Technical Workgroup Meeting II

Helsinki
April 06, 2017

arvato
BERTELSMANN

IT SOLUTIONS

Agenda

Arvato

Company structure and competencies

Project details

Planning structure and project details of the Finnish NMVS project

Onboarding

Onboarding approach / procedures for software suppliers

Technical details

Information about connection scenarios, web service groups and the current web service interface

Next steps

Which are the next steps?

Who will have to contribute what?

IT SOLUTIONS

Bertelsmann
Internationally Leading Media and Service Company

FACTS & FIGURES

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

BERTELSMANN

IT SOLUTIONS

RTL GROUP

Penguin Random House

G+J

arvato BERTELSMANN

BE PRINTERS

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

*FY 2015

BERTELSMANN

↓ 100%

arvato
BERTELSMANN

↓ 100%

arvato
SYSTEMS

Media & Services Company

BPO Service Provider
- **Logistics**
- **CRM**
- **Finance**
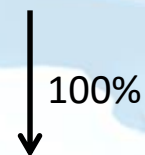
IT Service Provider

IT SOLUTIONS

Arvato
Global Setup – Local Approach

France:
16 locations

UK:
Beverley/ Willerby
Birmingham
East Riding
High Wycombe
Liverpool
London

Belgium:
Antwerp
Brussels
Zaventem

Netherlands:
Abcoude
Hilversum
Venlo
Venray

Poland:
Plewiska
Szczecin
Poznan
Blonie
Warsaw
Gadki

Kitchener

Vancouver

USA:
Berryville
Dallas
Dulles
Duncan, SC
Horsham
Louisville, KY
Mountain View
New York
Pleasant Prairie, WI
Reno
Valencia, CA
Weaverville, NC

Malmö

Dublin

Yaroslavl

Tallinn

Czech Republic:
Brno, Prague
Mlada Boleslaw
Stochov

Vienna

Budapest

Lisbon
Porto

Spain:
8 locations

Casablanca
Marrakesh

Turkey:
Ankara
Diyarbakir
Istanbul
Izmir

New Delhi

Gurgaon

Bergamo

Athens

Mexico DF
Monterrey
Juarez

Switzerland:
Adligenswil
Baar
Pratteln
Rotkreuz
Schlieren

Germany:
57 locations

Changchun

Beijing

Shanghai

Hangzhou

Xiamen

Shenzhen

Hong Kong

Manila

Guangzhou

Bangkok

Singapore

Bogota

Lima

São Paulo
Guarulhos
Hortolândia
Manaus

Buenos Aires

Port Elizabeth

Sydney

IT SOLUTIONS

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
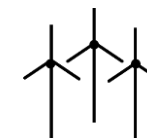
Arvato's background towards the FMD-Business

Microsoft
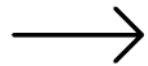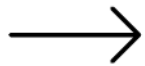
Product Serialization
against software piracy

Arvato's background towards the FMD-Business

Product Serialization
against software piracy

Secure National Hub *to*
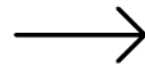*prevent Car Insurance Fraud*

IT SOLUTIONS
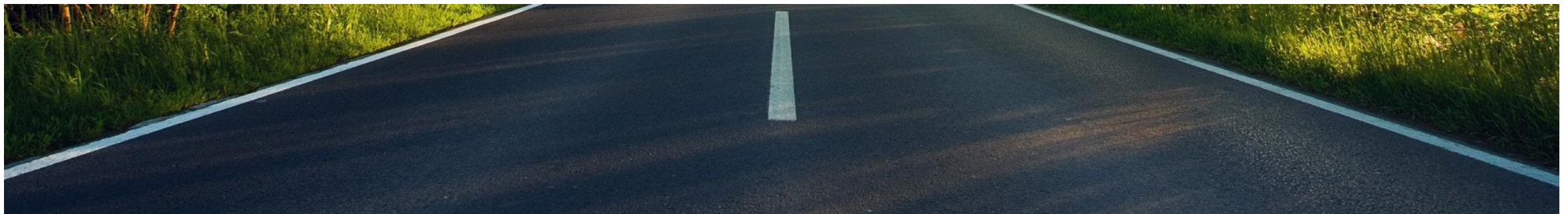
Arvato's background towards the FMD-Business

Product Serialization
against software piracy

Secure National Hub *to prevent Car Insurance Fraud*

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

IT SOLUTIONS

Arvato's background towards the FMD-Business

Product Serialization
against software piracy

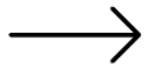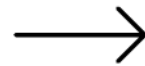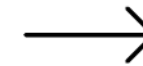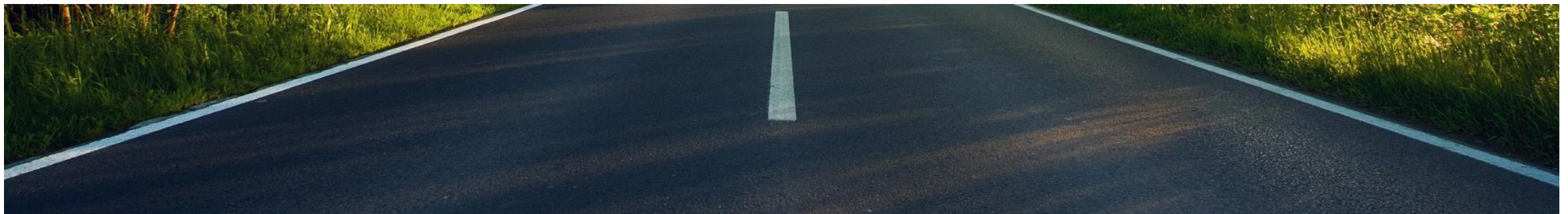**Secure National Hub** *to prevent Car Insurance Fraud*

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

First **National Verification System** *in Europe*

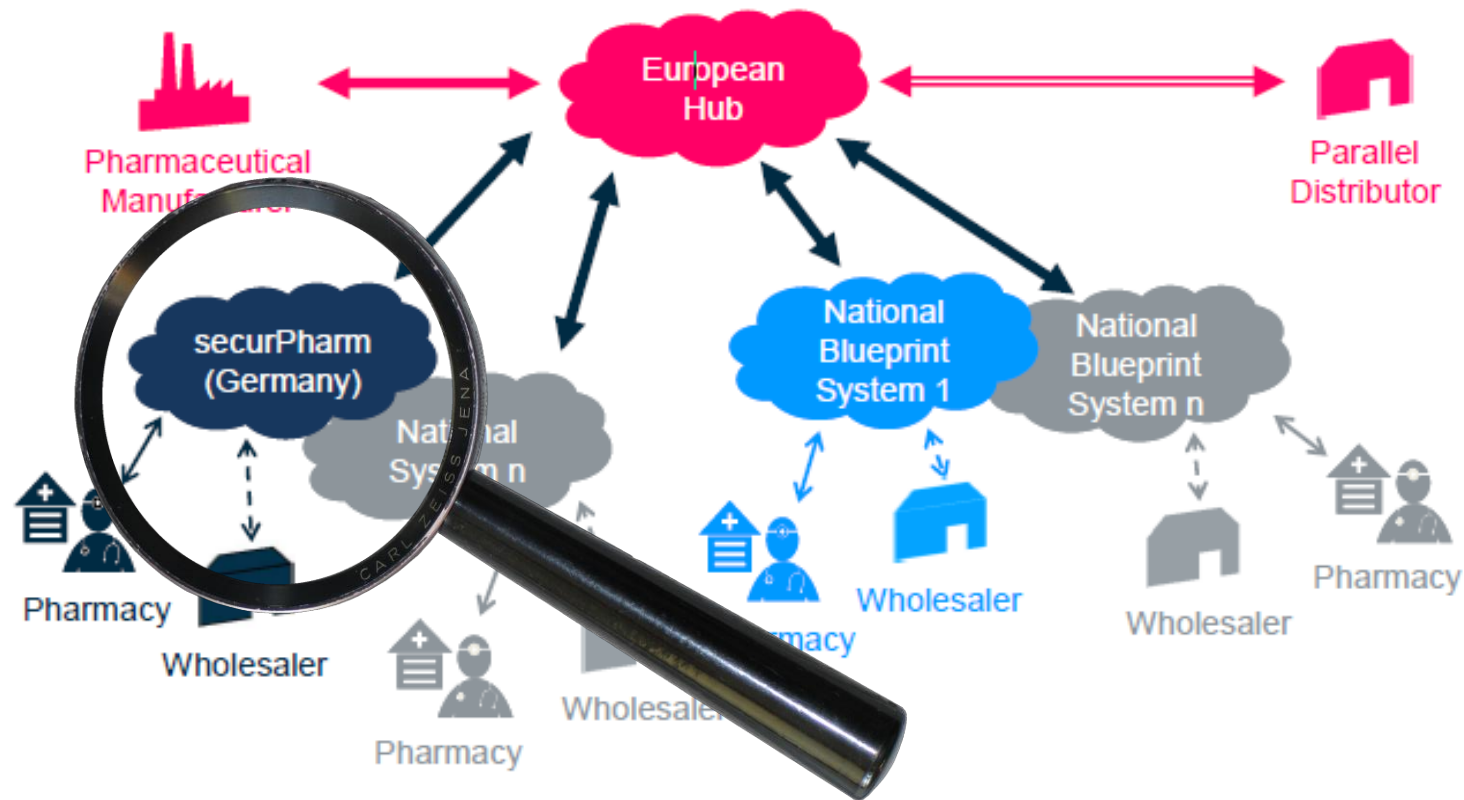IT SOLUTIONS

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

IT SOLUTIONS

… and another customer- Norway: first operational Blueprint project
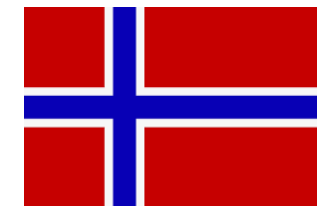
Signature of Letter of Intent with NMVO Norway, 7th June 2016

IT SOLUTIONS

Arvato National Verification System: Customers

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

✓ Agreements:

Contracting / Mutual Agreements:
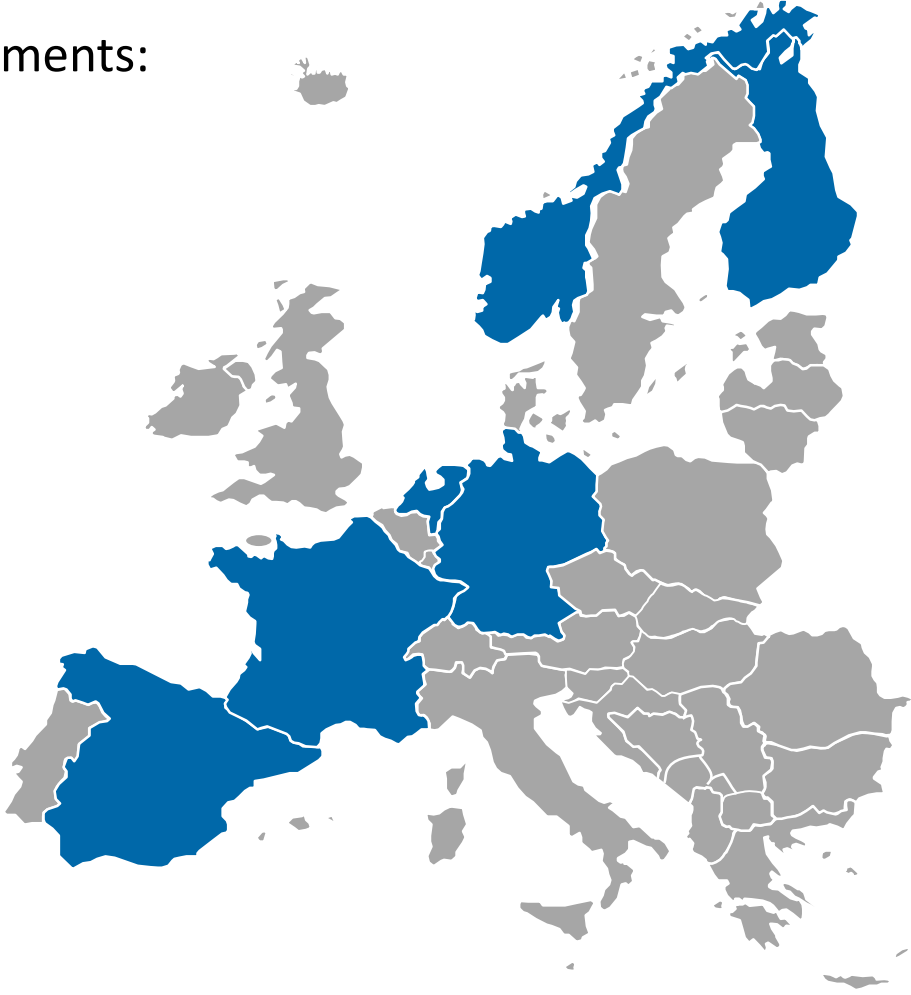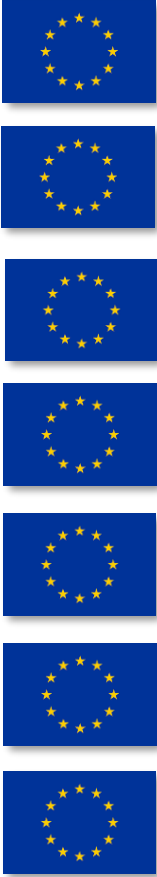
IT SOLUTIONS

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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:

Feb 1, 2017

Feb 9, 2019

| **Phase 1** Initialization | **Phase 2** *Ramp-up stage A* Onboarding of early-bird MAHs | **Phase 3** *Ramp-up stage B* Onboarding of early-bird pharmacies/wholesalers Onboarding of MAHs | **Phase 4** *Ramp-up stage C* Onboarding of remaining pharmacies/wholesalers and MAHs | **Phase 5** Production |

→ Feb – April 2017   → May – Dec 2017   → Jan – Mar 2018   → Apr – Oct 2018   → Nov 2018 – Feb 2019

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→ What are the results of each phase?
  Let's go through the five phases shown.

Phase 1	Phase 2	Phase 3	Phase 4	Feb 9, 2019	Phase 5
Initialization	*Ramp-up stage A* Onboarding of early-bird MAHs	*Ramp-up stage B* Onboarding of early-bird pharmacies/wholesalers Onboarding of MAHs	*Ramp-up stage C* Onboarding of pharmacies/wholesalers and MAHs		Production
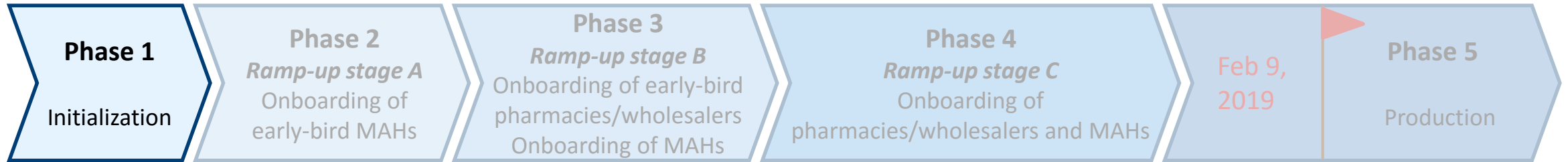
Results of Phase 1:

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 („early birds") 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

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Planning, Detail View
Phase 2: Ramp-up Stage A (May – Dec 2017)

Phase 1	Phase 2	Phase 3	Phase 4		Phase 5
Initialization	*Ramp-up stage A* Onboarding of early-bird MAHs	*Ramp-up stage B* Onboarding of early-bird pharmacies/wholesalers Onboarding of MAHs	*Ramp-up stage C* Onboarding of pharmacies/wholesalers and MAHs	Feb 9, 2019	Production
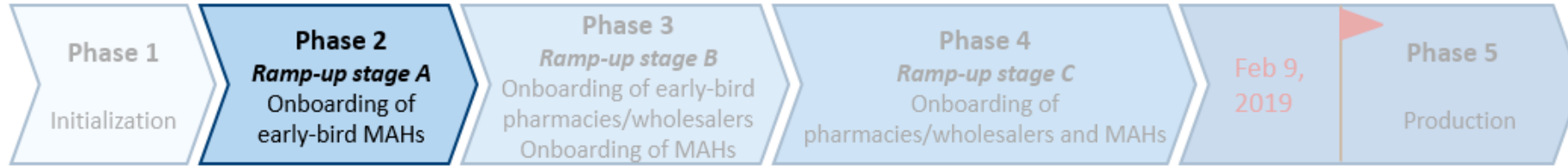
During phase 2, the highlighted information flows will be tested:

MAH

Parallel Distributor

Data upload (products, packs)

EU Hub (EMVS)

Data upload (products, packs)

National Blueprint System (NMVS Finland)

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Phase 1	**Phase 2** *Ramp-up stage A* Onboarding of early-bird MAHs	**Phase 3** *Ramp-up stage B* Onboarding of early-bird pharmacies/wholesalers Onboarding of MAHs	**Phase 4** *Ramp-up stage C* Onboarding of pharmacies/wholesalers and MAHs	Feb 9, 2019	Phase 5
Initialization					Production

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 („early birds") 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

IT SOLUTIONS

Planning, Detail View
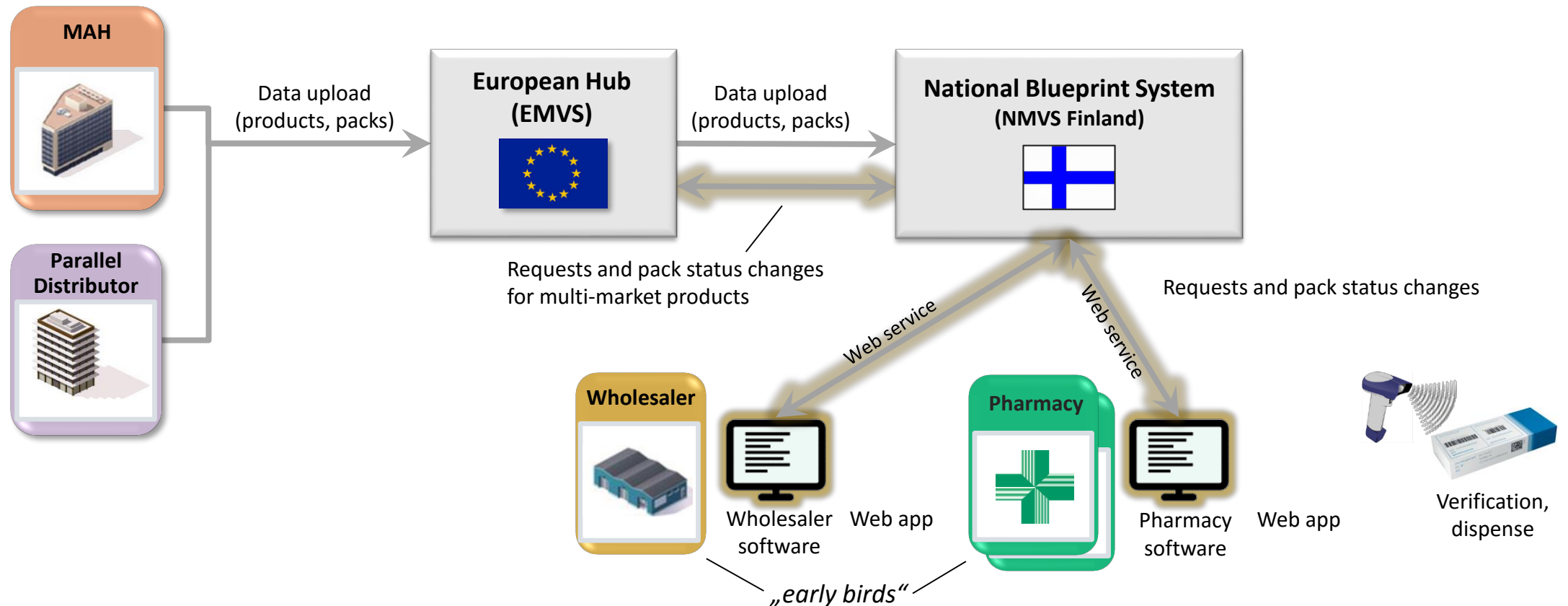## Phase 3: Ramp-up Stage B (Jan – Mar 2018)

Phase 1	Phase 2	**Phase 3**	Phase 4		Phase 5
	Ramp-up stage A	*Ramp-up stage B*	*Ramp-up stage C*		
	Onboarding of	Onboarding of early-bird	Onboarding of	Feb 9, 2019	
Initialization	early-bird MAHs	pharmacies/wholesalers	pharmacies/wholesalers and MAHs		Production
		Onboarding of MAHs			

Results of Phase 3:

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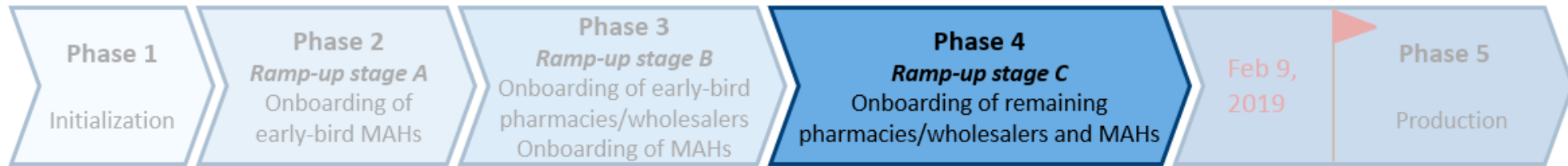- The web app is no longer available.

Organization
- The onboarding of the major part of the pharmacies and wholesalers has been prepared.
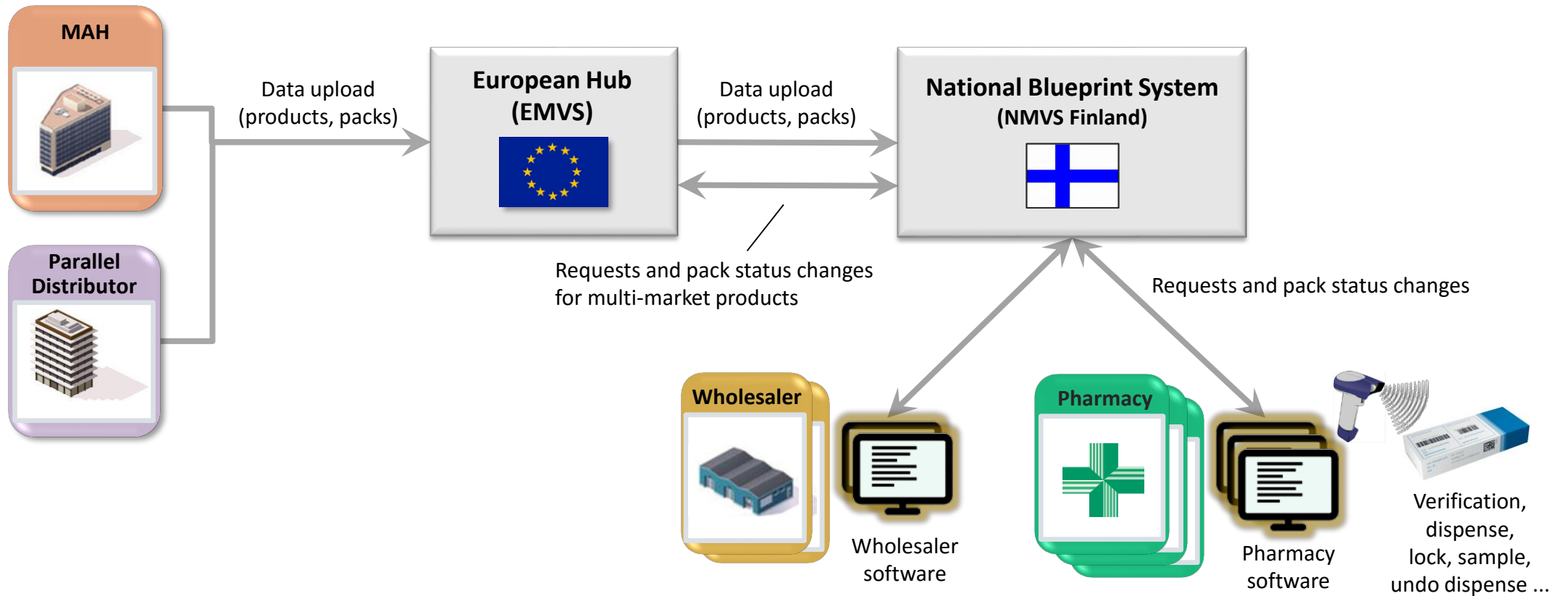
New functionalities
- The NMVS web services are fully functional, including multi-country transactions.
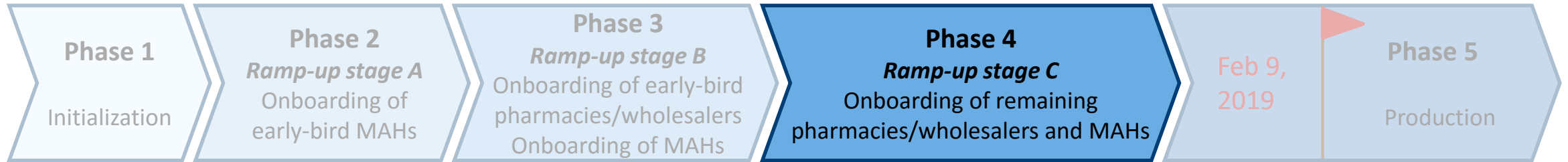
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During Phase 4, the functionality of the various pharmacy and wholesaler software systems will be tested:

IT SOLUTIONS

Planning, Detail View
Phase 4: Ramp-up Stage C (Apr – Oct 2018)

Phase 1	Phase 2	Phase 3	Phase 4		Phase 5
Initialization	*Ramp-up stage A* Onboarding of early-bird MAHs	*Ramp-up stage B* Onboarding of early-bird pharmacies/wholesalers Onboarding of MAHs	**Phase 4** *Ramp-up stage C* Onboarding of remaining pharmacies/wholesalers and MAHs	Feb 9, 2019	Production

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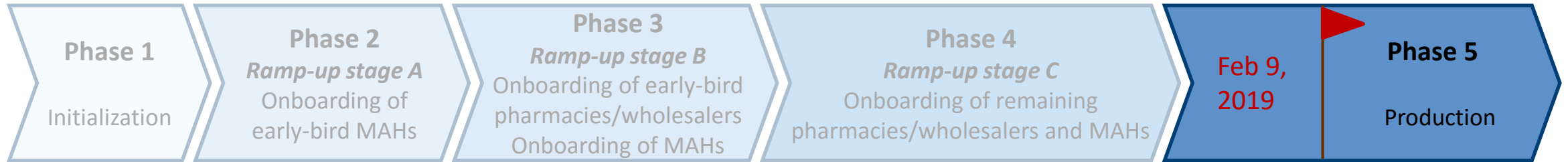
Organisation
- The software suppliers have trained their users at pharmacies and wholesalers.

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.

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Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Initialization	*Ramp-up stage A* Onboarding of early-bird MAHs	*Ramp-up stage B* Onboarding of early-bird pharmacies/wholesalers Onboarding of MAHs	*Ramp-up stage C* Onboarding of remaining pharmacies/wholesalers and MAHs	Feb 9, 2019 Production

Results until Feb 9, 2019:

New functionalities

- The new pharmacy/wholesaler software systems have been installed at <u>all</u> 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.

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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

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What exactly needs to be done? (2)

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- 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

IT SOLUTIONS

What exactly needs to be done? (3)

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- 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**

IT SOLUTIONS

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Onboarding

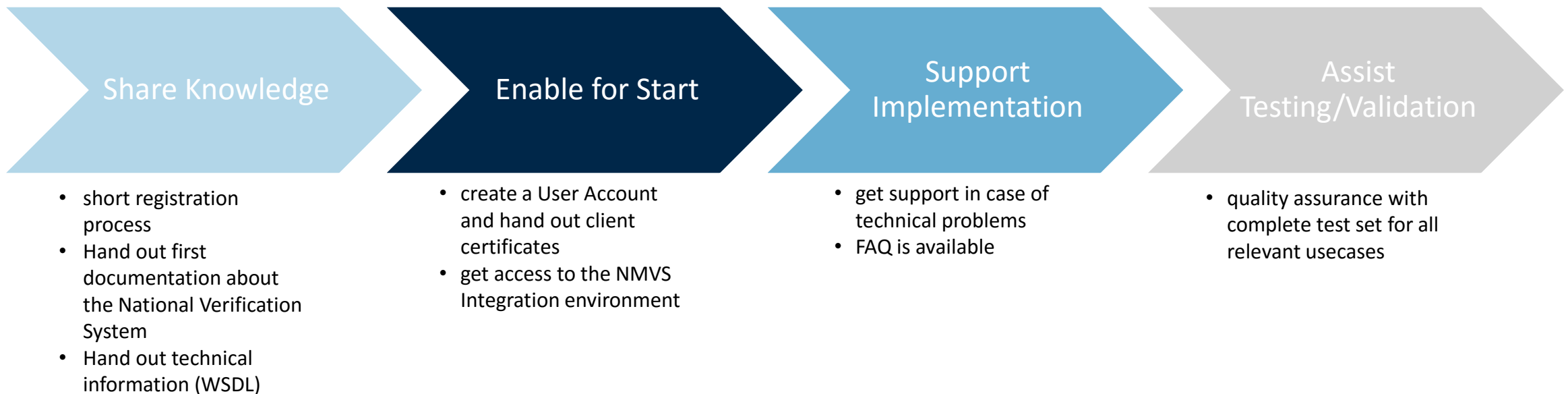Onboarding approach / procedures for software suppliers

Technical details

Information about connection scenarios, web service groups and the current web service interface
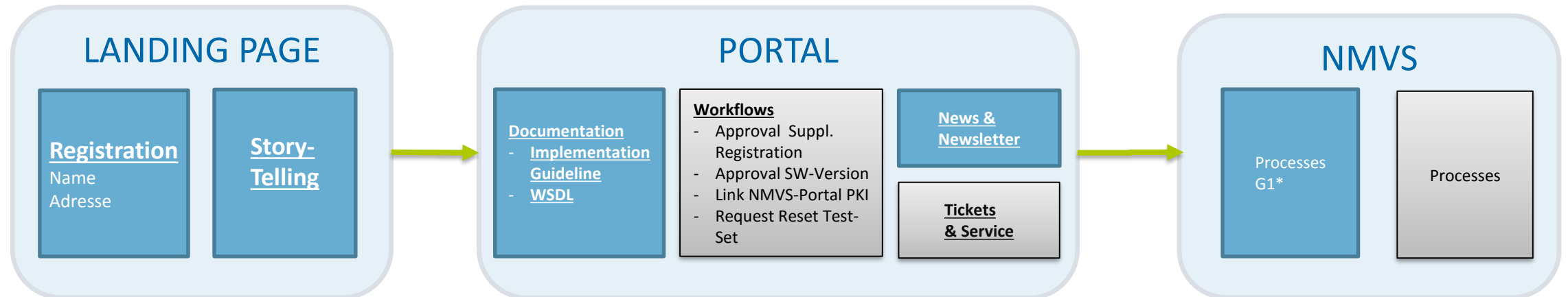
Next steps

Which are the next steps?

Who will have to contribute what?

IT SOLUTIONS

Our Onboarding Approach

Share Knowledge	Enable for Start	Support Implementation	Assist Testing/Validation
• short registration process • Hand out first documentation about the National Verification System • Hand out technical information (WSDL)	• create a User Account and hand out client certificates • get access to the NMVS Integration environment	• get support in case of technical problems • FAQ is available	• quality assurance with complete test set for all relevant usecases

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Our Onboarding Approach

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| Share Knowledge | Enable for Start | Support Implementation | Assist Testing/Validation |

LANDING PAGE

Registration
Name
Adresse

Story-Telling

PORTAL

Documentation
- **Implementation Guideline**
- **WSDL**

Workflows
- Approval Suppl. Registration
- Approval SW-Version
- Link NMVS-Portal PKI
- Request Reset Test-Set

News & Newsletter

Tickets & Service

NMVS

Processes G1*

Processes

COMPLETED

APRIL 2017

JULY 2017

AUGUST 2017

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Onboarding Process step by step

Within the onboarding process we distinguish between a connection to the Integration and Production Environment.
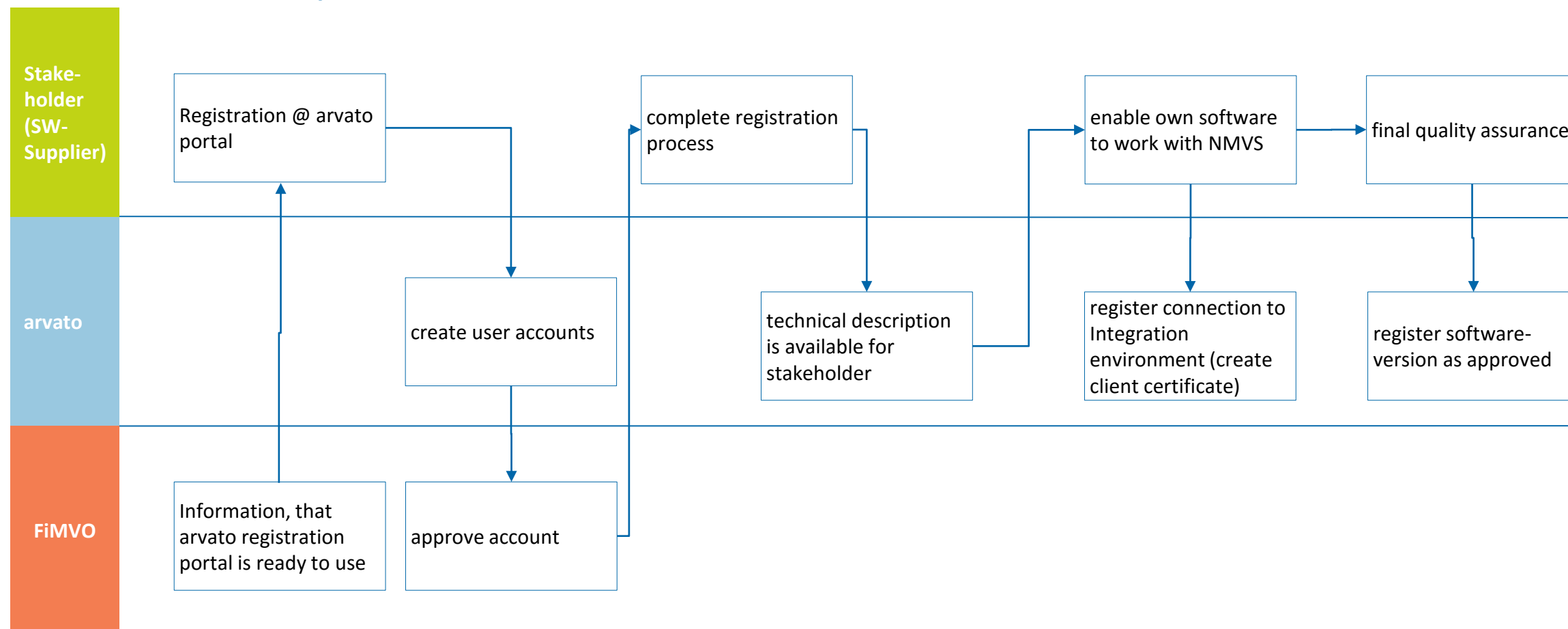
At first, an arvato web portal is available for all relevant stakeholders (software supplier, wholesaler, Hospital IT-organizations) who have to enable their software to get in contact to the NMVS. These stakeholders have to pass a short registration process and the FiMVO has to approve the stakeholder. After that, the stakeholders have access to the software development kit, additional information, FAQ and are able to set some ticket requests.

With the available technical information, the stakeholders can plan their development streams and empower their software for a productive use. For the connection to the Integration environment, a client certificate will be handed out by arvato to the stakeholder.
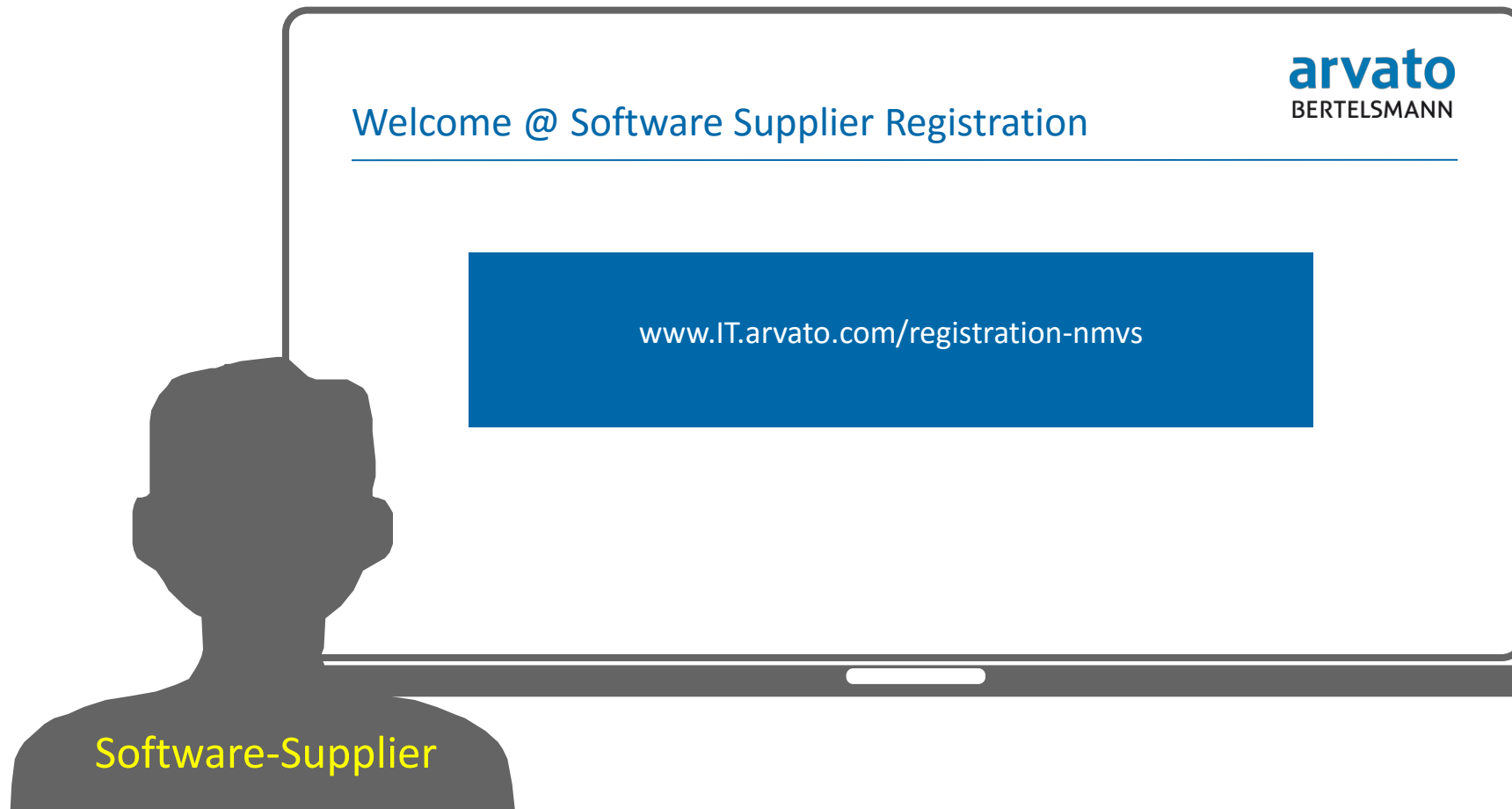
arvato delivers a set of test data to support the quality assurance at the stakeholder.

The stakeholder can request a final quality check, if he passes this, a use of the stakeholder software is permitted for the production environment.

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Landing Page

Welcome @ Software Supplier Registration

www.IT.arvato.com/registration-nmvs

Software-Supplier

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Software Supplier Registration

Welcome @ Software Supplier Registration

Login	
User	PharmSoft Ltd.
Password	XXXXXXXX

Submit login data

Registration

Reset Password

Software-Supplier

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Login

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Welcome @ Software Supplier Registration

Login	
User	PharmSoft Ltd.
Password	XXXXXXXX

Submit login data

Registration

Reset Password

Software-Supplier

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SW-Supplier Registration

Welcome @ Software Supplier Registration

Task „Approval"
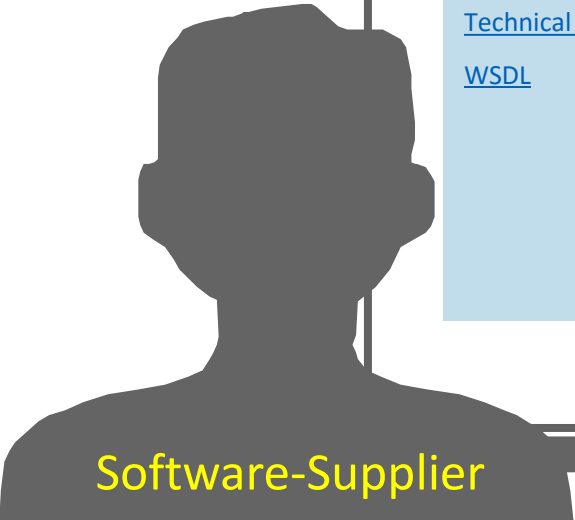
User Data		Company Data	
Salutation	Mr.	Country	United Kingdom
First name	Victor	Company Name	PharmSoft Ltd.
Last name	Blashnik	Street / No	High Street 77
E-mail address	victorblashnik@gmail.com	ZIP / City	RG4 7ZD Reading
Telephone	+44 17 34872322	Software name & version	PharmSoft Easy 3.00

Approve   **Reject**

FiMVO-Admin

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Registered Software Supplier

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IT SOLUTIONS

Scenario 1 – Connection via a aggregator with anonymous end user

- Each pharmacy directly connected to the national pharmacy association system
- Trusted connection between pharmacy and national pharmacy association system
- Onboarding only for national pharmacy association (aggregator) system
- Client-ID / User-ID / Password are known for the national pharmacy association
- pharmacies are anonymous in the NMVS
- WEB-GUI need to be hosted by the association system
- ➤ no Blue-Print Scenario

IT SOLUTIONS

Scenario 2 – Connection via a aggregator with pseudonymous pharmacy information
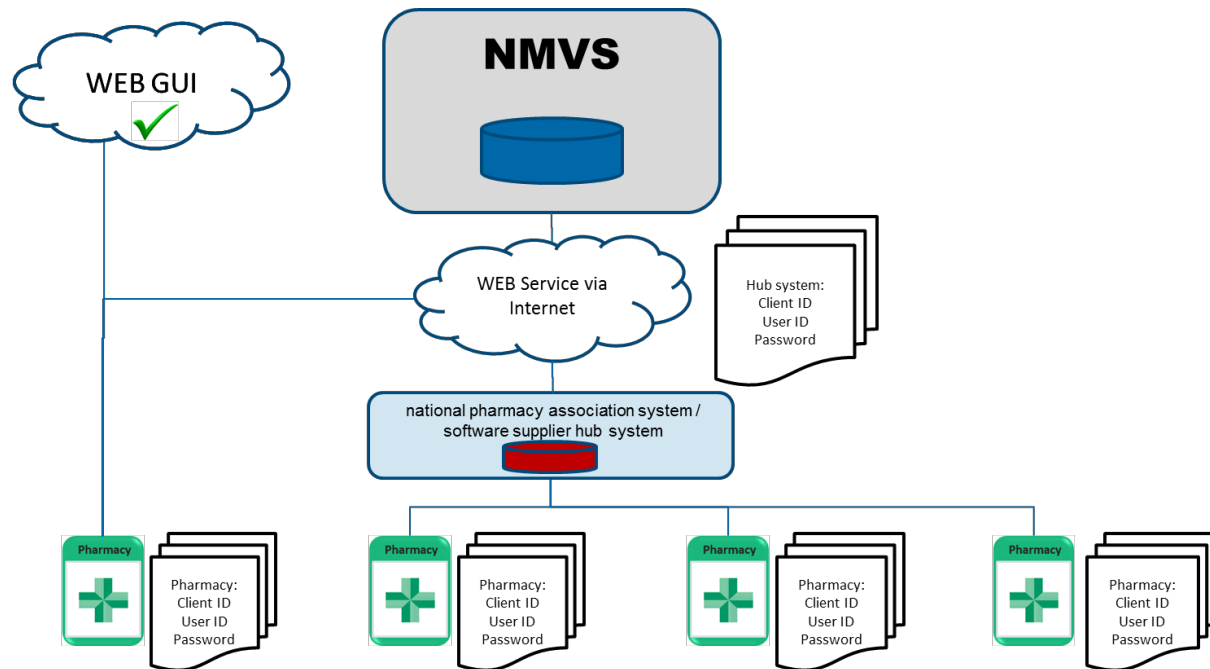
- Each pharmacy directly connected to the national pharmacy association system (aggregator)
- Trusted connection between pharmacy and national pharmacy association system (aggregator)
- Onboarding for each pharmacy has to be done by the national association
- Client-ID / User-ID / Password are known for the national pharmacy association system (aggregator)
- national pharmacy association systems (aggregator) forwards the User-ID at least as pseudonym
- Password of each pharmacy not known in the NMVS
- WEB-GUI requires own user registration
  - ➤ enlarged Blue-Print Scenario
  - ➤ no consolidation of User Information

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Scenario 3a – Standard Blue-Print Connection with pseudonym users
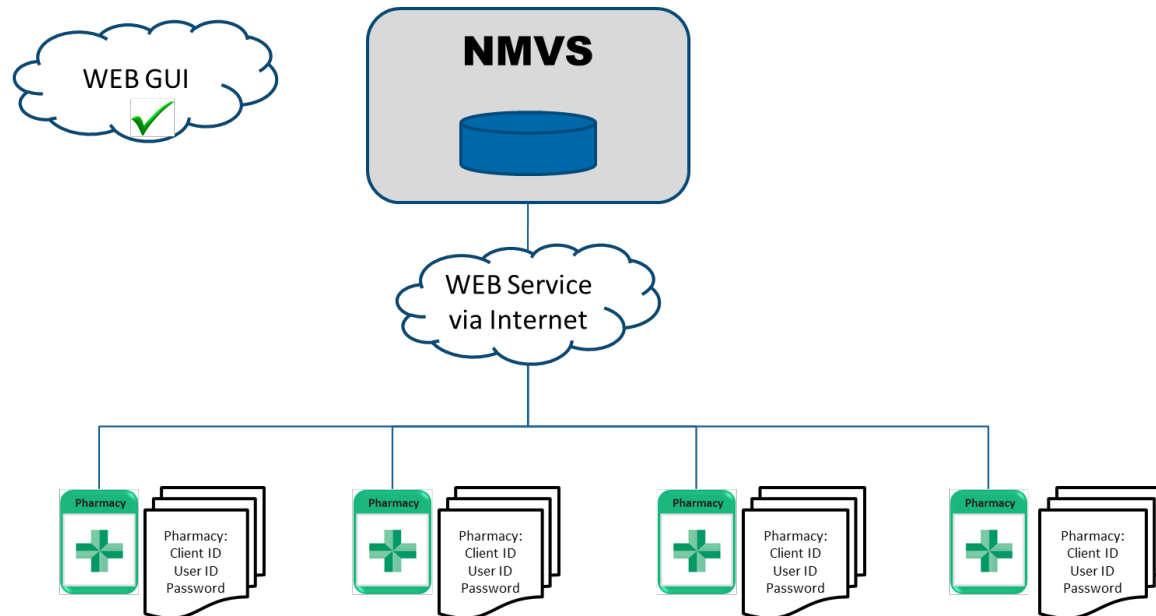
- Each pharmacy directly connected to the NMVS
- Onboarding for each pharmacy with complete distribution of onboarding information by the NMVO
- Client-ID / User-ID only as pseudonym within the system
- Password from pharmacy are known
- Certificate for the user is necessary
- Wholesalers are similar to pharmacies
- Use of WEB-GUI is possible, if the user use the pseudonym information as credentials.

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Scenario 3b – Standard Blue-Print Connection
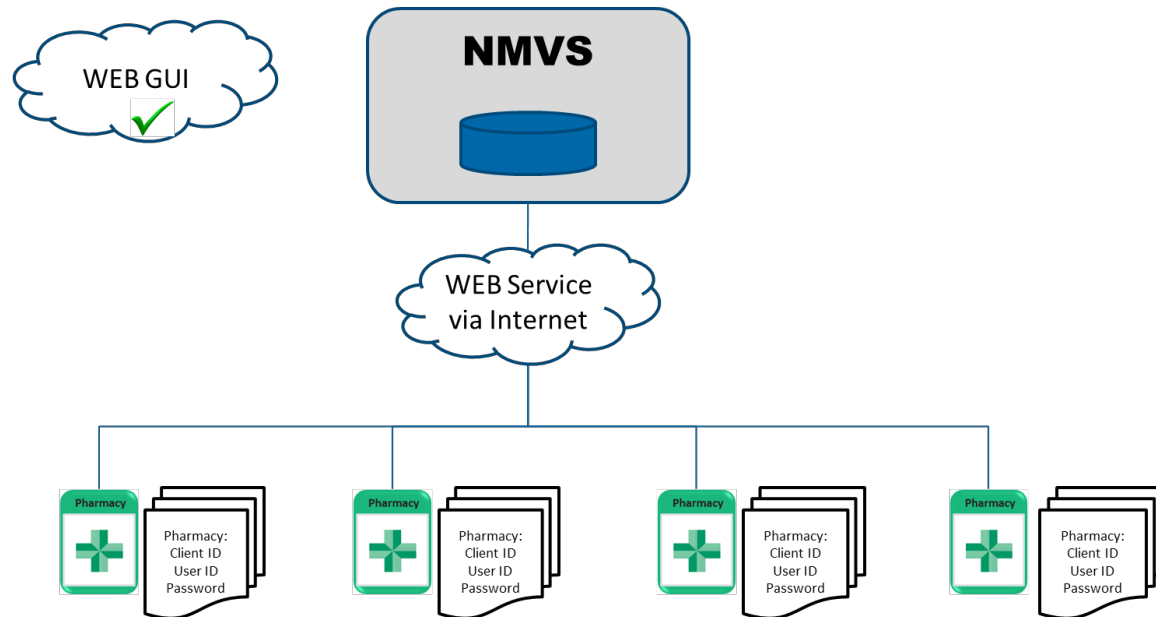
- Each pharmacy directly connected to the NMVS
- Onboarding for each pharmacy
- Client-ID / User-ID / Password from pharmacy are known
- Certificate for the user is necessary
- Wholesalers are similar to pharmacies

Connection scenarios - Problems

- The latest URS requires a web frond end service in case of a failure in the pharmacy software.

- A web frontend service requires the same authentication policies than the pharmacy software.

- With the use of central pharmacy systems a web frontend use might be problematic, due to the fact, that either the password need to be stored in 2 systems or 2 different password need to be used by the end-user.

- Different use cases in the system makes it relevant, that a single pharmacy is known at least by an pseudonym in the NMVS – Scenario 1 does not fulfil this requirement!

IT SOLUTIONS

Who needs to be connected?

Scenario	Integration-Environment	Production-Environment
Scenario 1 – Connection via a central HUB-System with anonymous end user	SW-Supplier (only HUB-System provider) Wholesaler-IT	HUB-System (aggregator) Wholesaler
Scenario 2 – Connection via a central HUB-System with pseudonymous pharmacy information	SW-Supplier (HUB-System provider) Hospital-IT, Wholesaler-IT	HUB-System (aggregator) Wholesaler Pharmacies (Web-Interface only!)
Scenario 3a – Standard Blue-Print Connection with pseudonym users	SW-Supplier Hospital-IT Wholesaler-IT	Wholesaler Pharmacies
Scenario 3b – Standard Blue-Print Connection	SW-Supplier Hospital-IT Wholesaler-IT	Wholesaler Pharmacies

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- Are all pharmacies/wholesalers directly connected to the NMVS?
- Are all pharmacies/wholesalers known by unique user and password information in the NVMS?
- Are all pharmacies/wholesalers known at least by a pseudonym?
- Is it necessary to work with anonymised pharmacy/wholesaler information?
- Is a web frontend service, like requested in the URS, relevant for the business in the country?
- Is it possible, that the national hub provider (aggregator) host the web frontend?

IT SOLUTIONS

Functional & technical documentation

- **Distribution pack 1** (available at the software-supplier-portal):
  - DOCS (DRAFTS):
    - Implementation_Guideline_NMVO 0.9 (PDF)
    - BP 1.0 Interface Description for Distributors (Excel)
    - BP 1.0 NMVS API Reference Distributors Interface (PDF)
  - WSDL (DRAFTS):
    - WSDL-XSD-FOR-DISTRIBUTORS
  - XML-Examples (DRAFTS):
    - BP 1.0 Interface Description for Distributors XML Example
    - BP 1.0 Interface Specification Administration

- **Distribution pack 2** (delivery date needs to be defined – approx. 07-2017):
  - Update of distribution pack 1
  - Complete technical interface description
  - Implementation examples for webservice-clients:
    - Single Transactions
    - Offline concecpt
    - Bulk concept
    - Java-example
    - #C Example
    - Generic test concept

IT SOLUTIONS

Web Service Groups - Overview

- The following web service **groups** exist (1):

  - Submit Single Pack Transaction
    Single pack transactions, e.g. *Verify Single Pack, Dispense Single Pack, Destroy Single Pack*

  - Undo Single Pack Transaction
    Reverse single pack transactions, e.g. *Undo Dispense*

IT SOLUTIONS

Web Service Groups - Overview

- The following web service **groups** exist (2):

  - Submit Bulk Transactions
    Bulk transactions are lists of transactions with the same product, batch id and transaction type.
    They are generated by wholesalers to handle large quantities of packs, e.g. *Bulk Verify Packs*, *Bulk Export Packs.*

  - Request Bulk Transaction Result
    Bulk transactions are processed asynchronously. These web services are used to fetch the results of previously submitted bulk transactions.

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Bulk Transactions – Function Principle

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

| **Header:** Product Number Batch Id Transaction Type Client Transaction Id | **List Element 1:** Serial Number 1 | **List Element 2:** Serial Number 2 | ... | **List Element n:** Serial Number *n* |
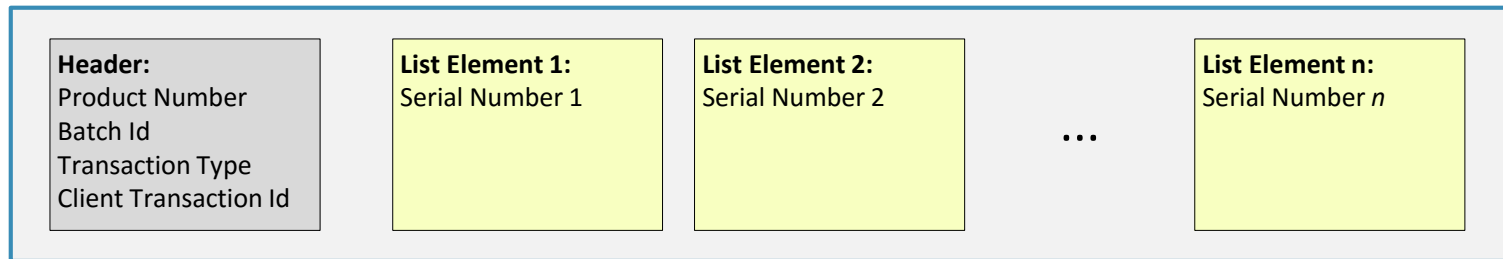
Request the result of the bulk request:

| **Header:** Product Number Batch Id Transaction Type Client Transaction Id | **List Element 1:** Serial Number 1 Result 1 | **List Element 2:** Serial Number 2 Result 2 | ... | **List Element n:** Serial Number *n* Result *n* |

IT SOLUTIONS
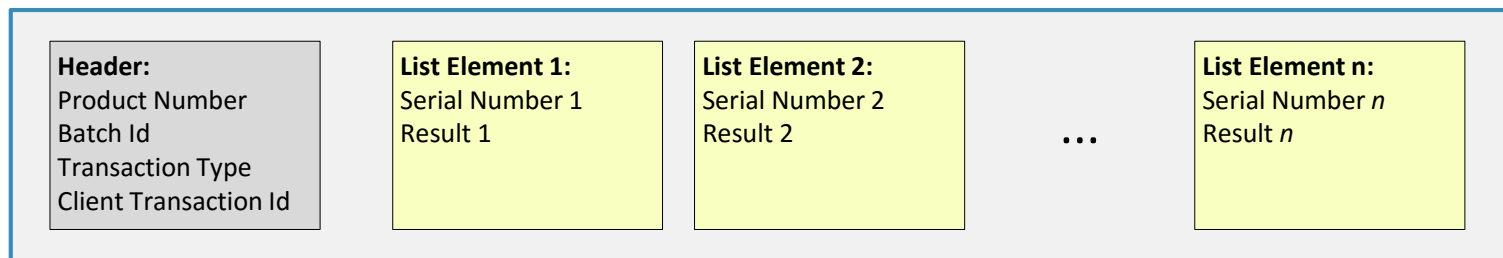
Web Service Groups - Overview

- The following web service **groups** exist (3):

  - Submit Offline Bulk Transactions ("Offline Recap")
    Offline bulk transactions contain transactions with heterogeneous products and transaction types.
    They are generated by pharmacies when the local transaction buffer is emptied after an offline period.

  - Request Offline Bulk Transaction Results ("Offline Recap")
    Offline bulk transactions are processed asynchronously.
    These web services are used to fetch the results of previously submitted offline bulk transactions.

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Offline Bulk Transactions – Function Principle

Submit a list of <u>heterogenous</u> single pack requests as one bulk request (pharmacies only):

Header: Client Transaction Id	**List Element 1:** Product Number 1 Serial Number 1 Transaction Type 1	**List Element 2:** Product Number 2 Serial Number 2 Transaction Type 2	...	**List Element n:** Product Number n Serial Number n Transaction Type n
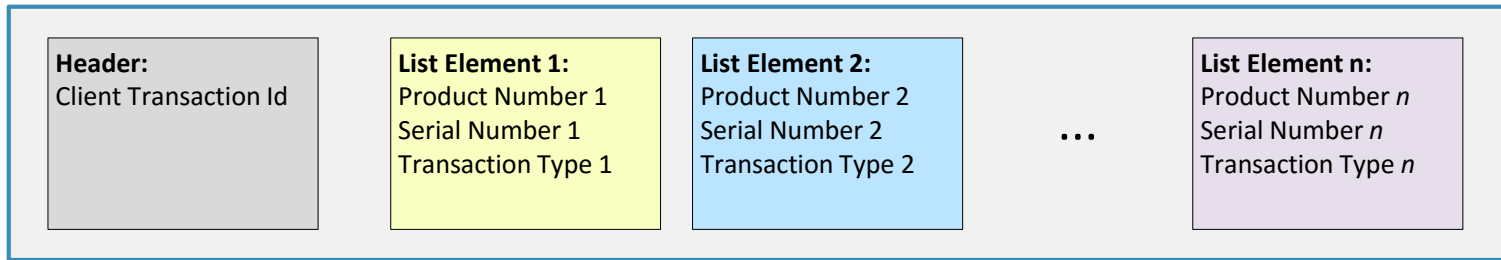
Request the result of the offline bulk request:

Header: Client Transaction Id	**List Element 1:** Client Transaction ID 1 Product Number 1 Serial Number 1 Transaction Type 1 Result 1	**List Element 2:** Client Transaction ID 2 Product Number 2 Serial Number 2 Transaction Type 2 Result 2	...	**List Element n:** Client Transaction ID n Product Number n Serial Number n Transaction Type n Result n

IT SOLUTIONS
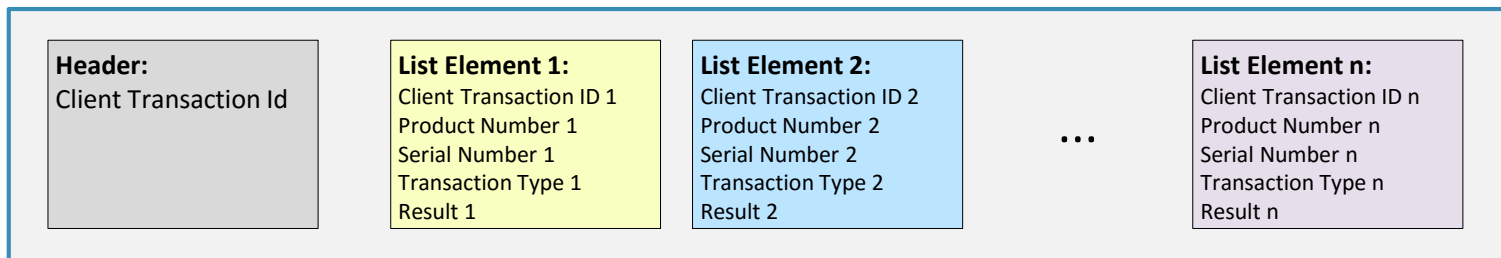
Web Service Group – Single Pack Transactions (1)

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

Pharmacies are **not** allowed to submit this type of transaction

Wholesalers are allowed to submit this type of transaction

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Web Service Group –Single Pack Transactions (2)

Web Service Id	Web Service Name/Description	Pharmacy	Wholesaler
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).		X
G182	**Stolen Single Pack Manual Entry** Report that a single pack has been stolen, with manual data entry. Assumption: The serial number is still available (e.g. from an earlier scan).		X
G111	**End-to-End Test to Scan a Single Pack** Used to validate a pharmacy/wholesaler before admission to the production environment.	X	X

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Web Service Group – Undo Single Pack Transaction

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

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Web Service Group – Bulk Transactions (1)

	Web Service Name/Description	Pharmacy	Wholesaler
G115	**Bulk Verify packs** Submit a list of serial numbers (same product) for verification.		X
G125	**Bulk Dispense packs** Submit a list of serial numbers (same product) to report the corresponding packs as *dispensed*.		X
G135	**Bulk Destroy packs** Submit a list of serial numbers (same product) to report the corresponding packs as *destroyed*.		X
G145	**Bulk Export packs** Submit a list of serial numbers (same product) to report the corresponding packs as *exported*.		X
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.		X
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.		X
G175	**Bulk Lock packs** Submit a list of serial numbers (same product) to report the corresponding packs as *locked*.		X
G185	**Bulk Stolen packs** Submit a list of serial numbers (same product) to report the corresponding packs as *stolen*.		X

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Web Service Group – Bulk Transactions (2)

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

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Web Service Group – Bulk Result

Web Service Id	Web Service Name/Description	Pharmacy	Wholesaler
G116	**Bulk Verify Packs Result** Fetch the result of a previously submitted *bulk verify* transaction		X
G188	**Request Bulk Pack Operation Result** Fetch the result of a previously submitted bulk transaction other than *bulk verify*.		X
G199	**Request Pickup Ids for Bulk Transaction Result** A *pickup id* is used to refer to the results of a previous bulk transaction. If such pickup ids have been lost for some reason, this web service recovers all pickup ids whose results have not been fetched yet.		X

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Web Service Group – Offline Bulk Transactions

Web Service Id	Web Service Name/Description	Pharmacy	Wholesaler
G195	**Offline Bulk Transaction** An offline bulk transaction contains multiple single transactions with heterogeneous products and transaction types. It is generated by pharmacies when the local transaction buffer is emptied after an offline period.	X [1]	

[1] Only such transaction types are allowed within offline bulk transactions which are permitted as single transactions for pharmacies.

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Web Service Group – Offline Bulk Transaction Result

Web Service Id	Web Service Name/Description	Pharmacy	Wholesaler
G196	**Request Offline Bulk Transaction Result** Request the result of a previously submitted *offline bulk transaction*.	X	

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Web Service Parameter Structures – Example

Web Service Id	Web Service Name/Description	Input	Output
G110	**Verify Single Pack** Verify a single pack. This does not change the status of the pack.	I1 - Single pack	O1 - Single 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).	I1 - Single pack	O1 - Single pack
G122	**Dispense Single Pack Manual Entry** Dispense a single pack with manual data entry. Only the serial number will be submitted.	I2 - Manual single pack	O1 - Single pack
G130	**Destroy Single Pack** Report a single pack as destroyed.	I1 - Single pack	O1 - Single pack
G140	**Export Single Pack** Report a single pack as exported.	I1 - Single pack	O1 - Single pack
G150	**Sample Single Pack** Report that a single pack has been provided to authorities for sampling purposes.	I1 - Single pack	O1 - Single pack
G160	**Free Sample Single Pack** Report that a single pack has been given away as a free sample.	I1 - Single pack	O1 - Single pack
G170	**Lock Single Pack** Report that a single pack has been locked, e.g. to provide time for further investigations.	I1 - Single pack	O1 - Single pack

This is a reference to the <u>input</u> parameter <u>structure</u> of this web service

This is a reference to the <u>output</u> parameter <u>structure</u> of this web service

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Pharmacy/Wholesaler Interface
Status Mar 2017 (DRAFT):

BP 1.0 Interface
scription for Distri

List of web services

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Service Group Identifier	Description
WS_SINGLE_PACK	File: WS_SINGLE_PACK.wsdl Description: Web services to submit single pack transactions.
WS_BULK	File: WS_BULK.wsdl Description: Web services to submit a bulk of packages in one transaction and to get the result. All packages in one request belong to one batch. Different batches in one request are not allowed.
WS_OFFLINE_SYNC	File: WS_OFFLINE_SYNC.wsdl Description: Web services to transmit transactions that are built-up while the NMVS is not reachable in order to get the result of processing. One request may contain different single transaction requests.
WS_MASTER_DATA	File: WS_MASTER_DATA.wsdl Description: Web services to get all products from NMVS.
WS_SUPPORT	File: WS_SUPPORT.wsdl Description: Web services for support functions e.g. changing passwords.
WS_PKI	File: WS_PKI.wsdl Description: Web services for PKI operations e.g. to retrieve the client certificate. This service does not require a client certificate itself to be invoked.

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Technical Connection

arvato
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→ HTTPS

→ TLS 1.1 / 1.2 are supported

→ Cipher
  → ECDHE-ECDSA-CHACHA20-POLY1305
  → ECDHE-RSA-CHACHA20-POLY1305
  → ECDHE-ECDSA-AES128-GCM-SHA256
  → ECDHE-RSA-AES128-GCM-SHA256
  → ECDHE-ECDSA-AES128-SHA256
  → ECDHE-RSA-AES128-SHA256

→ SOAP -Simple Object Access Protocol (SOAP 1.2)
→ Web Service Description Language (WSDL 1.1)
→ WS-I Basic Profile 1.1.1

→ Charset Encoding: Standard UTF-8

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→ Two factor authentication
  → user/password in SOAP payload
  → client certificate (https connection)

→ Client certificates
  → X.509 standard
  → PKCS#12 container for enrollment
    → contains:
      → public/private key pair
      → client certificate

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→ DNS
  → all technical endpoints have registered DNS names
  → before connection attempt dns resolution needs to be done
  → ip addresses can change over time

→ Client certificate validation
  → only use valid client certificates, no connection attempts with expired certificates should be done

→ Latency
  → use http keep alive for low latency synchronous transactions

→ Ping-Service
  → NMVS web services provide a simple "ping service" to test the general connectivity to NMVS. The service can also be used for holding connections (http keep alive) to prevent from connection timeouts.

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→ Connection termination

The client should drop connections when no activity is expected in a reasonable amount of time.

→ Reconnection policy

Detailed policy will be supplied with the final documentation. In general the policy will be based on increasing time frames between failed connection attempts.

→ Parallelism

In general, a client should not maintain more than one connection to each service endpoint of the NMVS. In case of higher parallelism on synchronous services, it is possible to open additional connections. For services with asynchronous processing, it is not allowed to submit requests in parallel as processing order cannot be guaranteed in that case.
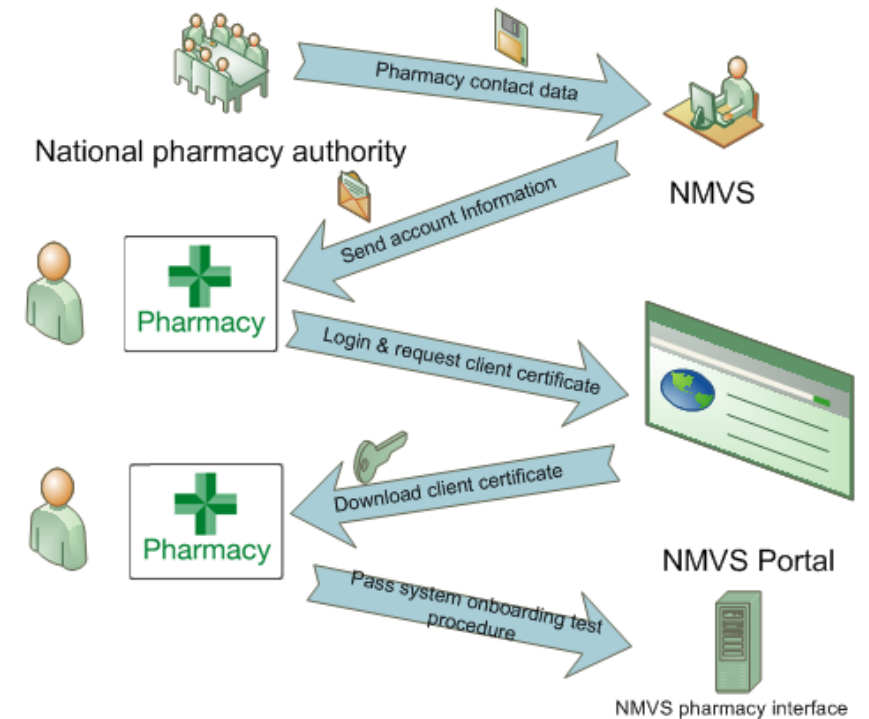
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1. National authority sends pharmacy contact data to NMVS/NMVO operations

2. Operations-Team creates account and sends initial account data and OTP (one time password) for client certificate.

3. Pharmacist downloads client certificate with account data and OTP

4. Import client certificate to POS System

5. Pass connection test – onboarding finished

Note: Step 3 should be integrated in POS client software.

Pharmacists only needs to enter account data and OTP.

Download of certificate and installation is handled by POS software.

For this procedure the NMVS provides web services.

National pharmacy authority

Pharmacy contact data

NMVS

Send account Information

Pharmacy

Login & request client certificate

NMVS Portal

Download client certificate

Pharmacy

Pass system onboarding test procedure

NMVS pharmacy interface

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Q & A (March 2017)

Question	Answer
Is there an aggregated numbering available for bulk-transactions?	Currently there is no aggregation functionality specified in the EMVO URS.
What happens if the pharmacy connection goes down and NMVS is unreachable?	This event is addressed by the "offline" capability that is described in the EMVO URS. The NMVS provides a
If there is an alert in the NMVS, who gets those alerts? For example, when a falsified pack has been detected.	Alerts are recorded in the NMVS and visible via reporting. Dependend on the use-case the alert is pushed the EU Hub
If an Undo-action has been done, should there be a reason for the action?	The NMVS requires no reason information for Undo-Operations.
Hospital pharmacies buy medicines directly from Germany, which use a PPN product code. Can the PPN code be verified by the Finnish NMVS (as Finland will use GTIN) ?	All NMVS interfaces support GTIN/NTIN and PPN coding scheme. We assume the question referes to a use case that is called "Intermarket Transaction". This is described in detail in EMVO URS 20/10/2016 - Part VII
When can the Undo bulk process be performed?	Right after the Do-Process has been performed.

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Agenda

Arvato

Company structure and competencies

Project details

Planning structure and project details of the Finnish NMVS project

Onboarding

Onboarding approach / procedures for software suppliers

Technical details

Information about connection scenarios, web service groups and the current web service interface

Next steps

Which are the next steps?

Who will have to contribute what?

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Next Steps

- **Connection scenario**
  - Clarification and finalization of the requirements in regards to the connection scenario (as soon as possible)
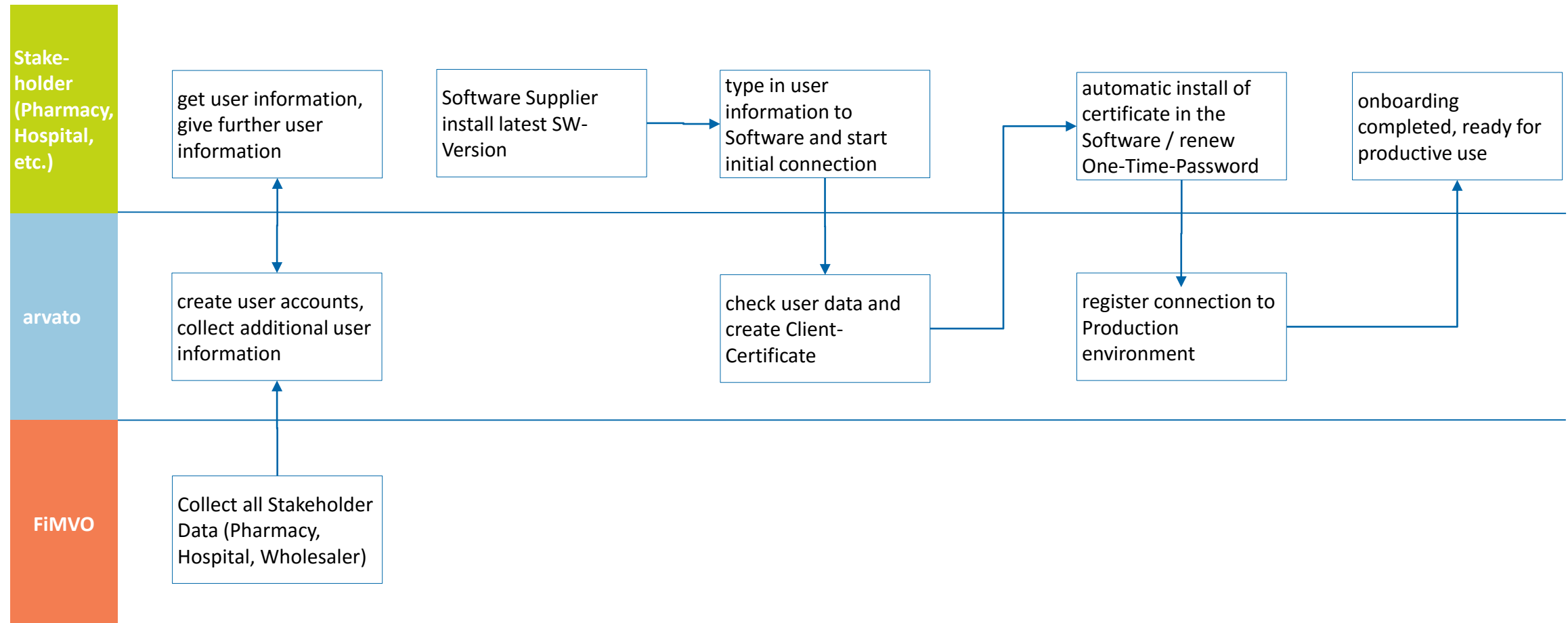
- **(As of) 2017-04-10:   Revision/Update of distribution pack 1**
  - Update all documents

- **(As of ~) 07-2017:   Distribution pack 2**
  - Provision of distribution pack 2
  - Complete interface description
  - Add implementation-examples for webservice clients
  - 3rd software suppliers workshop

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Thank you / Kiitos!

Backup slides

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Onboarding Process step by step (Connection to PROD-Environment)

Stake-holder (Pharmacy, Hospital, etc.)

| get user information, give further user information | Software Supplier install latest SW-Version | type in user information to Software and start initial connection | automatic install of certificate in the Software / renew One-Time-Password | onboarding completed, ready for productive use |

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| create user accounts, collect additional user information | check user data and create Client-Certificate | register connection to Production environment |

FiMVO

Collect all Stakeholder Data (Pharmacy, Hospital, Wholesaler)

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Onboarding Process step by step

Parallel to the software development, all users for the production environment will be contacted by the FiMVO.

For this, the FiMVO lists all pharmacies, hospitals, wholesaler etc. who need to be connected to the production environment within the administration portal. In the next step arvato will create all necessary user information / password and will create letters or e-Mails (at least 2 for each stakeholder). These letters can be sent out directly by arvato or by a FiMVO-partner.

With the user and password information, the software supplier for the pharmacy can roll out the latest software in the pharmacy. The credentials have to be deposited in the software and a first connection to the production system is possible. Within this first service call, a further client certificate will be handed over to the pharmacy software.

The outlined process is nearly the same for hospitals and wholesalers.

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