AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

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TGA consultation on data matrix codes and serialisation of medicines

Response from the Australian Commission on Safety and Quality in Health Care

Contents

Summary

The Therapeutic Goods Administration (TGA) proposes a new Therapeutic Goods Order (TGO) 106 – *Medicines Standard for Serialisation and Data Matrix Codes*. The Australian Commission on Safety and Quality in Health Care (the Commission) strongly supports the TGA's proposal to standardise data matrix codes and serialisation. This is anticipated to improve availability of important medicine data and support consumer-centred care.

TGO 106, and accompanying guidance, provides sponsors with standard requirements for using a data matrix code on the primary pack or when a medicine is serialised at either primary pack or unit dose level.

Use of data matrix codes will enhance the interoperability of digital systems throughout the medicines supply chain (both locally and globally). They will support sponsors, consumers and health professionals to make safer and more informed decisions in a timely manner.

The targeted TGA medicine recall 'track and trace' program will be enabled by use of data matrix codes on medicine packaging in the event of a medicine safety issue. More broadly, access to additional medicine information, such as the batch number and expiry date will assist health services and health professionals. Automatically downloaded batch numbers and expiry dates within electronic medicines management (eMM), administration and dispensing software systems, will help prevent potential consumer harm from the dispensing or administration of an expired or recalled medicine.

Introduction

On 2 July 2020, the TGA published a public consultation paper, data matrix codes and serialisation of medicines (**Appendix A**).

The Commission notes the purpose of this initiative outlined within the TGA's *Better healthcare – A vision for use of data matrix codes and medicines traceability*. This document outlines Australia's need to participate in the growing global technology transformation and implement robust, standardised systems. These systems will facilitate international trade and interoperability, and include many 'track and trace' benefits:

- reduced medication errors by ensuring the correct medicine is dispensed to the patient
- automated recording and transfer of data in electronic systems, including adverse event reporting
- authentication of a product by tracking medicines through the supply chain
- increased ability to target specific medicines involved in a medication safety recall
- detailed visibility of stock quantities and locations, allowing better management of potential medicine shortages, including the conservation of medicines.

The Commission strongly supports the intent of the draft *TGO 106 Medicines Standard for Serialisation and Data Matrix Codes,* and accompanying Guidance.

The Commission also recommends the TGA consider:

a. including medicines exported from Australia in the Standard

b. including experimental products such as biologicals and vaccines in the standard or provides clarity on reasons for exemption

c. mandating sponsor and manufacturers apply TGO 106 when registering new medicines/entities or when applying for labelling and/or packaging changes to registered medicines

d. including additional information within the implementation guidance for TGO 106 on the patient safety and supply chain benefits of using data matrix codes and serialisation of medicines

e. ensuring existing machine-readable codes, such as linear barcodes are retained to support existing technology in the supply chain

Context

Around the world, scanning technologies have been introduced at various stages in the medication management process to:

- Reduce medication errors and associated harm
- Improve the quality safety and efficacy of health services.

In Australia, machine-readable codes (for example, linear barcodes and QR codes) are already in use. Most medicine labels allow the scanning of a medicine for identification and automatic upload into digital systems such as eMM, prescribing and dispensing software.

In 2017, the Commission published a report on Barcoding and other scanning technologies to improve medication safety in hospitals. This focussed on two types of scanning technologies and indicated a preference for two-dimensional (2D) barcodes, a type of data matrix code.

Scanning and other digital technologies already support closed-loop medication management systems[1,2] and assist hospitals seeking high stage certification by the Healthcare Information Management Systems Society (HIMSS).

Background

In healthcare, machine-readable codes may be used on medical devices, supplies, room locations, patients, staff, medicine containers (primary packs) and individual patient doses, or dose units[3]. Healthcare requires as much information as possible about the medicine or medical device to ensure enhanced accuracy and safety. For example, the batch number and expiry date of an individual medicine.

Machine-readable codes, such as linear barcodes, can only hold a limited amount of information. By comparison, data matrix codes have more features and can hold hundreds of times more information in a smaller space, for example, as a 2D code.

Data Matrix codes can be used in 'track and trace' systems and eMM systems as they:

- Provide safety across the supply chain
- Allow better data capture and record-keeping on medicines throughout the supply chain and medication management pathway
- Can facilitate more effective targeted medicine recalls to consumer level in the event of a medicine safety problem
- Ensure enhanced medicine security by blocking counterfeit medicines entering the supply chain.

Standardising data matrix codes will ensure consistent availability of important medicine data that supports safe and quality use of medicines. Standardisation will also support integration with global supply chains and when transacting business. International healthcare jurisdictions already recognise the importance of medicines serialisation for controlling and validating the medicine supply chain. Safety is enhanced by creating continuous, documented "ownership" of a medicine from the manufacturer to the consumer.

As technology and digital systems mature, consumers will also be able to verify information about their medicines. This will include whether they are taking the correct medicine and checking whether it is expired or the subject of a recall. In addition, they will be able to retrieve information about how to take the medicine and whether they are allergic to any of a medicine's ingredients.

Feedback

Support for the Draft standard on use of data matrix codes and serialisation of medicines

Feedback on **Appendix A (Consultation paper)** is provided with consideration of the questions posed by the TGA.

The Commission strongly supports the initiative to standardise data matrix codes and serialisation of medicines. It is anticipated this will ensure accessibility and readability of important medicine data and support safe and quality use of medicines.

Response to consultation questions

Question 1: Do you think the requirements set out in the draft standard are clear and easy to understand?

The Commission believes the draft standard is clear and supports the requirements for data matrix codes and serialisation of medicines on all levels of packaging in line with local and international requirements.

Question 2: Do you think the draft standard applies to the right medicines? Should there be other exemptions?

No other exemptions are identified. However, the Commission supports inclusion of medicines exported from Australia in the standard.

The Standard requires the data matrix code to be formatted 'in accordance with the GS1 General Specifications requirements for a Data Matrix. These specifications are derived to ensure 'a single, globally recognised format for the data encoded in the matrix'

Standardisation of data matrix codes and serialisation of medicines is an international objective. A 'combination of product number (GTIN) and serial number' creates a 'globally unique character chain for the unit' and improves international identification and traceability.

In 2019, collaborative work between the International Hospital Federation (IHF) and GS1 was published in a special journal issue on the topic of traceability and barcoding[5]. A survey of IHF members (including Australian members) was conducted to elicit the benefits of identifier technology and assess the implementation level by hospitals globally. The reported benefits derived from using identifiers, were:

- overall patient safety (for 90% of respondents),

- physical tracking (80%)
- optimisation of the supply chain (75%)
- provision of an integrated information system (75%).

Experimental products such as biologicals and vaccines should also be included in the standardisation with no clear reason for the exemption.

Question 3: Do you think the requirements in the draft standard are suitable?

The Commission believes the requirements are suitable. However, suggests building in scope for review and inclusion of additional requirements consistent with local and international medicine regulation development. This would allow for alignment with any technological advances in digital system integration, and future requirements for product tracking and tracing.

Question 4: For medicines that are already serialised, or utilise data matrix codes, do you think the delayed commencement period is adequate?

The Commission is not in a position to provide specific comment on the timeframe; however, encourages the implementation by sponsors and manufacturers so that the benefits may be realised. Supply chain safety and security will be an early advantage provided the relevant scanning technology is in place.

Question 5: Do you think anything is missing from the draft standard?

No

Question 6: Do you think the guidance is clear and easy to understand?

The Commission believes the guidance document is clear and will assist sponsors and manufacturers to implement the requirements within TGO 106. It also includes practical information that ensures shippers, pallets etc. also include the relevant machine-readable code on the outer of the 'logistic units.

Question 7: Is there anything you would like to be included in the guidance?

The Commission suggests including additional information on the benefits of implementation of TGO 106. Whilst compliance with TGO 106 is mandatory, if the medicine does not already have a data matrix code, there is no compulsion for a sponsor or manufacturer to pursue this initiative. The Commission supports the mandatory application of data matrix codes and serialisation of medicines, to encourage the uptake more broadly. Ideally this would be built in to the process for registration application of new medicines/entities or when sponsors apply for changes to the labelling and packaging of medicines already registered in Australia.

Including some of the relevant information on why the standard has been developed and benefits of data matrix codes from within the TGA's consultation document and/or reference to the TGA's *Better healthcare – A vision for use of data matrix codes and medicines traceability* would be useful as background information within the guidance document.

The content of the data matrix code is not limited, and this could be emphasised. Sponsors and manufacturers may include additional information at their discretion, for example the manufacturing date.

Further considerations

Implementation of the standard could lead to an unintended premature elimination of linear barcodes from medicine labelling and packaging. Whilst this initiative does not aim to

replace or remove the need for linear barcodes, sponsors and manufacturers could revise packaging to include the data matrix whilst deleting the linear barcode in a single process. The premature loss of the linear barcode would have a huge impact if replacement scanning technology is not in place. Many components of the supply chain are only capable of reading a linear barcode. For example, in the dispensing process; for loading automated storage cabinets; and within pharmacy robotics and medicine compounding. Guidance must address the implementation to avoid unintended consequences given the existing reliance on scanning technologies,

The Commission offers assistance to the TGA in disseminating information through its communication channels during implementation.

Discussion

The Commission is responsible for the development and support of the National Safety and Quality Health Service Standards including standards for medicines management and quality use of medicines in health services. The Commission through its safety initiatives in electronic medication management supports health professionals and health services to continuously improve medication management, including improved safety and security within the supply chain. Enhancing the information about medicines within a machine-readable code will support more timely response to medicine recalls and prevent medication related harm. The Commission's Principles for the safe selection and storage of medicines includes strategies that rely on machine-readable codes being available to assist clinicians with the safe selection of a medicine and as a key component of a closed-loop medication management system[4].

Documenting consumer's drug allergies in the medical record and medication charts are an essential medication safety initiative to prevent patient harm. Drug allergy information is critical when making therapeutic decisions, especially in sensitive individuals. Allergy to excipients is often under-recognised and results in incorrectly attributing an allergic reaction to the active ingredient. This may impact clinical decisions for the consumer over many years. Capturing information on excipients in the data matrix will assist information and recording of drug allergies.

The TGA's proposal has the potential to minimise unnecessary medication-related harm. The Commission supports the TGA's proposal as an important initiative to enhance medication safety. The Commission welcomes further opportunities to review any revisions to the TGA's consultation.

Appendices

A: Therapeutic Goods Administration. TGO106 – Data matrix codes and serialisation of medicines. Public consultation paper. Version 1.0, June 2020.

References

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3. ISMP Canada www.ismp-canada.org/barcoding/download/ResourceGuide/BarCodingResourceGuideFINAL_SectionI.pdf
4. Principles for the safe selection and storage of medicines – Guidance on the principles and survey tool. Sydney: ACSQHC; 2020. In press.
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