Programme for DMVO's information meeting for MAH's on October 24th. 14.00-17.00 hrs.

1. **Welcome and introduction**
   By Chairman of DMVO's Board and CEO of Lif, Ida Sofie Jensen
2. **Patient safety – and the authorities' expectations to MAHs and DMVO in connection with the FMD and the new rules of safety features on the packaging of medicinal products**
   By Team Leader in the Danish Medicines Agency, Jakob Lundsteen
3. **EMVO and onboarding of the European database EMVS (" the hub")**
   By Head of Commercial and Partner Management in EMVO, Tobias Beer
4. **Coffee break**
5. **Status of the establishment of the Danish Medicines Verification System: DMVS**
   By Chairman of DMVO's IT working group, Director of DLI MI Martin Jordt Andersen.
6. **DMVO – and the Danish contract and payment model**
   By Chairman of DMVO's working group, Senior Project Manager in DMVO, Tina Hou Marer
7. **Summarising and closing of the meeting**
   By Head of DMVO's Secretariat, Lars Tanderup

DMVO Dansk Medicin Verifikation Organisation

DMVO Dansk Medicin Verifikation Organisation

Welcome and introduction

By Ida Sofie Jensen CEO of Lif and Chairman of DMVO's Board

The launch pad is the fight against falsified medicines

- EU's directive on falsified medicines (2011/62/EU) requires that all prescription medicines have safety features.
- The directive also requires establishment of a joint, European IT system with national / regional databases.
- Characteristic model: Presupposes that the MAH and other stakeholders establish and run the system.

DMVO Dansk Medicin Verifikation Organisation

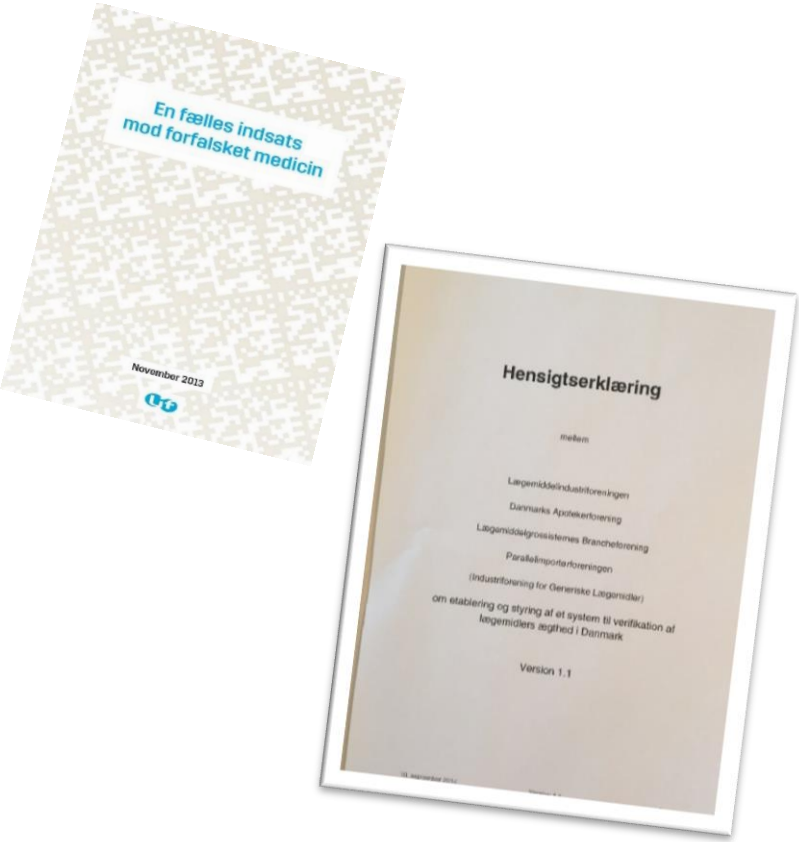
The European system

- At the European level the work is performed via the European Stakeholder Model (ESM) where the most important players were gathered.
- Formed the basis of EMVO which was established in February 2015.

DMVO Dansk Medicin Verifikation Organisation

The process in Denmark

- In Denmark we also decided to use the so-called ”stakeholder model”
- At the beginning the stakeholder group comprised of:
- Lif, the Association of Danish Pharmacies, MEGROS, the Association of Parallel Distributors of Pharmaceuticals and Amgros
- Later the Danish Generic and Biosimilars Medicines Industry Association (IGL) joined the group
- Later on the Memorandum of Understanding was prepared which formed the basis of the further work



DMVO Dansk Medicin Verifikation Organisation

DMVO ApS

- DMVO was formally established November 21st. 2016
- With the 3 trade associations as shareholders
- All 6 stakeholders are members of the Board


STIFTELSESDOKUMENT

FOR

DANSK MEDICIN VERIFIKATION ORGANISATION APS

igL Industriforeningen for Generiske og Biosimilære Lægemidler

MEGROS

PFL

LIF

AMGROS

Danmarks Apotekerforening

DMVO Dansk Medicin Verifikation Organisation

DMVO ApS

- The first Board meeting was held in January 2017.
- The secretariat was established in the beginning of 2017.
- Work at full speed in order to be ready in February 2019.

DMVO Dansk Medicin Verifikation Organisation

DMVO Dansk Medicin Verifikation Organisation

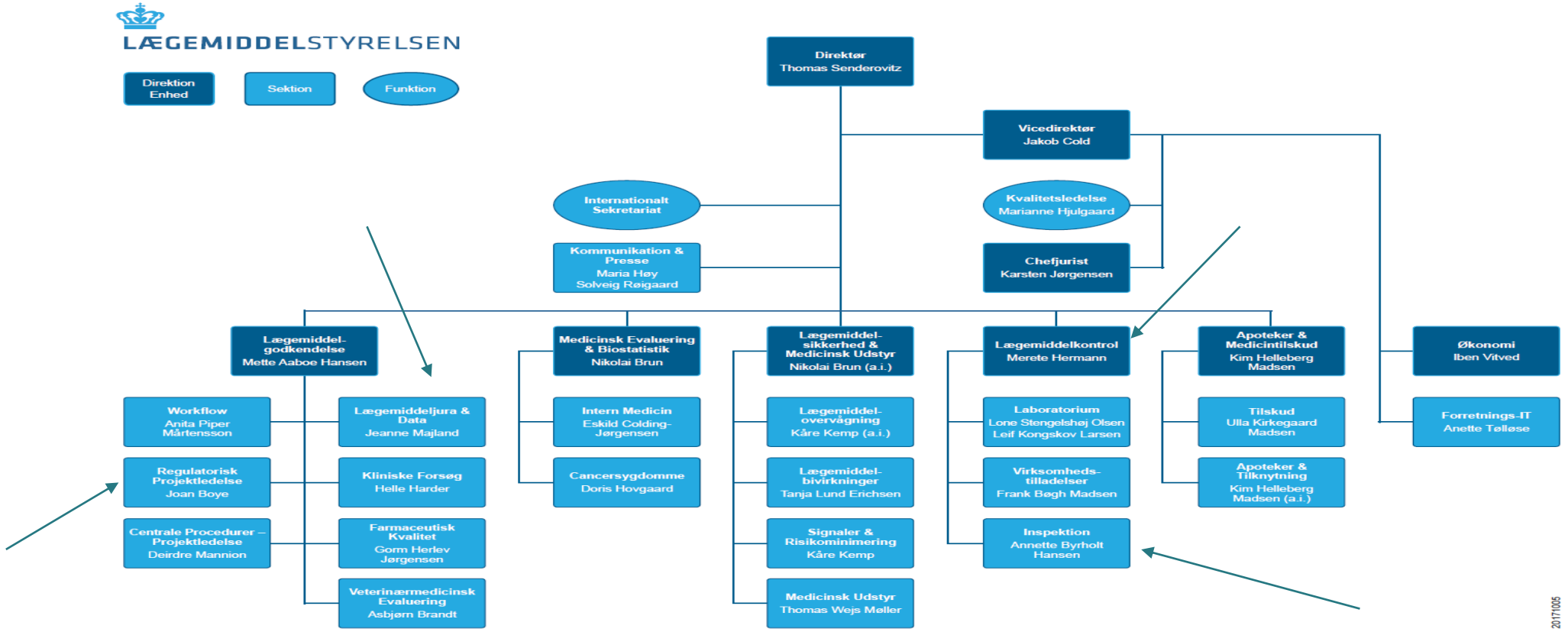
DMVO – stakeholder meeting October 24th.2017

Status from the Danish Medicines Agency

JAKOB LUNDSTEEN, TEAM LEADER, UNIT FOR MEDICINES LICENSING

Agenda

- Introduction
- Organisational location
- Implemented rule changes
- Planned rule changes
- Collaboration forums and sources of information


LÆGEMIDDELSTYRELSEN
Direktion Enhed
Sektion
Funktion
Direktør Thomas Senderovitz
Vicedirektør Jakob Cold
Internationalt Sekretariat
Kvalitetsledelse Marianne Hjulgaard
Kommunikation & Presse Maria Høy Solveig Røigaard
Chefjurist Karsten Jørgensen
Lægemiddel-godkendelse Mette Aaboe Hansen
Medicinsk Evaluering & Biostatistik Nikolai Brun
Lægemiddel-sikkerhed & Medicinsk Udstyr Nikolai Brun (a.i.)
Lægemiddelkontrol Merete Hermann
Apoteker & Medicintilskud Kim Helleberg Madsen
Økonomi Iben Vitved
Workflow Anita Piper Mårtensson
Lægemiddeljura & Data Jeanne Majland
Intern Medicin Eskild Colding-Jørgensen
Lægemiddel-overvågning Kåre Kemp (a.i.)
Laboratorium Lone Stengelshøj Olsen Leif Kongskov Larsen
Tilskud Ulla Kirkegaard Madsen
Forretnings-IT Anette Tølløse
Regulatorisk Projektledelse Joan Boye
Kliniske Forsøg Helle Harder
Cancersygdomme Doris Hovgaard
Lægemiddel-bivirkninger Tanja Lund Erichsen
Virksomheds-tilladelser Frank Bøgh Madsen
Apoteker & Tilknytning Kim Helleberg Madsen (a.i.)
Centrale Procedurer – Projektledelse Deirdre Mannion
Farmaceutisk Kvalitet Gorm Herlev Jørgensen
Signaler & Risikominimering Kåre Kemp
Inspektion Annette Byrholt Hansen
Veterinærmedicinsk Evaluering Asbjørn Brandt
Medicinsk Udstyr Thomas Wejs Møller
20171005

Implemented and planned rule changes

The Danish Medicines Act

- Section 59 a: requirements for safety features
- Section 14 (2), no. 4: *"amend, suspend or recall"*
- Section 44 (2), no. 6: access to companies that set up and administer data storage systems
- Section 104 (1), no. 1: penality regulation re section 59 a

Executive Order on the Labelling of Medicinal Products

- Safety features and exception regarding anti-tampering devices

Executive Order on Good Distribution Practice for Medicinal Products

- Distribution for technical purposes and preparedness

Collaboration forums and sources of information

- Expert working group on Safety Features

- For national products – CMDh:

  http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Falsified_Medicines/CMDh_345_2016_Rev00_02_2016_1.pdf

- For central products – EMA:

  http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/02/WC500201413.pdf

- Q/A on the Danish Medicines Agency's homepage

  http://laegemiddelstyrelsen.dk/da/godkendelse/godkendelse-af-medicin/sikkerhedselementer-paa-laegemidler

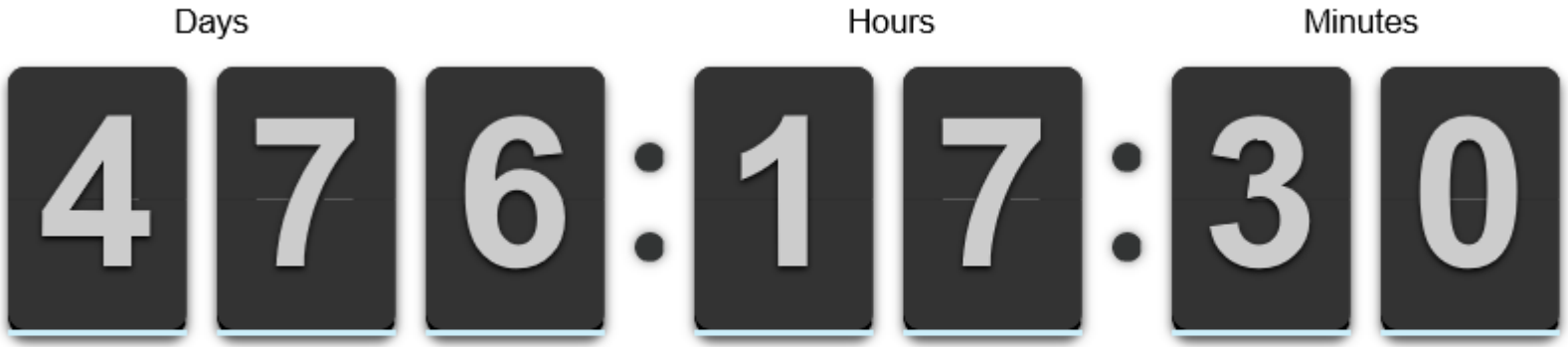
Follow us

EU Hub On-boarding:

Updates and Must-Knows about the EU-Hub On-boarding Process

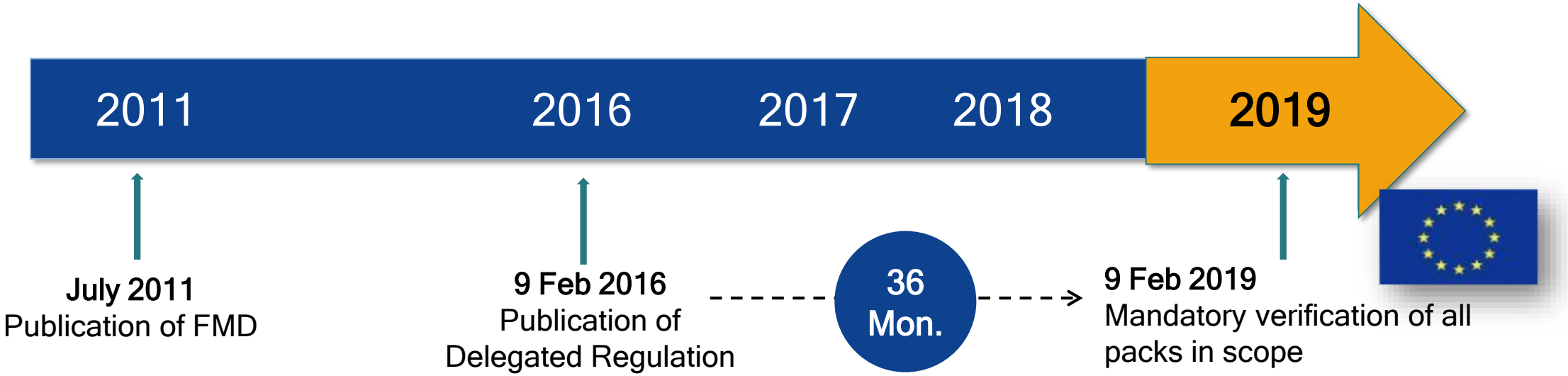
Tobias Beer
Head of Commercial & Partner Management Department
European Medicines Verification Organisation

The Countdown is running



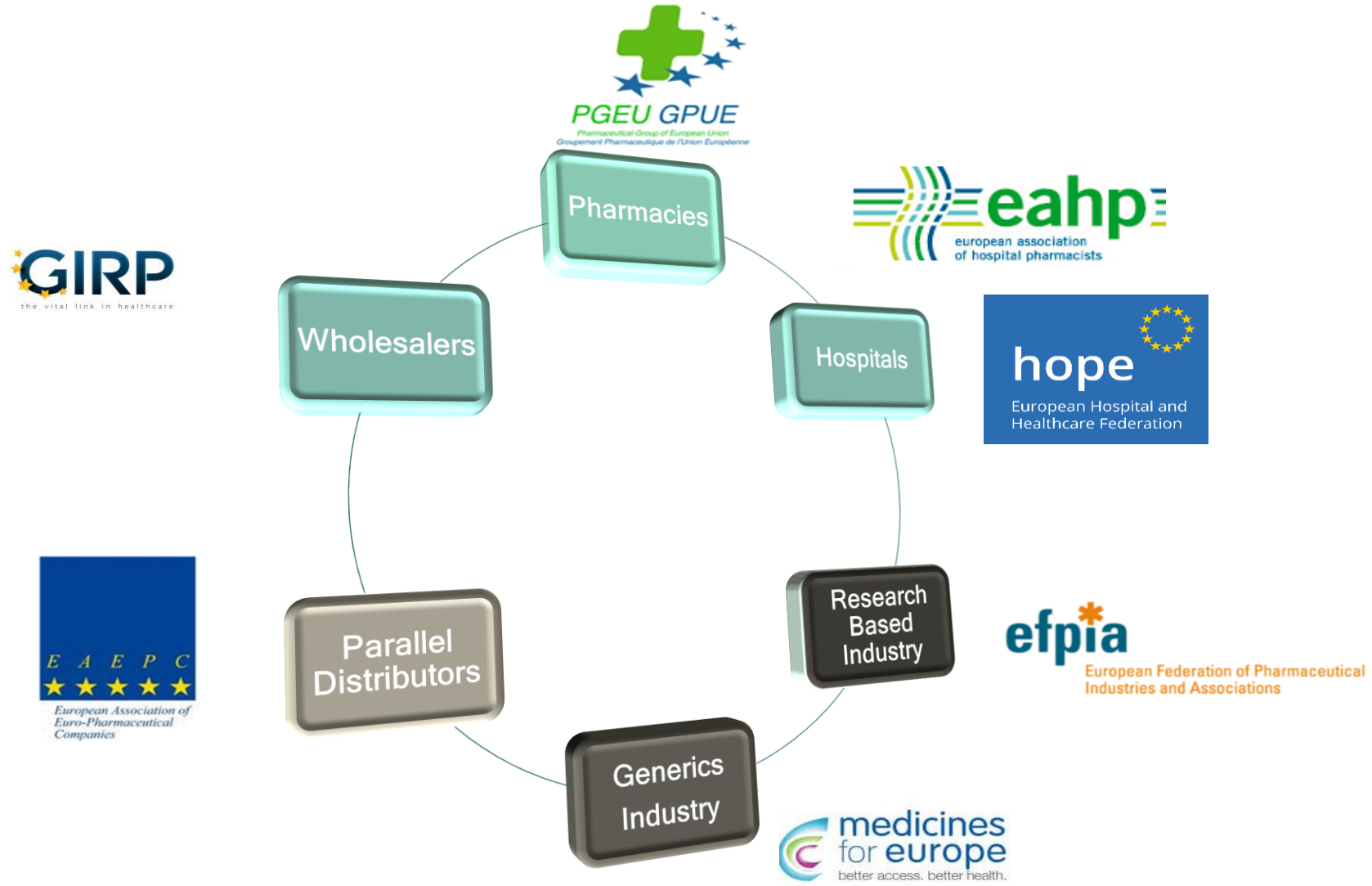
"The Countdown is running. Implementation has to be finished till February, 9th 2019."

FMD Legislation and Delegated Act



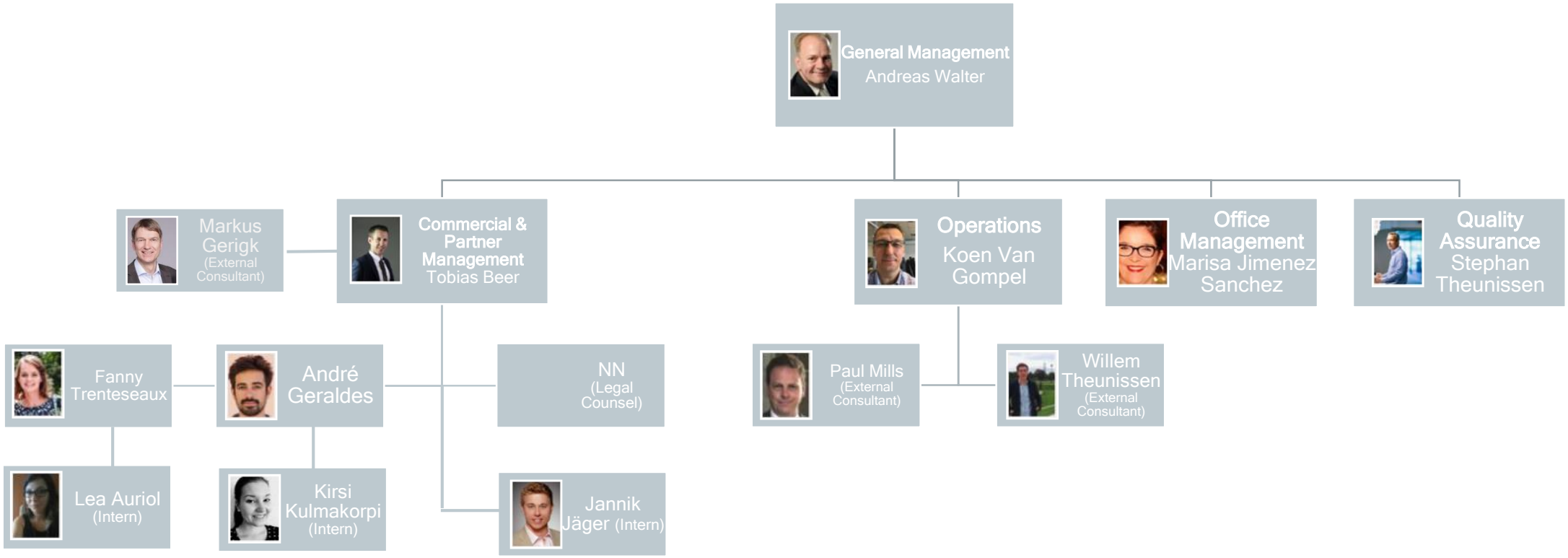
- **Connect approx. 2,500 companies to the EMVS**
- Establish National Systems in 32 countries
- Connect many thousand Pharmacies and Wholesalers
- Serialise all affected pharmaceutical packs (10.5 bn)

EMVO Members

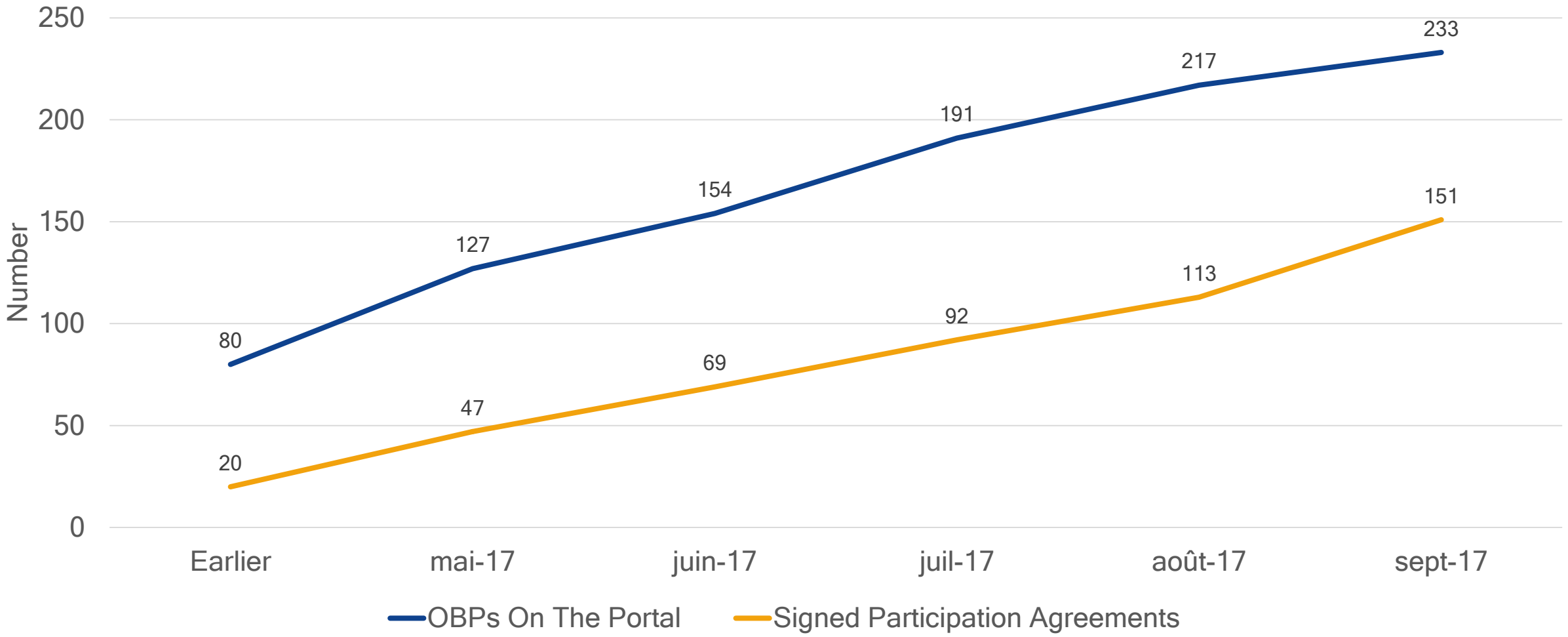


organisational chart

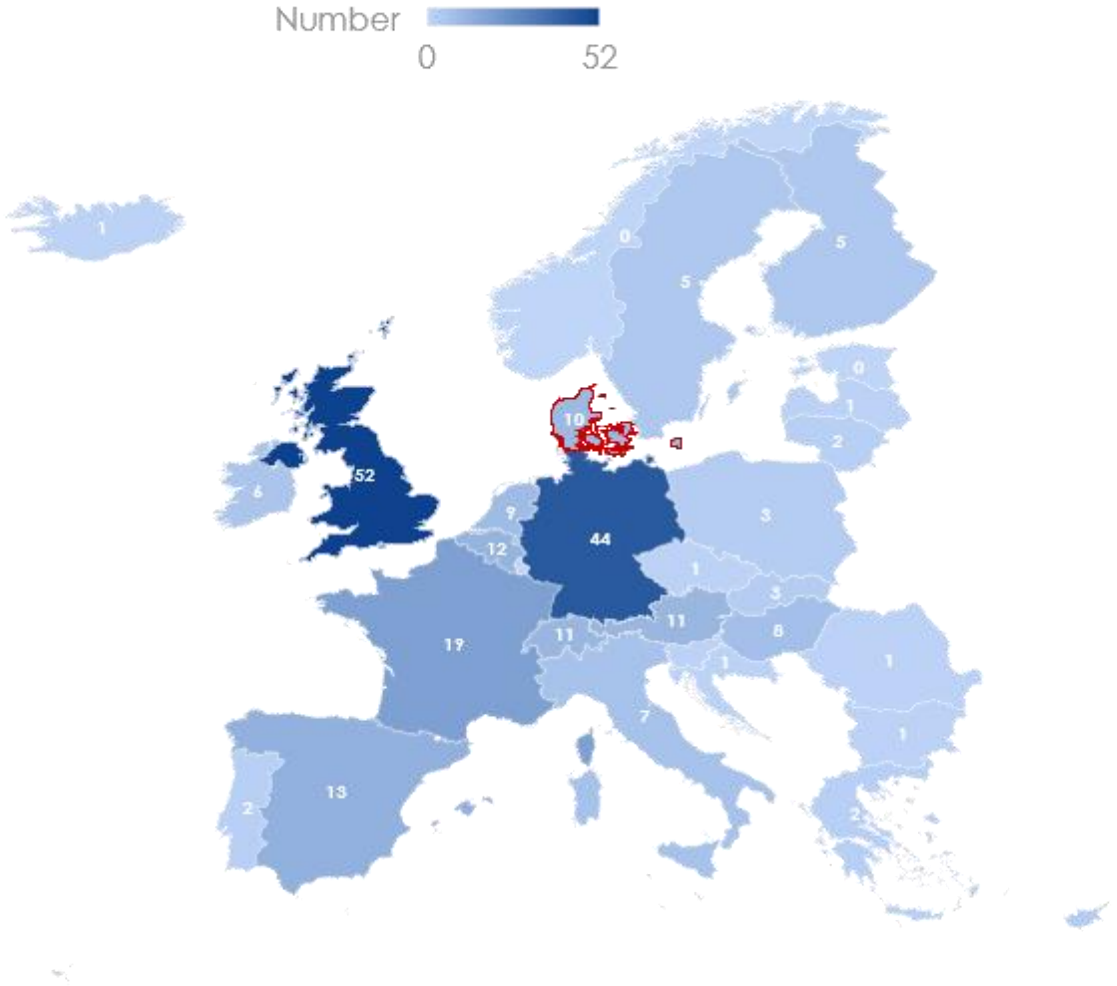
EMVO Board of Directors
President: Hugh Pullen (EFPIA)
Vice-President: Sonia Ruiz Morán (PGEU)
Treasurer: Richard Freudenberg (EAEPC)
Monika Derecque-Pois (GIRP)
Adrian van den Hoven (Medicines for Europe)

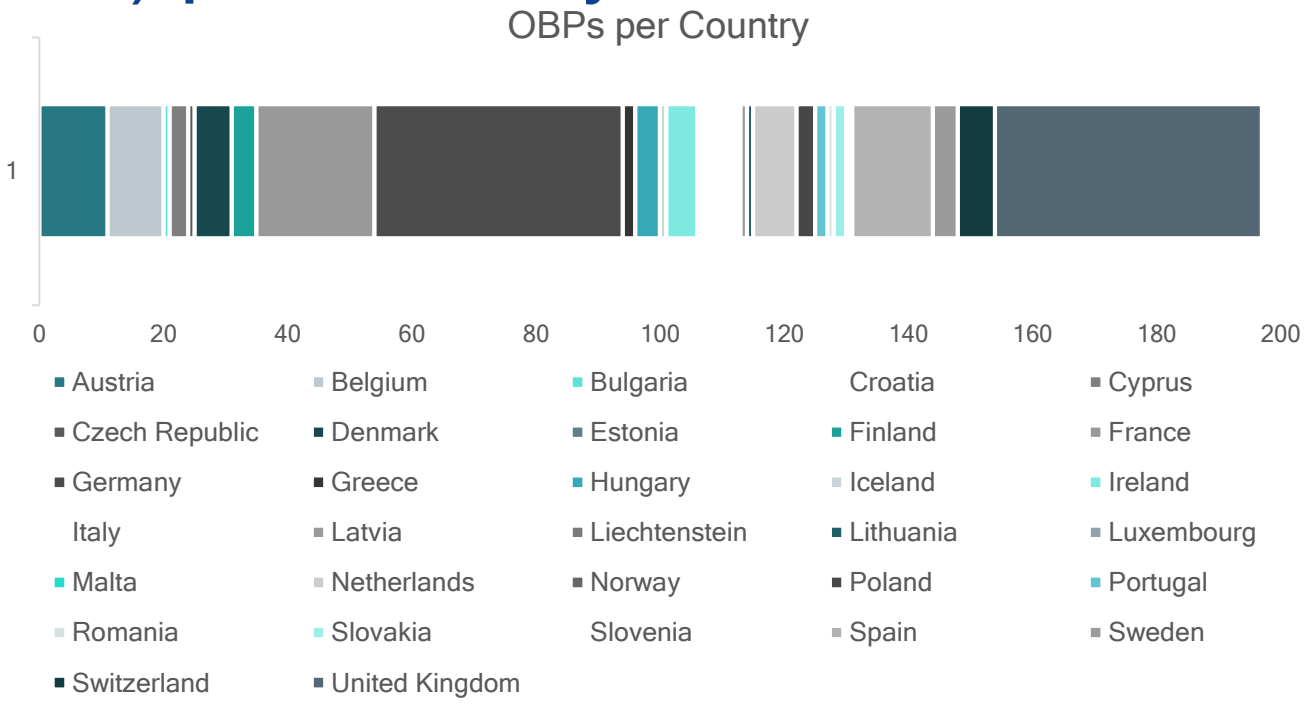


Status Contractual on-boarding



On-boarding Partner (OBP) per Country





Additional non-EU countries:

1 OBP

3 OBPs

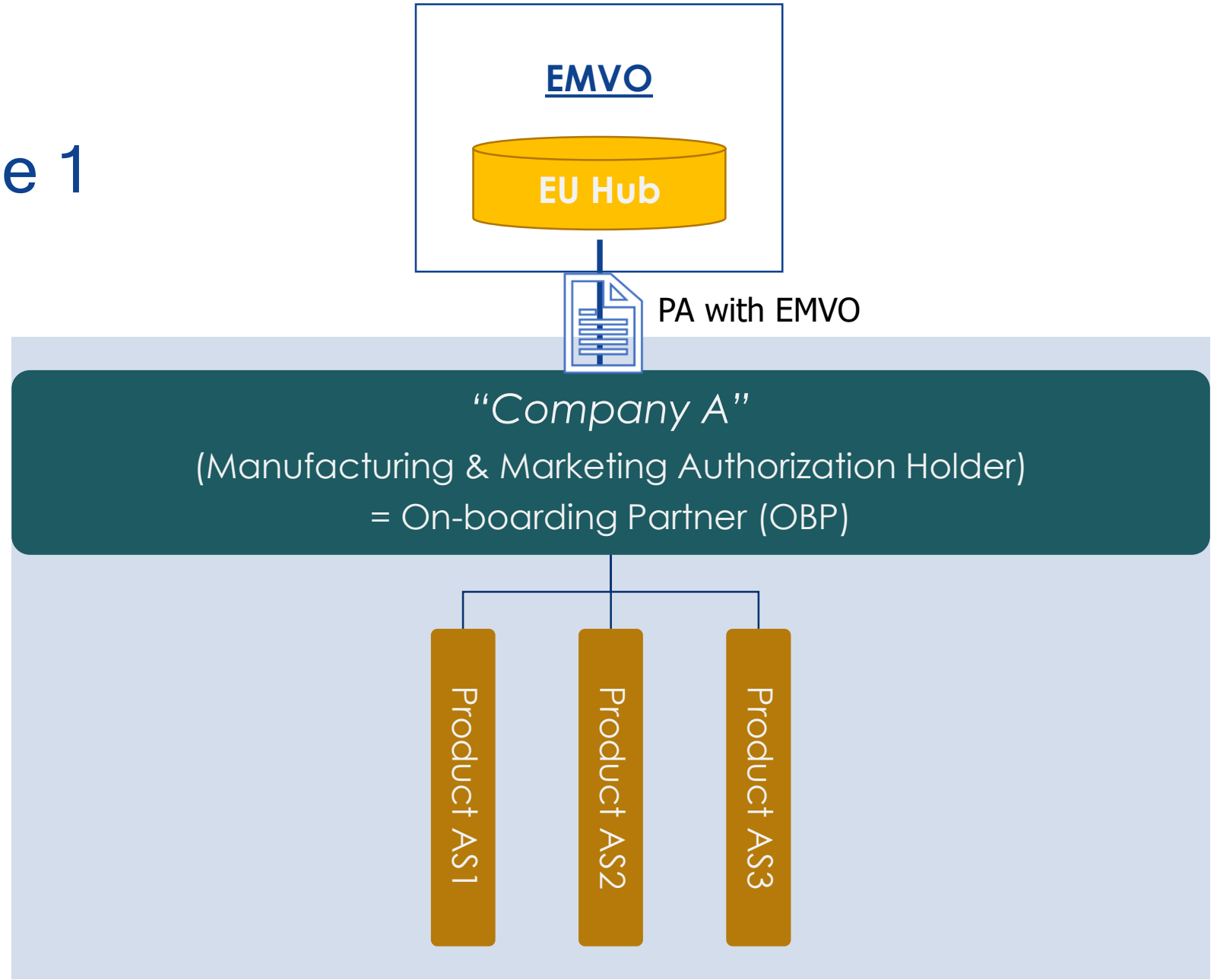
emvo European Medicines Verification Organisation

What is an “OBP”?

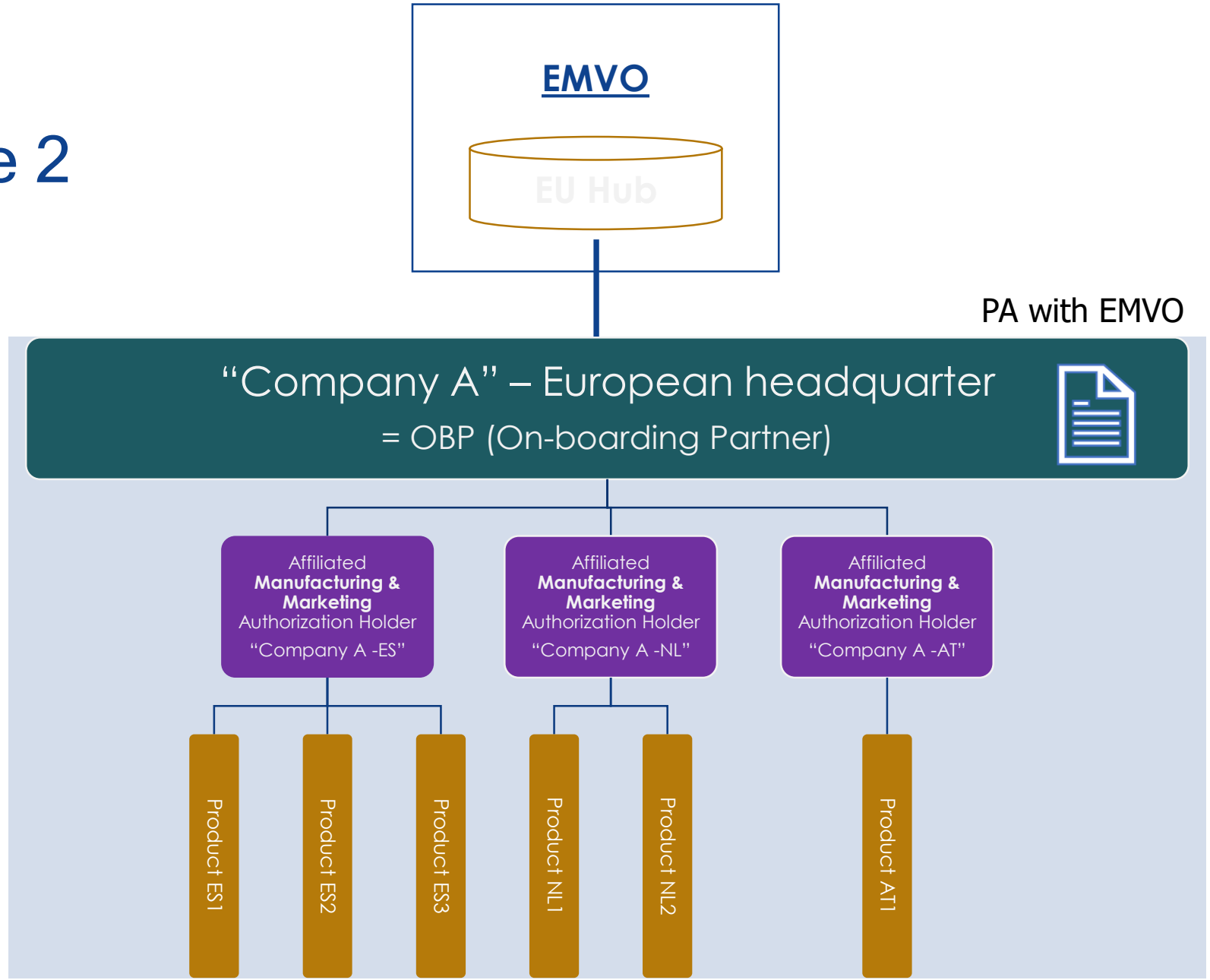
- OBP means **On-Boarding Partner**. The OBP is the contracting party of EMVO; it concludes the Participation Agreement (PA).
- The OBP **represents the Marketing Authorization Holders (MAH)** on behalf of which it will upload data for in the European Hub. It has therefore to be legally authorized to conclude contracts on behalf of a MAH/a group of MAHs.
- The OBP has to be **affiliated (*) to the MAH(s)** on behalf of which it will upload data in the European Hub.
- The OBP should be located in the European Economic Area.
- **The OBP can only upload product data for:**
  - its affiliated MAHs
  - a manufacturer as long as the marketing authorization of the related products lies within the OBP corporation.

(*) Affiliate shall mean, in relation to a Party, any other person affiliated with such Party within the meaning of Article 11 of the Belgian Code of Companies (it being understood, for the avoidance of doubt, that the definition set out in said Article 11 is agreed to also apply to non-Belgian persons).

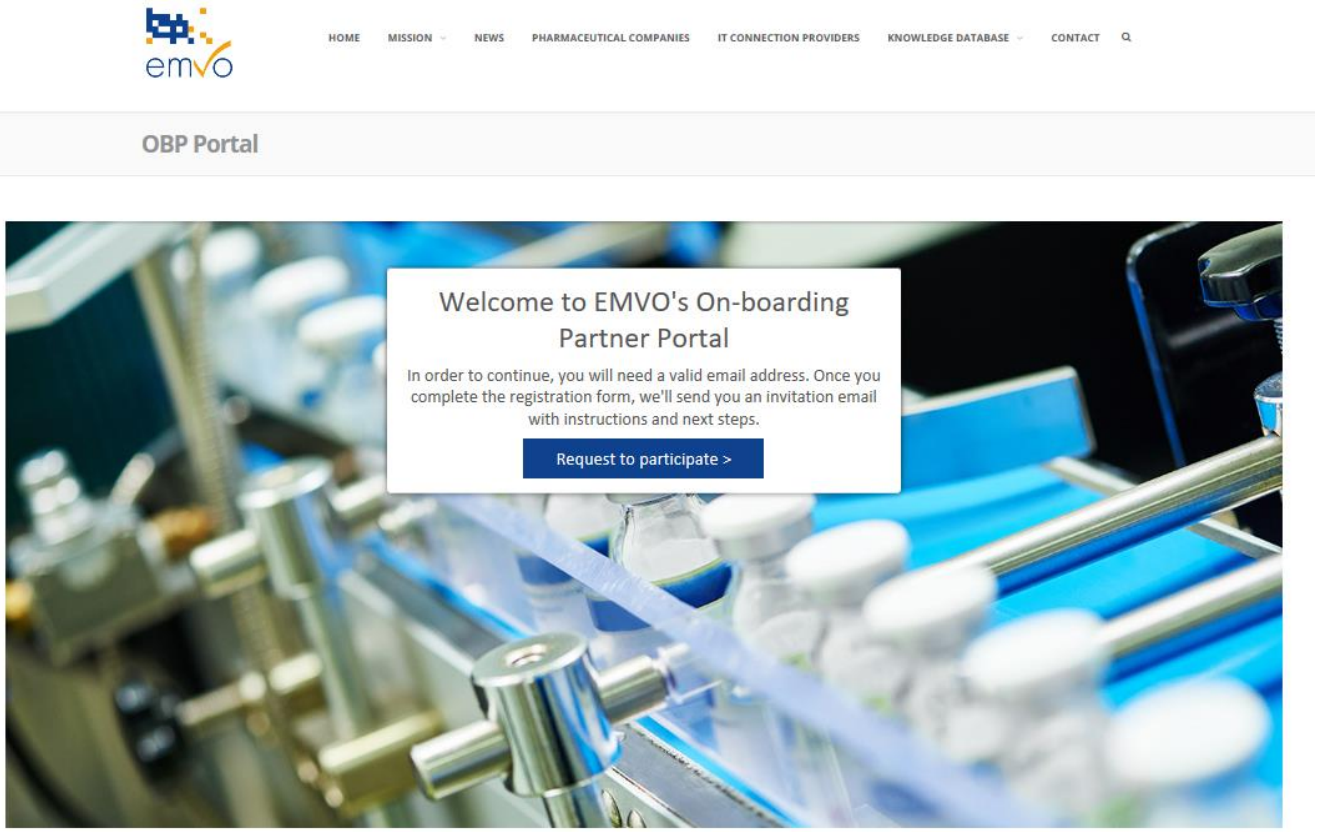
Example 1


EMVO
EU Hub
PA with EMVO
"Company A"
(Manufacturing & Marketing Authorization Holder)
= On-boarding Partner (OBP)
Product AS1
Product AS2
Product AS3

Example 2


EMVO
EU Hub
PA with EMVO
"Company A" – European headquarter
= OBP (On-boarding Partner)
Affiliated Manufacturing & Marketing Authorization Holder "Company A -ES"
Affiliated Manufacturing & Marketing Authorization Holder "Company A -NL"
Affiliated Manufacturing & Marketing Authorization Holder "Company A -AT"
Product ES1
Product ES2
Product ES3
Product NL1
Product NL2
Product AT1

How does the On-Boarding work?

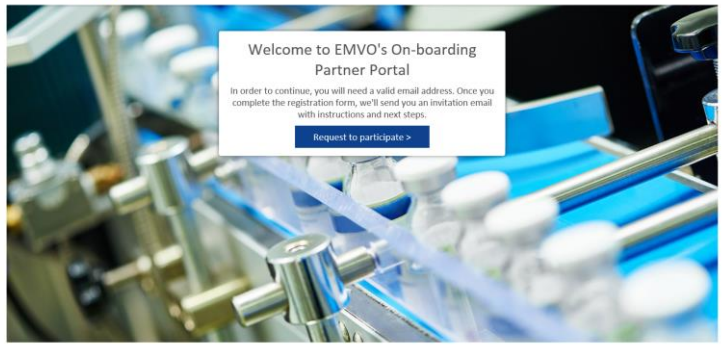


https://emvo-medicines.eu/home/obp/obp-portal/

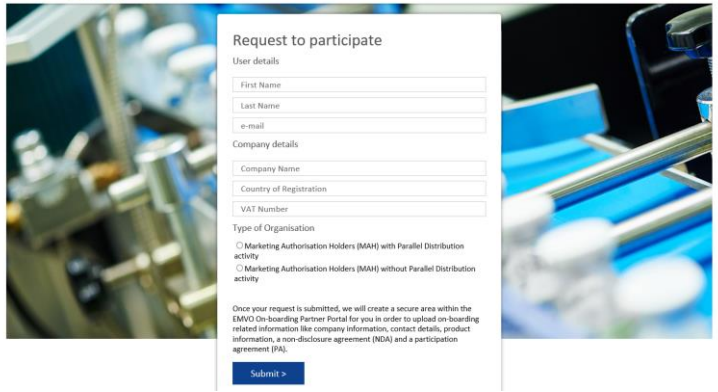
European Medicines Verification Organisation

How to request to participate

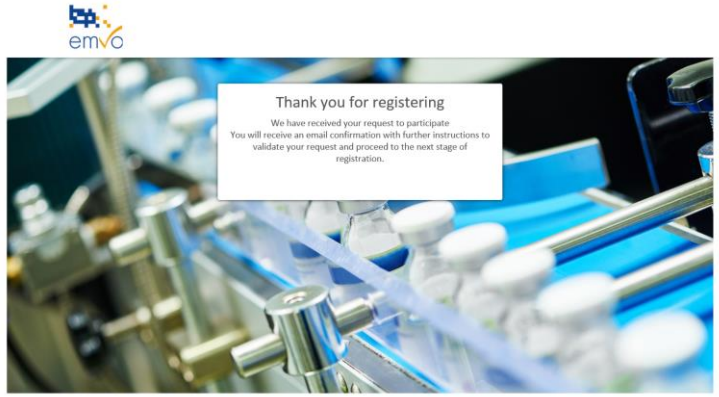
1. Via website - link



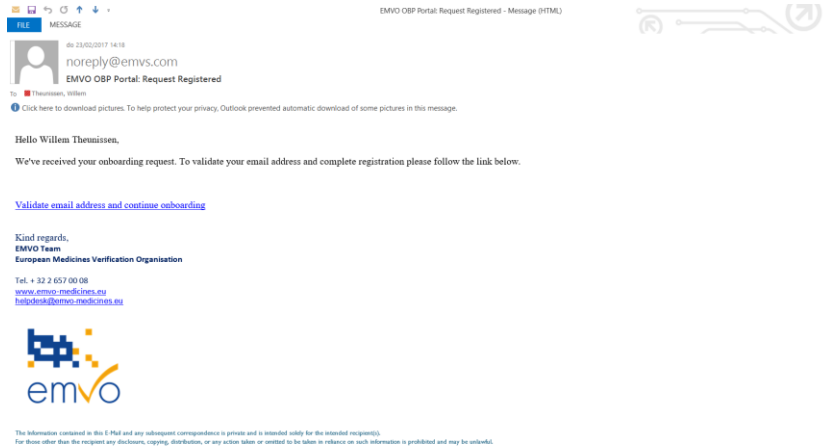
2. Fill in User + Company details



3. You'll be directed to the confirmation screen

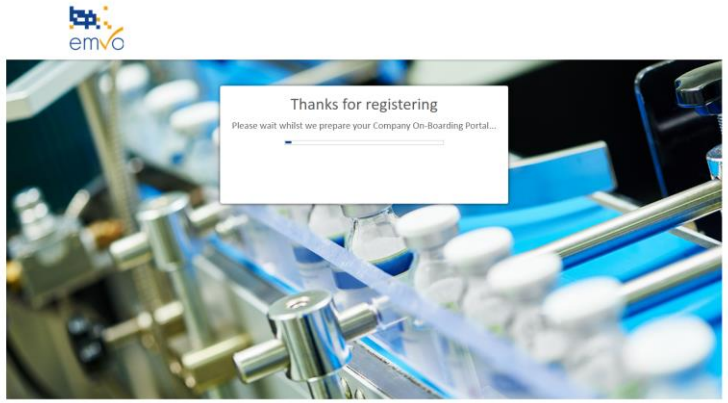


4. Check your email to validate your account

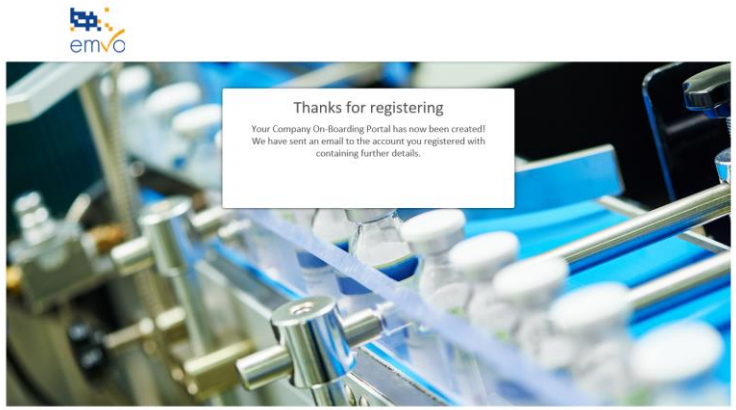


How to request to participate

5. Your company portal will be created

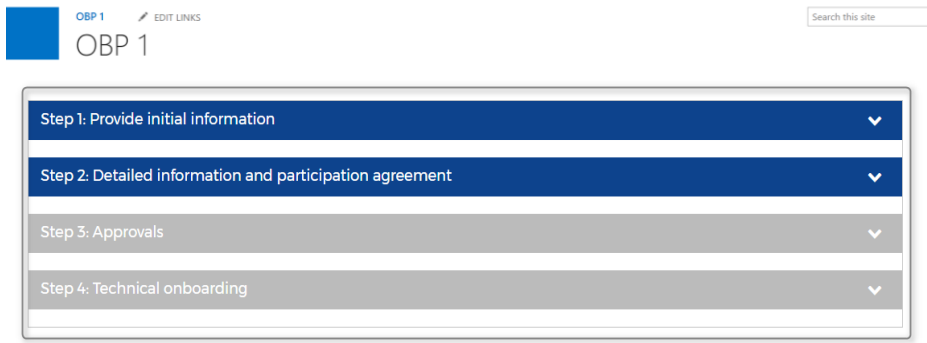


6. Your company portal is created

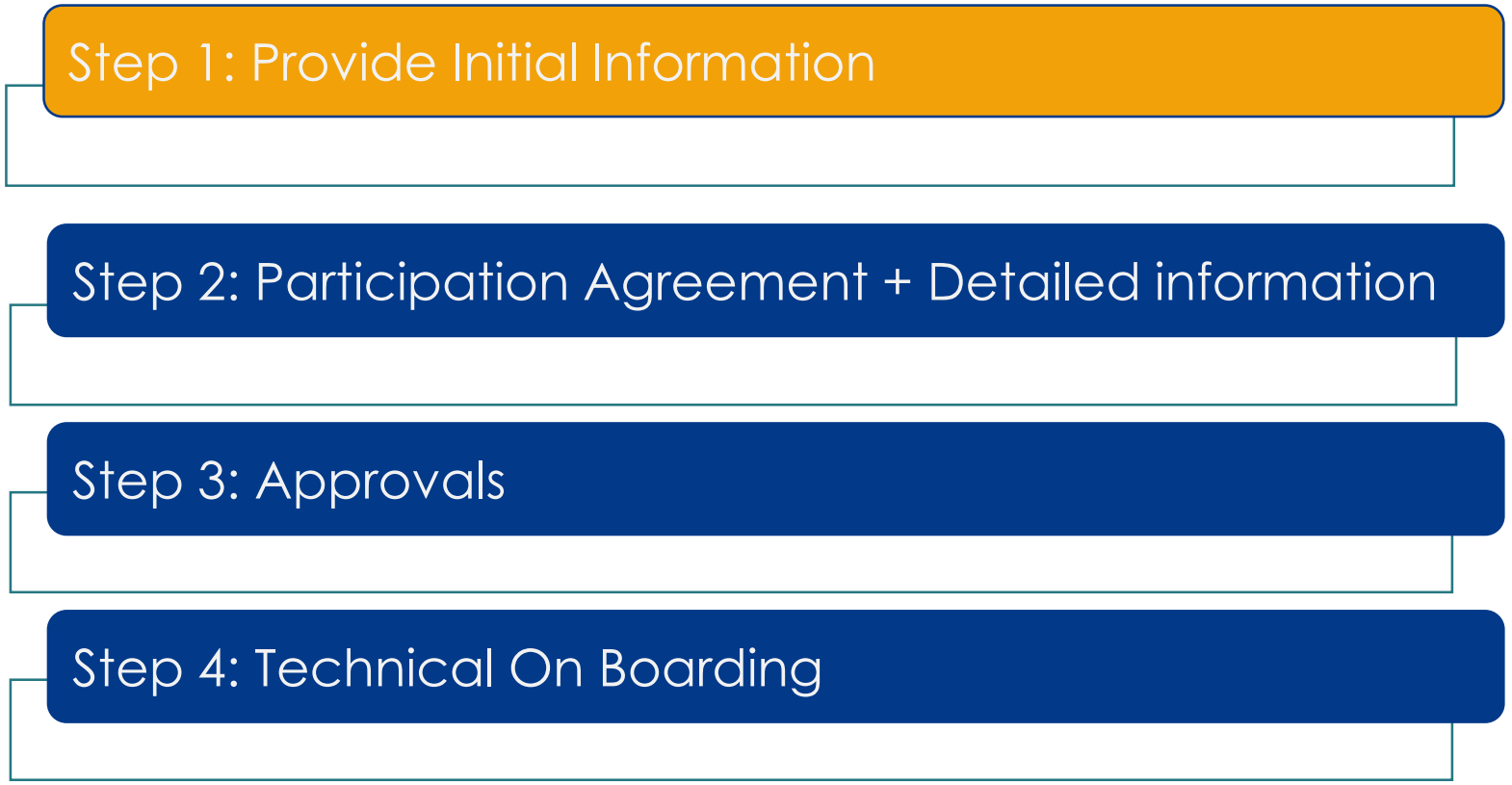


7. Follow the instructions in your email to login to your Company portal

8. Your Company portal is ready to On board



On-Boarding Partner Portal

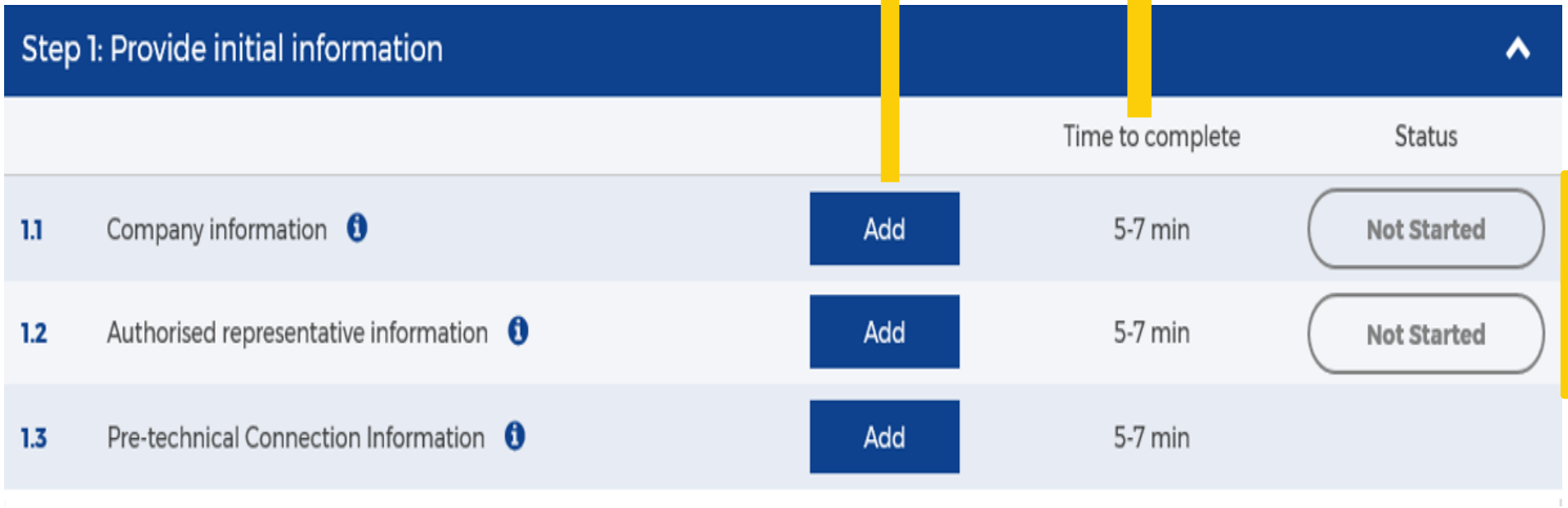


Step 1: Provide Initial Information

Trigger step 1:
Successful Request to Participate

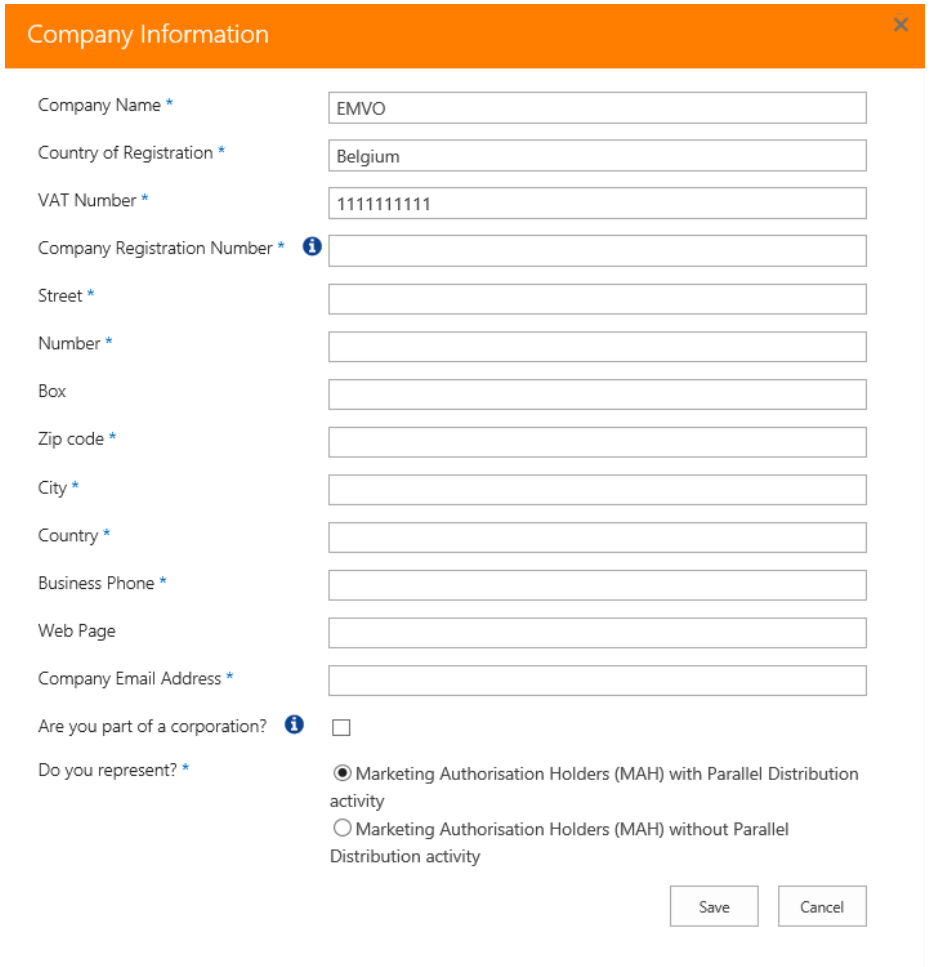
To add or modify the requested information

Estimated time to complete



Status:
Not Started
In Progress
Complete

1.1 Company Information



Company name

- ✓ make sure to provide the full official name of your company

Company identification numbers: VAT and Company registration number

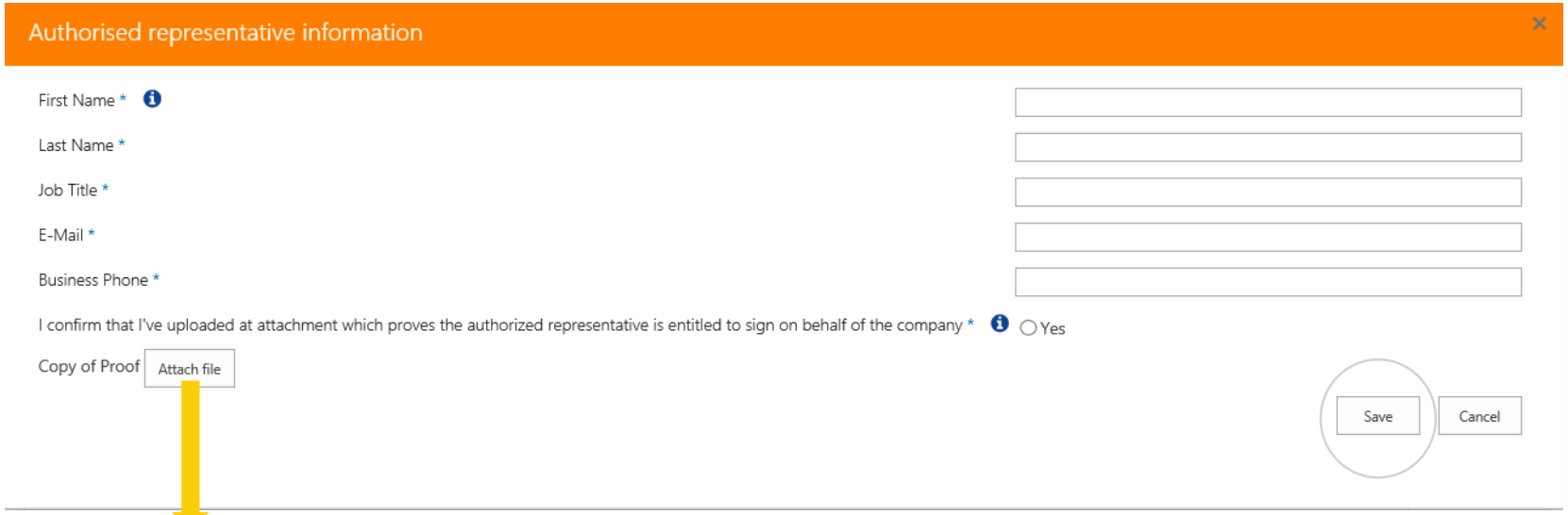
- ✓ make sure not to get confused between the OBP company, the parent company, and the MAHs information.
- ✓ make sure to include the full sequence of digits, no typo, and the initial country identification letters in front, if necessary

Country name / Country of registration

- ✓ make sure to provide the Country name, not the one of the county

1.2 Authorised Representative

Please provide the **information related to the Authorised Representative** together with a copy of proof attesting of the authorisation of that person to sign on behalf of the company.



Mandatory in order to proceed with the further steps

Note 1:
The **Authorised Representative (AR)** is the person authorised to sign on behalf of the company. The AR will sign the Participation Agreement.

Note 2:
A document listing all the National Registers in Europe where to find the relevant copy of proof for your company is available on our website in its download section.

Frenquently committed errors

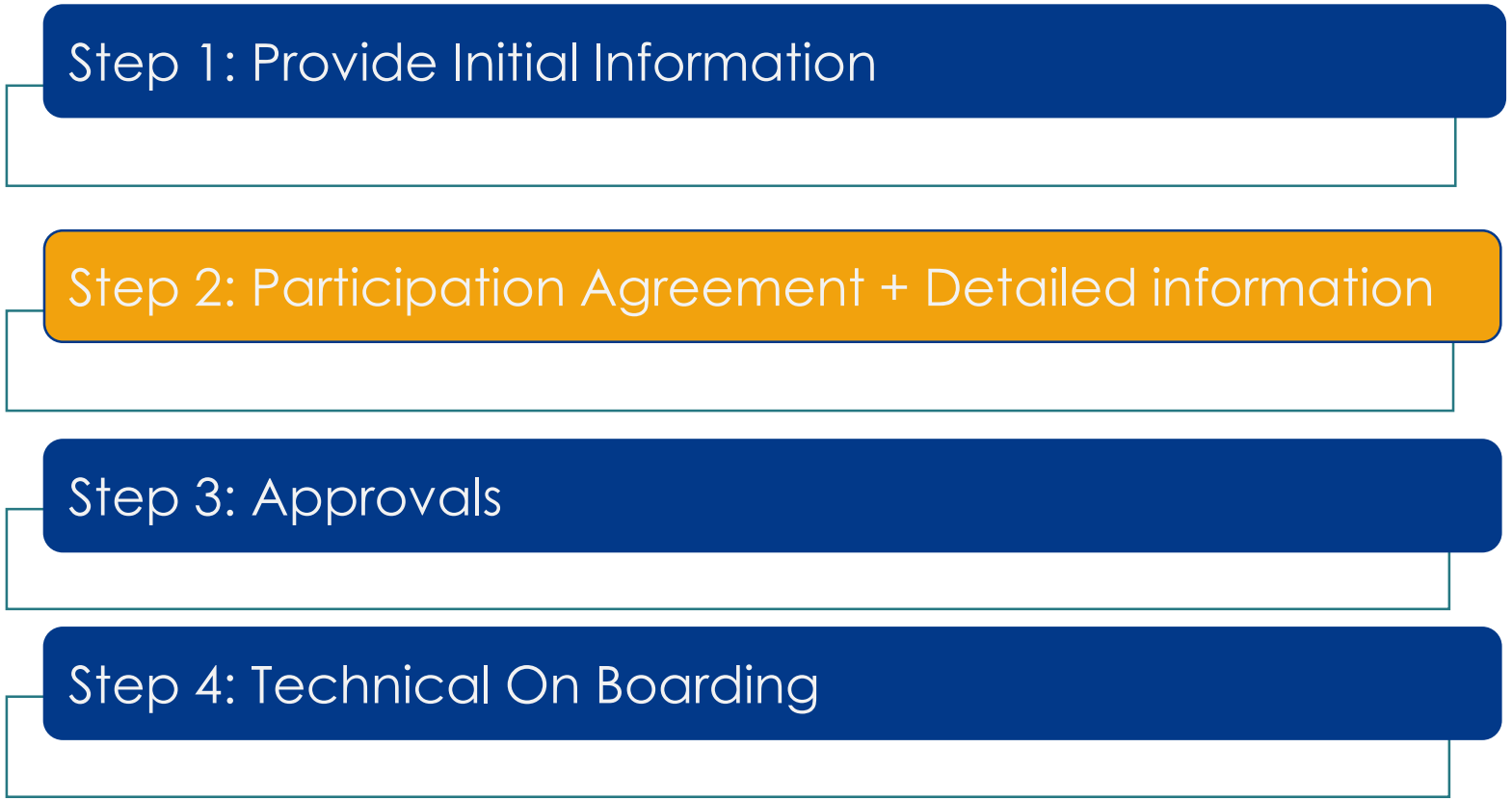
Copy of proof of the Authorised Representative

Purpose: check the authorisation of your named Authorised Representative (AR) to sign on behalf of the company

- ✓ An official register (please consult the National Registers list for european countries on our website: https://emvo-medicines.eu/wp-content/uploads/2017/06/National-Registers-for-obtaining-the-Copy-of-Proof.pdf)
- ✓ The AR is to be explicitly named in the official register together with his/her senior management position and/or his/her explicit authorization
- ✓ Validity of the document with respect to a potential expiration date

List of National Registers available on EMVO website

On-Boarding Partner Portal

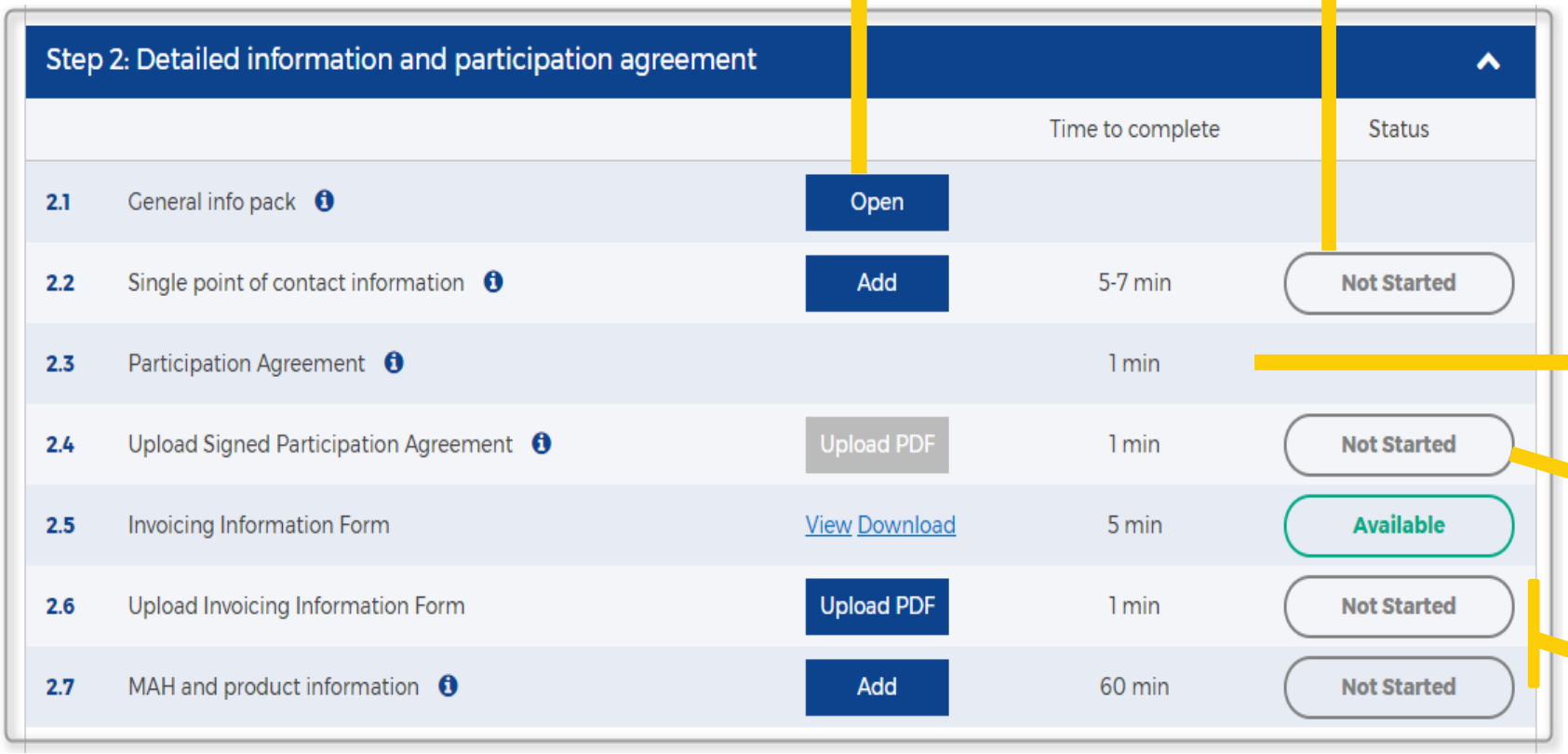


Step 2: Detailed information and Participation Agreement

Trigger step 2:
Successful Initial Information and Authorise Representative copy of proof

Download General Info Pack

Status:
Not Started
Completed



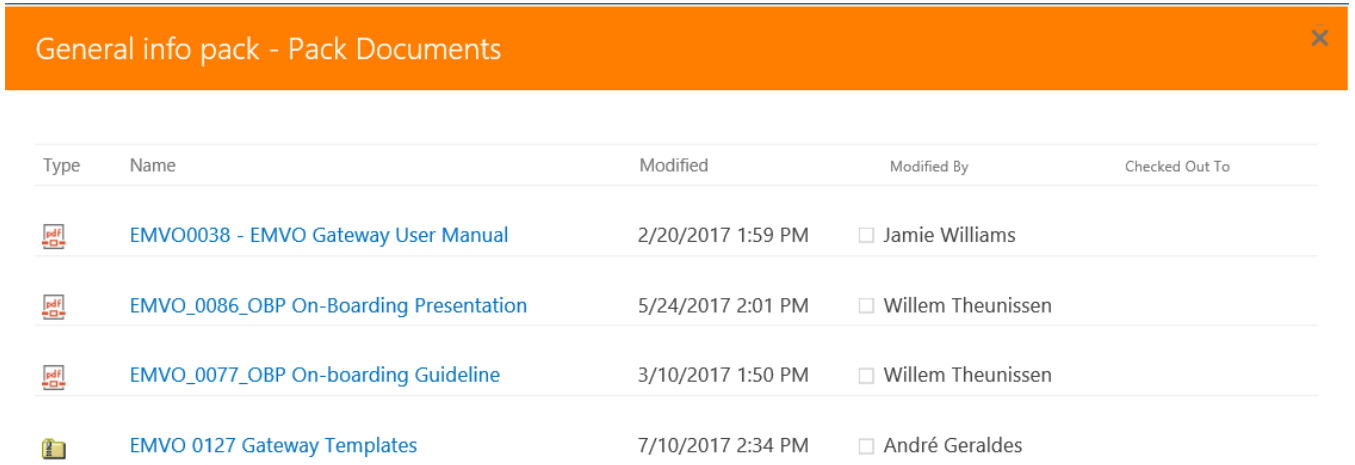
View and Download prefilled Participation Agreement (PA)

Status:
Not Started
Awaiting Approval
Approved
Rejected

Status:
Not Started
Completed

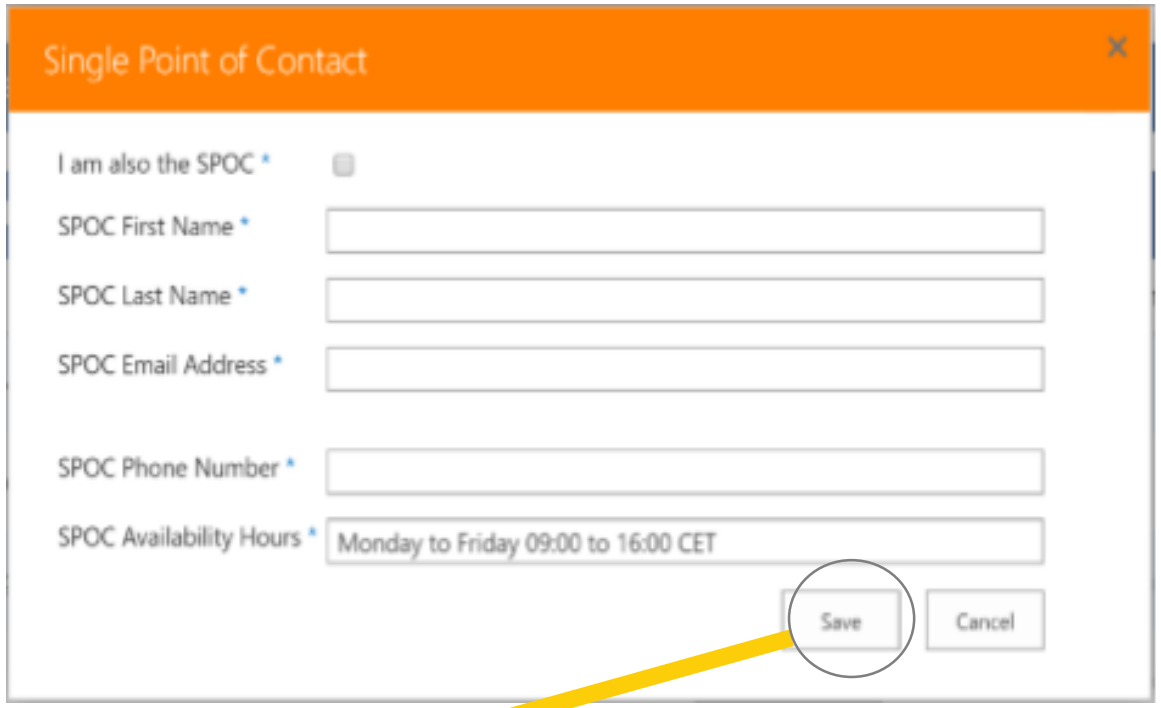
A sample of the PA is available on our website in its download section.

2.1 General Info Pack



In that documentation you will find the explanation of **each step** on the portal and the **corresponding requirements** as well as a user manual for the **EMVO Gateway.**

2.2 Single point of contact



Action:
A prefilled Participation Agreement will be generated

Note 1:

- The SPOC details will be **listed in the PA**.
- By signing the PA, the **Authorised Representative will confirm the SPOC appointement**.
- The SPOC will be the responsible for **providing all the required information** in the OBP Portal.
- When the SPOC contact details will be listed, s/he **will receive credentials via e-mail**. At the moment of his/her first login in the portal, **the initial Registration Requester's credentials will be revoked**.
- If the **SPOC is the same person as the Initial Registration Requester**, (s)he will be able to access the Portal **with the credentials** received **in the first place**.

Note 2:

- The **second SPOC** contact details are optional.
- They will be used in case the first SPOC is not available.
- The second SPOC will not receive credentials.

Initial Registration Requester Credentials

IMPORTANT NOTE !

The SPOC is the only person having the credentials to access the portal. However, in the event the Initial Registration Requester is the same person as the SPOC, s/he will be able to access the portal with the credential received in the first place.

OBP Contract with EMVO

The Participation Agreement (PA)

- Contractual framework for **participation in the On-boarding project**, e.g.
  - Use of the EMVO Gateway
  - Interface development
  - Connect to the HUB
  - SDK

- Includes a **Non-Disclosure Agreement** covering the **provision of Confidential Information** by EMVO, e.g on
  - European Hub
  - EMVO Gateway

- Purpose: **Execution of Technical On-Boarding**

EMVO will only counter-sign the PA and send it back only when the legitimacy check will be successfully passed

OBP Contract with EMVO

The Parti nt (PA)

- Contractual fr **g project**, e.g.
- Includes a **nfidential**
  - Purpo **ding**

NO CONTRACT NEGOTIATON

Frenquently committed errors

Contracts

- ✓ Consistency between the named Authorised Representative in step 1.2. and the person that actually signed the contracts
- ✓ No ammendments
- ✓ Two (2) hardcopies have to be sent to EMVO via post
- ✓ Both hardcopies are signed and both are original versions (not scanned)

On-Boarding Fee

One-Time Fee per OBP

OBPs with more than 12 MAHs in Europe	20,000 €
OBPs with 6 to12 MAHs in Europe	10,000 €
OBPs with 3 to 5 MAHs in Europe	8,000 €
OBPs with 2 MAHs in Europe	6,000 €
OBPs with 1 MAH in Europe	3,000 €

2.5 Invoicing information

Mandatory fields

INVOICING FORM
Please fill in the form and return to
helpdesk@emvo-medicines.eu

Legal Entity information: **1. Entity to which the invoice is billed**	
*Legal entity Name	
* Address	
Contact name	
*E-mail address	
*Number of MAH's Please note that the number of MAHs you are asked to fill in has to be the total number of MAHs on behalf of which your OBP is going to upload data into the European Hub. Please use the drop-down menu.	1 MAH in Europe
*VAT Number	
Your PO number (if required)	
Legal Entity information: **2. Entity to which the services are provided** (Only complete this section if different to section above)	
*Legal entity Name	
Company Name/Department	
Address	
Contact name	
E-mail address	
Recipient of the invoice (Only complete this section if the invoice is to be sent to an address other than above under section 1)	
Company Name/Department	
Address	
Contact name	
E-mail address	

* Mandatory
Comments : .....

EMVO (European Medicines Verification Organisation) aisbl TVA BE 0638.801.022 | Permanent Office: Rue de la Loi 28, Boîte 21 B-1040 Bruxelles | T : +32.2.657.00.08 | Invoicing Information Form Version 1.0

In *Number of MAHs* the OBP has to chose from a **drop-down menu** the **total number of MAHs** it will upload data for in the European Hub.

Note:
A sample of this document is available on our website in its download section.

2.7 MAH AND PRODUCT INFORMATION

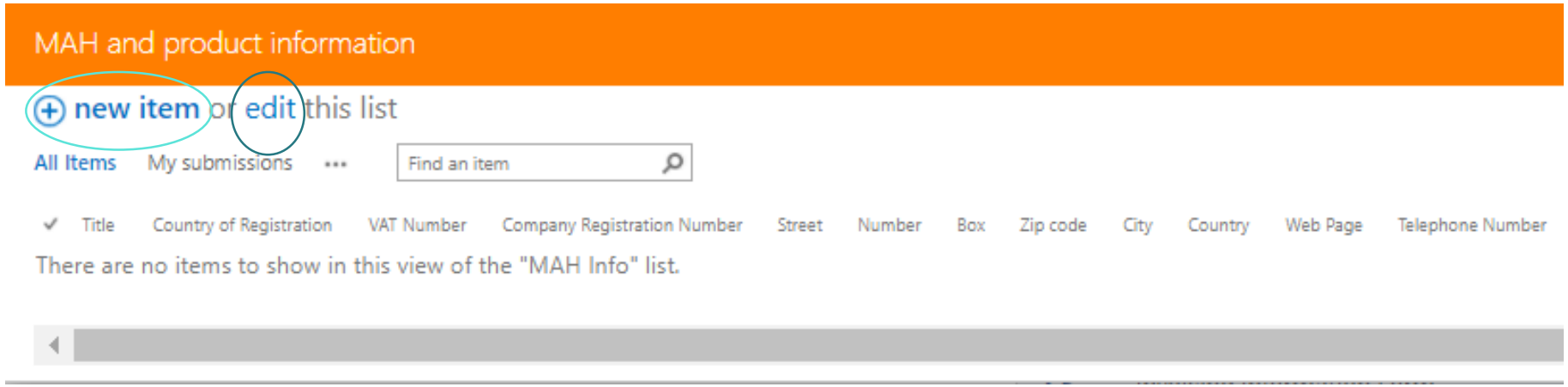
Note 1:

- ***New item*** allows the OBP to add a new MAH into the list.
- ***Edit*** allows the OBP to copy paste an excel sheet with all its MAHs listed, using the exact same name and location of the columns as shown in that section.

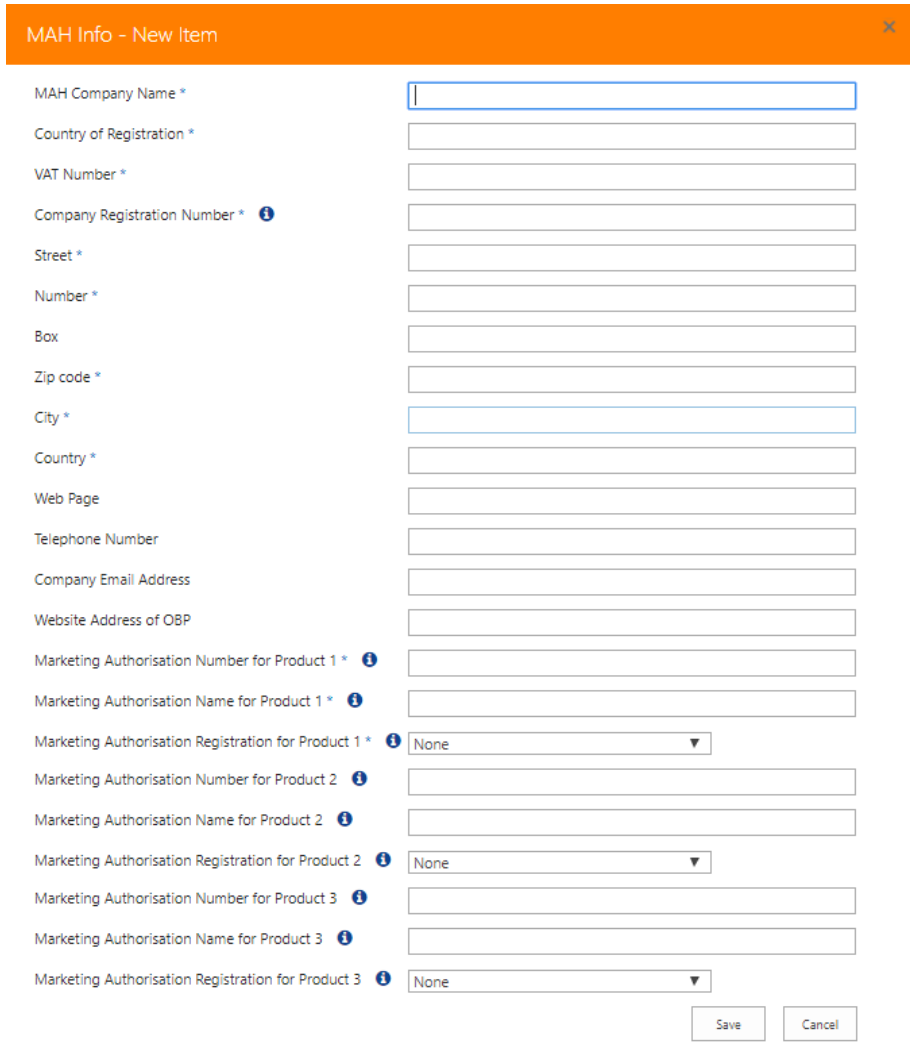
Note 2:

For the purpose of the Legitimacy Check the OBP has to provide a minimum of one MAH and a minimum of one corresponding product information.

In the end, the OBP will have to fill-in the whole list of MAHs for which it will upload data in the European Hub.



2.7 MAH AND PRODUCT INFORMATION



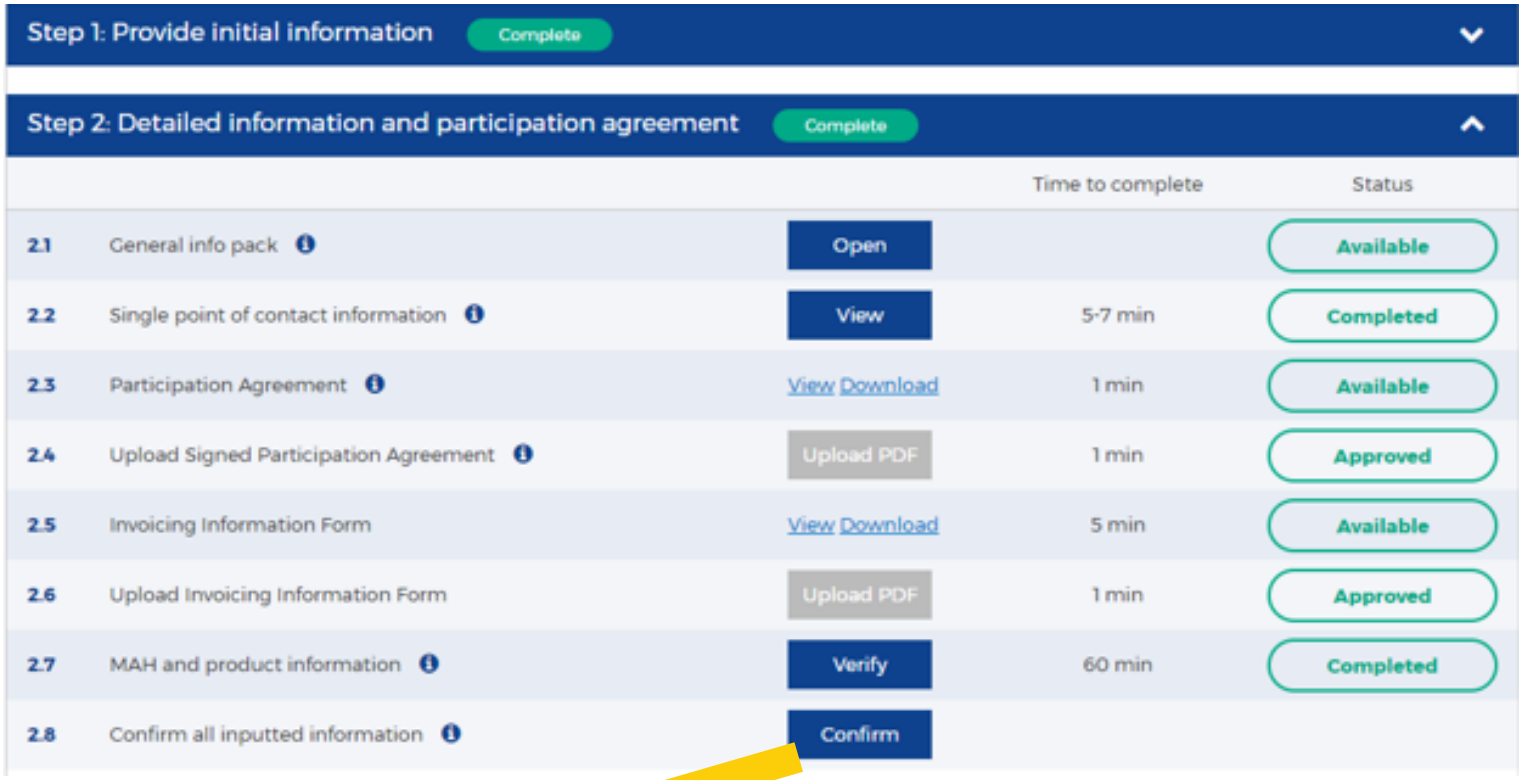
Note:
Product information;

- The **Marketing Authorisation Number** is the licensed number related to the number of the product that the MAH received when applying for Marketing Authorisation

- The **Marketing Authorisation Name**; together with the name, please mention the strength and the pack size of the product in order to allow EMVO to identify the exact product presentation linked to the Marketing Autorisation Number.

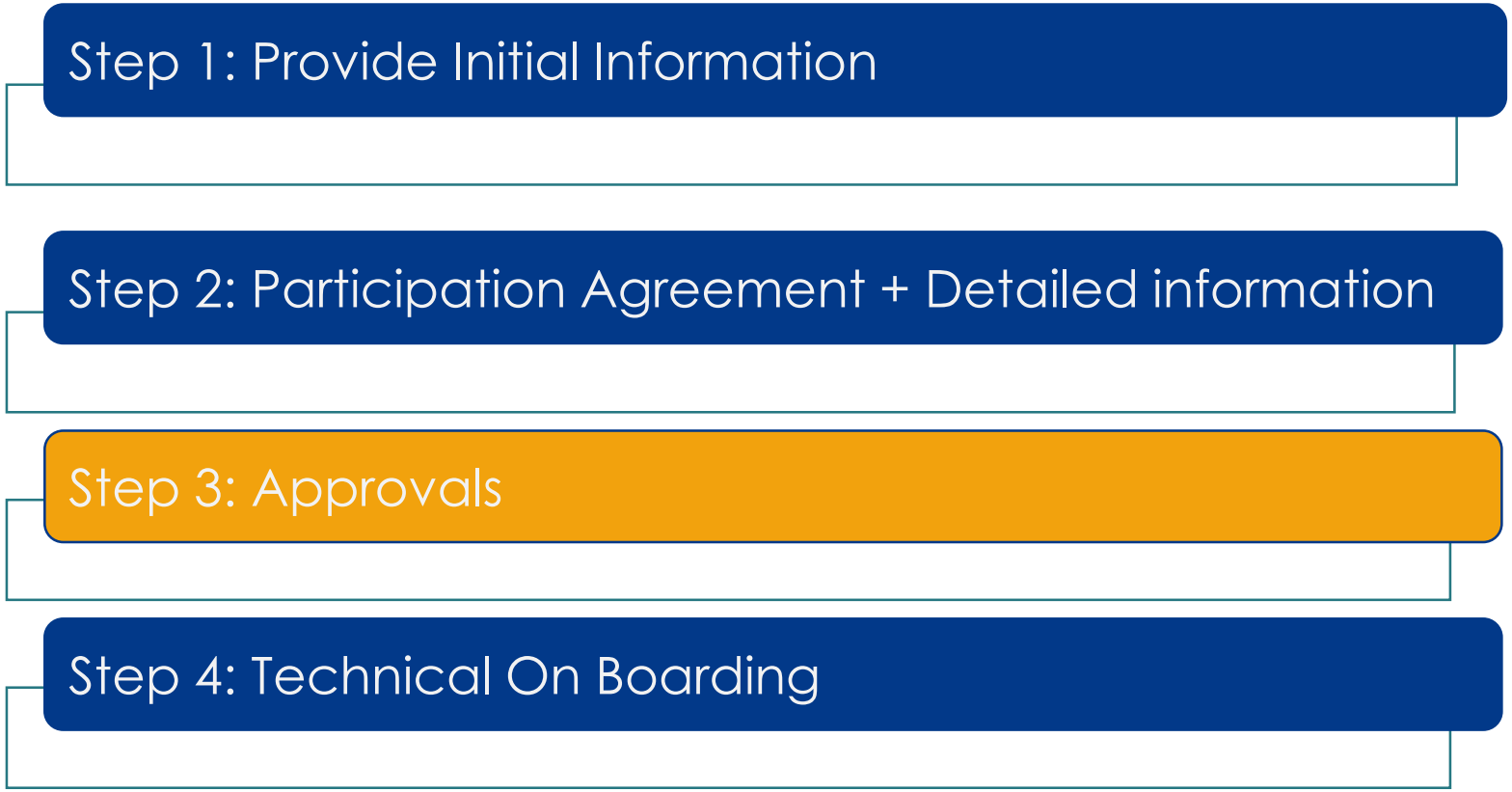
- The **Marketing Authorisation Registration** refers to the country covered by the marketing authorization and may be centralized.

2.8 CONFIRM ALL INPUTTED INFORMATION

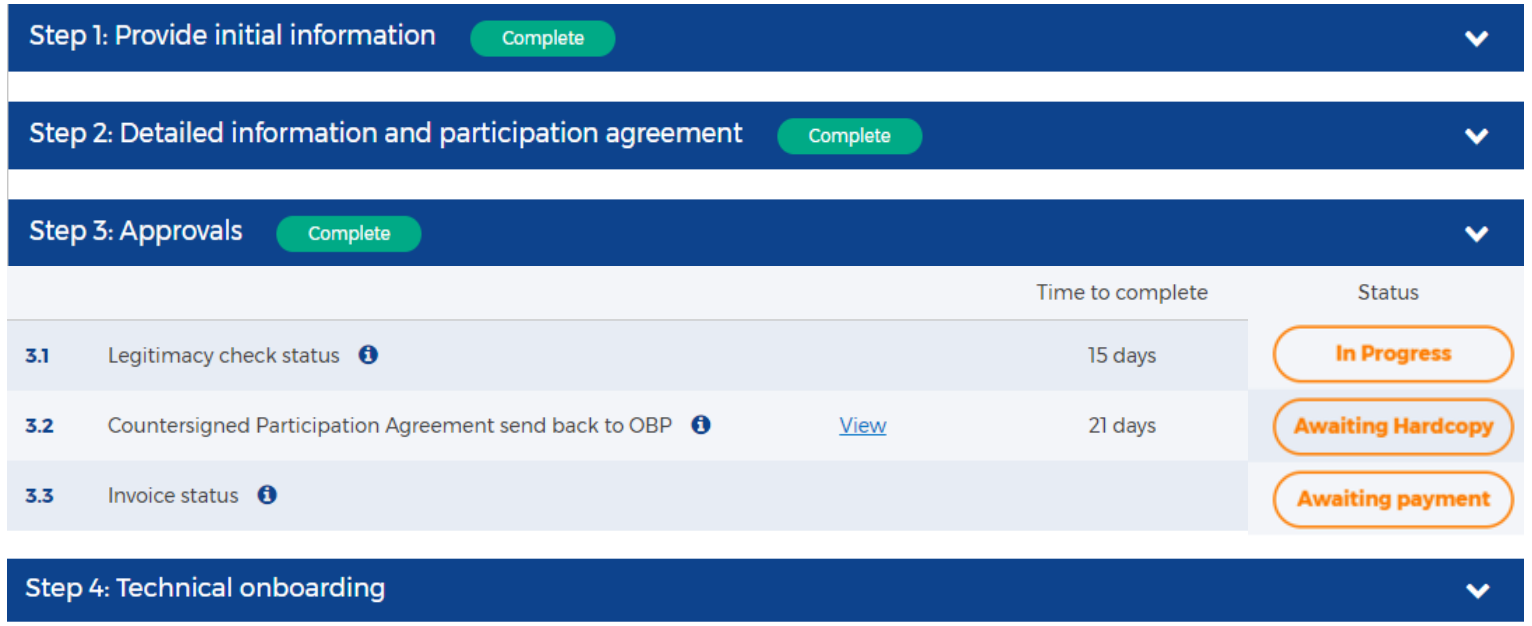


By clicking on the *Confirm* button the SPOC **confirms the accuracy** of the information provided on the portal.

On-Boarding Partner Portal



Step 3: Approvals



Please note that EMVO is going to check the reception of the payment and update those status every two weeks.

Note 1:
The outcome of the **Legitimacy Check** will be communicated to the OBP's SPOC via e-mail.

In the event that the Legitimacy Check outcome is not successful the OBP will have the possibility to modify the information provided.

Note 2:
If and only if the Legitimacy Check outcome is successful, the Participation Agreement will be **countersigned by EMVO** and one hardcopy will be sent back to the OBP by post.

Note 3:
Only when the Legitimacy Check is successful and the payment of the On-boarding fee has been received, the OBP will be granted **access to the Technical On-boarding.**

Legitimacy check

- Triggered **when the SPOC confirms** the accuracy of the information provided on the portal
- Around **50 parameters checked**
- **Direct and indirect** checks are conducted
- **Outsourced**: conducted totally independently from EMVO – ensuring efficiency, accuracy and objectivity
- The check is **conducted by actual people** – ensuring a solution-oriented and reflexive approach
- Standardised and **impartial** process

Step 4: Approvals

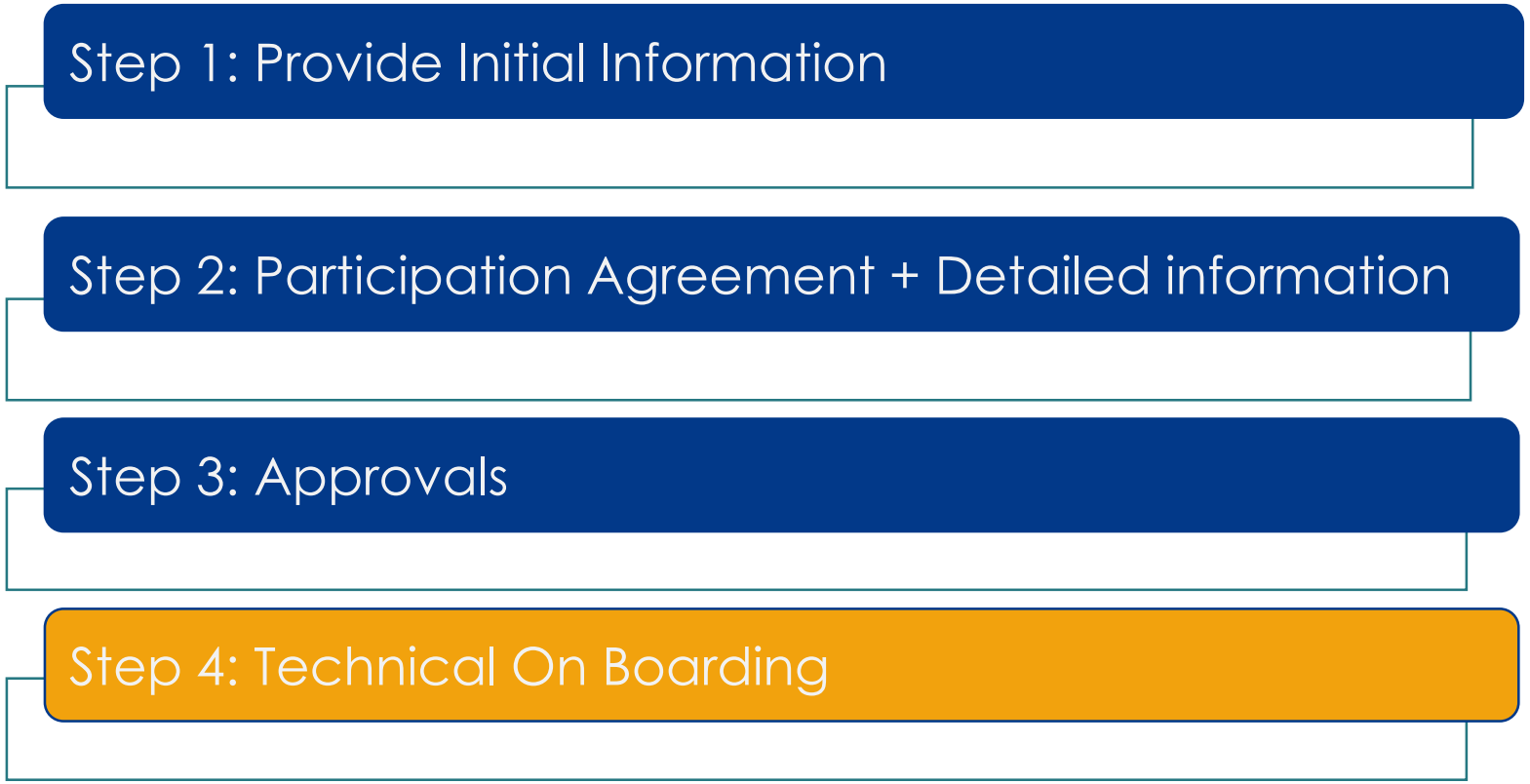
- The outcome of the Legitimacy Check will be communicated to the OBP via e-mail. And the status will be **updated on the portal.**

- In the event that the Initial Legitimacy Check **outcome is not successful** the OBP will have the possibility to **modify the information provided**.

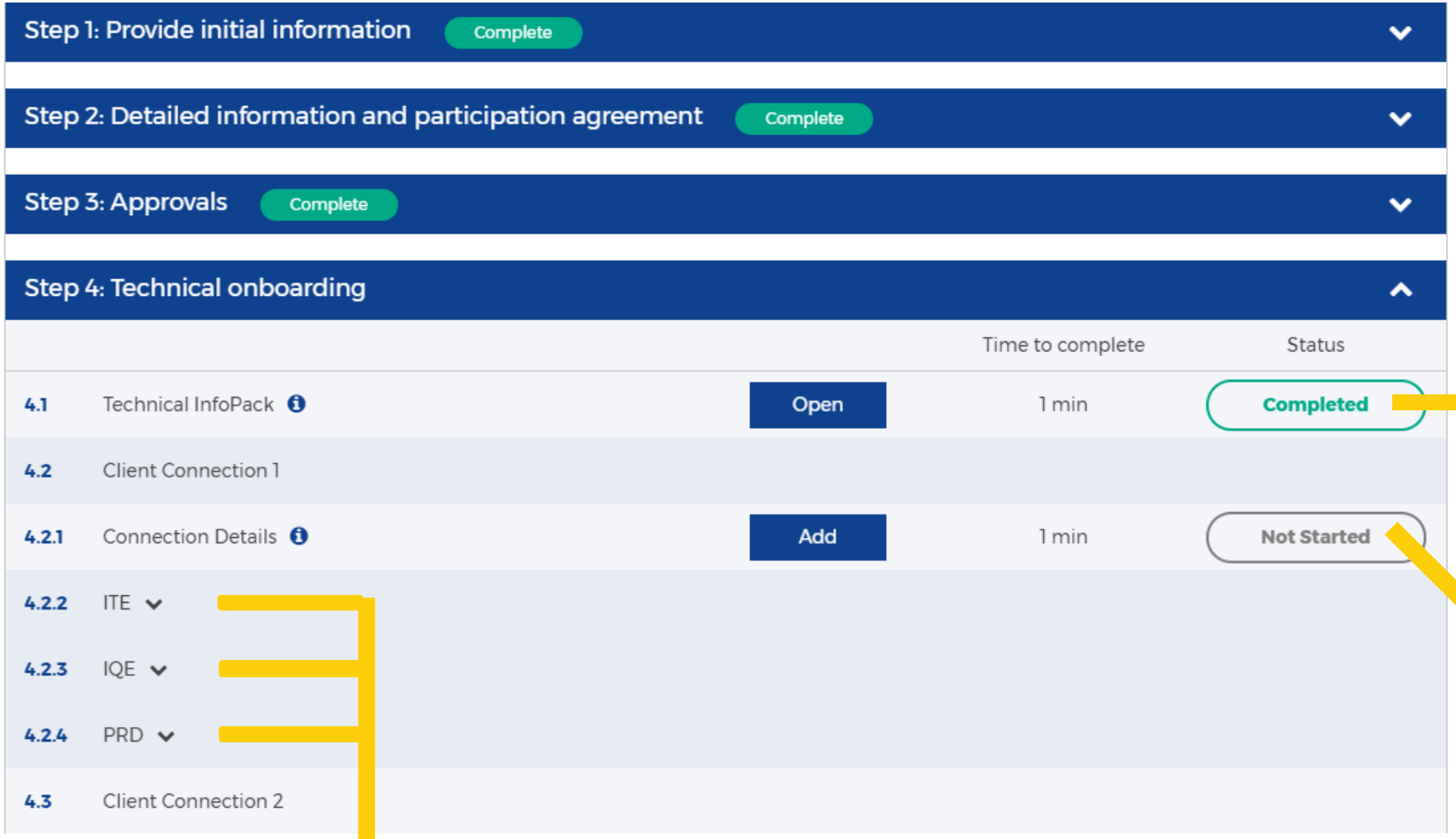
- If and only if the Legitimacy Check outcome is successful, **the Participation Agreement will be countersigned by EMVO** and one hardcopy will be sent back to the OBP by post.

→Only when the **Legitimacy Check is successful** and **the payment of the On-boarding fee has been received**, the OBP will be granted access to the **Technical On-boarding.**

On-Boarding Partner Portal



Step 4: Technical On-boarding



Access sub-steps

Trigger step 4:
- Step 3 completed

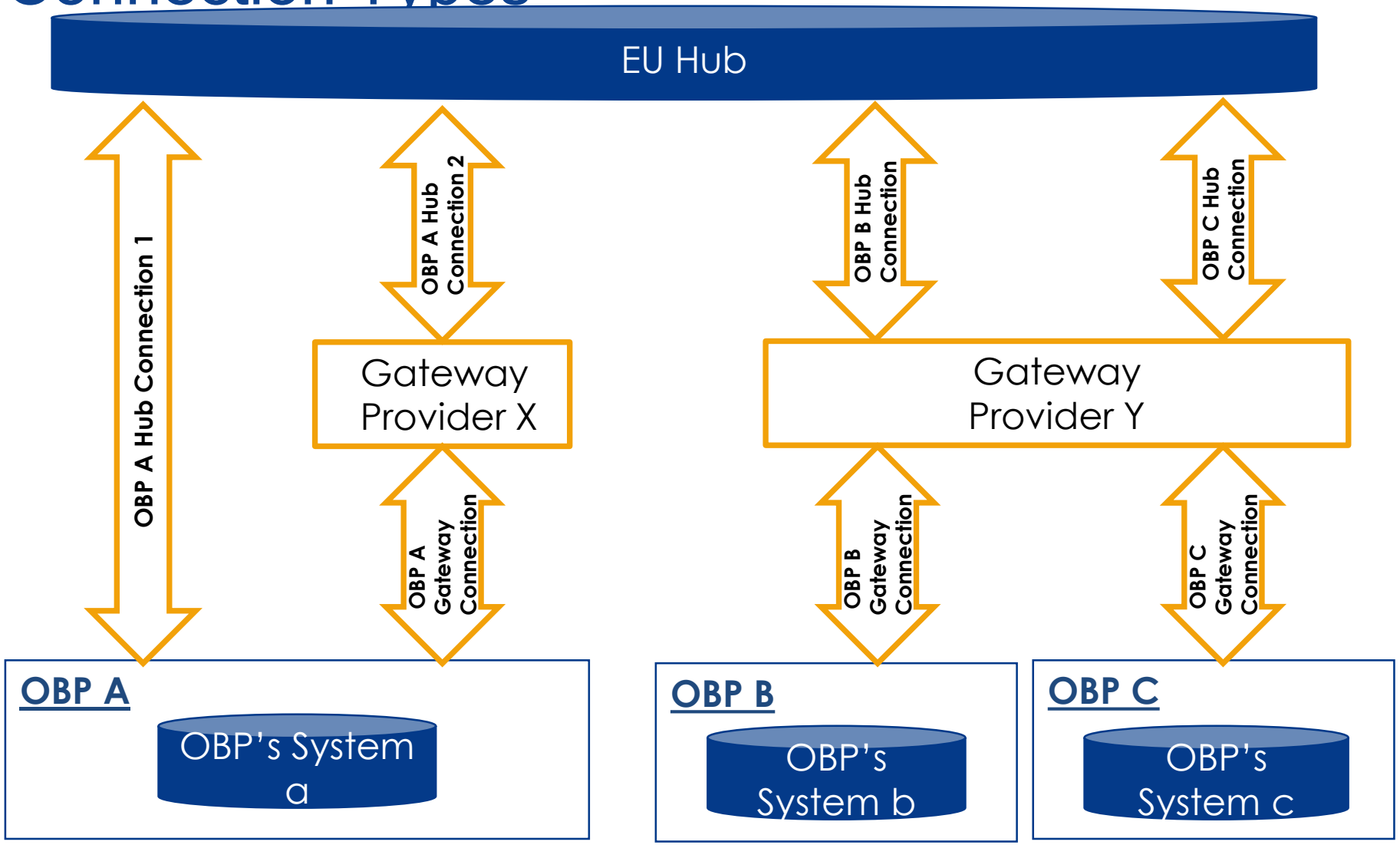
Note:
If you make use of a Gateway Connection, step 4.2.2 (ITE) is optional

Status:
Not Started
Completed

Status:
Not started
Completed

Access sub-steps

Connection Types



Agenda

- Static Master Data
- Market Specific Master Data

Agenda

Static Master Data

Market Specific Master Data

Static Master Data

Element Name	Description	Example	Reference
Product Code	The logistics code on the pack and contained within the new Data Matrix code. Will be either a GTIN, NTIN or PPN only.	05060141900015	Logistics / Supply Chain Mgmt.
Coding Scheme	Can only be either GTIN (where a GTIN or NTIN is used for the product code) or PPN	GTIN	Simple choice GTIN/PPN
There are some degrees of freedom for the following 5 fields. Please refer to the table in Appendix 1 for guidance or to the reference[1] below			
Name	The (invented) name + strength + pharmaceutical form. *Other languages than English might be used, please refer to your regulatory submission.*	Amoxicillin Effective Medicines 500mg Capsules WQX®"Plus" 80mg/25 mg Filmtablette	QRD, Annex 1, sec 1
Common Name	International Non-proprietary name (INN) or the usual common name of the active substance(s), if part of the full name of the medicinal product.	Amoxicillin Telmisartan/Hydrochlorotiazide	QRD, Annex 1, sec 1 (name element only)
Pharmaceutical Form	The single full Standard Term of the European Pharmacopeia, using the plural form if appropriate (https://standardterms.edqm.eu/)?	Capsule Filmtablette	QRD, Annex 1, sec 3

Dansk Medicin Verifikation Organisation

Static Master Data

Element Name	Description	Example	Reference
Strength	The pharmaceutical strength of the product. This should be consistent with the quantity stated in the quantitative composition and the posology. (Will be a repetition of what is entered as part of the full name)	500mg 80mg/25 mg	QRD, Annex 1, sec 1
Pack Type	Should be the pack type that bears the safety features using a Standard Term of the European Pharmacopeia	Box, Bottle, Bag	
Pack Size	The number of re-packable doses in the pack. Where the pack is not readily re-packable, the value should be set as '1'. e.g. a pack of tablets that can be readily re-packed* and therefore this value will represent the number of tablets in the pack. A powder or syrup cannot be readily re-packed and therefore, regardless of volume, the pack size will be set as '1'. Please refer to the table in Appendix 2 for examples *if the pack could not be split, e.g. a 28-day supply of contraceptive, the value is 1	28	The pack size can be derived from QRD, Annex 1, sec 6.5 but this is often not the same as the re-packable dose.

MVO Dansk Medicin Verifikation Organisation

Agenda

- Static Master Data
- Market Specific Master Data

Market Specific Master Data

Element Name	Description	Example	Reference
Member state ISO Code	Two letter country code from ISO 3166-1 alpha-2 defining the local market	DE	List of ISO Codes (Appendix 3)
National code	It is required to insert the national code if requested by the NMVO (see Appendix 4). If not, it is recommended to insert the code (when it exists), however it is left to the discretion of the OBP to decide.	1234567	Appendix 4
Article 57 code/PCID	Article 57 code: xEVMPD EV Code which is assigned by EMA after successful transmission of MPD (Master Product Data) to xEVMPD. Packaged Medicinal Product Identifier (PCID): ISO IDMP/SPOR identifier if already existing. If multiple code exists for the market, select one only.	PRD115784	Key as assigned by EMA upon submission of a new record to EVMPD

Market Specific Master Data

Element Name	Description	Example	Reference
MAH ID	Use the IDMP/SPOR OMS Organisational ID when available for the marketing authorization holder. This field is optional. Exception Germany: For interim period keep IFA registration number until further notice.	48101	
MAH Name	Registered name of the MAH in the market (stated in row 1).	World Class Medicines Limited	QRD, Annex 1, sec 7
MAH Address	Postal address for the MAH detailed above.	14 Harper Street, Lincoln, LN6 3PW, UK	QRD, Annex 1, sec 7
Serialisation Flag	Fill in "True"	**True**	n/a
List of Wholesalers with ID, name and address See Appendix 5 for guidance	This will be a list organised as <ID> (if available) <Name> <Address>. The list should contain the details of each wholesaler (eqv.) who is contracted by, or **on behalf of**, the MAH detailed above (thus only pertinent to the stated local market) to handle the product represented by the product code in table 1 row 1. The ID is optional and reserved for future inclusion when Wholesalers are identified as meticulously as MFR's and MAH's.	ID=N/A Name = 'Better Wholesaling GmbH' Address = 'Neue Strasse 12, 10119 Berlin, Germany'	n/a

Dansk Medicin Verifikation Organisation

How to speed up the process right from the start?

Collect Information:

1. Visit EMVO **Download Section** https://emvo-medicines.eu/downloads/

2. Consult our **training videos**:
   - OBP Check-list for contractual On-boarding
   - The On-boarding Partner Portal

3. Visit EMVO Knowledge Data Base https://emvo-medicines.eu/faq/
   - Who will be the **On-Boarding Partner?**
   - What is my Company Registration number and VAT number?
   - Who can and will be the **Authorized Representative**?
   - Who can and will be the **Single Point of Contact**?
   - How many **MAHs** does the OBP represent?
   - And many more…

THE CPM TEAM

Tel. Helpdesk: +372 611 90 44
E-Mail: helpdesk@emvo-medicines.eu

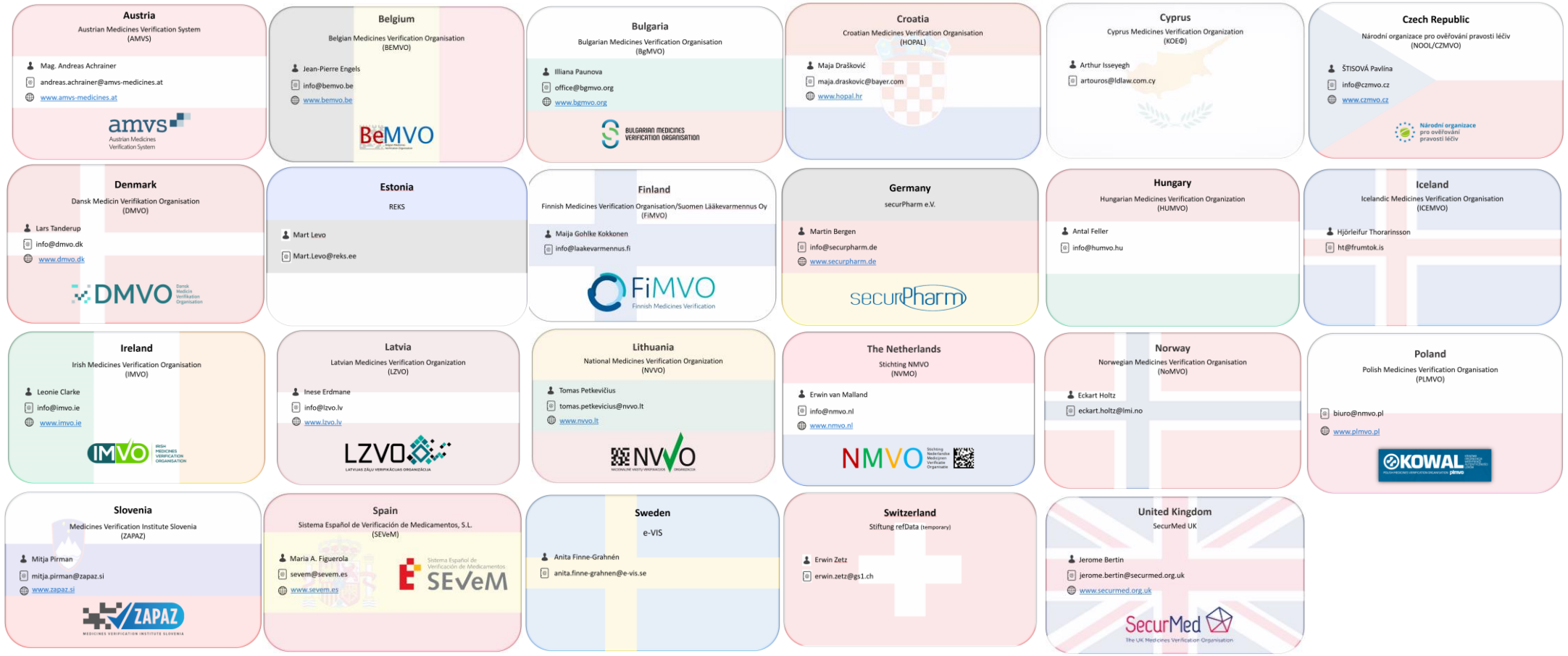



NN



Head of CPM	CPM Member	CPM Member	Legal Counsel	CPM Intern	CPM Intern	CPM Intern	Service Center

Status in other countries



Back-up

DMVO Dansk Medicin Verifikation Organisation

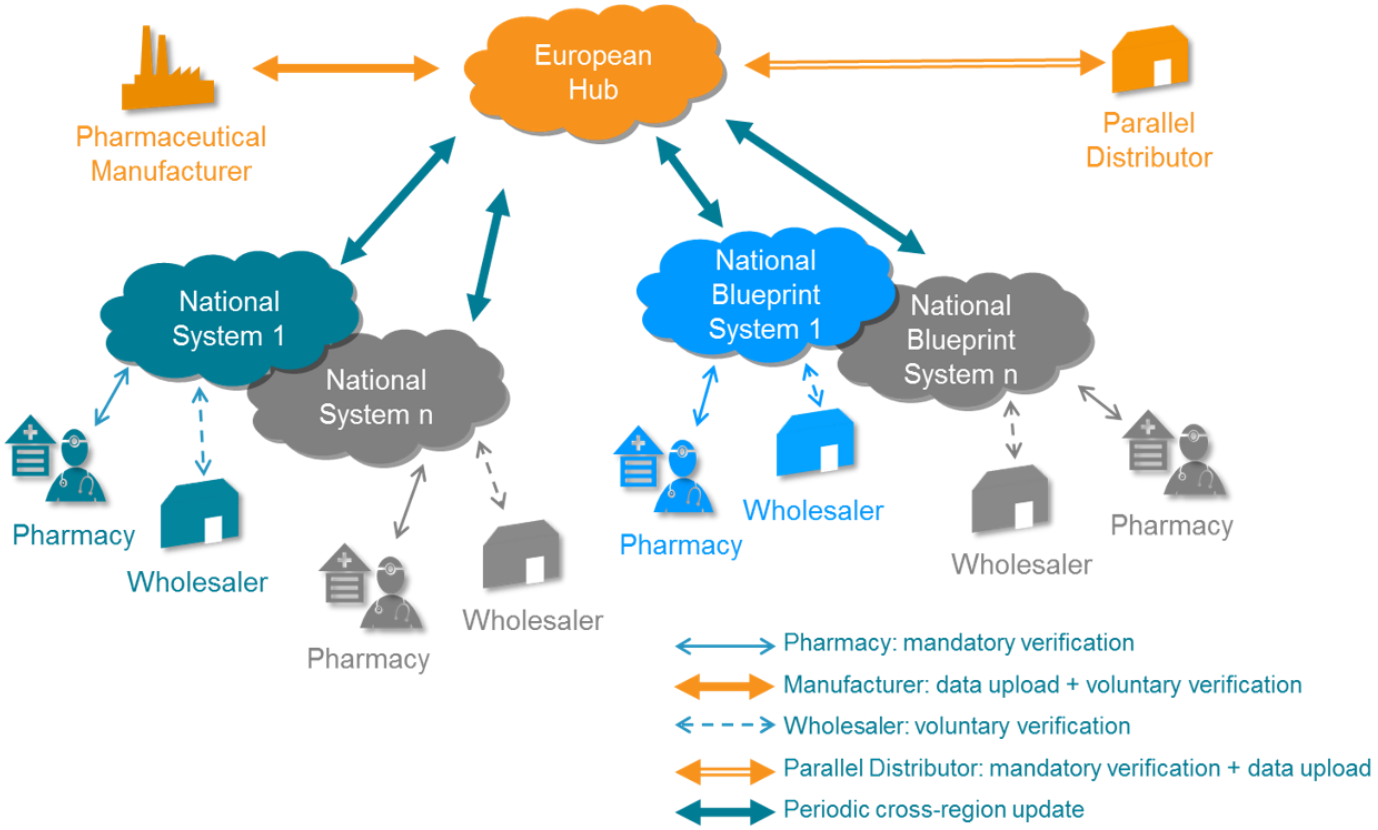
How far are we in the process of establishing the Danish Medicines Verification System, DMVS?

About the process regarding choice of IT supplier

Who has been involved from Denmark?

Who has been selected to be DMVS' supplier in Denmark?

The system shall be operational as of February 9, 2019!



DMVO Dansk Medicin Verifikation Organisation

Background and process of choice of IT supplier

- EMVO has selected three IT suppliers as so-called blueprint providers in advance. This included three suppliers with whom EMVO had negotiated a “mimimum contract”. The suppliers could guarantee that they were able to solve the task regarding implementation of the national data verification system.

- At the meeting with the stakeholder group on May 20, 2015 it was decided to set up an IT group. This group should participate in joint, Nordic workshops and later also hold national workshops.

- On the basis of these presentations the group agreed to sort out one of the suppliers and continue the negotiations with the remaining two suppliers.

- After this several, national workshop were held with both suppliers. At these workshops all Danish stakeholders participated and their business partners – among others, the pharmacies’ IT suppliers.

DMVO Dansk Medicin Verifikation Organisation

Background and process of choice of IT supplier

- After these workshops we entered into an agreement with expert IT lawyers with knowledge and experience in negotiating such contracts.

- The IT lawyers had, before the start of the negotiations, confidential meetings with all stakeholders, so crucial elements for the individual stakeholder were made clear for the lawyers. After this, a negotiating group was set up with two IT lawyers and the Manager of DLI MI Martin Jordt Andersen.

- After this parallel negotiation procedures were commenced with the two suppliers.

- After a long negotiating process with the two suppliers, a visit was arranged at both suppliers' headquarters in the beginning of 2016. Here all Danish stakeholders had the opportunity to meet the employees of the two suppliers' business partners' and get a better understanding of the two suppliers' approach and processes.

DMVO Dansk Medicin Verifikation Organisation

Board meeting on January 24, 2017

- Review of the entire process regarding choice of IT supporter from set up of an IT working group with participants from all stakeholders to a process with workshops for all stakeholders and IT suppliers and finally a long and thorough negotiating process.

- The Board agreed that the work and choice of IT supplier had been very thorough and the process in the IT group and the collaboration had been good. They also agreed that both IT suppliers would be able to solve the task satisfactorily.

- There was a clear majority among the stakeholder group's IT group representatives for selecting Solidsoft Reply as supplier of the Danish solution. After a short discussion all members of the Board agreed to support the recommendation in the agenda about entering into a contract with Solidsoft Reply.

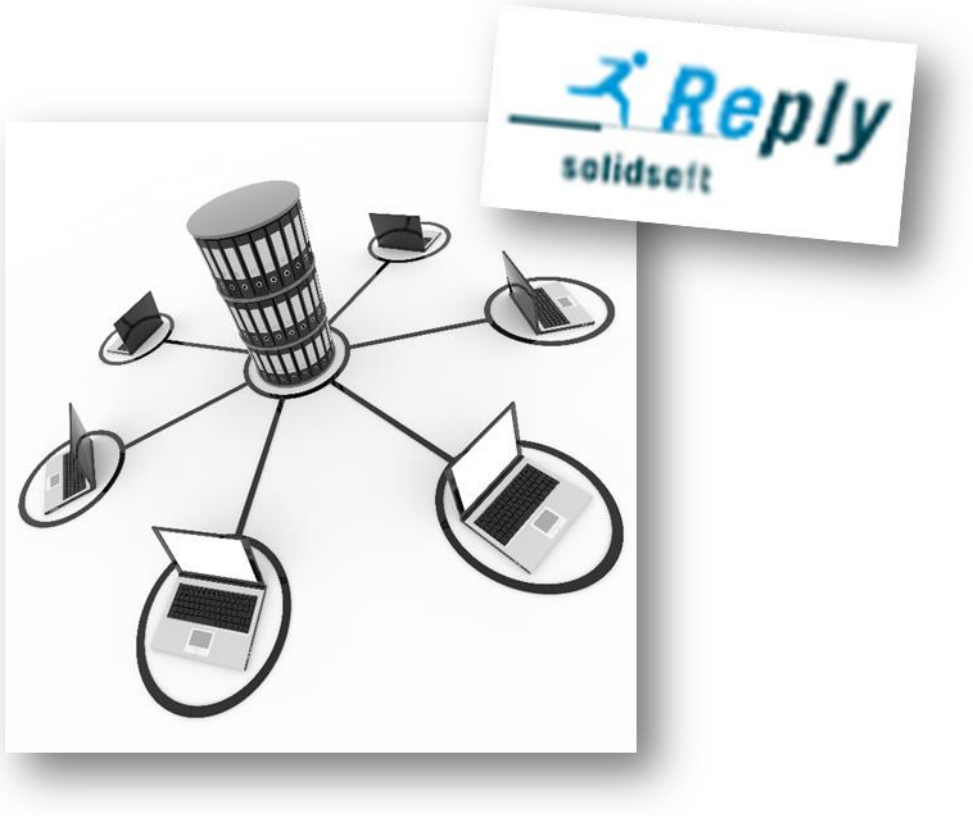
Criteria for assessing IT suppliers

1. General Business - legal, business capabilities, reputation, contractual risk
2. Business Model and Technology
3. Technical Capabilities - team, quality, response time, dataprotection fulfill directive, MVO, and Articles of the MVO
4. EMVO blueprint approach
5. Project Management - roles and responsibilities, Change request, end to end understanding
6. Functional Capabilities - documentations, other functional evaluation
7. Implementation propability
8. Support Business Processes of the MVO
9. Collaboration with IT supplier
10. Price

DMVO Dansk Medicin Verifikation Organisation

Establishment of Danish Medicines Verification System - DMVS

- DMVO's secretariat is in close collaboration with Solidsoft working to establish the Danish database.
- An IT project coordinator has been employed in DMVO's secretariat. She takes care of (the daily) dialogue and collaboration with Solidsoft. Weekly skype meetings are held.
- This work is primarily of crucial importance for especially wholesalers and (hospital) pharmacies.



DMVO Dansk Medicin Verifikation Organisation

Working groups under the DMVO auspices – joint meetings / workshops at present

- IT working group:

- The ”old” IT stakeholder group continues in a new role and will, among other things:

- Discuss the problems and suggest input on a more overall level in the implementation phase.

- Act as a sparring partner in general in relation to the work that DMVO’s secretariat shall perform together with Solidsoft Reply in connection with the implementation of the Danish database.

- Holding of workshops with Solidsoft Reply.

- ”New” working group:

- Seek to coordinate the processes in the entire supply chain in the period until February 9, 2019. This will include, among other things, that the working group shall:

- ensure that no bottlenecks / supply problems occur in the transition period until 2019 on the basis of the ongoing implementation work in the supply chain, including proposals for possible transition solutions.

- Suggest possible input to DMVO about contact to authorities regarding possible, specific problems.

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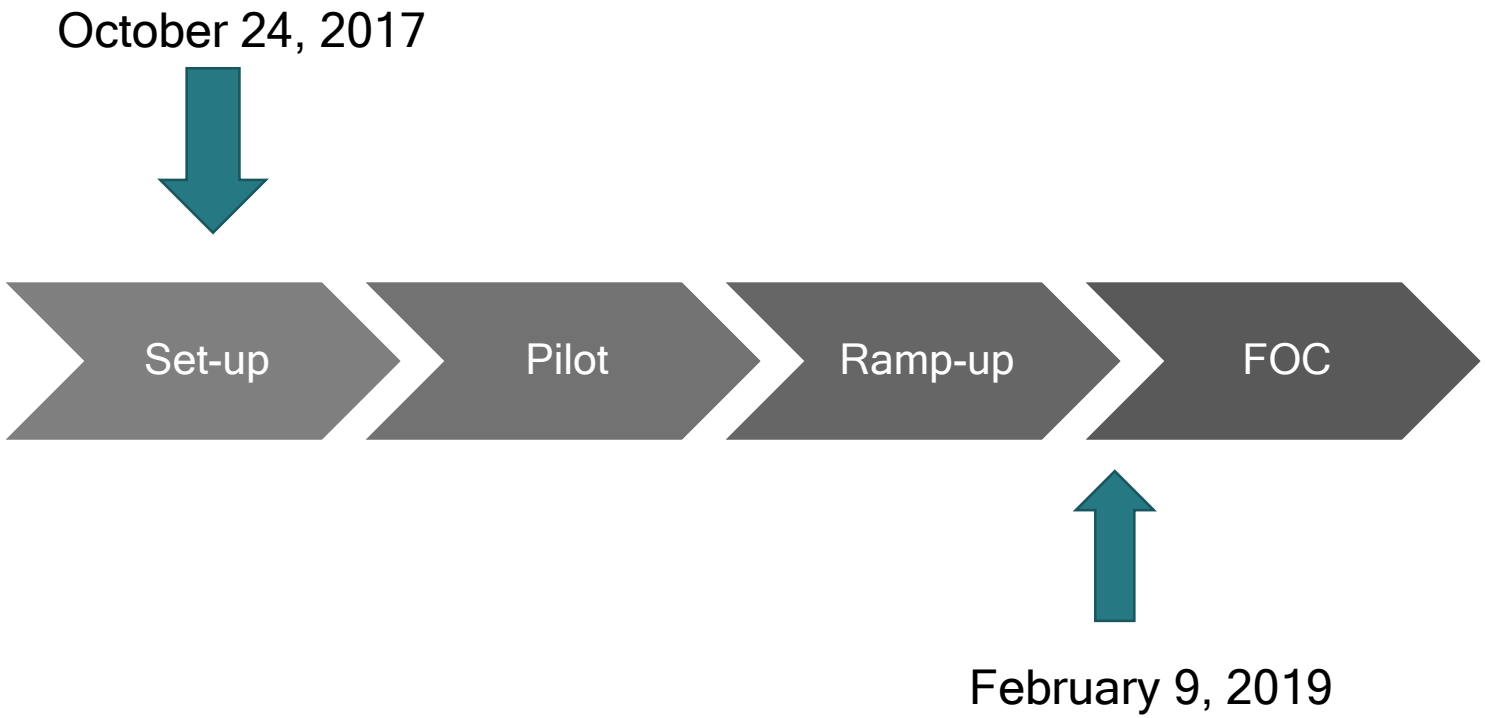
The implementation phase has four phases



DMVO Dansk Medicin Verifikation Organisation

The Set-up phase – now!

Phase: System Set-up	Start: May 2017	End: No later than end February 2018
Scope: Solidsoft Reply will work collaboratively with the Danish MVO to prepare for the Pilot stage of the project. Solidsoft Reply will also instantiate the technical system during this period.		
Entry Criteria	• Contract signed	
Exit Criteria	• NBS Production System deployed • NBS Production System accepted • NBS ready for Pilot Participants	
Major Activities and Milestones	• Stakeholder Communication Meeting • IT Supplier Workshop • ITE deployed • IQE deployed • Pilot participants agreed and on-boarded • Pharmacy and Wholesaler systems upgraded	

DMVO Dansk Medicin Verifikation Organisation

The Pilot phase of the project – which is a fully functional system (not a test) – starts March 2018

Phase: Operating Pilot	Start: No later than start March 2018	End: Expected August 2018
Scope: The Pilot phase of the project is a fully functional system using live data, but with a limited number of participants. The purpose of the pilot phase is to ensure that the Danish MVO and Solidsoft Reply are operating effectively in readiness for the ramp-up		
Entry Criteria	• System Set-up phase complete	
Exit Criteria	• No valid major claims against NBS • Either DMVO state the Pilot Phase is complete; Or 60 working days after full functionality has been deployed, whichever occurs first	
Major Activities and Milestones	• Live packs in the supply chain • Start scanning live packs and interacting with the European Hub • Testing of revised Pharmacy and Wholesaler SOPs	

DMVO Dansk Medicin Verifikation Organisation

The purpose of the pilot project:

- Through a controlled process to implement a limited number of typical user organisation to ensure that everything is working as designed and tested. The pilot project includes verification of the implementation process for end-user applications, the end-user's standard working procedures, support channels etc.
- The participants in the pilot project act in production as the first users.
- It is very important that all parties involved take action against possible challenges in order to assess, plan and make possible, necessary changes.
- Just before the closing of the pilot project all parties involved report their results, and on the basis of achieved experiences it will be assessed if something needs to be changed prior to the "Ramp-up" phase.
- The participants in the pilot project will be divided into smaller groups comprised of 1 pharmacy, 1 wholesaler and 1 manufacturer.

DMVO Dansk Medicin Verifikation Organisation

Purpose of the pilot project - continued

- New date - March 1, 2018
- Registered participants in the pilot project
  - Wholesalers – TMJ and Nomeco – timetables are received
  - The pharmacies' IT suppliers – Cito IT
  - Hospital pharmacies -
  - Manufacturers / parallel importers - Orifarm, Roche A/S, Sandoz and Bayer (April 2018)
- Workshop 2 for participants in the pilot project – by the end of November 2017
  - Requirements specification & timetable

DMVO Dansk Medicin Verifikation Organisation

Ramp-up - scale

Phase: Operating Ramp-up	**Start: Expected August 2018**	**End: No later than 8th February 2019**
Scope: Following a successful Pilot, the operational system will then be used to on-board the remaining pharmacies, wholesalers in parallel with the Manufacturers and Parallel Distributers		
Entry Criteria	• Operating Pilot phase complete	
Exit Criteria	• Either all stakeholders on-boarded to NBS; Or 8th February 2019, whichever occurs first	
Major Activities and Milestones	• On-boarding of remaining pharmacies to the NBS • On-boarding of remaining wholesalers to the NBS • On-boarding of remaining manufacturers and wholesalers to the European Hub • Increasing pack data flowing through the system	
Phase: Full Operating Capacity	Start: Feb-19	End: Until end of service
Scope: Starting in February 2019 the operational system will be run at Full Operating Capacity (FOC)		

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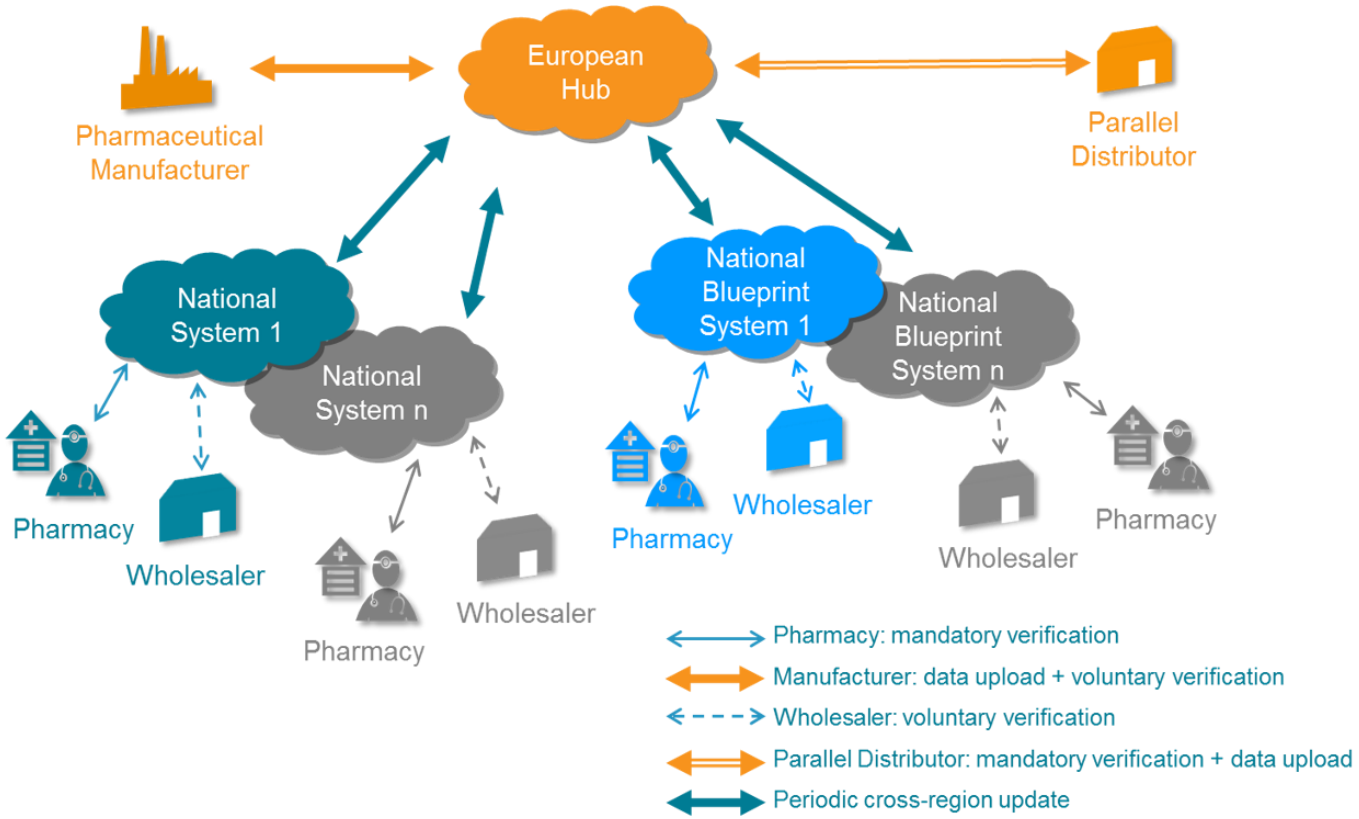
Completion



DMVO Dansk Medicin Verifikation Organisation

DMVO
Dansk
Medicin
Verifikation
Organisation

DMVO

The Danish contract and payment model

Financing model, Denmark

Around Europe different financing models are chosen.

For some countries it is a challenge to finance the Ramp Up phase.

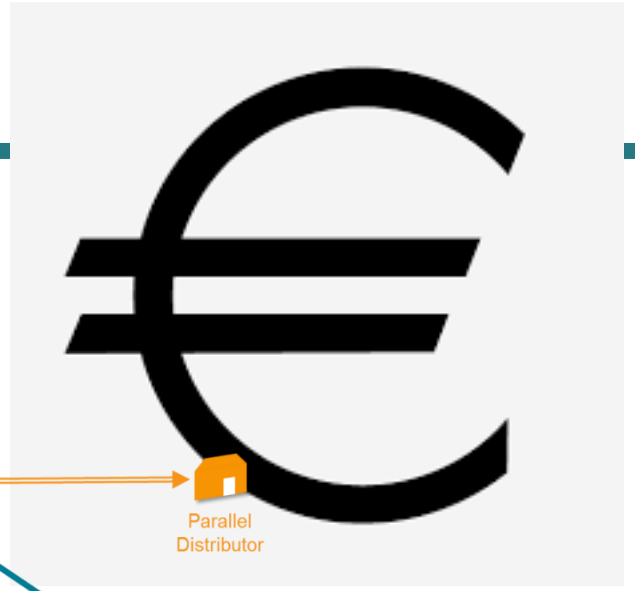
Denmark has chosen a model where no companies shall pay before the system is fully operational. The lender (DLI) will get its loan back when the directive enters into force in the beginning of 2019.

DMVO Dansk Medicin Verifikation Organisation

Who shall pay – What does the legislation say?

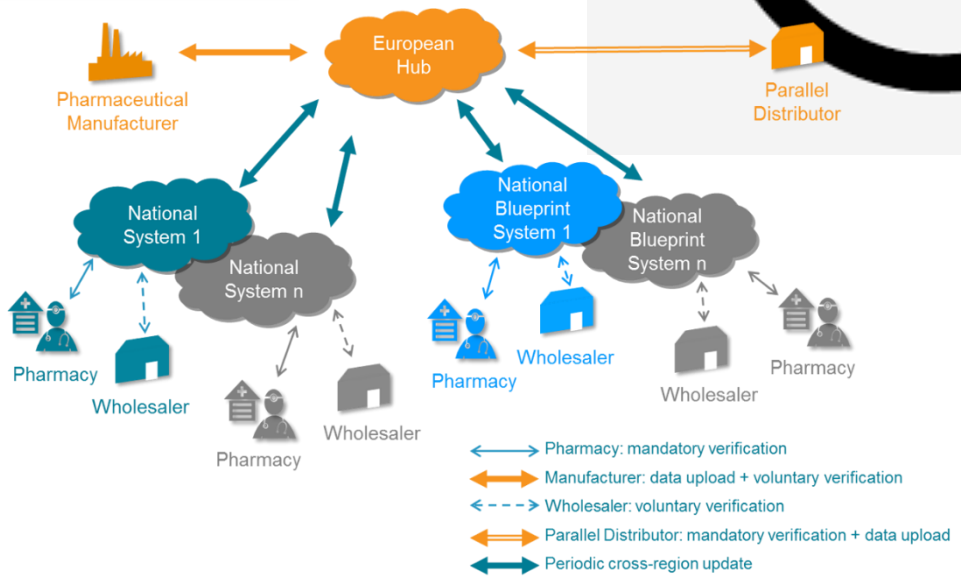
The Danish Medicines Act:

§ 59 b. Fremstillere af lægemidler og indehavere af markedsføringstilladelser til lægemidler, der er forsynet med sikkerhedselementer, skal oprette, forvalte og tilgængeliggøre datalagre i et samlet datalagringssystem i overensstem-



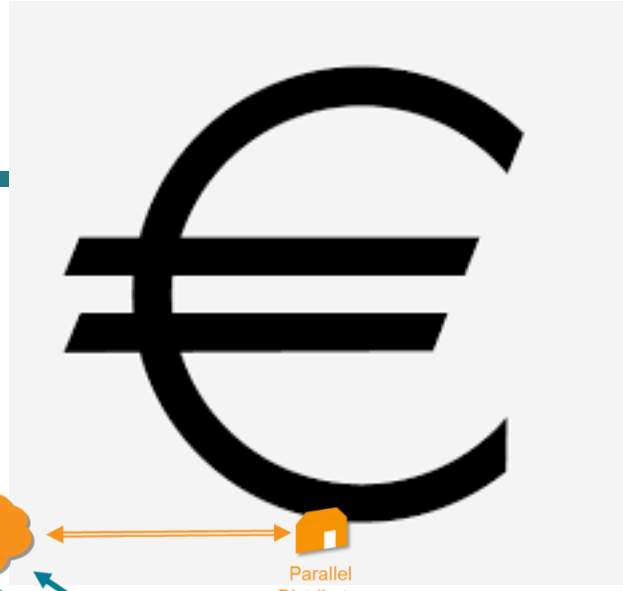
FMD/DR: ”The costs for the data storage system are paid by the manufacturer of pharmaceuticals that are provided with the safety features, c.f. article 54a, section 2, litra e) in directive 2001/83/EU”.

If you would like to introduce your product on the Danish market as of February 9, 2019, you have to pay an annual verification fee as of 2019 per MAHs (holder of one or several marketing authorizations).



DMVO Dansk Medicin Verifikation Organisation

Who shall pay and how much?

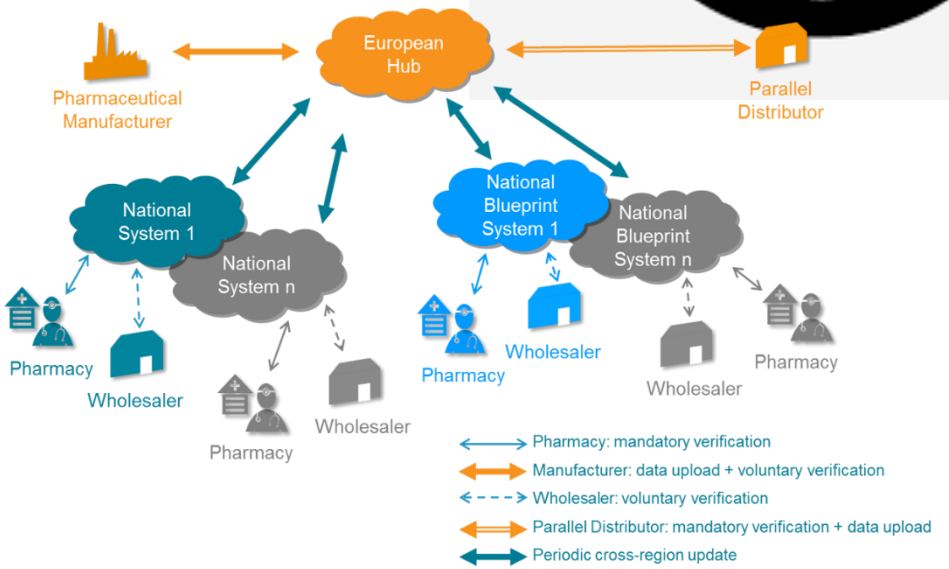


The rules:

> **§ 59 b.** Fremstillere af lægemidler og indehavere af markedsføringstilladelser til lægemidler, der er forsynet med sikkerhedselementer, skal oprette, forvalte og tilgængeliggøre datalagre i et samlet datalagringssystem i overensstem-

The Board has at it's meeting on April 20, 2017 decided that the one-off registration fee via a discount scheme is made progressive – the earlier entering into the contract with DMVO the least expensive.

The Board decided that the further fact-finding mission regarding the number of MAH's and determination of fees as far as possible shall take place in close dialogue with the Danish Medicines Agency.



DMVO Dansk Medicin Verifikation Organisation

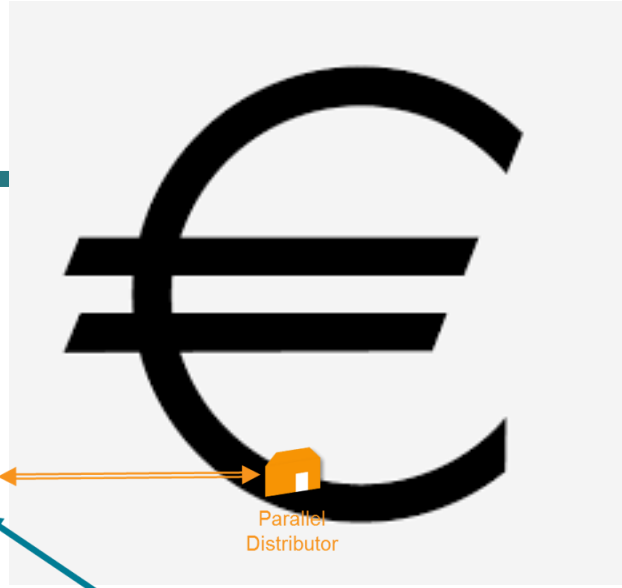
Who shall pay and how much?

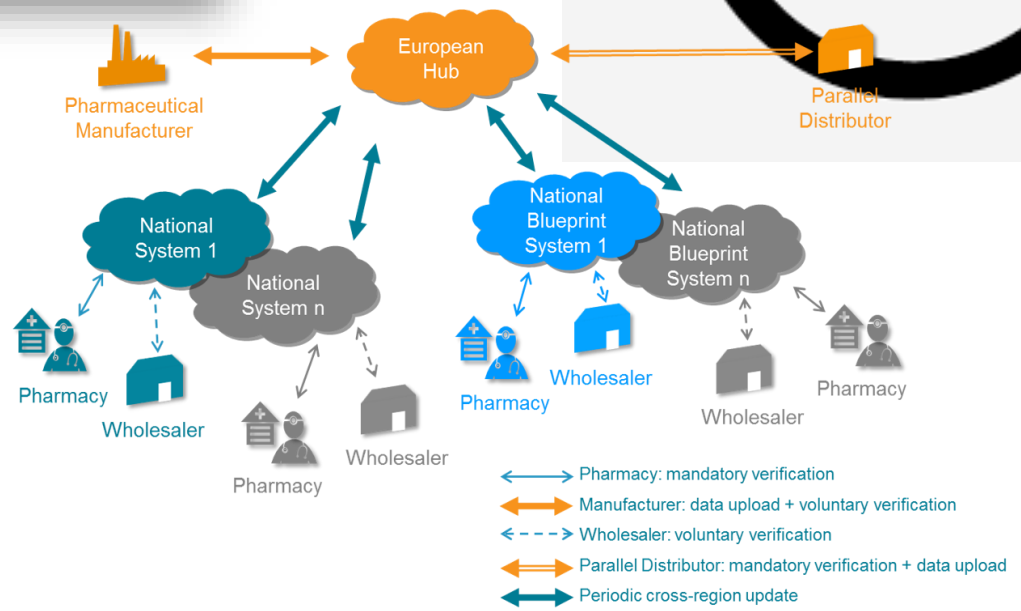
The rules:

§ 59 b. Fremstillere af lægemidler og indehavere af markedsføringstilladelser til lægemidler, der er forsynet med sikkerhedselementer, skal oprette, forvalte og tilgængeliggøre datalagre i et samlet datalagringssystem i overensstem-

The Board has decided that a one-off registration fee and an annual fee shall be paid for the first time in 2019.

It has been decided that a one-off registration fee and an annual fee for 2019 shall fall due in 2019, and that we in Denmark take our starting point in the model that is chosen on an European level, e.g. a flat fee structure.





DMVO Dansk Medicin Verifikation Organisation

Basis for pricing of fees

In June 2017, the Danish Medicines Agency and DMVO jointly forwarded a letter to a consolidated gross list of possible MAH's.

In September 2017, a reminder was forwarded to the MAHs from whom we have received no response.

230 MAHs are for now registered with their contact details and will receive the contract directly.

DMVO Dansk Medicin Verifikation Organisation

Contract formulation

Preparing the contract DMVO has been inspired by the Belgian and Finnish MAH contract.

An IT lawyer has been responsible for the formulation and the legal content.

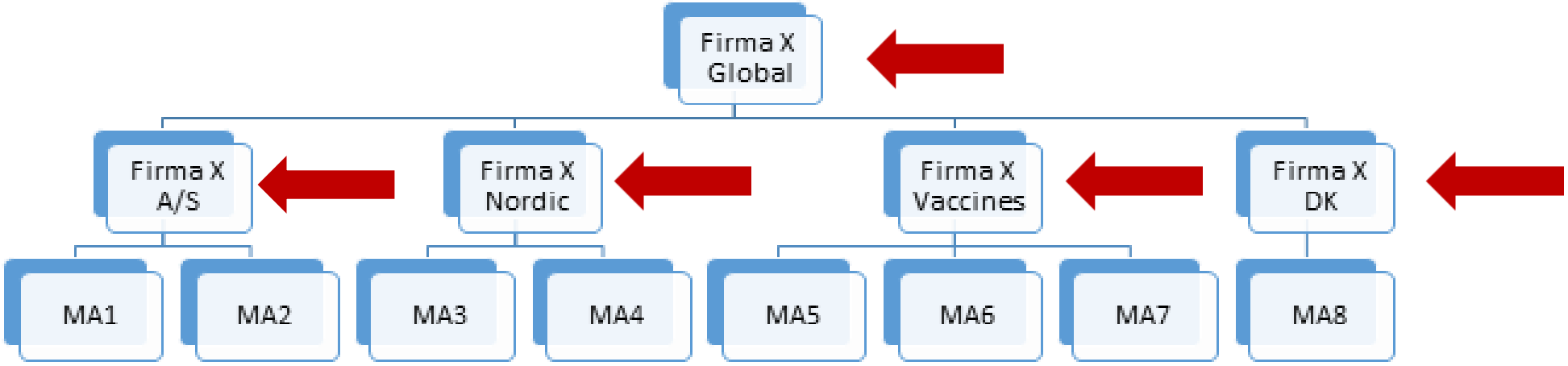
A smaller review group has had the opportunity to review and comment on the contract. Submitted comments have been incorporated.

The members of the DMVO Board from the paying parties have approved the main content and principles in the contract and payment model that we present today.

DMVO Dansk Medicin Verifikation Organisation

The contract – with whom will we enter into the contract?

The formulation of the contract enables a parent company (Company) to enter into the contract on behalf of several MAHs and one MAH can enter into the contract directly with DMVO. Each MAH has to pay no matter the contract includes one or several MAH's.



DMVO Dansk Medicin Verifikation Organisation

Progressive one-off registration fee

A decision supported by the Board has been made regarding a progressive one-off registration fee.

Payment of the one-off registration fee falls due no later than January 31st. 2019.

After February 9, 2019 new MAH's also have to pay a one-off registration fee.

One-off registration fee (Component A)					
	Registration Deadline	Payment Deadline	FEE (VAT excl) per MAH	Discount	Amount to pay (VAT excl)
Check the box of your choice					
☐ Wave 1	Contract signing from 01-November-2017 to 31-March-2018	31-Jan-2019	€20 000,00	50%	€10 000,00
☐ Wave 2	Contract signing from 01-April-2018 to 30-September-2018	31-Jan-2019	€20 000,00	25%	€15 000,00
☐ Wave 3	Contracts signing from 01-October-2018 to 31-December-2018	31-Jan-2019	€20 000,00	0%	€20 000,00
Existing MAHs registering later than 31. December 2018 may have to pay an extra administration fee.					

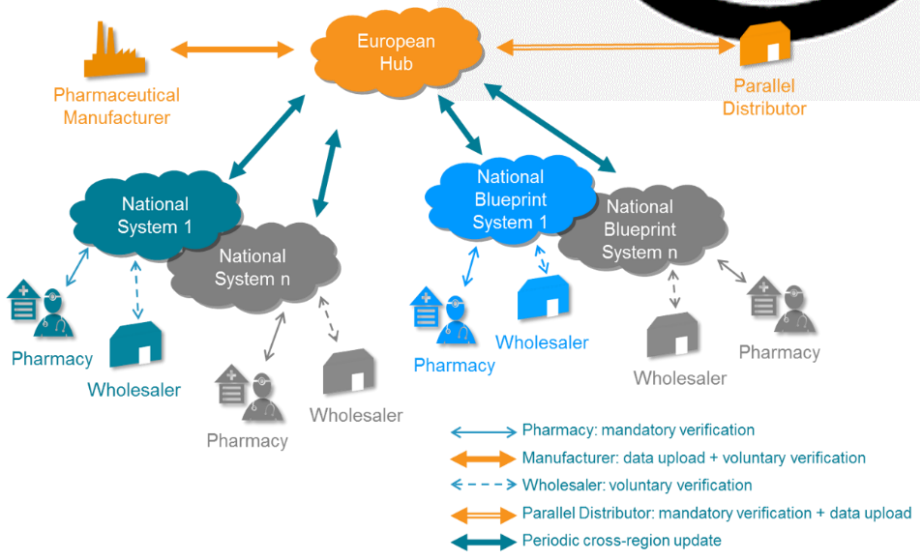
DMVO Dansk Medicin Verifikation Organisation

What about the annual verification fee?

The annual verification fee is adopted by the Board in November 2018 and takes into account the number of MAHs.

The annual verification fee is calculated per MAH and is based on overheads by running DMVO and the related medicines verification system and comprise a flat fee (same fee for all) corresponding to the European model.

The annual verification fee will for the first time be payable no later than March 1st. 2019. Subsequently on January 15 each year.



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MAH's in Denmark

- The Danish Medicines Agency estimates
  - 750 MAHs in the system – approximately 8% doublets shall be sorted out
  - 420 are active - approximately 8 % doublets shall be sorted out

- About 230 representatives with a turnover in Denmark
- The representatives have jointly 288 active MAH's at present.
- All MAH's shall on-board before February 9, 2019 in order to be able to sell prescription medicines in the future.
- A little incentive has been incorporated into the model, so the earlier the least expensive

- DMWO has compared with the medicinal product statistics
  - 35 MAH's are not registered by the Danish Medicines Agency, but are selling their products in Denmark
  - 2500 drug IDs are lacking (PI, hospital own production, SSI etc.)
  - 751 MAH's have Rx drug IDs which fulfill the conditions for verification
  - 288 MAH's have had Rx sale in 2015-2017
  - In practice a little lower number of MAH's in 2019 are expected.

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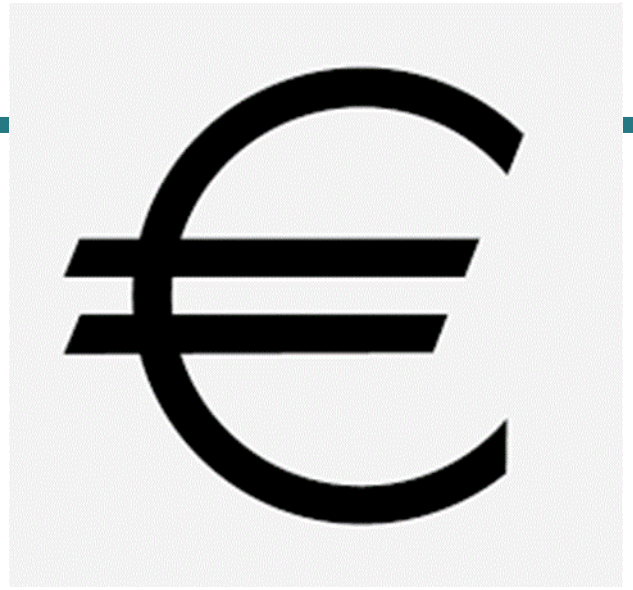
Example of annual fee with 230 MAH's



The basis is 230 MAH's, annual fee about DKK 41,000 per MAH

- Large generics – 9 MAH's, 9.5 million packages, 325 brands, turnover of DKK 670m
  - Annual price approx. DKK 369,000
- Large original, 5 MAH's, 5.5 million packages, 98 brands, turnover of DKK 340m
  - Annual price approx. DKK 205,000
- Small original, 1 MAH, 2200 packages, 5 brands, turnover of DKK 1.2m
  - Annual price approx. DKK 41,000

- If this set-up gives a surplus/ deficit, it will be charged / returned by the annual fee in the future.
- There is no incentive to wait until after 2019 – you will have to pay for on-boarding and index regulation for all new MAH's.

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The process from here

During November 2017 the contract will be forwarded directly to all MAH's who have been registered at DMVO no later than October 31, 2017.

In connection with the contract it will be specified how to sign and return the contract.

DMVO is for now looking into the opportunities for electronic signature and return of the contract. Information will follow with the forwarding of the contract.

If you have any further questions, please do not hesitate to contact DMVO.

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Back-up

What is the definition of a MAH

MAH (the holder of the marketing authorization) is the company that is the holder of the issued marketing authorization for a medicinal product.

It will often be the company that have applied for and have an approved marketing authorization, but the marketing authorization can be handed over to another company after the approval is issued.

The holder of the marketing authorization is responsible for the marketing of the medicinal product.

The appointment of a representative does not exempt the holder of the marketing authorization for his/hers legal responsibility.

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