Questions and answers for pharmaceutical companies regarding the primary pack identifiers

What kind of packages are concerned?

Q: How about products that are not high alert medications? Will all products that need to be prepared on the ward and taken out from the secondary package before preparing, be concerned?

A: The hospitals wish to have a primary pack identifier on *all single packs inside multi packages* in the future, regardless of the type of product. However, as this is a recommendation, not a requirement, there is no time limit connected to this implementation. But surely something that hospitals will take into consideration during hospital tenders soon.

Q: Does the recommendation also concern small packages, for example single pre-filled syringes, where the space is very limited?

A: Yes, it concerns all primary packages. A 2D data matrix can luckily be printed very small and still be readable.

Q: How about blister packs, are there some specific medicines where companies are encouraged to print scannable codes also on the primary pack for blister packs?

A: Primary pack identifiers on blisters aren't first priority for hospital pharmacies.

Q: What is the recommendation for containers with oral tablets?

A: These have not yet been discussed as they are not prioritized by the hospitals.

Q: Medical device is not mentioned. Will medical device also be in scope of this recommendation later?

A: Medical devices have not been in discussions within this topic (yet). From the perspective of hospitals, it is important is to get medication administration safer and more effective vs current situation.

The UDI identifiers on the medical devices should be implemented according to the MDR regulations. Please see https://www.gs1.org/industries/healthcare/udi for more information.

The format of the identifier

Q: Is it an acceptable solution, that due to Amgros requirements in Denmark, we are using identifiers on primary packaging of the medicines consisting of a 2D matrix containing the Vnr (no GTIN, exp date or batch number)?

A: The Vnrs do not change as often as a product code needs to be changed, so using the Vnr is not a good solution in the long run, although it's better than not having any identifier at all of course.
But the recommendation is that the product code used in the 2D data matrix on the primary package should be a **GTIN**.

Q: The primary packages do not need to have the GTINs printed readable for the eye, the 2D data matrix is enough, is this correct?

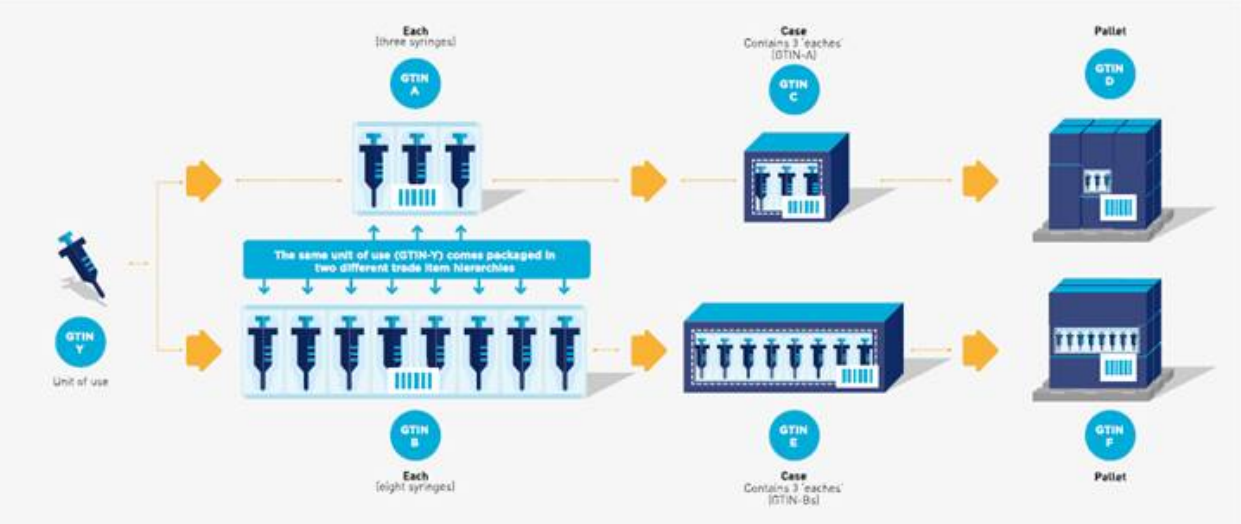
A: Yes, the 2D data matrix is enough.

Q: Is it a must to have a 2D Data matrix format or is QR or a linear barcode still acceptable on primary packaging as for Amgros?

A: The data *carrier* is less important in this case, the important thing is that the carrier contains the product code, GTIN.

Q: How about pre-filled pens inside bigger pack sizes - can the single pen inside a multipackage of 5 pens have the same GTIN as the single pen inside the multipackage of 10 pens?

A: Yes, please see the picture below from the GS1 document "GS1 Healthcare GTIN Allocation Rules Standard" according to the GTIN rules, the GTIN for the single pen can be the same despite the size of the multipackage (see picture below).



Packages containing several components

Q: How should we handle products which are powder in bottles, and which in addition to the powder vials contain vials with water for injection. Can the powder vial label have the same GTIN as the secondary package? Does the water vial need to be labelled?

A: For the company to follow the GS1 rules, also the diluent should be identified with a separate GTIN. Please see the picture below from the GS1 "Position paper on the identification of the primary package level of drugs" - link in guideline. Even if the secondary package and the active powder bottle are both "one dose", according to the GS1 rules, the product code on the outer package and on the inside vials must differ because the content is not 1:1.)

Primary packaging: some examples

The following illustrations provide examples of common primary packaging forms for medicinal products. Each is identified with its own GTIN, and optionally with variable information such as lot/batch and expiry date.

Single vials, or combinations of vials and their diluent, identified each with its own GTIN

Future needs and other questions

Q: Could you comment on the future need for the corresponding data carriers for wholesale packaging and pallets (aggregation)? Does it have to follow a system? For example, building on the GTINs on the outer packages previously allocated for the serialization requirement, but showing the different packaging levels hierarchy? Could this work?

A: Yes, it can be assumed that GTIN standards work also for aggregation