

National Blueprint System Romania Kick-Off Meeting

Bucharest
Feb 9, 2018

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Agenda

Introduction

Falsified Medicines
Directive & Delegated
Act

Project Challenges

Planning

High-level overview of
the project plan

Technical Overview for Software Suppliers

Presentation of NMVS
web services

Software Supplier Onboarding

Onboarding procedure
for Software Suppliers

Next Steps, Q&A

Next project steps

Questions and Answers

We have to master one central challenge (1)

- **Many stakeholders are involved**

a) Organisers

- OSMO
- EMVO (Europ. Med. Verification Org.)

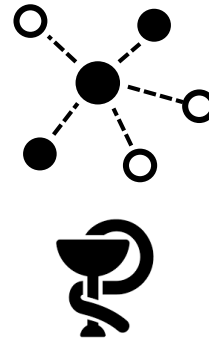


b) Authorities



c) Primary distributors

- Manufacturers
- Marketing authorization holders
- Wholesalers
- Parallel distributors
- Public pharmacies
- Hospital pharmacies



c1) Secondary distributors

- Army
- Prisons
- Airlines
- Nursing homes
- Drug treatment centers
- NGOs
- ...



d) Software providers

- Solidsoft (EMVS/EU Hub)
- Arvato
- Pharmacy/hospital/wholesaler
SW providers/IT departments

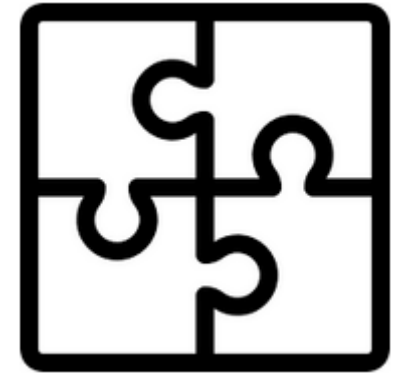


We have to master one central challenge (2)

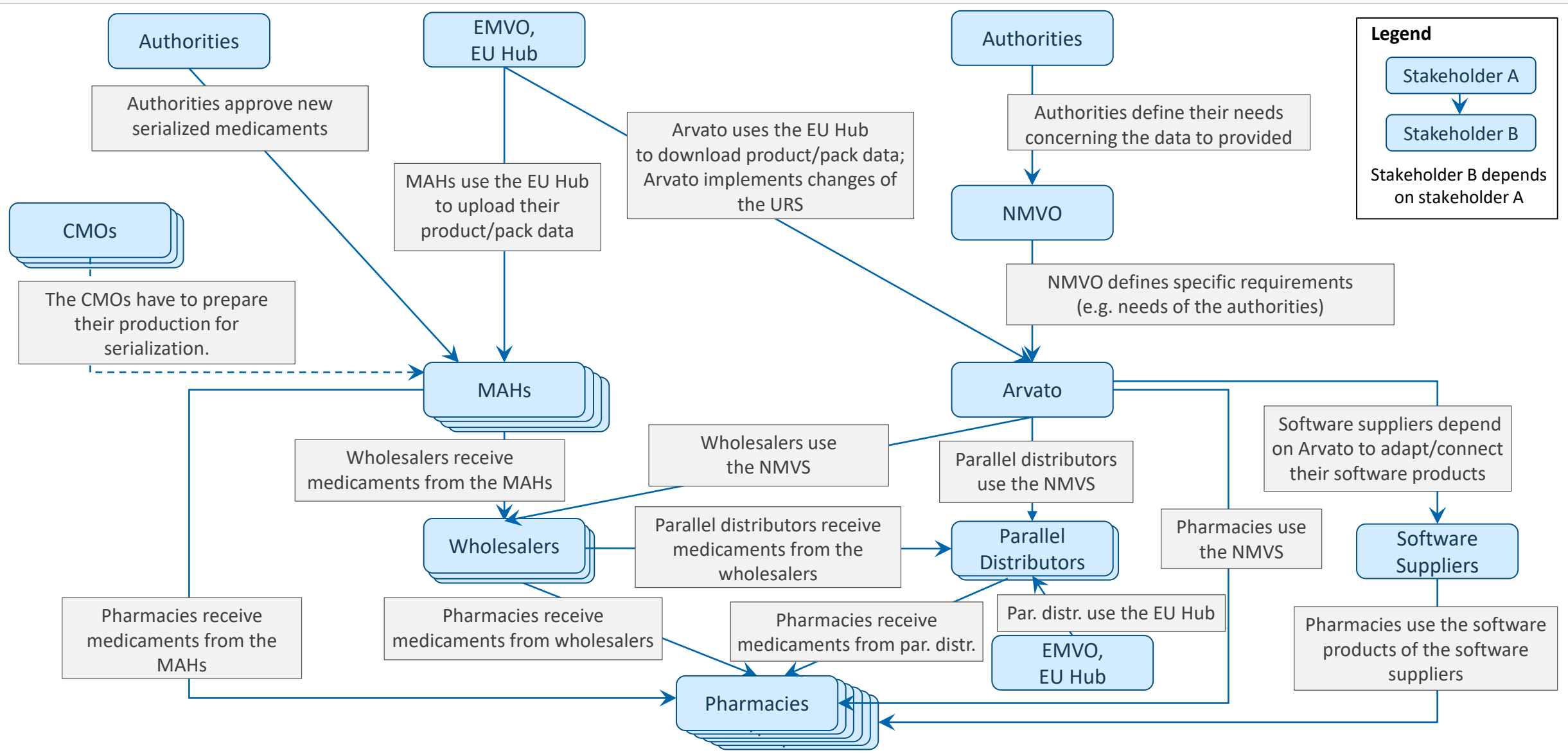
- **Organise Cooperation**

- The stakeholders must learn to act together in a new context.
- New overarching processes must be established.
- Stakeholders are depending on each other,
i.e. delays and errors will propagate and accumulate downstream.

=> Let's have a (very) short look at which dependencies exist.



An ecosystem of stakeholders must learn to cooperate smoothly



Dependencies have significant effects - Example

What is the delay for a new serialized medicament to make its way from the manufacturer to the patient?



Our experience in Germany: >100 days

What exactly needs to be done? (1)



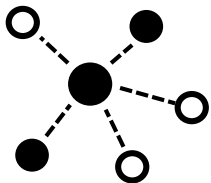
- **Manufacturers have to ...**

- ... introduce pack serialisation: package design, regulatory approval, production preparation, production start)



- **Marketing Authorisation Holders (MAHs) have to ...**

- ... adapt their IT systems to handle serialised products
- ... to connect with the EU-Hub and start uploading product and pack data
- ... manage the necessary data that is required for the serialisation process



- **Pharmacies and Wholesalers have to ...**

- ... align with their software suppliers
- ... introduce upgraded IT systems for scanning of 2D data matrix codes
- ... onboard to the NMVS system (certificates, access rights, etc.)
- ... train their employees
- ... adapt their daily business processes
- ... wait for serialized packs to propagate through the supply chain
- ... manage detected falsifications including false positives



What exactly needs to be done? (2)



- **Software suppliers have to ...**

- ... understand the NMVS web service interface and specify the required changes to their software products
- ... adapt their IT systems to handle serialized products
- ... implement and test the specified changes to their software products
- ... coordinate the rollout of their new software product releases to the pharmacies



- **Romanian authorities have to ...**

- ... clarify as soon as possible, together with the all the stakeholders, the necessary national implementation rules
- ... manage cases of suspected falsification



- **OSMR has to ...**

- ... keep an overview of all the stakeholders involved and their respective progress in the project
- ... align with the Romanian authorities
- ... establish an internal QMS system and have it approved by EMVO
- ... formally validate the NMVS

What exactly needs to be done? (3)



- **The EMVO has to**

- ... manage >2,000 pharmaceutical companies („Onboarding Partners“, OBPs) from all over Europe through which MAHs upload their data to the EU Hub
- ... check and approve National Medicine Verification Systems from 29 countries
- ... specify further requirements (e.g. aggregation, MAH IDs)



- **The EU Hub has to ...**

- ... handle transactions from multiple countries
- ... handle multi-market products/transactions
- ... handle inter-market transactions

Many interwoven processes cause a high overall complexity.
The ecosystem as a whole needs sufficient time to settle down.

There is no time to waste until go live.
All stakeholders need to be aware of that.



365 days until Feb 9, 2019

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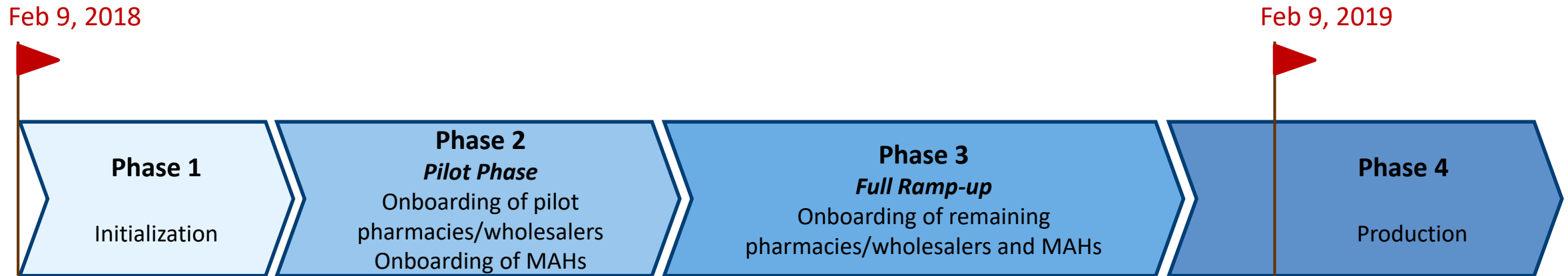
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Time Planning, High Level Perspective

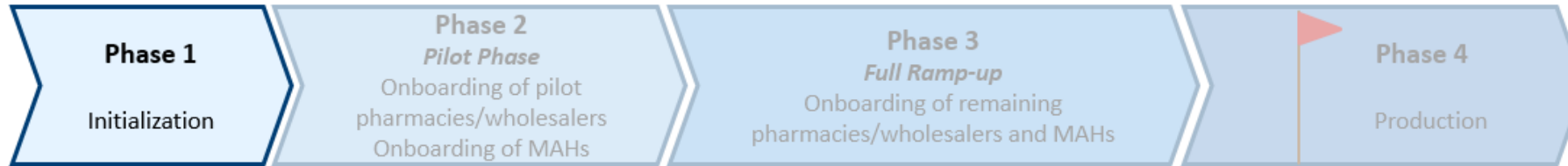
- There are exactly 12 months left until medicine verification becomes mandatory in Europe
- This is our plan to finish the project within the available time frame:



- What are the activities in each phase? Let's go through each phase.

Planning, Detail View

Phase 1: Initialization

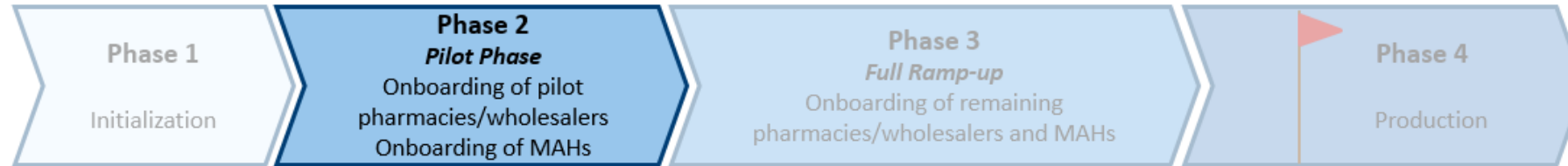


Inform stakeholders & setup infrastructure

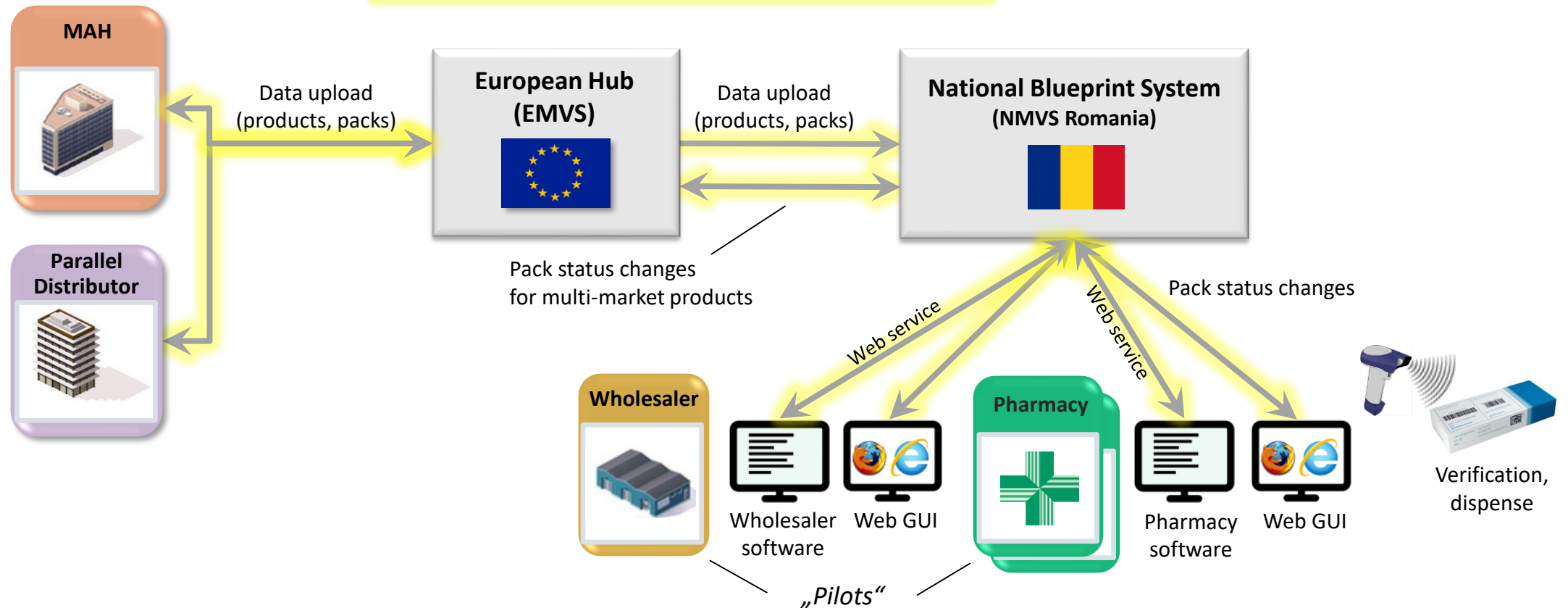
- Clarify the national implementation rules
- Identify and inform pharmacies, hospitals, and wholesalers
- Enable software suppliers to start developing
- Set up infrastructure
 - Install servers for test and production
 - Deploy software
 - Perform user acceptance tests and end-to-end tests

Planning, Detail View

Phase 2: Pilot Phase

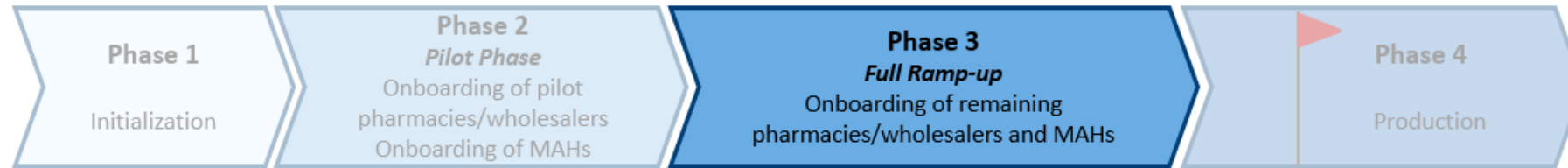


Test data flows end-to-end:

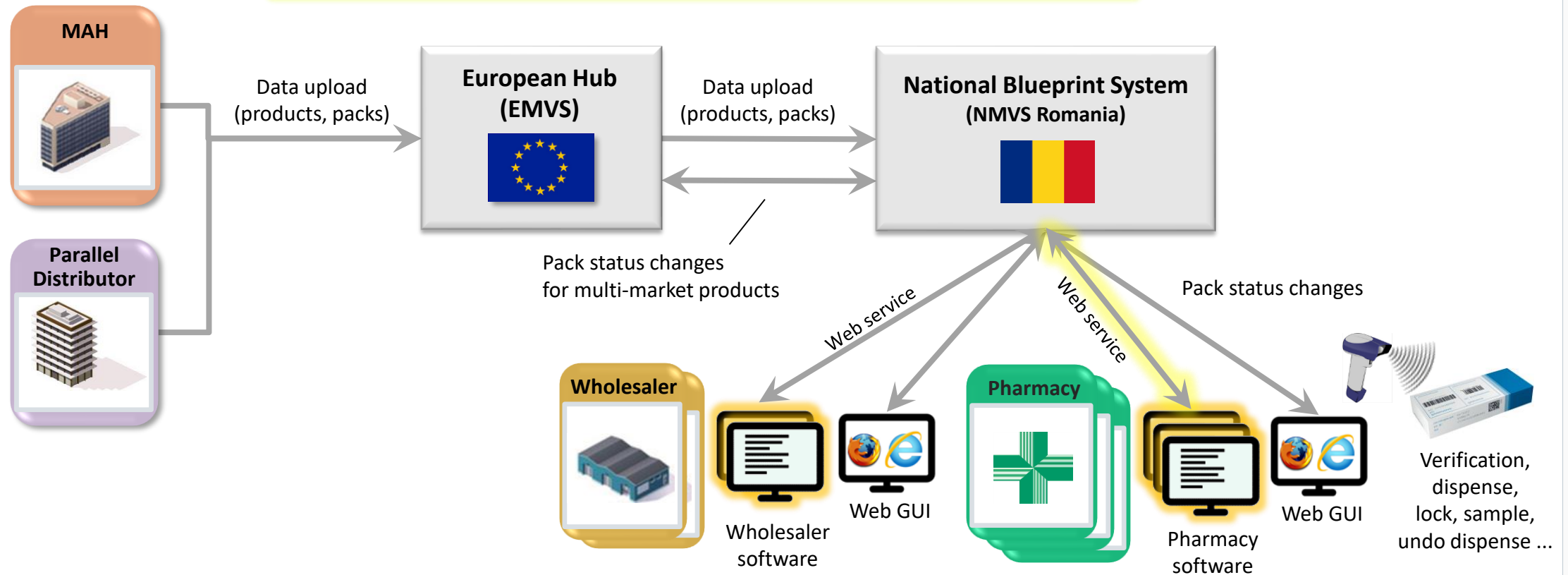


Planning, Detail View

Phase 3: Full Ramp-up

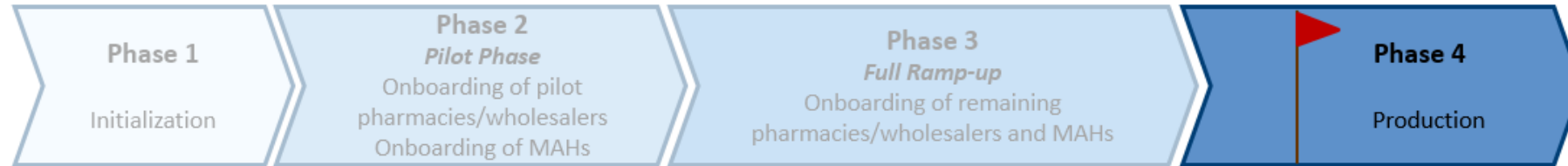


Establish pharmacy and wholesaler software:



Planning, Detail View

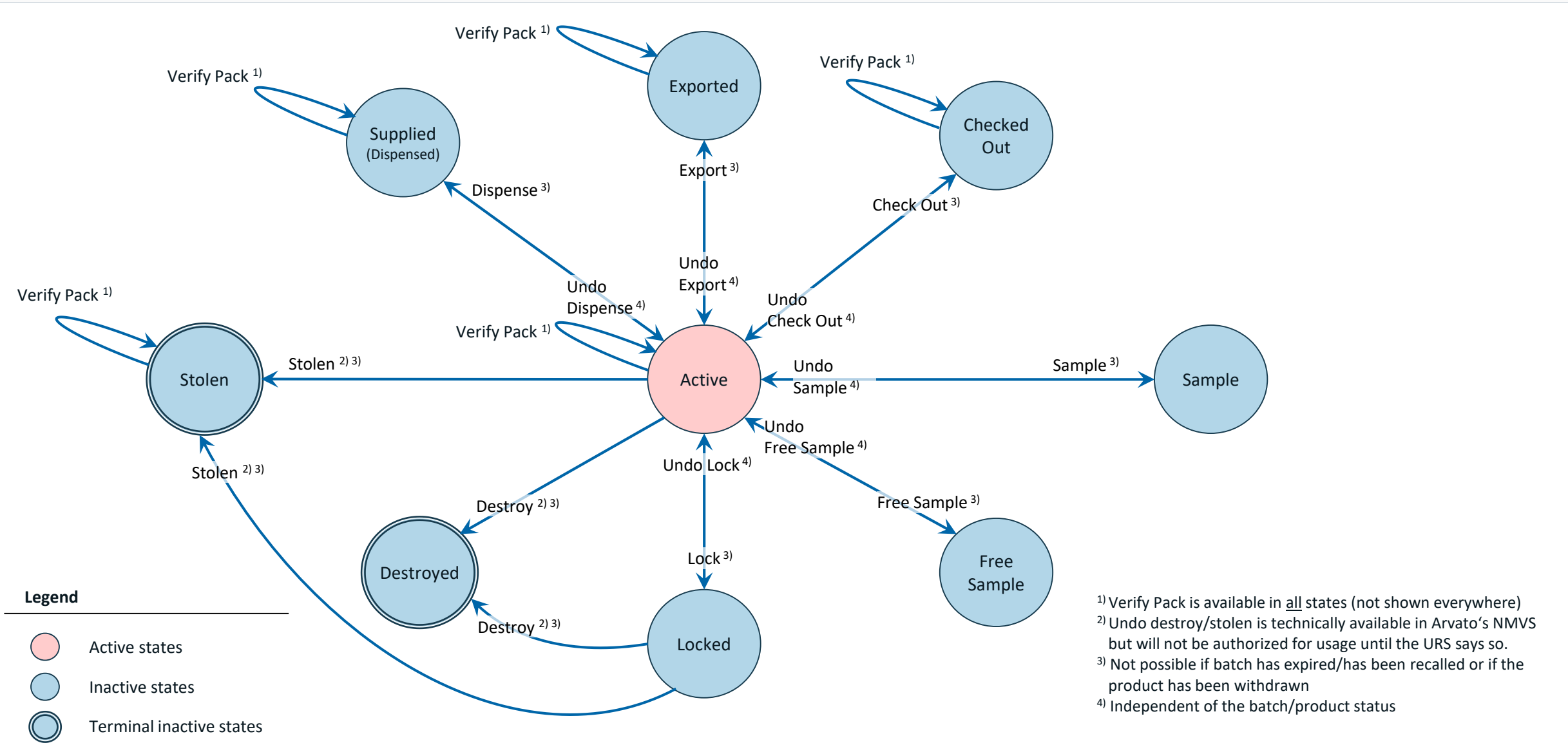
Phase 4: Production



Enter productive phase *before Feb 9, 2019*

- Onboard late-coming stakeholders
- Start using the system on the national level
- Fix issues within the ecosystem, e.g. communication problem between IT systems
- Start to report and follow up suspected falsifications

Pack Status Transitions



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Transaction Types, Overview

Transaction Type	Pharmacy ¹⁾	Wholesaler ¹⁾
<i>Verification</i>	X	X
<i>Dispense</i>	X	X
<i>Destroy</i>	X	X
<i>Export</i>		X
<i>Sample, for authorities/sample archives</i>	X	X
<i>Free sample, for healthcare professionals</i>		X
<i>Lock</i>		X
<i>Stolen</i>		X

¹⁾ X = Transaction authorized, including hospital pharmacies

Source: EMVO, URS EMVO_0015 European Medicines Verification System: Requirements Specification Part II, version 2016-10-20

Web Service Group – Single Pack Transactions (1)

Web Service Id	Web Service Name/Description
G110	Verify Single Pack Verify a single pack. This does not change the status of the pack.
G120	Dispense Single Pack Dispense a single pack using a scanner. All data matrix fields will be submitted (incl. product number, batch number, expiry date).
G122	Dispense Single Pack Manual Entry Dispense a single pack with manual data entry. Only the product number and the serial number will be submitted.
G130	Destroy Single Pack Report a single pack as destroyed.
G140	Export Single Pack Report a single pack as exported.
G150	Sample Single Pack Report that a single pack has been provided to authorities for sampling purposes.
G160	Free Sample Single Pack Report that a single pack has been given away as a free sample.
G170	Lock Single Pack Report that a single pack has been locked, e.g. to provide time for further investigations.

Web Service Group –Single Pack Transactions (2)

Web Service Id	Web Service Name/Description
G180	Stolen Single Pack Report that a single pack has been stolen. Assumption: The data matrix content is still available (e.g. pack has been emptied or data from an earlier pack scan are still available).
G182	Stolen Single Pack Manual Entry Report that a single pack has been stolen, with manual data entry. Assumption: The product number and the serial number is still available (e.g. from an earlier scan).

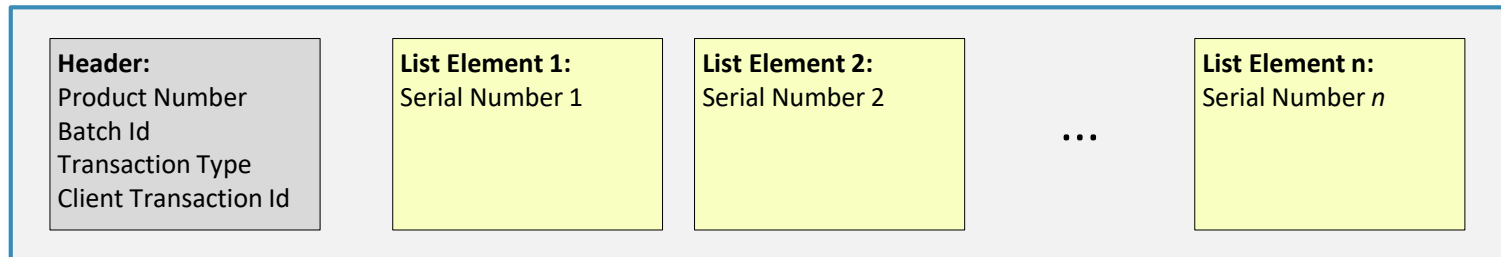
Web Service Group – Undo Single Pack Transaction

Web Service Id	Web Service Name/Description
G121	Undo Dispense Single Pack Reverse the effect of a previous <i>dispense</i> transaction (G110 or G120).
G131	Undo Destroy Single Pack ¹⁾ Reverse the effect of a previous <i>destroy</i> transaction.
G141	Undo Export Single Pack Reverse the effect of a previous <i>export</i> transaction.
G151	Undo Sample Single Pack Reverse the effect of a previous <i>sample</i> transaction.
G161	Undo Free Sample Single Pack Reverse the effect of a previous <i>free sample</i> transaction.
G171	Undo Lock Single Pack Unlock a previously locked pack.
G181	Undo Stolen Single Pack ¹⁾ Reverse the effect of a previous <i>stolen</i> transaction (G180 or G182).

¹⁾ Technically possible but currently not permitted by URS

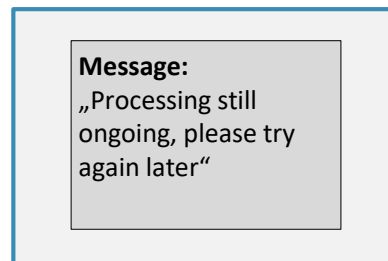
Bulk Transactions – Function Principle

Submit a list of homogeneous single pack requests as one bulk request (wholesalers only):

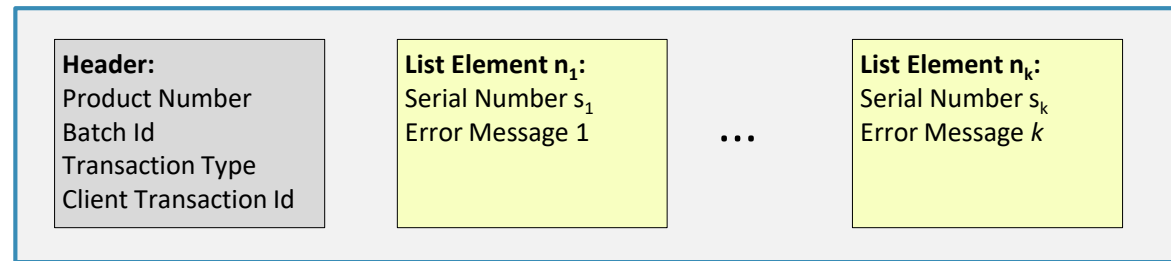


Request the result of the bulk request, two possible results:

a) Ongoing processing



b) Processing finished (only errors are returned):



Web Service Group – Bulk Transactions (1)

Web Service Id	Web Service Name/Description
G115	Bulk Verify packs Submit a list of serial numbers (same product and batch) for verification.
G125	Bulk Dispense packs Submit a list of serial numbers (same product and batch) to report the corresponding packs as <i>dispensed</i> .
G135	Bulk Destroy packs Submit a list of serial numbers (same product) to report the corresponding packs as <i>destroyed</i> .
G145	Bulk Export packs Submit a list of serial numbers (same product) to report the corresponding packs as <i>exported</i> .
G155	Bulk Sample packs Submit a list of serial numbers (same product) to report that the corresponding packs have been provided to authorities for sampling purposes.
G165	Bulk Free sample packs Submit a list of serial numbers (same product) to report that the corresponding packs have been given away as free samples.
G175	Bulk Lock packs Submit a list of serial numbers (same product) to report the corresponding packs as <i>locked</i> .
G185	Bulk Stolen packs Submit a list of serial numbers (same product) to report the corresponding packs as <i>stolen</i> .

Web Service Group – Bulk Transactions (2)

Web Service Id	Web Service Name/Description
G127	Bulk Undo Dispense packs Submit a list of serial numbers (same product) for which the effects of a previous <i>dispense</i> transaction shall be undone.
G137	Bulk Undo Destroy Packs ¹⁾
G147	Bulk Undo Export Packs
G157	Bulk Undo Sample Packs
G167	Bulk Undo Free Sample Packs
G177	Bulk Undo Lock Packs
G187	Bulk Undo Stolen Packs ¹⁾

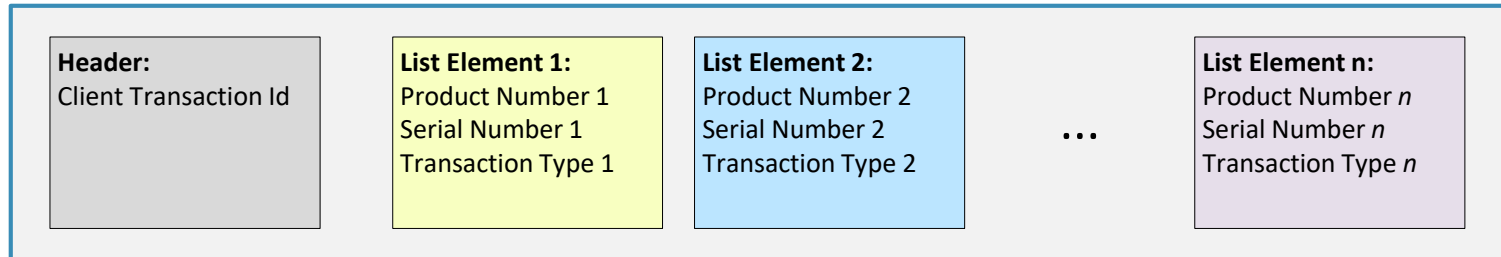
¹⁾ Technically possible but currently not permitted by URS

Web Service Group – Request Bulk Transaction Results

Web Service Id	Web Service Name/Description
G116	Bulk Verify Packs Result Fetch the result of a previously submitted <i>bulk verify</i> transaction
G188	Request Bulk Pack Operation Result Fetch the result of a previously submitted bulk transaction other than <i>bulk verify</i> .

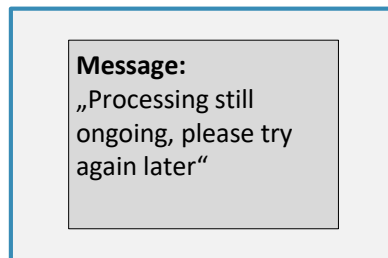
Mixed Bulk Transactions – Function Principle

Submit a list of mixed single pack requests as one bulk request (pharmacies only):

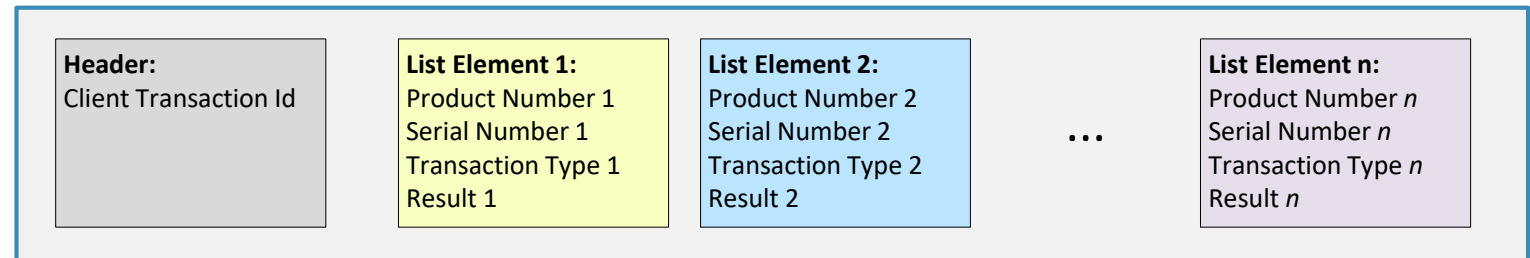


Request the result of the bulk request, two possible results:

a) Ongoing processing



b) Processing finished:



Web Service Group – Mixed Bulk Transactions

Web Service Id	Web Service Name/Description
G195	Mixed Bulk Transaction ¹⁾ A mixed bulk transaction contains multiple single transactions with heterogeneous products and transaction types. As an example, it is generated by a pharmacy when the local transaction buffer is emptied after an offline period.

¹⁾ Only such transaction types are allowed within mixed bulk transactions which are permitted as single transactions for a user.

Web Service Group – Request Mixed Bulk Transaction Results

Web Service Id	Web Service Name/Description
G196	Request Mixed Bulk Transaction Result Request the result of a previously submitted <i>mixed bulk transaction</i> .

Web Service Group – Request Pending Bulk Transaction IDs

Web Service Id	Web Service Name/Description
G199	Request Pending Bulk Transaction IDs Request a list of transaction ids of the bulk transactions which are still pending at the time of the request. If such ids have been lost for some reason, this web service recovers all bulk transaction ids whose results have not been fetched yet.

Web Service Group – Others

Web Service Id	Web Service Name/Description
G445	Change Password Change the password of the current end user
G615	Download certificate Down a new certificate for the current user

Available as of Nov 2018:

Web Service Id	Web Service Name/Description
G101	Download Product Master Data Request a list of master data of all verifiable products currently registered in the NMVS database

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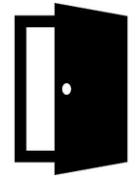
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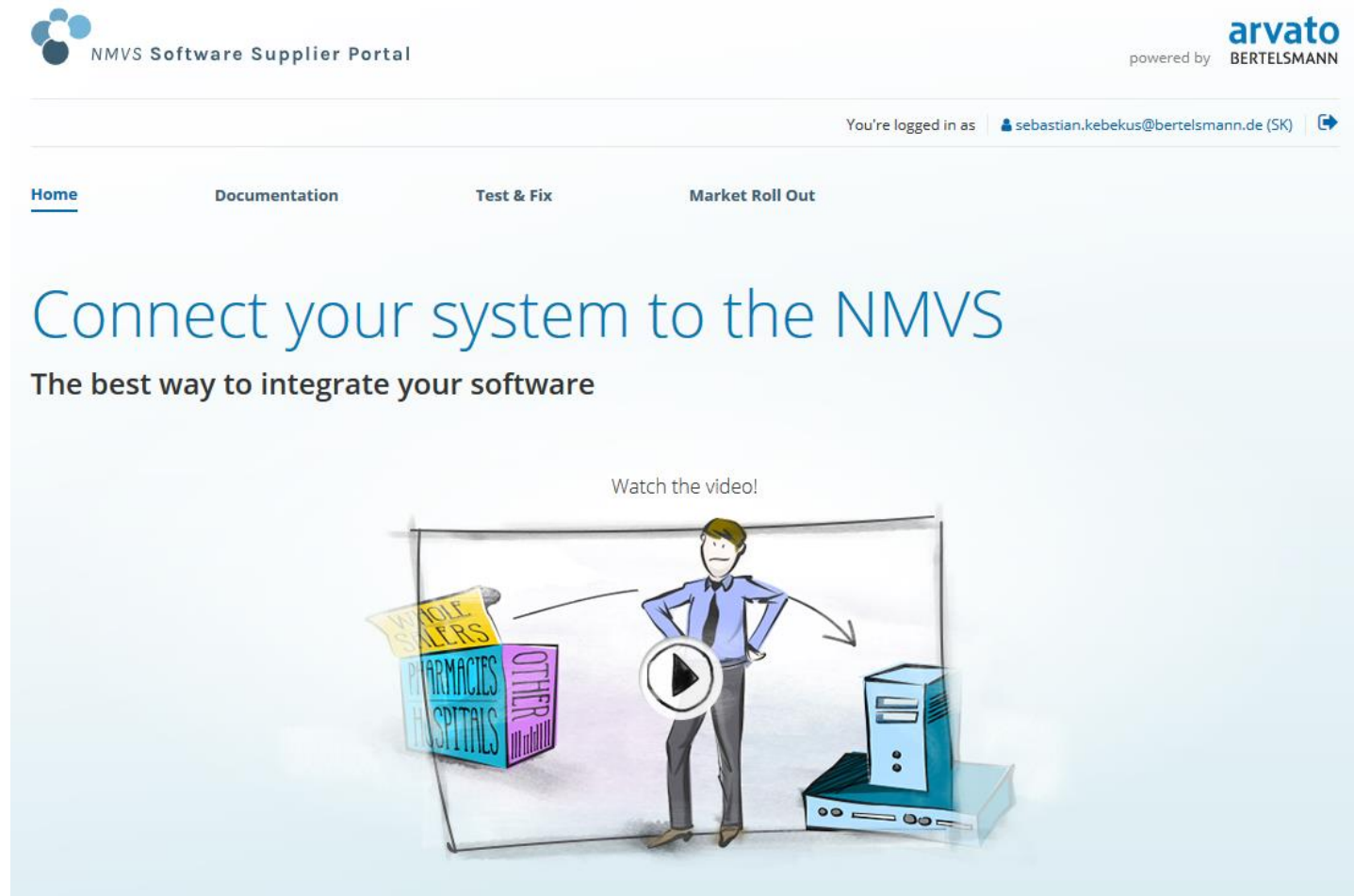
Onboarding Procedure for Software Suppliers (1)

- (1) Software Supplier registers itself with the Software Supplier portal and applies for access.
- (2) NMVO checks the request and approves access to the Software Supplier Portal.
- (3) Software Supplier ...
 - downloads documentation (handbooks, WSDLs, XML)
 - checks for news & updates
 - submits questions and service requests
 - downloads certificates for the NMVS Integration Environment
 - downloads test sets to ...
 - ... test against the NMVS Integration Environment
 - ... qualify its software for the NMVS Production Environment



Software Supplier Portal Walkthrough

<https://wappnmvsportal.azurewebsites.net/register> = Registration address
<https://sws-nmvs.eu/?destination=portal> = Portal address



Ask our
help line!

Contact

✉ support@sws-nmvs.eu

FAQ

In this section you find relevant questions and answers.

Find below a list of our frequently asked questions. If you have any further questions or suggestions for new FAQ, please contact our support.



Login Data

1. **When does my password for the Generic NMVS Integration Environment expire?**

Certificates

2. **Why do I need a certificate?**

Certificates

3. **When does my user certificate expire?**

Login Data

4. **How do I generate a new password for the Generic NMVS Integration Environment?**

Testing

Software Supplier Portal Content (1)

Manuals		Technical Documents	WSDL	Legal Documents	Others
Type	Name	Date modified		File size	
	Testing - Step by Step.pdf This document gives a short introduction how to start testing on the portal.	02/06/2018		522.2 KB	
	Implementation Guideline NMVO.pdf This guideline describes the business processes in the National Medicines Verification Systems in a blueprint style. It also provides an overview of the related web services for the distributor interface.	02/06/2018		3.8 MB	
	Software Supplier Test Documentation NMVS v1.0.pdf This manual describes the test cases which can be executed by software suppliers that connect to the Arvato Systems NMVS. These test cases offer the possibility to verify the integration of the software supplier system to the NMVS.	02/06/2018		2.0 MB	
	Software Supplier Onboarding Guide v2.1.pdf This manual describes the test cases, which can be executed by software suppliers that connect to the Arvato Systems NMVS. These test cases offer the possibility to verify the integration of the software supplier system to the NMVS.	02/06/2018		491.8 KB	

Software Supplier Portal Content (2)

Manuals		Technical Documents	WSDL	Legal Documents	Others
Type	Name	Date modified		File size	
	NMVS_End Points.pdf All relevant end points are listed in this document.	02/06/2018		232.0 KB	
	TD-014 BP 1.0 Interface Description - Catalog Translations.xlsx Overview of existing catalog types and return codes which can be translated into country language.	02/06/2018		59.0 KB	
	TD-001 BP 1.0 Interface Description - G100 Distributor Transactions.xlsx Interface description for distributor transactions.	02/06/2018		468.5 KB	
	Csharp_Java_SoapUI_Examples.zip This Zip-file contains SoapUI examples that can be used for testing.	02/06/2018		379.8 KB	

Manuals		Technical Documents	WSDL	Legal Documents	Others
Type	Name	Date modified		File size	
	NMVS - WSDL - XSD.zip This Zip-file contains WSDL files for testing.	02/06/2018		29.9 KB	
				 Download	

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Next Steps

1. Review and align final version of business requirements
(e.g. pharmacy/hospital integratio scenario, end user authentication)
=> Objective:
 - *Get a detailed view of what needs to be done and plan the project*
2. Install the Romanian Blueprint NMVS infrastructure & system
=> Objectives:
 - *Install servers and deploy software for Romanian NMVS*
 - *Establish a connection between the EU Hub and the NMVS*
 - *The NMVS can receive product/pack data from the pilot MAHs*
 - *The pilot pharmacies/hospitals/wholesalers can send pack transactions*
3. Onboard pharmacy/hospital/wholesaler software suppliers
=> Objective:
 - *The software suppliers can prepare themselves to connect their software packages with the NMVS*

Questions & Answers

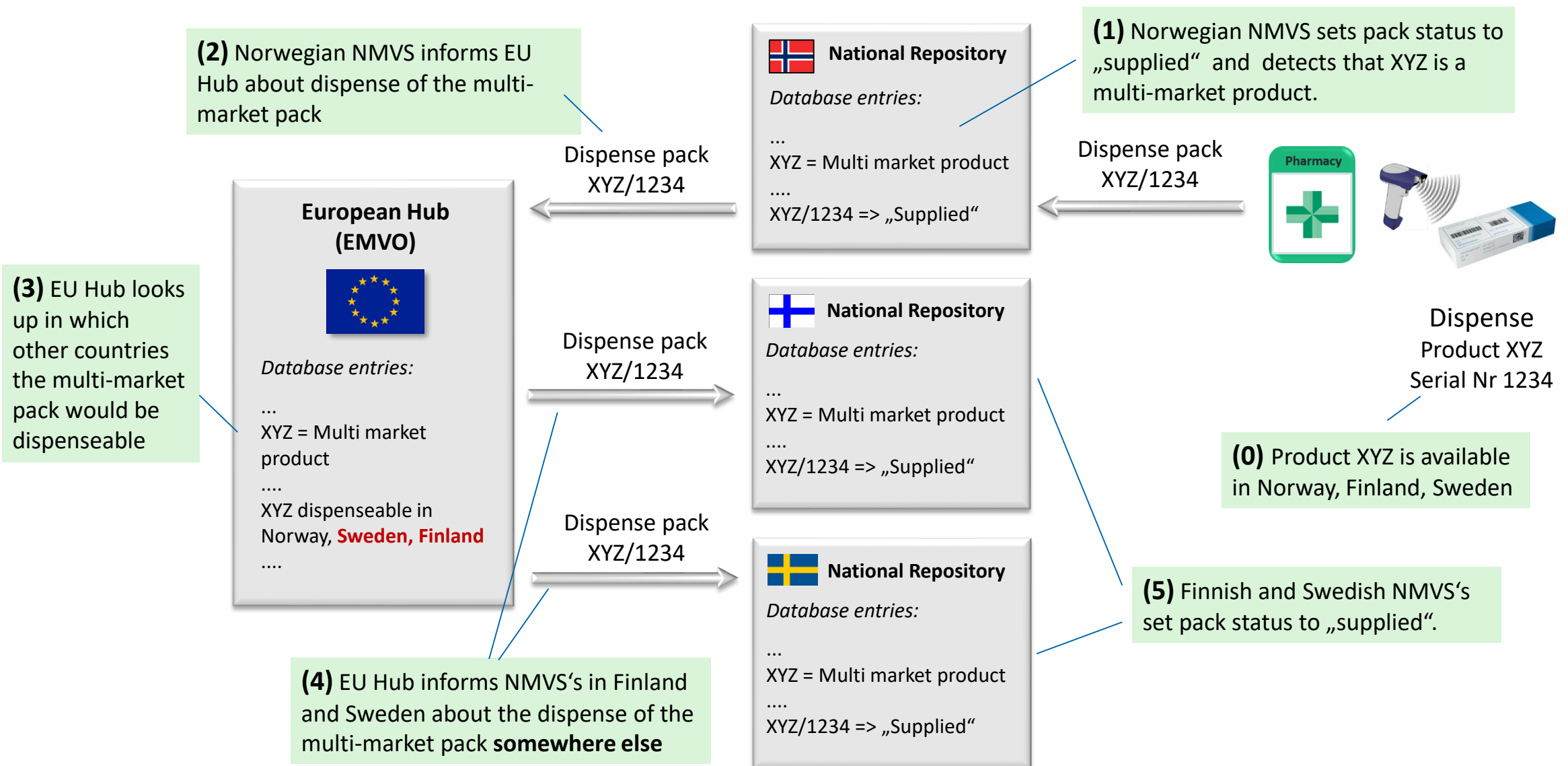
Thank you for your attention !

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+49 (5241) 80-75454

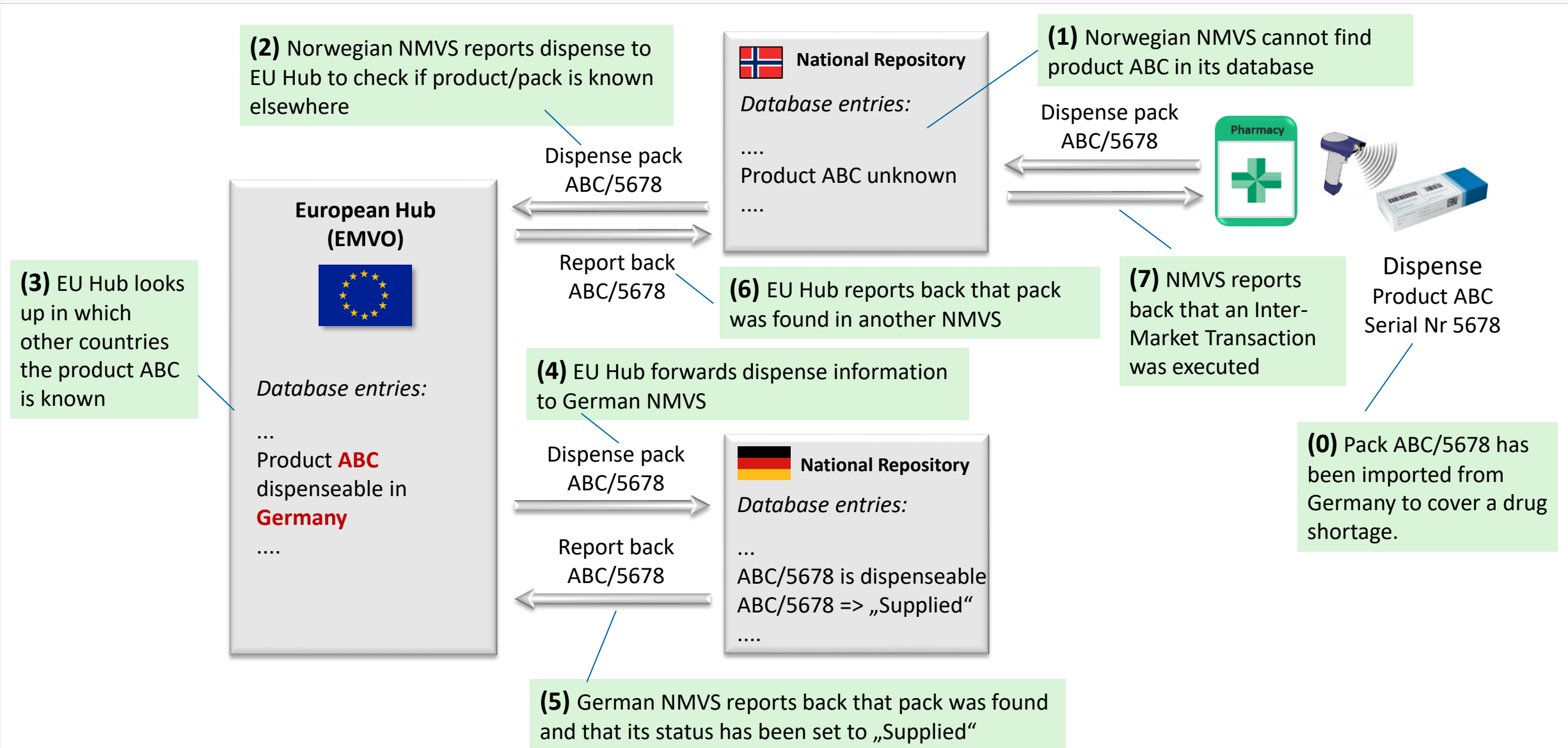
Alexandru Chetrusca – Local NMVS Project Manager
Alexandru.Chetrusca@bertelsmann.de
+40 769 011 265

Backup Slides

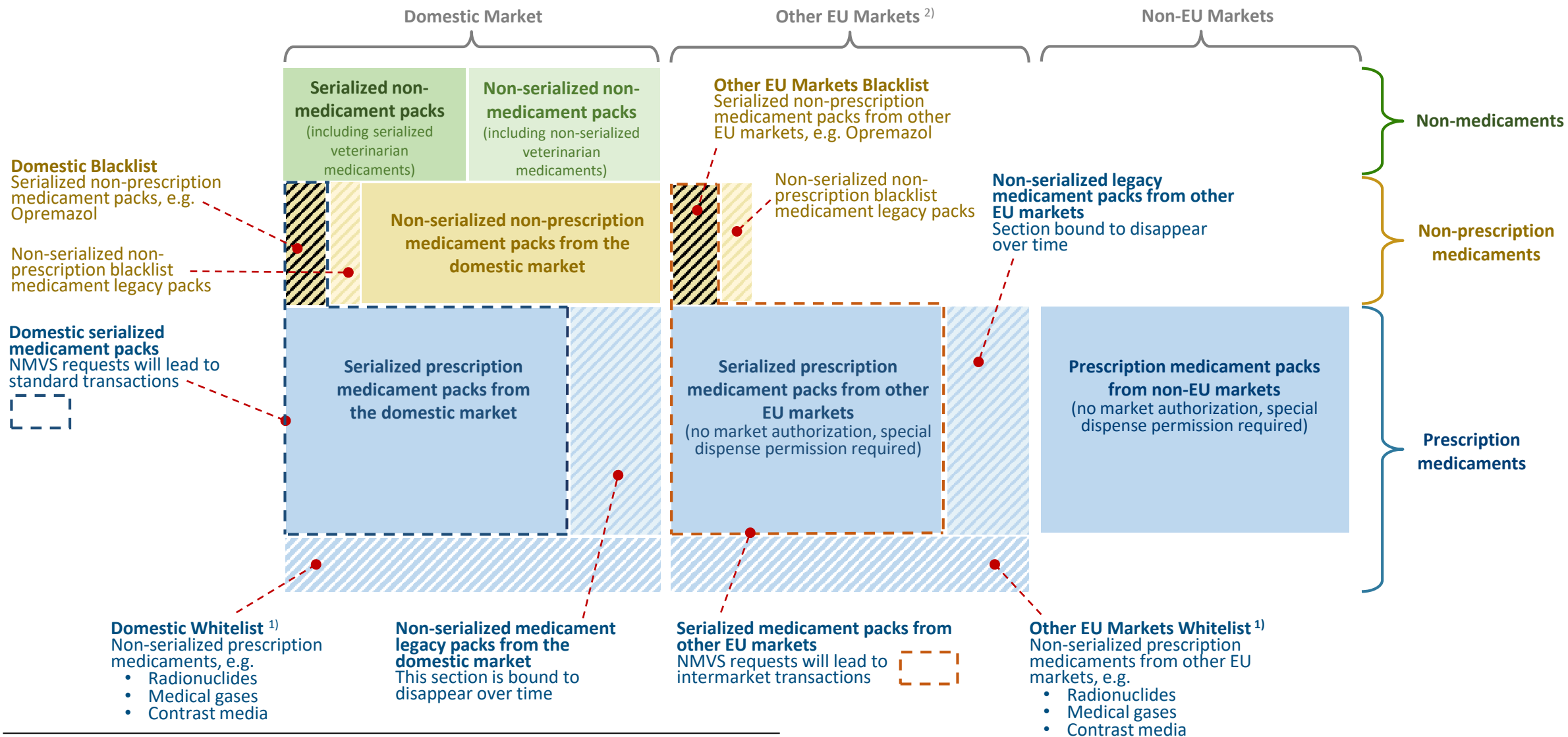
What happens when a Multi-Market Pack is dispensed? Example:



What is an Inter-Market Transaction? Example:



Serialized Product Landscape



¹⁾ Whitelist products must never be serialized

²⁾ This includes „late“ EU markets like Italy or Greece

Serialized Product Landscape

Decision Table: When should the NMVS be requested?

Domestic product with market authorization

Serialized	Medicament	NMVS Call	Registered in the domestic NMVS	Comment
No	*	No	No	A non-serialized pack cannot be verified, e.g. an older legacy pack or a whitelist medicament
Yes	No	No	No	Serialized non-medicament
Yes	Yes	Yes	Yes	Serialized pack, standard case

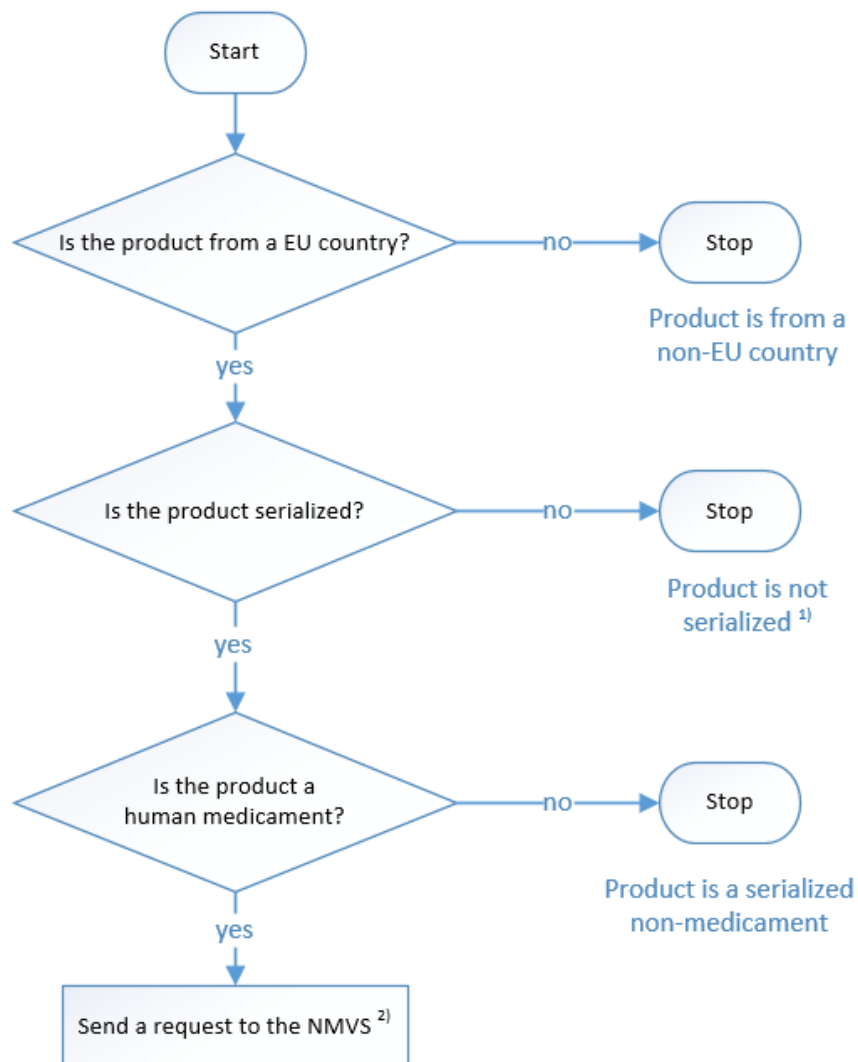
Product from another EU market without market authorization

Serialized	Medicament	NMVS Call	Registered in other NMVS	Comment
No	*	No	No	A non-serialized pack cannot be verified, e.g. an older legacy pack or a whitelist medicament
Yes	No	No	No	Serialized non-medicament
Yes	Yes	Yes	Yes	This will lead to an Intermarket transaction

Product from another non-EU market without market authorization

Serialized	Medicament	NMVS Call		Comment
*	*	No		Products from non-EU markets can never be verified

How to decide whether to send an NMVS request from a local software



¹⁾ This also covers the possible case (e.g. in France) that a pack has a datamatrix code which does not contain a serial number.

²⁾ If the product code is not available in the local NMVS, the NMVS will automatically launch an intermarket transaction.

Which data are exchanged in a single pack transaction? (1)

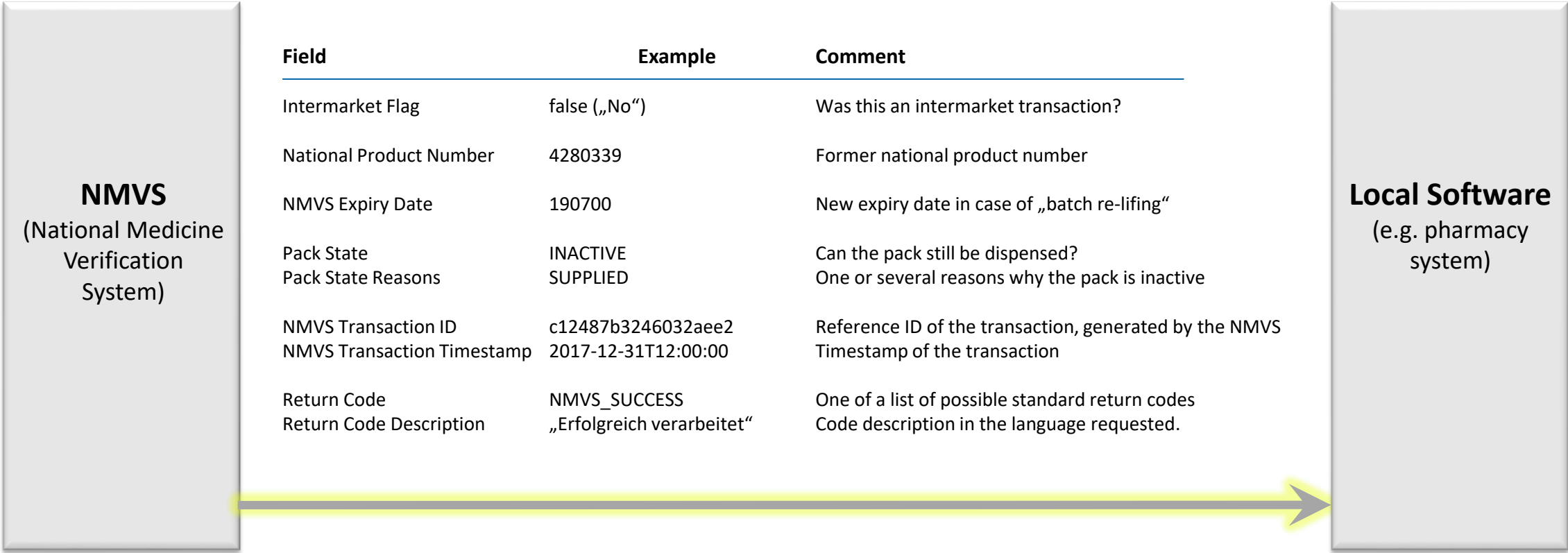
Data fields which are sent from the local software to the NMVS (selection):



Field	Example	Comment
User Group ID	276504	Code for the user's group, e.g. pharmacies of chain ABC
User ID	3142	Individual user id, e.g. a particular pharmacy
Password	„opensesame“	Access password
Sub User ID	2	Optional identifier
Product Number	09088881234569	Product number of the scanned pack
Code Scheme	GTIN	Code scheme of the product number (GTIN or PPN)
Serial Number	123456789A1234	Serial number of the scanned pack
Batch Number	AHBE4W	Batch number of the scanned pack
Expiry Date	190500	Expiry date of the scanned pack
Client Transaction Id	2f47ca8404bb21993d9	Reference ID of the transaction, generated by local software
Language Code	deu	Code of the language in which messages are to be sent back

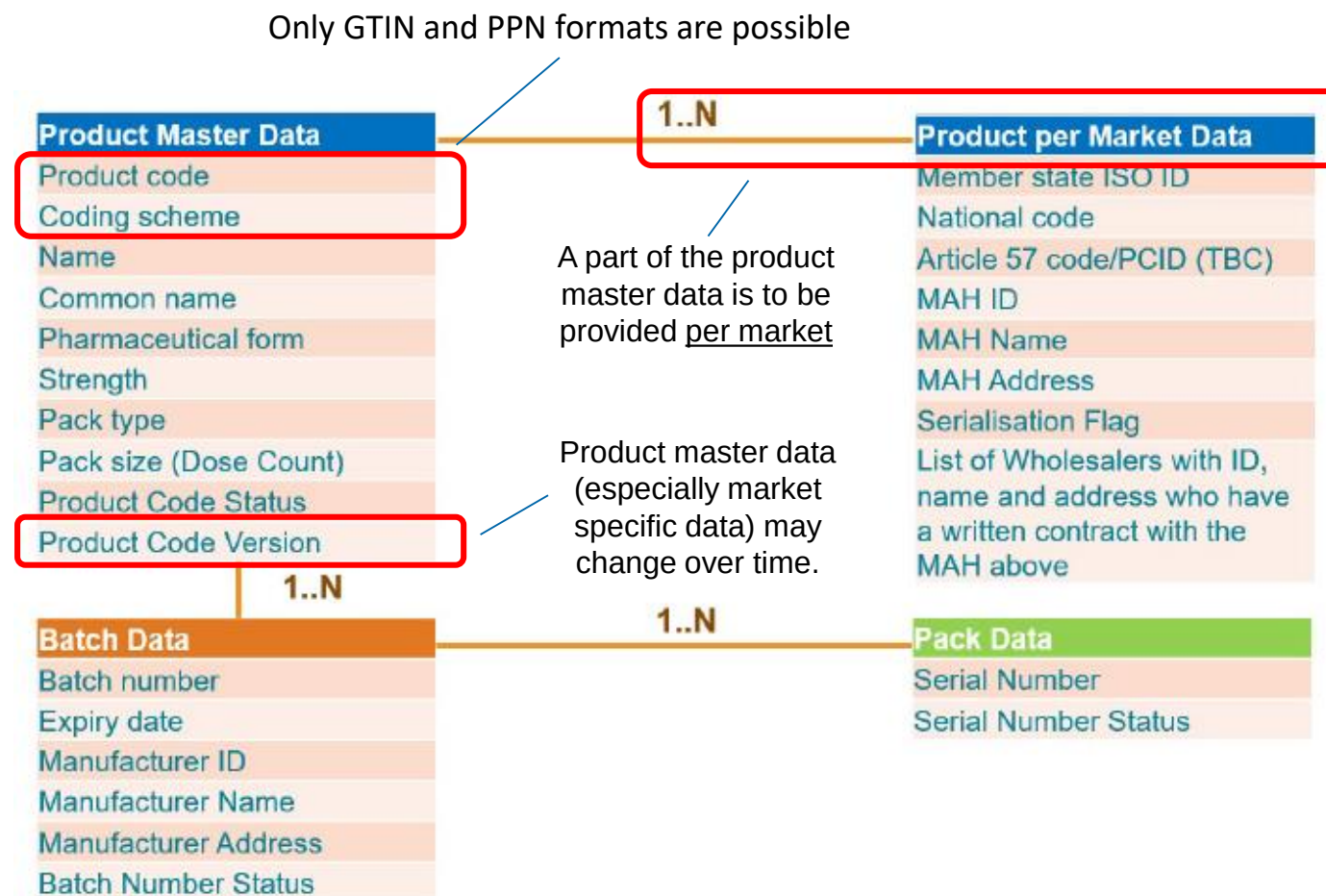
Which data are exchanged in a single pack transaction? (2)

Data fields which are sent back from the NMVS to the local software (selection):



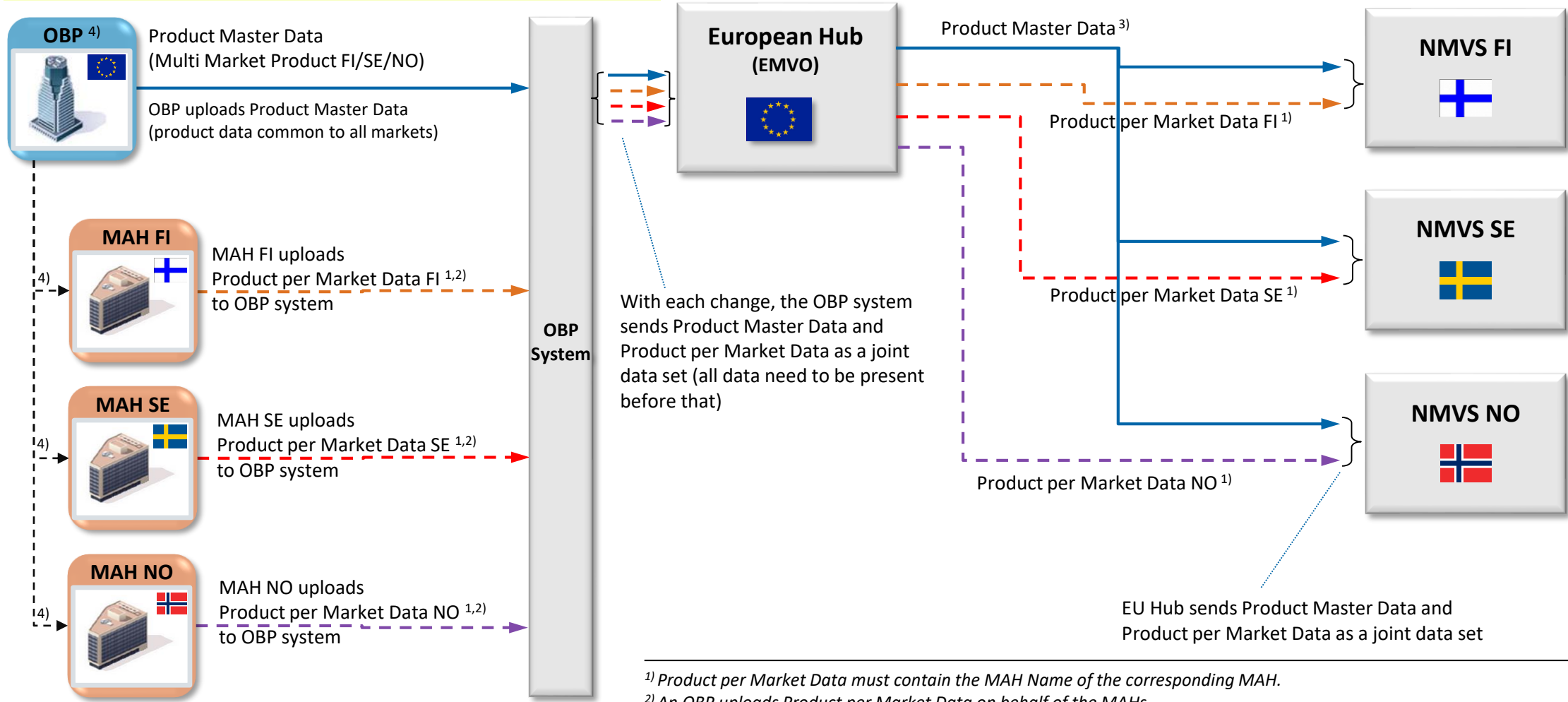
EU Hub Product Data Model

Extract from EMVO User Requirement Specification (URS) :



Product Master Data & Market Data Distribution - Example

Example: Multi-market product is available in FI, SE, and NO



¹⁾ Product per Market Data must contain the MAH Name of the corresponding MAH.

²⁾ An OBP uploads Product per Market Data on behalf of the MAHs.

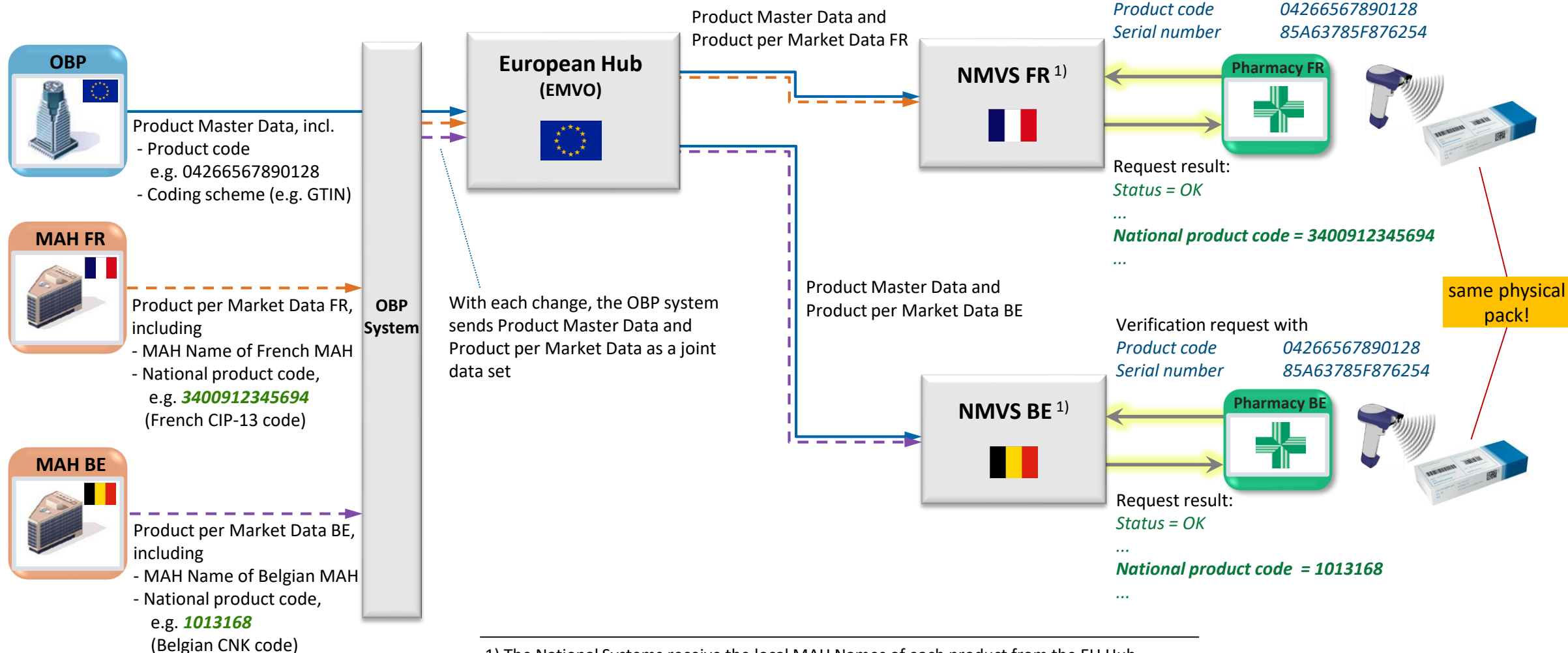
³⁾ The EU Hub does not send the OBP ID to the National Systems.

⁴⁾ An OBP (Onboarding Partner, e.g. Roche, Bayer) grants marketing rights for its own medicaments (patents, brand names) to local MAHs (Marketing Authorization Holders). See also <https://emvo-medicines.eu/faq/>, „What is an OBP? What is an MAH?“

Product Master Data & Market Data Distribution

MAH Names and National Codes

Example: Multi-market product with GTIN = 04266567890128 is available in FR and BE



Batch and Pack Data Distribution

Multi-Market Product

Example: Multi-market product with GTIN = 04266567890128 is available in FR and BE

