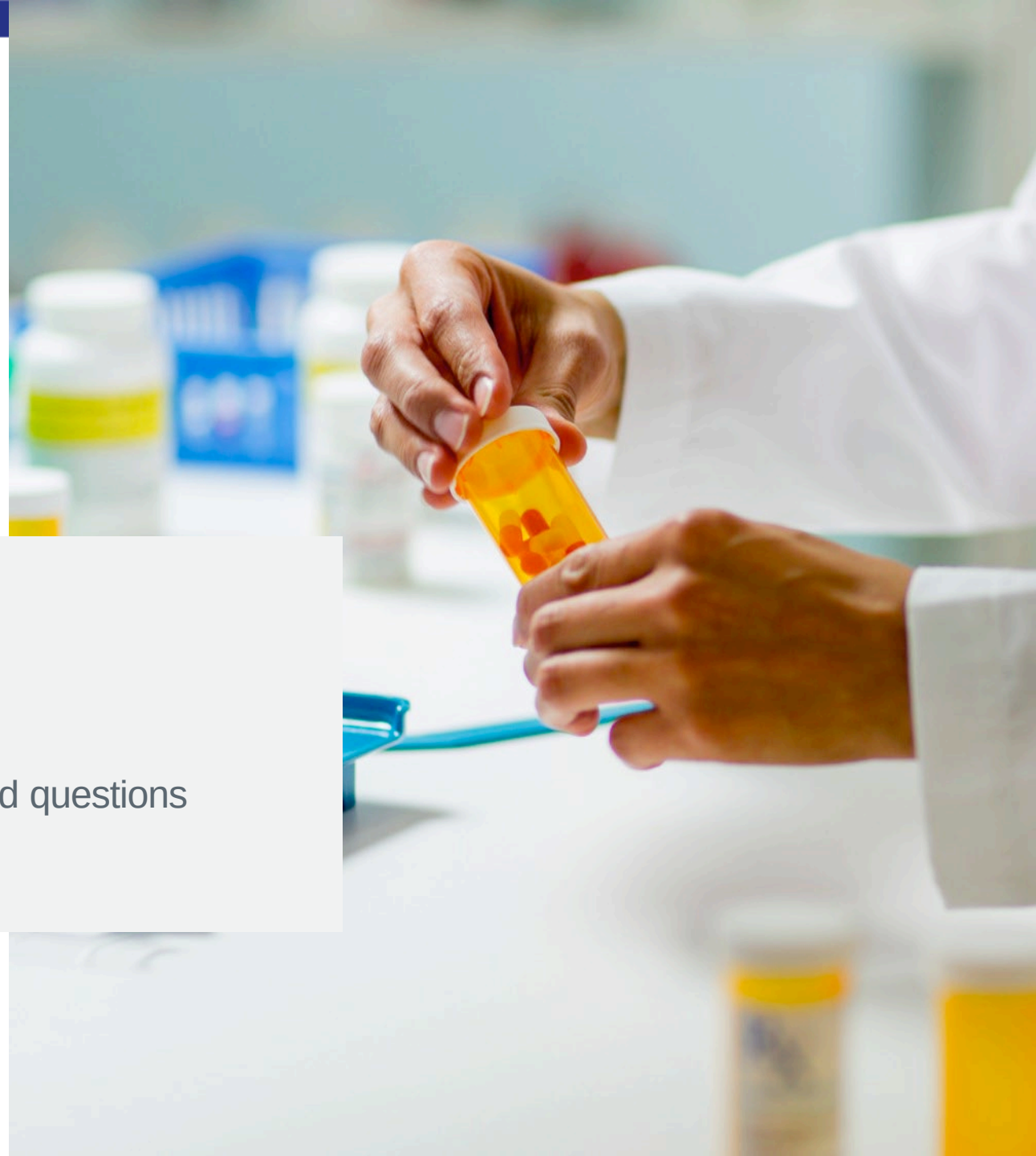
Agenda

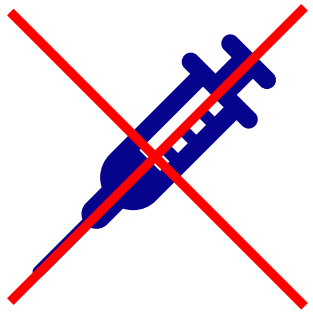
1. **Australian UDI: what we know so far**
2. Future UDI project plan
3. How can you get involved?
4. Australian UDI key topics and frequently asked questions
5. Questions and Answers



What we know so far

AusUDID Data Dictionary with the required data elements drafted

Medical devices required to meet UDI requirements

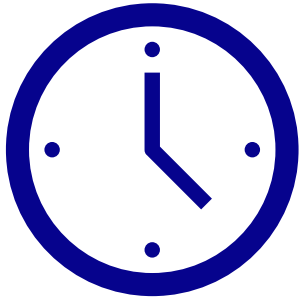


Medical devices exempt from meeting UDI requirements

Data supply methods

Issuing Agencies

Areas we are yet to finalise



Timing of the UDI implementation and impact on sponsors who are also responding to the European Commission's implementation of new Medical Device Regulations (MDR)

Clarifying the UDI requirements for retail only devices

Amending the implementation timing for in vitro diagnostic devices (IVDs)

Rules for managing changes to UDI data for devices that have multiple sponsors

Requirements for devices in Surgical Loan Kits and System or Procedure Packs

Acceptance of UDI labelling from other countries, e.g: Japan

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Future UDI project plan

Q3 2023 | Q4 2023 | Q1 2024 | Q2 2024

Final consultations

- Consultation on remaining policy areas
- Sponsor testing of ePatient Information Leaflets (ePILs), Machine to Machine (M2M), National Product Catalogue (NPC)
- UDI Hub refreshed

Regulatory drafting

- Government consideration of UDI policy proposals
- Regulatory drafting
- Sponsor testing of ePILs, M2M, NPC
- Data Dictionary & technical documentation in place

AusUDID readiness

- AusUDID Release package ready
- Supporting documents, Guidance and user guides finalised

Voluntary compliance

- UDI amendments effective
- AusUDID is live
- Sponsor onboarding

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How can you get involved?

Sponsors and manufacturers provide feedback on AusUDID Pre-Production

Join our regular UDI Technical Working Group (TWG)

Visit the UDI Hub

Participate in external testing of AusUDID functionality

Contact one of the recognised accredited Issuing Agencies

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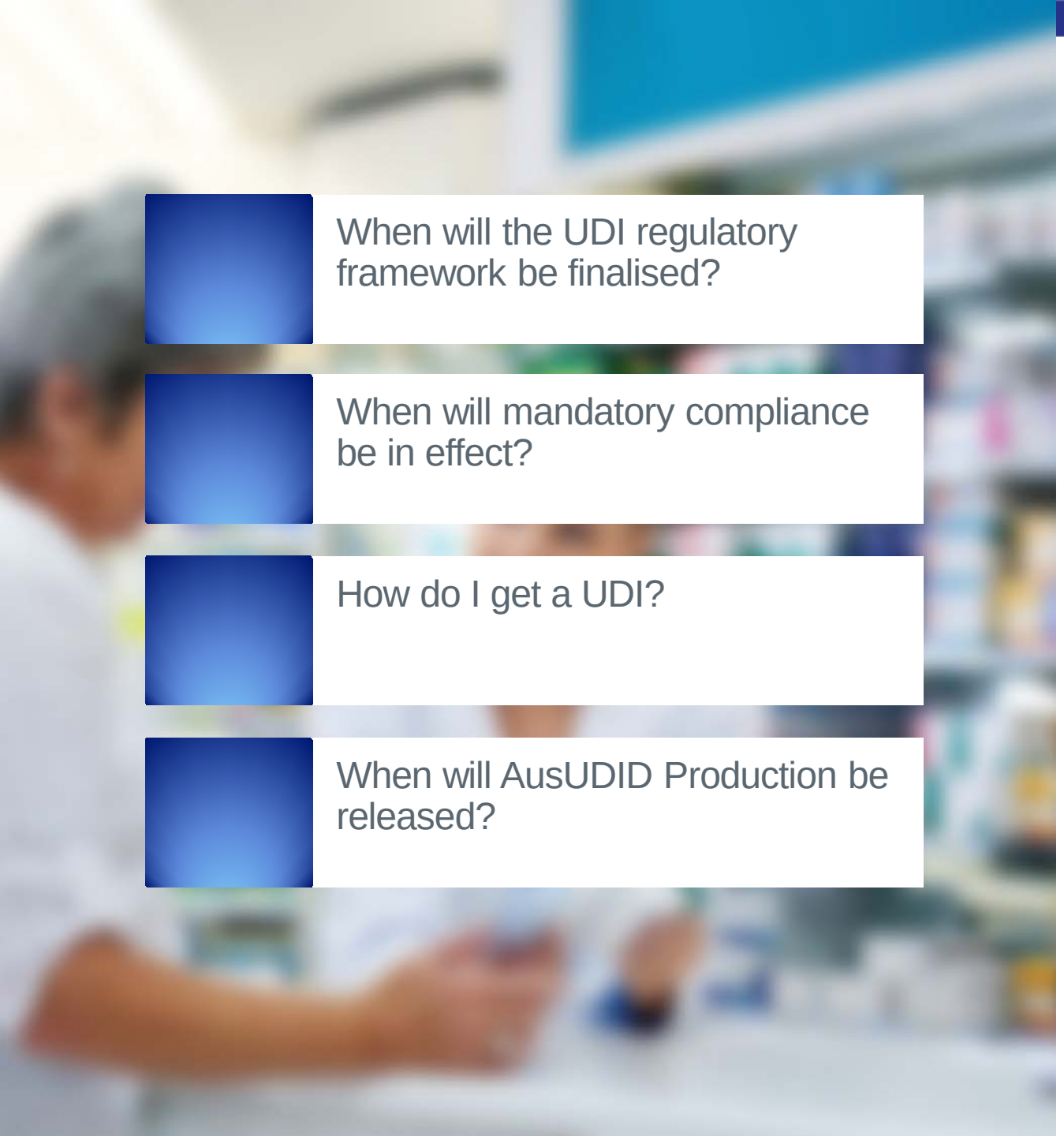
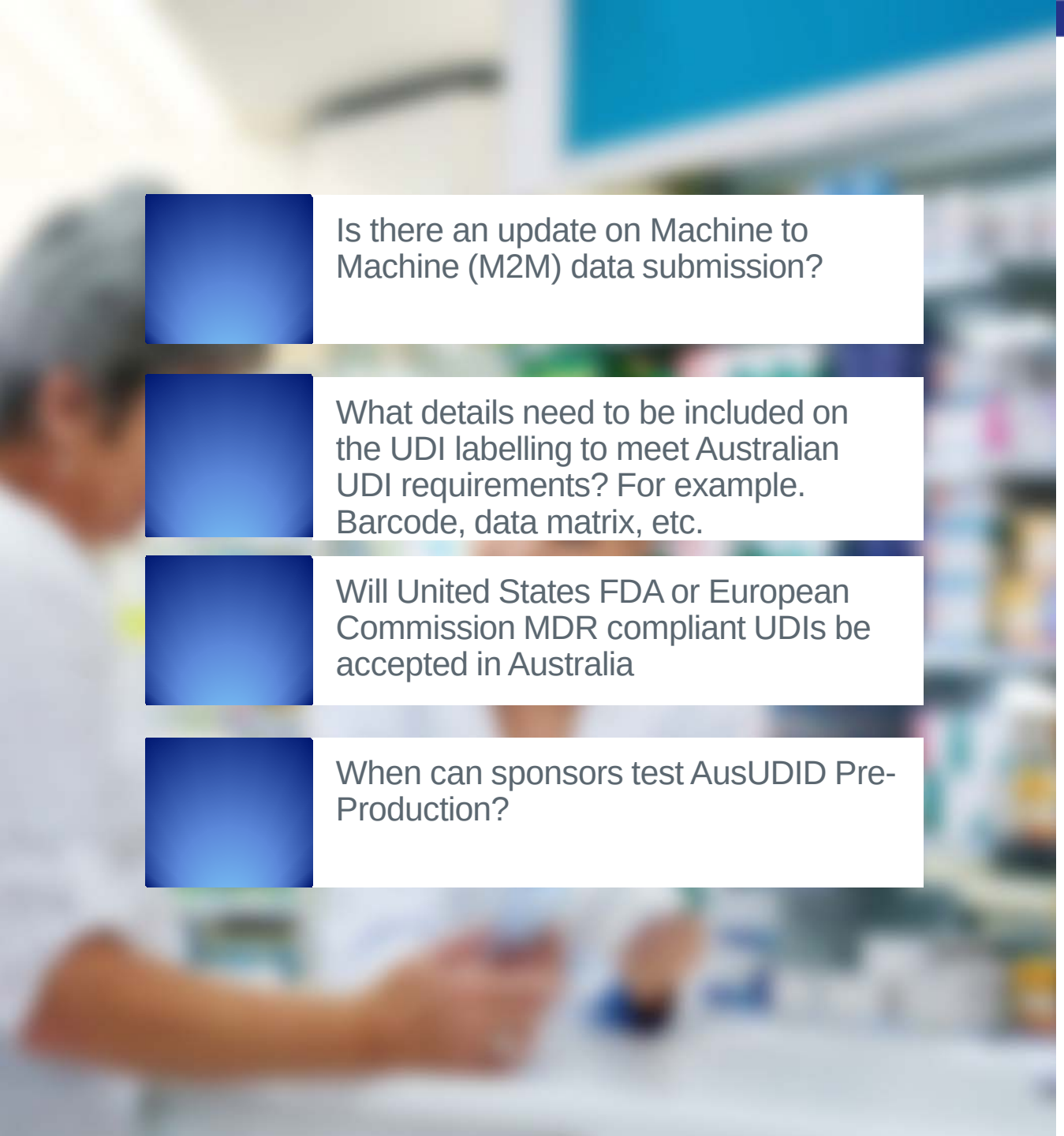


- When will the UDI regulatory framework be finalised?
- When will mandatory compliance be in effect?
- How do I get a UDI?
- When will AusUDID Production be released?

Key Topics and Frequently Asked Questions



- Is there an update on Machine to Machine (M2M) data submission?
- What details need to be included on the UDI labelling to meet Australian UDI requirements? For example. Barcode, data matrix, etc.
- Will United States FDA or European Commission MDR compliant UDIs be accepted in Australia
- When can sponsors test AusUDID Pre-Production?

Pre-Webinar Questions

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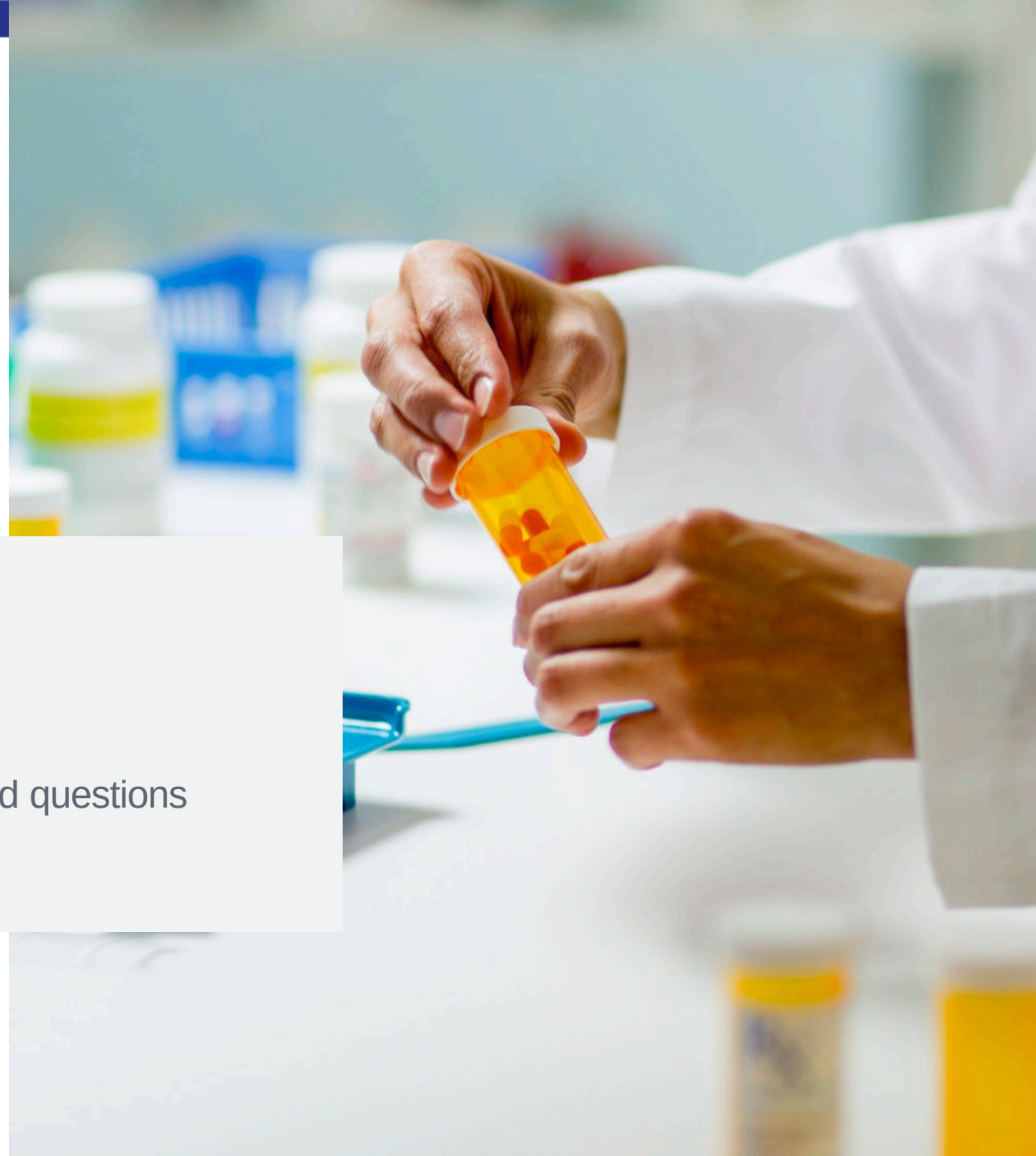

Questions?

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Website and link references

UDI Hub	https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-system
Third UDI consultation paper	https://www.tga.gov.au/resources/consultation/consultation-detailed-considerations-implementing-proposed-australian-medical-device-udi-regulatory-framework *Closed on 11th October
Second UDI consultation paper	https://www.tga.gov.au/consultation/consultation-exploring-options-introduction-australian-unique-device-identification-udi-system
First UDI consultation paper	https://www.tga.gov.au/consultation/consultation-proposal-introduce-unique-device-identification-udi-system-medical-devices-australia
Previous webinars	https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-system/unique-device-identification-system-communications-and-stakeholder-engagement

Contact us

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TGA Twitter	https://twitter.com/TGAgovau
TGA YouTube	https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw
TGA topics blog	https://www.tga.gov.au/blogs/tga-topics
TGA Linkedin	https://www.linkedin.com/company/therapeutic-goods-administration/
TGA Instagram	https://www.instagram.com/tgagovau/?hl=en

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration