

NMVS Finland Pharma Industry Meeting

Helsinki
April 7th, 2017



Arvato

Company structure and competencies

Challenges

Which challenges have to be mastered?
Who is affected?

Planning

Which planning structure is proposed to finish the project within the given time frame?

Next steps

Which are the next steps?
Who will have to contribute what?

How did we get here today?



It's always a good idea to start with the customer ...



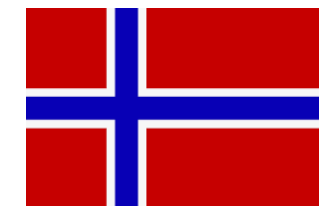
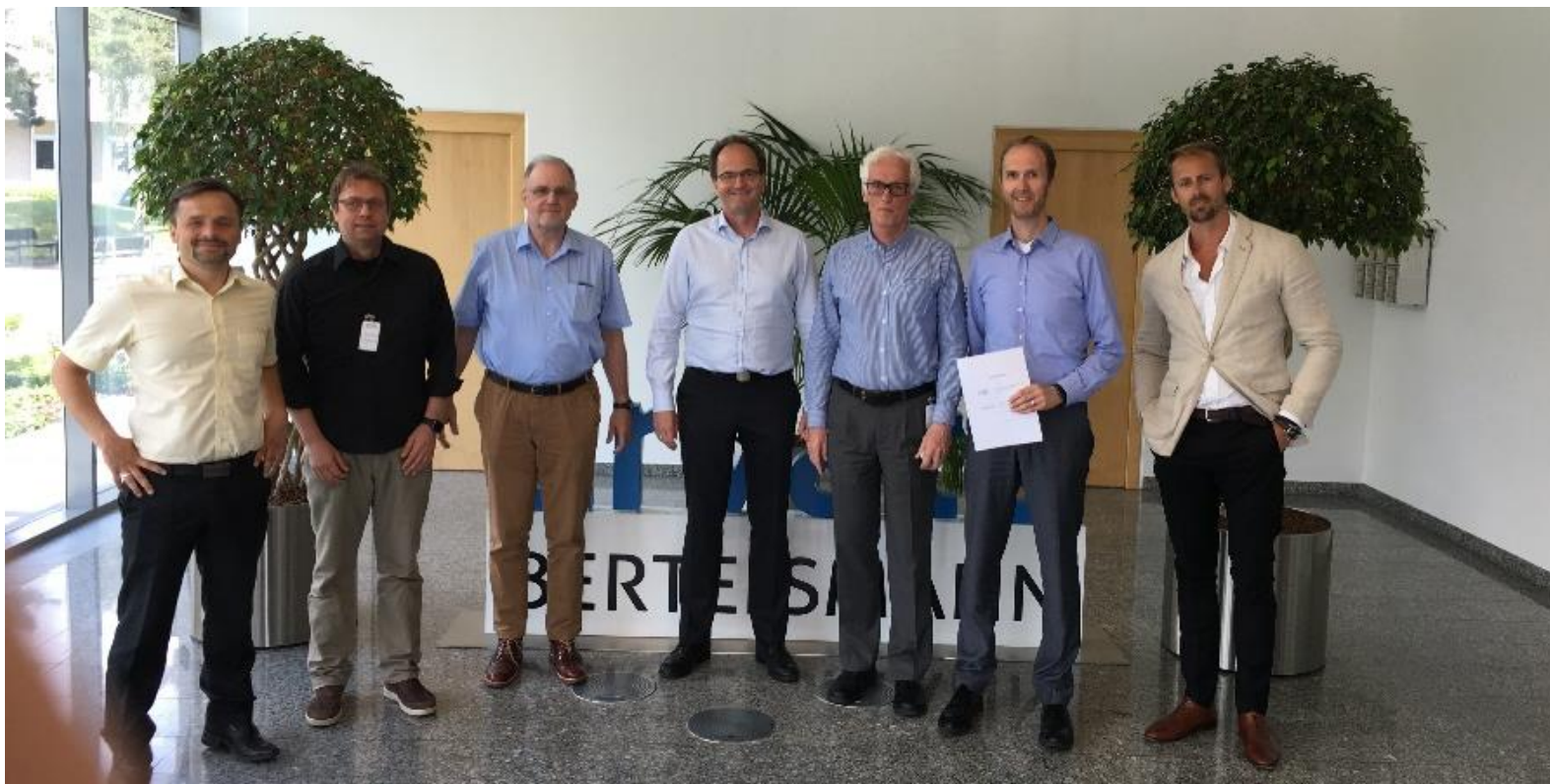
Signature of securPharm Service Provider Contract (NMVO Germany)

August 1, 2012

“We looked for a reliable supplier for our project but we found a partner who exceeded our expectations. The project was delivered in time, quality and budget, data are managed securely, stakeholders are connected and aligned.”

Peter Krug, Managing Director ACS & VFA

... and another customer- Norway: first operational Blueprint project



Signature of Letter of Intent with NMVO Norway, 7th June 2016

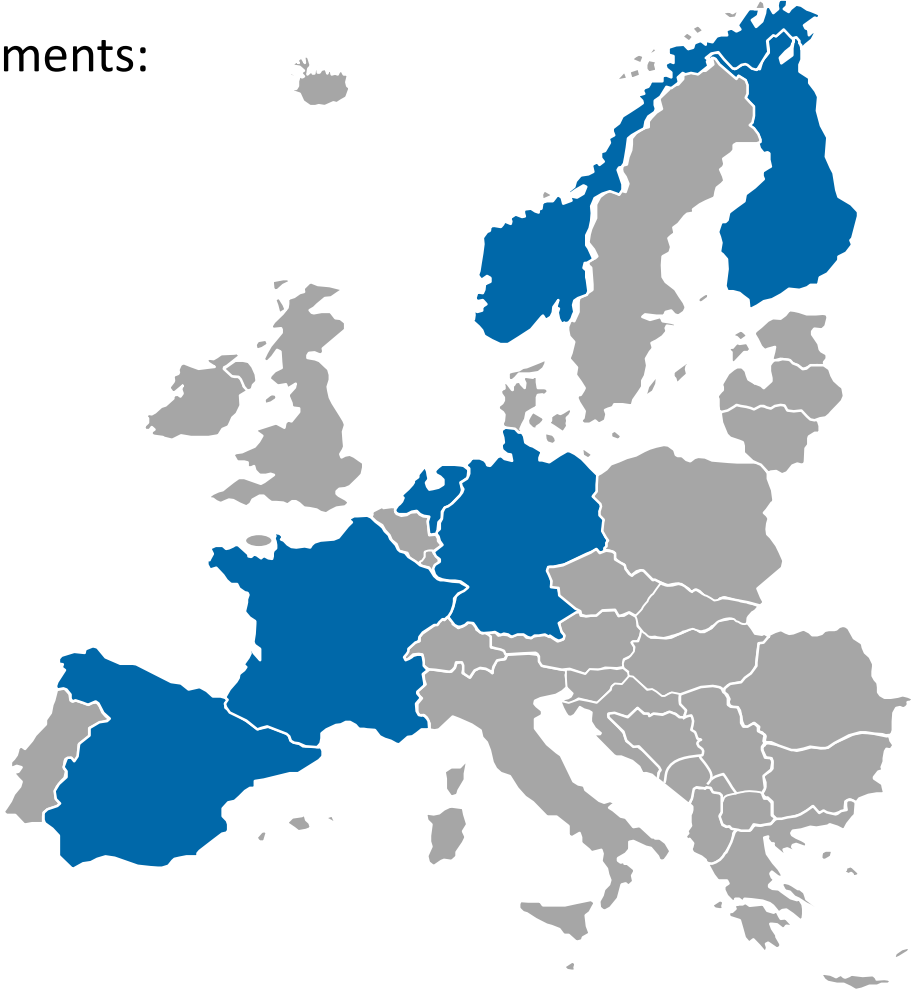
Arvato National Verification System: Customers

Current Scope: All countries within the European Economic Area (EEA)

✓ Agreements:



Contracting / Mutual Agreements:



Bertelsmann
Internationally Leading Media and Service Company

FACTS & FIGURES

- 17.1 bn € turnover*
- 117.249 employees in about 50 countries

BERTELSMANN



The No. 1 European broadcaster



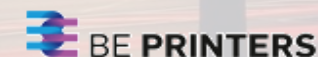
The world's largest book publishing group



Europe's biggest magazine publisher



Leading European BPO provider



International print and communications service provider

*FY 2015

Facts & Figures

REVENUES	OPERATING EBIT	EMPLOYEES
€ 17,1 BN	€ 2,485 M	117,249

REVENUES	OPERATING EBIT	EMPLOYEES
€ 4,84 BN	€ 394 M	70,653

REVENUES	EMPLOYEES	WORLDWIDE SITE
€ 418 M	> 3,000	> 25

BERTELSMANN

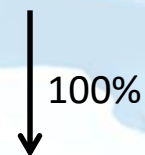
Media & Services Company



arvato
BERTELSMANN

BPO Service Provider

- Logistics
- CRM
- Finance



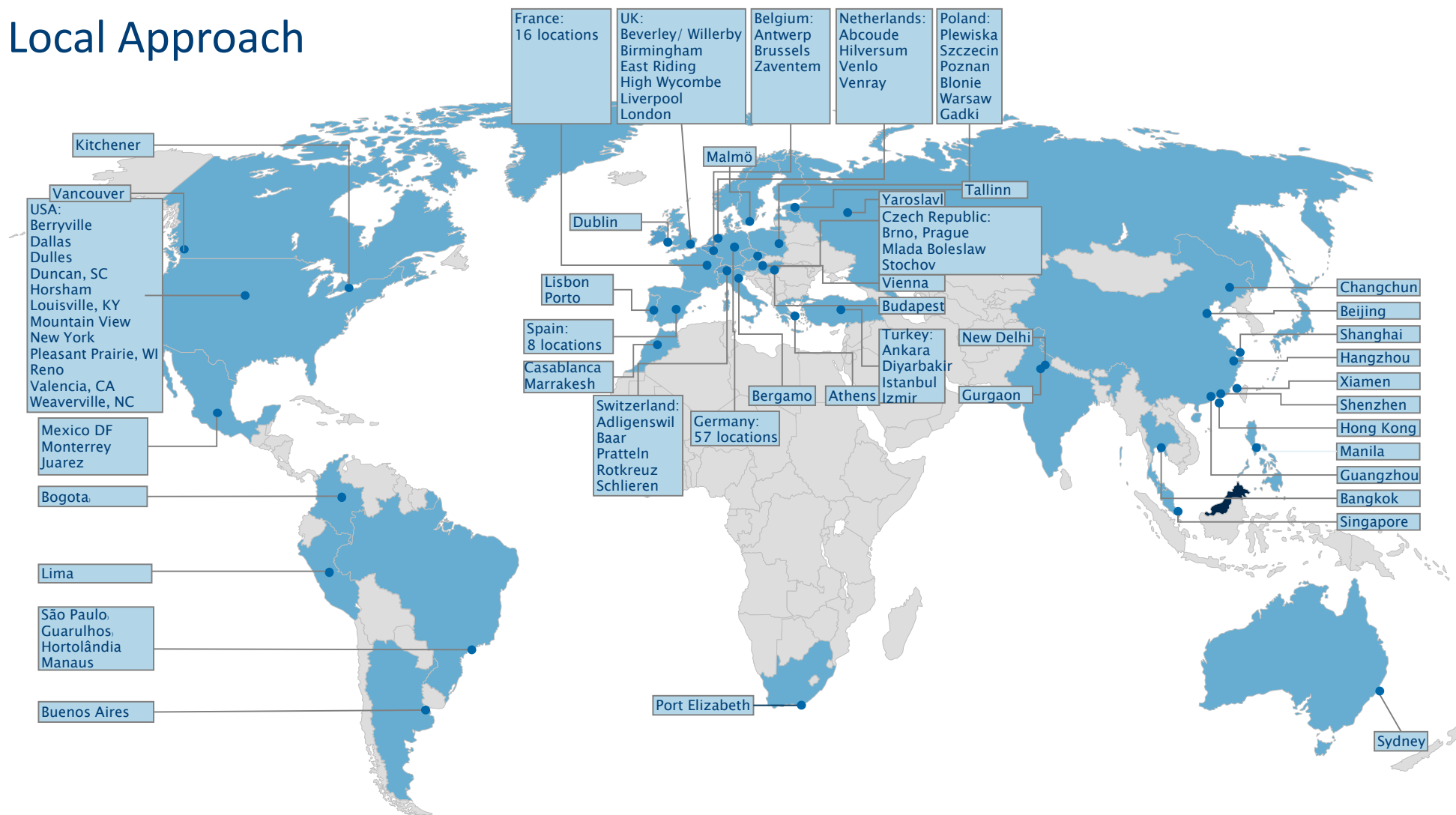
arvato
SYSTEMS

IT Service Provider

IT SOLUTIONS

*FY 2015

Arvato Global Setup – Local Approach



Arvato – A Partner for Plan-Build-Run Projects

Deep expertise – but independent from single IT vendors

CONSULTING

- Business Consulting
- Management Consulting
- Technology and Process Consulting

SYSTEMS INTEGRATION

- Digital Transformation Solutions
- Sector specific Solutions
- Cloud, Big Data, Mobile Solutions
- ERP, BW, WCMS, CRM, Finance etc.
- Technology Expertise/Partner:
SAP, Microsoft, Adobe, hybris

INFRASTRUCTURE SERVICES

- Infrastructure consulting and design
- Application Management
- Managed Services
- Hosting – own Data Centers
- Service Desk

Key Sectors



COMMERCE



HEALTHCARE



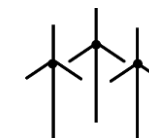
MANUFACTURING



MEDIA &
ENTERTAINMENT



PUBLIC



UTILITIES

Arvato's background towards the FMD-Business



Product Serialization
against software piracy



A Long History in Serialization

Example Microsoft:

- Product serialization against software piracy since 1998
- Worldwide download and licencing platform for Microsoft Windows
- Global management of serial numbers and license keys
- Strict SLAs and security rules
- Global track & trace for serialized DVDs
 - DVD production, wholesale, retail
 - Microsoft Xbox games, MS Office etc.



 <p>Microsoft</p>  <p>Windows 8</p>	<p>Digital download & Licensing in 141 countries</p>
<p>Offered in 37 languages 23 currencies</p>	<p>Top Target for Counterfeit</p>

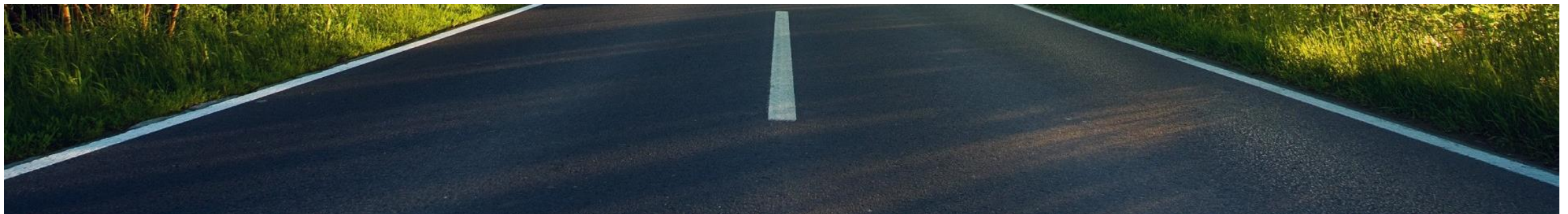
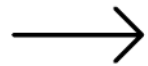
Arvato's background towards the FMD-Business



Secure National Hub to
prevent Car Insurance Fraud



Product Serialization
against software piracy



Secure National Hub to Prevent Car Insurance Fraud

- Car insurance fraud has a great financial impact
- Arvato Systems runs an anti-fraud system for the entire German car insurance industry since 2012
- Highest standards for availability and data security
- Arvato has no interest in exploiting customer data

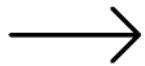
Key Facts	
Insurance Companies	470
Connected Insurance Agencies	> 50,000
Verifications per Day	Up to 3 mio
Average Time Roundtrip	220 ms



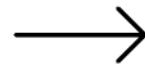
Arvato's background towards the FMD-Business



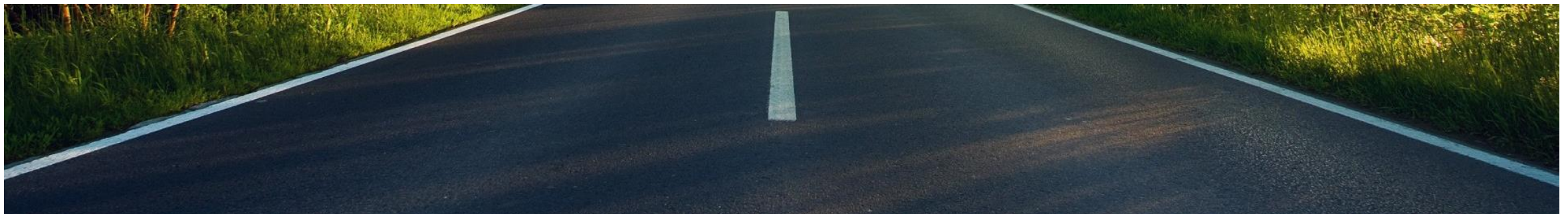
Product Serialization
against software piracy



Secure National Hub to
prevent Car Insurance Fraud



Pharma and Healthcare has become a **Core Business**



Pharma and Healthcare has become a core business

Pharma/Biopharma



Pharma Serialization/Verification



Medical Technology



Healthcare figures 2014

- > 1,100 employees
- > 160 Mio € revenue

Arvato's background towards the FMD-Business



Product Serialization
against software piracy



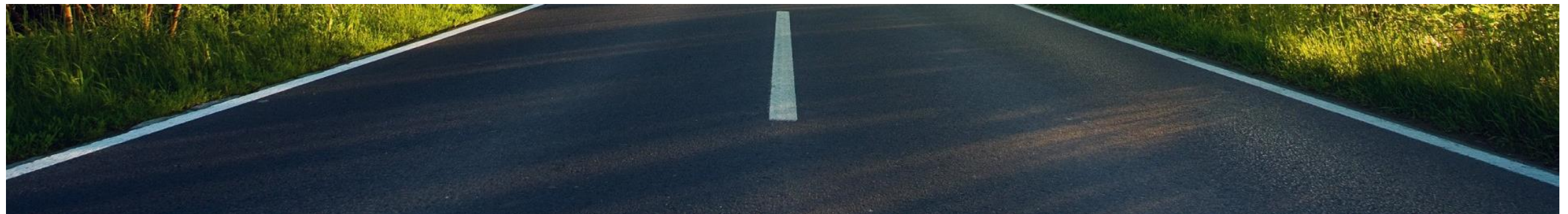
Secure National Hub to
prevent Car Insurance Fraud



Pharma and Healthcare has become a **Core Business**

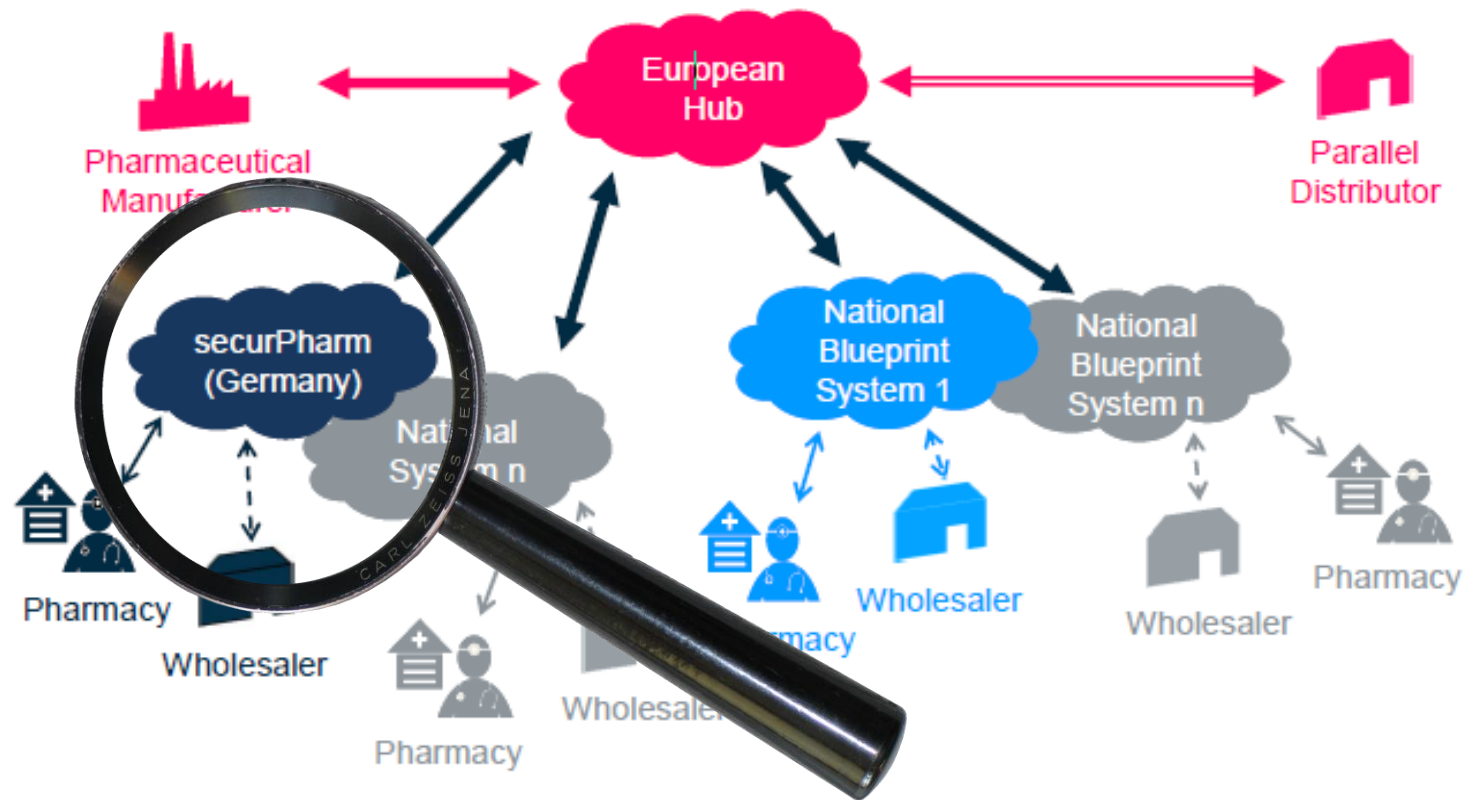


First National Verification System in Europe



The securPharm System is fully compliant with ESM/EMVO

> 90% of the Blueprint processes are already operational



- System runs in productive mode
- Fully integrated with EU Hub
- Fully compliant with FMD/EMVO

securPharm – Industry Partners

Each of these companies uploads serial numbers to the securPharm System:

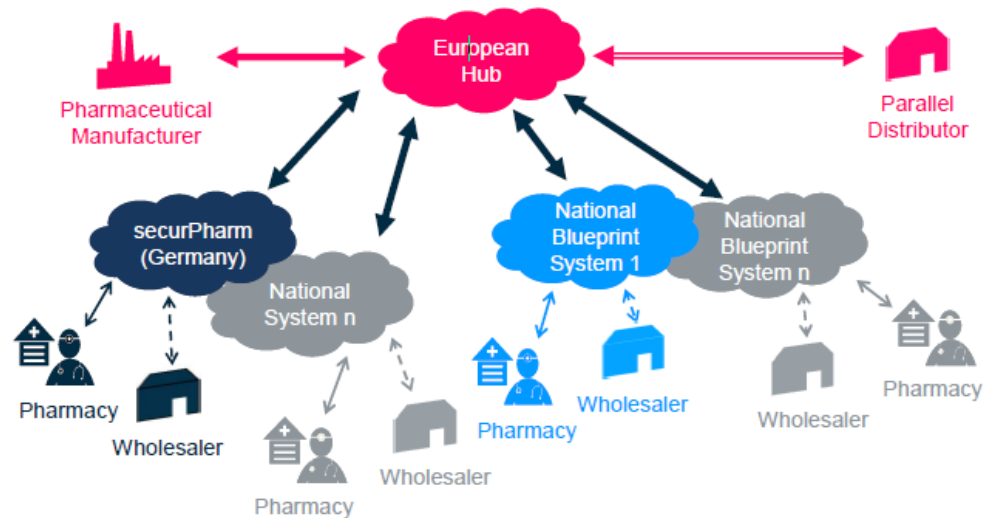


Status January 1, 2017:
100 participating companies

Arvato's Footprint in Serialization

NATIONAL VERIFICATION SYSTEMS

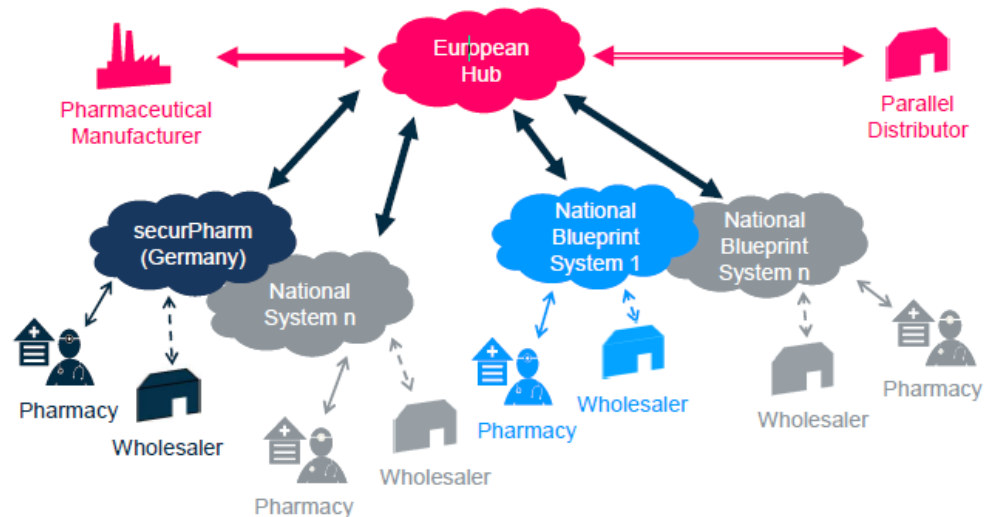
Selected BluePrint Provider by EMVO



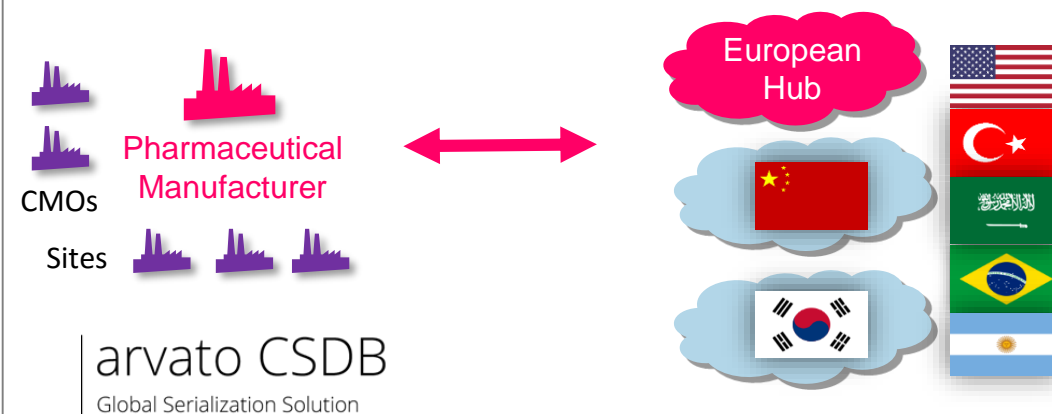
Arvato's Footprint in Serialization

NATIONAL VERIFICATION SYSTEMS

Selected BluePrint Provider by EMVO



COMPANY SOLUTION



- Manage Serialization Processes on company level (MAH)
- Connect to all relevant markets

Serialization – National activities across the globe



Product

Arvato CSDB

Number of projects

More than 30

Number of serialized Packs

More than 2 Billion

Focus of projects

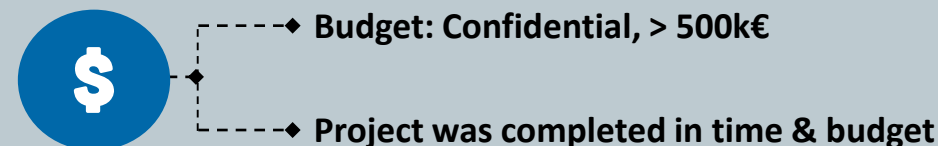
Requirements from Turkey, China and South Korea

Customer reference - Meda

IT service provider since 2012

- Full Service provider of the Serialization platform CSDB*, managing all internal serialization processes
- Target markets: China, Korea, Europe, Germany
- Technologies used: JAVA, PostgreSQL, CSDB , Arvato-internal Platforms

**Corporate serialization database, Arvato Systems serialization solution for companies*



Arvato Systems has been running pilot projects for MEDA since 2012, focusing on specific markets and production lines. The rollout to other subsidiaries and production facilities (CMOs) is currently ongoing. Integration of CMO's is also in scope and also expansion towards other Markets (Korea etc.).

Arvato is currently implementing the serialization solution CSDB to many other Pharma companies.

Arvato

Company structure and competencies

Challenges

Which challenges have to be mastered?
Who is affected?

Planning

Which planning structure is proposed to finish the project within the given time frame?

Next steps

Which are the next steps?
Who will have to contribute what?

We have to master one central challenge

- Many stakeholders are involved in the establishment of a NMVS:

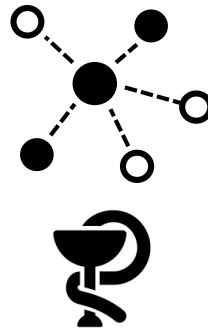
a) Organisers

- NMVO
- EMVO



b) Primary distributors

- Marketing authorization holders
- Contract manufacturers
- Wholesalers
- Parallel distributors
- Public pharmacies
- Hospital pharmacies



c) Software providers

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



d) Authorities



b1) Secondary distributors

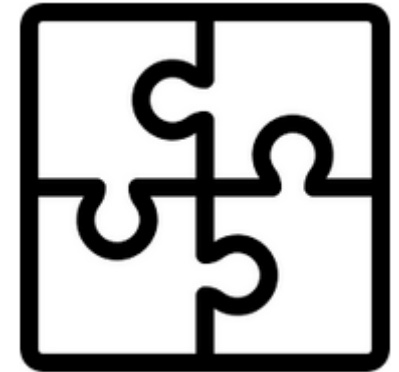
- Army
- Prisons
- Airlines
- Nursing homes
- Drug treatment centers
- NGOs
- ...



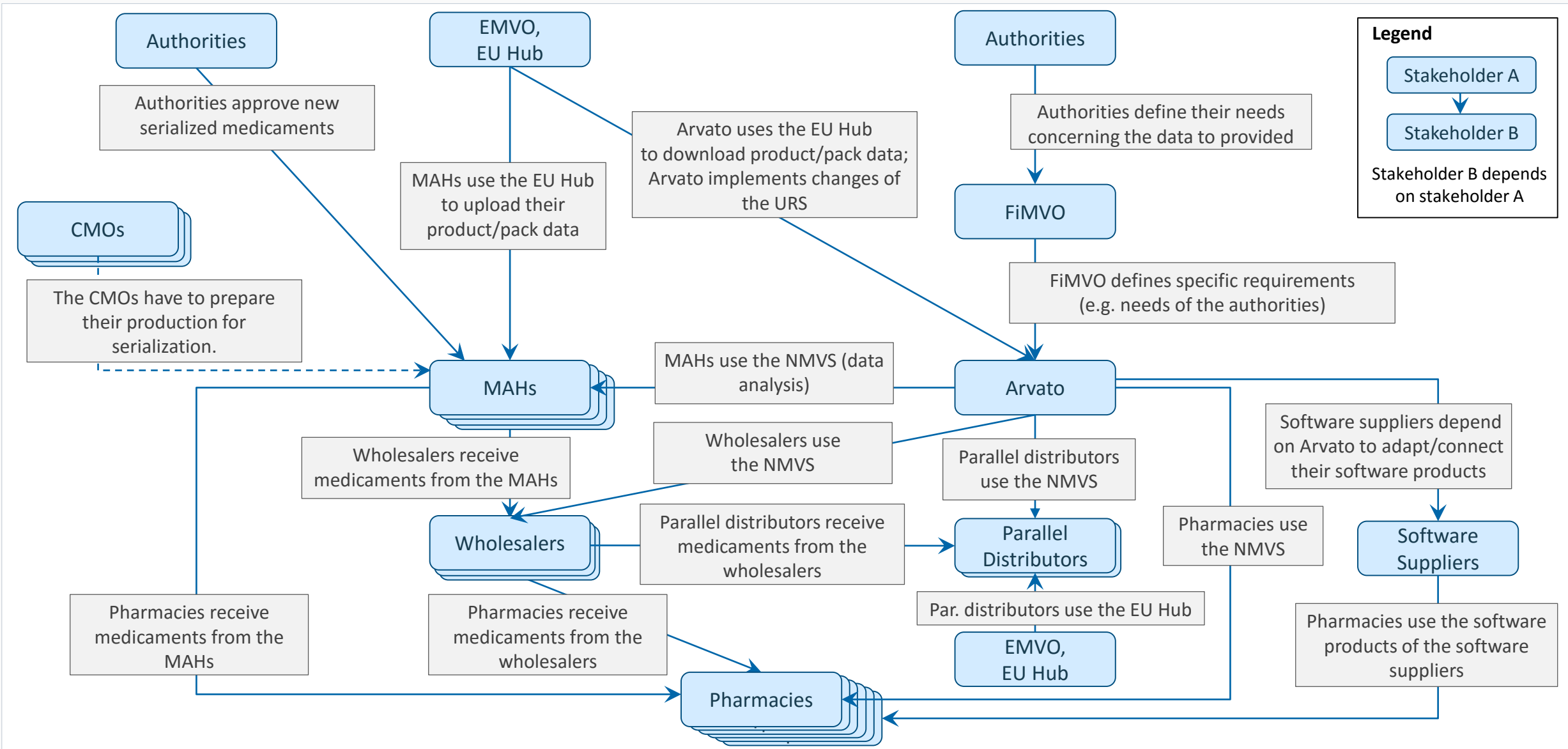
We have to master one central challenge (2)

- Organize 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.



A complex web of stakeholders must learn to cooperate smoothly



What exactly needs to be done? (1)

- All MAHs must
 - Introduce serialization for their products (package design, regulatory approval, production preparation, production start)
 - Synchronize with their manufacturers (CMOs)
 - Synchronize with their wholesalers
 - Connect with the EU-Hub and start uploading product data and pack data
 - Adapt their IT systems to handle serialized products (incl. EU Hub interface)
 - Manage falsifications including false positives

- All wholesalers/par. distributors must
 - Synchronize with their MAHs
 - Adapt their IT systems to handle serialized products (incl. NMVS interface)
 - Manage both serialized and non-serialized products for a transition time
 - Wait for serialized products to be delivered by all their MAHs
 - Manage falsifications including false positives

What exactly needs to be done? (2)

- All pharmacies must
 - Align with their software suppliers
 - Introduce upgraded IT systems for scanning of serialized products
 - 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
- All software suppliers must
 - Understand the NMVS web service interface and specify the required changes to their software products
 - Reserve implementation capacities
 - Implement and test the specified changes to their software products
 - Coordinate the rollout of their new software product releases to the pharmacies

What exactly needs to be done? (3)

- The EU Hub will for the first time have to ...
 - ... handle transactions from multiple countries
 - ... handle multi-market products/transactions
 - ... handle inter-market transactions (new requirement)
- FiMVO will have to ...
 - ... keep an overview of all the stakeholders involved and their respective progress in the project
 - ... align with the Finnish authorities
 - ... manage detected falsifications including false positives
- General aspects
 - The NMVS must be formally validated by the FiMVO and approved by EMVO
 - Further URS changes by EMVO are likely to occur in the future and will have to be considered

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



How long it takes until new serialized medicines arrive at the pharmacies depend on several things. (In Germany ~140 day)

How long will it take in your case?

Lessons learned from securPharm

14 OF THE FIRST 20 PILOT
PARTICIPANTS HAD BAD
VERIFICATIONS AT THE BEGINNING

TAKE CARE OF VERIFICATIONS BY
NEW TECHNOLOGY

BE AWARE OF DIFFERENT
STAKEHOLDERS

Y ↔ Z



Numerous interwoven processes cause a high global 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.

Arvato

Company structure and competencies

Challenges

Which challenges have to be mastered?
Who is affected?

Planning

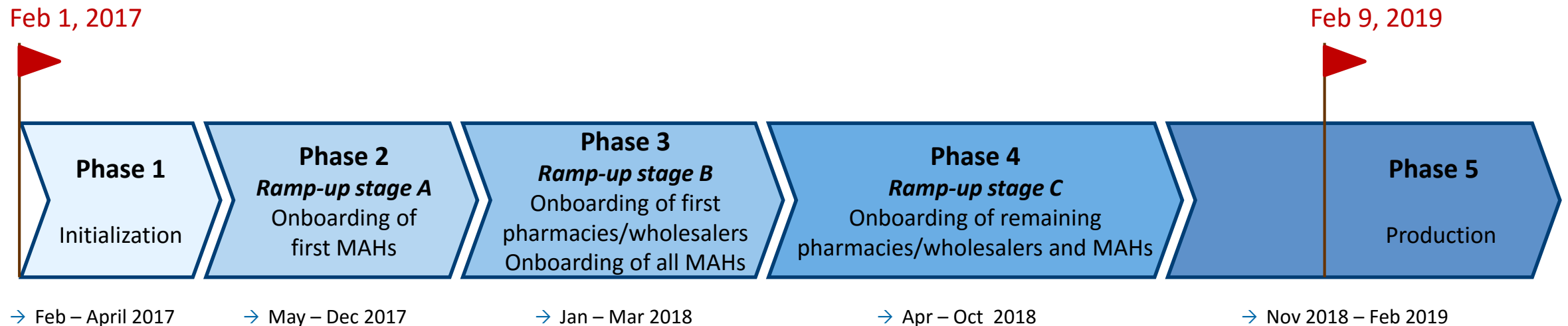
Which planning structure is proposed to finish the project within the given time frame?

Next steps

Which are the next steps?
Who will have to contribute what?

Time Planning, High Level Perspective

- There are roughly 22 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 results of each phase?
Let's go through the five phases shown.

Planning, Detail View

Phase 1: Initialization (Feb – Apr 2017)



Results of Phase 1:

Organization

- A final requirements analysis for the Finnish NMVS has been made
- The major project decisions have been taken
- The planning is complete
- The description of the NMVS web service interface has been made available to the software suppliers of pharmacies and wholesalers
- A group of MAHs has been chosen to test the basic information data flow in Phase 2

New functionalities

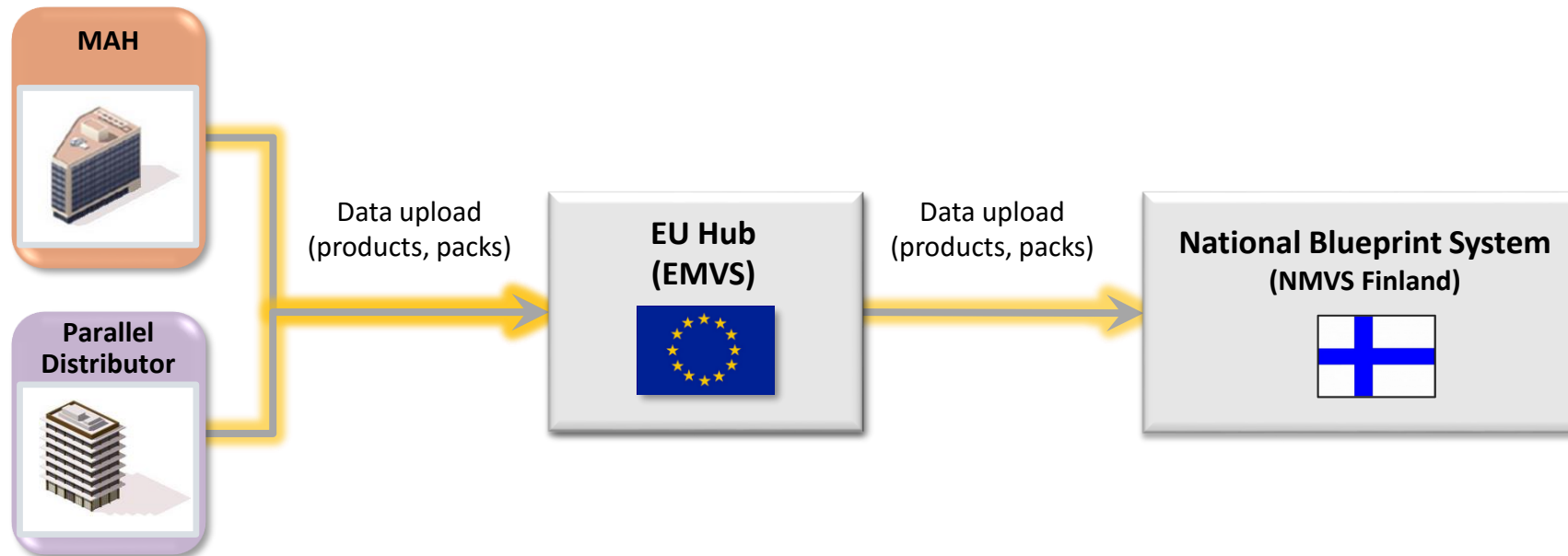
- The first MAHs are preparing the production of serialized medicines
- The first MAHs are able to upload product/pack data to the EU Hub

Planning, Detail View

Phase 2: Ramp-up Stage A (May – Dec 2017)



During phase 2, the highlighted information flows will be tested:



Planning, Detail View

Phase 2: Ramp-up Stage A (May – Dec 2017)



Results of Phase 2:

Usage

- The first serialized packs have been manufactured and put into the supply chain.
- Product/pack data have been transferred to the NMVS, i.e. the information flow between MAHs and the NMVS via the EU Hub has been tested.

Organization

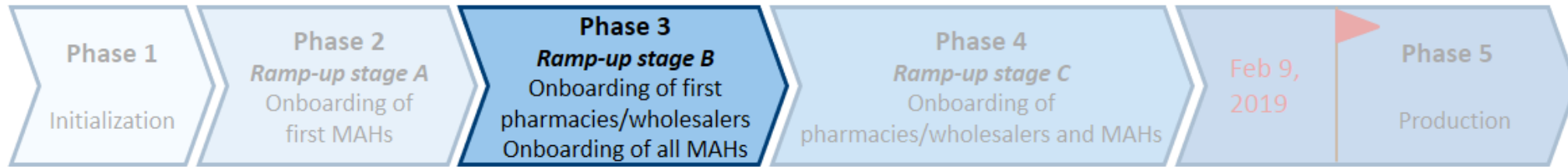
- A small group of pharmacies and wholesalers has been chosen to test the verification/dispensing of medicines in Phase 3

New functionalities

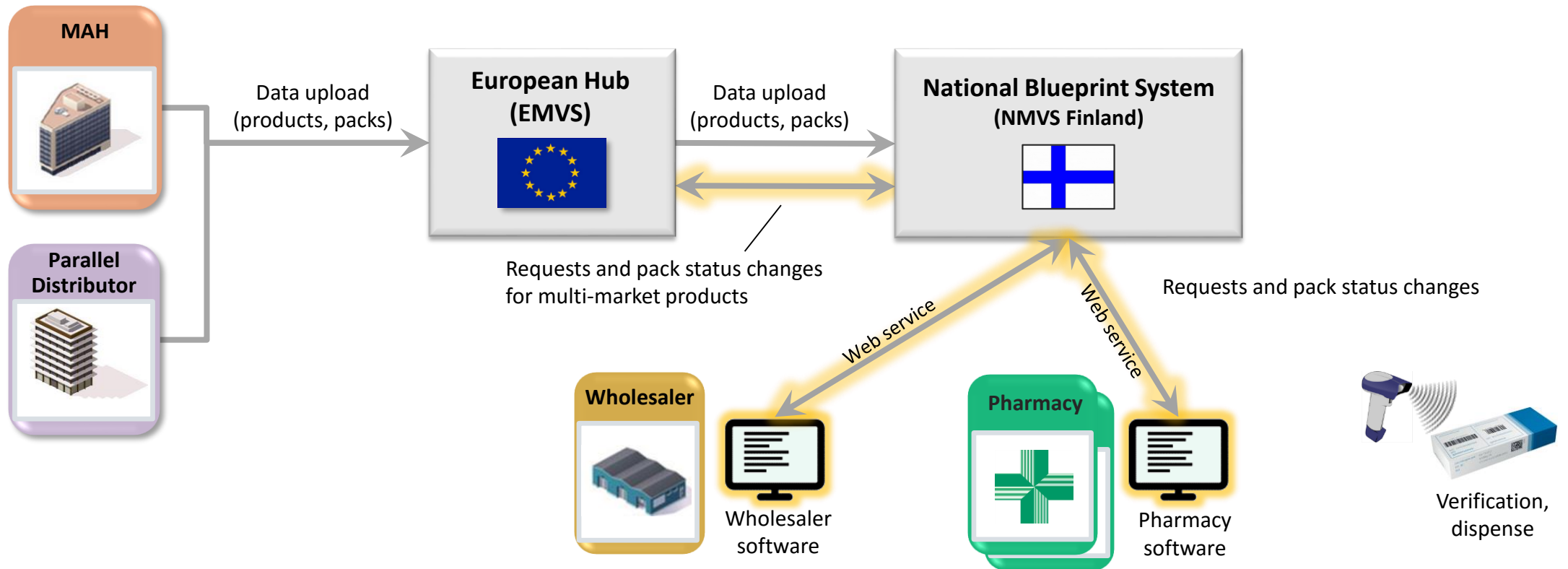
- The first pharmacy software suppliers have already connected their software products with the NMVS web services interface
- A connection between the Finnish NMVS the EU Hub has been established
- The EU Hub can upload product/pack data to the Finnish NMVS

Planning, Detail View

Phase 3: Ramp-up Stage B (Jan – Mar 2018)



During Phase 3, additional data flows will be tested:



Planning, Detail View

Phase 3: Ramp-up Stage B (Jan – Mar 2018)



Results of Phase 3:

Usage

- The first serialized medicines have arrived at the pharmacies/wholesalers.
- The software suppliers have connected their pharmacy/wholesaler software with the NMVS web services.
- The first pharmacies/wholesalers have verified/dispensed the first serialized medicines, i.e. the information flow between the MAHs and the NMVS has been tested end-to-end.
- The web app is no longer available.

Organization

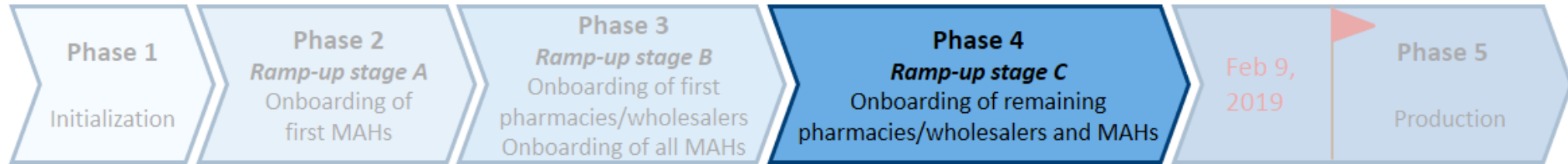
- The onboarding of the major part of the pharmacies and wholesalers has been prepared.

New functionalities

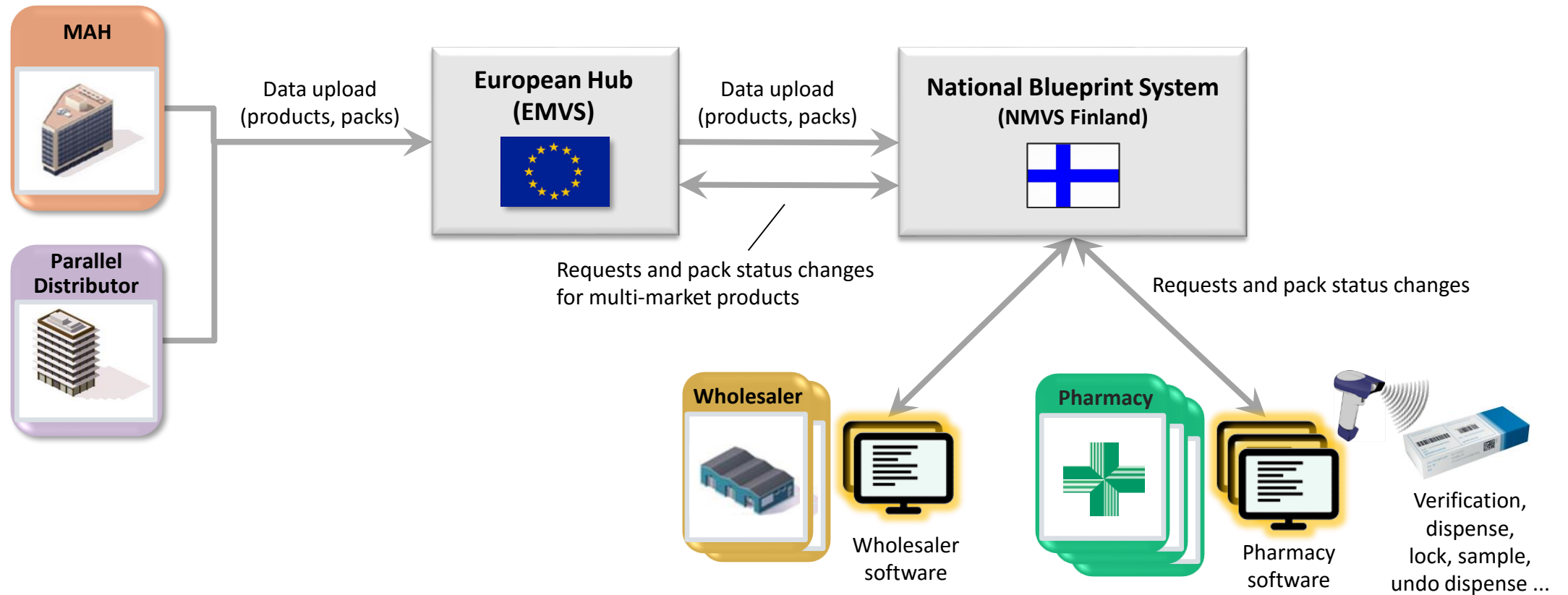
- The NMVS web services are fully functional, including multi-country transactions.

Planning, Detail View

Phase 4: Ramp-up Stage C (Apr – Oct 2018)



During Phase 4, the functionality of the various pharmacy and wholesaler software systems will be tested:



Planning, Detail View

Phase 4: Ramp-up Stage C (Apr – Oct 2018)



Results of Phase 4:

New functionalities

- All software suppliers have connected their systems with the NMVS web services.
- The new pharmacy/wholesaler software systems have been installed at almost all pharmacies and wholesalers.

Organisation

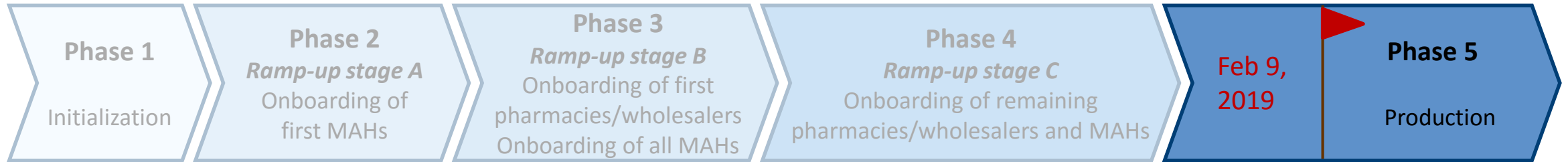
- The software suppliers have trained their users at pharmacies and wholesalers.

Utilization

- The new software version have already been used at the pharmacies and wholesalers.
- The vast majority of medicine packs on the Finnish market is now serialized.

Planning, Detail View

Phase 5: Production (Nov 2018 – Feb 2019)



Results until Feb 9, 2019:

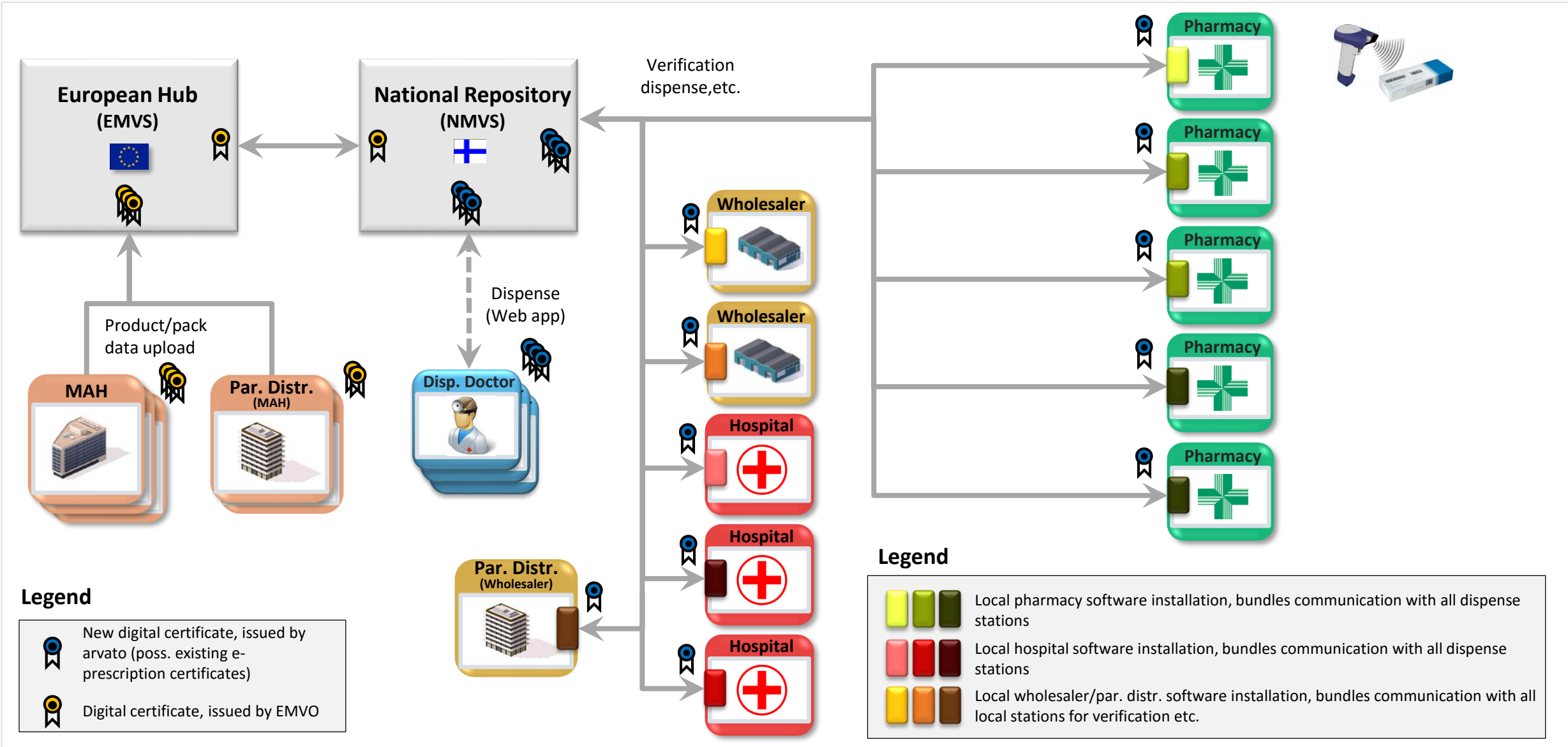
New functionalities

- The new pharmacy/wholesaler software systems have been installed at all pharmacies and wholesalers

Utilization

- The verification of medicines has become a routine at the pharmacies and wholesalers.
- Almost all medicine packs on the Finnish market are now serialized.

NMVS System Architecture Overview



Arvato

Company structure and competencies

Challenges

Which challenges have to be mastered?
Who is affected?

Planning

Which planning structure is proposed to finish the project within the given time frame?

Next steps

Which are the next steps?
Who will have to contribute what?

Next Steps

1. Review and finalization of business requirements (Connection scenarios, changed URS)
=> *Objective:*
 - *Planning finished*
2. Select MAHs for Phase 2
=> *Objectives:*
 - *The first MAHs are preparing the production of (at least some) serialized medicines*
 - *The first MAHs are able to upload product master data and pack data to the EU Hub*
3. Arvato starts to install the Finnish NMVS infrastructure & system
=> *Objectives:*
 - *The connection between the EU Hub and the NMVS has been established*
 - *The NMVS can receive product/pack data from the MAHs*
4. Provide the NMVS web service description to the pharmacy/wholesaler software suppliers
=> *Objective:*
 - *The software suppliers can prepare themselves to connect their software packages with the NMVS*

Thank You!

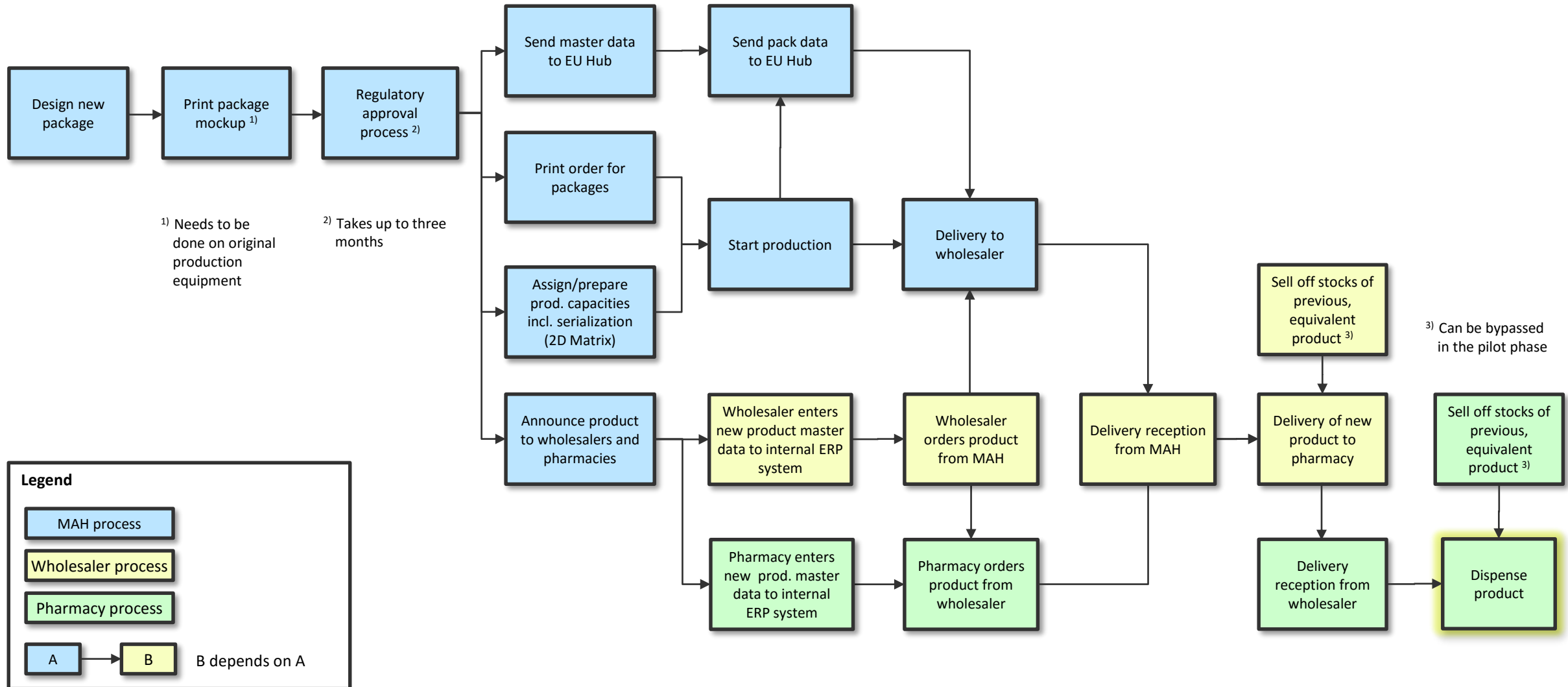
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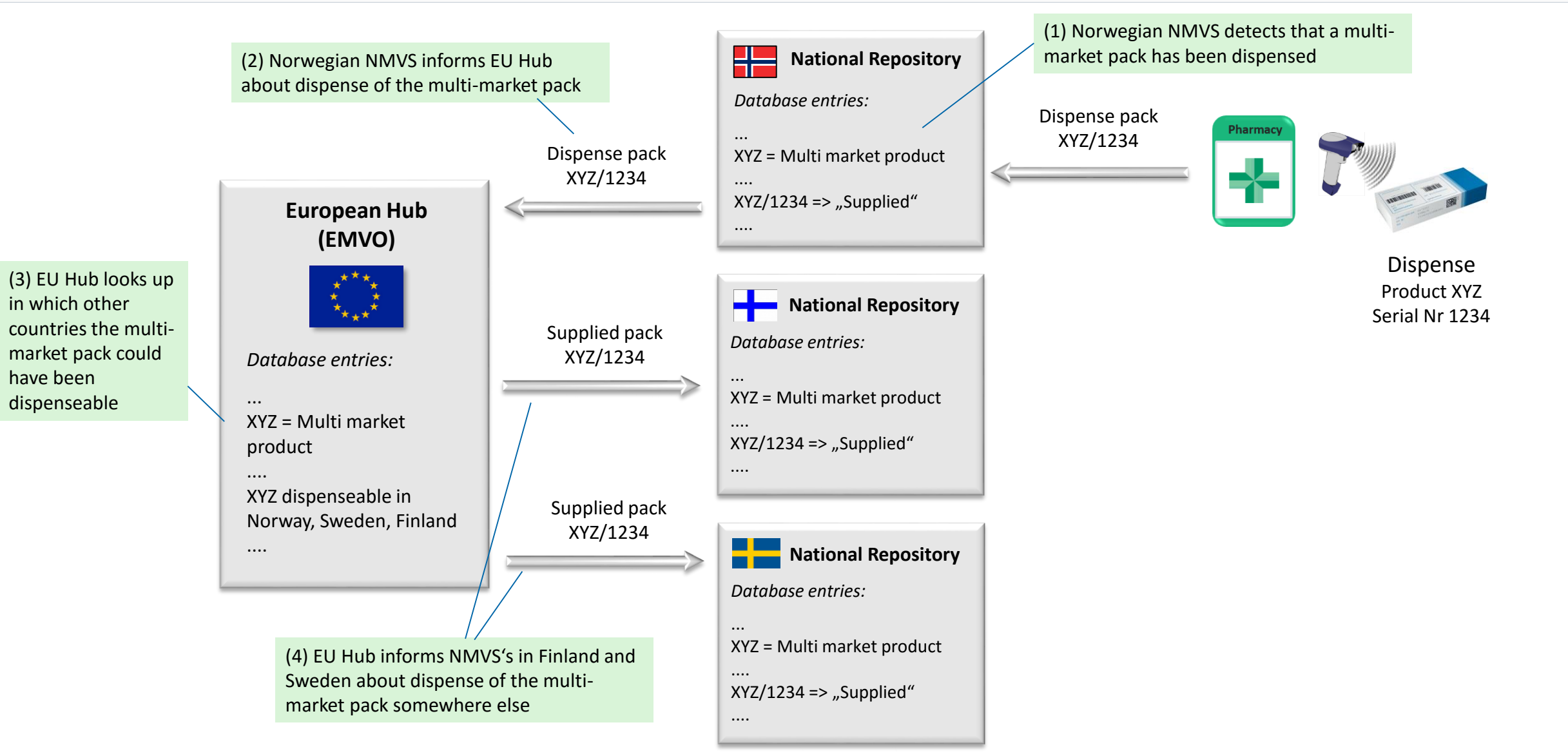
Backup slides

Process chain to introduce a new product variant into the market

Assumption: The new product is a variant of an already existing product, so no marketing/sales process is required.



What are Multi-Market Transactions?



What are Inter-Market Transactions?

