Recall Reforms: the Future of Market Actions

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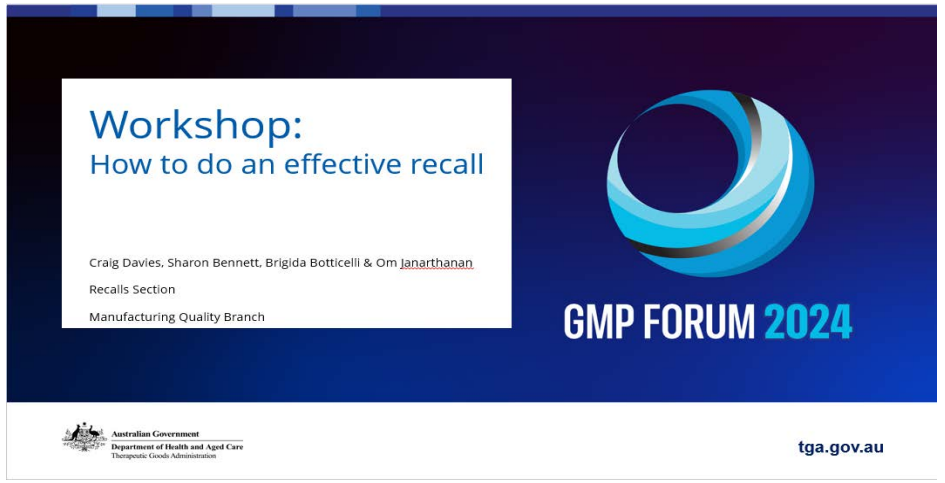
GMP FORUM 2024

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration



Day 2 Presentation Times:

Recalls 101 – 9:00am, Courtyard Room

Workshop – 11:00am, Eureka Room 1

Recall Reforms Program

Project Team – key members

DAVIES, Craig

Director • MDPQD MQ Recalls SN

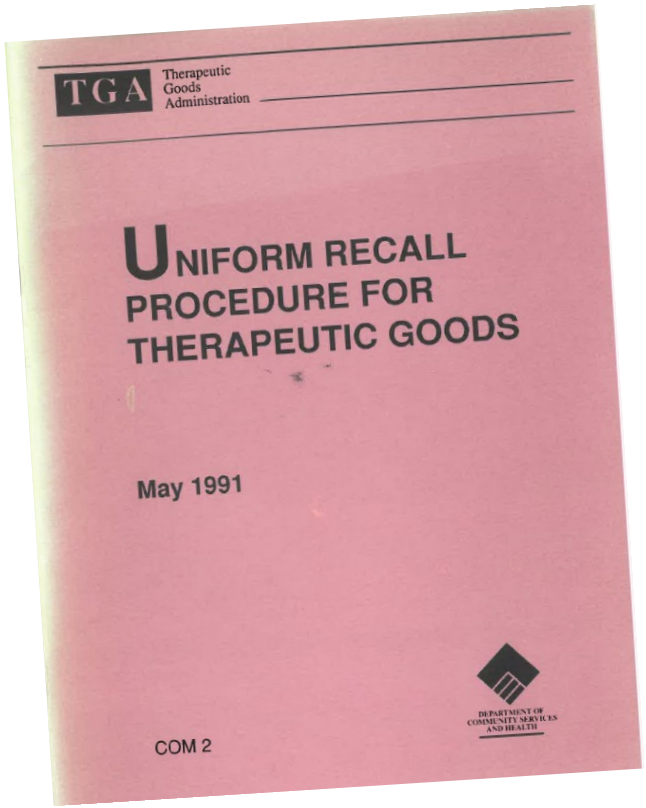
COLEMAN, Nathan

Project Manager • MDPQD MQ Recalls SN

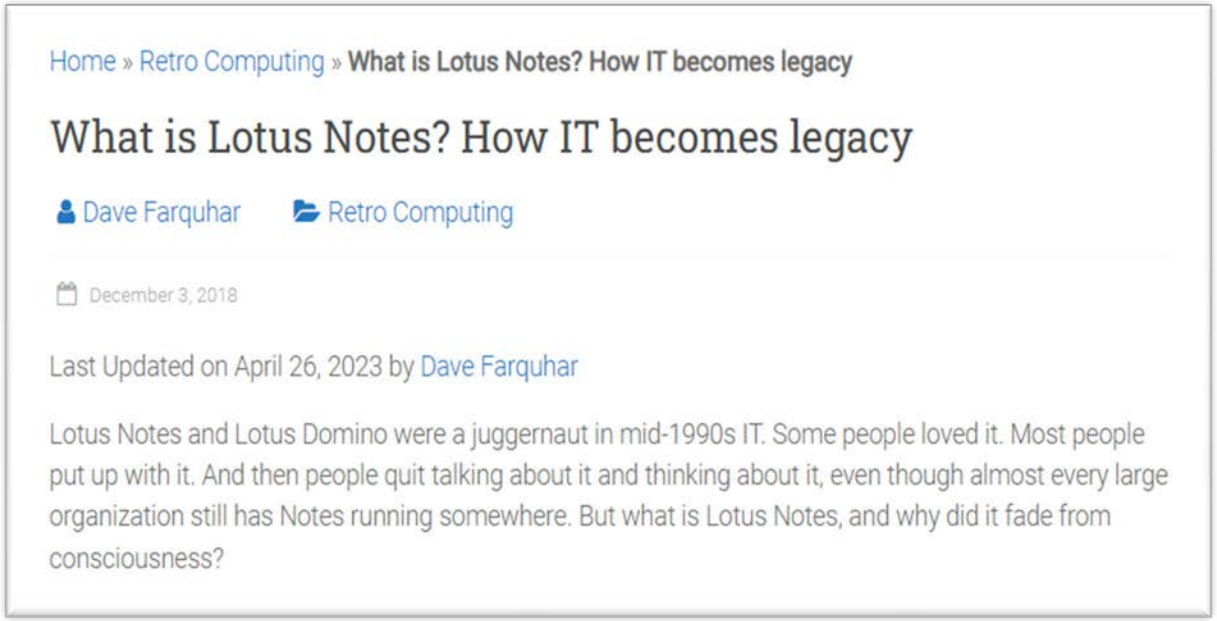
CASEY, Jack

MDPQD MQ Recalls SN

Background



URPTG Publication Date	Length
1991	20 Pages (Exc. Appendices)
2019, V.2.2	84 Pages (No Appendices)



Consultation and discovery activities

Consultation Hub

Find, read and respond to recent consultations from the Therapeutic Goods Administration (TGA) and also the Office of Drug Control (ODC).

Open consultations are below. Find earlier consultations using the search bar above. We publish submissions after a consultation closes and then add our decisions.

Discovery activities: key feedback

- Streamline recall processes
- Put key information up front
- Change recall action terminology
- Provide clarity:
  - timing of release of information
  - recall action risk assessments
- Provide new templates for submitting information
- QR Codes/eSurveys to improve response rates
- Sponsors review of Early Advice before distribution

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Therapeutic Goods Recall Processes

Discussion Paper January - March 2023

Seeking feedback on improvements to the recalls process

Version 1.0, January 2023

Discussion Paper themes

1. Increasing awareness and understanding about recalls
2. Improving communication
3. Better recall descriptions
4. Improving sponsor letters and other recall documents and
5. Reporting progress with a recall.

Consultation outcomes

Externally:

Website improvements

URPTG Updates

- Streamlined procedure
- Shorter length
- New Terminology

Communication approaches

- Stakeholder engagement
- Clear writing style
- Workshops

Internally:

- IT Improvements
- Legislation Review
- Quality Management – SOPs / WIs
- Continuous improvement

What we've delivered so far:

What we Removed:

- Bad Guidance
  - Repetitive
  - Outdated
  - Inconsistent
- Reporting
  - 3 → 2 reports
  - Flexibility re: timing of reports

What we Improved:

- Guidance - When and how:
  - To contact the Recalls Section
  - To report actions to the ACCC
  - We conduct Early Advice activities
  - We assess hazard classification
- Recalls Templates
- Jargon-free communication

URPTG Publication Date	Length
1991	37 Pages
2019, V.2.2	84 Pages
2024, V.2.4	57 Pages

Recall action templates

Templates to help you with your communications under the Uniform recall procedure for therapeutic goods (URPTG).

Last updated: 26 March 2024

The following templates are referenced in the Uniform recall procedure for therapeutic goods (URPTG).

Customer letter

- Sponsor's customer letter [Word, 38.06 KB]
- Alternate customer letter - tabulated format [Word, 19.1 KB]

Customer response form

- Customer response form [Word, 34.02 KB]

Customer/ distribution list

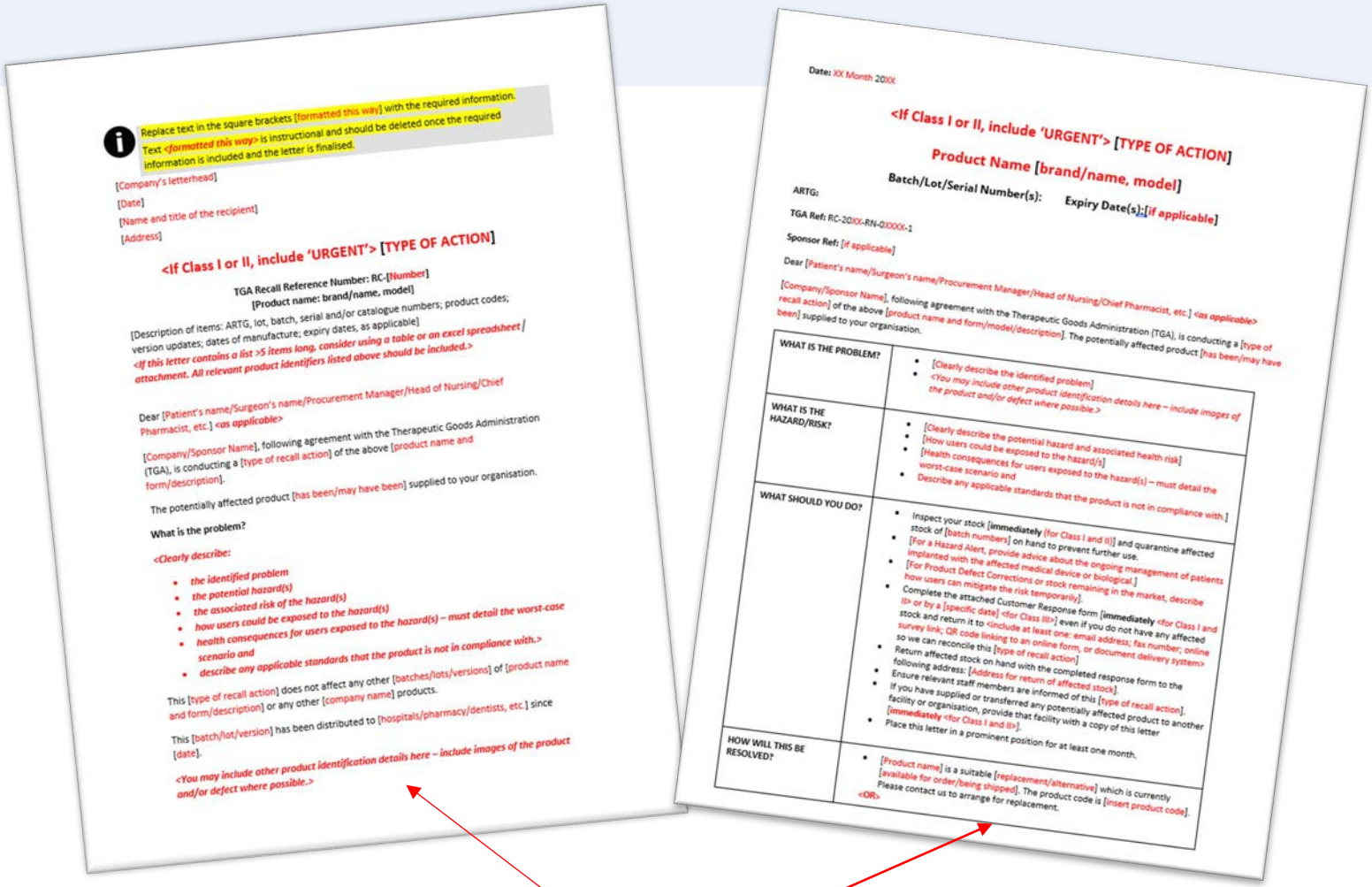
- Customer/distribution list - mock example [Excel, 26.24 KB]

Consumer level notice

- Consumer level notice [Word, 143.01 KB]

Reporting forms

- Interim and closeout report templates (6 and 12 weeks) [Word, 20.22 KB]
- Biologicals and Bloods Report Form [Word, 118.5 KB]



Replace text in the square brackets [formatted this way] with the required information.
Text <*formatted this way*> is instructional and should be deleted once the required information is included and the letter is finalised.

[Company's letterhead]
[Date]
[Name and title of the recipient]
[Address]

<If Class I or II, include 'URGENT'> [TYPE OF ACTION]

TGA Recall Reference Number: RC-[Number]
[Product name: brand/name, model]

[Description of items: ARTG, lot, batch, serial and/or catalogue numbers; product codes; version updates; dates of manufacture; expiry dates, as applicable]
<If this letter contains a list >5 items long, consider using a table or an excel spreadsheet / attachment. All relevant product identifiers listed above should be included.>

Dear [Patient's name/Surgeon's name/Procurement Manager/Head of Nursing/Chief Pharmacist, etc.] *<as applicable>*

[Company/Sponsor Name], following agreement with the Therapeutic Goods Administration (TGA), is conducting a [type of recall action] of the above [product name and form/description].

The potentially affected product [has been/may have been] supplied to your organisation.

What is the problem?

<Clearly describe:

- *the identified problem*
- *the potential hazard(s)*
- *the associated risk of the hazard(s)*
- *how users could be exposed to the hazard(s)*
- *health consequences for users exposed to the hazard(s) – must detail the worst-case scenario and*
- *describe any applicable standards that the product is not in compliance with.>*

This [type of recall action] does not affect any other [batches/lots/versions] of [product name and form/description] or any other [company name] products.

This [batch/lot/version] has been distributed to [hospitals/pharmacy/dentists, etc.] since [date].

<You may include other product identification details here – include images of the product and/or defect where possible.>

Date: XX Month 20XX

<If Class I or II, include 'URGENT'> [TYPE OF ACTION]

Product Name [brand/name, model]

ARTG: **Batch/Lot/Serial Number(s):** **Expiry Date(s):[if applicable]**

TGA Ref: RC-20XX-RN-0XXXX-1

Sponsor Ref: [if applicable]

Dear [Patient's name/Surgeon's name/Procurement Manager/Head of Nursing/Chief Pharmacist, etc.] *<as applicable>*

[Company/Sponsor Name], following agreement with the Therapeutic Goods Administration (TGA), is conducting a [type of recall action] of the above [product name and form/model/description]. The potentially affected product [has been/may have been] supplied to your organisation.

WHAT IS THE PROBLEM?	• [Clearly describe the identified problem] • *<You may include other product identification details here – include images of the product and/or defect where possible.>*
WHAT IS THE HAZARD/RISK?	• [Clearly describe the potential hazard and associated health risk] • [How users could be exposed to the hazard/s] • [Health consequences for users exposed to the hazard(s) – must detail the worst-case scenario and • Describe any applicable standards that the product is not in compliance with.]
WHAT SHOULD YOU DO?	• Inspect your stock [**immediately** (for Class I and II)] and quarantine affected stock of [batch numbers] on hand to prevent further use. • [For a Hazard Alert, provide advice about the ongoing management of patients implanted with the affected medical device or biological.] [For Product Defect Corrections or stock remaining in the market, describe how users can mitigate the risk temporarily]. • Complete the attached Customer Response form [**immediately** <for Class I and II> or by a [specific date] <for Class III>] even if you do not have any affected stock and return it to <include at least one: email address; fax number; online survey link; QR code linking to an online form, or document delivery system> so we can reconcile this [type of recall action] • Return affected stock on hand with the completed response form to the following address: [Address for return of affected stock]. • Ensure relevant staff members are informed of this [type of recall action]. • If you have supplied or transferred any potentially affected product to another facility or organisation, provide that facility with a copy of this letter [**immediately** <for Class I and II>]. • Place this letter in a prominent position for at least one month.
HOW WILL THIS BE RESOLVED?	• [Product name] is a suitable [replacement/alternative] which is currently [available for order/being shipped]. The product code is [insert product code]. Please contact us to arrange for replacement. <OR>

Topics: Medical devices safety | Medicines safety | Regulatory compliance | Safety | Therapeutic goods regulation

What’s coming next: New recall terminology

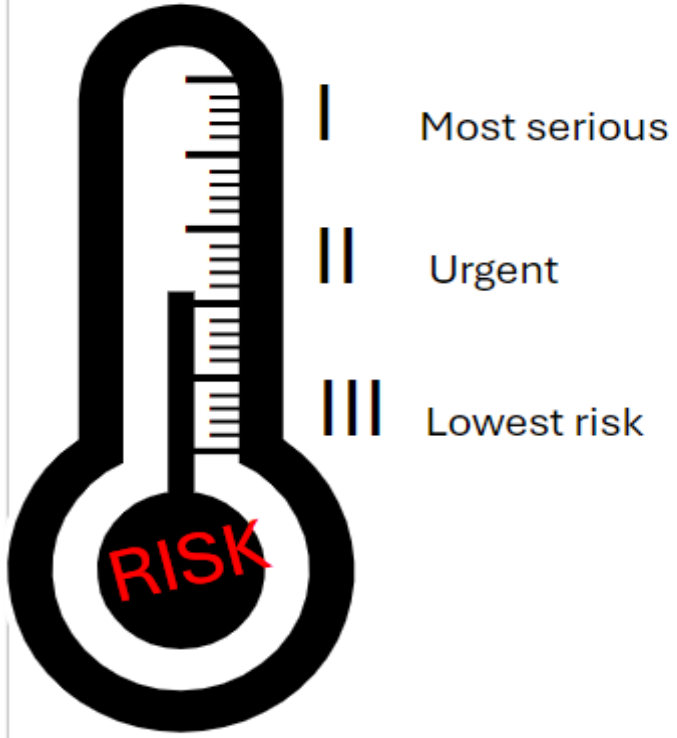
- ~~Recall Actions~~
  - Recall
  - Product Defect Correction
  - Hazard Alert
  - Product Defect Alert
- ~~Non-recall Actions~~
  - Safety Alert
  - Quarantine
  - ~~Product Notification~~
  - ~~Product Withdrawal~~

New ‘Market Actions’

- **Recall**
- **Product Correction**
- **Product Alert**
- **Quarantine**

Key Definitions for Market Actions

How serious is the problem?



I Most serious

II Urgent

III Lowest risk

"Class"

How is the problem being fixed?

- Recall ☑
- Product Correction ☐
- Product Alert ☐
- Quarantine ☐

"Action"

Who needs to know?

- Wholesale
- Hospital
- Retail
- Consumer

"Level"

IT updates

Supporting crucial updates to the recall processes

TBA Recalls Notification Form

- Sponsors submit problems to the TGA
- Attach supporting information
- Uploads into RAMP Database and generates recall reference #

RAMP Database

- TGA review and assessment
- Generates supporting recall documents
- Feeds into SARA

SARA (System for Australian Recall Actions)

- Displays some information from RAMP
- Publicly available summary recall information

IT upda

Supporting crucia
the recalls proce

TBS

- Informative help text
- Form time-out disabled
- ice Identifiers

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sers

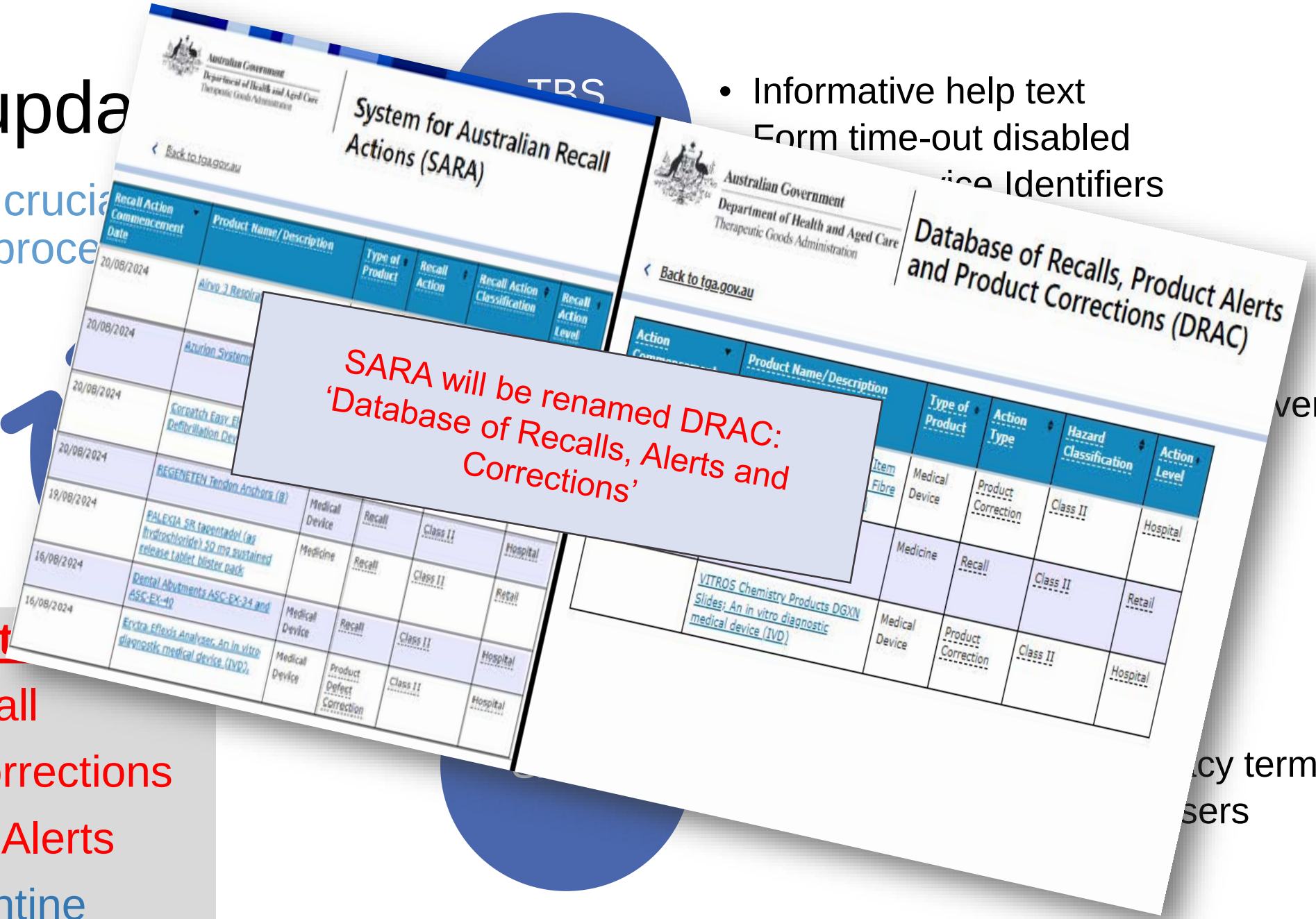
New 'Market

Recall

Product Corrections

Product Alerts

Quarantine



SARA will be renamed DRAC:
'Database of Recalls, Alerts and Corrections'

Legislation Review

Supporting recalls processes

- What powers do we have?
- Are they fit for purpose?
- What may need to change?

Legislation Review

Findings for mandated actions

Recalls and Product Alerts:
Public notification and recall of:

- Medicines – s30EA
- Biologicals – s32HA
- Medical Devices – s41KA

Product Corrections:
Imposing conditions on ARTG entries:

- Medicines – s28
- Biologicals – s32EE
- Medical Devices – s41FP

Quarantines:
Suspension of ARTG entries

- Medicines – s29D
- Biologicals – s32FA
- Medical Devices – s41GA

Legislation Review

Other findings

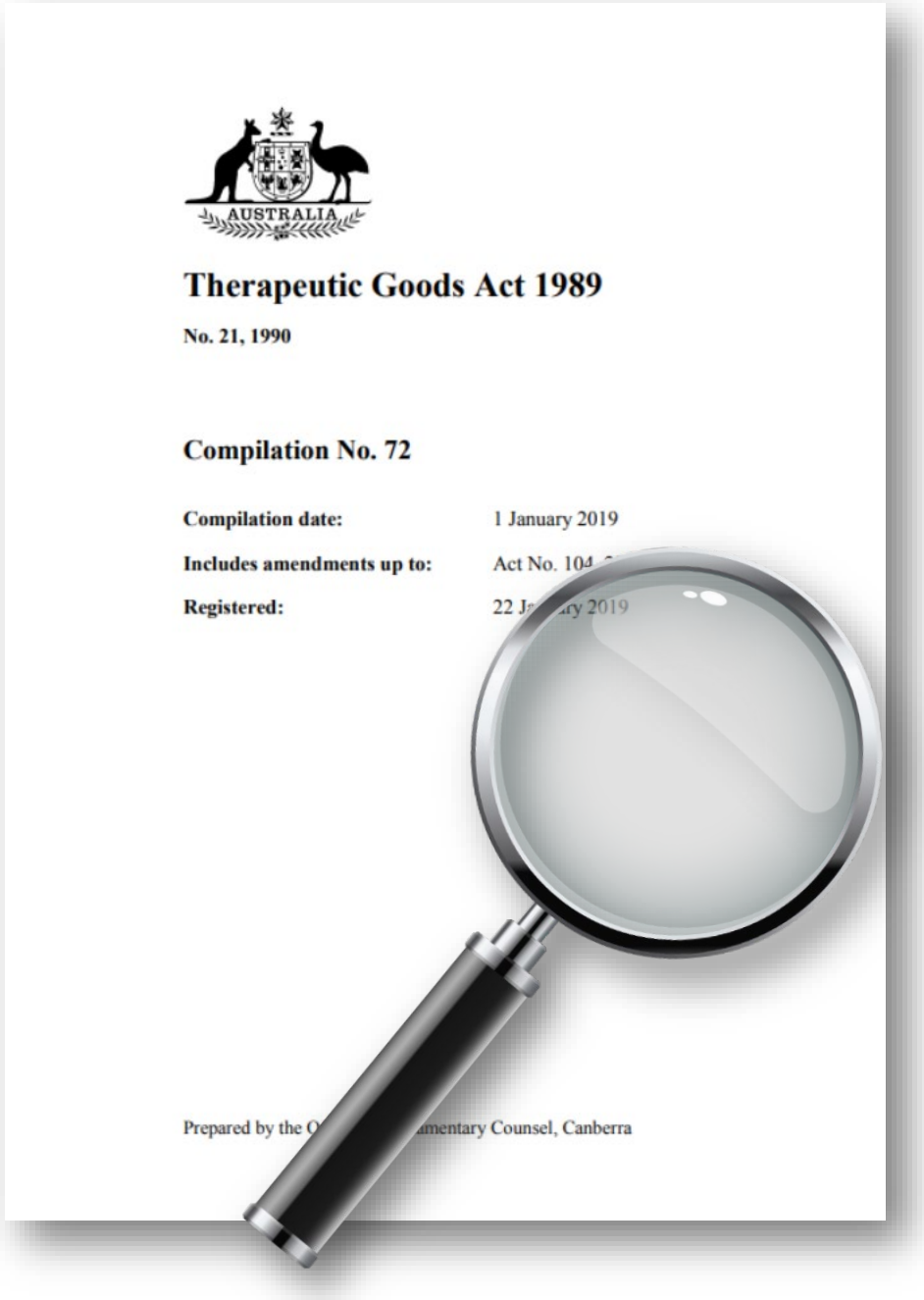
Requiring information or documents:

- Medicines – s31
- Biologicals – s32JA
- Medical Devices – s41JA

- Where there has been an actual or potential contravention of the Act or regulations – s45AB

Other recall circumstances:

- Where actual or potential tampering has occurred – s42V



Coming Up

New guidance document

- Terminology
- Information flow
- More templates and clarifications

IT updates ‘go live’

Web content

- Digital Service Standards
- Continuity of information

Possible legislative amendments?

Continuous Improvement

Questions?

Scan this QR code with your device to submit a question

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