Industry standard for product codes

Definitions
In this context, by **product code** we mean GTIN (Global Trade Item Number) which is placed in a machine-readable code, either GS1 DataMatrix/2D matrix code (hereafter 2D code) or linear barcode (e. g., EAN-13).

There are the following types of GTIN:

Type of GTIN	Number of digits	Format according to GS1 standard
GTIN-8	Totally 8 digits	*Cannot* start with 0
GTIN-12	Totally 12 digits	*Can* start with up to three 0s
GTIN-13	Totally 13 digits	*Cannot* start with 0
GTIN-14	Totally 14 digits	*Cannot* start with 0

Note that when a product code is included in a 2D code, it will be displayed with leading 0 (zero) if it is GTIN-12 or GTIN-13 in connection with the 2D code. This is because a 2D code can be used for GTIN-14, and then "available spaces" are filled with 0. These leading 0s are not part of the GTIN. GTIN-8 is normally not used in 2D codes, only in linear barcodes on small units.

Term	Definition
Consumer Unit	Consumer packaging/sales packaging.
Inner Pack	Packaging at a level below consumer packaging/sales packaging.
Packaging level	The level the packaging has in relation to the preparation. The primary level is closest to the preparation.
Closed loop medication management	Method to ensure that the right patient receives the right medicine, in the right dose, at the right time and in the right way. «Closed loop medication management» is electronic support for medication management from requisition to dispensing. This includes scanning barcodes, both on the medicine and the patient.

Legal basis
Falsified Medicines Directive (FMD) 2011/62/EU
Regulation on safety features (Delegated Regulation (EU) 2016/161)
Forskrift om legemidler til mennesker (Legemiddelforskriften)

Purpose
The industry standard is intended to contribute to that:

- all packages to be sold through pharmacies can be scanned, whether they are medicines or commodities.
- medicines that are covered by the FMD are automatically checked against the NMVS database in connection with prescription dispensing.
- inner packages of medicines can be scanned in a closed loop medication management.

- the GS1 standard is followed for the use of GTIN.
- GS1 or ISO/IEC standard should be used when coding a machine-readable code.

Sources of information
NOMA (Sikkerhetsanordninger for legemidler)
GS1 (DataMatrix Guideline, General Specifications, Healthcare GTIN Allocation Rules)
VnrWiki (Change situations vnr vs. GTIN, Product codes)

Standard
All packages sold in pharmacies should preferably have a machine-readable code so that the package can be scanned. For prescription medicines with MA, there is a requirement for a 2D code according to the Falsified Medicines Directive with given exceptions, see **Legal basis** and **Sources of information**. For other medicines and commodities, either a 2D code *or* a linear barcode can be used. It is not desirable with several machine-readable codes on the same package.

For pharmacies and hospitals to be able to scan a 2D code or linear barcode, the product code included in the code must be registered to the relevant article number (Vnr) on farmalogg.no, see FAQ. Farmalogg also forwards product codes to SAFEST.

New product codes must be registered *before* the package with a new product code is delivered to the wholesaler/pharmacy.

- If the package has the same Vnr, a new product code must be registered to the existing Vnr. A Vnr can have an infinite number of product codes Consumer Unit.
- If the package has *a new Vnr*, the package must be registered as **a new product** and with **a new product code**.

When changing the package, the product code must be changed if the GS1 standard requires this. In addition, the product code **must always be changed when the Vnr changes**.

Product code on inner packaging for medicines, enteral nutrition and dietary supplements
Inner packages should preferably have a machine-readable code, so that both the Inner Pack and Consumer Unit can be scanned in a closed loop medication management.

If a package consists of several different packaging levels, e.g., 5x10x2 ml, it is sufficient that there is a product code on the outer packaging and smallest packaging unit. In this case, it means that there should be a product code on 5x10x2 ml (Consumer Unit, tertiary level) and 2 ml (Inner Pack, primary level). For the intermediate packaging of 10x2 ml (Inner Pack, secondary level) there may be a product code, but there is no requirement for it.

When the ratio between Consumer Unit and Inner Pack is 1:1 (e.g., a box contains only one vial), according to the GS1 standard, the same product code can be on the Consumer Unit and the Inner Pack. In such cases, the product code is only registered as product code Consumer Unit, but the packaging level is set to *primary level* to indicate that the product code is on the packaging closest to the preparation.

- Note that according to the GS1 standard, a GTIN should uniquely identify a package, which means that it is only possible to use the same product code on the Consumer Unit and the Inner Pack when the ratio is 1:1. E.g., if there are several vials in the box, or there is a needle in addition to the vial, the same product code *cannot* be used on the box and vial.

When changing the product code on a package, all packaging levels above must change the product code according to the GS1 standard. This means that if the product code is changed on the Inner Pack, the product code must also be changed on the Consumer Unit.

When changing the inner packaging, the product code must be changed if the GS1 standard requires it, just like for the Consumer Unit.

Coding of 2D codes on Inner Pack
2D code on Inner Pack must at least contain GTIN, but it is desirable that also the batch number and expiry date are included if possible. These must be coded with Application Identifiers (AI):

AI	Type of information	GS1 standard	Correct coding of machine-readable code on packaging
01	GTIN	(01)01122334562378	0101122334562378 10A1C2E3G41517320514
10	Lot – batch number	(10)A1C2E3G415	
17	EXP - YYMMDD	(17)320514	

When the product code is to be used in a 2D code on the Inner Pack, it is important that this is coded correctly so that it is scannable. Note the following when coding a 2D code:

- There should *only* be one 2D code.
- The predefined length of GTIN in 2D code is 14 digits. If GTIN-12 or GTIN-13 is used, leading 0s must be added so that there are a total of 14 digits.
- Application identifiers should be coded *without* parentheses.
- There must *not* be inserted line breaks or spaces between elements/application identifiers.
- The field for date should *only* contain numbers.
- The code must *not* be placed on a transparent background.
- The X dimension (height and width) of the 2D code must be according to the GS1 standard.

Examples of wrong and right coding of the machine-readable code on the package:
⃠ (01) 05714764112378 (17) 04/2027 (10) 101D23
☑ 0105714764112378172704301010 1D23

⃠]d20105714764112378170420271010 1D23
☑ 0105714764112378172704301010 1D23

Sources of additional information
Amgros (Technical guide – Barcode labelling)
GS1 (Application Identifiers, DataMatrix Barcode Guide)
VnrWiki (Standard identifiers on human primary packages in the Nordics)

This industry standard is anchored by:

Apotekforeningen LMI FARMA NORGE Forening for Generiske og Biotilsvarende Medisiner NOMVEC SYKEHUSAPOTEKENE