Technical Alert

Updated - System for Australian Recall Actions (SARA) database

New - TGA Data matrix (Serialisation) "TGO 106" consultation

TGA Pharmacovigilance Risk Assessment Survey

SARA Database

The System for Australian Recall Actions (SARA) database's search facility has been successfully updated. The project was undertaken in response to requests from industry and other stakeholders to provide better access to TGA recall data.

Until now, search results were only available as PDF reports, but users are now able to download search results of summary recall data in editable, MS Excel format, in addition to the existing PDF reports.

The anticipated key benefits of this new functionality include:

- convenient access to current and historical recall action data which assists with the identification and removal of therapeutic goods from the supply chain, through the conduct of hospital-based or state / territory health department initiated stock and audit reconciliation processes;
- sponsors, as the prime users of the TGA's recall process and SARA, will be able to review historic recalls data relating to their own products, with a view to conducting an internal reconciliation to ensure all the actions for the products they sponsor have in-fact been actioned appropriately in terms of both, timeliness and completion of the required recall action;
- enhanced access, transparency and reduced regulatory burden through users acquiring 'self-serve' style, ready access to large volumes of recall action data; and
- further recognition of industry and stakeholder expectations that critical TGA data sets are readily accessible.

The new functionality is now live at https://www.tga.gov.au/recall-actions-database.

TGA Data matrix (Serialisation) "TGO 106" consultation

The TGA is seeking feedback on proposed requirements for serialisation and the use of data matrix codes on the labels of certain medicines in the Australian supply chain. The consultation, **closing 13 August 2020**, proposes a new Therapeutic Goods Order (106) as a Standard for Serialisation and Data Matrix Codes.

While the Standard will **not mandate** the serialisation of medicines nor the use of data matrix codes on medicines, it is proposed that compliance with the TGO 106 is expected for medicines when:

- a data matrix containing a Global Trade Item Number (GTIN) is used on the primary pack, or
- when a medicine is serialised, either at the primary pack or unit dose level.

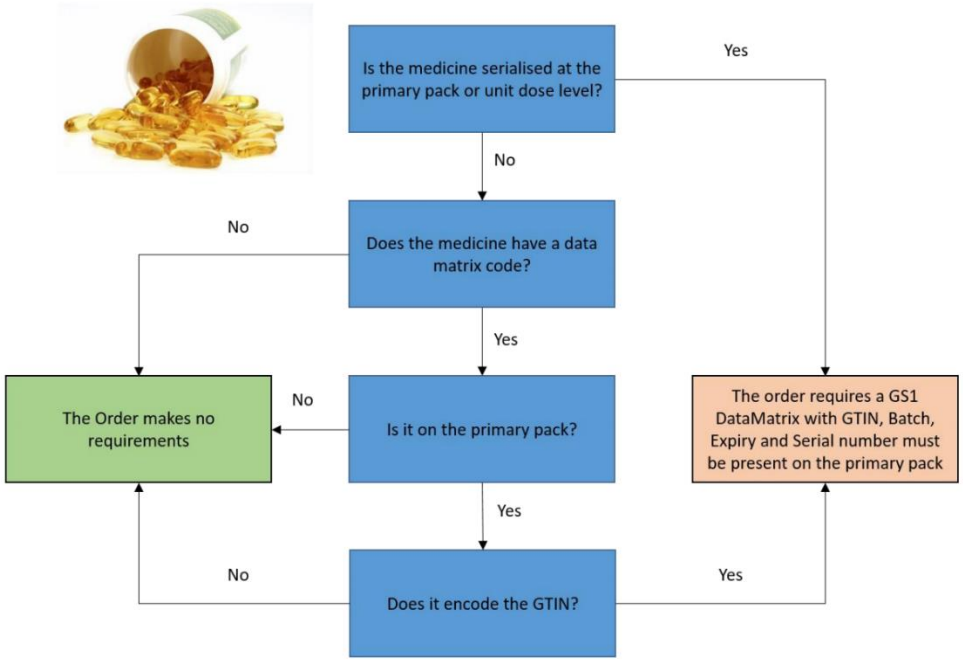

Figure 3 - When requirements of the Order apply

The draft TGO 106 sets out the requirements that are proposed to apply where the medicine sponsor chooses to do either of these, in which case the proposed standard stipulates:

- the information that must be encoded
- additional information that can be included
- how this information must be formatted.

The background document '*Better healthcare – a vision for the use of Data Matrix codes and medicines traceability*' has been included in the consultation package to assist understanding of how and why 2D codes are being adopted in global medicine supply chains.

Prohibition against advertising: The TGO 106 guidance notes that a data matrix and the information it encodes may not be used to advertise, nor link to advertising or otherwise be used for promotional purposes. This does not apply to other machine-readable codes which may be used for promotional purposes in accordance with the Act and The *Therapeutic Goods Advertising Code*.

Members who are already serialising medicines/using data matrix GTIN, or who are intending to, are encouraged to contact CMA with their feedback on the proposed consultations.

Resources

- TGA Consultation page on the new Therapeutic Goods Order 106 - Data matrix codes and serialisation of medicines
- TGO 106 - Data matrix codes and serialisation of medicines consultation paper
- Consultation document: Draft Therapeutic Goods (Medicines—Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2020
- TGA draft proposal: Guidance for TGO 106
- Background for industry: Better healthcare: a vision for use of data matrix codes and medicines traceability

TGA Pharmacovigilance Risk Assessment Survey

The TGA have announced the release of a Pharmacovigilance Risk Assessment Survey, now available for members to complete via the Pharmacovigilance Inspection Program page of the TGA website. The Survey will remain open until **30 September 2020.**

The Pharmacovigilance Risk Assessment Survey, published every two years, targets medicine sponsors and is used to inform the TGA about a sponsor's medicine portfolio, pharmacovigilance system, inspection history and compliance with Australian pharmacovigilance legislation and guidelines. The TGA use the information from these surveys to prioritise and schedule pharmacovigilance inspections

The TGA have advised that any sponsor who has at least one medicine included in the ARTG should complete the survey. **Medicine sponsors that do not complete the survey will be assigned the highest survey risk score.** The survey risk score will be combined with other risk information known to the TGA, to prioritise and schedule pharmacovigilance inspections.

Sponsors are encouraged to complete the survey prior to **30 September 2020**.

Resources

- TGA guidance for medicine sponsors
- TGA Pharmacovigilance responsibilities of medicine sponsors