Tell us what you think about the standard (7 questions)

a. Were there any areas of the standard that were not clear or need further explanation

The standard document is simple, clear, and understandable.

b. Do you think the standard applied to the right medicines?

ACT Health agrees with the inclusions and exclusions stated in Part 1 Item 6 of the standard.

ACT Health would like to see stronger requirements for medicines with high potential for misuse, abuse, and diversion to ensure products are serialised into a Data Matrix as per TGO 106 in future changes.

c. Do you think the requirements are suitable?

ACT Health believe the requirements are suitable. The following feedback is provided in the context of extending the standard in future phases:

While ACT Health understand the challenges associated with modernisation of scanning hardware across the industry to shift from linear (1D) to Data Matrix (2D), the draft standard could do more to drive the uptake and use of Data Matrix in products:

- for consumers currently ready to scan (for example – to check on the provenance of their medicine or to check if their product has been recalled); and
- to remove the barrier for future adoption.

In its current form, the standard allows any medicinal product that uses only a linear GS1 barcode to be exempt from the standard.

Driving more products to adopt the GS1 standards and implement the Data Matrix will result in greater benefit realisation. With its current definition, TGO 106 will push medicinal product providers that are either using non-standard serialisation or those already on-board with GS1 identifiers to extend their compliance, while not actually mandating anything for providers that are falling behind in serialisation and have not started to adopt the standards.

The following table is provided to highlight the areas where TGO 106 will be effective and can be improved:

Medicinal product current state	Example	TGO 106 Status	Required action	Compliance Effort	End to end supply chain benefit realisation
Product already contains SGTIN, Batch, Expiry details in GS1 Data Matrix	Large multinational manufacturer medicinal product	Already compliant	None – already compliant	NA	High
Product contains GTIN in Data Matrix however no serialisation or other data.		Applies, must move to serialisation of products and add extra content into the Data Matrix	Adopt serialisation within manufacture/packaging processes	High	High

Product contains GTIN in linear GS1 barcode however no Data Matrix currently used.	Small-medium manufacturer medicinal product	Does not apply	None (Suggest should be included in next stage)	NA *Would be High if added to the standard*	Medium *Would be High if added to the standard*
Product is serialised however identification and serialisation does not comply with GS1 standard	Product from a vendor located in a country where GS1 standards have not been adopted	Applies, must move to adopt GS1 Data Matrix	Adopt GS1 standards and apply to new Data Matrix on labels	High	High
Product is not serialised, and identification does not comply to GS1 standard	Hospital manufactured one off medicinal product(s).	Does not apply	None – does not apply	NA	Low

ACT Health are seeking to implement procurement standards that mandate purchasing of only products that comply with the GS1 standards for product identification and National Product Catalogue (NPC) information maintenance. This move will create operational efficiencies and ultimately improved patient outcomes. To date this approach has been hindered due to gaps in the product inventory range required to deliver service. ACT Health is hopeful TGO 106 will be a significant step toward this target state.

ACT Health recommends that TGO 106 be modified within the next 2-3 years to mandate the use of Data Matrix and GS1 coding.

The Standard is silent on standards for unit dose data matrix coding and serialisation. ACT would recommend drafting some detail for unit dose Data Matrix and GS1 coding similar to the recommendations outlined in the Society of Hospital Pharmacists Association (SHPA) position statement *"Closing the loop of medication management in hospitals to improve patient safety with barcoding technology on unit dose packaging"*.

d. The standard will take effect 12 months after registration as a legislative instrument, do you think the delayed commencement period is adequate?

ACT Health already use optical barcode scanners and are equipped and ready to scan the GS1 Data Matrix containing the Global Trade Item Number (GTIN), Serial number, batch/lot number and expiry date details.

Medicinal products produced by CHS at present are not serialised and as such are not mandated under the standard. However, to realise closed loop medication management ACT will explore options for GS1 labelling of internally produced medications ahead any future TGA extension of the standard.

Given the standard has retained the linear GS1-128 barcodes that contain only the GTIN to support older (near end of life) scanners, ACT Health believe the 12 months commencement of the standard is sufficient.

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

Part 2 – Requirements:
7 General requirements: could be strengthened to include products using only GTIN in a linear barcode at present.
8 Application of data matrix code part (5): The statement provides the justification for Data Matrix being applied to the label of each unit of product as being to minimise the risk of inadvertent reading of any other machine-readable code on the label. This justification is a little confused and suggest shorting the statement to the requirement without the justification OR change the justification to "as to enable production unit scanning at the point of consumption or other appropriate points in the supply chain."
9 Labelling of logistic units: This item branches into broader use of GTIN and potential use of SSCC standards form GS1. Suggest making a reference to the GS1 general specification under this point.

f. If your medicine already has a data matrix code that includes a GTIN on its primary pack, it will now need serialisation. How will this affect you?

For medicinal products produced by ACT Health/Canberra Health Services, these products are not currently serialised. However, ACT Health vision for closed loop medication management will require internally produced medicinal products to be appropriately serialised which will then result in TGO 106 being applicable. ACT Health already aligns all internally produced identifications with the GS1 standards.

g. If you serialise your medicines you must use a data matrix that confirms to the standard. How will this affect you?

From a product consumption perspective, ACT Health existing and emerging information systems take full advantage GS1 standard keys and data elements included in the Data Matrix. The standard will be a significant enabler to achieving closed loop medication management in addition to improving product advisory and recall processes.

From a product production perspective, ACT Health are looking to serialise products to enable closed loop medication management.

Tell us what you think about the guidance (2 questions)

a. Were there any areas of the guidance that were not clear or need further explanation?

ACT Health believe the guidance when read from end to end is clear. The definition of terms is very helpful and critical given the difference in definition of the *primary pack* between the TGA and GS1. The barcode examples may be a source of confusion for anyone that does not read the document sequentially.

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

ACT Health believe the guidance is suitable. The following feedback is provided in the context of extending the standard in future phases:

Page 5 Figure 3: This figure allows any non-serialised medicinal product to bypass the Order if they do not currently have a Data Matrix code, or if there is a Data Matrix; that code does not

contain the GTIN. With an objective of ensuring all medicinal products contain at least a GS1 GTIN, and SGTIN where the product is serialised, this flow is flawed. The following simplified alternative removes references to existing data matrix barcodes to remove the misleading pathway to the order making no requirements: