GMP FORUM 2023

Forward vision: regulation of manufacture and supply

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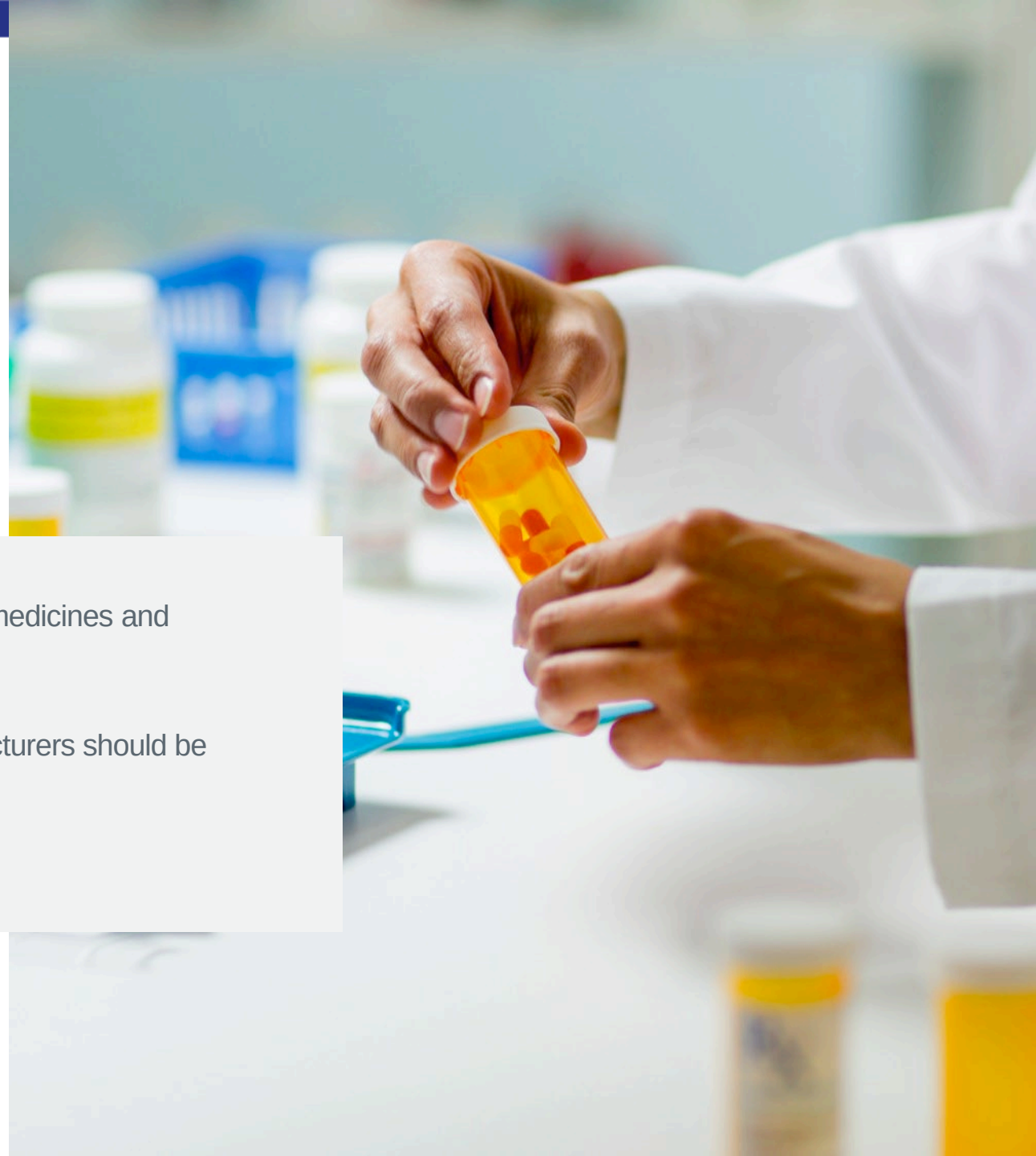
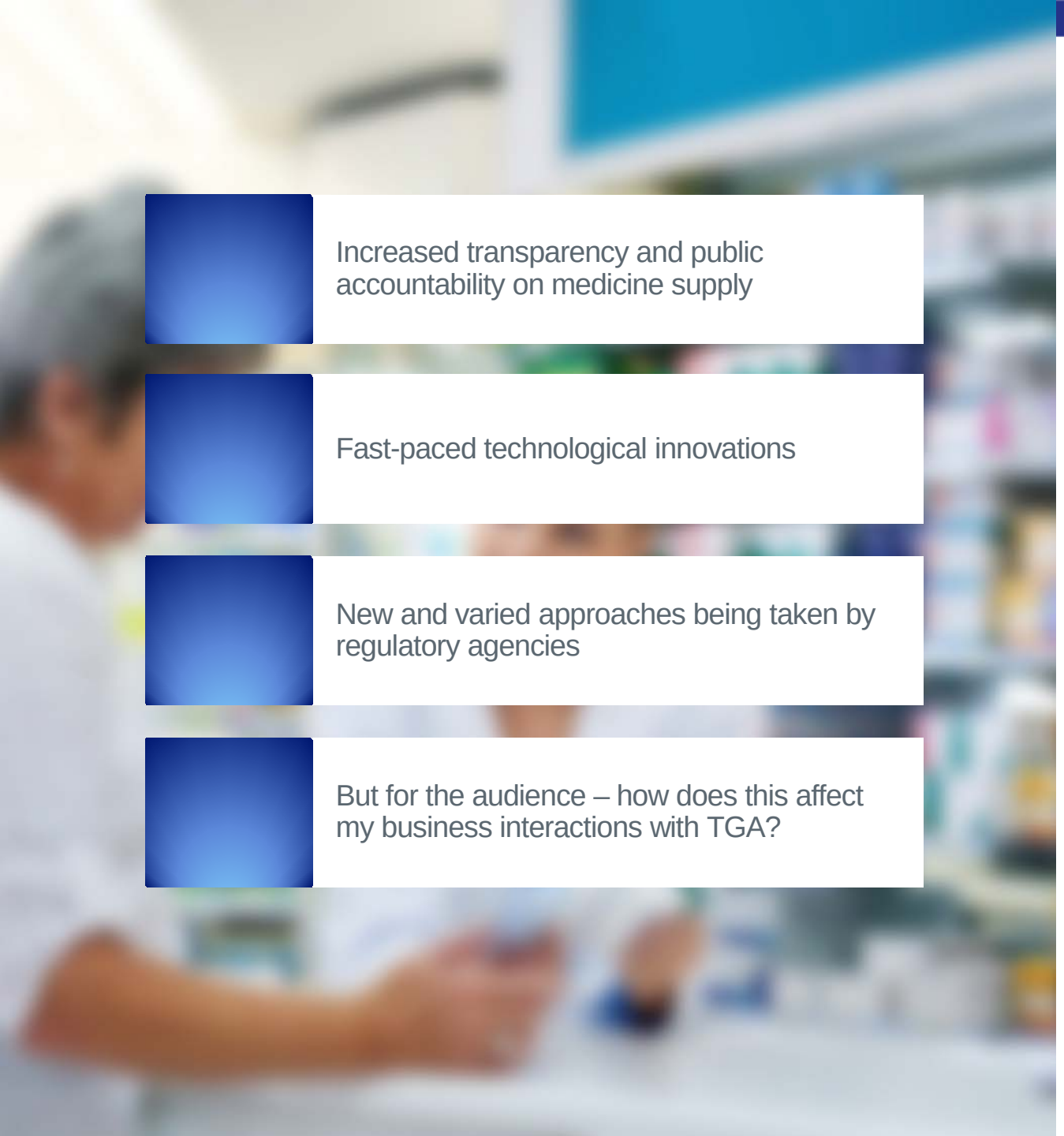
Setting the scene

The way we do things is changing!



- Outline some factors that may affect Australia's regulation of medicines and biologicals
- Suggest why we think TGA, Australian sponsors and manufacturers should be aware of these and make changes
- Open discussion – this is not a lecture!



- Increased transparency and public accountability on medicine supply
- Fast-paced technological innovations
- New and varied approaches being taken by regulatory agencies
- But for the audience – how does this affect my business interactions with TGA?

Disruptors to our current approach to regulation

3 themes and an assessment

- Patient and consumer expectations
- Manufacturing/technology advances
- Changes for the TGA
- What does this mean for me (when applying to the TGA)?

Patient and consumer expectations

We all want more …

- Access to more information about each medicine
  - Location of manufacturer(s)
  - All ingredients and their source
- Reliable supply
  - Management of shortages
  - Efficient, effective recall actions
  - Environmental concerns

New manufacturing approaches and technologies

Affecting both industry and the regulator

- Site-based technology vs product specific manufacture
- Manufacturing by the bedside
- Product knowledge management
- Tech-driven GMP inspections: remote and hybrid

TGA is changing …

… because the world is changing around us

- COVID19 pandemic – required flexible approaches
- Increasing rate of change … new regulation and guidance/educational materials
- Transition from emergency use/provisional approvals
- Non-traditional access pathways: medicinal cannabis supply in Australia
- Increasing use of
    - IT /electronic data
    - data-sharing approaches – security!
    - reliance mechanisms

What does this mean for you?

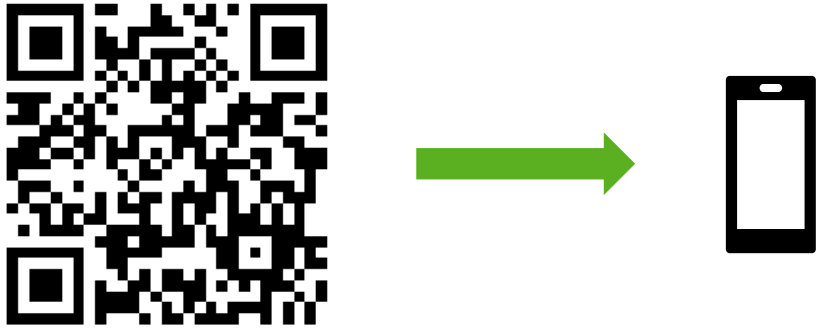
How to ask questions

Verbal questions:

Raise your hand to ask a verbal question. A member of the GMP Forum staff will provide a roaming microphone.

Written questions:

Scan the QR code below or click the link in your calendar to access Slido via your mobile device. You can submit your question, and vote on other questions submitted.



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Coming up next in this room

Jenny Hantzinikolas
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Remote Inspections: the past, present and future