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The European FMD - Medicines barcode identification with GS1 DataMatrix

Ulrike Kreysa, Senior Vice-President Healthcare, GS1 Global Office
Bucharest, Romania, 9th February 2019





31 556 926 Seconds
525 948,766 Minutes
8 765,81277 Hours

365 Days
52 Weeks
12 Months
ONE Year



Protecting patients - the EU Falsified Medicine Directive



EU Falsified Medicine Directive 2011/62/EU (FMD)

http://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf

EU Commission Delegated Regulation 2016/161

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_en.pdf

Prevent the entry into the legal supply of falsified medicinal products by requiring the placing of safety features consisting of a **unique identifier** and an **anti-tampering device** on the packaging of certain medicinal products for human use for the purposes of allowing their **identification and authentication**.



Where does GS1 play a major role ?





The Unique Identifier in the DA

Source: EU Commission Stakeholder Meeting, February 2016



The UI - Composition

- The UI will contain:
 - **Product code:** ISO-compliant (ISO 15459); < 50 characters; globally unique; issued by ISO-compliant coding agencies;
 - **Serial number** (max 20 characters; randomised)
 - A **national reimbursement or identification number** (optional)
 - **Batch number**
 - **Expiry date**

- UI also ISO-compliant (ISO 15418; ISO 15434).

Product code	Serial number	Batch number	Expiry date
(01)09876543210982	(21)12345AZRQF1234567890	(10)A1C2E3G4I5	(17)180531

Illustrative example – not binding

Global standards - GS1 by the numbers



1 million

**over 1 million
companies worldwide
use GS1 standards**

150 countries

**25 industries served
across 150 countries**

6 billion

**Barcodes scanned
more than 6 billion
times per day globally**

112 MOs

**112 Member
Organisations
around the world**



Voluntary, Global Healthcare User Group



To lead the healthcare sector to the successful development and implementation of **global standards** by bringing together **experts** in healthcare to enhance **patient safety** and **supply chain efficiencies**.

GS1 Healthcare - an expanding, committed community of globally engaged stakeholders



...and there are many more companies working with GS1 at a local level

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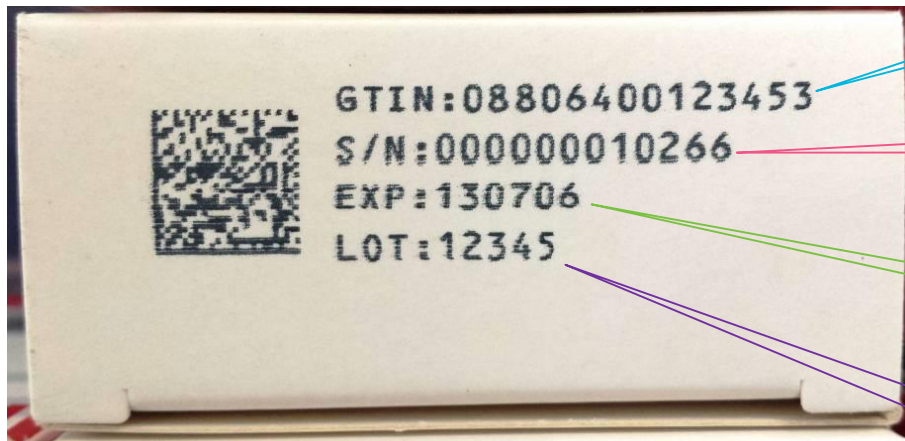
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Globally unique product code & serialisation



Product Identifier
(GTIN)

Serial Number

Expiry date

Lot/Batch number

From GS1 linear to GS1 DataMatrix



(01)1022222333334(17)091231(10)A1345B(21)1234

Item identifier

Expiry date

Batch number

Serial number



(04)0761234567890(17)100503
(10)AC3453G3(21)123



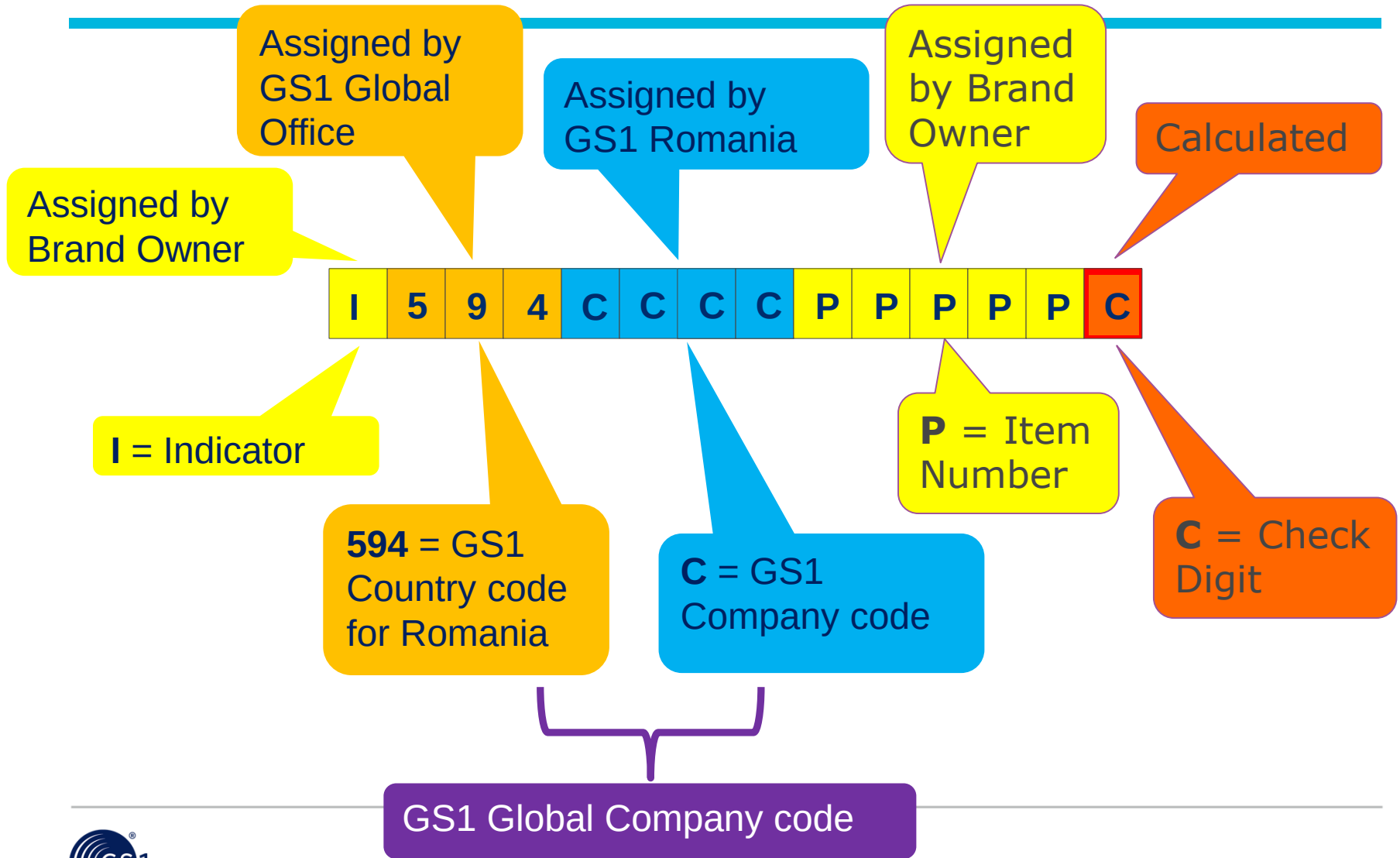
GS1 Application Identifiers...

01	GTIN (Global Trade Item Number) – 14 digit numeric
10	Batch / Lot – up to 20 characters - alphanumeric
17	Expiry Date – format is YYMMDD – so for today 170324
21	Serial Number – up to 20 characters - alphanumeric

Sequence: GTIN first - then recommend to have fixed length - followed by variable length

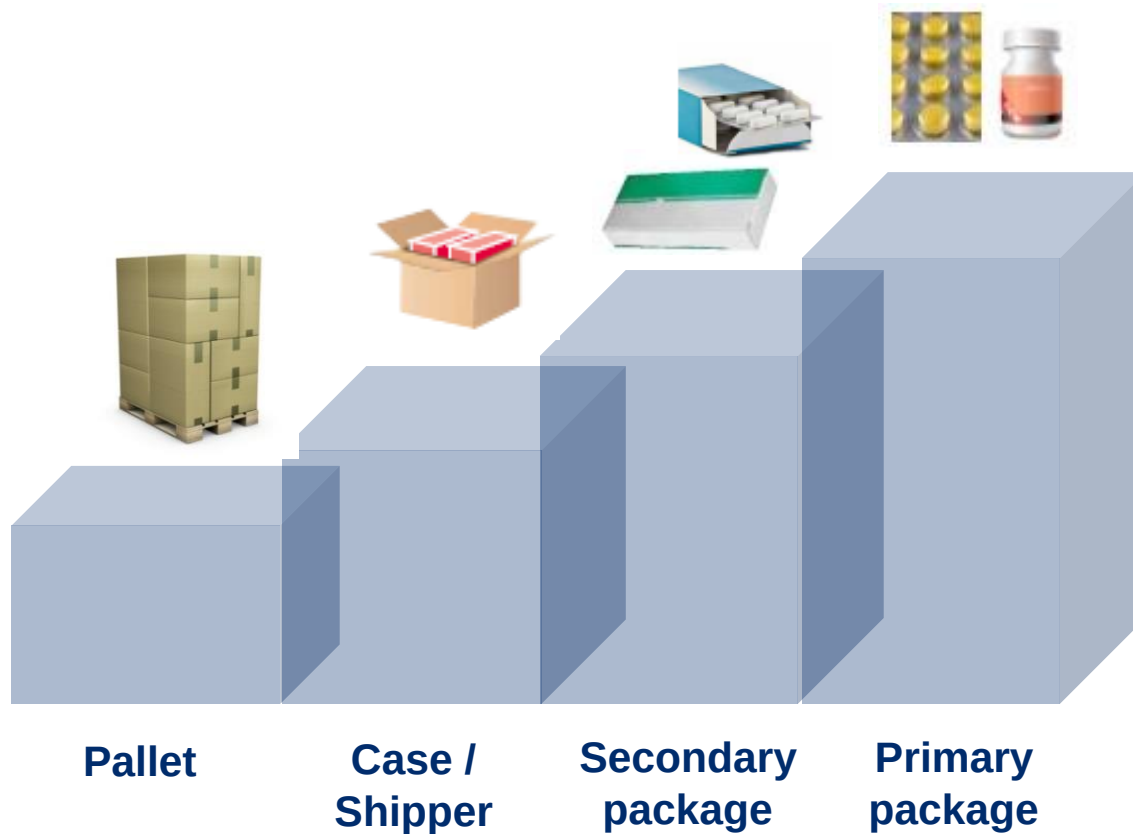


Anatomy of a GTIN-14...

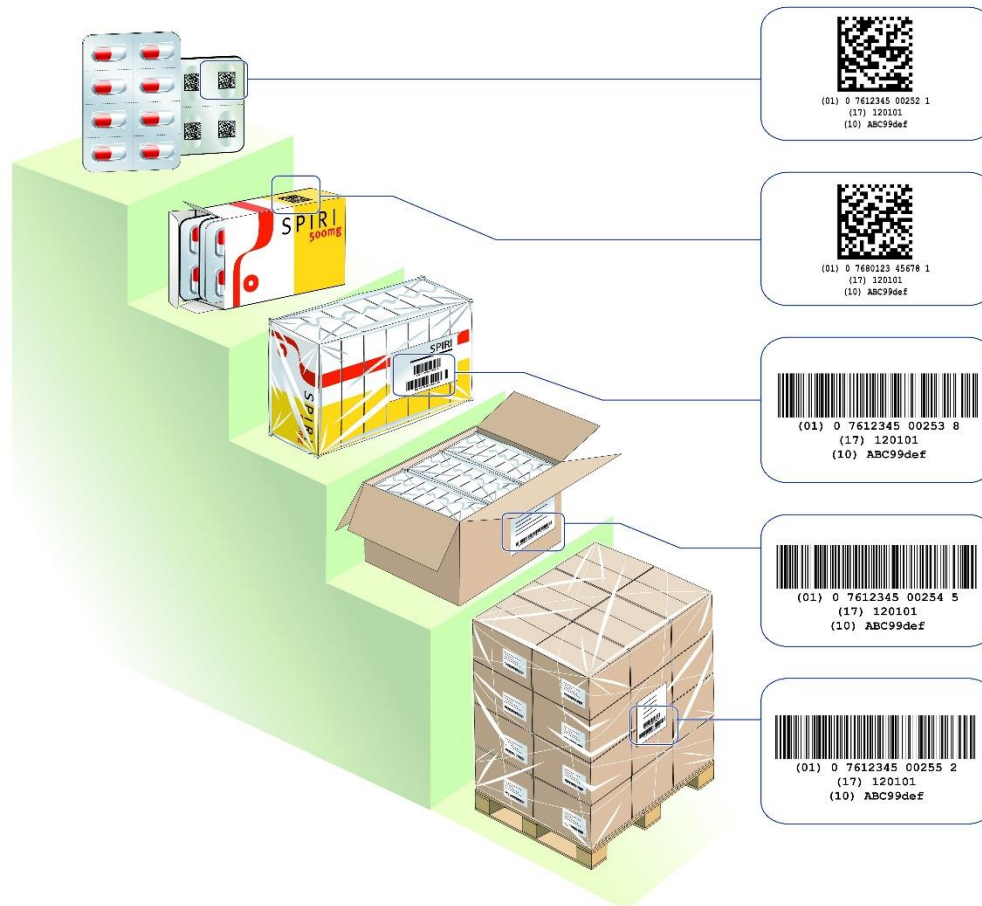


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Different packaging levels require different GTIN's



Ideally - identifiers and data carriers at all packaging levels



NOTE: Data carriers shown are for illustration purposes only!



Note: Images shown are for illustration example only, refer to local regulations and/or the latest version of the GS1 General Specification for more detail.

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The coding situation in Europe today



21 countries have a **full GS1 GTIN⁽¹⁾ code structure**

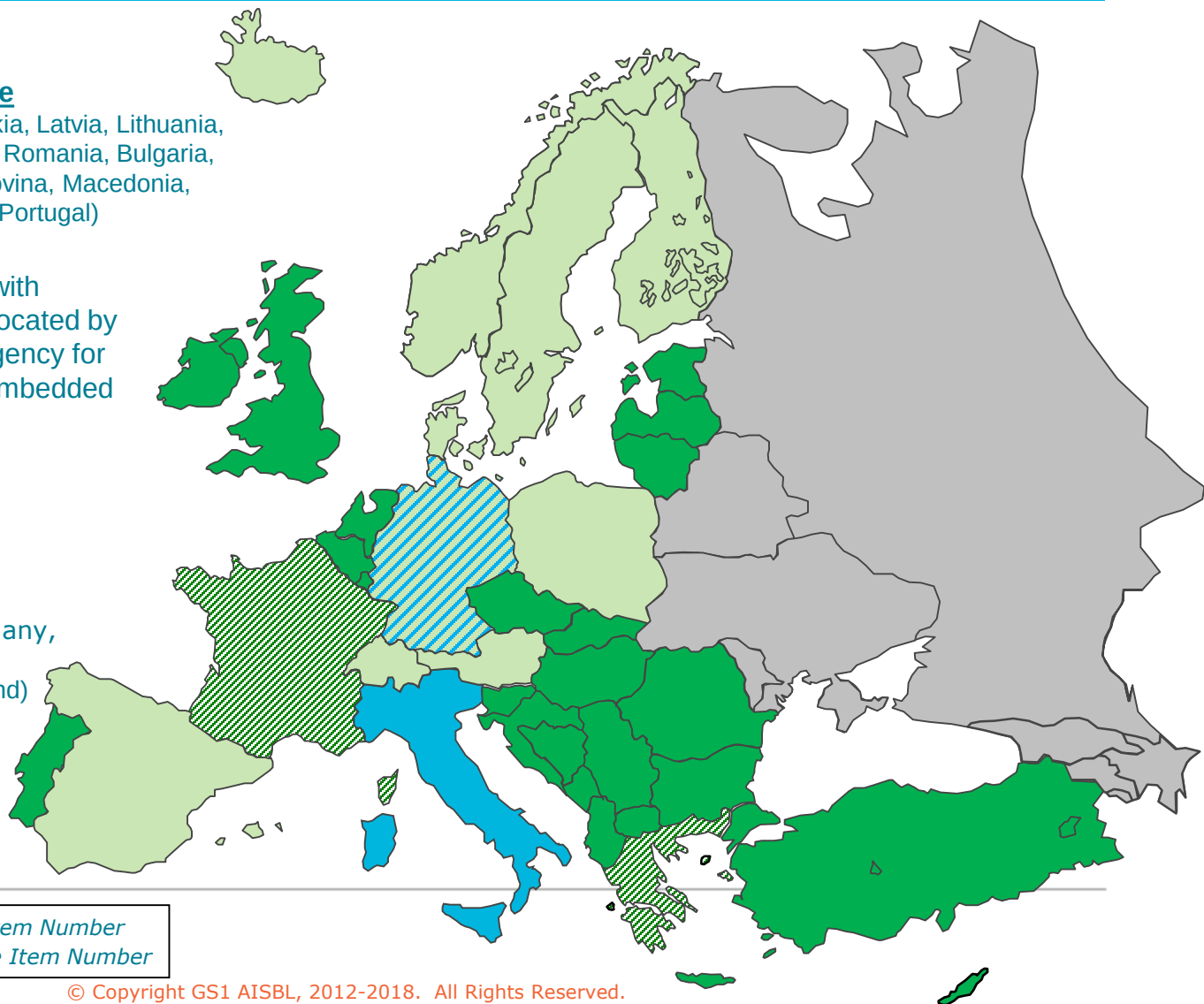
(UK, Ireland, Czech Republic, Slovakia, Latvia, Lithuania, Estonia, Malta, Netherlands, Turkey, Romania, Bulgaria, Serbia, Albania, Bosnia and Herzegovina, Macedonia, Croatia, Cyprus, Slovenia, Hungary, Portugal)

2 countries use **a GS1 NTIN⁽²⁾** with product identification number allocated by a number bank or an external agency for the coding of pharmaceuticals embedded in GS1 data structure
(France, Greece)

10 countries allow **GS1 GTIN AND GS1 NTIN**

(Austria, Denmark, Finland, Germany, Iceland, Norway, Poland, Spain, Sweden, Switzerland)

2 countries use their own **non-GS1 compatible solution**
(Germany, Italy)

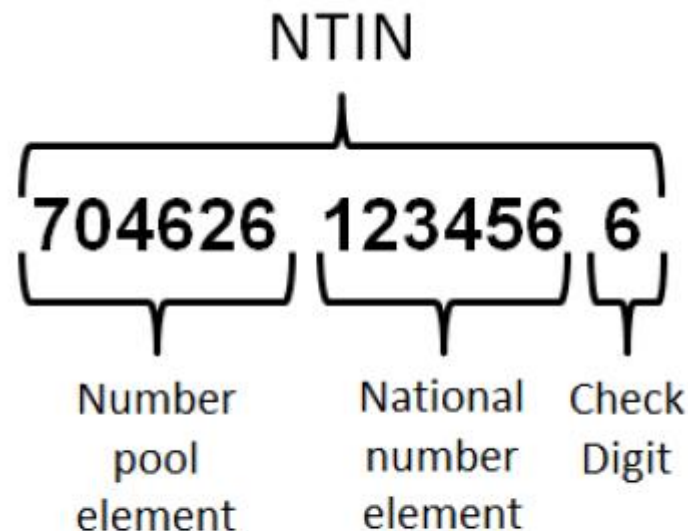


(1) GTIN: Global Trade Item Number
(2) NTIN: National Trade Item Number



What is a NTIN?

- A National Trade Item Number – from the GS1 numbering pool, not assigned by the manufacturer, but by 3rd parties (e.g. a national regulator)



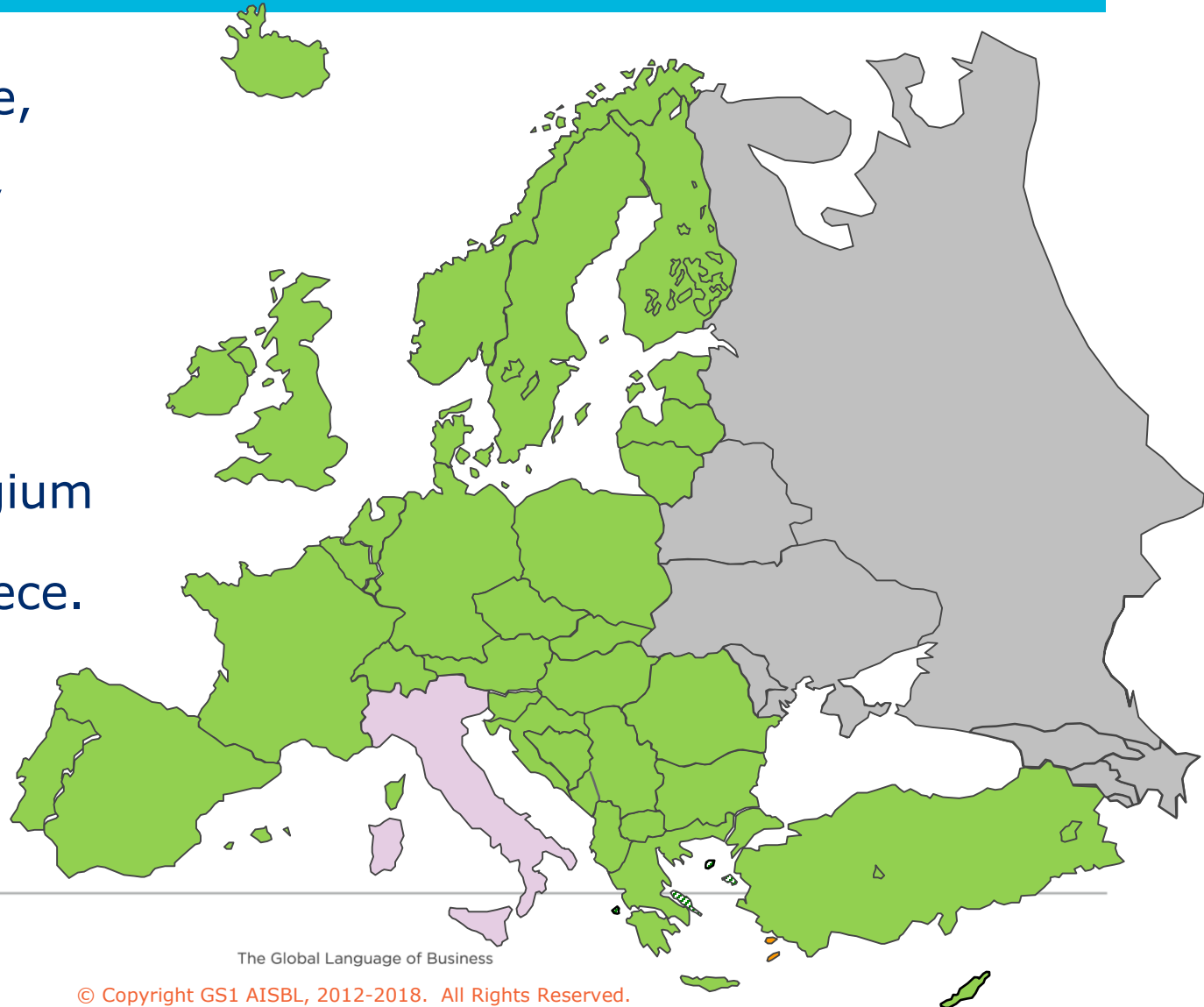
NOTE: Example for illustrative purposes only based on the format common for the Nordic countries of Denmark, Norway, Iceland, Finland and Sweden

The move towards harmonisation and GS1 standards in Europe



Belgium, Greece,
Italy
until 9 February
2025.

Implementation
announced
for 2019 in Belgium
and
for 2021 in Greece.



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Multiple markets taking a pack

- ❑ Any number of GTIN markets can be in a shared pack group*
- ❑ Only 1 NTIN market can be in a shared pack group

**Subject to labelling requirements and space on the packaging*

Existing pack				
Mkt 1	Mkt 2	Mkt 3	Take the worst colour	What to use in the Data Matrix
GTIN	GTIN	GTIN	Pack Group can be retained	Hopefully all 3 GTINs are the same on the shared pack
NTIN	GTIN	GTIN	Pack Group can be retained	Use the NTIN
NTIN	NTIN	GTIN	2 NTINs - group must be split	Pack can no longer be shared

Other considerations

- If an NHRN is also used there may be technical constraints on how many lines of data can be encoded in the Data Matrix
- NTIN + NHRN in the Data Matrix is not supported by the standards
- Once a PPN is used in the barcode no other GS1 standard using market can share that pack as they are not compatible within the same barcode



Source: GSK & Pfizer presentation, GS1 Global Conference, 2017
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	Market	Bulgaria	Croatia	Estonia	Germany	Hungary	Ireland	Latvia	Lithuania	Malta	Netherlands	Romania	Slovakia	Slovenia	UK	Cyprus	Czech Republic	Denmark	Finland	Iceland	Norway	Poland	Sweden	Belgium	France	Liechtenstein	Switzerland	Austria	Greece	Spain	Luxembourg	Portugal	Italy
Market	Country Code	GTIN	GTIN	GTIN	GTIN / NTIN or PPN	GTIN	GTIN	GTIN	GTIN	GTIN	GTIN	GTIN	GTIN	GTIN	GTIN	GTIN	GTIN	GTIN or NTIN	GTIN or NTIN	GTIN or NTIN	GTIN or NTIN	GTIN or NTIN	GTIN or NTIN	National -> GTIN	NTIN	NTIN	NTIN	NTIN	NTIN	NTIN	Mix ?	National	National
Bulgaria	BG	BG																															
Croatia	HR		HR																														
Estonia	EE			EE																													
Germany	DE				DE																												
Hungary	HU					HU																											
Ireland	IE						IE																										
Latvia	LV							LV																									
Lithuania	LT								LT																								
Malta	MT									MT																							
Netherlands	NL										NL																						
Romania	RO											RO																					
Slovakia	SK												SK																				
Slovenia	SI													SI																			
UK	UK														UK																		
Cyprus	CY															CY																	
Czech Republic	CZ																CZ																
Denmark	DK																	DK															
Finland	FI																		FI														
Iceland	IS																			IS													
Norway	NO																				NO												
Poland	PL																					PL											
Sweden	SE																						SE										
Belgium	BE																							BE									
France	FR																								FR								
Liechtenstein	LI																									LI							
Switzerland	CH																										CH						
Austria	AT																											AT					
Greece	GR																												GR				
Spain	ES																													ES			
Luxembourg	LU																														LU		
Portugal	PT																															PT	
Italy	IT																																

GTIN:GTIN - allowed

NTIN:GTIN – allowed*

NTIN:NTIN – not allowed

National:Any – not allowed**

This table is a snapshot and will change over time

There are choices of coding scheme in some markets

Source: GSK & Pfizer presentation, GS1 Global Conference, 2017

GTIN:GTIN - allowed
NTIN:GTIN – allowed*
NTIN:NTIN – not allowed
National:Any – not allowed**

This table is a snapshot and will change over time
There are choices of coding scheme in some markets

Keep yourself informed

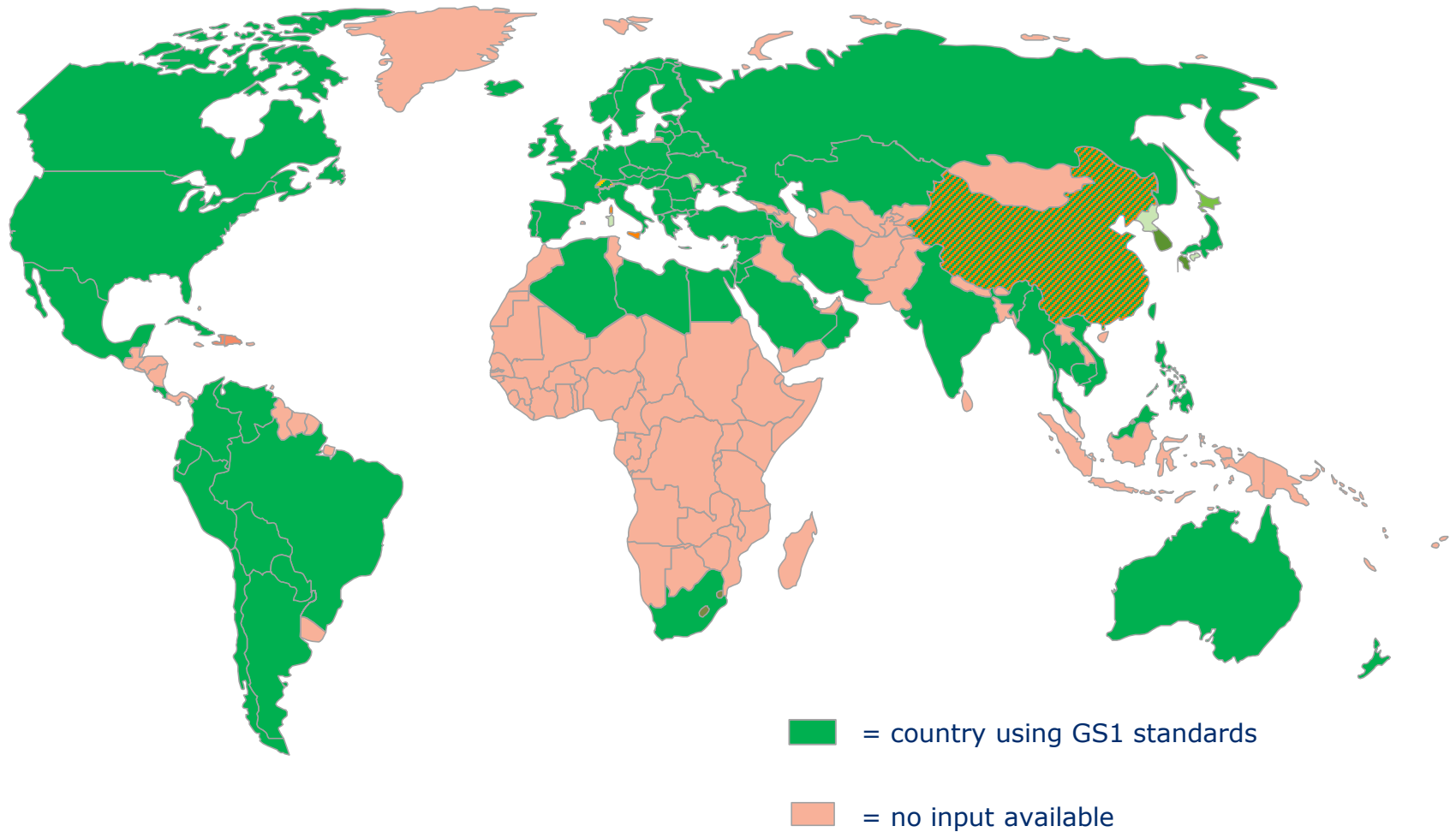


- Bi-weekly conference calls of specific Public Policy group
- Contribute and watch the EU FMD Coding Tracker
- Important information to make changes now
- Multi-country packs

Country	Coding status	Coding short-term dev.
Austria	NTIN	Meeting on 19 Jan.2017 (GS1 Austria) Under discussions: GTIN + PZN cross-referenced in the DataBase
Belgium	National code	Moving to GS1: stakeholders pushing for GTIN Group of local representatives of manufacturers has been set-up
Bulgaria	GTIN	
Croatia	GTIN	
Cyprus	GTIN	
Czech Republic	GTIN	Need to require new AI
		Possible to use NTIN or GTIN until 2019. All new registered product after 2019 must have a GTIN. No deadline to changing existing NTIN to GTIN. National code will stay on the pack but not in the barcode. Update from workshop of 9 Jan. 2017: • The two main wholesalers have announced that they intend to be able to handle more than one barcode reference per VNR in Q3-2017. That will make it possible to make a transition from NTIN to GTIN for that part of the supply chain. They also focus on being able to handle GTIN-14 when implementing this change. • BUT the Pharmacies have not started a project to be able to establishing the NMVO before e project. So they will not be n NTIN to GTIN at Q3-2017. ot either.
Denmark		
Estonia		
		until 2019. All new product
		ng NTIN to GTIN. pack but not in the barcode.
Finland		



Harmonisation around the identification of pharmaceuticals

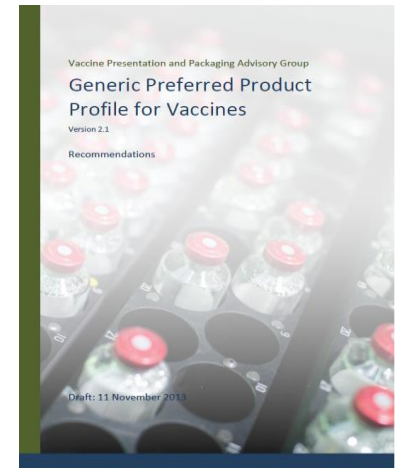


For the developing countries: WHO and USAID/UNFPA



- 2015 Generic Preferred Product Profile for Vaccines (PSPQ2) recommends barcodes with **GS1 standards (GTIN, lot number and expiry date) on all packaging levels** used by manufacturers, with the exception of primary packaging

http://www.who.int/iris/bitstream/10665/148168/1/WHO_IVB_14.10_eng.pdf



- USAID and UNFPA requirements for reproductive health products will be put into action now – same approach: **GTIN, lot number, expiry date – later serialisation**

<https://www.ghsupplychain.org/news-type/innovations>

<http://summit2017.familyplanning2020.org/commitment.html>

Identification Guidelines for Reproductive Health Products

Reproductive Health Global Traceability Advisory Group



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Interagency Supply Chain Group (ISG) Adoption of global GS1 standards



The ISG: **Bill and Melinda Gates Foundation, DFID, Global Affairs Canada, the Global Drug Facility, KfW, the Global Fund, Gavi, NORAD, UNDP, UNFPA, UNICEF, USAID, World Bank, WFP and WHO** published a position paper in August 2017 on the **adoption of GS1 standards** committing to the process of transitioning to include established, global data standards as part of their procurement requirements and support country uptake of these standards.

**From the Interagency Supply Chain Group:
Visibility for Health Systems: Adoption of Global Data Standards (GS1)**

About the ISG
The broad purpose of the Interagency Supply Chain Group (ISG) is to share information and seek greater alignment across supply-chain investments to bring more impact to individual agency supply chain strategies. The group promotes coordination both globally across programs, and locally through national leadership with the overall aim of improving the efficiency and effectiveness of in-country supply chains. The ISG is an informal partnership of 15 major actors involved in providing supply chain support to countries: Bill and Melinda Gates Foundation, DFID, Global Affairs Canada, the Global Drug Facility, KfW, the Global Fund, Gavi, NORAD, UNDP, UNFPA, UNICEF, USAID, World Bank, WFP and WHO.



Boxes of medical supplies are sorted before being distributed among the mobile health brigades at the Chikwelele District hospital in Malawi, Mozambique, in July 2016. ©UNICEF/IRC.

Background
Medicines supply chain execution and responsiveness require synchronization of supply and demand, as well as the orchestration of three flows of commerce, that are the movement of goods, information and funds, across an increasing number of logistics and trading partners, spanning a wide (if not global geographic) region. Whilst the implementation of traceability systems has been identified by National Regulatory Authorities as a useful and efficient tool to combat falsification and illicit distribution of medical products, only some countries have issued progressive traceability regulation. Many have not, and are still assessing various implementation mechanisms, after

naïvetes or otherwise have not approached this topic at all*. The international community has recognized the need to support countries in determining what these best approaches are. Since 2014, the international development community has promoted the use of global data standards (GS1) to provide a wider and harmonized framework for supply chain visibility, strengthening anti-counterfeiting measures and sharing of data between parties. The Interagency Supply Chain Group recognizes the value for advocating for both effective and sustainable solutions to enable traceability and safe passage of medicines through national supply chains and have committed to strengthening this response accordingly.

Current activities of the ISG

- Strengthen global and country advocacy for the adoption of GS1 standards and traceability systems with countries, in collaboration with other relevant stakeholders.
- Accelerate the understanding and adoption of an open and global supply chain standard, globally, through technical support, education, and collaboration with manufacturers.
- Collaborate to improve donor procurement guidelines, including the requirement for the use of GS1 standards for identification and barcoding on the different packaging levels, and coordinate with manufacturers on an implementation timeline.
- Develop a roadmap & timeline for the adoption of GS1 standards in labeling all health commodities and products.
- Provide technical assistance to several countries in defining parameters necessary to implement National Traceability Systems. These include development and finance implementation plans for barcoding of health commodities for member states, e.g. support to the Government of Ethiopia to implement a nation-wide adoption of barcoding technology.

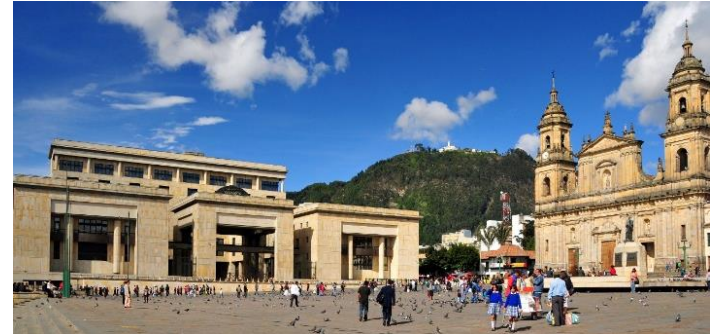
* Fourth meeting of the member state mechanism on standardized procurement of essential medicines, 13 November 2014, provisional agenda item 4.2. Existing technologies and 'track and trace' models in use and to be developed by member states. Draft document submitted by Argentina.



GS1 Healthcare across the world



- 33rd global conference in Bogota, Colombia from 10 to 12 April 2017
- First conference in Africa in Addis Ababa, Ethiopia from 8 to 10th May 2017 supported by international organisations like USAID...



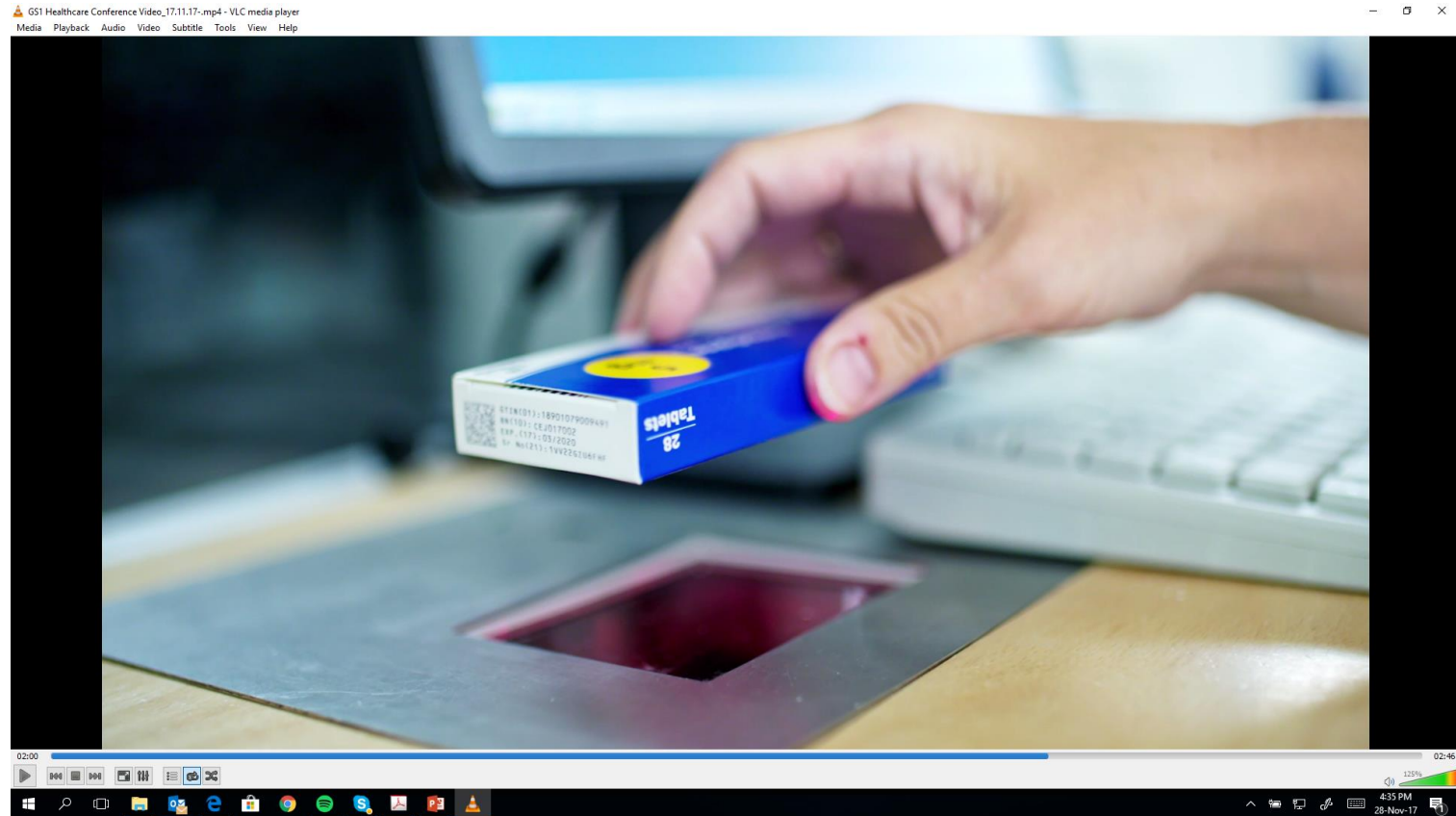


Summarising...

- Barcoding technology and global standards are valuable tools to improve patient safety, fight counterfeits and increase visibility in the supply chain and with that the efficiency
- A globally harmonized approach will be less complex and costly



Improvement of care



GS1 UK Healthcare video November 2017



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Contact Details

Ulrike Kreysa

Senior Vice-President Healthcare

GS1 Global Office, Brussels

E ulrike.kreysa@gs1.org

W www.gs1.org/healthcare

