Response to the TGA Consultation: TGO 106 Data matrix codes and serialisation of medicines

Background:

The stakeholders to this submission are pleased to have the opportunity to provide a response to this consultation regarding the proposed Therapeutic Goods (Medicines – Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2020.

We welcome the approach that has been undertaken in consulting with the stakeholders throughout the process in developing this Therapeutic Goods Order. We see the resulting standard as a significant step towards supporting the alignment of Australia with many other countries regarding how medicines can be managed throughout their entire supply chains from manufacturing through to patients and consumers. This emphasis on harmonising of fundamental principles is especially well received.

We have endeavoured to provide responses to the specific questions raised within the consultation, reflecting both global and Australian based user communities. In addition, we have also provided some comments where GS1 has experience from working with other regulators, or asked some additional questions where these have been raised from our stakeholder community but they perhaps did not fit within the structure of the consultation questions. All feedback is of course provided in an effort to help support and guide your process and ensure that the resulting standard is effective in underpinning the future needs of the sector as a whole.

We look forward to providing continued support throughout the process to complete this review and to continue to work to support the development of the future traceability requirements for medicines in Australia.

Executive approval of this submission:

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About the respondents:

About GS1

GS1 is a neutral, not-for-profit organisation that develops and maintains the most widely used global standards for efficient business communication.

We are best known for the barcode, named by the BBC as one of "the 50 things that made the world economy". GS1 standards improve the efficiency, safety and visibility of supply chains across physical and digital channels in 25 sectors. Our scale and reach – local Member Organisations in over 114 countries, 1.5 million user companies and 6 billion transactions every day – help ensure that GS1 standards create a common language that supports systems and processes across the globe.

About GS1 Healthcare

GS1 Healthcare is a neutral and open community bringing together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards, enhancing patient safety, and operational and supply chain efficiencies.

The development and implementation of GS1 standards is led by the experts who use them: pharmaceutical and medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, solution providers, governmental and regulatory bodies, and trade associations. Evidence available from industry implementations shows that GS1 identification, data capture and data sharing standards in healthcare deliver tangible benefit to all stakeholders. Global members of GS1 Healthcare members include more than 130 leading healthcare organisations worldwide.

About GS1 Australia

GS1 Australia works in Healthcare to support adoption and implementation of interoperable GS1 standards within the Australian healthcare industry to enhance patient safety, and operational and supply chain efficiencies.

Our local community is guided by leading healthcare stakeholders and experts in our Healthcare User Community to ensure we effectively represent Australia in the development on our global standards and guidelines and that we also have a program that supports the implementation of our standards in accordance with local needs. Our diverse stakeholders in our local healthcare community include pharmaceutical and medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, solution providers, governmental and regulatory bodies, trade associations, clinicians, supply chain professionals and most importantly patients and consumers of healthcare.

Stakeholders

GS1 Australia has coordinated this submission on behalf of our broad healthcare user community. This response also takes into account feedback from some of Australia's large retailers as they also manage medicines in their supply chains and stores. This response has also had input and been approved by the broader global GS1 Healthcare community to ensure it is consistent with similar global requirements. The Stakeholders to this submission are very pleased to have the opportunity to respond to this consultation and remain keen to support the TGA throughout the decision-making process.

Responses to consultation questions:

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

Feedback from different parts of our stakeholder community have had differing responses to the standard. There is general appreciation of the fact that this has been created in consultation with the sector and is endeavouring to provide much needed guidance for those organisations who see 'serialisation' as a necessity for their supply chains and patient safety.

Whilst the manufacturing community have understood the detail contained in the standard due to their having previously implemented 'serialisation' and use of GS1 standards within Data Matrix barcodes, other groups such as those in distribution channels, the solution provider community, those within health provider organisations and those from within pharmacies were perhaps less clear. These groups have reported that they were unsure how this would impact them or what action they might need to take once the standard was in place. We have encouraged them to read through the Vision document to help with understanding this further as many had not read this positioning document.

One specific area that has been raised by many stakeholders from the manufacturing community especially is confusion regarding the use of the term 'Primary Pack'. It is acknowledged that the phrase used by the TGA reflects the terminology as used within Australian therapeutic goods regulation and it is defined with the TGA Acronyms and Glossary (*link contained within Note 1*) however for manufacturing organisations this is easily confused with 'Primary Packaging' which is defined by WHO and others as the packaging that has direct contact with the product. As this is different to other regulations of this type internationally there is concern about ongoing confusion this will cause.

The manufacturing community and others have also raised several questions related to the implementation beyond the standard coming into effect as proposed. Some of these we acknowledge fall outside of the remit of the TGA, however we have provided in response to this consultation as inputs into any future work to build towards the Vision for use of data matrix codes and medicines traceability. We have endeavoured to capture these in the Additional feedback section at the end of this document.

(Please refer additional feedback: Note 1)

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

Feedback received from stakeholders has been supportive of the broad application of this standard and its limitations to exemptions. As the standard contains no specific mandates regarding compliance for products this allows it to be applied across all products types where it will be both relevant and beneficial to the Australian Health system and patients.

We did receive some questions from stakeholders regarding how this standard would interrelate to TGO91 and TGO92 as there are differences in some exemptions within these documents. We suggest that this clarification may be possible within the guidance document for TGO106 and that post commencement of this new standard perhaps the guidelines for those Therapeutic Goods Orders may be updated with appropriate cross references.

(Please refer additional feedback: Note 2)

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

Our stakeholders have agreed with the principles of the draft standard and the requirements contained within it.

Though the proposed commencement date is clear, as mentioned in our notes related to question 1 we have been asked to request some further clarification of any dates related to compliance to the standard and whether we will also see a transition period to all medicines complying to this standard in future. This question has been raised across our stakeholder community as each group needs to plan for investment in technology, process changes and so forth and this is challenging across all groups without some specifics as they must balance investment based on necessary prioritisation.

We acknowledge that any requirements related to such dates and transitions may be provided in separate orders in future, however, have provided further details in notes to support the need for this clarity.

(Please refer additional feedback: Note 3)

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

Based on our review of products within the marketplace and data collected from our stakeholders, where products are already in the Australian market and are serialised they are already utilising GTIN and Data Matrix in line with the GS1 General Specifications so would already comply to this standard. We have also discovered that little data related to this serialisation is currently being shared throughout the chain which probably leaves the available serialisation adding little value. Interestingly however the availability of the expiry date and batch information is being used in some cases to help manage the product especially within pharmacies.

Feedback so far has not included any concerns regarding the commencement date as there is no mandate to change by this date, it simply impacts products from this point on where serialisation of the product will be preferred to be applied.

As per previous responses, there are still some clarifications requested regarding any subsequent dates from specific product compliance, but we acknowledge this may be provided in separate orders.

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

Stakeholders have asked questions related to clarifications of some areas within the draft standard. As many have already been highlighted in previous responses to earlier questions, rather that repeating this feedback in detail we would simply highlight the requests for further clarification of aggregation requirements and logistics units being needed and refer you to previous notes and responses.

In addition to these some questions have been asked by our hospital pharmacists stakeholders regarding 'unit dose' identification which is needed to support effective closed loop medication management. Unit doses are mentioned within the guidance but are not referenced in the standard and this may also be confusing for implementers and users alike.

One final point we have been asked to raise is that as it is common practice for medicines to be produced for sale across both the Australian and New Zealand markets. For the manufacturing stakeholder group this is a consideration in the process not only in implementing this standard itself but also any subsequent requirements related to the management of product that may be serialised. Though multimarket packs are not the case for all medicines, for many lower volume products the ability to manage consistently across both markets can be critical to ensuring cost effective production and therefore product availability for patients in both countries. It will also be critical as the standard is implemented within the future Vision to ensure we are able to maintain the security within the supply chains taking into account the multimarket aspect so this is not viewed as leakage or diversion from the Australian market.

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

Feedback related to the guidance has been largely positive from all of our stakeholder community, especially where they have read all of the corresponding documents including the Vision and have a good understanding of other relevant Therapeutic Goods Orders that are referenced or related (for example: The Therapeutic Goods Advertising Code or TGO91 Standard for labels of prescription and related medicines).

The guidance is clear, well-structured and assists in clarifying some of the points that are not covered in detail within the standard itself.

Some feedback related to areas of improvement have been provided once again in Additional notes

(Please refer additional feedback: Note 4)

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

As with all new standards and therapeutic goods orders, our stakeholders appreciate that the guidance will improve and be updated over time as the use of the standard increases and further orders may be put in place where it becomes a foundation.

As many of our global stakeholder community have had a lot of experience in implementing this kind of standard in other countries we have consolidated some of the additional points that they feel could be included in the document in order to assist with effective implementation and maximum benefit for the health system and patients it supports.

(Please refer additional feedback: Note 5)

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

Our stakeholder community who would be responsible for the identification of medicines to be sold in the Australian market are in many cases already following this process for other parts of their businesses as it has been required within other trade lanes in order to meet other regulatory or trading partner requirements.

Though the introduction of this requirement in Australia would still have impact to their businesses, requiring changes to production for the Australian market, may have indicated that this will be a manageable change if it is able to be implemented with a reasonable time frame to transition. The bigger impact to our manufacturer stakeholders' would be if the requirements in Australia differ greatly from those of other countries or if there are sudden time frames for implementation of the coding.

As previously mentioned the concern of many of this stakeholder group is in the additional requirements that are undefined in the standard and guidance related to data sharing and any aggregation requirements. To minimise impact to the sector and to ensure costs are manageable such requirements need to be clear and the timelines must be realistic to ensure that not only compliance but also accuracy can be assured. This is especially so for any smaller companies who may not have had large exposure to this from global markets.

Downstream from the manufacturer will also be impacted by this change with the need to invest in technology to manage products using the new codes. There are great advantages to all these stakeholders in areas such as more effective inventory management, improved visibility of product that may have been impacted by recalls, reduction of possibility of diversion, substitution or falsified product however this only becomes realised if the majority of medicines have these codes and underlying traceability systems have been established, so with no timeframes for industry to change such investment may be unlikely for many.

All stakeholders will have some challenges related to the solutions they use to manage their products. In many instances significant investment will be needed in order to be able to meet the requirements that come with a comprehensive 'traceability' system but as this remains undefined proactive investment will be limited. Further clarity by working with the sector to define this system would be welcomed by all our stakeholder groups.

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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

The feedback from our Manufacturing stakeholders are that they understand the requirements and as many have implemented for other markets the impacts will be in planning transition of products to minimise costs and impacts to packaging lines.

Downstream stakeholders in distribution channels, pharmacies, health providers, solution providers and consumers require further clarity on what impact this will have to them at this stage as it is undefined by this order.

Additional Feedback:

Note 1 **Questions/Comments related to draft standard (Consultation question 1)**

a. The standard references *Labelling of Logistics units* (Part 2, Point 9) which is an important part of managing accurate and secure supply chains and distribution, however it does not specifically state how this is to be done. Clarification of this would be important for effective implementation.
b. There is no reference within the standard regarding aggregation of product. It is shown from experience in other countries that this is a complicated process that needs to be well defined in order to make serialisation and any subsequent 'Track & Trace/Traceability' solution successful in implementation phases
c. Though the detail related to how to identify and support data capture through machine readable codes is well received, there are questions related to how the data related the serialised product is expected to be shared, where it will need to be collected and so on. Though the Vision document documents some use cases which is seen positively, the data flows need to be well defined as part of effective implementation.
d. The reference to the supply chain in the draft standard was one term that caused some stakeholders to not understand that the standard had application to their processes in the future. It has been suggested that explaining that the supply chain extends from manufacturing processes through to the patient and consumer would be of benefit as all touch points through this chain are part of the 'supply chain' and would need to understand the improvements and potential impact that this standard might have in the future.
e. Many stakeholders have expressed concern that in fact taking no action towards serialising their products is an option under the new standard. Though this leaves manufacturers to change proactively if they wish or further dates may be specified elsewhere across the stakeholder groups some have expressed uncertainty as a result of this lack of deadline as they are unsure when to invest in technology upgrades to manage the changes to how products will be identified.
f. What impact, if any, will there be on packs already in market before the date TGO106 comes into effect where they may have been serialised in some other way. Obviously, it is not possible for this to be retrospectively applied on products already in circulation without great impacts however ensuring this is clear in the standard and the guidance will be helpful to implementation once again to help manage expectations across the diverse stakeholder map.
g. There are a small number of stakeholders who are already using GTIN to identify their products and GS1 DataMatrix (Data Matrix barcode that encodes data according to GS1 standards). As they currently do not serialise their products, instead only using GTIN, batch number and expiry date, they are concerned that they will not be in a position to serialise products by the date that the new standard comes into effect, therefore they would be forced to take a step backwards to only have the linear barcode with GTIN only. This is perhaps something that could be clarified within the Guidance documentation if not within the standard, but certainly to return to only having the GTIN in the linear code would be a negative for Australian healthcare.
h. Primary Pack – defined in TGA Acronyms & Glossary https://www.tga.gov.au/acronyms-glossary#summary-p

Note 2

Questions/Comments related to exemptions within the standard (consultation question 2)

a. The use of this standard specifically exempts the use of this identification for products approved under section 19 or 19A including those medicines for clinical trials. As these same standards are well documented for the specific use within clinical trials environments we have been asked to request clarification that this exemption does not preclude this from occurring, it is simply that it will not be required to comply with this standard. This standard can be accessed via the link below for reference https://www.gs1.org/docs/barcodes/GS1_ClinicalTrial_Application_Standard.pdf

Note 3

Questions/Comments related to requirements suitability within the standard
(Consultation question 3)

a. Further to the reference regarding time frames, some further background to why this request is being made includes:
   i. Manufacturers managing packaging line changes
   ii. Manufacturers managing distribution channel capability changes/uplift
   iii. 3PL/4PL/Wholesaler and other similar distribution partners making adjustments to systems capability
   iv. Investment needed across many stakeholder groups in 2D scanning capability (which currently sits at a low % across the sector in Australian pharmacies)
   v. Solution providers making required changes to software solutions and implementing across their user bases
   vi. Pharmacies (& retailers) making adjustments to processes used to manage pharmaceutical products
   vii. Health providers and health departments ensuring capability upgrades are rolled out across their complex networks of systems and processes.
   viii. Healthcare procurement agencies ensuring selection of appropriate hardware, software and other systems or services used to manage medicines across their organisations
   ix. Adjustments to processes and procedures used within all stakeholders and the subsequent effective management of these changes
   x. Consumer applications adding new functionality for users to help them manage their medicines

Note 4

Comments related to clarity and ease of understanding of the guidance (Consultation question 6)

a. Feedback related to 'Page 11 Example – Label with multiple codes' has been that this diagram showing the positioning of three machine readable codes close together requires some improvement.
    i. The inclusion of 'scan here' under the QR which is intended to prompt consumers to link to product information may be confusing for clinicians who would be scanning one of the other two codes often under time pressure.
    ii. The proximity of multiple codes may cause confusion for automated scanning equipment. GS1 standards recommend adjacent placement of barcodes that can be used for the same application. In the case of the QR codes on products as these are not used for supply chain (ie only used to access product information or websites) it would be recommended to have this placed further away from the Linear and Data Matrix both of which could be used for supply chain purposes.
b. The standard and the guidance state that the Linear code must not be replaced, however as this has in fact been the case in many countries globally with the implementation of uniform use of Data Matrix, we would recommend some consideration be given to this wording to allow for this eventuality and minimise the need for large amendments to the standard.
c. As some references to machine readable codes are also made in other guidance documents (specifically the one related to TGO91) we would suggest that wherever possible there is consistency in the guidance documents as many stakeholders will be working across both documents. Allowance for QR codes continues however these have previously been specified as not for product identification purposes for example.
d. As already mentioned, as the TGA definition of 'Primary Pack' and the more commonly used term 'Primary Packaging' differ, our suggestion is that perhaps further expansion on this textually and the inclusion of a diagram to illustrate what is meant to ensure limited confusion given the closeness of terms and different meanings.
e. Feedback related to 'Page 9 Serial Numbers' is that this section contains contradictions, first suggesting that a minimum of four alphanumeric characters are required then recommending the serial numbers contain only numeric digits. In addition, as the GS1 standards allow for alphanumeric up to 20 digits and recommendations for these as safety features are generally to ensure the inclusion of alpha characters and that the serial number is created randomly.
f. Feedback regarding 'Page 8 Application of the data matrix code' as this includes reference to the need to ensure that serial numbers are not re-used for a particular GTIN. As a reinforcement of the GS1 General Specifications which state that GTIN must NOT be re-used we would suggest that this section also reinforces this point if possible. This is especially important with increased linkages from the GTIN to the Australian Medicines Terminology to match clinical concepts used in prescribing to the physical products being prescribed as it can impact safety of patients and accuracy of patient records.

Note 5

Comments related to inclusions in the guidance (Consultation question 7)

a. As the stakeholders who may need to refer to this guidance may be broad, we would suggest some more general introduction to the guidance is included to introduce who the audience of the guidance are and perhaps to help to contextualise the standard with simplified references to the use cases that have been identified in the 'Vision' document. The clarification of the 'supply chain' within this introduction will also improve engagement and understanding of the application of the standard for many stakeholder groups.
b. Though shown on the images where the linear code and the Data matrix are present, the reference to the need for the GTIN within the Linear Code and the 2D code to be the same requires reinforcement due to the issues which have been experienced in the past. As this issue had been addressed previously as part of implementation of TGO91 and the guidance for this order was updated to include clarification of this point, we also suggest similar guidance is provided in this document in addition to the section on Page 10. (Section 1.5.10 Medicine labels – Guidance on TGO 91 and TGO 92 V2.1 July2019)
c. As referenced in feedback in Note 1, we would once again reinforce the benefit of greater detail within the section related to Logistics Units and how to manage aggregations of serialised Primary Packs (in broader terms secondary packaging or trade product packs).

Instead of repeating comments included in our response to question 6 (contained in Additional Note 4), we would like to suggest that these also be reviewed in light of consultation question 7 where they relate to inclusions.