efpia
European Federation of Pharmaceutical Industries and Associations

Multi-Market Pack Coding Requirements
EFPIA Position

Executive Summary

The Falsified Medicines Directive and its Delegated Regulation stipulate that the pack shall only be permitted to carry a single two-dimensional barcode for the purposes of identification and verification of the authenticity of the pack. This places a significant challenge on the pharmaceutical supply chain as each market served by the pack has to be able to use and share a single code. This is particularly relevant for those countries requiring the inclusion of the national reimbursement number in the 2D datamatrix barcode: the combined use of multiple national/national reimbursement numbers in the 2D datamatrix barcode is not allowed according to global data standards.

The continued use of existing reimbursement codes by all Member State health care systems does not require their inclusion in the 2D datamatrix barcode since they will be available in all national repositories or database systems and therefore immediately accessible to all stakeholders connected to the repositories' system.

Most countries will have to amend their legislation in order to accompany the implementation of the Falsified Medicines Directive and its Delegated Regulation. In this context, EFPIA proposes to support GTIN only, i.e. option 1 below which is in line with the GS1 position and actively engage with member states to seek support and if necessary, local legislative amendment. Option 2 will be supported in lieu of option 1 to permit time for member states to amend local legislative requirements to remove any requirement for the local reimbursement number to be part of the machine readable code (bar code).

Background

The global market for medicinal products constantly provides challenges for logistics operations. Europe represents a micro-view of the global challenges with its 28 markets.

One of the largest challenges is ensuring that sufficient product is available to serve all market requirements without over-production. One means of reducing the logistical complexity is the production of packs that can be used within multiple markets without the need for market specific modification. This provides a simplified production process and minimises the costs involved when serving multiple markets (one pack for many being more generally flexible and cheaper than one pack per market).

The issue with multi-market packs is however complex. Currently the legislation permits multi-market packs to bear multiple linear barcodes (one for each market) each containing the local reimbursement number (where applicable). Whilst painful to print, and slightly confusing to use, this does permit a highly flexible solution to the issue and it is currently widely used.


EFPIA Brussels Office
Leopold Plaza Building ✱ Rue du Trône 108
B-1050 Brussels ✱ Belgium
Tel: + 32 (0)2 626 25 55 ✱
www.efpia.eu ✱ info@efpia.eu

The Falsified Medicines Directive (Directive 2011/62/EU) and the supporting Commission Delegated Regulation ((EU)2016/161) now stipulates in Article 9 that the pack shall only be permitted to carry one single barcode that in turn contains the information used to establish the authenticity of the pack. “Medicinal products having to bear the safety features pursuant to Article 54a of Directive 2001/83/EC shall not bear on their packaging, for the purpose of their identification and verification of their authenticity, any other visible two- dimensional barcode than the two-dimensional barcode carrying the unique identifier”. This places a significant challenge on the pharmaceutical supply chain as each market served by the pack has to be able to use and share a single code.

The current industry standard bar coding system is that specified by GS1. This system is used widely for both prescription and over the counter medicines. Indeed, the global retail market would not function without the use of a common standard for coding and the retail industry, as well as many others, makes wide-scale use of the GS1 standard. For the identification of medicinal products the large majority of EU Member States already use the GS1 Global Trade Identification Number (GTIN) comprising a GS1 company prefix, an item reference (identification code) and check digit. The GTIN provides companies with the same unique product identification for all their operations globally.

The national healthcare reimbursement number (NHRN), where used is vital for the member state health care systems as well as for supply chain stakeholders. Industry acknowledges that health care systems cannot be reasonably expected to change to use a different reimbursement code. However, the continued use of existing reimbursement codes by all Member State health care systems does not require their inclusion in the 2D datamatrix barcode since they will be available in all national repositories or database systems. Most countries will have to amend their legislation in order to accompany the implementation of the Falsified Medicines Directive and its Delegated Regulation. If some Member States insist on the inclusion of their national healthcare reimbursement number in the 2D datamatrix barcode then some multi-market pack combinations widely used today would have to be split.

The following recommendations permit continued use of multi-market pack combinations and of existing reimbursement codes by all member state health care systems with no health care system changes anticipated.

Option 1

Ideally, to minimise production and logistics complexities and to provide maximum flexibility for product movement, each pack should be coded using a single GTIN with each member state obtaining their local reimbursement number via a guaranteed 1:1 database lookup. The lookup process only needs to be undertaken by the system client users – e.g. pharmacy and wholesaler.

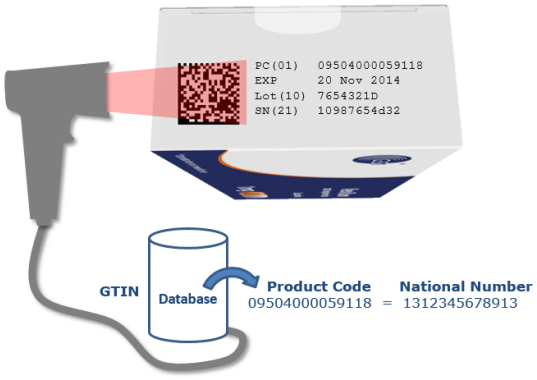

Figure 1 – GTIN-only coded pack

This scenario allows the same pack to be used in all markets with each market able to access their own local/national reimbursement code directly from a database using the GTIN as the look-up (key). The EMVS European Hub will provide this linkage information to each national system (NMVS).

This option also permits the use of the smallest possible printed code as it will only ever contain four data elements (product code, expiry date, batch code and serial number).

Option 2

In the case where a member state has a legal prerogative or requirement to have their local reimbursement number encoded into the DataMatrix code, the GS1 standard has the ability to represent multiple reimbursement numbers within a single code by adding extra data elements referred to as NHRN codes (National Health Reimbursement Numbers). NHRN application identifiers (the numbers that delineate and identify the data elements) are assigned on-demand by GS1 and currently four have been allocated as detailed in the table below.

Application Identifier	National Healthcare Reimbursement Number			Organisation
710	X_1	variable length	X_{20}	Germany IFA
711	X_1	variable length	X_{20}	France CIP
712	X_1	variable length	X_{20}	Spain National Code
713	X_1	variable length	X_{20}	Brazil ANVISA
nnn (*)	X_1	variable length	X_{20}	Country "A" NHRN Authority
(*) An example to illustrate future additional NHRNs. If additional NHRN AIs are required, a request for a new NHRN AI SHALL be made through the GS1 GSMP.				

Note: Companies wishing to apply one of the listed NHRN AIs will need to associate that NHRN AI to the trade item's GTIN according to the NHRN AI rules and should contact their GS1 Member Organisation for further considerations of use.

Figure 2 - NHRN Allocation

Use of these NHRN elements increases the complexity and size of the printed code and therefore this method has the potential to a) restrict the markets a given pack can be used and b) restrict the location on the pack where the code can be printed (due to the size increase). The consequences of either being larger packs, more SKU's to serve the increased quantity of markets requiring special packs, decreased pack quantity per pallet shipped and increased production and shipping costs.

When reading a code containing an NHRN, the client system should read the entire code, determine the content of the NHRN for their market and then use this value as the local reimbursement number.

This process within the client system software of selecting the appropriate NHRN from the scanned data stream requires that each client system is upgraded to be able to decode the new data element. Arguably, this is as much effort/cost (perhaps more) than the suggested database look-up solution using the GTIN alone as the product code.


Figure 3 - GTIN coded pack with included NHRN

The size of the printed code is not simply important in terms of overall theoretical dimensions, it is also important because some in-line printing technologies have a physical limit to the height of the code printed. One extremely popular printing technology that is used extensively within the pharmaceutical industry (and in many cases, investment has already been made), is Thermal Inkjet (TIJ) technology. This system makes use of industry standard piezo-electric print-head units and provides a maximum single head print height of 12.7mm. The DataMatrix specification allows for the module (square dot) dimension to shrink when more data is contained within a constrained code size, however a smaller matrix size presents issues for some commonly used scanners found in pharmacies for example, and the EFPIA coding guidelines (as well as GS1) recommend a minimum matrix size of 0.3mm (-0.045mm +0.315mm).

Summary

Industry advocates the use of a GTIN-only coding system for multi-market packs as described in option 1 and seeks to engage with member states where the legal situation requires the local reimbursement number to be part of the DataMatrix code.

In lieu of agreement or legal landscape modifications, industry should adopt the scenario of using added NHRN elements as described by option 2 but only where one or more of the markets being served by the pack require the local reimbursement number encoded within the DataMatrix code.

In all cases, industry should adopt the standard of printing the local reimbursement number for all served markets in human readable representation, potentially pre-printed, and clearly marked to determine the market ownership of the number(s) displayed. Pre-printed data avoids the complexities of in-line printing and vision inspection of human readable data elements.

References

Figure 1 – GTIN-only coded pack and Figure 3 - GTIN coded pack with included NHRN: GS1 Discussion Paper - Recommendations on a harmonised implementation of the EU Falsified Medicines Directive using GS1 standards

Figure 2 - NHRN Allocation: GS1 General Specification Release 16, Jan 2016 Fig 3.8.13-2

EFPIA
June 2017


EFPIA Brussels Office
Leopold Plaza Building ✱ Rue du Trône 108
B-1050 Brussels ✱ Belgium
Tel: + 32 (0)2 626 25 55 ✱
www.efpia.eu ✱ info@efpia.eu