Workshop: How to do an Effective Recall

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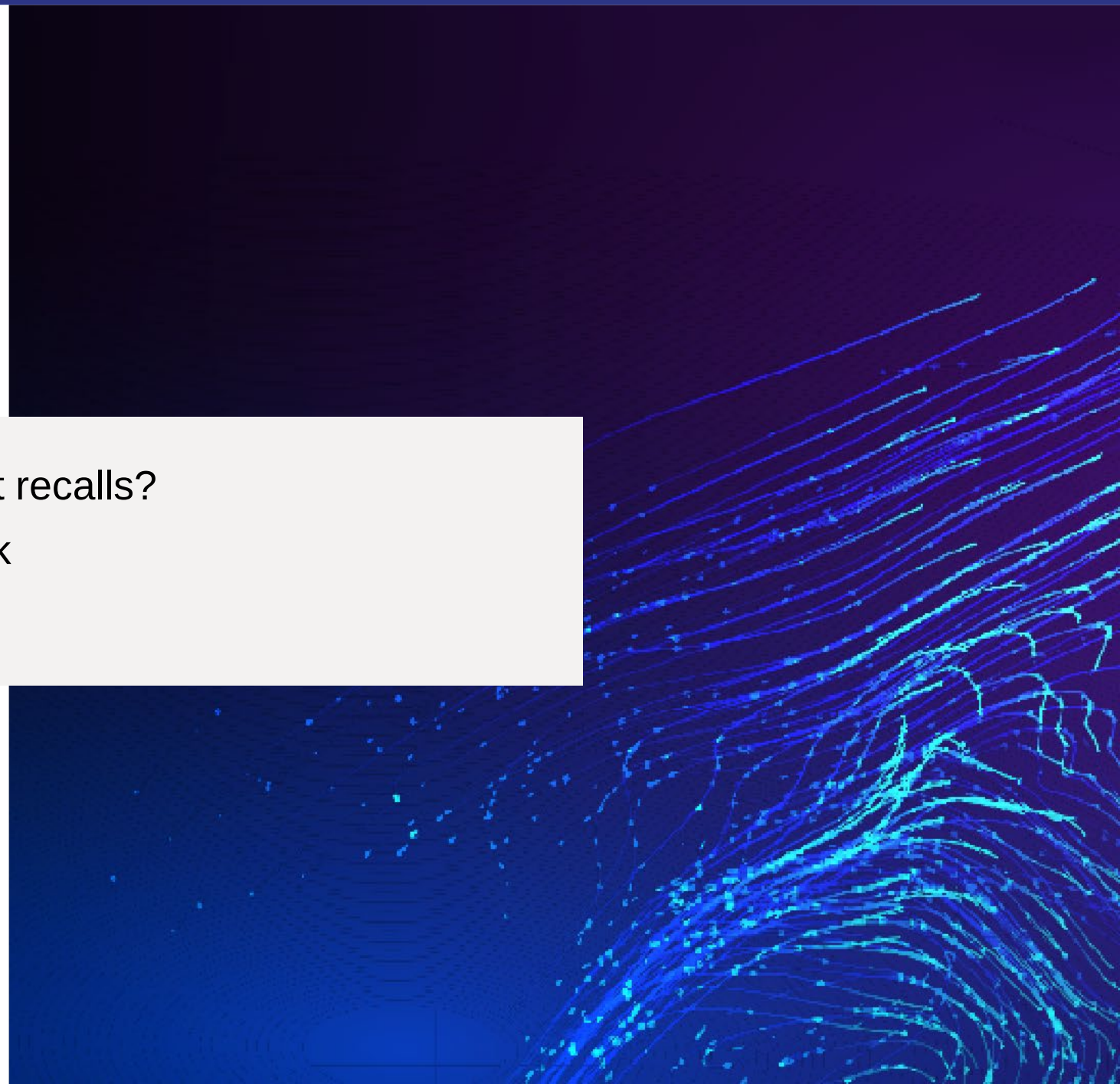
Agenda

- Quick quiz - what do you know about recalls?
- Interactive case studies – group work
- Wrap up



What do you know about recalls?

Question 1: Which reason below would result in you needing to undertake a recall action?

Question 2: When do you need to contact TGA to do a recall action?

a) Your product does not work as intended.
Contact TGA when you have removed it from the market.

b) The manufacturer says so.
Contact TGA within a month.

c) The goods are already supplied to the market and a problem with the safety, efficacy, performance, presentation or quality has been identified.
Contact TGA as soon as possible but within a week.

The answer is: C

All actions should be submitted to the TGA as soon as possible via the TBS portal so they can be assessed, agreed to and actioned

What do you know about recalls?

Question 3: What is the document that gives guidance on undertaking a recall action in Australia?

a. Recalls in Australia (RIA)

b. Uniform Recall Procedure for Therapeutic Goods (URPTG)

c. Australian Recalls of Therapeutic Goods (ARTG)

The answer is: B

The Uniform Recall Procedure for Therapeutic Goods (URPTG)

What do you know about recalls?

Question 4: What information is required to be submitted with your recall notification?

a. Customer letter

b. Customer list

c. Customer response form

d. HHE / Risk assessment documentation

e. All of the above

The answer is: E

All of the above

The Customer letter, customer list, response form and HHE / Risk assessment documentation are all required when you submit your notification.

Activity – Recall case studies

Please see the written hand outs and additional question prompts

1. **Australia's Miracle Cure**
   - About Health Hazard Evaluations (HHEs)
   - What makes a good HHE, what should it contain

2. **Best Buddi Bandages**
   - About the suitability of information provided
   - What is needed and how should it be formatted

3. **Guerilla Infusion Sets**
   - About choosing the right action
   - Why is one action more suitable than another

4. **CalmEase**
   - Consumer level recalls
   - Why they are needed and what is required

Activity – Interactive case studies

Case study 1: Australia's Miracle Cure

This group was asked to review an inadequate HHE and consider the following from the perspective of a TGA.

Recall Coordinator:

1. Is this enough information to be able to confidently gauge the risk to patients?

2. If not, what additional information does this HHE need for you to be able to gauge the risk to patients?

3. You later request additional details from the sponsor, *Drugs R Us.* They state that is not required, because they only received one complaint and the sample has not been tested yet. Is this response appropriate?

Activity – Interactive case studies

Case study 2: Best Buddi Bandages

This group was asked to review an email from the sponsor and the three attachments provided - a customer letter, customer list & risk assessment information.
Following review, they were asked to consider:

- If they had enough information to assess the action?
  What is clear / unclear?
  What questions would they need to ask the sponsor?

- What should the action type be:
  Recall, Safety Alert, Product Defect Alert, other?

- What should the action level be – wholesale, hospital, retail, consumer?

- What should the classification level be:
  Class I, II or III?

- Is the key message clear in the customer letter?
  What would they change?
  What else would they suggest to improve this action and how it was communicated to TGA?

Activity – Interactive case studies

Case study 3: Guerilla Infusion Sets

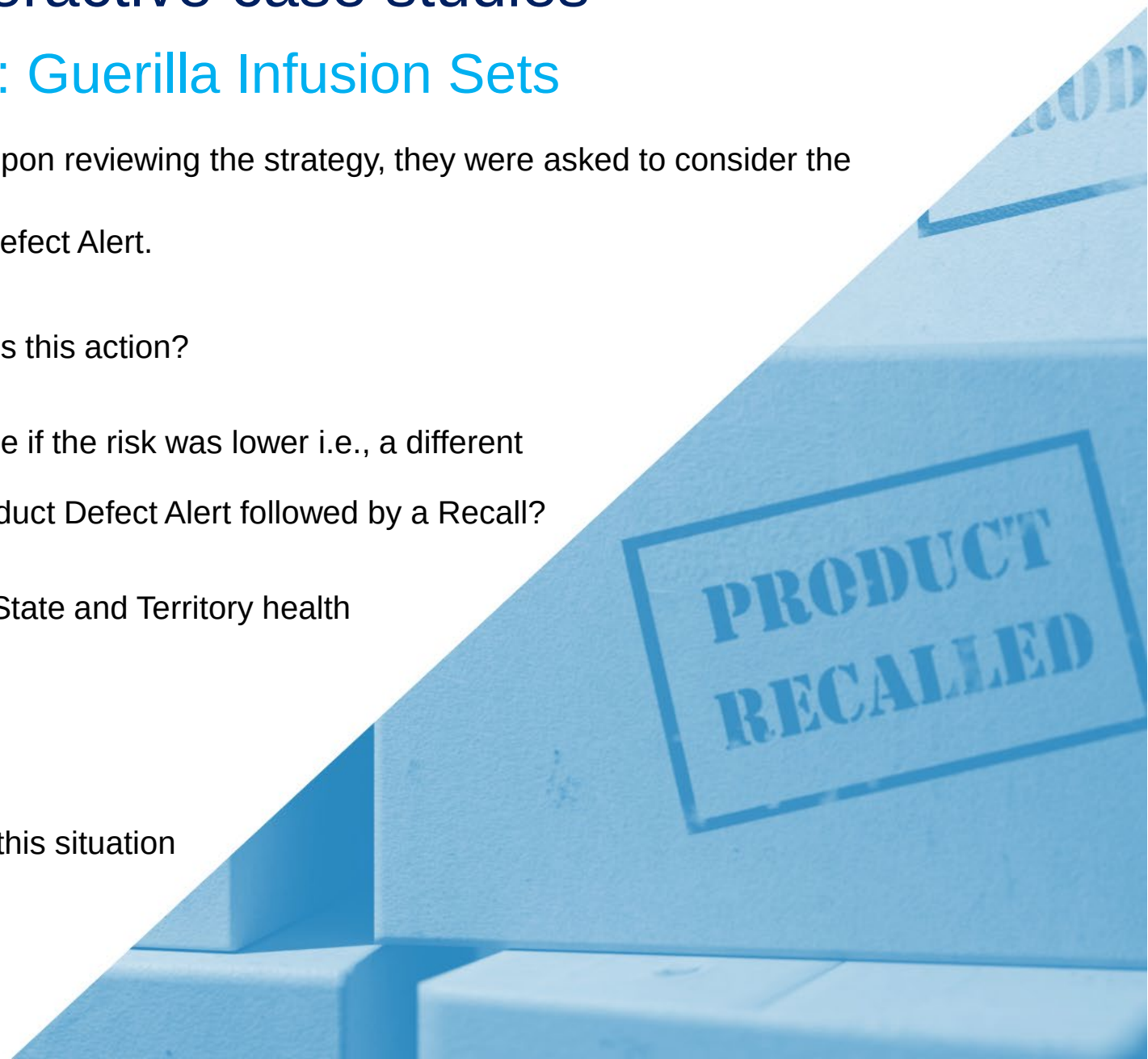
This group was asked to review an action strategy. Upon reviewing the strategy, they were asked to consider the following:

- The sponsor submitted this action as a Product Defect Alert.
  What were the main reasons for this?
  Why did TGA agree?
  What other information might be needed to assess this action?

- How might the assessment of this problem change if the risk was lower i.e., a different device, or the under-delivery was only 2%?
  Would there still need to be two actions i.e. a Product Defect Alert followed by a Recall?

- As part of this action the TGA consulted with the State and Territory health department representatives.
  Why do you think we did this?
  Why don't we do this for every recall action?
  Who else could we have contacted?

What else could either the sponsor or the TGA do in this situation to mitigate the risks?



Activity – Interactive case studies

Case study 1: CalmEase Complementary medicine

This group was asked to review a draft customer letter and explanation of the problem with the product. Following review, they were asked to consider the following:

- What are the risks of undeclared allergens in complementary medicines, and how do these risks align with the URPTG's requirements for initiating a recall?
- Additionally, what type and level of recall action would be appropriate?
- Would a Public Communication Strategy be required in this case given there is no traceability of end user customers?
- They decided a communication strategy is required. Therefore, what information might need to be included in the Communication Plan?
- Who else might need to be notified of this problem?

Find out more

Recall actions	https://www.tga.gov.au/safety/recall-actions
Managing a recall	https://www.tga.gov.au/how-we-regulate/monitoring-safety-and-shortages/manage-recall
The Uniform Recall Procedure for Therapeutic Goods – ‘URPTG	https://www.tga.gov.au/resources/resource/reference-material/uniform-recall-procedure-therapeutic-goods-urptg

Questions?

Scan this QR code with your device to submit a question

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Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration