NCA perspective on the opportunities the Delegated Regulation (EU) 2016/161 on safety features brings within and beyond its anti-falsification remit

Damjan Bonač - Pharma Supply Chain & Logistics Forum - 19.10.2023

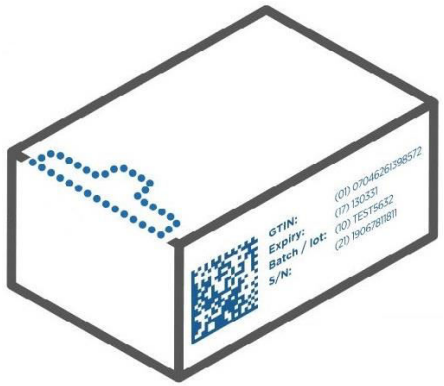
Content of presentation

- Legal framework & Structure of the system
- Implementation & State of play
- Benefits & Improvements

Legal framework

The Falsified Medicines Directive (Directive 2011/62/EU)

- Obligatory safety features – a unique identifier and an anti-tampering device.
- Published on 1 July 2011, and applies since 2 January 2013.
- It amended Directive 2001/83/EC.



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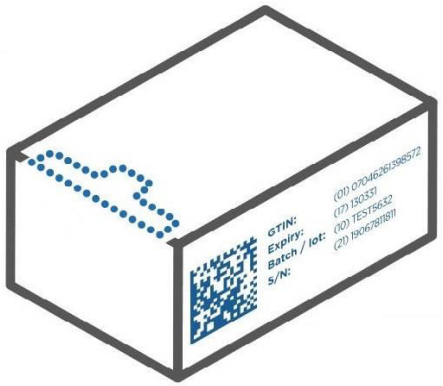
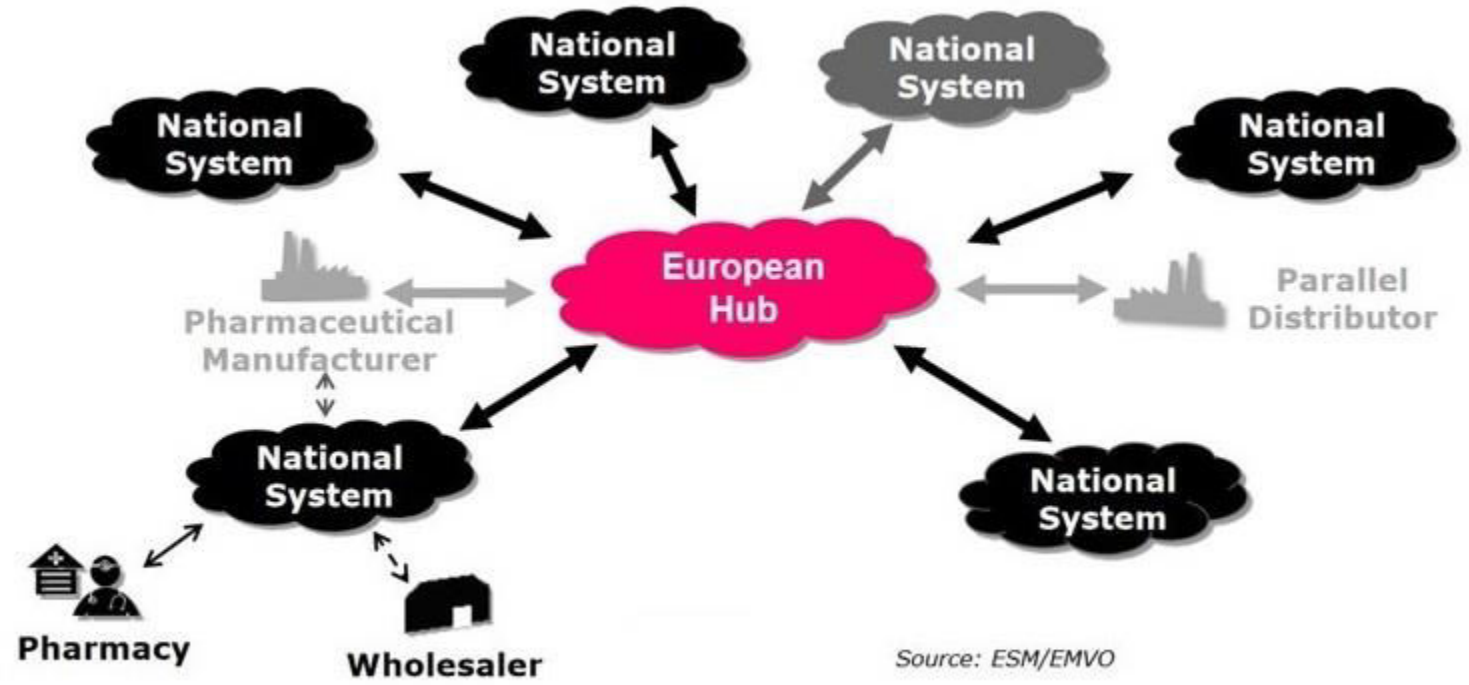


Commission Delegated Regulation (EU) 2016/161

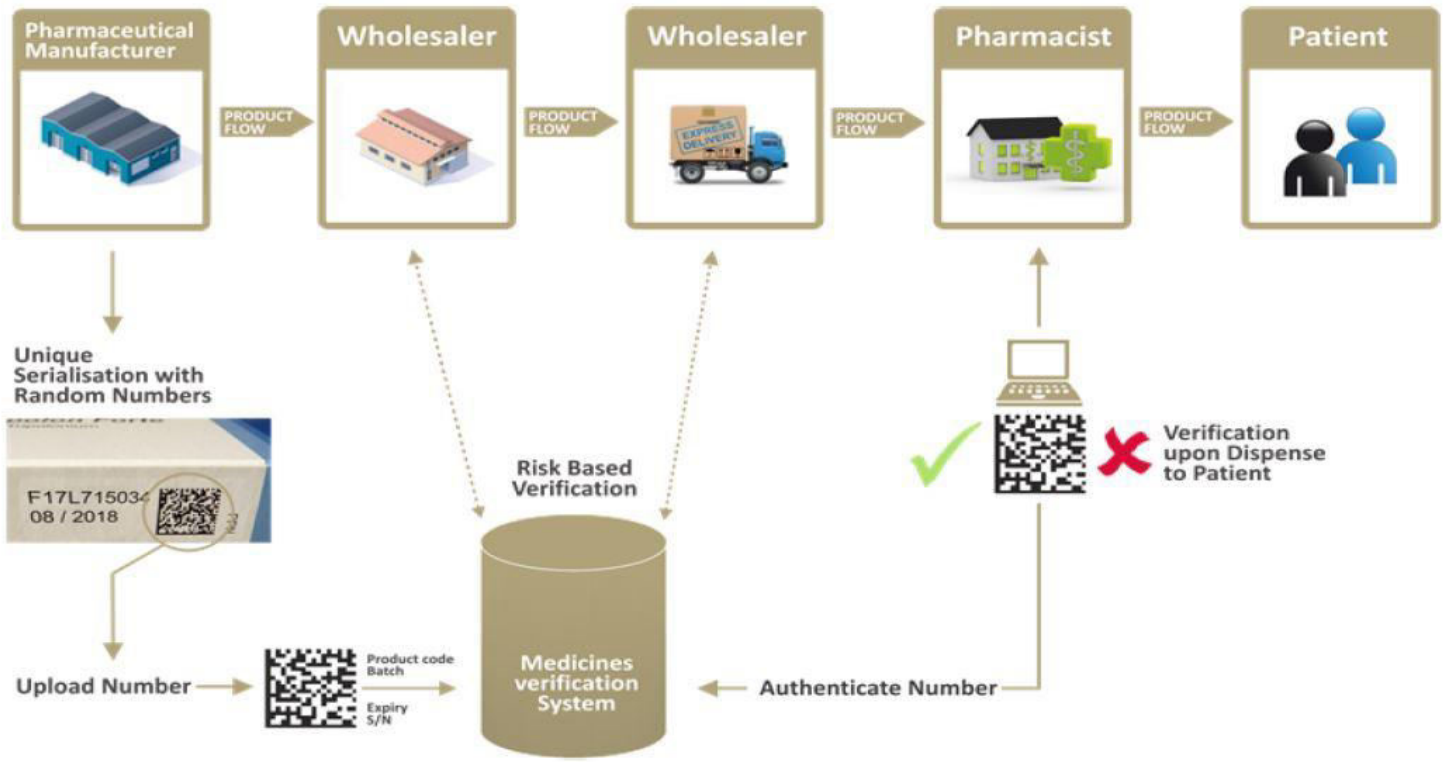
- Details the characteristics of the safety features, how medicine authenticity should be verified and by whom.
- Establishment, management, structure and accessibility of the repositories system.
- Adopted on 2 October 2015, apply as of 9th February 2019.

System structure



Point-of-dispense verification

- End-to-end ≠ full track and trace



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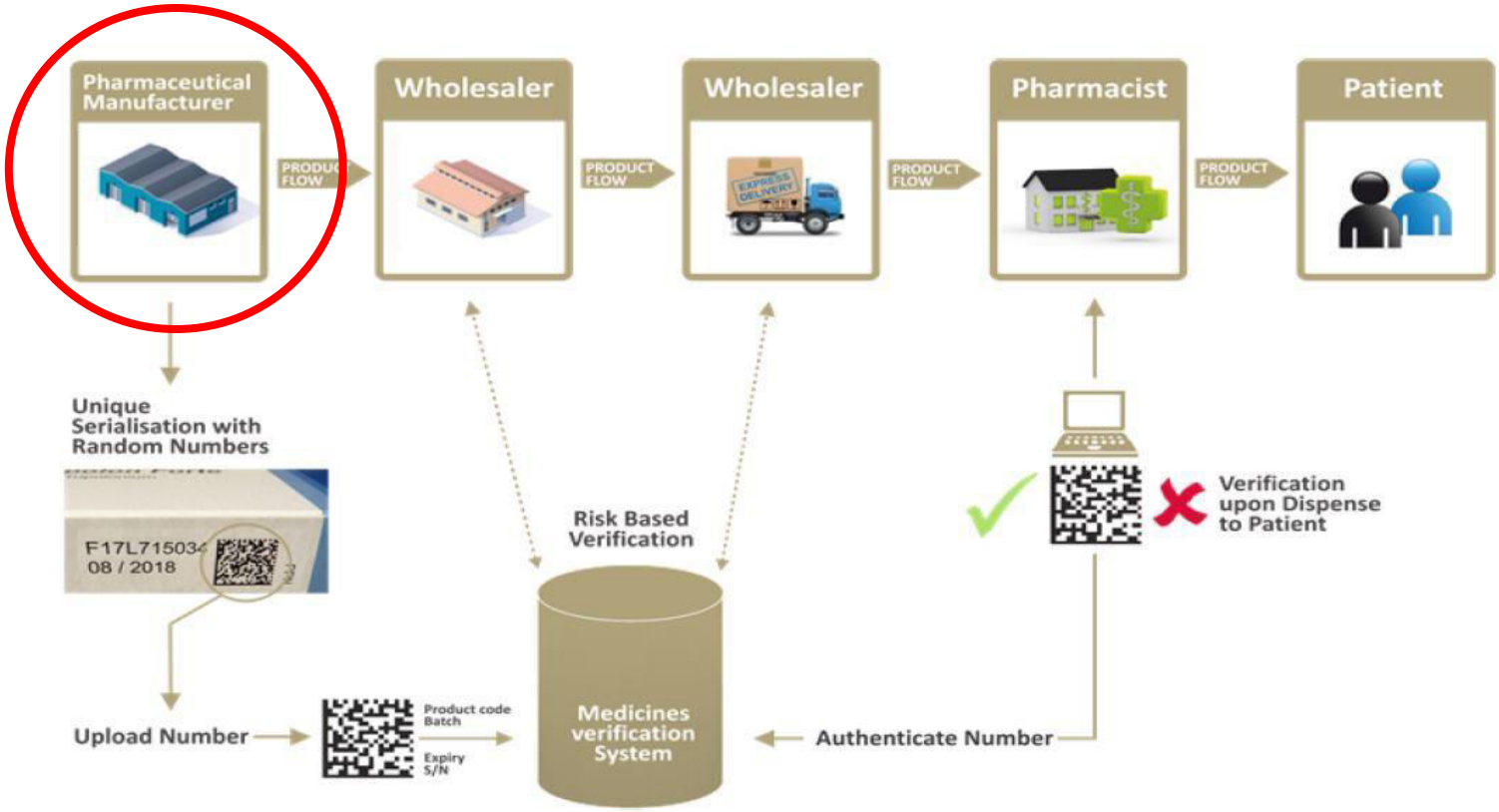

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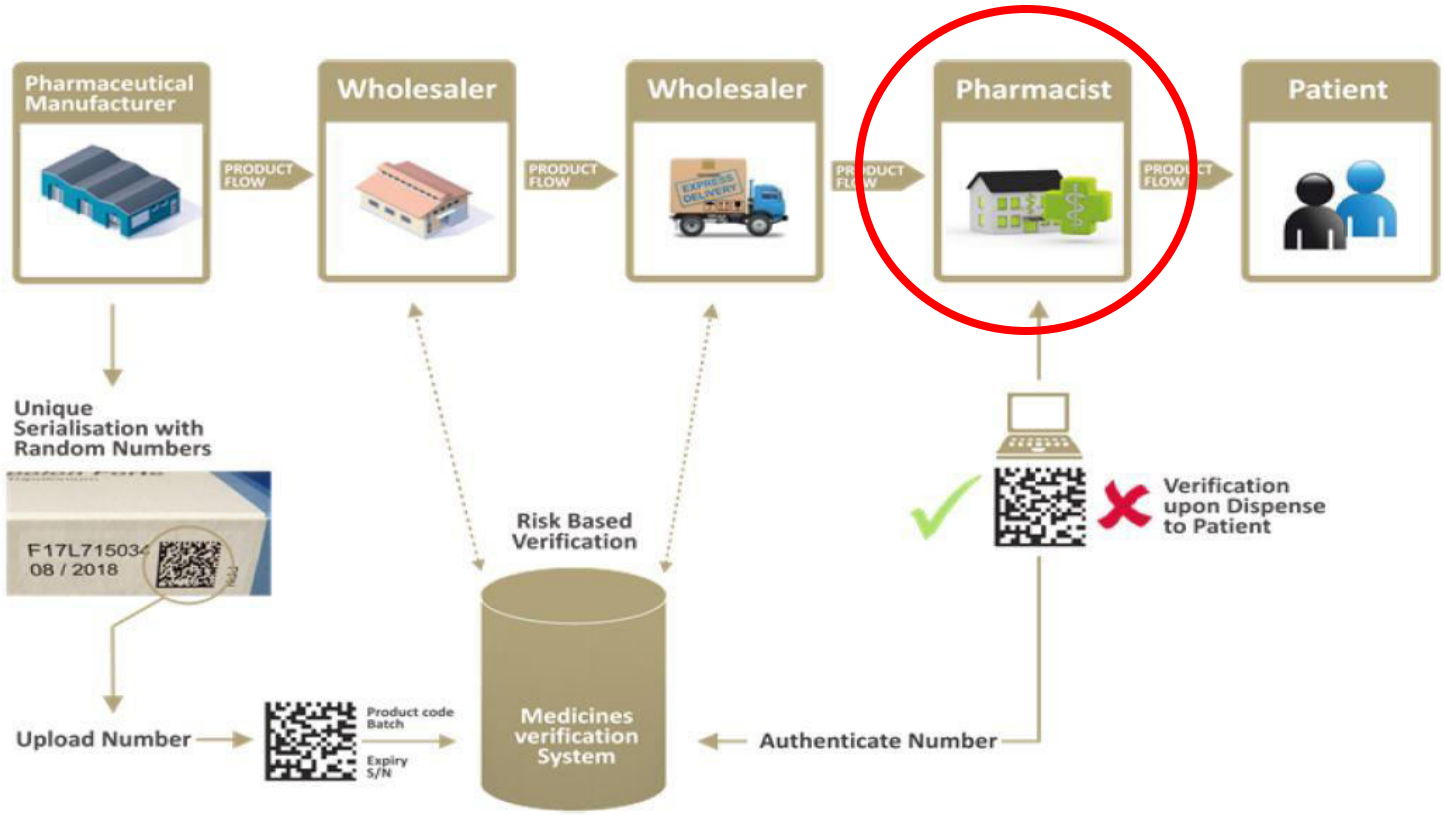

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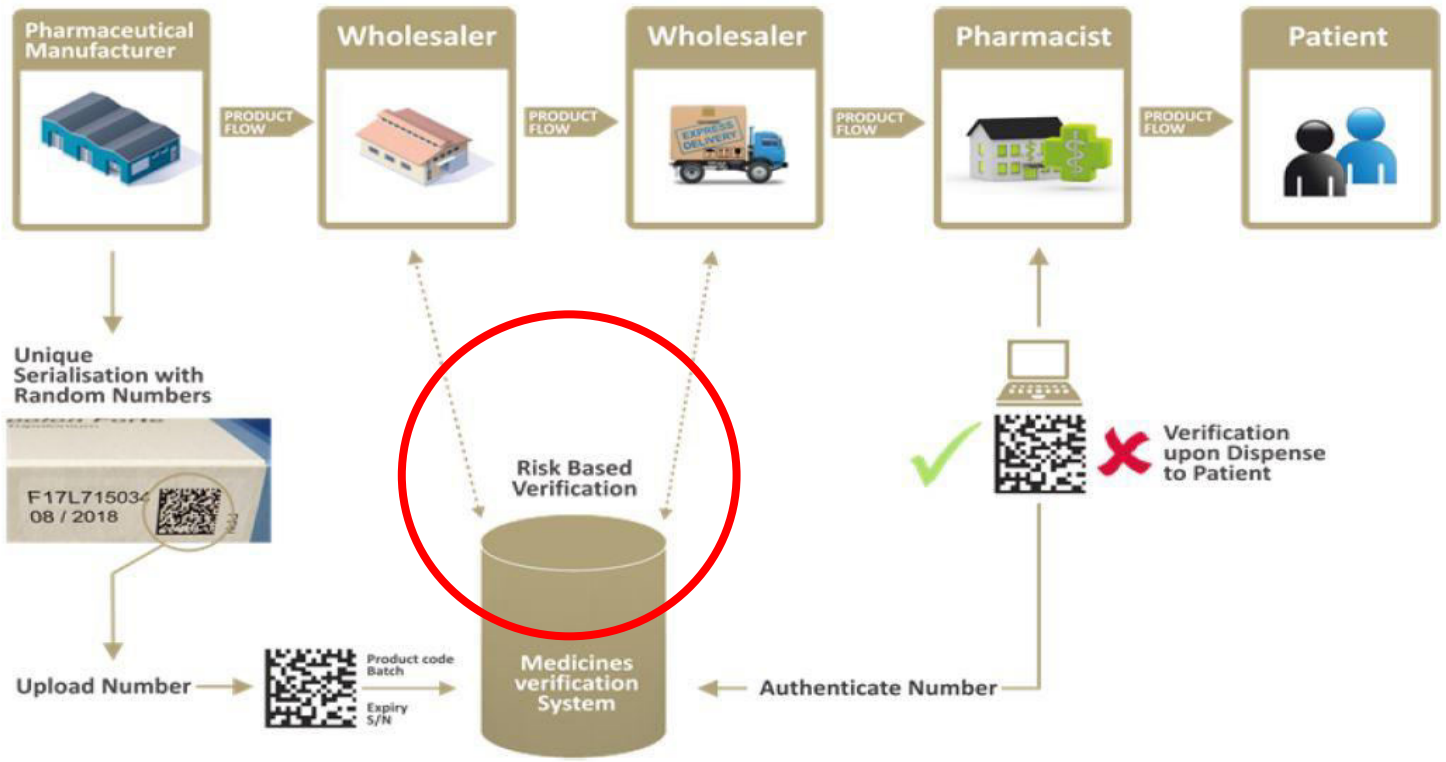
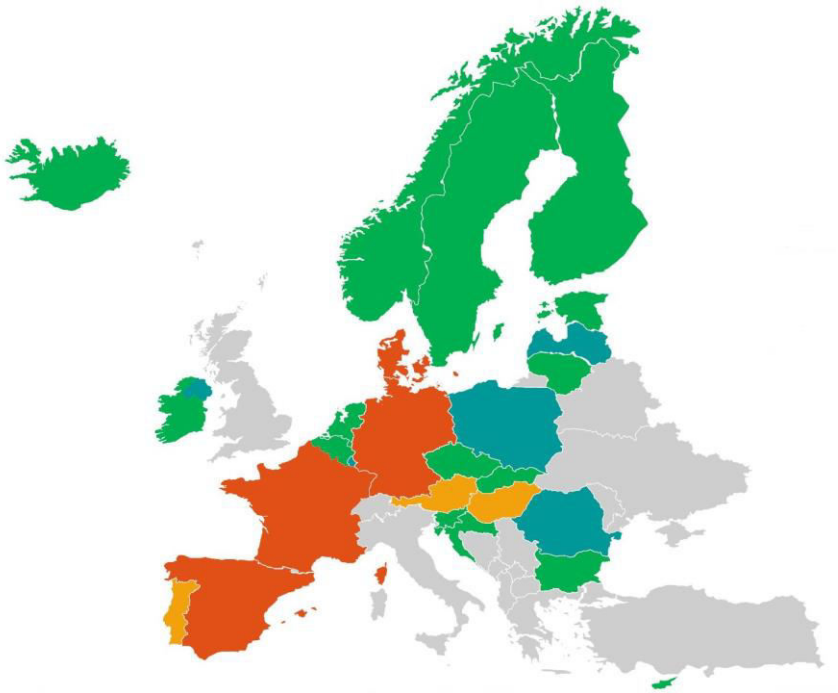
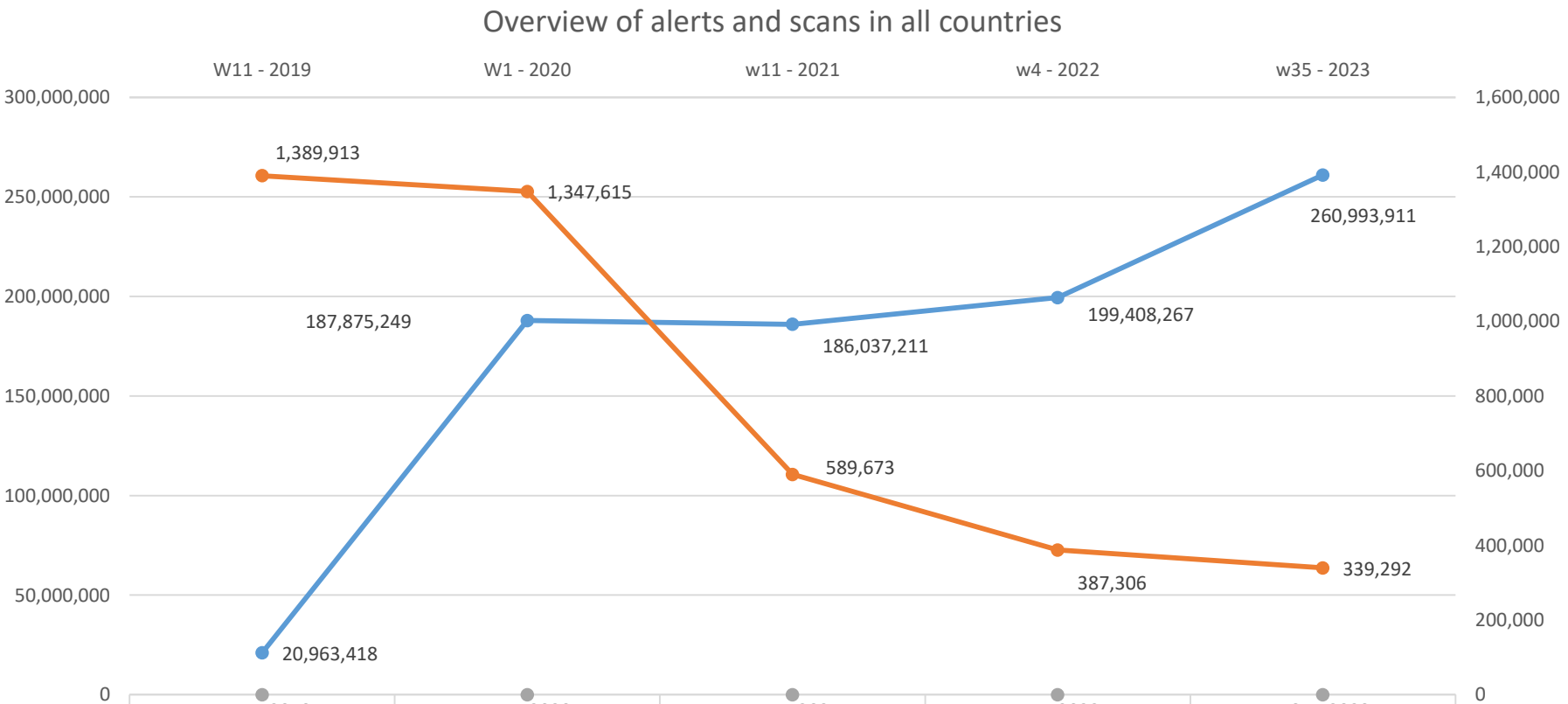


Implementation



- Start - 9th February 2019
- Need for „stabilization periods“
- Stabilization periods prevented disruptions in the supply chain, but prolonged implementation phase.
- Ending the stabilization means that pack that triggered an alert must not be supplied and every alert has to be fully investigated.

Implementation



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Scans	20,963,418	187,875,249	186,037,211	199,408,267	260,993,911
Aletrts	1,389,913	1,347,615	589,673	387,306	339,292
%	6.63%	0.72%	0.32%	0.19%	0.13%

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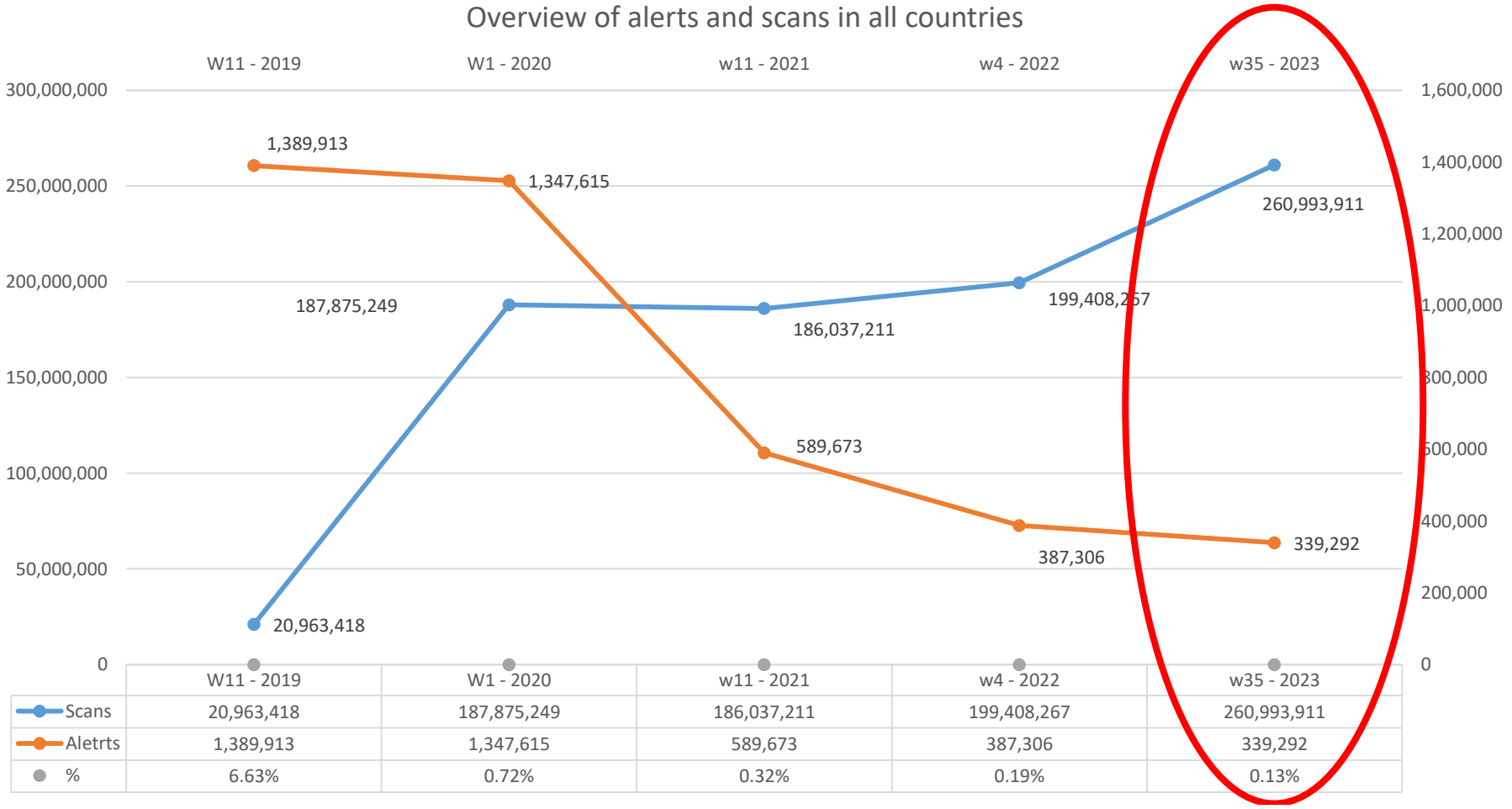

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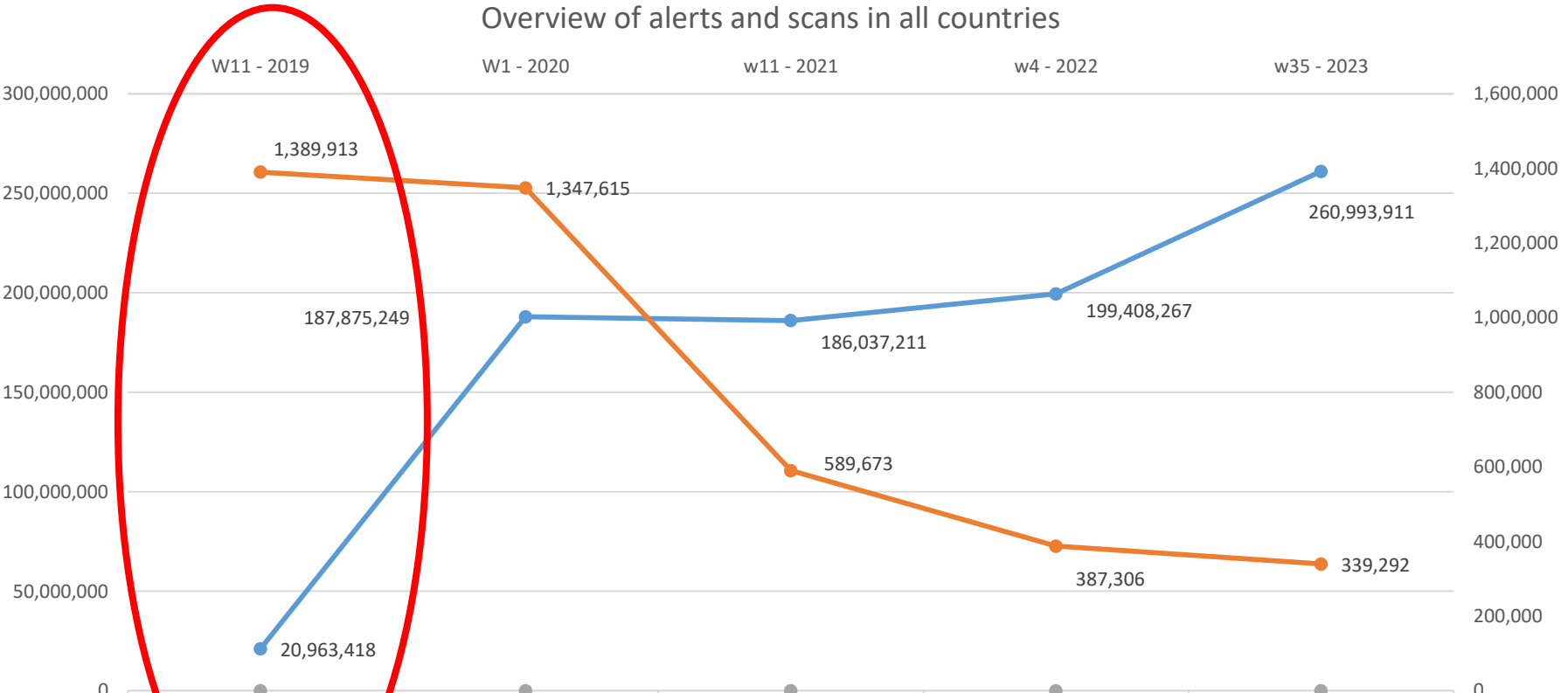

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State of play – current data SI

1.000.000 scans per week.

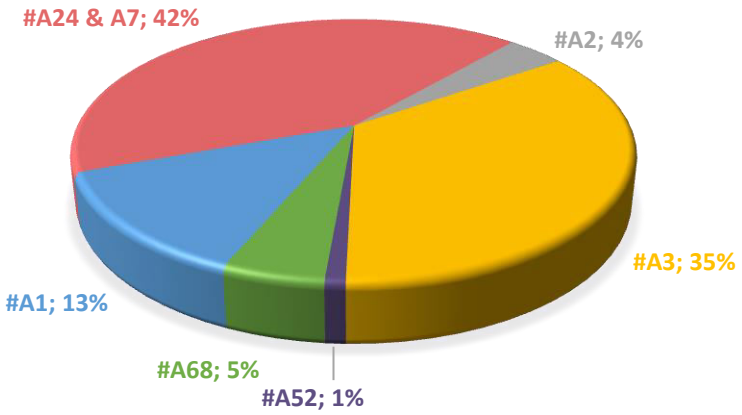
130 relevant alerts per week.

Frequent alert types:

#A24 & A7 - Attempt to decommission an already decommissioned pack

#A2 - Bach ID unknown & #A3 - unknown serial number

#A1 - Product code unknown



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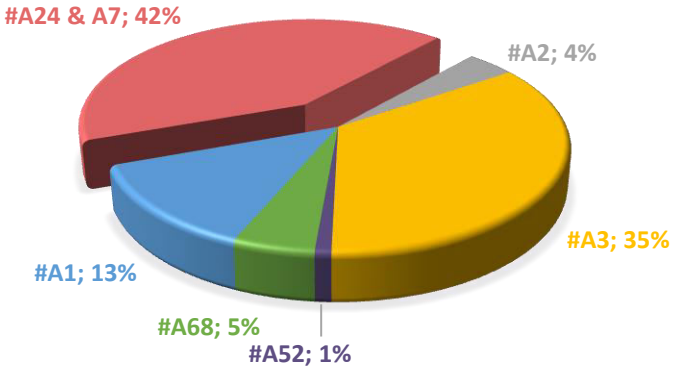

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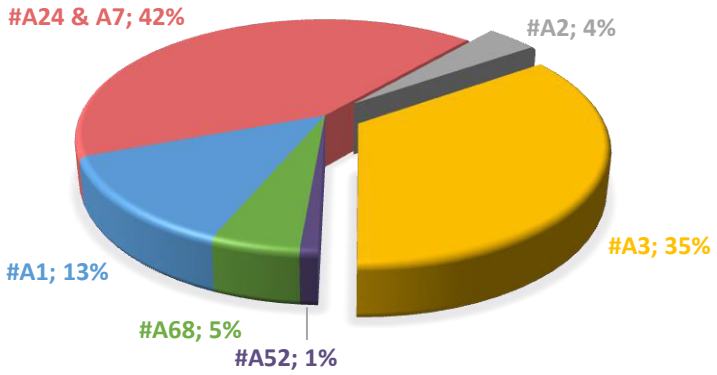

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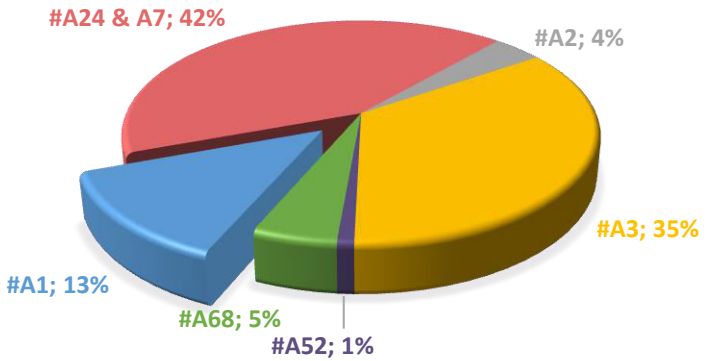


Benefits

How many falsified packs have been found so far?

Benefits

Quality defect:

- A parallel trader noticed a leak inside a blister.
- The packaging was sent back to be destroyed but was accidently shipped to pharmacy.
- #A24 & A7 alert was triggered - Attempt to decommission an already decommissioned pack.
- The system prevented supply.

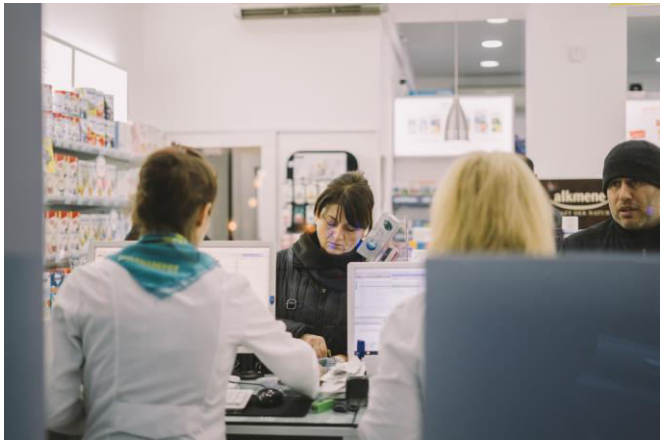
Benefits

Returns of medicines by patients:

- #A24 & A7 alert is triggered - Attempt to decommission an already decommissioned pack.

- Pharmacy response:

  „By mistake, we almost released boxes that were intended for destruction. There was mistake in the handling and stacking of medicines. Human error in tidying up, the pack was put on the shelf instead in the box for waste medicines. ***The system prevented the supply.****“*



Benefits

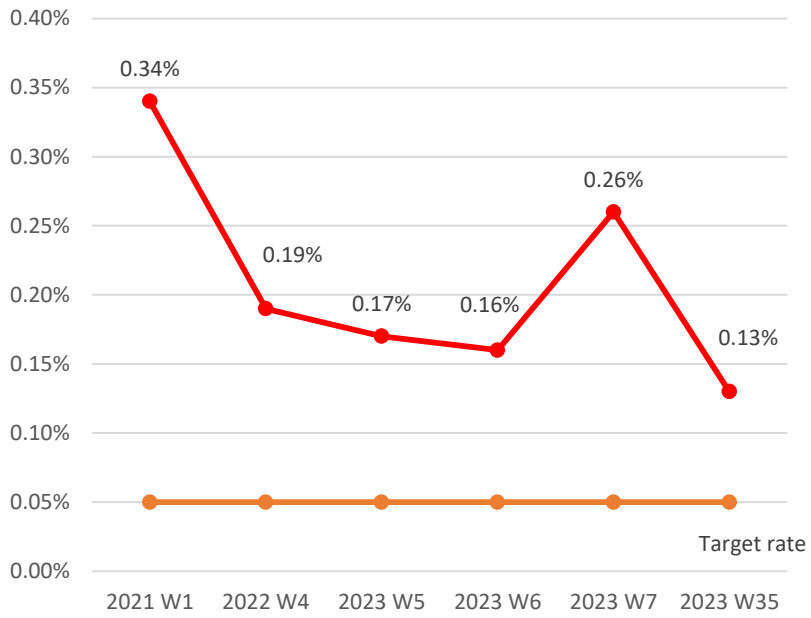
Importance of an ATD:

- Theft of the medicinal product.
- An alert was not triggered.
- ATD just on the top of the pack.
- Medicines could be replaced with falsified ones.

Next steps?

Eliminate technical alerts

- Number of false alerts too high.
- EMVO target rate: less than 0,05%.
- Not all issues are complex.
- We must fix the causes of false alerts and not just silence them.



Improve compliance rate

Inspection of SI pharmacies:

- Overall compliance of pharmacies is good.
- Deviations were noticed with specific medicines.
- Verification rate should be 100%.

Deactivated	Supplied	%	Medicinal product
524	539	97,2	Plivit D3 4000 i.e./ml peroralne kapljice
99	183	54,1	Asentra 50 mg film. obložene tabl.
643	649	99,1	Nalgesin forte 550 mg film. obložene tabl.
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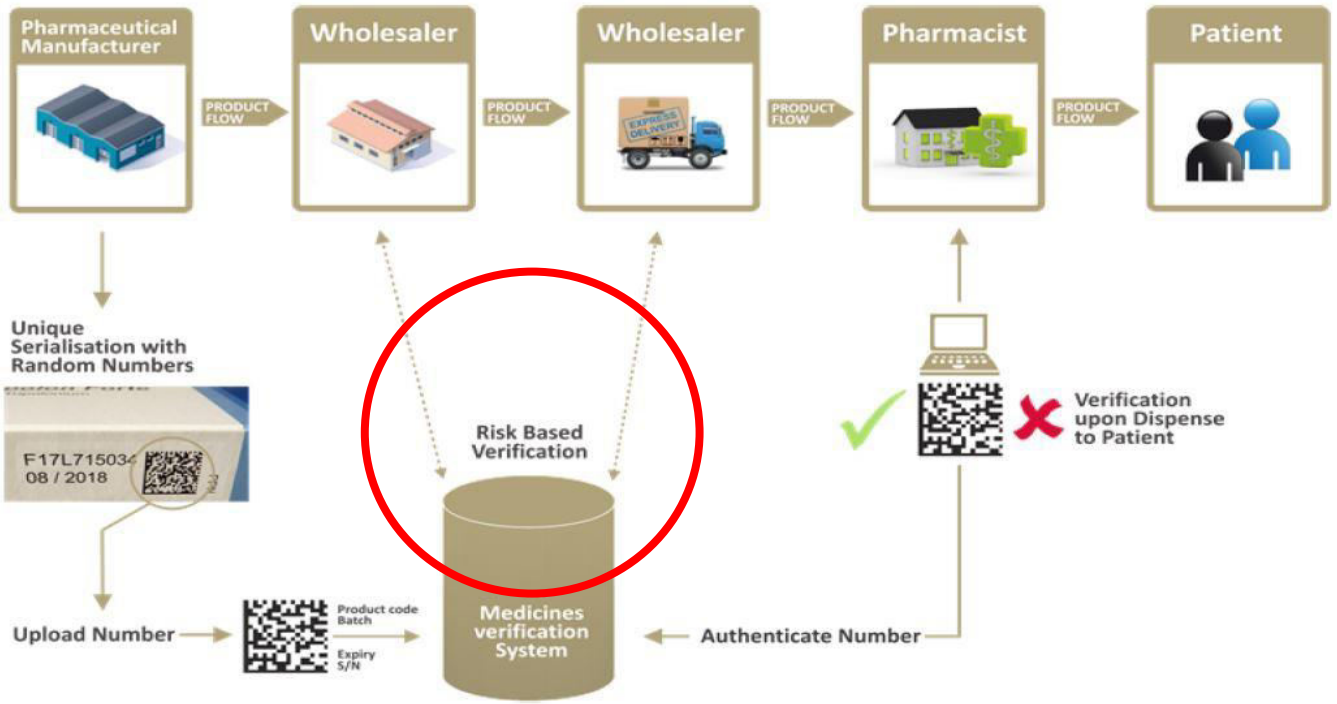
Transition to full track and trace?

Report Details				
Operation	**Date/Time (UTC)**	**Entity Location ID**	**Entity Location Name**	**Entity Location Address**
UPLOAD	18/08/2021 08:18:38	EU:[redacted]	GlaxoSmithKline [redacted]	[redacted] EU,
DECOMMISSION (SUPPLIED)	19/02/2022 09:27:13	SI:0f31ba9f-[redacted]	Lekarna [redacted]	[redacted] Ljubljana, 1000, SI



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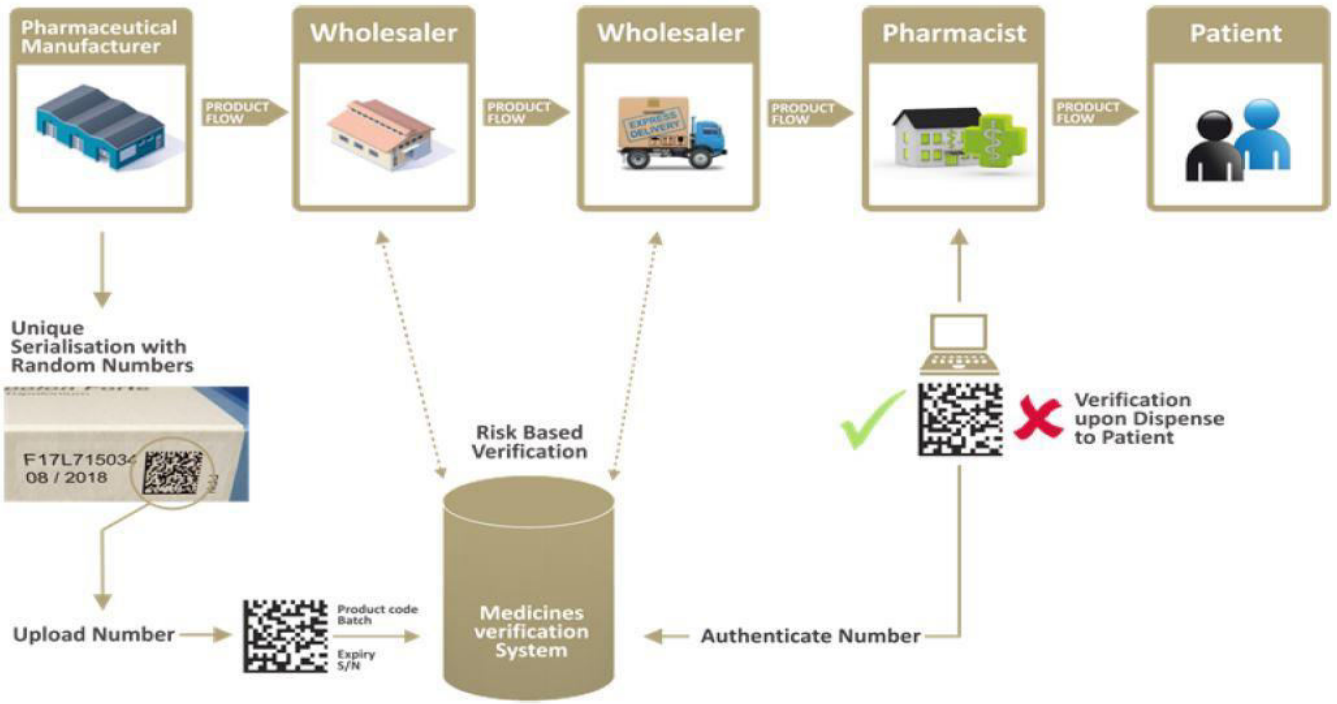
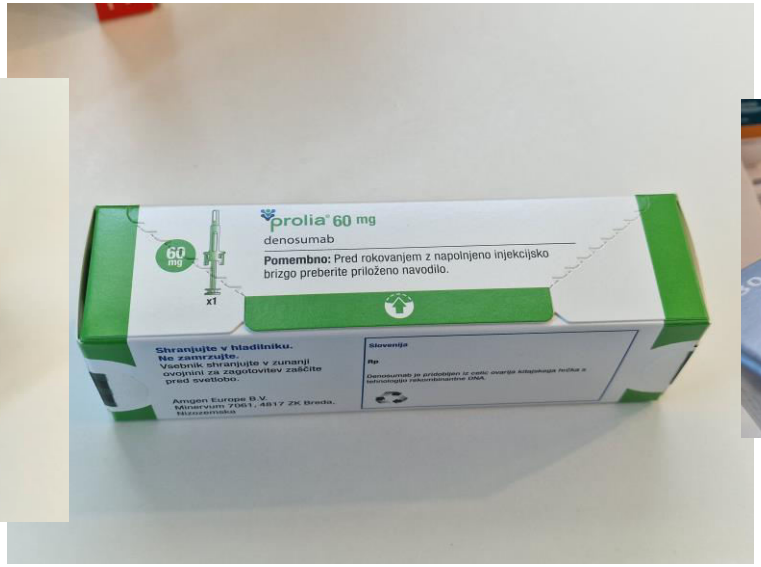


We should not neglect ATD!



We should not neglect ATD!

- No mandatory rules on ATD design.
- ISO 21976:2018; Packaging — Tamper verification features for medicinal product packaging.

EMVS opportunities?

Could the system be used for monitoring of shortages?

Article 39

Access by national competent authorities

A legal entity establishing and managing a repository used to verify the authenticity of or decommission the unique identifiers of medicinal products placed on the market in a Member State shall grant access to that repository and to the information contained therein, to competent authorities of that Member State for the following purposes:

(a) supervising the functioning of the repositories and investigating potential incidents of falsification;

(b) reimbursement;

(c) pharmacovigilance or pharmacoepidemiology.

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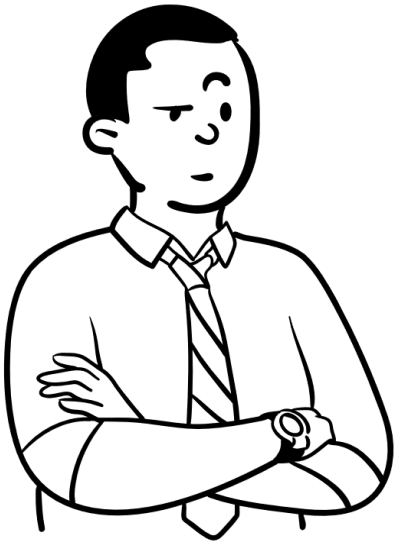

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Sektor za splošne zadeve */ General Affairs Division*

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