Annex 2: MS coding requirements

Member State	Product Code (PC)		National Health Reimbursement Number (NHRN)					Timing	Conclusion	
	GTIN	Other	On pack	In Product Code	Human readable	In UI	Use system look-up	Formal confirmation by Health Authority	Overview human readable	Number of elements in 2D barcode
AT - SMP (1)	No	NTIN with PZN embedded	No	Yes (NTIN with PZN embedded)	No	No	Yes		4 lines: no GTIN	4
AT - MMP(1)	Yes	NTIN with PZN embedded (if compatible with other markets)	No	No, in case of GTIN	No	No	Yes		4 lines: GTIN	4
BE (2)	Yes		No	No	No	No	Yes	Royal Decree of 3 February 2019 and Royal Decree of 21 November 2018	4 lines: GTIN	4
BG	Yes		No	No	No	No	No		4 lines: GTIN	4
CY	Yes		No	No	No	No	No		4 lines: GTIN	4
CZ	Yes		Yes	No	No	No	No	Amendment bill was adopted 30.01.2019	4 lines: GTIN	4
DE - SMP (1)	No	NTIN or PPN (PZN embedded in both)	Yes	Yes (NTIN or PPN with PZN embedded)	Yes	No	No		4 lines: no GTIN	4
DE - MMP (1)	Yes	PPN (PZN embedded)	Yes	No, in case of GTIN Yes, in case of PPN	Yes	Yes, in case of GTIN No, in case of PPN	No		5 lines: GTIN + NHRN	5
DK(3)	Yes	NTIN with Vnr embedded	No	No	No	No	No	Confirmed by authorities	4 lines: GTIN 4 lines: no GTIN	4
EE	Yes		No	No	No	No	No	As published in OJ on 09.02.2016	4 lines: GTIN	4
ES (9)	Yes	NTIN (EAN13 with NHRN embedded)	Yes	Yes, if a NTIN is used. If a GTIN is used, NHRN is included as 5th element of the 2D barcode	Yes (pre-printed by law on the upper right-hand corner on the front of the box, not close to the barcode)	Yes, if a GTIN is used	No	Informative Note of the AEMPS (published in July 2017)	Either 4 lines (NTIN as PC) or 5 lines (GTIN + NHRN)	Either 4 lines (NTIN as PC) or 5 lines (GTIN + NHRN)
FI (3)	Yes	NTIN with Vnr embedded	No	No	No	No	No		4 lines: GTIN	4

Member State	Product Code (PC)		National Health Reimbursement Number (NHRN)					Timing	Conclusion	
	GTIN	Other	On pack	In Product Code	Human readable	In UI	Use system look-up	Formal confirmation by Health Authority	Overview human readable	Number of elements in 2D barcode
FR(4)	Only on a few MMP to be determined and through experimentation	NTIN with CIP embedded	Yes	Yes	Yes (CIP mandatory on the pack)	No	No	Confirmed by authorities	4 lines: no GTIN	4
EL (5)	No	NTIN								
HU	Yes		No	No	No	No	No		4 lines: GTIN	4
HR	Yes		No	No	No	No	No		4 lines: GTIN	4
IE	Yes		No	No	No	No	No		4 lines: GTIN	4
IS (3)	Yes	NTIN with Vnr embedded	No	No	No	No	No	tbd	tbd	Most likely 4
IT		Bollino								
LI	Yes	GTIN with embedded Swissmedic MA- and Pack-Number	No	No	No	No	No		4 lines: GTIN	4
LV	Yes		No	No	No	No	No		4 lines: GTIN	4
LT (6)	Yes		No	No	No	No	No		4 lines: GTIN	4
LU (7)	Depending on country of origin		No	No	No	No	Yes		Depending on country of origin	
MT	Yes		No	No	No	No	No		4 lines: GTIN	4
NL	Yes		No	No	No	No	No		4 lines: GTIN	4
NO (3)	Yes	NTIN with Vnr embedded	No	No	No	No	No		4 lines: GTIN	4
PL	Yes		No	No	No	No	No	tbd	4 lines: GTIN	4
PT	Yes		Yes	No	Yes	Yes	No	Legislation published 24 April 2018	5 lines: GTIN + NHRN	5
RO	Yes		No	No	No	No	No		4 lines: GTIN	4
SK	Yes		No	No	No	No	No		4 lines: GTIN	4
SI	Yes		No	No	No	No	No	Confirmed by authorities	4 lines: GTIN	4
SE (3)	Yes	NTIN with Vnr embedded	No	No	No	No	No		4 lines: GTIN 4 lines: no GTIN	4
UK	Yes		No	No	No	No	Yes	Entered into force 9.02.2019	4 lines: GTIN	4

(1): SMP: Single Market Pack; MMP: Multi-Market Pack.

(2) Belgium used the CNK-code as Product Code and as NHRN but has switched to a GTIN product code with look-up tables for finding the corresponding CNK-code. Pre-FMD products with CNK codes can still be present in the market.

(3) Denmark, Finland, Iceland, Norway, Sweden: GTIN for new products and NTIN for existing products (termination date for new NITNs is set on 09/02/2019). The Vnr is not used as a NHRN and should not be uploaded to the EU Hub as a National Code in the Market Specific Data. The Vnr is not affected by e-verification. It is an old system which still is used but for other purposes. Companies can use

either an NTIN or a GTIN as long as the code is unique. The current NTIN can only be retained if it is unique to the pack (not always the case today in Sweden). In the NTIN, the Vnr is embedded but that is not of any significance for e-verification. If a company change to GTIN as the unique product code, there is no impact on the Vnr, it can be kept (and is printed on the pack) but it can never be embedded in the GTIN.

(4) France: Use of GTIN on multi market packs and look-up under discussion.

(5) Greece: under discussion by Greek authorities: according to latest information, they are likely to opt for GTIN with no inclusion of the national reimbursement number.

(6) Lithuania: Stakeholders have decided to adopt the GTIN (not imposed by NCA). The NHRN is not required so no changes in legislation on this matter.

(7) Luxembourg: Luxembourg currently uses the PZN as Product Code for products originating from Germany and the CIF-CIP as Product Code for products originating from France; it will use GITN for products originating from Belgium.

(8) Portugal: The stakeholders have decided to adopt the GTIN (not imposed by INFARMED). The NHRN is already printed on the packaging in human readable format as it is the national marketing authorization number and is also used for reimbursement.

(9) Spain: the Spanish Medicines Agency wants to have the National Health Reimbursement Number included in the data matrix. The NHRN is a 6-digit number plus a control digit. It is embedded in EAN13 code (847000 + NHRN+ CD). The NHRN must also be printed on the upper right-hand corner on the front of the box, not close to the bar code by law.

(10) Product code for AT-authorised medicinal products according to Austrian coding requirements.