

National Medicine Verification System

Software Supplier Workshop

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Tallinn, June 14th, 2018



Who are we?

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Bertelsmann at a Glance





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Penguin Random House

Bertelsmann

Printing Group





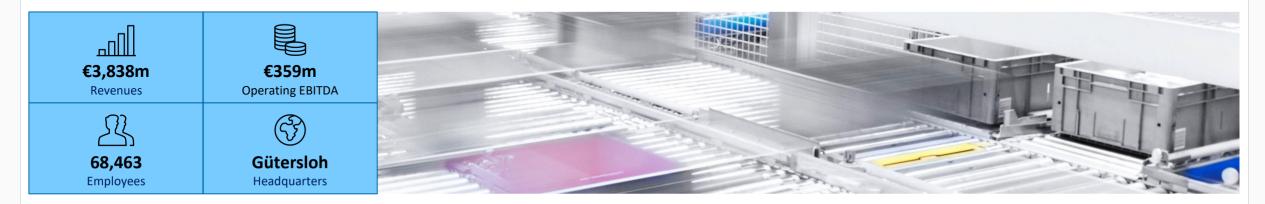
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Bertelsmann Education Group



Arvato – A leading international service provider





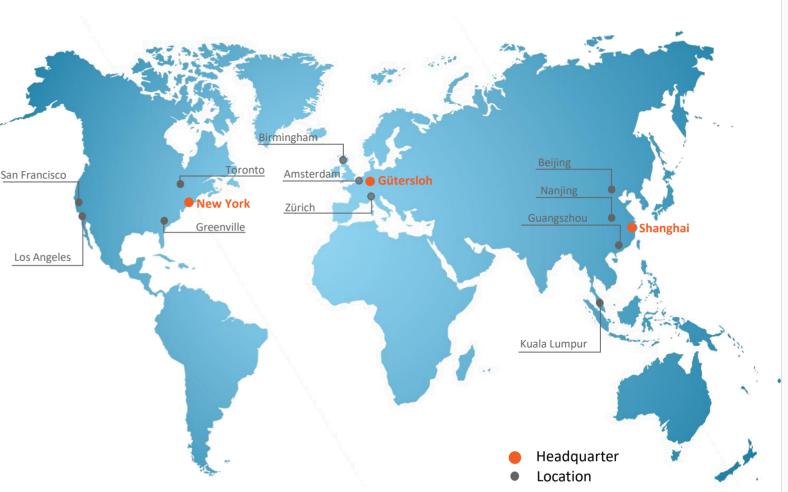
- Service portfolio: CRM services, supply chain management, financial services, IT services
- more than 1,1 billion parcels delivered a year
- 600 million customers serviced in customer loyalty systems
- 170 million online credit checks performed per year
- Runs more than 70 online shops for numerous international fashion brands

Arvato Systems -Systems integration and infrastructure services





- Comprehensive IT solutions for the trade, logistics and shipping and media industries as well as for utility companies and public administrations
- Competence in the key areas of BPM, Cloud Computing, CRM and E-Commerce
- Know-how in robust technologies, including Microsoft and SAP
- A broad spectrum of infrastructure Services, including Managed Services, and an according Application Management



Further locations in Germany:

e.g. Baden-Baden, Berlin, Bielefeld, Bremen, Dortmund, Düsseldorf, Hamburg, Köln, Leipzig, München, Ratingen, Rostock, Walldorf

European Footprint

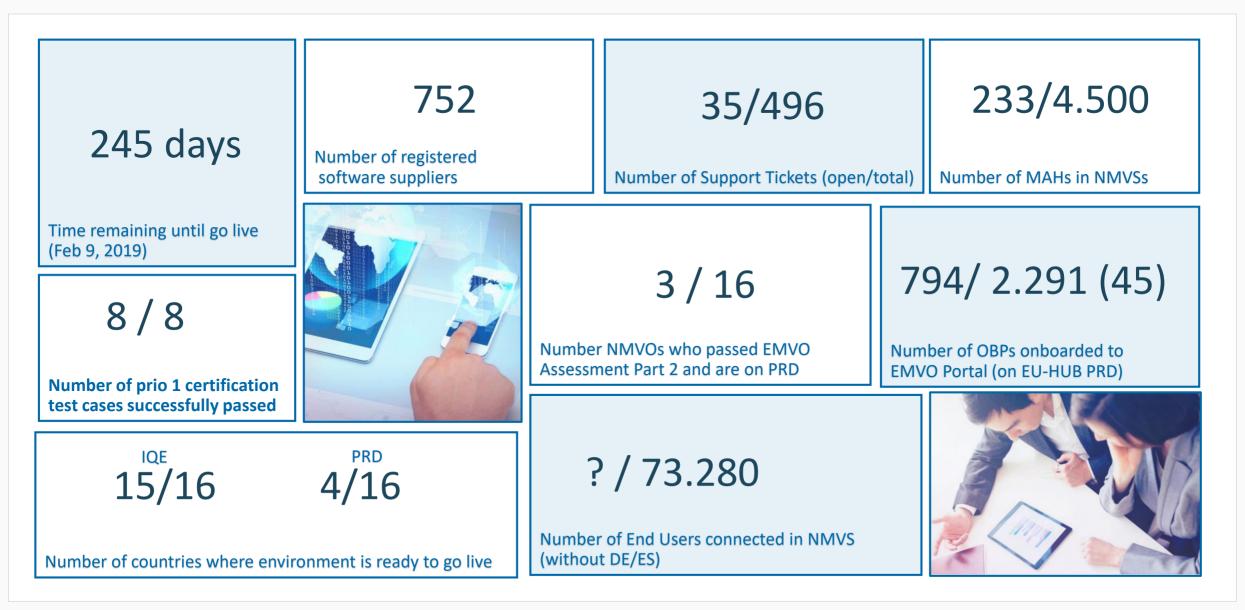
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Arvato is ready to support with local resources.

Arvato has over 150 locations within 22 countries in Europe.

NMVS KPI Dashboard







Before we start to talk about integration scenarios/technical topics/etc. we first need to take a look at the:

• Regulatory Framework

and then



• NMVS Web GUI.

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Web GUI, URS / Regulatory Framework

Requirements Specification Part VII: Additional Requirements for Delegated Regulation Compliance - Extract

6. National Blueprint System GUI (for Client)

Each National System, Blueprint or Standalone, is required by Article 35(i) (i) to include a graphical user interface (GUI) for use by wholesalers and persons authorised or entitled to supply medicinal products to the public (hereafter referred to as 'end clients'), for the purposes of verifying the authenticity of the unique identifier and decommissioning it **in case of failure of their own** software.

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The GUI will be provided in the form of a web-based 'portal'. Each client location will be provided with single hardware token (or similar alternative) and access credentials, an "account". It is a requirement that the GUI only be operable from a single location and that it cannot be used in a portable (location to location) manner. This GUI implementation will not include the concept of user administration beyond the resetting or changing of a single set of access credentials. It is vital that the connection implementation, beyond being compliant with the security and access requirements defined elsewhere within the EMVS URS, does not also incur an overhead for the operator or owner in terms of user administration. If a low overhead means can be defined using a combination of the OAuth 2 protocol (as described for the NCA GUI) and a physical hardware token, this can be agreed during design elaboration.

Web GUI, URS / Regulatory Framework



Requirements Specification Part VII: Additional Requirements for Delegated Regulation Compliance - Extract

6.1. GUI Operation

The GUI for **end clients** shall provide the ability to permit continuance of their operation by the provision of a simple portal to the National (Blueprint) System. However, the Delegated Regulation is clear that this is only available for use when the client system has failed. It is not intended to be used as a low-cost entry point for smaller clients who would rather not invest in 'their own software'. To this end, the GUI shall be effective but not so effective that it represents a viable long-term alternative to 'own client software'.

The GUI shall:

- 1. Allow the entry of the pack:
 - a. Product Code
 - b. Serial Number
 - c. Batch ID (optional)
 - d. Expiry Date (optional)
- 2. Allow the pre-selection of applicable use-case (presented by actor/client type)
 - a. Wholesaler:
 - i. Verify a single pack
 - ii. Dispense a single pack
 - iii. Export a single pack
 - iv. Change the status of a pack to 'Stolen'
 - v. Change the status of a pack to 'Destroyed'
 - vi. Change the status of a pack to 'Sample'
 - vii. Change the status of a pack to 'Locked'
 - b. Persons authorised or entitled to supply medicinal products to the public:
 - i. Verify a single pack
 - ii. Dispense a single pack
 - iii. Change the status of a pack to 'Destroyed'
 - iv. Change the status of a pack to 'Sample'

The GUI shall not:

Permit use with a barcode scanner. This should be actively prevented by being unable to parse the incoming data from a barcode reader and split it into the component parts and also by preventing the automated keystroke based movement from one data entry box to another. This exclusion is a requirement to dramatically minimise the potential use of the GUI beyond its intended, and required scope.
 Provide any reporting capabilities.

GUI DEMO



- Two factors for GUI Authentication:
 - Password and Certificate.
- GUI Portal Access can be reached via
 - HTTPS access and Port 443
- GUI Portal Time-out Session 30 Minutes.
- End User will recieve 3 E-Mails:
 - 1.)User-Name 2.) Link to PKI portal and TAN to download and install the certificate. 3.)One time password
- Log in IQE Environment Core Release 1.1 :
 - https://portal-int-ee.nmvs.eu/NMVS_PORTAL/login.xhtml?dswid=-240
 - With Pharmacy user: KESKLINNA/LIIVALAIA333



—The Blueprint Solution—

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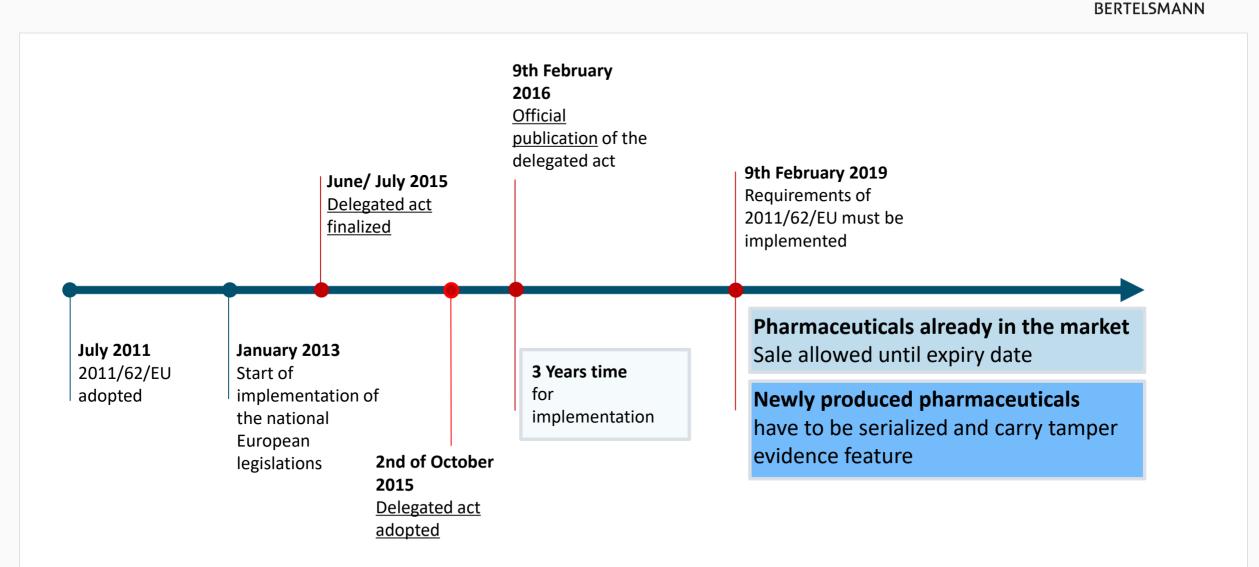
Our Mission



- Falsified / counterfeit medicines are a serious risk for the citizens all around the world
- New legislation published on the 9th February 2016 as delegated act
- This new legislation is mandatory for all EU members
- Pan-European strategy to fight illegal medicine products
- Based on a "Point-of-Dispense Verification"



EU Timeline



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Challenge: Many stakeholders are involved



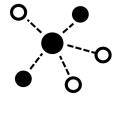
- Organisators
 - NMVO
 - EMVO
- Software providers
 - Solidsoft (EMVS/EU Hub)
 - Arvato
 - Pharmacy/hospital/wholesaler
 SW providers/IT departments
- Authorities







- Primary distributors
 - Marketing authorization holders
 - Contract manufacturers
 - Wholesalers
 - Parallel distributors
 - Public pharmacies
 - Hospital pharmacies
- Secondary distributors
 - Army
 - Prisons
 - Airlines
 - Nursing homes
 - Drug treatment centers
 - NGOs
 - ...









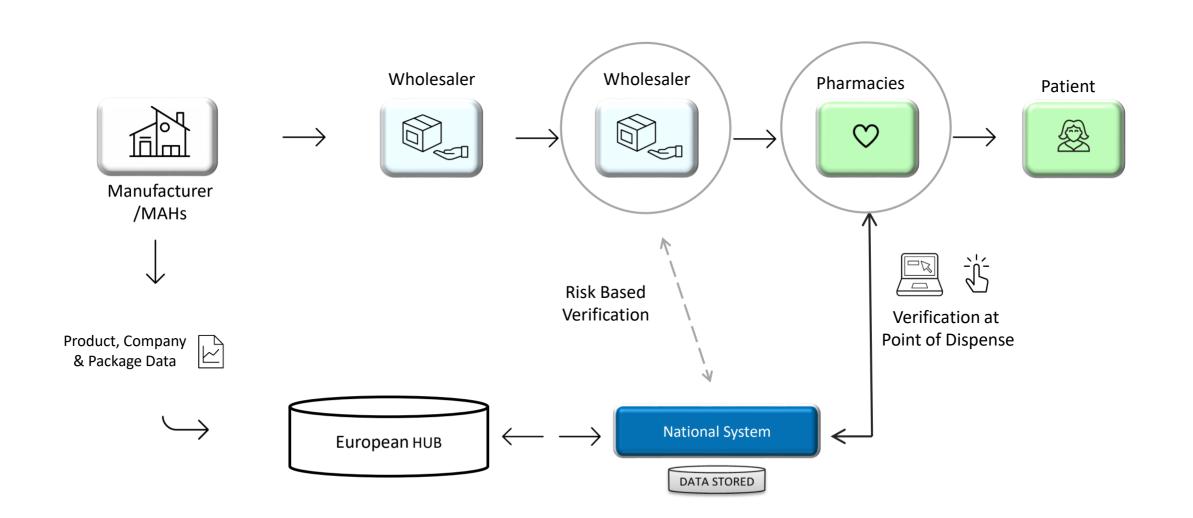




Verification by End Users

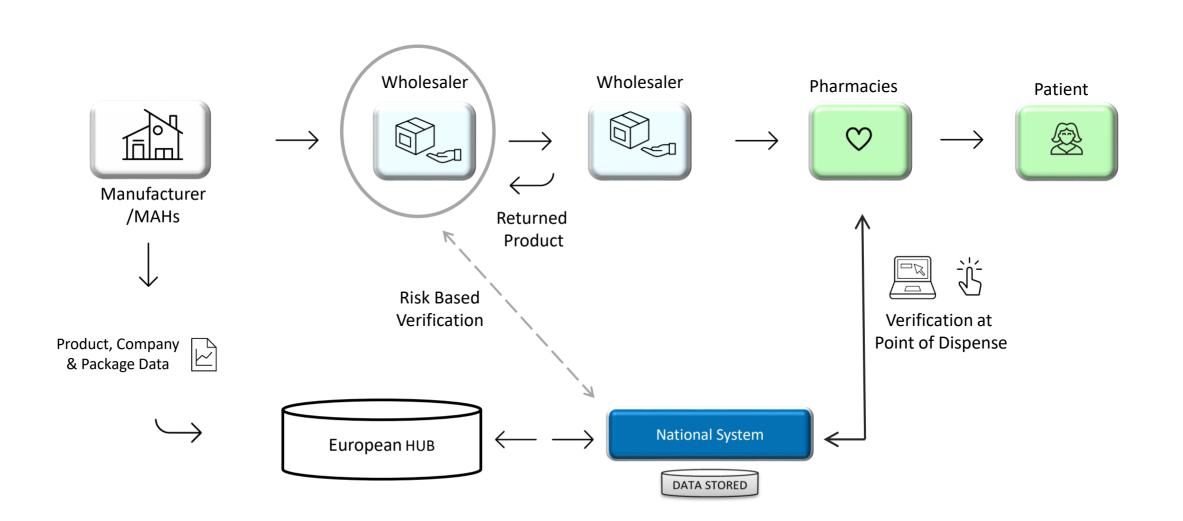
Pharmacies and additional Wholesaler Reporting and Verification





Wholesaler Returns Product Reporting and Verification



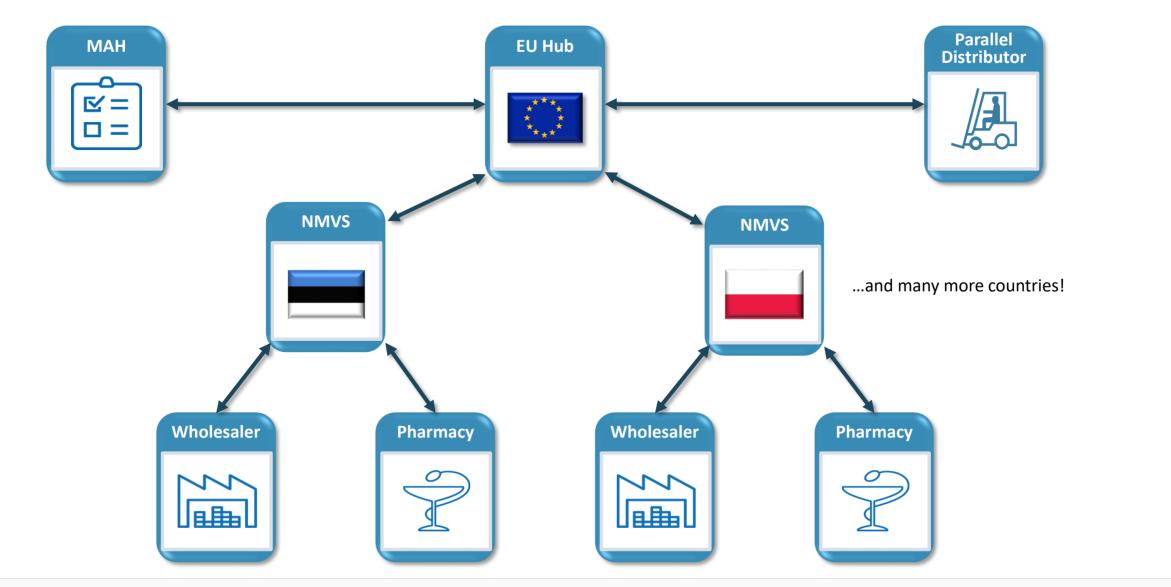




Connections and Data Workflows

Where the data goes

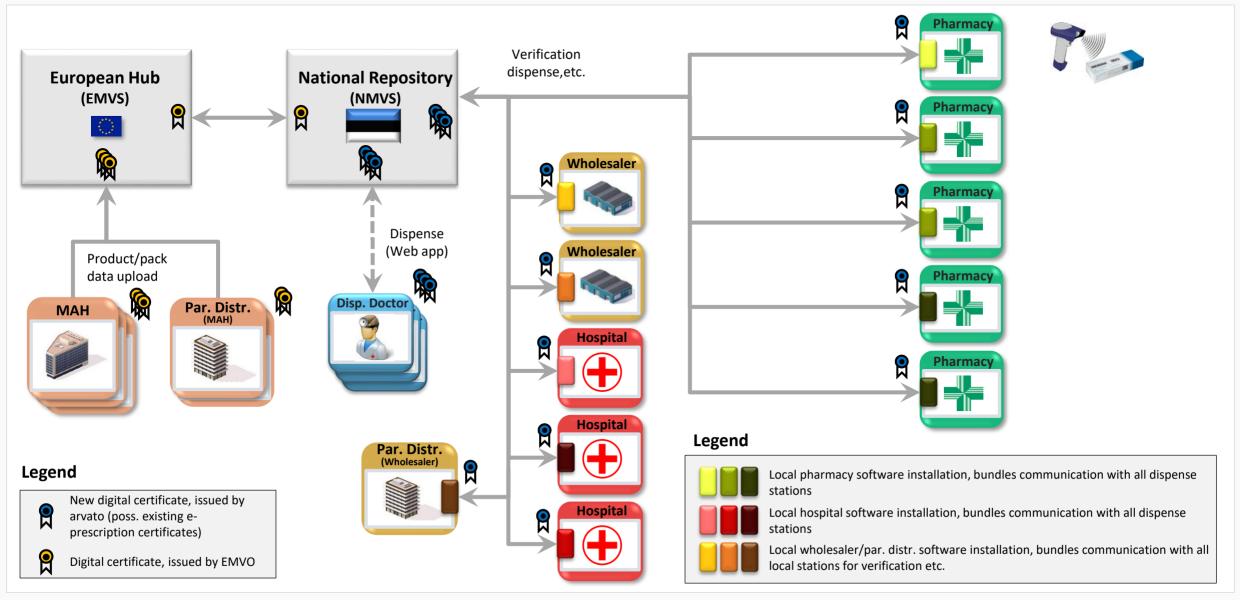




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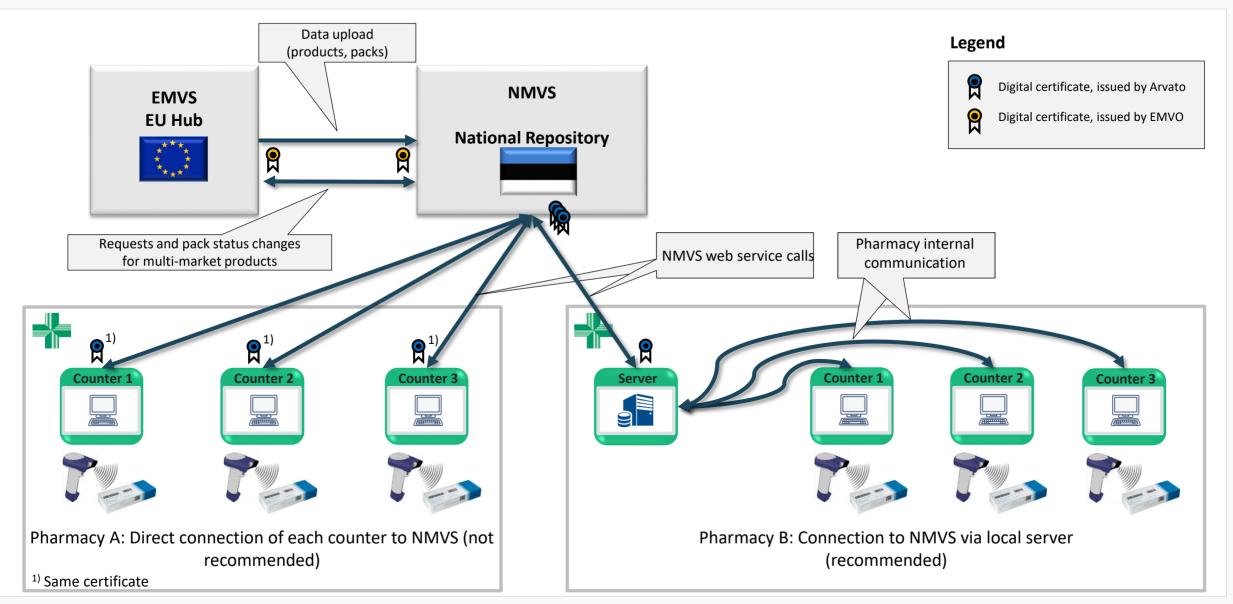
System Architecture Overview General





System Architecture Overview Cumulators

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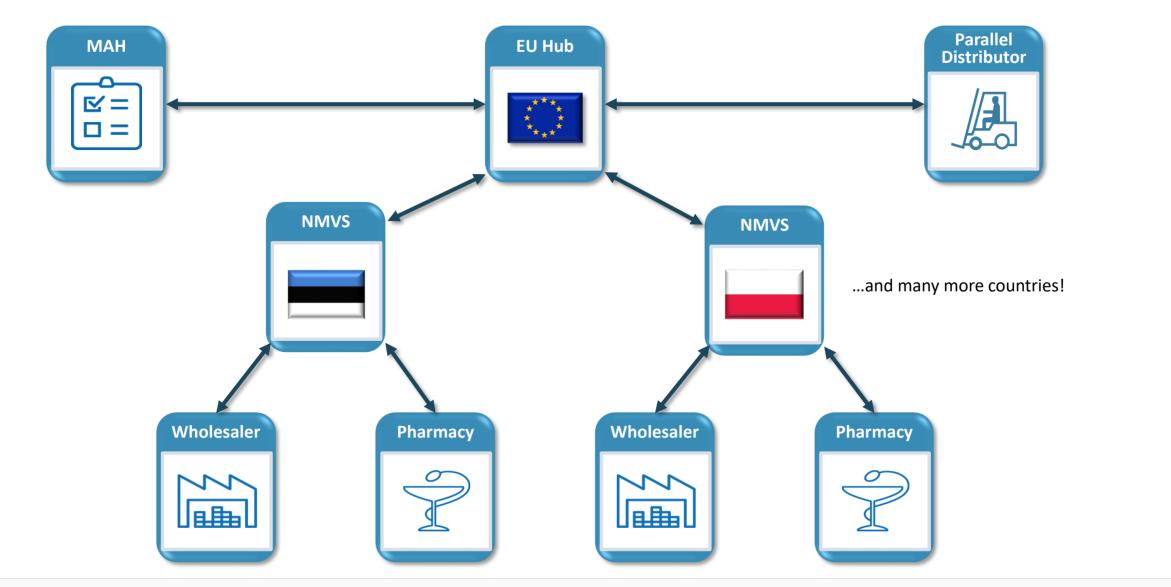


Multimarket / Intermarket

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Where the data goes





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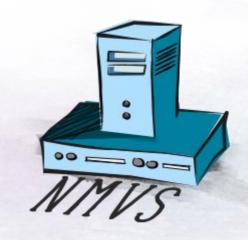


-Business Use Cases-

Business Use Cases / Transaction Types



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



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¹⁾ X = Transaction authorized,

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

Request / Response: Request



	XML Example
<g110request></g110request>	
<header></header>	
<auth authmethod=""></auth>	
<clientloginid>G4321-14-01RT</clientloginid>	
<userid>9821</userid>	
<password>838hdjLk#</password>	
Optional:	
<subuserid>9824</subuserid>	
<usersoftware name="EasyPharm" supplier="PharmSoft Ltd." version="3.2.0"></usersoftware>	
<transaction></transaction>	
<clienttrxld>c295a450-0caa-4cf1-8e62-c6165c4</clienttrxld>	
<language>deu</language>	
<body></body>	
<product></product>	
<productcode scheme="GTIN">05060141900015</productcode>	
<batch></batch>	
<ld>1264</ld>	
<expdate>171200</expdate>	
<pack sn="XVTR75973491006155"></pack>	

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Request / Response: Response



\rightarrow Verfication Responce

XML Example	
<g110response></g110response>	
<header></header>	
<auth></auth>	
<clientloginid>G4321-14-01RT</clientloginid>	
<userid>9821</userid>	
Optional:	
<subuserid>9824</subuserid>	
<transaction></transaction>	
<language>deu</language>	
<clienttrxid>c295a450-0caa-4cf1-8e62-c6165c4</clienttrxid>	
<nmvstrxid>c295a450-0caa-4cf1-7e62-c6865d41</nmvstrxid>	
<timestamp>2017-12-31T12:00:00</timestamp>	
<notification code="NMVS_NOTIFY_02" desc="</td"><td></td></notification>	
"The transaction was successfully processed using an old password.	
The password of your user account has changed, so please adjust your password as soon as possible.	
The password you are using will be deactivated in \$oldPWExpDate days."	
<body></body>	
<product></product>	
<productcode scheme="GTIN">05060141900015</productcode>	
Optional:	
<intermarketflag>true</intermarketflag>	
Optional:	
<nhrn>09556886</nhrn>	
Optional:	
<productinforef date="2014-12-31" modified="false">890754389</productinforef>	
<batch></batch>	
<id>1264<!--/d--></id>	
<expdate>171231</expdate>	
<expdatenmvs>2017-12-31</expdatenmvs>	
<pack sn="XVTR75973491006155" state="INACTIVE"></pack>	
0 to 20 repetitions:	
<reason>SUPPLIED</reason>	
<returncode code="NMVS_SUCCESS" desc="Successfully processed"></returncode>	
	Sorry, if the for

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Request / Response: Notifications

\rightarrow Notifications

Attributes	Detailed information	Description
H - Header data	•	
Notifications	NMVS_NOTIFY_AU_01	You are using an old password. The password of your user account has changed, so please adjust your password as soon as possible. The password you are using will be deactivated in \$1 day(s).
	NMVS_NOTIFY_AU_02	Your password will expire in \$1 day(s). Please change your password using the password-change function in the system. If your password expires, you will no longer be able to connect to the system.
	NMVS_NOTIFY_PMS_01	A new version of the NMVS terms and conditions are available. Please confirm the new terms and conditions within the next \$newTCStartDate day(s). If you do not confirm the new terms and conditions version in time, you will no longer have access to the system.
B - Pack data		
Pack state	ACTIVE	Pack is able to be dispensed
	INACTIVE	Pack is not able to be dispensed
	UNKNOWN	Pack is not able to be dispensed
Pack-related reasons	CHECKED_OUT	Pack is repacked into a new pack
	DESTROYED	Pack is destroyed
	EXPIRED	Batch is expired and is not allowed to be dispensed
	EXPORTED	Pack is exported and is not allowed to be dispensed
	FREESAMPLE	Pack is given away as a free sample
	LOCKED	Pack is locked and is not allowed to be dispensed
	RECALLED	Batch is recalled and is not allowed to be dispensed
	SAMPLE	Pack was given away as a sample for national authorities
	STOLEN	Pack is stolen and is not allowed to be dispensed
	SUPPLIED	Pack is supplied
	UNKNOWN	Product, batch or pack is unknown and not allowed to be dispensed
	WITHDRAWN	Product is inactive with the property withdrawn and not allowed to be dispensed

Please read TD-014 Catalogue Translations.xlsx

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How support Software Suppliers



Arvato supports you with...







Documentation and SDKs

Test and Dev environment (Sandbox) Helpdesk via Email and Phone

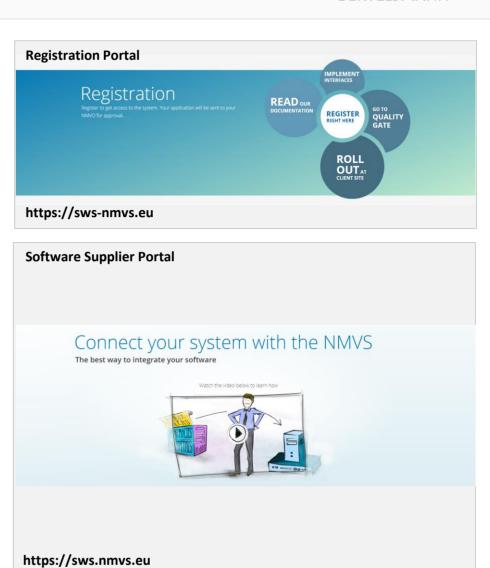
Onboarding Procedure for Software Suppliers Share Knowledge

- Software suppliers registers himself and
- agrees to Terms and Conditions.
- Kowal approves request

- Software supplier gets access to
- sandbox environment,
- documents,
- manuals,

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- SDKs (WSDLs, XMLs, handbooks),
- test documentation and test sets
- certificates for sandbox environment and
- qualification process for higher environments



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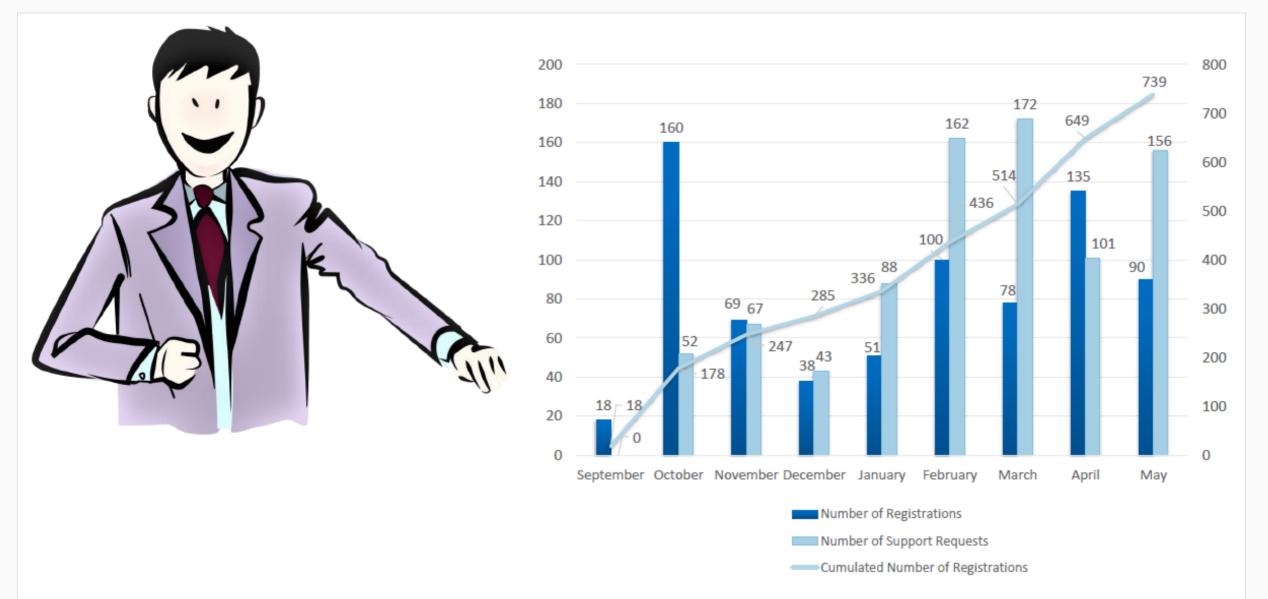


Share Knowledge

- short registration process
- Hand out first documentation about the National Verification System
- Hand out technical information (WSDL)

Registrations and Support Requests





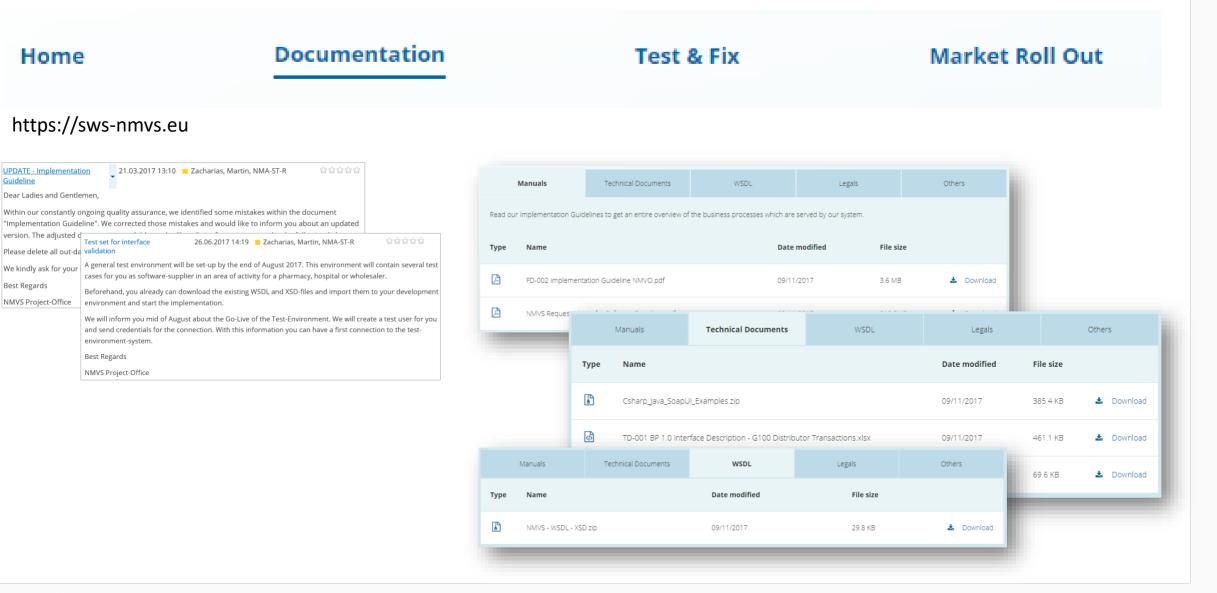
Onboarding Procedure for Software Suppliers

Overview Software Supplier Portal

Guideline

Best Regards

NMVS Project-Office



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Onboarding Procedure for Software Suppliers

Overview Software Supplier Portal

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Home	Documentation	Test	t&Fix	Market Roll Out
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	Create a Test-Package right h	ere		
	Test-Packages			
reate a Test-Package right				
Test-Packages	typical business cases and describe it in our test co which will cause defined return codes	oncept. In addition to that, you ca	n download serial numbers for your test	Get a new Test-Package
Test-Fackages	which will cause defined record codes.			
	st package available? Use our Test-Package generator. We outline se	veral typical business cases and	describe it in	
You'd like to start your tests, but there is no tes			describe it in	
You'd like to start your tests, but there is no tes	st package available? Use our Test-Package generator. We outline se ownload serial numbers for your test which will cause defined return		describe it in	
You'd like to start your tests, but there is no tes our test concept. In addition to that, you can do 1-DevTest	st package available? Use our Test-Package generator. We outline ser ownload serial numbers for your test which will cause defined return Please, download your test package: View Test Result			
You'd like to start your tests, but there is no tes our test concept. In addition to that, you can do	st package available? Use our Test-Package generator. We outline ser ownload serial numbers for your test which will cause defined return Please, download your test package: View Test Result Download test package	s and Used Packa		at the test case name is correct.
You'd like to start your tests, but there is no tes our test concept. In addition to that, you can do 1-DevTest	st package available? Use our Test-Package generator. We outline ser ownload serial numbers for your test which will cause defined return Please, download your test package: View Test Result Download test package	s and Used Packa	ges	at the test case name is correct.

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Questions and answers FAQs



FAQs Asked Questions

Question	Answer
How can we test the web services of your system?	For test purposes we set-up a general test-environment end of August 2017. This
	environment will contain several test cases for you as software-supplier in a role as
	Pharmacy or wholesaler.
Information: EMVO FAQ	EMVO has prepared a specific FAQ list, explaining important facts concerning their
	connection to the European Hub.
ĺ	How can we test the web services of your system? Information: EMVO FAQ

...





NMVS Software Supplier Support Team support@sws-nmvs.eu

Bevor you connect your software to the integration or production environment:

- Develop and test your software within the test and development environment.
- Bevor moving from test and dev environment to integration or production environment, the connection must be tested and certified.
- Certification is only valid for one version of the software. New versions need to be re-certified.



Test and Dev Environment (Sandbox)

Certification of Connection

Integration / Production Environment

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Helping hand: Additional support and sources of information



Please make sure to register if your are a SW supplier or an IT department: https://sws-nmvs.eu

Connect your system with the NMVS

The best way to integrate your software





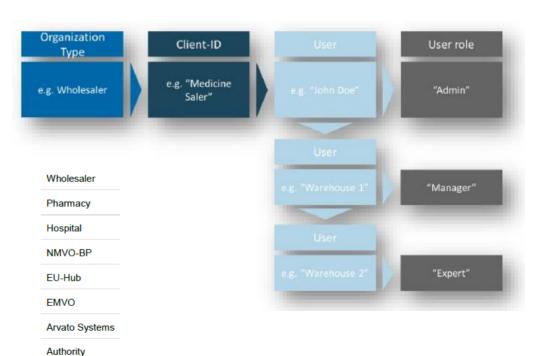


Users and Permissions

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Rights and roles

Hierarchy	Description					
Organization Type	The Organization Type allocates all possible rights for the processes used by the Client-ID. The Organization Type is set as standard by Arvato.					
Client-ID / User group	A Client-ID groups many users of one Organization Type. It is directly linked to an Organization Type. The Admin of the Client can control all users at this client.					
User	A User can be the technical end point or a physical user.					
Role	A role allocates the rights for a user and can be named by the Client.					
Sub-User	A Sub-User is an additional, optional information to structure bigger organizations like pharmacy-networks to deal with existing internal structures.					



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- With the first registration, a client gets the **user** credentials for an admin who is able to create further users with specific rights.
- **Sub-Users** are also possible for central pharmacy systems or pharmacy chains.
- 2-Factor authentication has to be used (Client Certificate + Password)

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Permission mapping

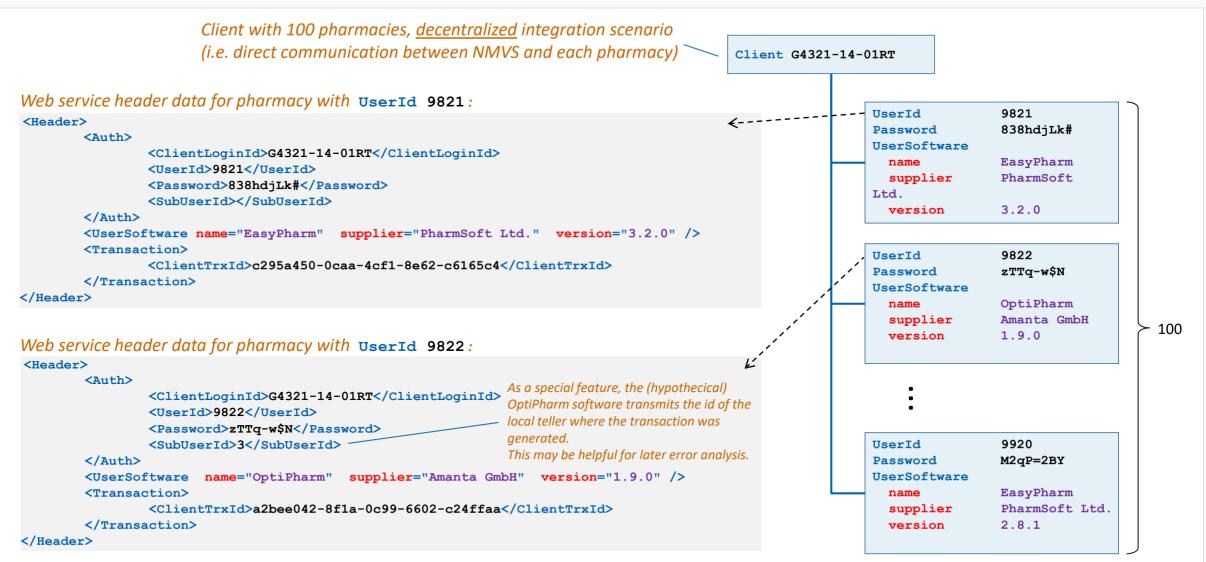


Permission Mapping

		Orgatype	atype Wholesaler		Pharmacy		Hospital		NMVO - BP		Authority		EU-HUB		EMVO		Arvato Systems	
		Channel	WS	GUI	WS	GUI	WS	GUI	V	VS GUI	WS	GUI	WS	GUI	WS	GUI	WS	GUI
G100 - Distributor Transactions																		
Single P	ack Transactions																	
G110	Verify single pack		Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	No	No	No	Yes	Yes
G120	Dispense single pack		Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	Yes	Yes
G122	Dispense single pack manual entry		Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	Yes	Yes
G130	Destroy single pack		Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	Yes	Yes
G140	Export single pack		Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes
G150	Sample single pack		Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	Yes	Yes
G160	Free sample single pack		Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes
G170	Lock single pack		Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes
G180	Stolen single pack		Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes
G182	Stolen single pack manual entry		No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes
G121	Undo dispense single pack		Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	Yes	Yes
G131	Undo destroy single pack		Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	Yes	Yes
G141	Undo export single pack		Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	Yes	Yes
G151	Undo sample single pack		Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes
G161	Undo free sample single pack		Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	Yes	Yes
G171	Undo lock single pack		Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes
G181	Undo stolen single pack		Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes
Homogenous Bulk Transactions																		
G115	Bulk verify packs		Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes
G125	Bulk dispense packs		Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes
G127	Bulk undo dispense packs		Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes
G135	Bulk destroy packs		Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes

Distributor Web Service Header, Example A: Direct, non-anonymous integration scenario







Technical details

Connection Details (1/4)



- 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

Connection Details (2/4)



- Two factor authentication
 - user/password in SOAP payload
 - client certificate (https connection)
- Client certificates
 - X.509 standard
 - <u>PKCS</u>#12 container for enrollment
 - contains:
 - public/private key pair
 - client certificate

Connection Details (3/4)

Handling on client side



- 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.

Connection Details (4/4)

Handling on client side

- 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.



Next steps

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What exactly needs to be done? (end users)

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All end users must

- Understand the verification process and the need for risk based verification
- Train their employees
- Rethink business workflows
- Get hold of software capable of verification

What exactly needs to be done? (software suppliers)

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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
- Download and read the main oboarding document from the software supplier portal: The Implementation Guideline (FD-002 Implementation Guideline)



