Single Unit Coding

Joint EFPIA and EAHP Guidance for Implementation.

7 September 2026*

Introduction and Background

In collaboration with EAHP, a coalition of industry partners have discussed and agreed the concept of extending the existing medicinal pack coding, as exemplified by the Falsified Medicines Directive, to the unit dose level.

The process would be applicable to many product presentations, e.g. vials, glass/plastic bottles, blisters, pre-filled syringes, pens, sachets, stick packs, ampoules, cartridges etc. where either multiple dose packages are provided or for combination products e.g. medications for oral or IV administration supplied as a solvent and an active ingredient in, for example, powdered form.

The driver for extending coding to the unit dose requirements comes primarily from a drive within the hospital sector to reduce medication errors, increase patient safety, and ultimately reduce mortality (resulting from increased accuracy of administration). It will also contribute to increase efficiency and reduce the burdens placed on staff, thus reducing staffing requirements and overall cost. Many in this sector are under immense pressure to increase service provision and quality with a static or often reducing budget allocation.

A joint exercise has therefore reviewed how to extend the coding that exists on the sales/primary pack, to something similar that will exist at each packaged single unit.

The long-term goal is for the single unit code to include sufficient information that would allow for the identification of the product the expiry date and the batch information.

Whilst this document defines these aspects, it also acknowledges that there are some significant challenges associated with, for example, pack dimension and manufacturer investment to e.g. provide variable information at blister pocket level. It should also be noted that this is an initiative that looks forward and enables a future "state" that currently only exists within a few forward-thinking care institutions. It is the firm desire from industry that most healthcare institutions can justify the advancements made possible by unit dose coding and secure the required investment to upgrade internal processes and training. The agreement outlined here does not allow for increased productivity within institutions that are unable to secure the investment to advance.

* The date of final joint agreement is 25 March 2026, corresponding to the EFPIA Board's approval. The EAHP Board endorsed the Joint Guidance at its January 2026 meeting.

Use Cases

This initiative has the following primary use cases.

- Bedside Scanning to reduce medication errors and thus increase patient safety.
- Entry of medication administration into electronic patient records and thus increase efficiency and reduce the burdens placed on staff.

What will the Single Unit Code look like and contain?

The implementation of Single Use Coding, as defined in this document, is based on the following design criteria:

1. The code will exclusively adopt the GTIN as the product identifier. Unlike the compromise permitted within the implementation of the European Medicines Verification System (EMVS), there is strictly no deviation from the GS1 standards being envisaged. This is vital to minimise supply chain disruption across the whole of Europe.

2. The data applied to the Single Unit will be a GS1 DataMatrix code.

3. The proposal takes three forms of coding into consideration with further explanation being provided later.

    a. Basic: GS1 DataMatrix containing the GTIN only. Used when more detailed forms cannot be applied for manufacturing reasons, e.g. lack of space.
    b. Advanced: GS1 DataMatrix containing the GTIN, Batch/Lot information and the Expiry Date.
    c. Advanced+: As for the Advanced but additionally containing elements of human readable information, which may be required for regulatory purposes.

4. In each case, the GS1 Specifications will be followed.
    a. GTIN will utilise the Application Identifier (01).
    b. Batch/Lot will utilise the Application Identifier (10) and
    c. Expiry Date will utilise the Application Identifier (17).
    d. The Expiry Date will be encoded in the form YYMMDD.

5. There is no requirement or accepted use case for extending the encoding to include a UI (serial number) element as established on the outer package in the Single Unit of use code. This does not require that manufacturers do not include serial number data if there is a use case to support it, however it is not included as part of this initiative. Should serialisation become a general requirement, it will be addressed as a separate discussion topic/project.

6. There is no scope for national derivatives i.e. national codes used in place of or in addition to the GTIN.

There is a clear preference from the hospital sector for unit doses to have at least the Advanced form of coding, however it is also acknowledged that the vast majority of the benefit derived from unit dose coding can be obtained from the Basic form with just the product code embedded within the DataMatrix. Internal hospital systems can be linked with the GTIN information in the code which in turn can provide all of the basic product information (e.g. product name, strength, form etc). The expiry date information does enable further validation of the product suitability, however this check is usually undertaken at pack level in any case. It is estimated, by both industry and the hospital sector, that up to 90% of the ideal requirements could be resolved using the Basic [GTIN only] coding form and a suitably integrated IT system.

The Basic form has advantages regarding the turnaround time with artwork changes and the ease with which the code can be applied to the unit dose – e.g. pre-printed onto the blister foil.

Manufacturers must, regardless of the coding form adopted, ensure that the hospital sector can easily access the product information relating to the GTIN applied to each unit dose.

In all cases, early engagement with the regulatory authorities is required to minimise delays and potential issues. This applies to both the industry and hospital sectors.

The facets stipulated above will enable the use cases stated:

- Bedside scanning to reduce medication errors is entirely possible with access to only the GTIN, the Basic proposal, and
- the Advanced proposal enables both use cases.

Human Readable Representation.

Acknowledging that there has been much discussion surrounding the inclusion of human readable representations of the product details on each Single Unit of Use, there are presentations where this is simply unreasonable.

With some presentations the inclusion of, for example, the product name, strength batch/lot information and expiry date is entirely feasible without the need for an increase to the product presentation dimensions. However, when looking at, for example, some smaller vials and blistered products, duplicating the human readable information in addition to adding the DataMatrix code to each single unit whilst retaining the existing presentation profile, is impossible. There are existing cases where the blister card is perforated, and the blister cells are larger. In these cases, existing regulations will still apply and the DataMatrix code will need to be placed in addition to the existing human readable elements.

All the data requested by hospitals for display in human readable form can be obtained using the information encoded within the DataMatrix code together with suitable database support. The healthcare institutions that do not possess the necessary IT infrastructure to scan the Single Unit Code (SUC) and obtain the required the human readable representations will need to update to take full advantage of this initiative. Such institutions manage to operate today, largely because they do not leverage unit dose coding or because they undertake a repackaging operation to utilise unit dose coding techniques. These institutions could continue to operate in the same manner until the required infrastructure was available to take advantage of the SUC described in this document.

Indeed, with a relatively low level of investment, a simple bedside scanning system using mobile devices (such as phones) and a common EAHP-wide database resource paired with a mobile app, would provide a robust and entirely workable solution to satisfy the bedside scanning use case using the Basic coding implementation.

Implementation Scope and Timing

The scope of SUC implementation, Basic or Advanced, will be the products with strong relevance to the secondary healthcare market, e.g. the hospital sector.

- All product launches of new product from [5] years post joint agreement of this document shall support the Advanced [at least the GTIN, Batch/Lot information and the Expiry Date] coding form defined earlier within this document.
- 50% of products falling into scope as of [10] years post joint agreement of this document shall support either the Basic [GTIN only] or Advanced [GTIN, Batch/Lot information and the Expiry Date] coding form. Manufacturers shall be able to determine which form best applies given the aforementioned restrictions.
- 80% of products falling into scope as of [15] years post joint agreement of this document shall support either the Basic [GTIN only] or Advanced [GTIN, Batch/Lot information and the Expiry Date] coding form. Manufacturers shall be able to determine which form best applies given the aforementioned restrictions.

The date of final joint agreement is 25 March 2026, corresponding to the EFPIA Board's approval. The EAHP Board had already endorsed the Joint Guidance at its January 2026 meeting.

Marketing Authorisation Holders and Manufacturers acknowledge benefit of the Advanced coding form over the Basic coding form and will suitably consider it in the decision about which form to implement.

In some cases, the Advanced+ [GTIN, Batch/Lot information, Expiry Date and some elements of human readable text] coding form, or derivation thereof, may be required by some markets due to regulatory constraints. This document does not serve to supersede such national requirements and as such, the manufacturer remains responsible for undertaking sufficient national due diligence prior to artwork submission.

Hospital pharmacists are committed to ensure the effective and suitable use of single unit coding to ensure patient safety in order to enable that:

- Further sharing of the EAHP statement on the need for barcoding of the single dose administered in hospitals and may consider updating the statement based on the guidance and other developments.
- 50% of hospitals in Europe as [6] years post joint agreement of this document shall be able to perform bedside scanning based on the basic coding as proposed in the document.
- 80% of hospitals in Europe as [10] years post joint agreement of this document shall be able to perform bedside scanning based on the basic coding while 50% based on the advanced coding as proposed in the document.
- Hospital pharmacists acknowledge the benefits of advanced and basic coding form and are committed to monitor the implementation of bedside scanning through recurring activities.

Monitoring

Both the industry and hospital sector agree to undertake the development of a dynamic means to monitor overall progress with the scope and timing detailed above and to record any challenges and solutions to challenges encountered.

How such a monitoring system will manifest itself will be the subject of further elaboration. Complexity and additional cost should be avoided unless necessary. Such monitoring systems could as easily involve the use of data exchange via agreed file types, e.g. Excel on an agreed update cycle (the increased administrative overhead of file exchange should be taken into account when deciding how best to create such a monitoring system).

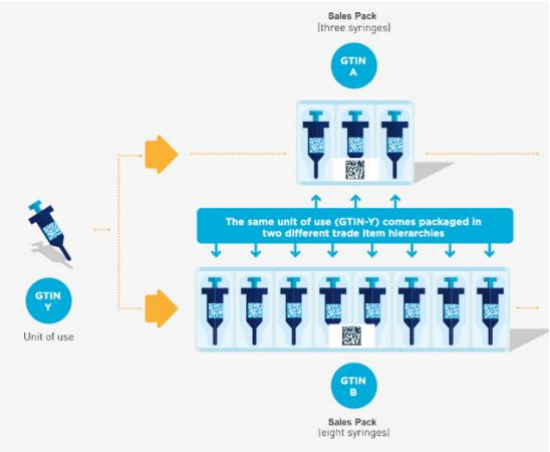
The monitoring system should be in place, at least in a basic form [2] years post joint agreement of this document. i.e. March 2028.

Appendix A – GTIN Assignment

As previously described within this document, the rules surrounding GTIN assignment shall follow [GS1 Healthcare GTIN Allocation Rules Standard.]

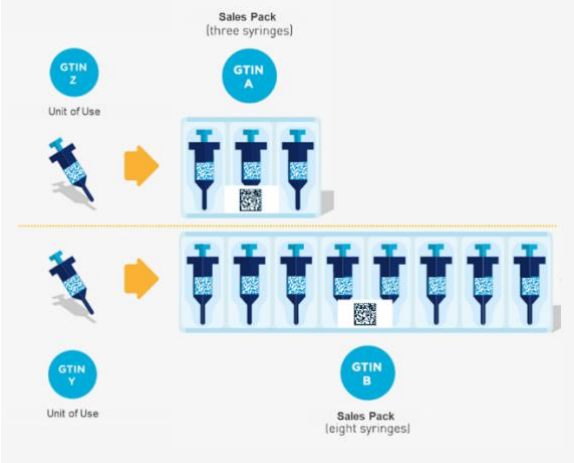
As each single unit of use is assigned a GTIN, the GTIN assigned needs to be unique to the specific presentation e.g., the blister presentation or the solvent, powder etc. The diagram below shows the logical principle of the GTIN assignment described.

In the following diagram we see a representation using the same GTIN Y for the unit making up two different presentations, each with a different unique GTIN A and B.

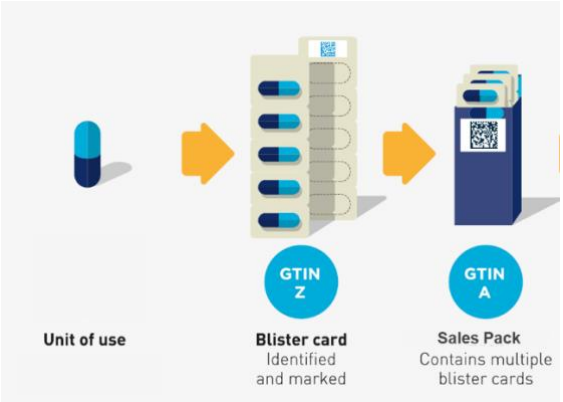


In the concept here it shows that the code applied to each syringe would be the same regardless of the number of syringes combined in one sales pack.

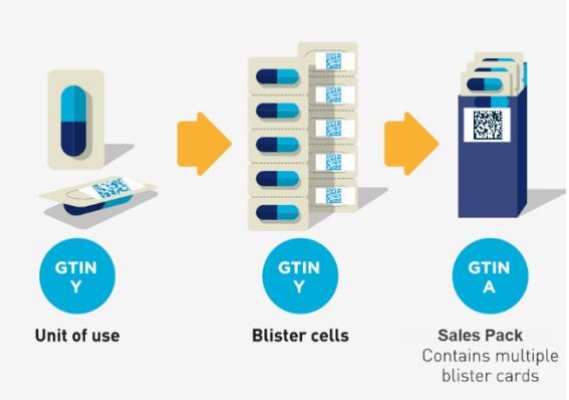
The following diagram displays the need for flexibility at the user level, where two different unique GTINs (GTIN Y and GTIN Z) have been assigned to the unit of use, the syringe, with these being subsequently packed into two different presentations, each again being assigned unique GTIN values (GTIN A and GTIN B). In short, it cannot be relied upon that the Unit of Use GTIN will be consistent across all packaging presentations.

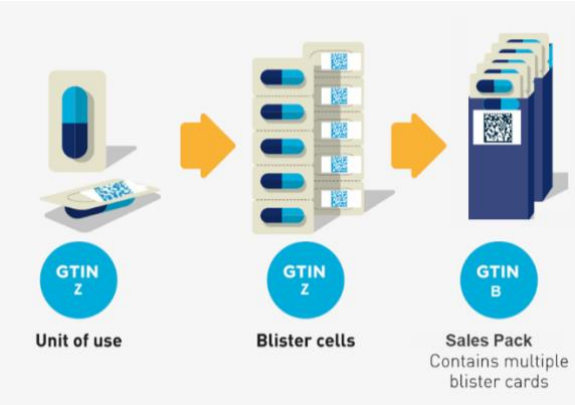


In addition, and this is specific to blister form product, in the case where the blister is not perforated, the blister card may only carry a single DataMatrix code.



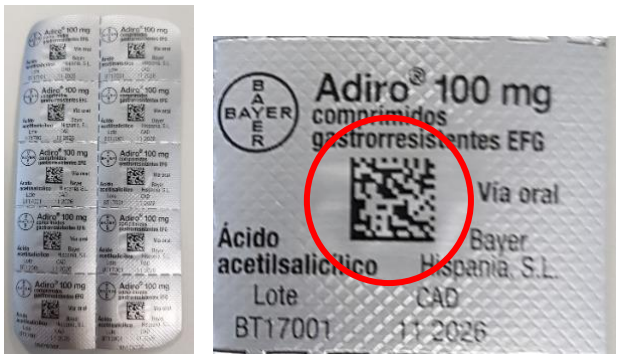
Finally, the two figures below show that for a given product (the same product) the code applied to each blister cell might be different depending on the number of blisters existing in the sales pack. This occurs because many manufacturers do not build their materials master down to the level of the blister card. As such it is imperative that the hospital sector systems allow for the use of multiple unit dose product codes for the same product and presentation.





Appendix B – SUC Examples

An example of how Single Unit Coding could be reflected is shown below.



Photographs kindly provided by Bayer AG

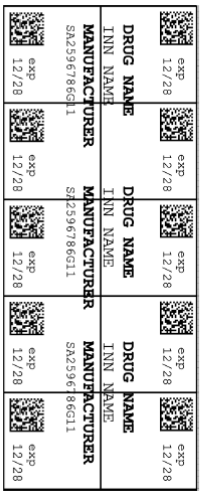
This example demonstrates a Basic implementation approach as only the product code is encoded. It also shows that the space requirement to print multiple human readable data elements is significant given (in this case), the tablet dimensions which are highlighted in “red”.

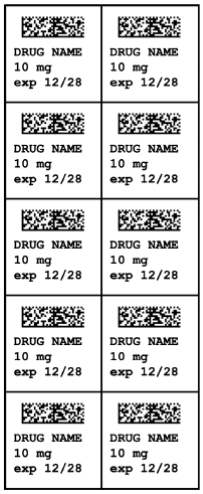
The following shows an example where static information is printed around the periphery if the blister card but not actually on each pocket.

Photograph copyright GS1 e.g. [https://www.gs1.at/sites/default/files/2020-05/GS1-Scan-Medikament-Innen.jpg]

The repetition of static data is not defined however to maximise the use case within, primarily secondary healthcare and care home locations, the more the static data can be repeated the easier the product will be to use.

Alternatively, where packaging technology allows, forms as shown below could be adopted.





These examples fit well with the Advanced+ form of coding where the unit dose is supplemented with elements of human readable information.