COMMISSION DELEGATED REGULATION (EU) 2016/161
Falsified Medicine Directive (FMD)

November 2017

Juergen Idinger

Falsified Medicine Directive (FMD)

Requirements

Packaging level: Secondary Packaging. Aggregation is volunteered
Tamper Evident solution: tbd

Data elements:
PC Product Code (GTIN/ NTIN)
SN Serial **N**umber
EXP
Lot Lot Number
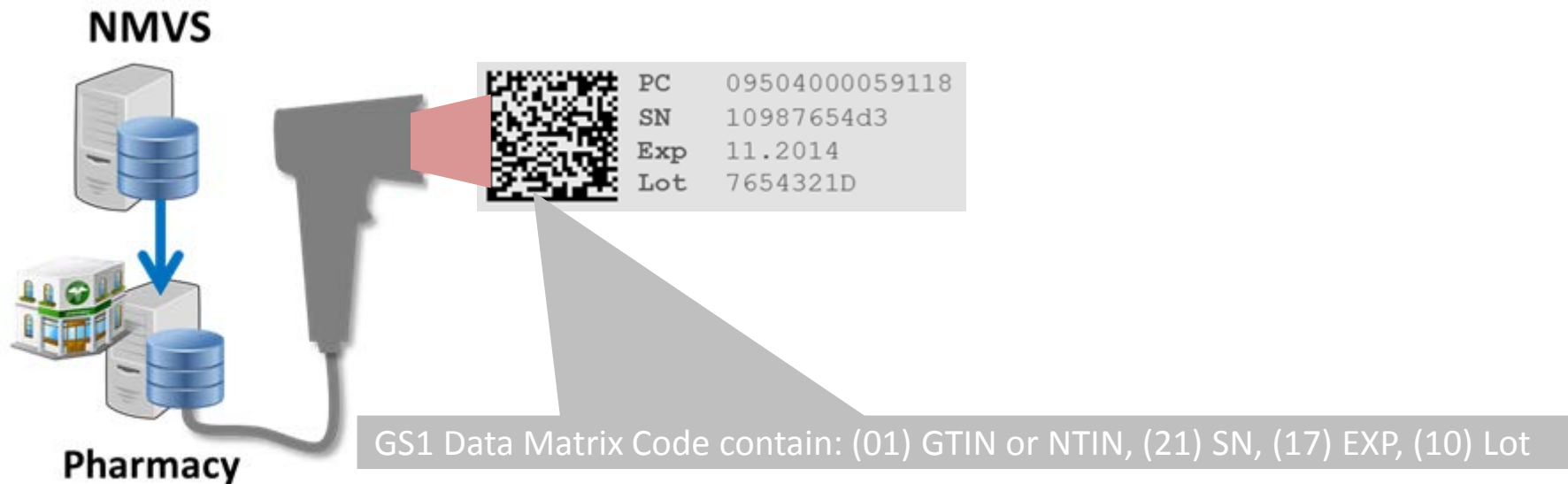**NN N**ational Reimbursement **N**umber (if applicable)

Data carrier: Data Matrix for unique identification

Deadline (date corresponds to Lot release for Market supply):
- Feb 9 2019
- Feb 9 2025 Belgium, Greece and Italy

Falsified Medicine Directive (FMD)

Serialization: Unit of Sales

GS1 Data Matrix Code contain: (01) GTIN or NTIN, (21) SN, (17) EXP, (10) Lot

Falsified Medicine Directive (FMD)

Data order: GS1 standard

- Use of AI (Application Identifier), allow user software to recognize type of data

- Order: Fix data numerical + variable data alpha numerical

Fix Data	Variable Data
(01) GTIN/ NTIN	(21) Serial Number
	(17) Expiry Date
	(10) Lot Number
	(71x) NN

Data Carrier	Level of Packaging
GS1 Data Matrix	Primary-, Secondary packaging
GS1 128 linear	Tertiary packaging, Pallet

Falsified Medicine Directive (FMD)

GTIN vs NTIN across Europe

GS1 - GTIN

Austria*, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark**, Estonia, Finland**, Germany*, Hungary, Iceland**, Ireland, Latvia, Lithuania, Malta, Netherlands, Norway**, Poland**, Portugal, Romania, Slovakia, Slovenia, Spain**, Sweden, Switzerland, UK

*   GTIN for multi country - shared packs
** Some countries will allow GTIN or NTIN

GS1 - NTIN

Austria*, France, Germany*

* For market specific packs

TBC

Italy and Greece (coding requirements under discussion)

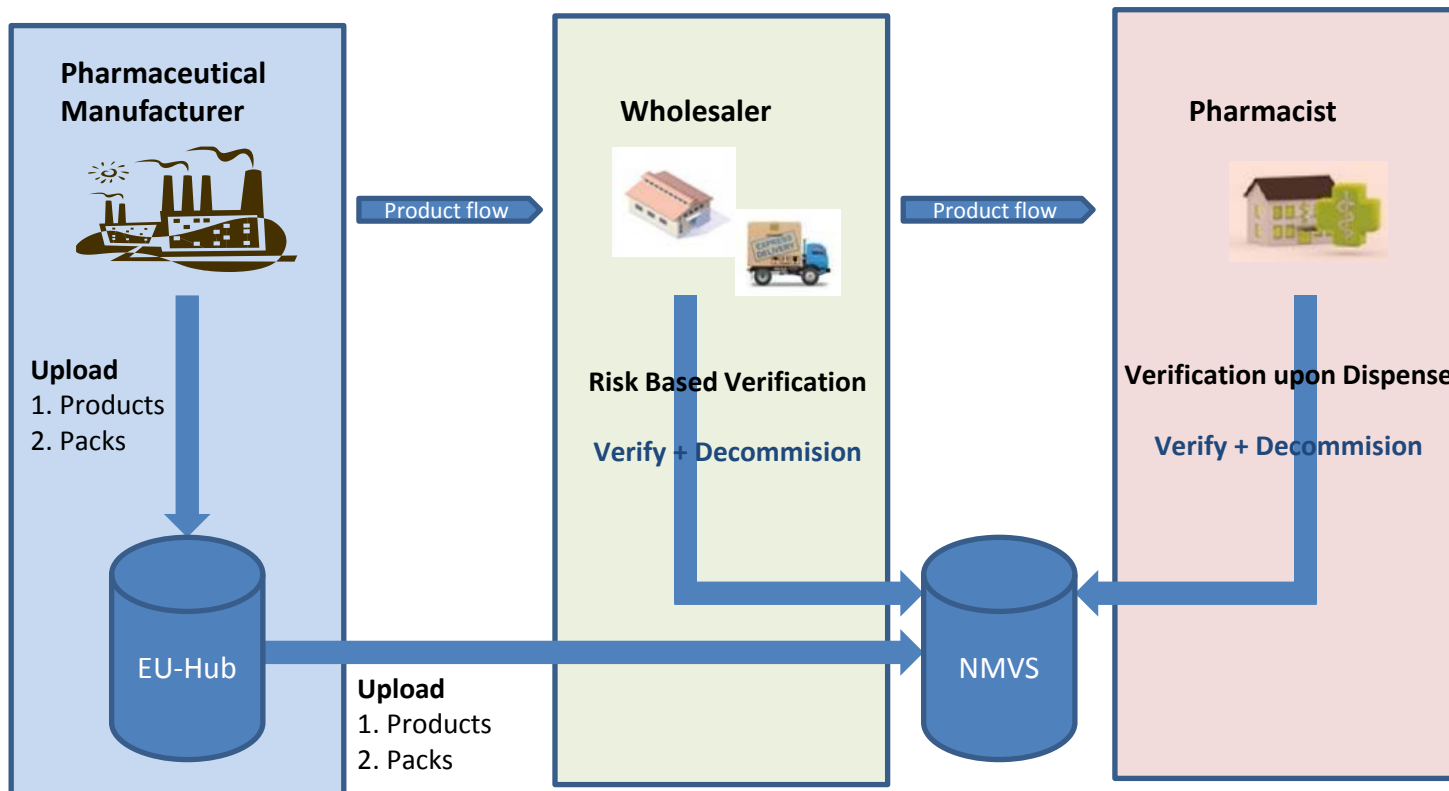Some countries (outlined in red) also require a national number in the 2D Barcode when using GTIN

Austria
- NTIN for national packs
- GTIN for multi market packs => Austrian EAN looked up in the repository (AMVS)

Falsified Medicine Directive (FMD)

Product flow

Impacts on Packaging Operations in general

- Optimize OEE (Overall Equipment Effectiveness) and setup time

- Increasing level of education for Operators at the packaging line

- GMP Requirements: adapt packaging process to minimize issues during packaging operations

Which countries already receive serialized Product ?

2010	2011	2012	2013	2014	2015	2016	2017
🇺🇸 USA	🇮🇪 Ireland	🇬🇧 UK	🇦🇷 Argentina	🇨🇳 China	🇦🇺 Australia	🇹🇷 Turkey	🇺🇸 USA
			🇨🇦 Canada	🇰🇷 South Korea			🇸🇦 Saudi Arabia
							🇦🇺 Australia