Identification of medicinal product packages for Switzerland and Liechtenstein

in the context of the Falsified Medicines Directive 2011/62/EU, the Delegated Regulation (EU) 2016/161 and the Swiss Therapeutic Products Act (TPC) Art. 17a

Version 1.4 | June 1st 2023

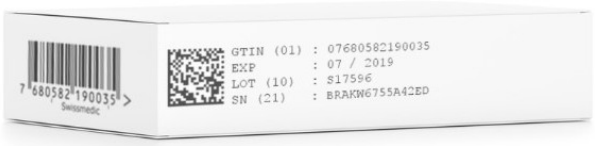
Version	Changes	Date
1.2	First launch	20.07.2018
1.3	Contact persons updated and outdated links replaced	28.02.2023
1.4	Recommendation under point 2 rewritten Contact person at GS1 Switzerland added	01.06.2023

Below you will find important information on the topic "Identification of medicinal product packages" in the context of the Falsified Medicines Directive 2011/62/EU, the Delegated Regulation (EU) 2016/161, the Swiss Therapeutic Products Act (TPA) Article 17a (see also chapter Weblinks), and the referencing of medicinal products in Switzerland by the Refdata foundation.

1 First, one shall distinguish between three elements for the identification of medicinal products:

1.1 Marking of the medicinal product package with a GS1 data carrier:

a. Currently, more than 90% of medicinal product packages in Switzerland are labelled with the 1D data carrier EAN-13.
b. Thanks to the EU-FMD, the medicinal product packages will in future be labelled with the 2D data carrier GS1 DataMatrix.
c. The EU-FMD is not yet mandatory for Switzerland. It is therefore possible that individual market partners will not yet be equipped with 2D scanners. However, it can be assumed that most pharmacies and hospitals are equipped with modern scanners.
d. If a drug manufacturer wants to label its products with both GS1 data carriers, THEN GTIN IN BOTH DATA CARRIERS SHALL BE IDENTICAL AND BOTH DATA CARRIERS SHALL NOT BE PRINTED ON THE SAME SHAFT SURFACE!
e. See example:



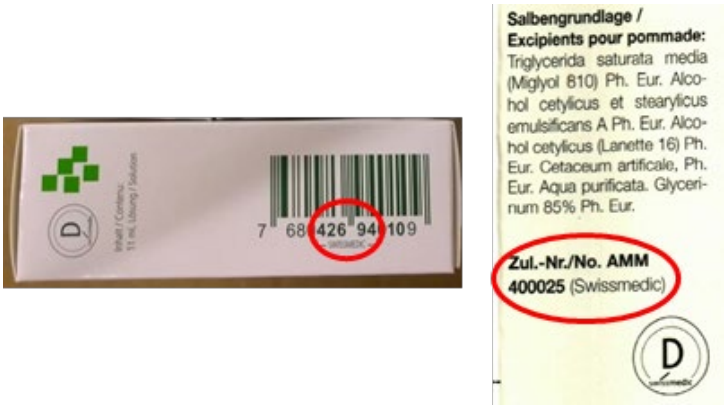
Picture: Example of an EAN-13 Barcode incl. the HUMAN READABLE INTERPRETATION (HRI) of Swissmedic Number and Datamatrix Code for use in Switzerland.

In this respect also consider the adaptation of 01.05.2018 of the Guidance document "Information on packaging" of Swissmedic, Chapter 11 Changes to packaging:

11.2 Minor changes that can be made by companies on their own initiative
…
g) Inclusion of a 2D data matrix
j) modification of placement of the EXP./Lot.:

1.2 Identification of the medicinal product with the GTIN:

a. Currently, more than 90% of medicinal products in Switzerland are identified with a GTIN with the prefix 7680.
b. The 13-digit numbers starting with 7680 are full-value GTINs that are UNIQUE WORLDWIDE and can be used WITHOUT RESTRICTION.
c. For the placing on the market of medicinal products, the prefix 7680 is NOT MANDATORY. Manufacturers can also use GTINs from company's own number range (from Switzerland or any other country) to identify their products.
d. For the codification of the GTIN in a GS1 DataMatrix prefix will be preceded by a 0 (zero) and will be 14 digits long.
e. The Swissmedic marketing authorisation number must be printed on the packaging in a human readable form.
   i. If the medicinal product packaging has been identified with a GTIN with prefix 7680, the Swissmedic marketing authorisation number shall be imbedded (left picture).
   ii. If the medicinal product has been identified with a GTIN from company's own number range, the Swissmedic authorisation number must be printed separately (right picture).
f. See example:



Picture: Example of a pack with an EAN-13 Barcode with HUMAN READABLE INTERPRETATION (HRI) of the Swissmedic Number and an example of a pack with only the HUMAN READABLE INTERPRETATION (HRI) of the Swissmedic number

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Please note that, according to the text put out for consultation on the requirements for the marketing authorisation of medicinal products, as from 1 January 2019, in addition to printing the Swissmedic marketing authorisation number, the **packaging code** provided by Swissmedic must also be printed.

1.3 Referencing of medicinal products in Switzerland

a. Refdata Foundation maintains a reference database of all medicinal products available in Switzerland.
b. For the referencing of a medicinal product, identification with a valid GTIN is mandatory. It is IRRELEVANT whether the medicinal product is identified with a GTIN with the prefix 7680 or with a GTIN from the company's own number range (from Switzerland or any other country).
c. Referencing serves as a data basis for many different IT applications on the marketplace.

2 Recommendation from the point of view of the Foundation Refdata, coordinated with the experts of GS1 Switzerland

The GS1 number range with the prefix 7680 will continue to exist as long as Swissmedic has not exhausted its numbering capacity of 5-digit registration numbers. Currently (2023), around 70% of the numbers have been used up, so that the remaining capacity should be sufficient for a few more years.
However, as soon as the 5-digit number capacity is used up, there will no longer be a new number range referenced by the Refdata Foundation. From then on, marketing authorisation holders will have to identify newly authorised packs with a GTIN from their own number range.

a. It is recommended that medicinal products which are already identified with a GTIN with the prefix 7680 should retain them until further notice (usually until the end of life). This avoids a large effort without any added value for all parties in the supply chain.

b. It is recommended that medicinal products that have never been identified with a GTIN should be identified with a GTIN from the company's own number range (from Switzerland or any other country).

c. It is assumed that by 2019 all persons authorised to supply medicinal products will be equipped with scanners capable of reading the GS1 DataMatrix 2D data carrier. Pharmaceutical manufacturers who still want to apply both data carriers on the packaging must comply with the requirements of point 1.1 (d.).

3 Weblinks

Information to the Refdata foundation: www.refdata.ch
Information to SMVO: www.smvo.ch
Information to GS1 Switzerland: www.gs1.ch

Click here to see the formal requirements on drug information for medicinal products for human use and packaging from Swissmedic. Here you will find the "Guidance document Packaging for human medicinal products HMV4".

Further information on legal requirements in Switzerland can be found in the document "Federal

Decree on the Approval and Implementation of the Council of Europe Convention on the Counterfeiting of Medicinal Products and Medical Devices and on Similar Crimes Harmful to Public Health (Medicrime Convention)". https://www.admin.ch/opc/de/federal-gazette/2017/6301 (GERMAN)

4 For questions about identification and referencing of medicinal packages

- Questions regarding **Referencing of medicinal products with Refdata Foundation** contact Nicolas Florin (nicolas.florin@refdata.ch)
- Questions concerning **Falsified Medicines Directive** in Switzerland and Liechtenstein contact:
  - Nicolas Florin (SMVO) - nicolas.florin@smvo.ch
  - Erwin Zetz (SMVS GmbH) - erwin.zetz@smvs-gmbh.ch
- Questions regarding **allocation or the of company GTINs or the verification of GS1 data carriers**, please contact the following person:
  - Anne van Berkel Meier (GS1 Switzerland) - anne.vanberkel@gs1.ch