Complementary Medicines Australia *submission to the Consultation on the new Therapeutic Goods Order 106 - Data matrix codes and serialisation of medicines*

To:
Therapeutic Goods Administration
Scientific Evaluation Branch

From:
Complementary Medicines Australia
PO Box 450 Mawson
ACT 2606

Telephone: 02 6260 4022
Facsimile: 02 6260 4122
E-mail: technical@cmaustralia.org.au
Website: cmaustralia.org.au

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Complementary Medicines Australia

Complementary Medicines Australia (CMA) appreciates the opportunity to provide feedback on the Consultation on the new Therapeutic Goods Order 106 - Data matrix codes and serialisation of medicines.

CMA is the peak body of the complementary medicines sector, representing approximately 80% of the sector by sales of complementary medicines. Our members include manufacturers, raw material suppliers, distributors, consultants, retailers, and allied health professionals. The sector has evolved into a globally recognised and respected industry contributing to health and preventative health strategies to help Australians live healthier lives, supporting patient-centered care and reducing the burden on the healthcare system wherever possible.

CMA Response to the Consultation on the new Therapeutic Goods Order 106 - Data matrix codes and serialisation of medicines

The Therapeutic Goods Administration (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 proposed requirements are outlined in:

- a draft Therapeutic Goods (Medicines—Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2020, hereafter described as 'the standard'; and
- draft Guidance for TGO 106 (Medicines – Standard for Serialisation and Data matrix Codes).

There has been wide global adoption of serialisation and 2D data matrix codes for medicines, most notably pharmaceuticals, in the last decade. These systems provide a channel to navigate the complex network of production and supply for supply chain stakeholders, including manufacturers, distributors and healthcare providers.

For complementary medicines and low-risk medicines, the use of data matrix codes and the serialisation of medicines has the potential to address the increasing uncertainty around the authenticity and safety of products sold in Australia and globally. Existing systems in use are primarily used in order to reassure consumers of authenticity, particurly for products that are

exported and sold globally, as well as to provide feedback to companies as to when potential counterfeiting may be occurring.

Data matrix codes offer a range of benefits including data security, enhanced readability, large information storage capacity in a compact space and anti-counterfeiting applications. Similarly, serialisation allows medicines to be traced back to the original source of supply which provides security for sponsors and, importantly, safety for consumers.

It is proposed that the requirements in the standard must be followed when a data matrix containing a Global Trade Item Number (GTIN) is used on the primary pack of a medicine, or when a medicine is serialised, either at the primary pack or unit dose level.

The implementation of TGO 106 is not intended to mandate serialisation, nor the use of data matrix codes on medicines. Instead, it sets out the requirements that are proposed to apply where the medicine sponsor chooses to do either of these. Where the above conditions are met, the standard stipulates:

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

While the use of serialistaion and data matrix codes on the labels of certain medicines in the Australian supply chain appears to provide an overall benefit to industry, CMA seek clarification on some issues within the draft guidance and standard.

We also note that the use of serialisation is in relatively early implementation, in trial stages, or not yet introduced, across much of the listed medicine sector. As such, it is possible that there may be issues that we have not identified in this submission as many of our members are not yet very familiar with these processes. If there are particular issues that may be of a concern for listed medicines that the TGA become aware of through consultation and implementation, we welcome further contact from the TGA on specific matters or questions.

Question 1.

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

The requirements set out in the draft standard are sufficiently clear and easy to understand, with the exception of the response to question 5.

We note that in the application of legislative compliance documents for listed medicines, there are occasionally misunderstandings about the meaning or application of particular parts or terms by evaluators and/or industry. For this reason, we suggest that the following terms are included in the Interpretation:

- Product information (Section 11).
- Consumer medicine information (Section 11).

Question 2.

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

The general requirements of the draft standard apply if a) a medicine is serialised; or (b) has a data matrix code applied to the primary pack which contains a GTIN, but does not apply to

> *"…a medicine that is:*
>
> *(a) an export only medicine; or*
>
> *(b) mentioned in item 1 of Schedule 5 to the Regulations; or*
>
> Note: Item 1 of Schedule 5 to the Regulations applies to therapeutic goods that are imported for use in the treatment of the importer or the importer's immediate family in certain circumstances.
>
> *(c) the subject of an approval or authority under section 19 or section 19A of the Act; or (d) blood or a blood product funded under the national blood arrangements and which is required to implement global barcode standards in accordance with the Barcode Specifications."*

It should also be specified that the standard does not apply to other goods which are exempt from certain requirements of the Act, including extemporaneously compounded medicines by practitioners (which may be subject to their own serialisation approaches), and other medicines that are not required to be included on the ARTG, such a exempt homoeopathic preparations and other medicines.

This approach appears to be comparable to products excluded under the US Drug Supply Chain Security Act that are not subject to the product identifier requirements.

Question 3.

Do you think the requirements in the draft standard are suitable?

Section 11 of the draft standard require that the information in a data matrix code must be consistent with any any human-readable information in or on the packaging, including higher and lower levels of packaging and product information and consumer medicine information relating to the medicine; and (b) the information in any other machine-readable code present on the label of the goods.

Section 12 includes a prohibition against advertising.

We do not agree with the above limitations and prohibitions, as long as any additional information is compliant with therapeutic goods regulations, which is not dissimilar to the use of sponsor webpages as a source of additional information. Label space has always been limited on listed medicines. In recent years, label space on listed medicines has in some circumstances reached crisis levels, due to increasing disclosure and advisory requirements:

- Far more extensive mandatory labelling requirements under the TGO 92 labelling order reforms from 2016-2021, where the expression of ingredients, quantities, and other mandatory statements have increased greatly.
- Additional and lengthy mandatory warning/advisory statements pertaining to Permissible Indications required by the 26BH instrument (introduced 2018-2021), for particular Permissible Ingredients required by the 26BB instrument (ongoing additions occurring, for example menthol); in addition to other mandatory statements.
- Additional qualifications required by changes to the Advertising Code and Permissible Indications qualifiers.
- Additional expectations by the regulatory branch in respect of lengthy statements in respect of ‘acceptable presentation’.

Sponsors may wish to use the avenue to provide the consumer with information that the consumer may usually access on a product website or similar channel. Provided that any information is consistent with the ARTG entry and with advertising rules, this should be considered acceptable.

Companies currently employing QR codes in their marketing campaign may strategically set themselves apart from competitors, as this is still perceived as an innovative strategy. Including limitations that limit competitive advantages unnecessarily may limit the uptake of the technology for listed medicines, and consequently, may limit the progress of other advantages.

In addition, the requirement that 2D codes cannot replace 1D linear codes in Section 10 appears unnecessarily limiting. 1D linear codes take a great deal of label space. With the rapid advance of digital systems, currencies, and blockchain technologies, there may be listed medicine brands who may choose to operate in new and specialised channels whereby 1D linear codes are not required. For example, there have previously been listed medicine brands that have operated solely by mail catalogues and phone orders in the past, completely bypassing the retail avenues, and similar approaches that bypass traditional retail and payment channels are likely to become increasingly common through digital technology, cryptocurrencies, social media and e-commerce platforms. A visual example is included for example on blockchain discussion on the SEO Sydney webpage, How Will QR Codes & Their Relationship With Blockchain Transform SEO?[1] It is our understanding that it would be possible for all systems in a supply chain to solely use 2D rather than 1D codes.

Also see question 2.

Question 4.

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

Sponsors of medicines that are already serialised may require additional resources to achieve the mandatory elements[2], and any remaining limitations, that must be encoded in a data matrix code on the primary pack, which will mean changes to the way medicines are manufactured, introducing a new level of complexity for sponsors[3].

For sponsors to comply with this regulatory change, in addition to maintaining compliance across a number of other ongoing regulatory responsibilities, financial and regulatory burden for a number of

[1] https://seosydney.com/seo-optimisation/how-will-qr-codes-and-their-relationship-with-blockchain-transform-seo/
[2] TGA (220). Data matrix codes and serialisation of medicines: Consultation paper
[3] Pharmout (2020). Serialisation Requirements in the Pharmaceutical Industry

sponsors may result. These issues, which are further discussed in questions 8 and 9, suggest that the proposed delayed commencement period of 12 months could be insufficient, both for sponsors of a large number of medicines to which the standard may apply, and for SMEs that may have difficulty implementing changes due to time and resource constraints, particularly due to the impacts of COVID-19.

COVID-19 is causing manufacturing delays in Australia, transitioning to working from home arrangements, major freight time and cost issues, and unpredictable supply and demand issues of both raw materials and products. In this environment, sponsors and manufacturers are having to work to some extreme prioritisation goals, to reallocate resources, and to delay implementation of non-critical projects.

For listed and complementary medicines, serialisation primarily offers an optional benefit to sponsors. Providing a longer lead-in time for those who are currently trialling or using serialisation and who may need to make changes in respect of the standard will help ease the burden for these important but non-critical projects. CMA proposes for listed and complementary medicines, a 3 year phase in period for those products to which the standard would apply.

Question 5.

Do you think anything is missing from the draft standard?

Section 8(4) of the standard states that:

> 'A data matrix code must be formatted in accordance with the requirements applicable to a GS1 DataMatrix as described in the GS1 General Specifications.'; and

Section 10(b)(i) and (ii) state:

> '(b) the information contained within the data matrix code must be transcribed in human-readable format that is:
>
> (i) located adjacent to the data matrix code, in accordance with the GS1 General Specifications; and
>
> (ii) in a form that would enable a user to interpret the data without knowledge of the GS1 General Specifications.'

The GS1 General Specifications referred to above is a large (488 page) document and the draft guidance states that "No other method of serialising complies with the standard." CMA proposes that, to facilitate sponsor compliance, particularly those who are new to the process and want to implement data matrix codes on their products, it would be helpful for the applicable sections of the GS1 General Specifications to be identified in both the standard and the guidance to support the accurate application and implementation of data matrix codes.

Question 6.

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

Page 4-5 of the guidance outlines the terminology used in the document and states:

> "Primary Pack has the same meaning as in the Act. Note that a primary pack is distinct from primary packaging. Primary packaging, as used in GS1 and GMP guidance, is the packaging which directly contacts the medicine (injection vial, tablet blister etc). The Act refers to this as the *container*. The primary pack as defined in the Act is usually *secondary packaging* in GS1 and GMP guidance. Sometimes the primary pack is also primary packaging, such as a bottle of fish oil capsules with no further packaging."

This statement has the potential to cause confusion for new or inexperienced sponsors or employees as it refers to three separate definitions in three separate documents and omits the interpretation of 'primary pack' and 'container'. In the interest of clarity, the interpretation of 'primary pack' and 'container' as per the T*herapeutic Goods Act 1989* should be included in the guidance:

> ***"primary pack***, in relation to therapeutic goods, means the complete pack in which the goods, or the goods and their container, are to be supplied to consumers."
>
> **"*container***, in relation to therapeutic goods, means the vessel, bottle, tube, ampoule, syringe, vial, sachet, strip pack, blister pack, wrapper, cover or other similar article that immediately covers the goods, but does not include an article intended for ingestion."

Question 7.

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

In addition to the issue addressed in questions 5 and 6, the section of the guidance 'Medicines that are not subject to the Order' omits 6(b) of the draft standard:

"(b) mentioned in item 1 of Schedule 5 to the Regulations; or

Note: Item 1 of Schedule 5 to the Regulations applies to therapeutic goods that are imported for use in the treatment of the importer or the importer's immediate family in certain circumstances."

In addition to the above, the TGA 'Better healthcare: a vision for use of data matrix codes and medicines traceability' document states that "From implementation of systems overseas, it is evident that transitions to the new technology take at least five years" in regard to the transition to data matrix codes for medicines. CMA seeks to clarify if this transition period will be adopted by the TGA, and that the proposed transition will also apply to listed medicine sponsors who are amidst transitioning, as well as for those who choose to newly adopt serialistaion and the use of data matrix codes.

Further, CMA notes that the guidance does include a statement about the prohibition against advertising however, while data matrix codes are read by 2D imaging scanners or vision systems which are typically used in warehousing settings rather than for consumer applications, some mobile phones may also be adapted to be used as a data matrix scanner. In order to provide clarity we suggest that:

a) The statement in the guidance is amended to include more specific information (below in bold) for sponsors in regard to machine readable codes that *are* permitted for promotional purposes:

   "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, **such as QR codes**, which may be used for promotional purposes in accordance with the Act and The Therapeutic Goods Advertising Code."; and

b) An education module/program be developed for sponsors to clarify compliance expectations by making a clear distinction between the permitted uses of 2D data matrix and QR codes.

Question 8.

Data matrix codes that contain a GTIN must follow the standard. Implementation of the standard will mean that if you use data matrix codes with a GTIN on the primary pack of a medicine, you must follow the standard and include serialisation. Will this affect your business? Tell us how.

Despite the overall benefits of the serialisation of medicines, financial implications and changes to the production of medicines are inherent, implementation and ongoing running costs are associated with serialisation on the primary pack of medicines which use data matrix codes with a GTIN. Sponsors will be required to source, purchase, install and validate serialisation equipment, such as 2D capable printers and scanning cameras on each production line, in addition to installing and validating secure software system capable of securely uploading and downloading serialisation data from regulators who are managing the serialisation data[2].

To stimulate uptake of the technology for listed medicines, the benefits and incentives must be worth the additional cost and any requirements that may be considered to be unreasonable or time-consuming 'red tape'. This is particularly important in the ability to stimulate uptake in SMEs whose resources may be relatively limited.

Challenges for sponsors may also present beyond the implementation and transition periods. Initially, difficulties understanding the technology, the customisation of software, staff education and awareness of changes to protocols and procedures may create obstacles, and problems with post-deployment management/maintenance of systems will undoubtedly occur from time to time. In light of the current proposed TGA compliance enforcement model, there is concern that implementation difficulties may lead to inadvertent sponsor non-complinace and consequently, sponsors may incur 'deficiencies', penalties or infringements, for issues that are not related to product safety, quality or effiacacy. In line with question 7, CMA propose that the TGA, as the regulator, should provide an educational module/program for sponsors which outlines compliance measures and clarifies compliance expectations, and reduces requirements that introduce the possibility of unnecessary non-compliance (or unnecessary Section 14 applications) such as 1D linear barcode requirement, or the limitation on providing additional qualifying information that would normally be on sponsor websites.

Question 9.

Implementation of the standard will mean that if you serialise your medicines you must use a data matrix that conforms to the standard. Will this affect your business? Tell us how.

As per question 8, implementation and ongoing costs will be associated with the use of data matrix codes that conform to the standard for serialised medicines. Scanning equipment (hardware and software) and increased demands for staff to implement and update information linked to data matrix codes will necessitate additional resources.

In addition, the guidance states that machine-readable codes should be physically distanced from each other to minimise the risk of inadvertent reading of the wrong code. This will involve modifications to the design and printing of labels to accommodate data matrix codes, which will require additional space within production facilities, which is often limited.

Conclusion

CMA recognises the benefits of a digital environment in ensuring accuracy in the identification and upload of medicine data and the traceability of medicines as they travel through the supply chain. The added benefit of the ability to effectively track the authenticity, supply and recall of medicines increases patient safety and is advantageous for sponsors. However, to guarantee the effective implementation of data marrix codes and serialisation, and to ensure sponsor compliance, certain aspects of the guidance and standard require further consideration.

The final version should give consideration to flexibility of application to ensure there are incentives available and minimal red tape.