



21 August 2020

Jenny Burnett
Director, Scientific Operations Management Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
2dbarcodes@tga.gov.au

Dear Ms Burnett,

RE: Consultation on the new Therapeutic Goods Order 106 - Data Matrix codes and serialisation of medicines

The Society of Hospital Pharmacists of Australia is the national professional organisation for more than 5,000 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is committed to facilitating the safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals. SHPA convenes an Electronic Medication Management specialty practice stream with over 900 members, of which many are responsible for leading and co-ordinating the implementation of digital health solutions in their hospitals and health services.

SHPA supports the development of Therapeutic Goods Order 106 (TGO 106) regarding Data Matrix codes and serialisation of medicines for the pharmaceutical industry sector, and recognises this is an important step towards establishing the appropriate parameters and specifications for serialisation and Data Matrix codes for medicine products.

SHPA understands the establishment of TGO 106 sets the specifications of Data Matrix codes and serialisation for the primary packaging (trade pack) of medicines, however, does not mandate its use. SHPA also understands that TGO 106 supplements the regulatory requirements regarding barcoding on secondary packaging and at the unit dose level as outlined in *Therapeutic Goods Order 91 - Standard for labels of prescription and related medicines* and *Therapeutic Goods Order 92 - Standard for labels of non-prescription medicines*.

SHPA recommends that TGO 106 should mandate the use of Data Matrix codes and serialisation of all medicines on the Australian Register of Therapeutic Goods (ARTG), to maximise the associated benefits to safety and quality of patient care and supply chain efficiency.

As discussed in the TGA's paper, *Better healthcare: a vision for use of Data Matrix codes and medicines traceability*, the use of Data Matrix codes and improved medicines traceability greatly supports the ongoing investments into electronic health systems by both federal and jurisdictional governments in all settings of care. The examples cited in the paper, such as improved inventory management, improved adverse event reporting and supporting closed loop medicines management, are all strongly supported by SHPA.

In 2019, SHPA released a position statement [Closing the loop of medication management in hospitals to improve patient safety with barcoding technology on unit dose packaging](#), which calls for the implementation of barcodes and barcode scanning technology at unit dose, primary packaging and secondary packaging levels for medications, to enable closed loop medication management.



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Beyond achieving quality and safety at the bedside with closed loop medicines management systems, information contained in a Data Matrix code will also be crucial in other medication safety activities. SHPA members support the use of Data Matrix codes and improved traceability as it will allow hospitals to:

- identify patients who have been administered or dispensed a recalled medicine;
- reduce wastage by assisting with inventory management to reduce incidence of expired medicines and wastage in hospitals, given medicines are stored in various areas of the hospital in theatres, emergency departments and ward-based pharmaceutical imprest; and
- assist health systems, hospital networks and hospitals to have oversight of and manage crucial stock shortages, determining where stock is available throughout Australia, a benefit leading to increased efficiency and cost-effectiveness.

Our experience of coordinating medicines stock, in particular critical care medicines, during the COVID-19 pandemic has reinforced our commitment to high quality and integrated digital medicine management systems. If you have any queries or would like to discuss our submission further, please do not hesitate to contact Johanna de Wever, General Manager, Advocacy and Leadership on jdewever@shpa.org.au.

Yours sincerely,



Kristin Michaels
Chief Executive

