



# Guidance for ensuring accuracy where GS1 DataMatrix are added to Pharmaceutical packs already containing EAN/UPC Barcodes

## Executive summary:

In order to ensure accuracy and traceability of products across complex supply chains, GS1 standards state that where there are multiple barcodes on a pack, they must contain the same Global Trade Item Number (GTIN).

## Background:

An increasing number of countries have adopted the GTIN contained within a 2D GS1 DataMatrix barcode to help support the traceability requirements for pharmaceutical products – both prescription medicines and over the counter (OTC) therapies. This is a globally interoperable approach, ensuring harmonisation of a product's unique identifier across international borders and helping to facilitate the sharing of joint packages in multiple countries, which is common practice today.

Many countries, like Australia, had already chosen to adopt the GTIN to identify these same products, historically requiring only a linear EAN/UPC barcode to facilitate the data capture at point of sale or point of dispense. Scanning technology investment and solutions therefore focussed on supporting the GTIN (formerly EAN or UPC) within those traditional barcodes.

As markets and industry are maturing in understanding the need for more data to manage products, we are seeing far greater availability of 2D barcode capable scanners within retail and hospitals where prescription medicines or OTC products are managed. The software solutions interpreting the data are also becoming better able to parse data from the 2D barcodes and support improvements to inventory management, and event-based product traceability at batch and individual pack levels.

## The need for multiple barcodes in Australia for Prescription & OTC medicines:

Whilst many countries have already made the transition from linear scanning to 2D scanning, Australia is still at a point of transitioning as the country upgrades the systems and scanners used along the prescription medicines and OTC supply chain<sup>1</sup>. Consequently, linear barcodes are still required to support the legacy needs of those who have not yet upgraded technology in addition to any 2D barcodes during the transition period.

In some cases, as the second barcode (the 2D GS1 DataMatrix) is being introduced to packs, brand owners or contract manufacturers have been allocating a different GTIN (made of a GTIN-14) for use within this barcode. The issue this creates is that the master data for the product that is used across the supply chain<sup>1</sup> for traditional identification, inventory management, linkage to clinical support or consumer information only references the original GTIN (a GTIN-13 encoded in a linear barcode), and therefore we have a 50% chance of product misidentification. This in turn introduces workarounds and delays in processes, causes errors due to lack of available data and introduces risk due to manual intervention within a clinical setting.

## Recommendations:

To ensure that no additional risk or inefficiencies are created by adding a second method of data capture, GS1 Australia advises that both barcodes (original linear barcode and the new introduced 2D GS1 DataMatrix barcode) must encode the same Global Trade Item Number (GTIN).

If a linear barcode (EAN-13) is present on the pack containing a GTIN-13 identification number, the recommendation is to add a leading 0 (zero) to the GTIN-13 in order to create the 14-digit GTIN needed for the GS1 DataMatrix code. This ensures that regardless of which barcode is scanned in any process from manufacturer through to patient it will always relate to the same product and the same data.

This position is consistent with GS1 General Specifications<sup>2</sup> and is supported by industry stakeholders who have highlighted this issue.

1. Supply chain in healthcare refers to any point from manufacturing all the way through to the patient or consumer  
2. GS1 General Specifications <https://www.gs1.org/standards/barcodes-epcrid-id-keys/gs1-general-specifications>