Program for informationsmødet for MAH'ere hos DMVO 24. oktober kl. 14.00-17.00

1. **Velkomst og indledning**
   v. bestyrelsesformand i DMVO, koncernchef i Lif, Ida Sofie Jensen
2. **Patientsikkerhed – og myndighedernes forventninger til MAH'ere og DMVO i forbindelse med FMD og de nye regler sikkerhedselementer på lægemidlers emballage**
   v. teamleder i Lægemiddelstyrelsen, Jakob Lundsteen
3. **EMVO og onboarding af den europæiske database: EMVS ("hub'en")**
   v. Head of Commercial and Partner Management i EMVO'en, Tobias Beer
4. **Kaffepause**
5. **Hvor langt er vi med etablering af det danske verifikationssystem: DMVS?**
   v. formand for DMVO's it-følgegruppe, direktør i DLI MI, Martin Jordt Andersen
6. **DMVO – og den danske kontrakt- og betalingsmodel**
   v. formand for DMVO's arbejdsgruppe, senior projektleder i DMVO, Tina Hou Marer
7. **Afslutning og opsamling**
   v. sekretariatschef i DMVO, Lars Tanderup

DMVO Dansk Medicin Verifikation Organisation

DMVO
Dansk
Medicin
Verifikation
Organisation

Velkomst og indledning

V. Ida Sofie Jensen koncernchef i Lif og bestyrelsesformand i DMVO

Afsættet er kampen mod falske lægemidler

- EUs direktiv om falske lægemidler (2011/62/EU) stiller krav om, at alle receptpligtige lægemidler får sikkerhedsanordninger.
- Kræver opbygningen af fælleseuropæisk it-system med nationale/regionale baser.
- Særegen model: Forudsætter, at MAH og andre stakeholders bygger og driver systemet.

DMVO Dansk Medicin Verifikation Organisation

Det europæiske system

- På europæisk plan varetages arbejdet igennem European Stakeholder Model (ESM), hvor de vigtigste aktører blev samlet.

- Dannede baggrund for EMVO, som blev stiftet i februar 2015.

DMVO Dansk Medicin Verifikation Organisation

Forløb i Danmark

- I Danmark valgte man også den såkaldte ”stakeholdermodel”
- Stakeholdergruppen bestod til at starte med af:
  - Lif, Apotekerforeningen, MEGROS, Parallelimportørforeningen og Amgros
  - Senere kom IGL også med
- Udarbejdede siden *Memorundum of Understanding,* der dannede baggrund for det videre arbejde

DMVO Dansk Medicin Verifikation Organisation

DMVO ApS

- DMVO ApS blev formelt stiftet den 21. november 2016
- Med de 3 industri-brancheforeninger som aktionærer
- Alle 6 stakeholdere er medlemmer af bestyrelsen

igL Industriforeningen for Generiske og Biosimilære Lægemidler

MEGROS

PFL

LIF

AMGROS

Danmarks Apotekerforening

DMVO Dansk Medicin Verifikation Organisation

DMVO ApS

Det første bestyrelsesmøde blev afholdt i januar 2017.

Sekretariatet etableret i starten af 2017.

Arbejder på fuld tryk med at gøre os klar til februar 2019.

DMVO Dansk Medicin Verifikation Organisation

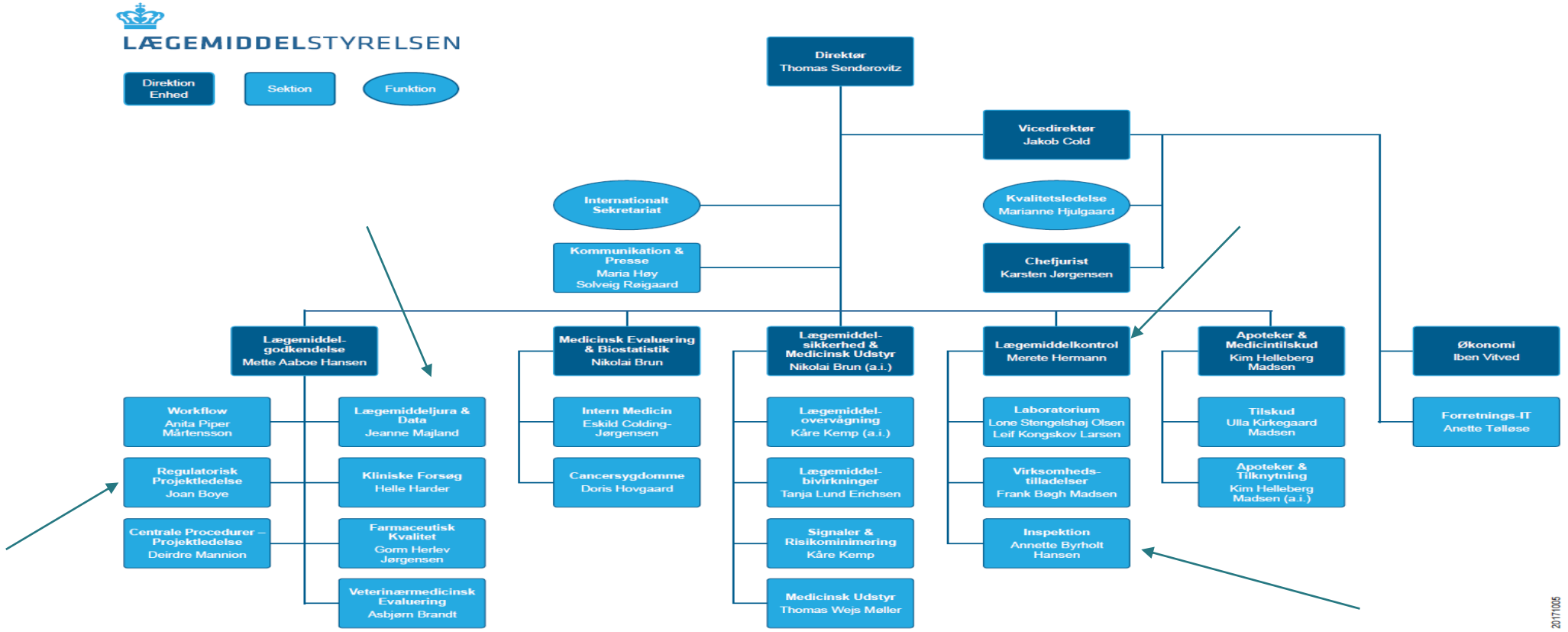
DMVO Dansk Medicin Verifikation Organisation

DMVO – Interessent den møde 24.oktober 2017

Status fra Lægemiddelstyrelsen

JAKOB LUNDSTEEN, TEAMLEDER, ENHED FOR LÆGEMIDDELGODKENDELSE

- Introduktion
- Organisatorisk placering
- Gennemførte regelændringer
- Planlagte regelændringer
- Samarbejdsfora og kilder til 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

Gennemførte og planlagte regelændringer

Lægemiddelloven

- § 59 a: krav om sikkerhedselementer
- § 14, stk. 2, nr. 4: "*ændre, suspendere eller tilbagekalde*"
- § 44, stk. 2, nr. 6: adgang til virksomheder, der opretter og forvalter datalagringssystemer
- § 104, stk. 1, nr. 1: strafbestemmelse ad § 59 a

Mærkningsbekendtgørelsen

- Sikkerhedselementer og undtagelse vedr. anbrudsanordninger

GDP-bekendtgørelsen

- Udlevering til tekniske formål og beredskabet

Samarbejdsfora og kilder til information

- Expert working group on Safety Features

- For nationale produkter – CMDh:

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

- For centrale produkter – EMA:

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

- Q/A på Lægemiddelstyrelsens hjemmeside

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

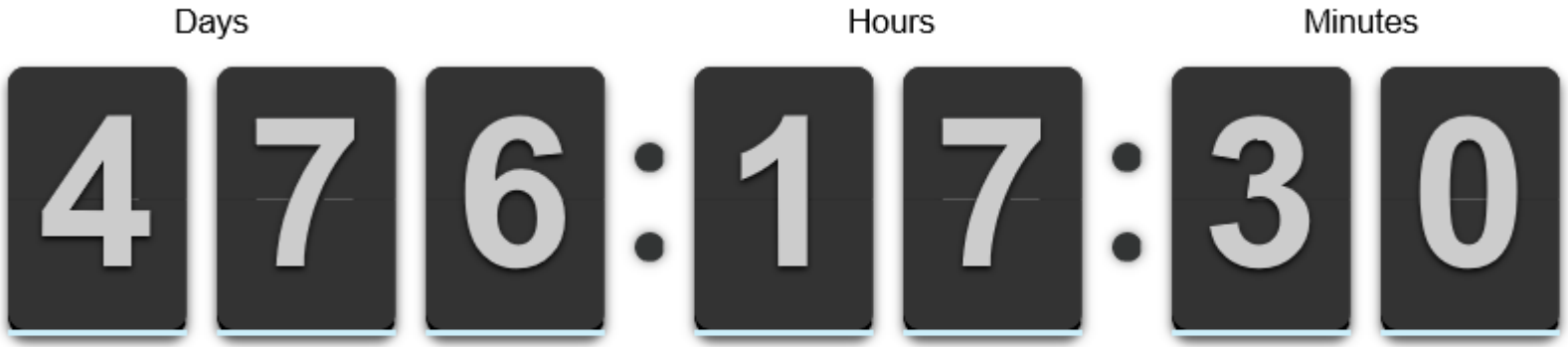
Følg os

EU Hub On-boarding:

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

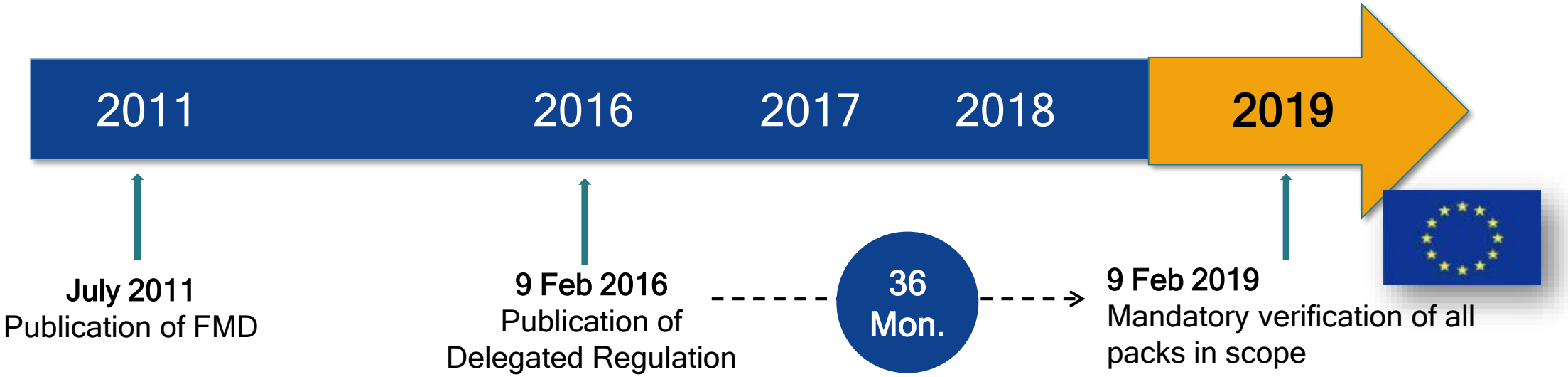
Tobias Beer
Head of Commercial & Partner Management Department
European Medicines Verification Organisation

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

Pharmacies

Wholesalers

Hospitals

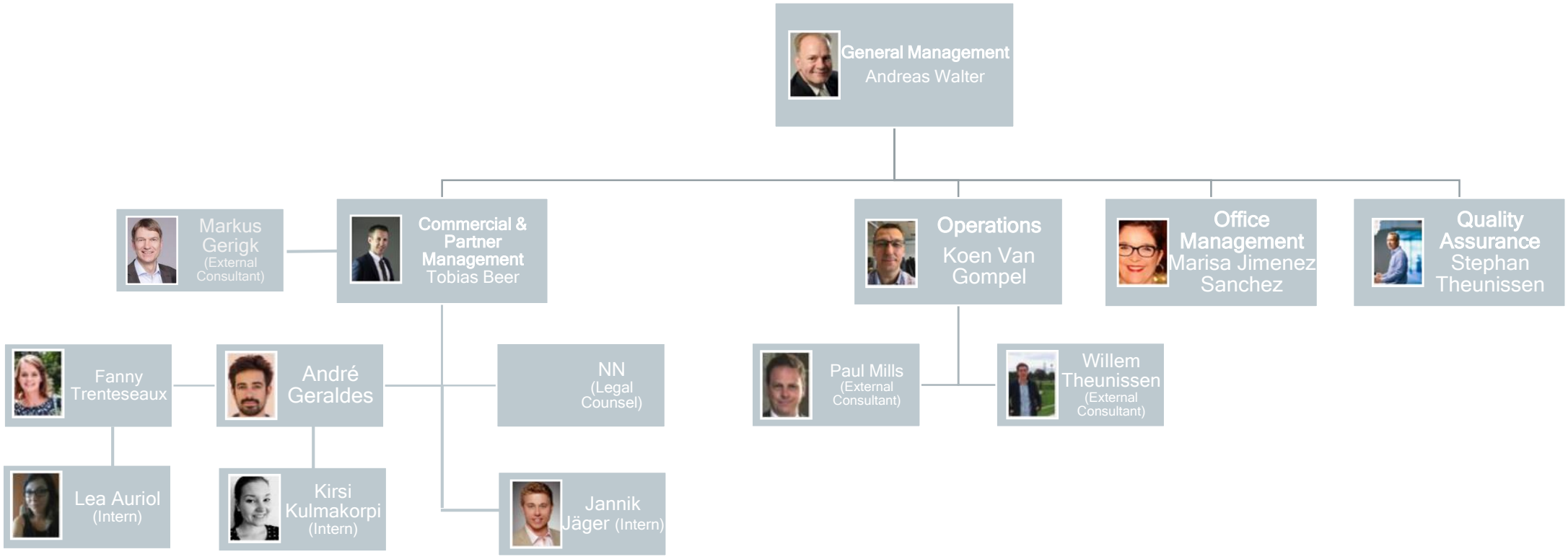
Parallel Distributors

Research Based Industry

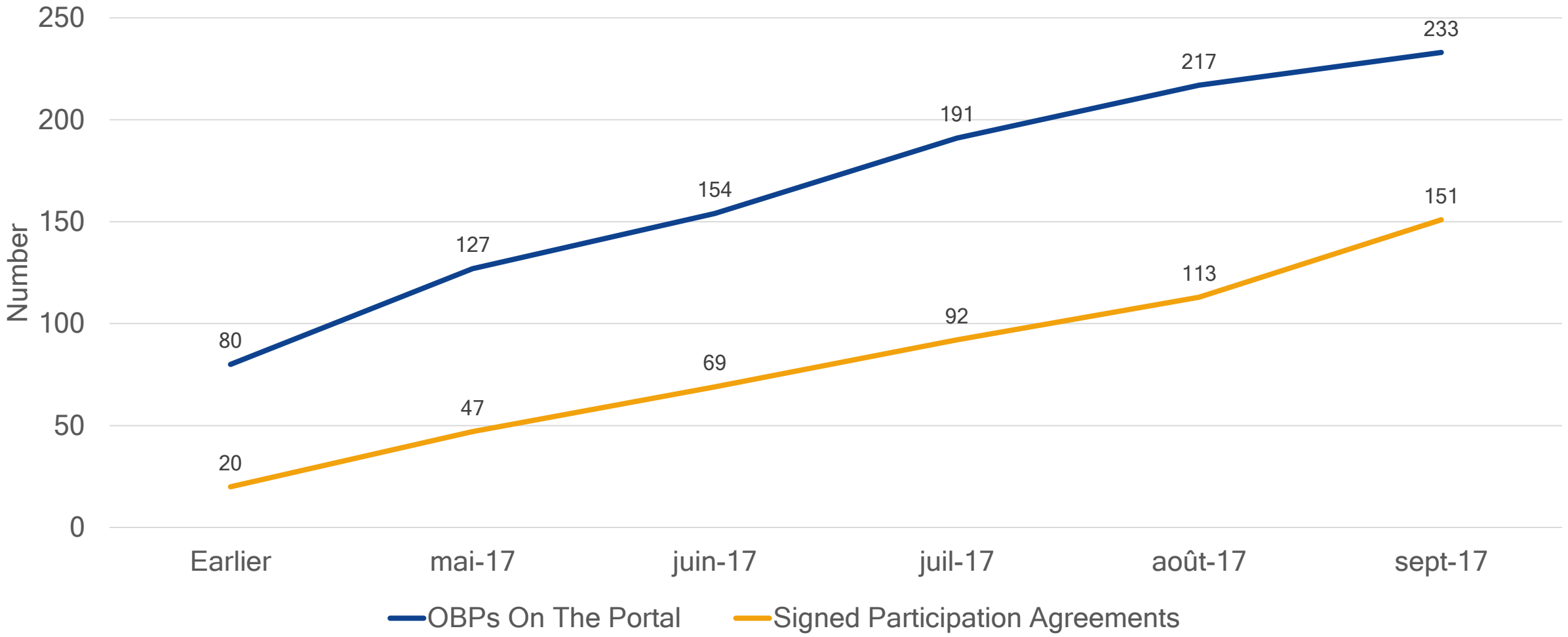
Generics Industry

organisational chart

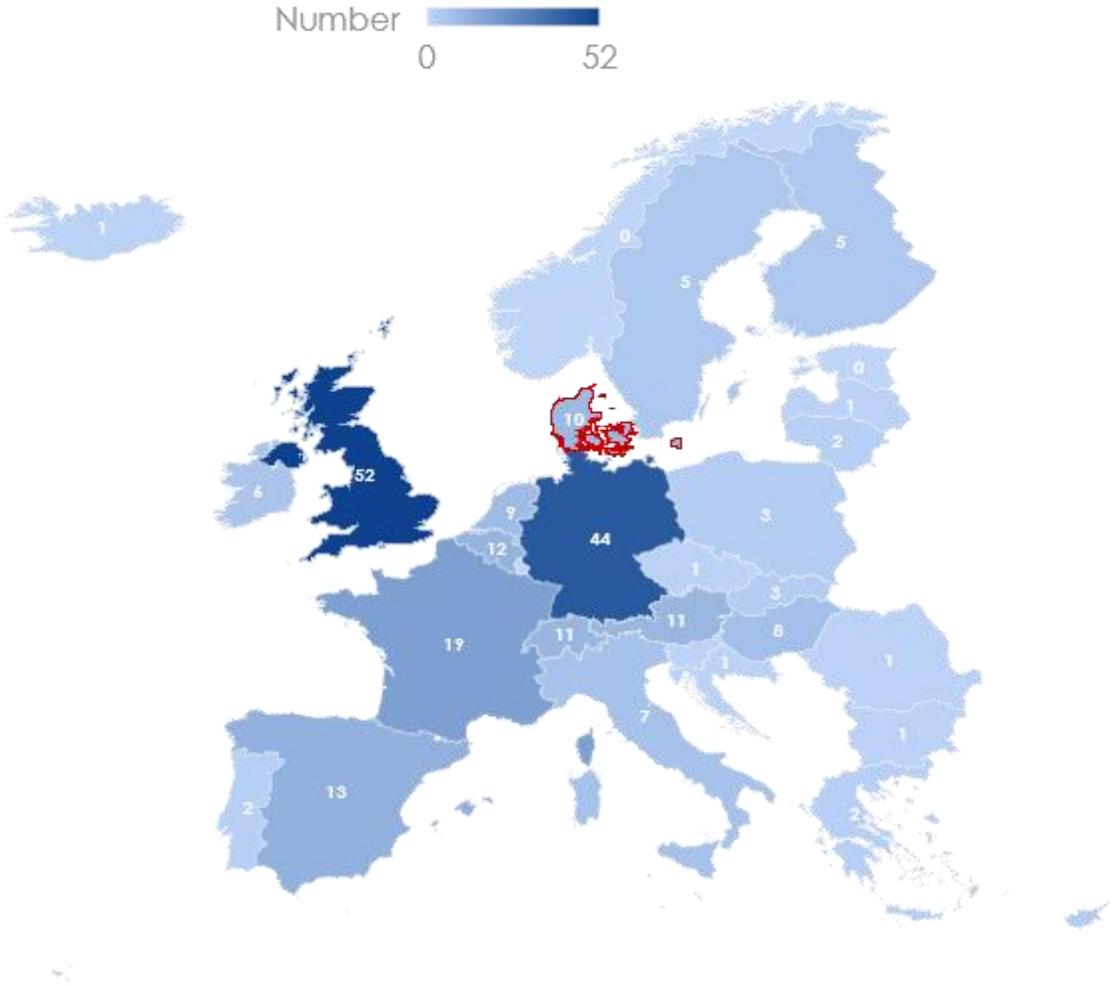
EMVO Board of Directors
President: Hugh Pullen (EFPIA)
Vice-President: Sonia Ruiz Morán (PGEU)
Treasurer: Richard Freudenberg (EAEPC)
Monika Derecque-Pois (GIRP)
Adrian van den Hoven (Medicines for Europe)

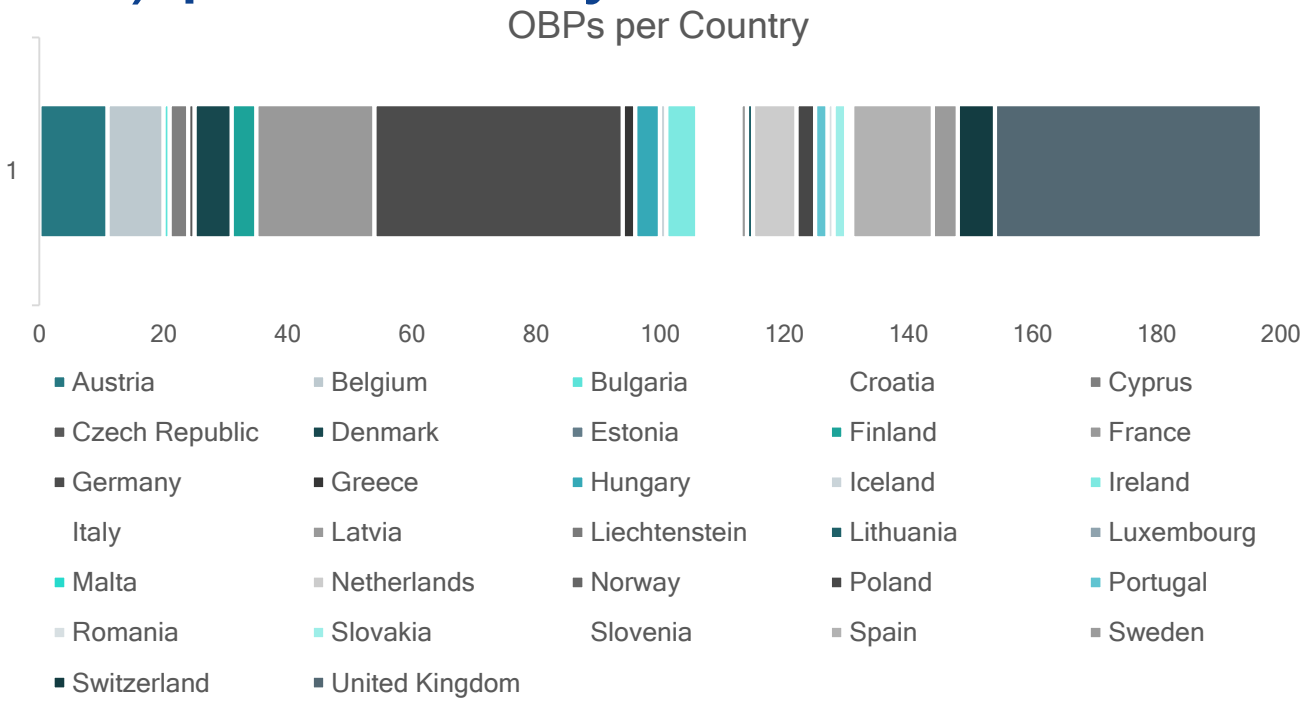


Status Contractual on-boarding



On-boarding Partner (OBP) per Country





Additional non-EU countries:

1 OBP

3 OBPs

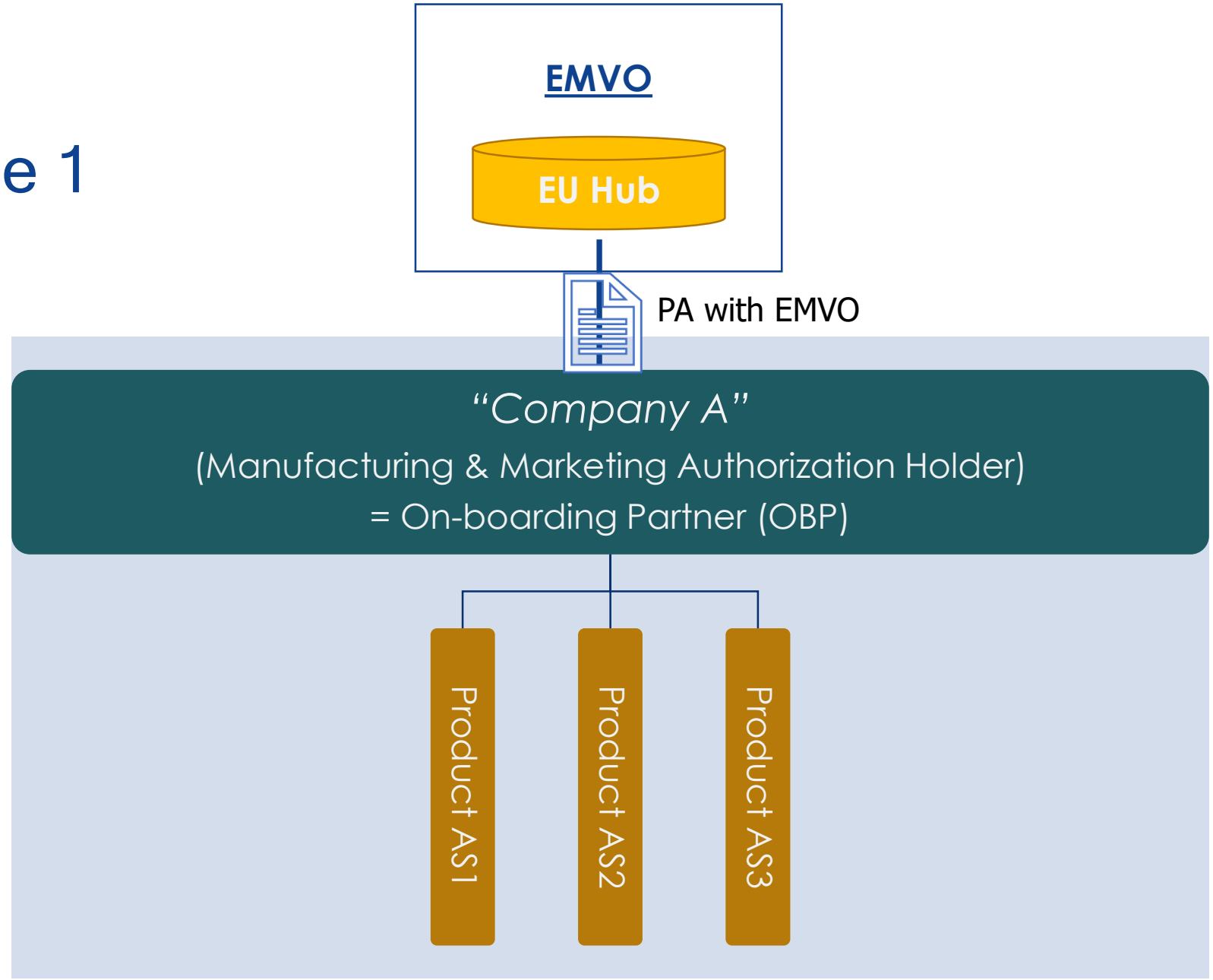
emvo European Medicines Verification Organisation

What is an “OBP”?

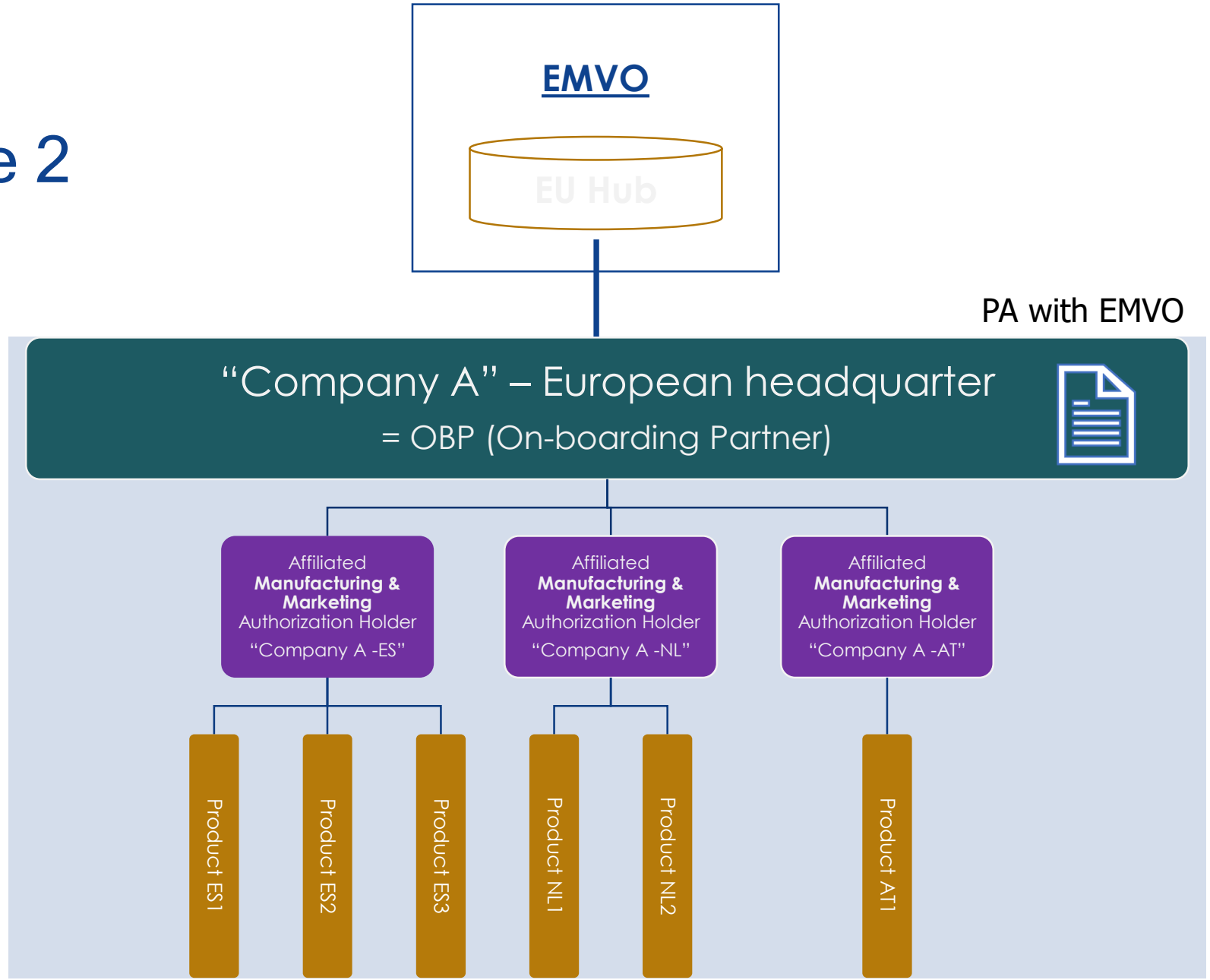
- OBP means **On-Boarding Partner**. The OBP is the contracting party of EMVO; it concludes the Participation Agreement (PA).
- The OBP **represents the Marketing Authorization Holders (MAH)** on behalf of which it will upload data for in the European Hub. It has therefore to be legally authorized to 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).

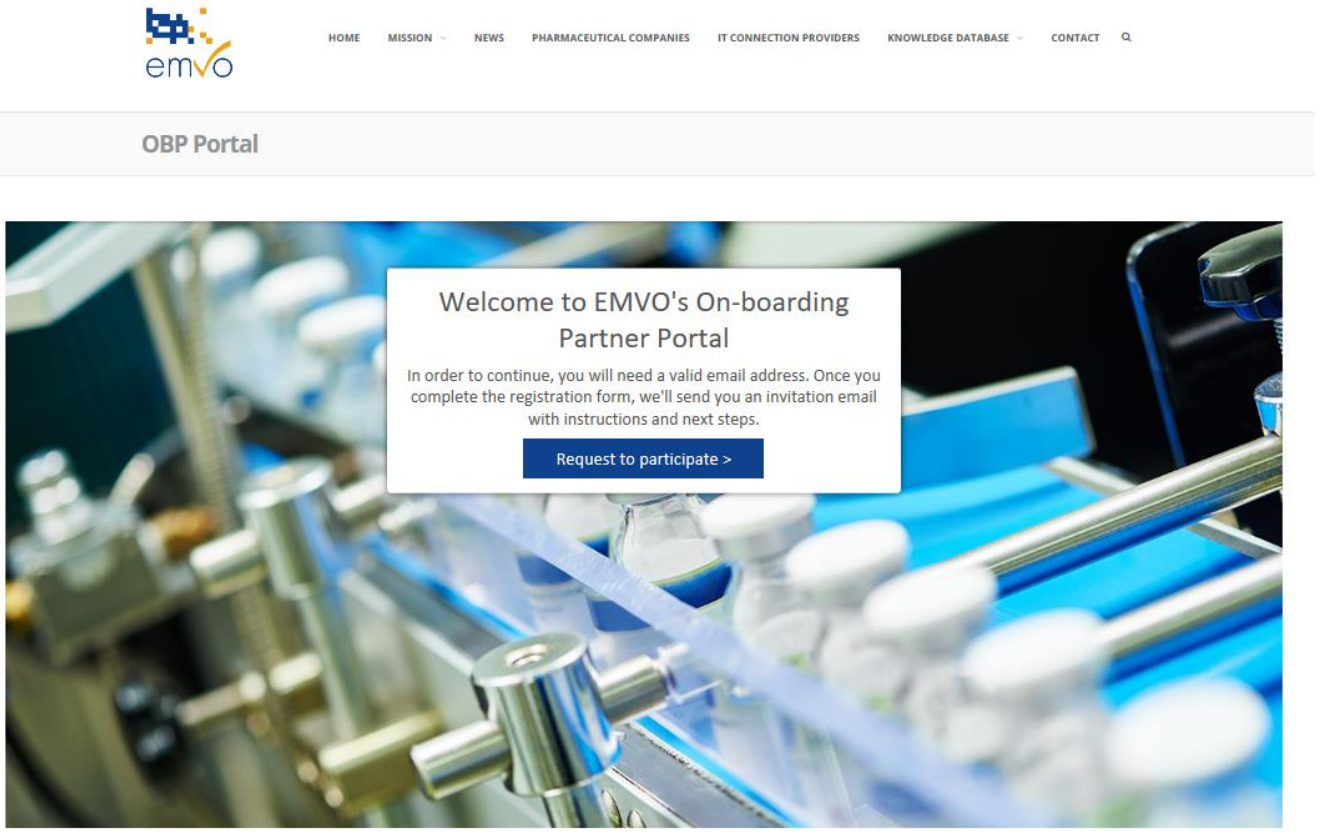
Example 1


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?

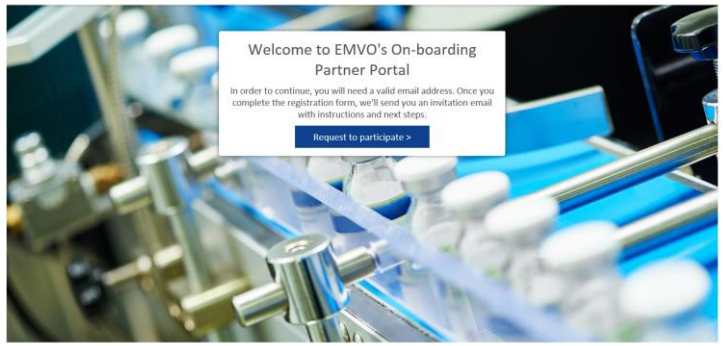


https://emvo-medicines.eu/home/obp/obp-portal/

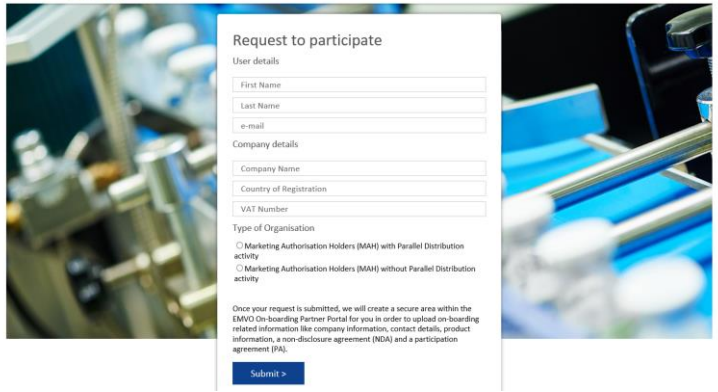
European Medicines Verification Organisation

How to request to participate

1. Via website - link

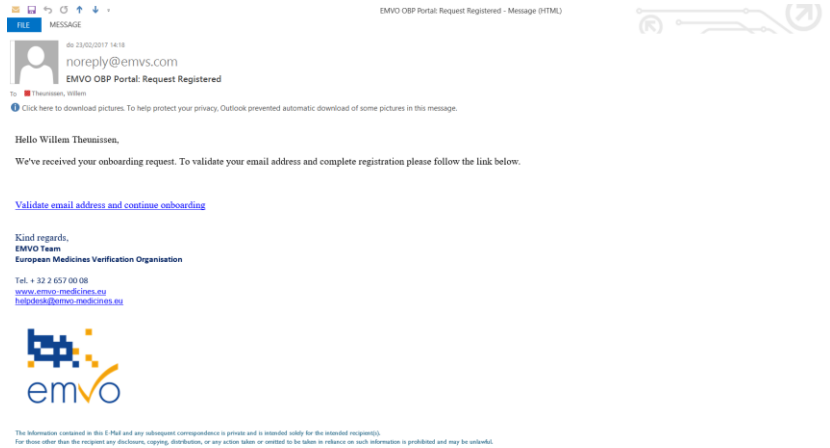


2. Fill in User + Company details



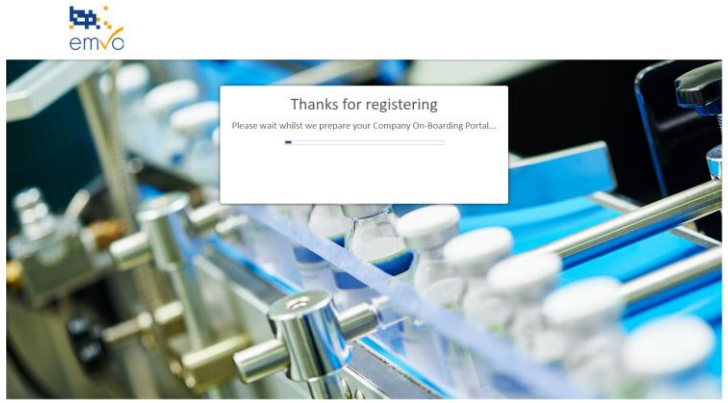
3. You'll be directed to the confirmation screen

4. Check your email to validate your account

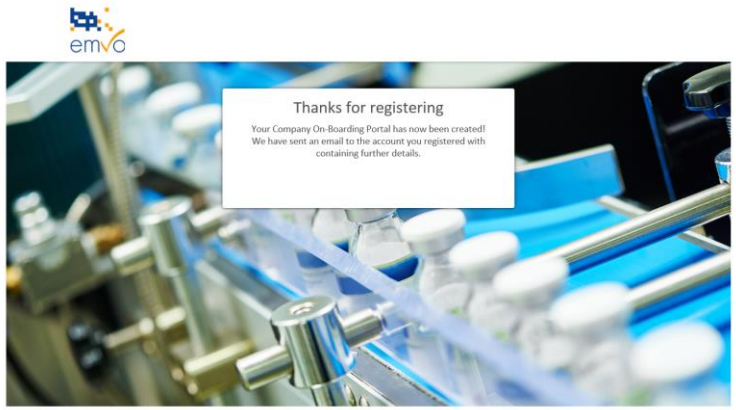


How to request to participate

5. Your company portal will be created

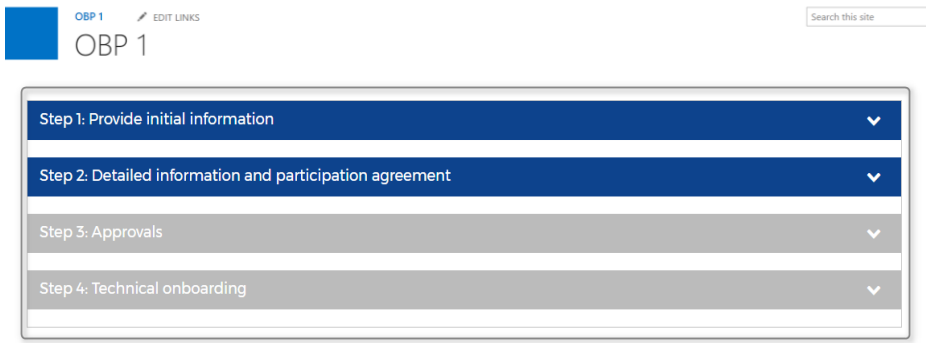


6. Your company portal is created

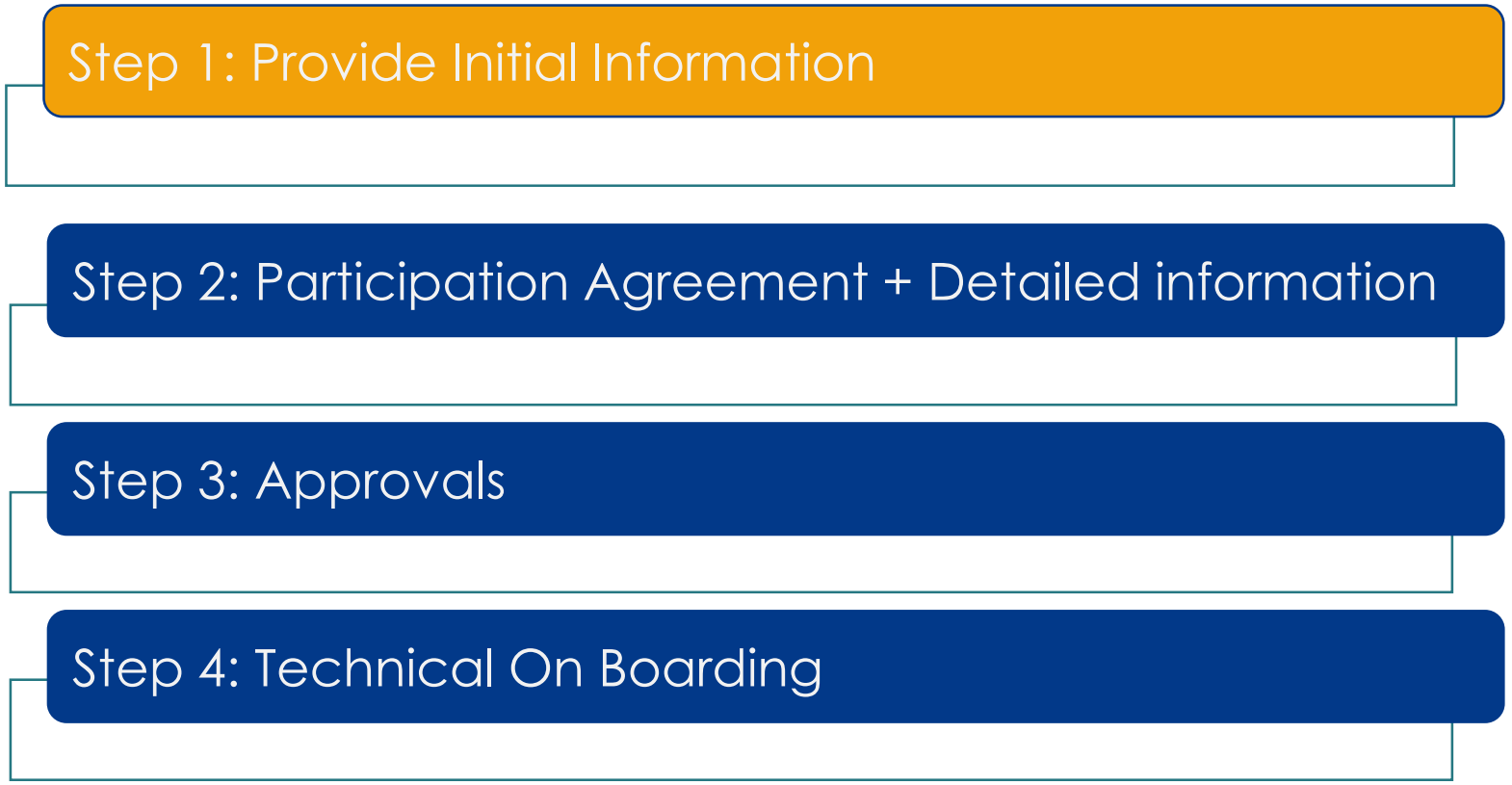


7. Follow the instructions in your email to login to your Company portal

8. Your Company portal is ready to On board



On-Boarding Partner Portal

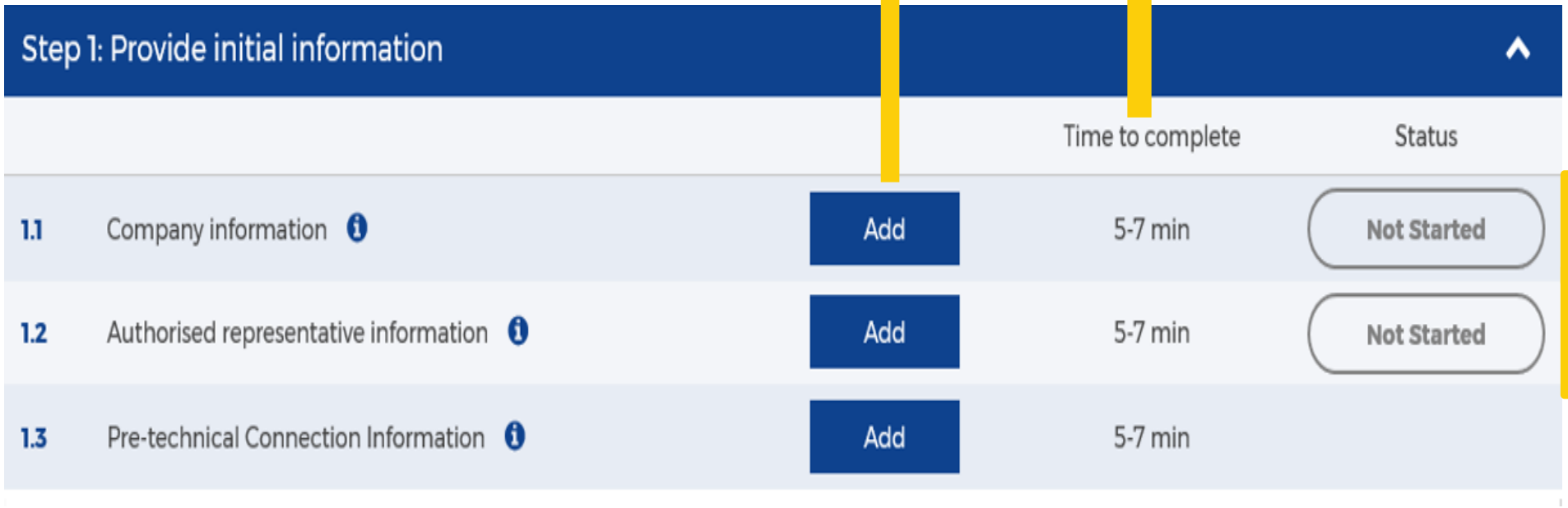


Step 1: Provide Initial Information

Trigger step 1:
Successful Request to Participate

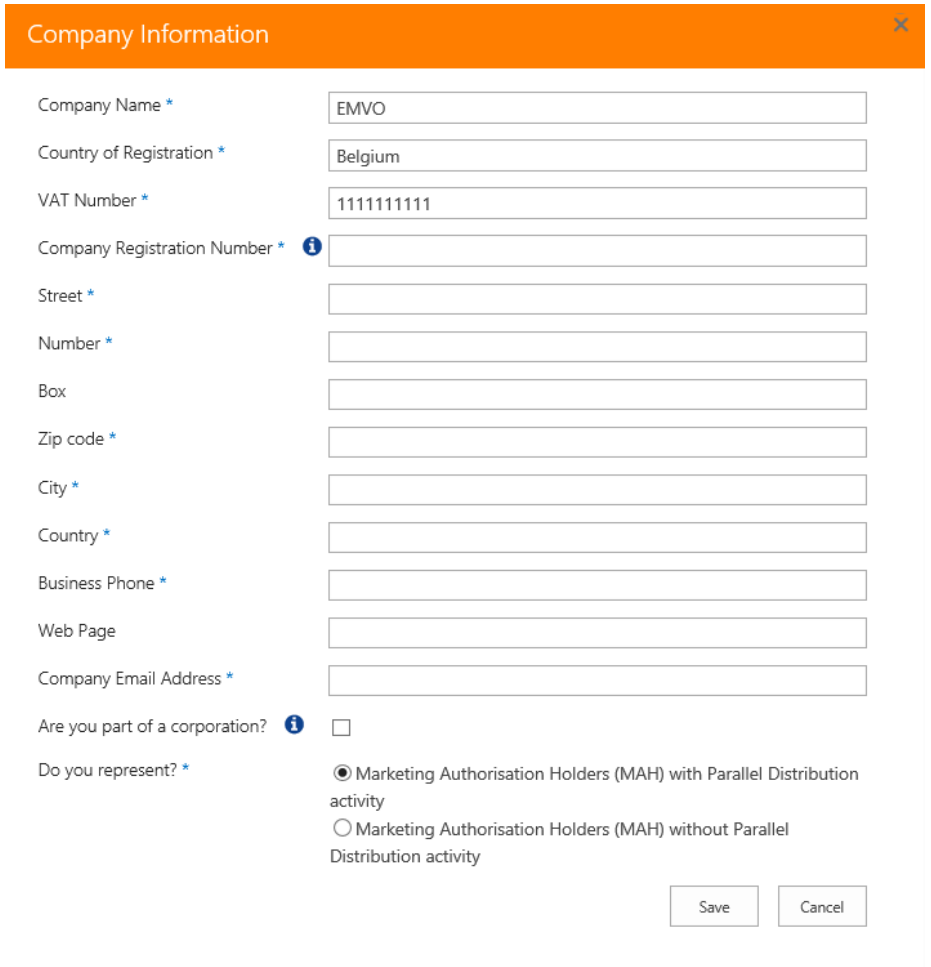
To add or modify the requested information

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

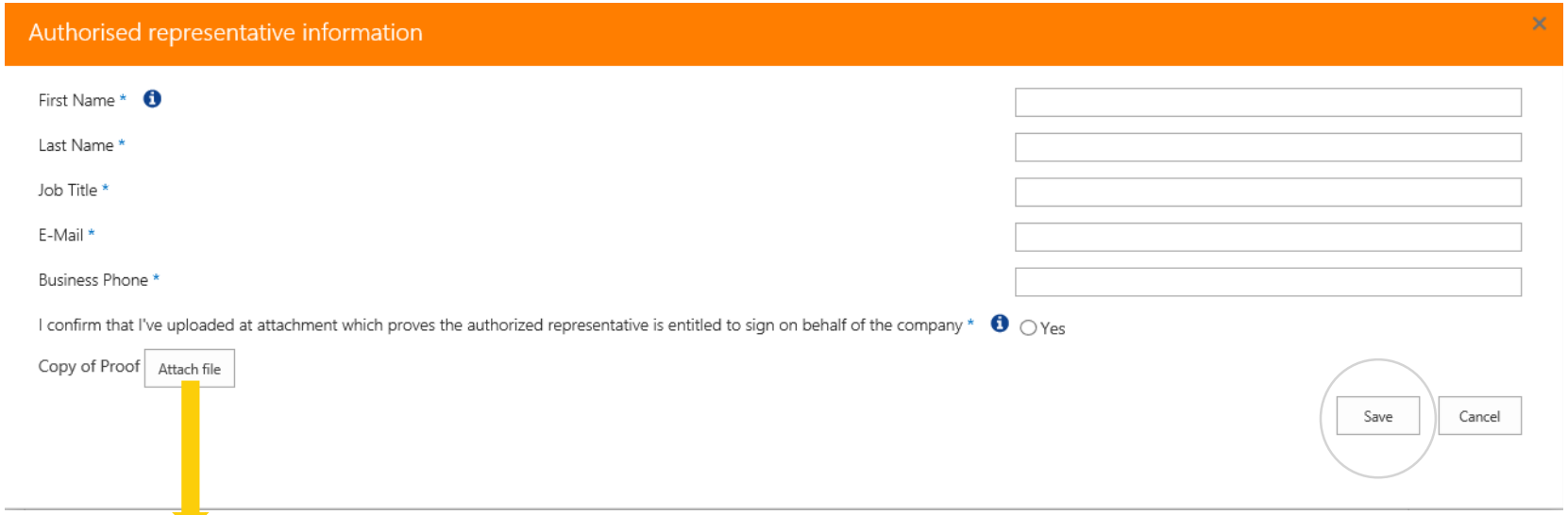
- ✓ make sure not to get confused between the OBP company, the parent company, and the MAHs information.
- ✓ make sure to include the full sequence of digits, no typo, and the initial country identification letters in front, if necessary

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

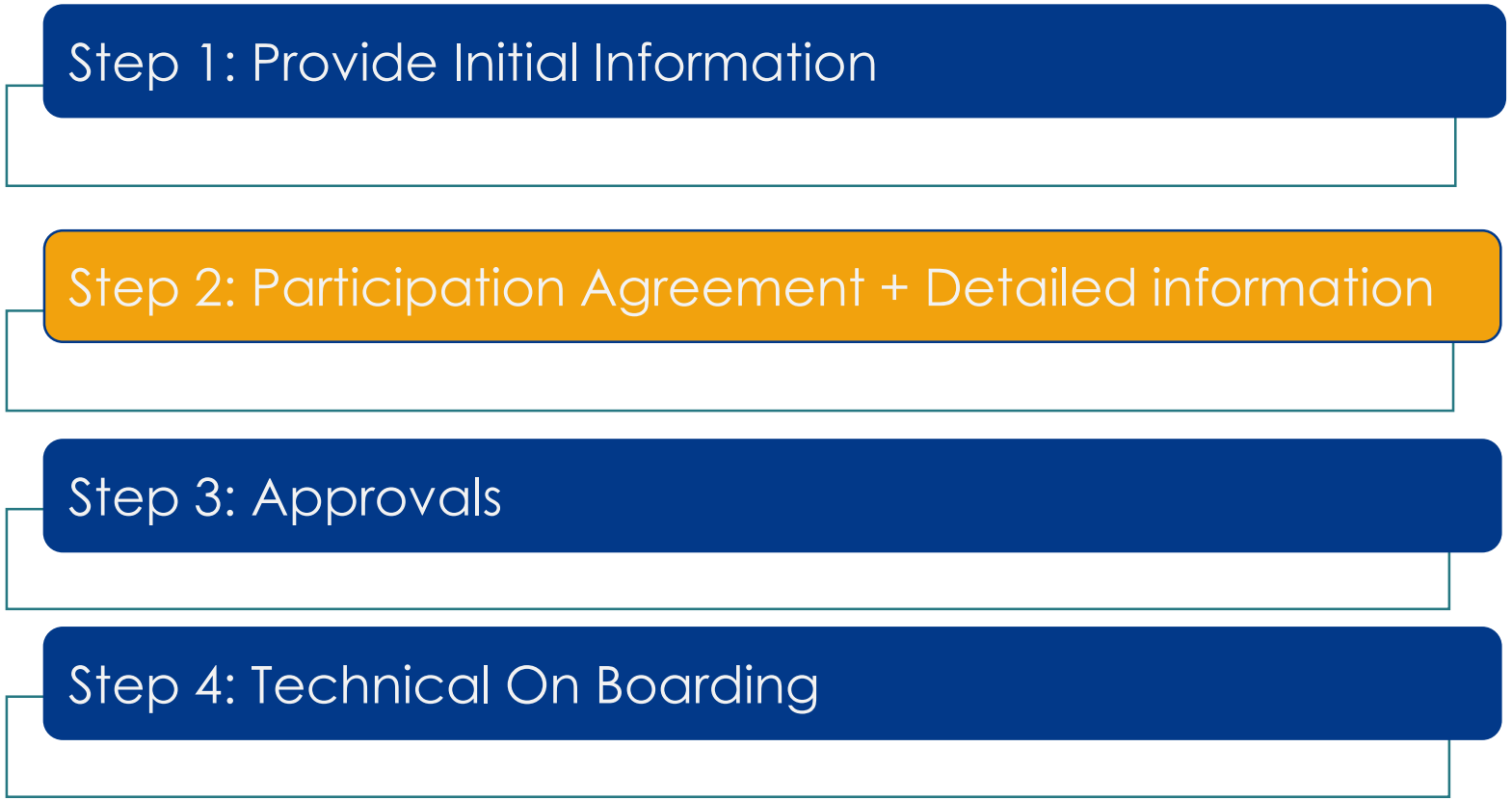
Copy of proof of the Authorised Representative

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

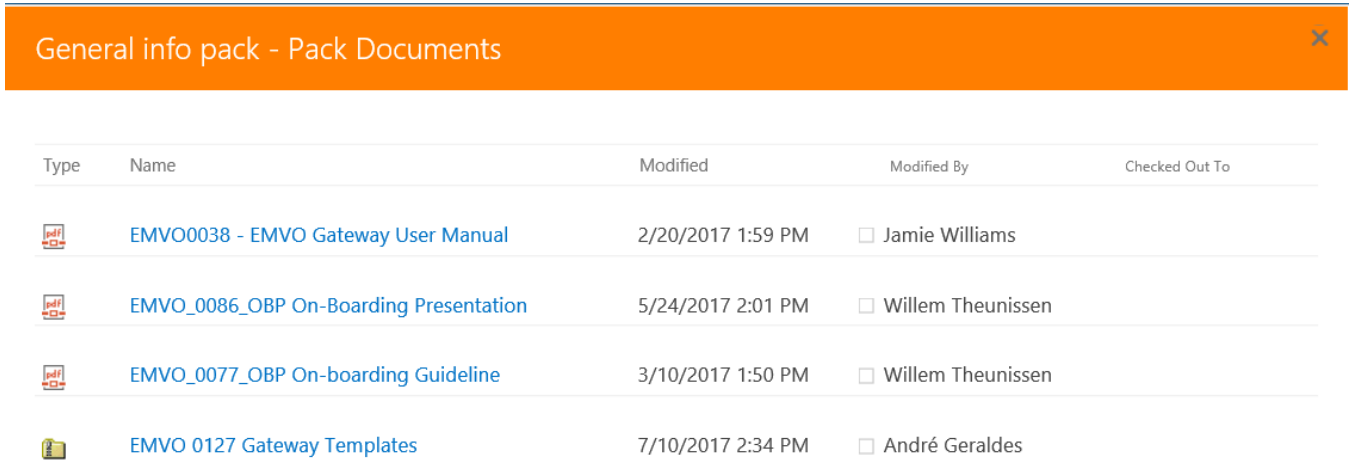
View and Download prefilled Participation Agreement (PA)

Status:
Not Started
Awaiting Approval
Approved
Rejected

Status:
Not Started
Completed

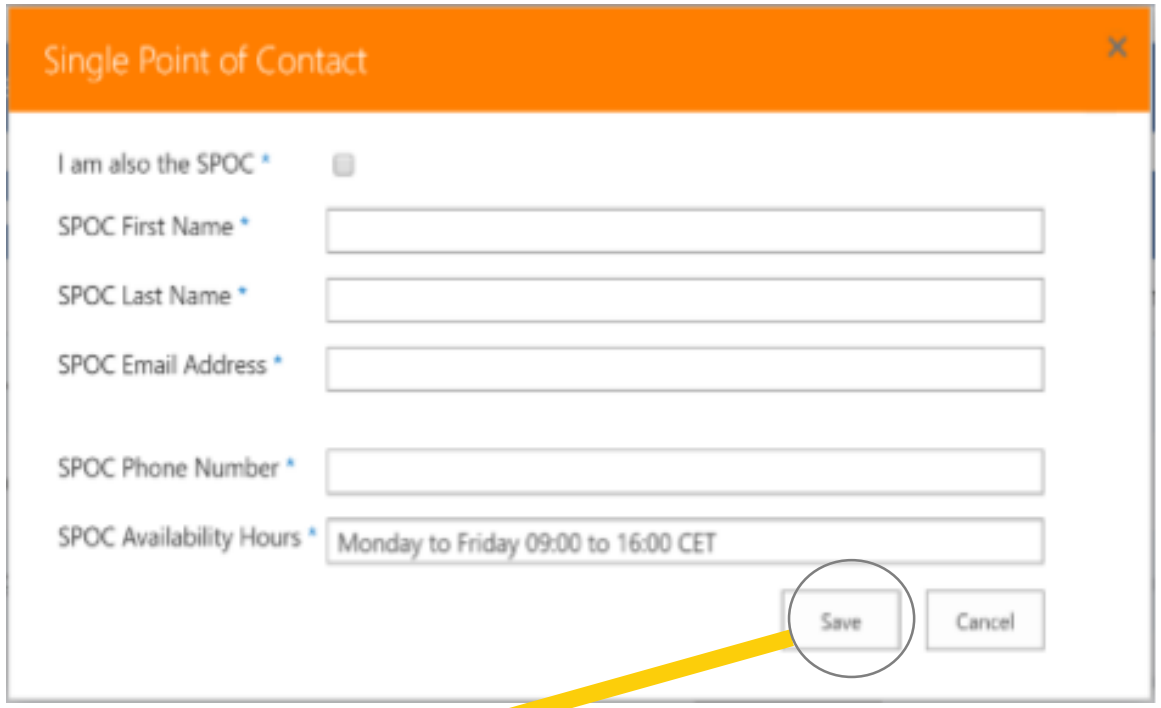
A sample of the PA is available on our website in its download section.

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

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

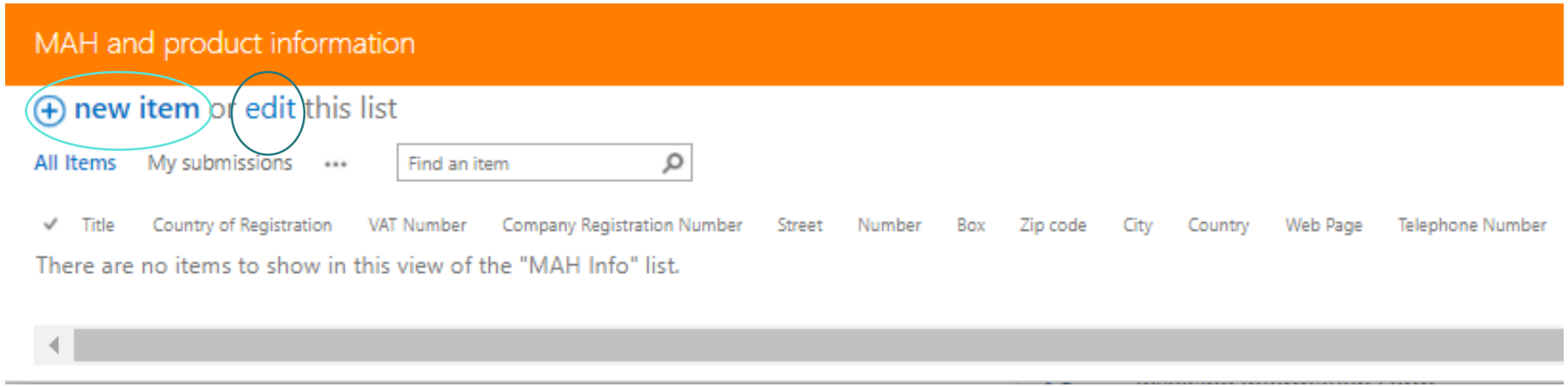
Note 1:

- ***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.

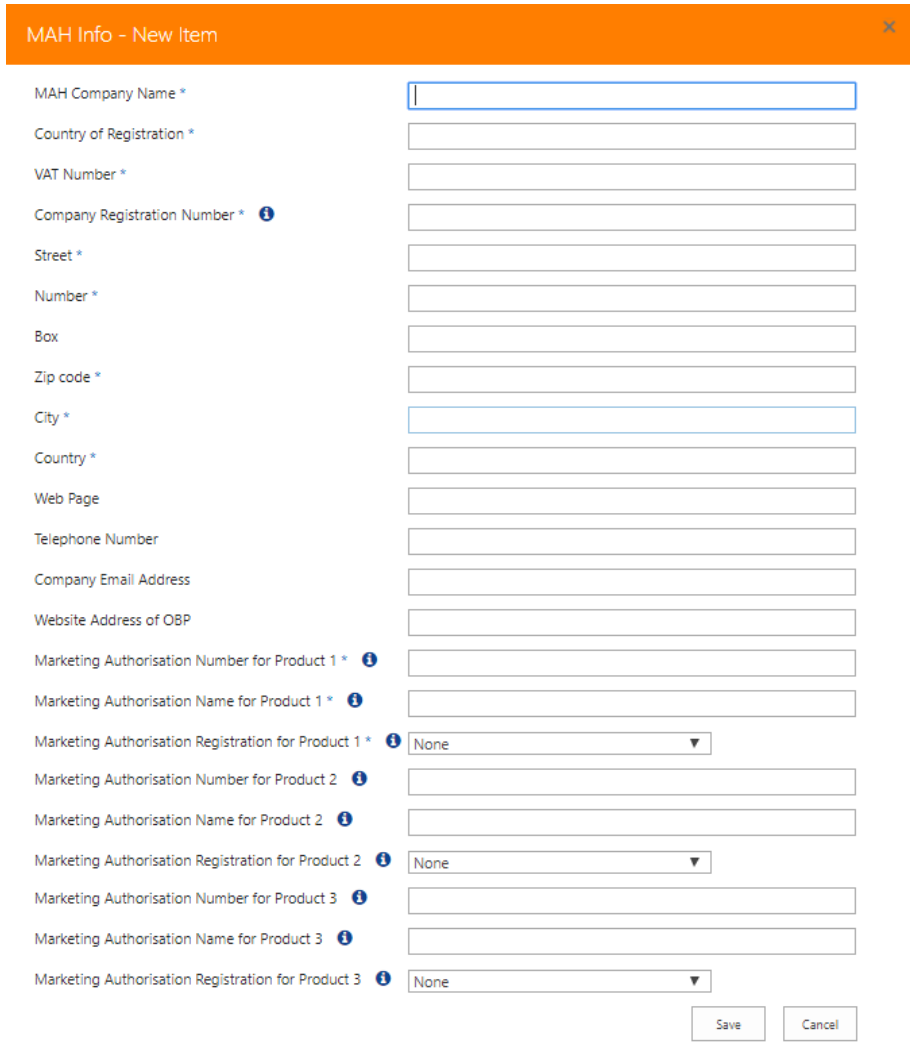
Note 2:

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



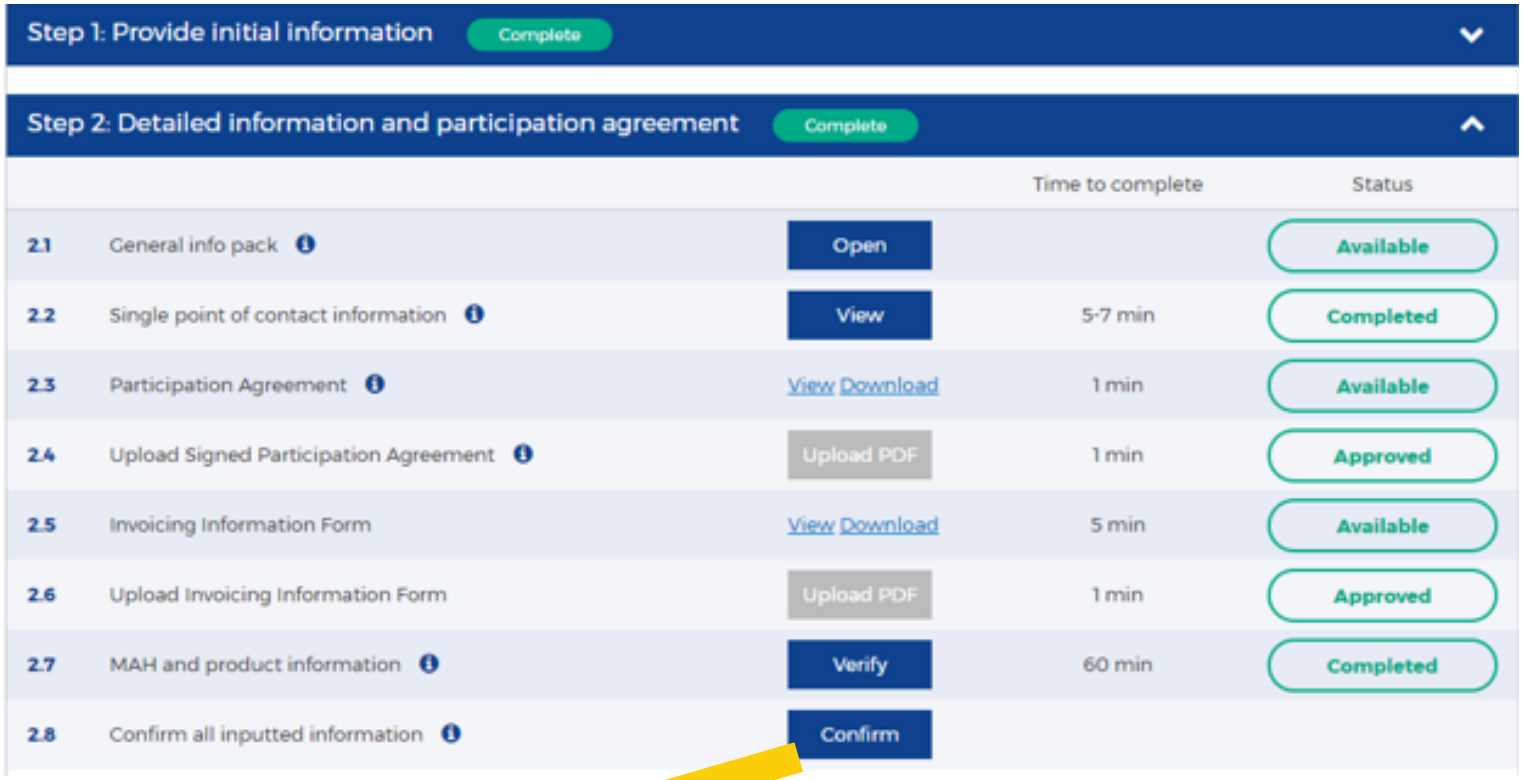
Note:
Product information;

- 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.

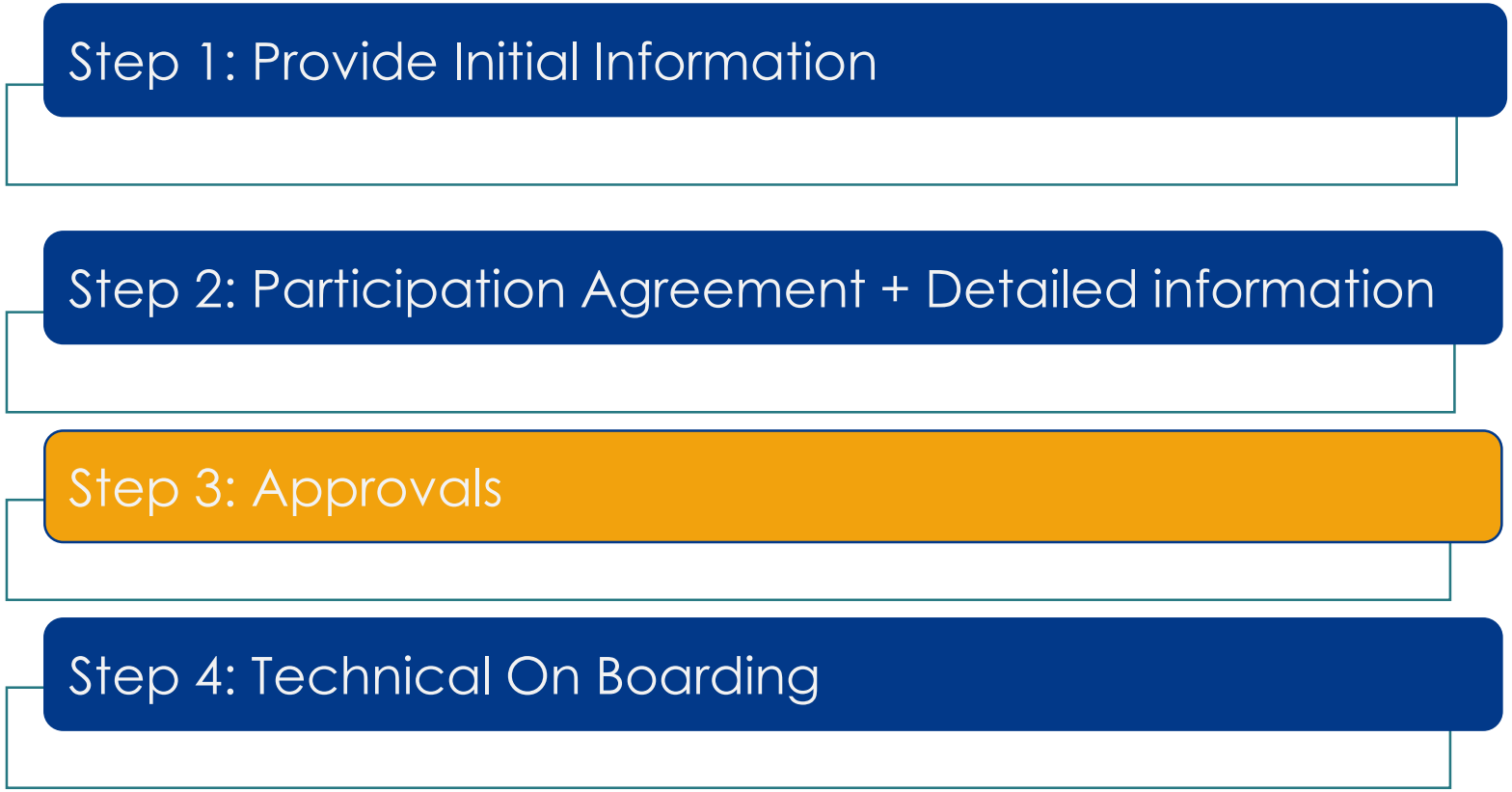
- The **Marketing Authorisation Registration** refers to the country covered by the marketing authorization and may be centralized.

2.8 CONFIRM ALL INPUTTED INFORMATION

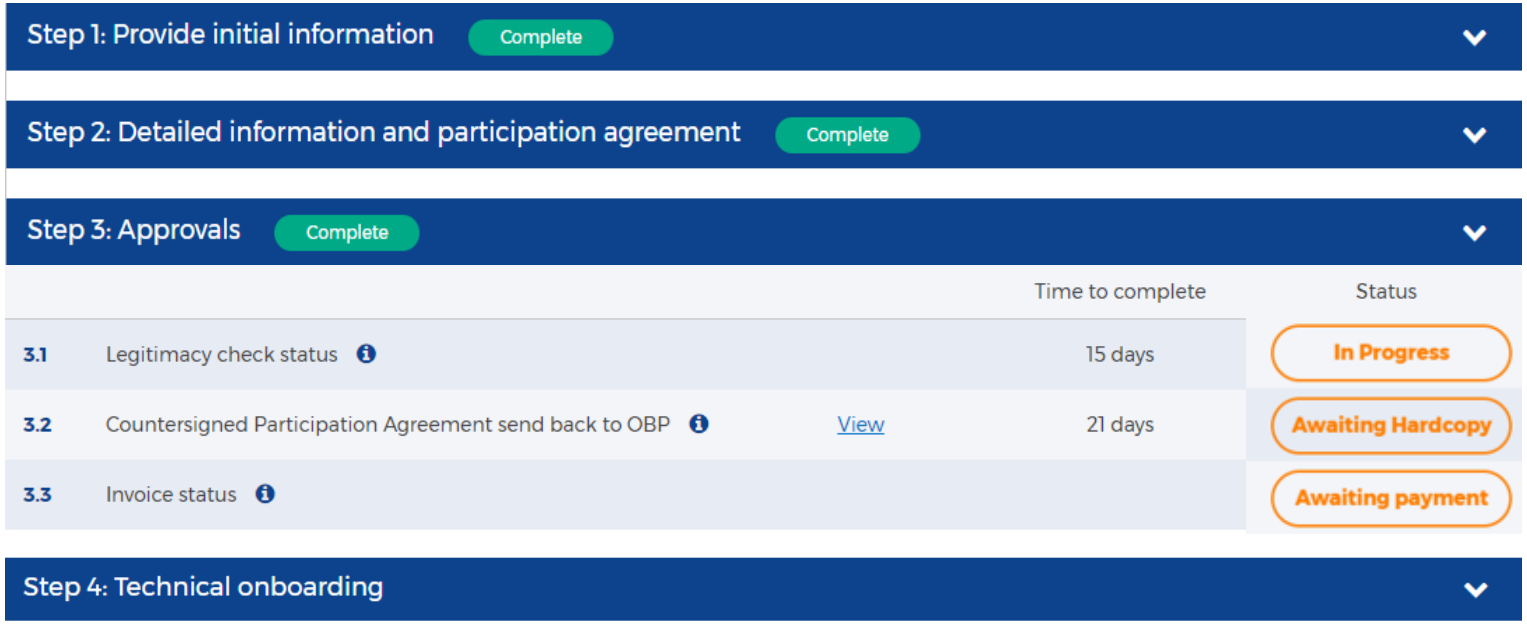


By clicking on the *Confirm* button the SPOC **confirms the accuracy** of the information provided on the portal.

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

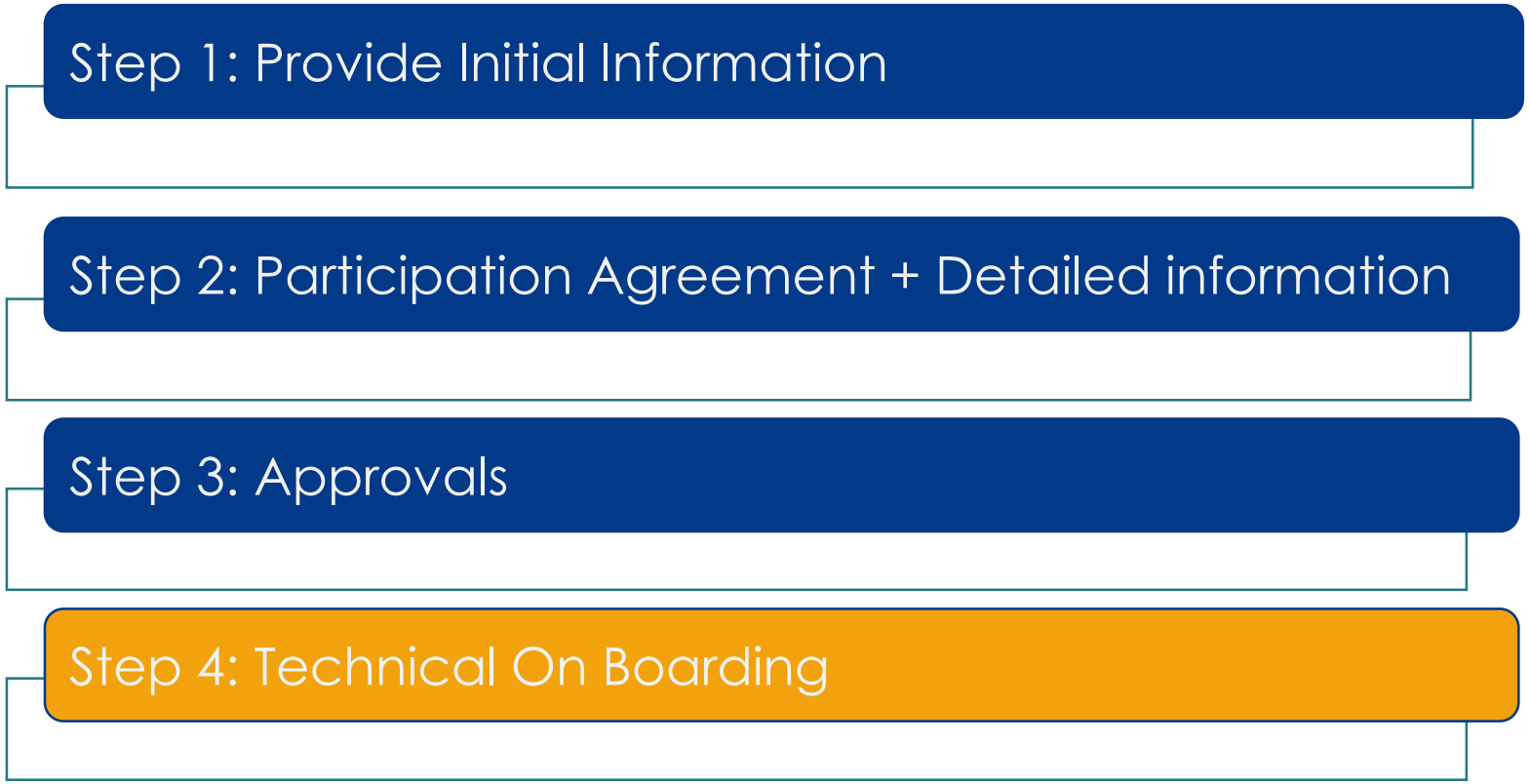
- The outcome of the Legitimacy Check will be communicated to the OBP via e-mail. And the status will be **updated on the portal.**

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

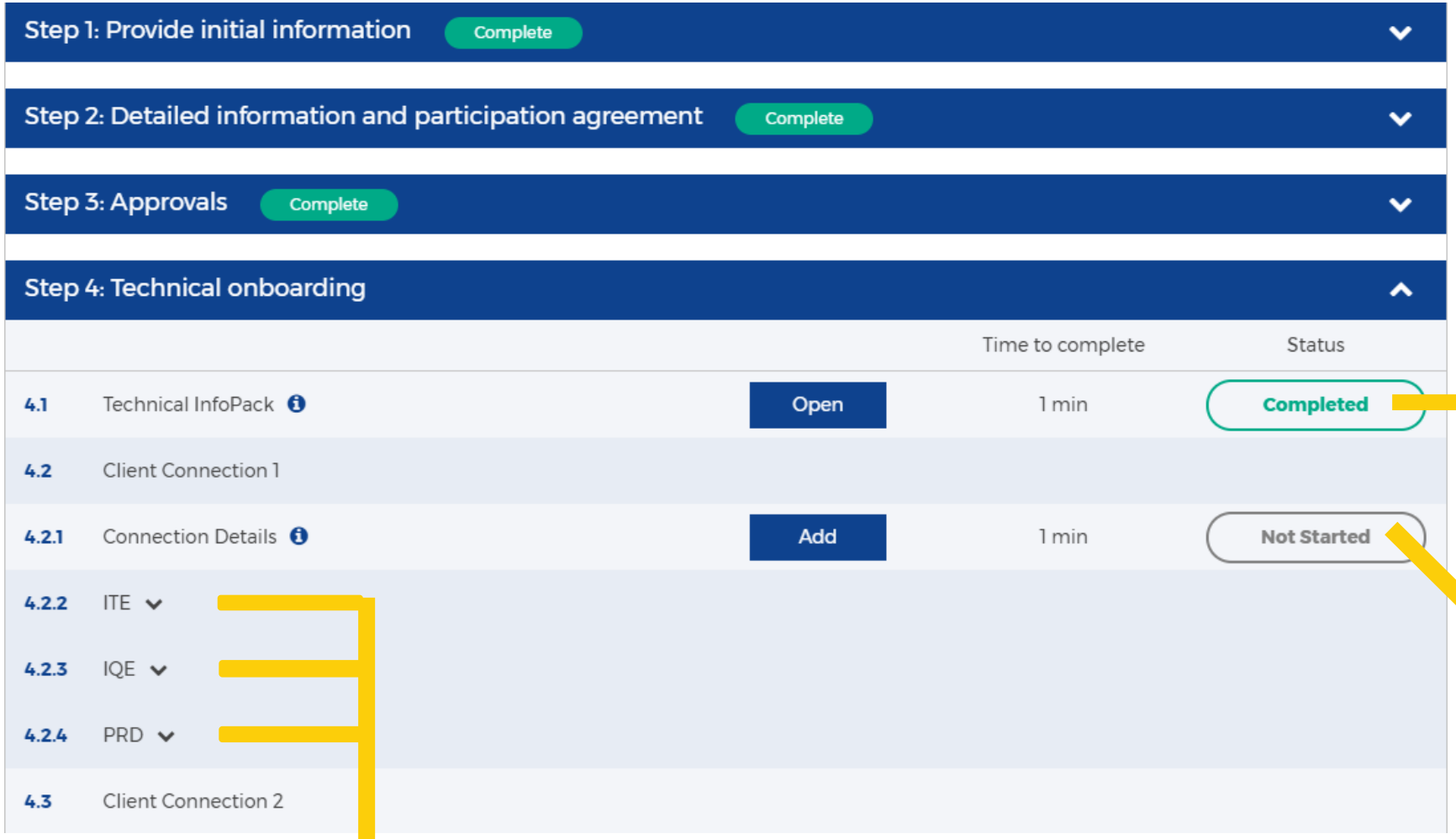
- If and only if the Legitimacy Check outcome is successful, **the Participation Agreement will be countersigned by EMVO** and one hardcopy will be sent back to the OBP by post.

→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

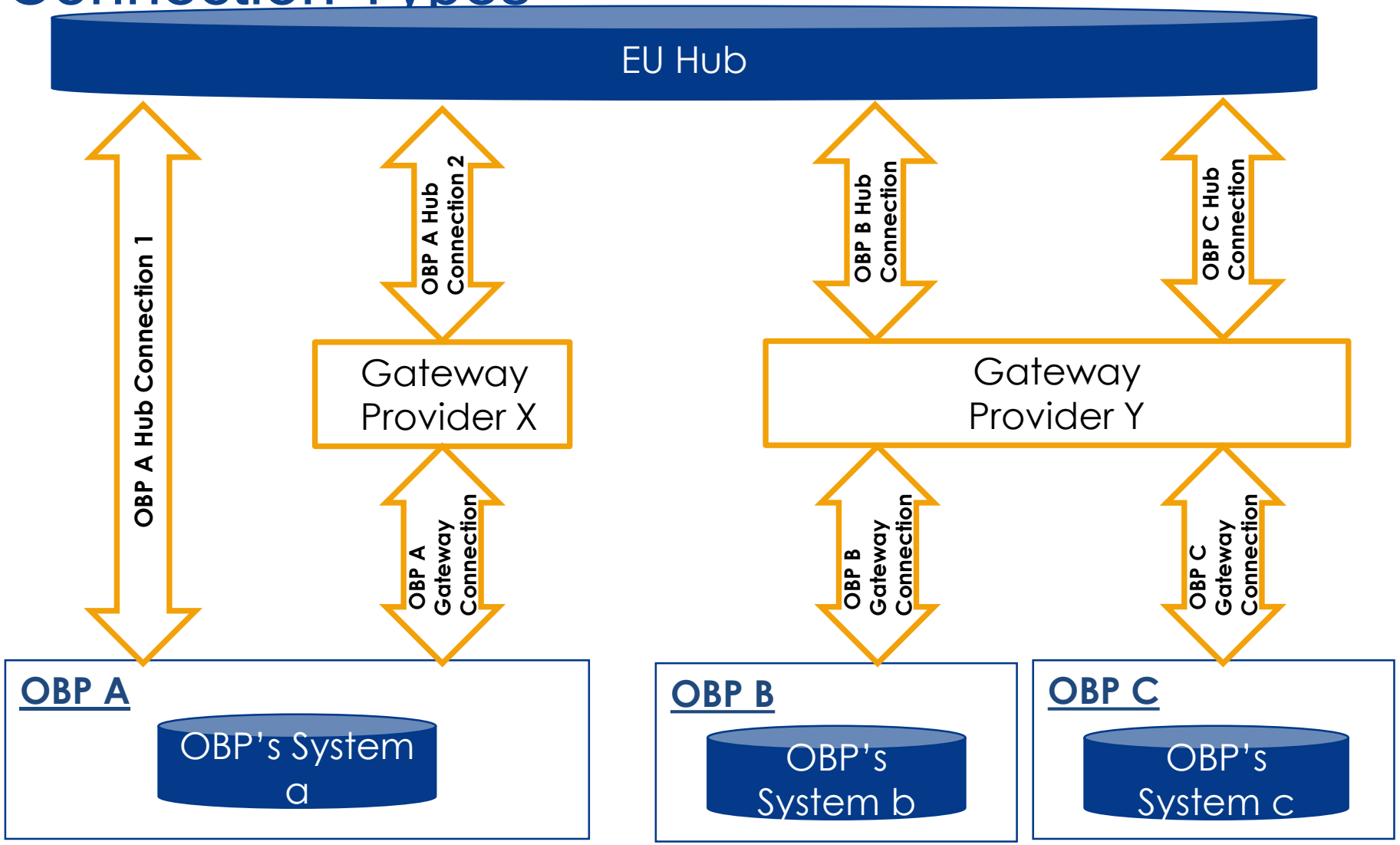
Note:
If you make use of a Gateway Connection, step 4.2.2 (ITE) is optional

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

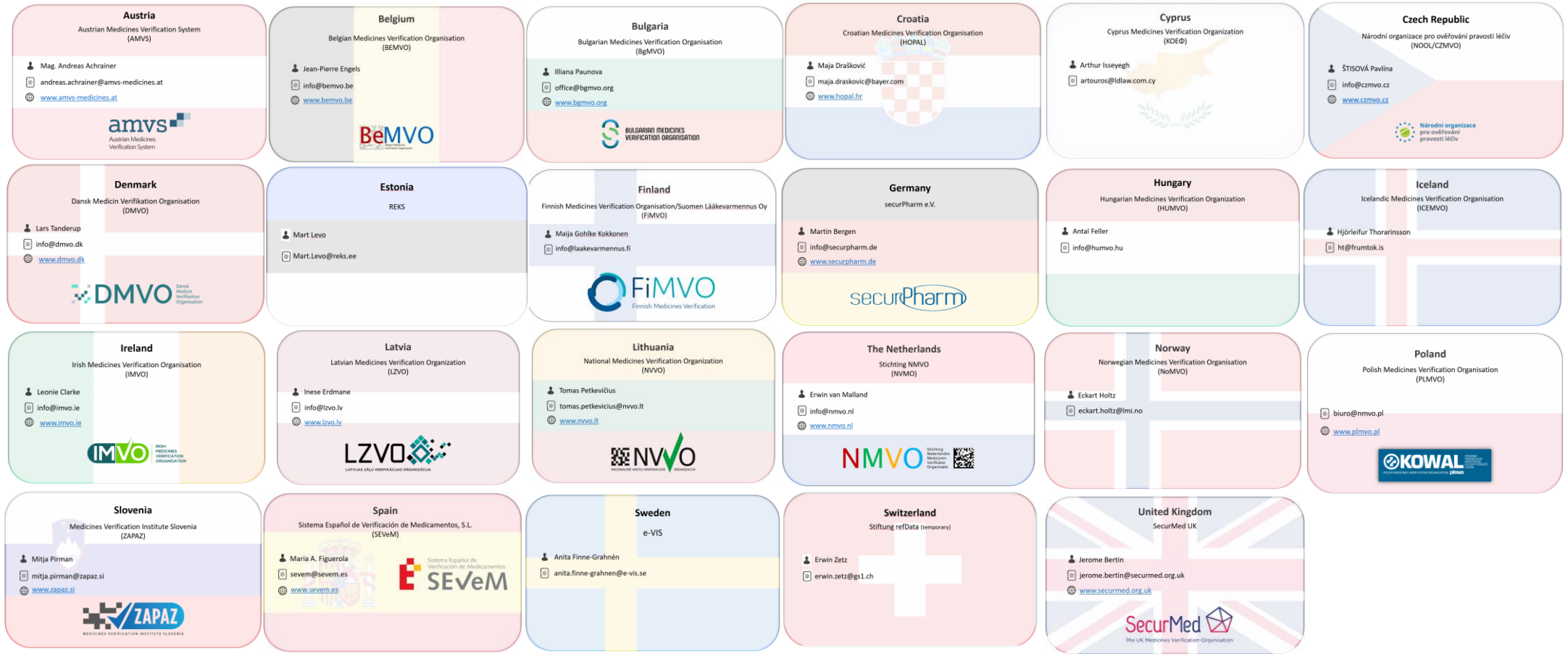



NN



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

Status in other countries



DMVO Dansk Medicin Verifikation Organisation

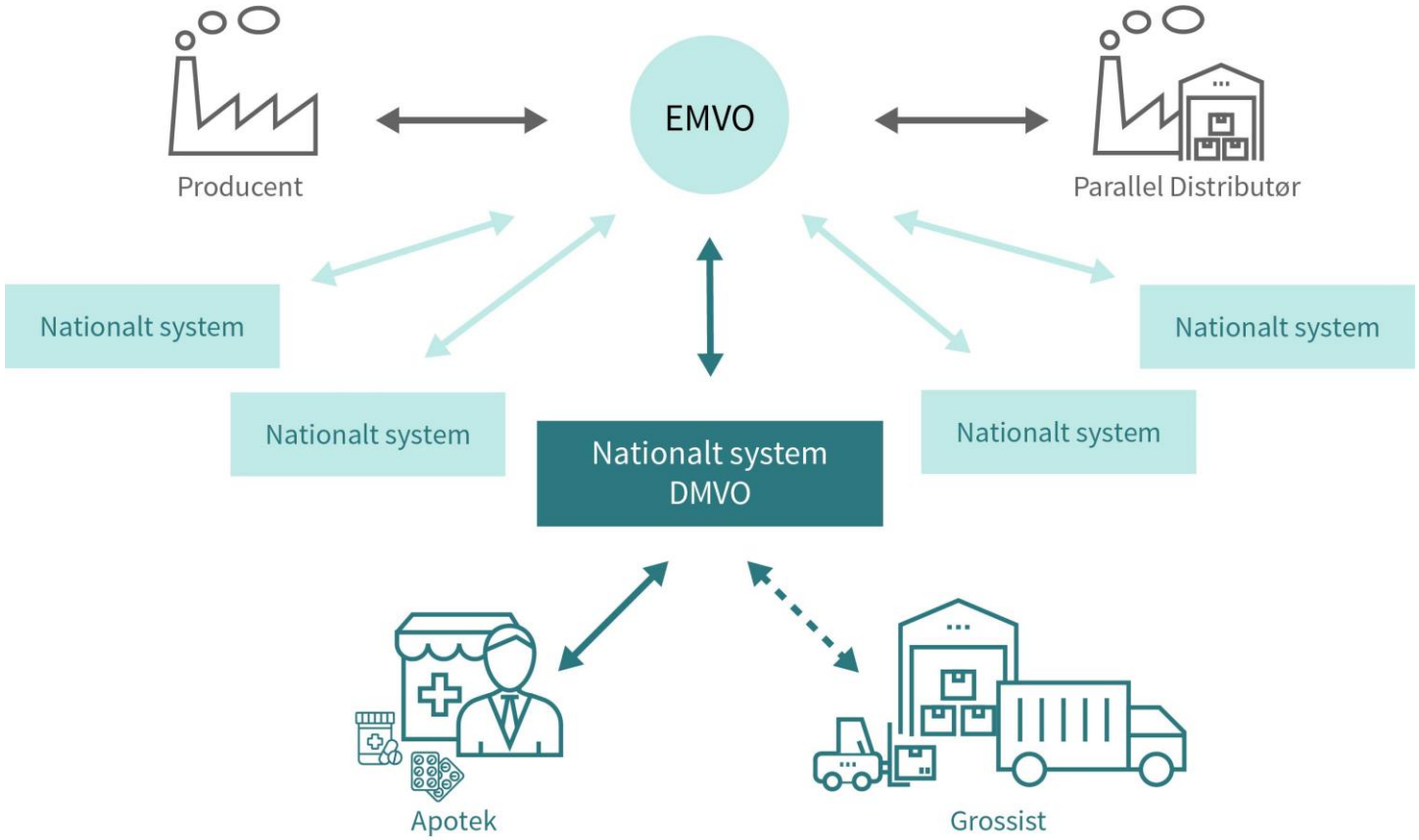
Hvor langt er vi med etablering af det danske verifikationssystem: DMVS?

Lidt om processen vedr. valg af IT leverandør

Hvem har været involveret fra Danmark?

Hvem er valgt til at være DMVS leverandør i Danmark?

Systemet skal fungere fra 9. februar 2019!



DMVO Dansk Medicin Verifikation Organisation

Baggrund og proces for valg af it-leverandør

- EMVO havde på forhånd udvalgt tre IT-udbydere, som såkaldte blueprint-providere. Dette indebar, at der var tre udbydere, som man havde forhandlet en "minimumskontrakt" med, og som man kunne garantere ville kunne løfte opgaven med etableringen af det nationale dataverifikationssystem.
- Der blev på møde i stakeholdergruppen den 20. maj 2015 besluttet at nedsætte en IT-gruppe. Denne gruppe skulle deltage i de fælles nordiske workshops, og senere også afholde nationale workshops.
- På baggrund af disse præsentationer, var der enighed i gruppen om, at man skulle frasortere en af udbyderne, og gå videre med forhandlingerne med de to resterende.
- Der blev herefter afholdt flere nationale workshops med begge udbydere. Ved disse workshops deltog alle danske stakeholdere, samt disses samarbejdspartnere – bl.a. apotekernes IT-leverandører.

DMVO Dansk Medicin Verifikation Organisation

Baggrund og proces for valg af it-leverandør

- Efter disse workshops blev der entreret med ekspert IT-advokater med viden og erfaring i at forhandle sådanne kontrakter.
- IT-advokaterne havde, inden man påbegyndte forhandlingerne, fortrolige møder med alle stakeholdere, således at det blev helt klart for advokaterne, hvilke elementer, der var afgørende for den enkelte stakeholder. Der blev herefter nedsat en forhandlingsgruppe med deltagelse af de to IT-advokater og direktør i DLI MI Martin Jordt Andersen.
- Der blev herefter påbegyndt parallelle forhandlingsforløb med de to udbydere.
- Efter et langt forhandlingsforløb med de to udbydere, blev der i starten af november 2016 arrangeret en tur til begge udbyderes hovedkvarterer. Her havde alle danske stakeholdere mulighed for at møde de to udbyderes samarbejdspartneres medarbejdere, og få en bedre forståelse af de to udbyderes tilgang og processer.

Bestyrelsesmøde den 24. januar 2017

- Gennemgang af det samlede forløb vedrørende valg af IT-udbyder. Fra man nedsatte en IT-arbejdsgruppe med deltagere fra alle stakeholdere, henover en proces med workshops for alle stakeholdere og IT-udbyderne, for til sidst at ende ud i et langt og grundigt forhandlingsforløb
- Enighed i bestyrelsen om, at arbejdet med valg af IT-udbyder havde været meget grundigt, og forløbet havde været godt i IT-gruppen, hvor der har været et godt samarbejde. Der var ligeledes enighed om, at begge IT-udbydere ville kunne løse opgaven tilfredsstillende.
- Der var et klart flertal hos stakeholdergruppens it-grupperepræsentanter for at vælge Solidsoft Reply som leverandør af den danske løsning. Efter en kort drøftelse var der tilslutning i hele bestyrelsen til indstillingen i dagsordenen om, at der indgås kontrakt med Solidsoft Reply.

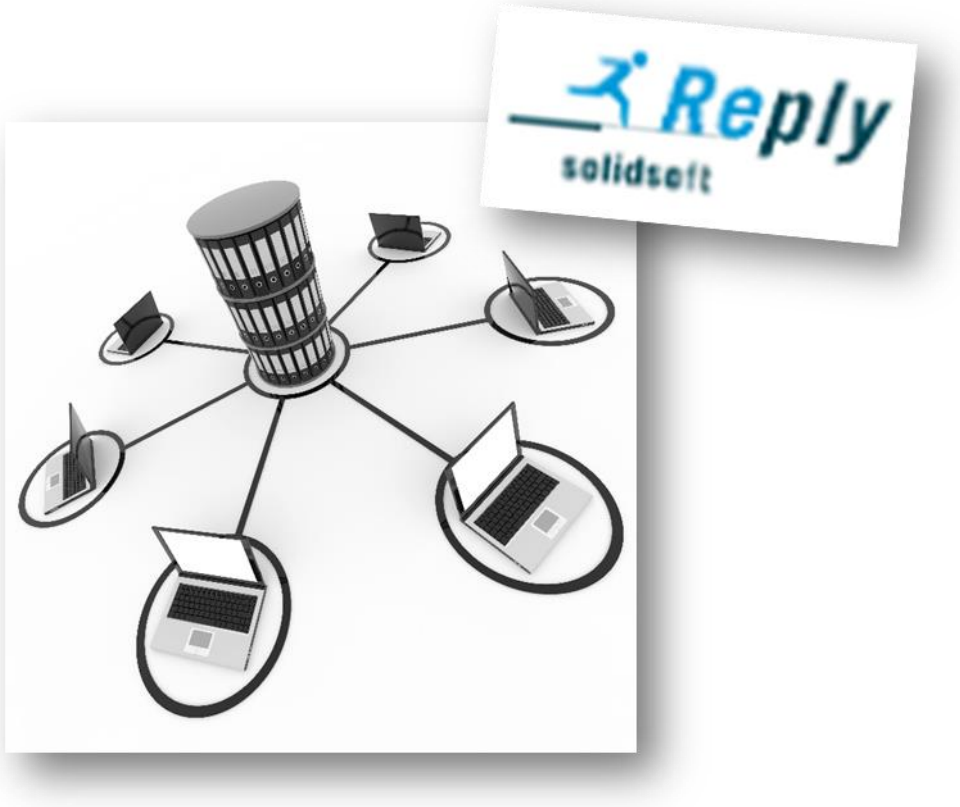
Criteria for assessing IT suppliers

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

Etablering af Dansk Medicin Verifikations System - DMVS

- DMVO's sekretariat er i tæt samarbejde med Solidsoft i fuld gang med arbejdet med at opbygge den danske database.
- Der er ansat en it-projektkoordinator i DMVO sekretariatet, der varetager (den daglige) dialog og samarbejde med Solidsoft og der holdes ugentlige skype-møder.
- Dette arbejde er primært af afgørende betydning for særligt grossister og (sygehus)apoteker.



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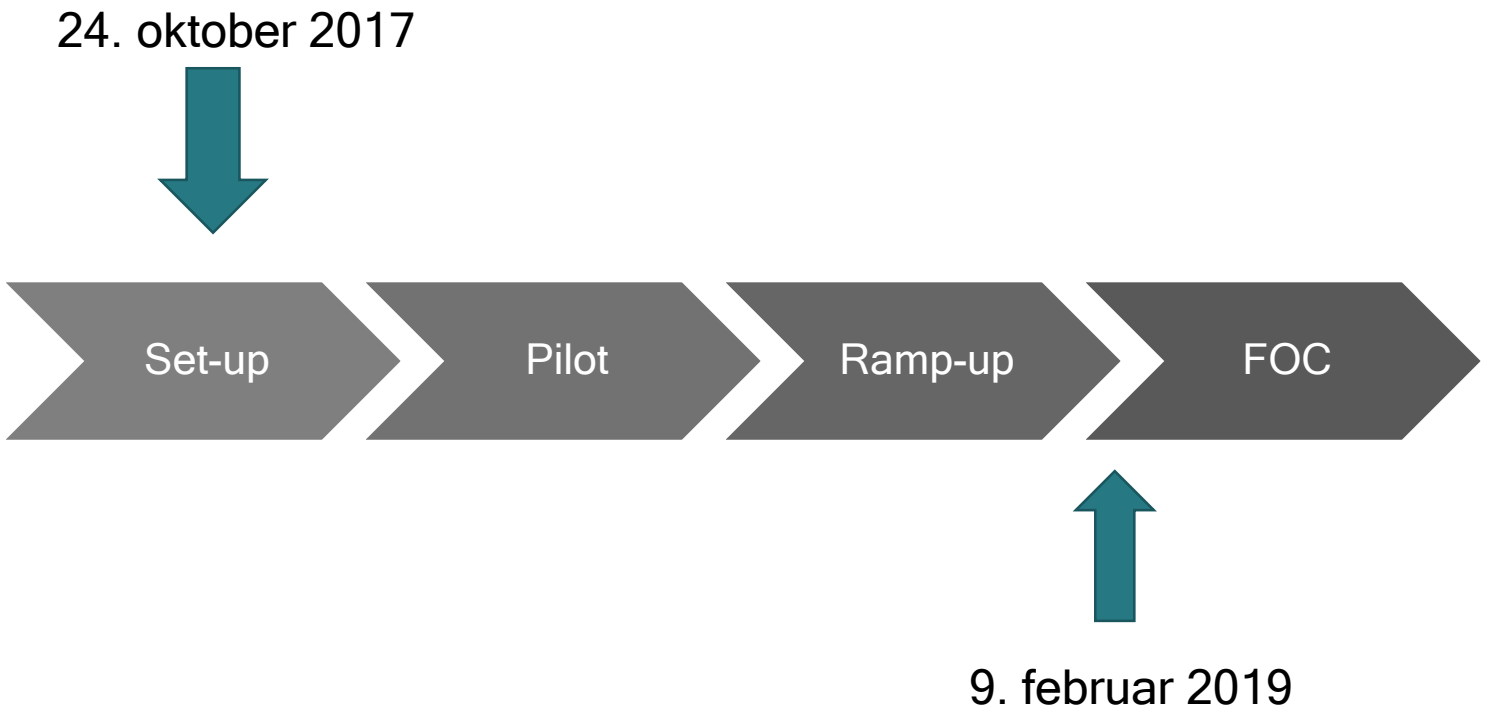
Arbejdsgrupper i DMVO-regi – pt. fælles møder/workshops

- It-følgegruppe:
- Den ”gamle” it-stakeholdergruppe fortsætter i ny rolle og skal bl.a.
- Drøfte problemstillinger og komme med input på et mere overordnet niveau i implementeringsfasen
- Fungere som sparringspartner overordnet i forhold til det arbejde, som DMVO’s sekretariat skal udføre sammen med Solidsoft Reply i opbygningen af den danske database
- Afholdelse af workshops med Solidsoft Reply.

- ”Ny” arbejdsgruppe:
- Søge at få koordineret processerne i hele forsyningskæden i perioden *indtil* 9. februar 2019. Dette indebærer bl.a., at arbejdsgruppen skal
- Sikre at der ikke opstår flaskehalse/forsyningsproblemer i overgangsperioden indtil 2019 på baggrund af det pågående implementeringsarbejde i forsyningskæden, herunder komme med forslag til evt. overgangsløsninger
- Komme med evt. input til DMVO om kontakt til myndigheder om evt. konkrete problemstillinger

DMVO Dansk Medicin Verifikation Organisation

Implementeringsplanen har fire faser



DMVO Dansk Medicin Verifikation Organisation

Set-up fasen – Nu!

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

Pilot – Som er drift(ikke en test) – Start Marts 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

Formål med pilot:

- Gennem en kontrolleret proces, at implementere et begrænset antal repræsentativt brugerorganisationer for at sikre, at alt fungerer som designet og testet. Pilot inkluderer verificering af implementeringsprocessen for slutbrugerapplikationer, slutbrugerens standard arbejdsprocedurer, supportkanaler mv.
- Pilotdeltagere agerer i produktion, som de første brugere.
- Der vil være et højt fokus på, at alle involverede parter griber ind overfor mulige udfordringer for at vurdere, planlægge samt foretage evt. nødvendige ændringer.
- Ved pilotfasens afslutning rapporterer alle involverede parter deres resultater, og ud fra opnåede erfaringer vurderes det, om noget skal ændres, forud for "Ramp Up" -fasen.
- Pilotdeltagere vil blive opdelt i mindre grupper bestående af 1 apotek, 1 grossist og 1 fremstiller.

DMVO Dansk Medicin Verifikation Organisation

Formål med pilot - fortsat

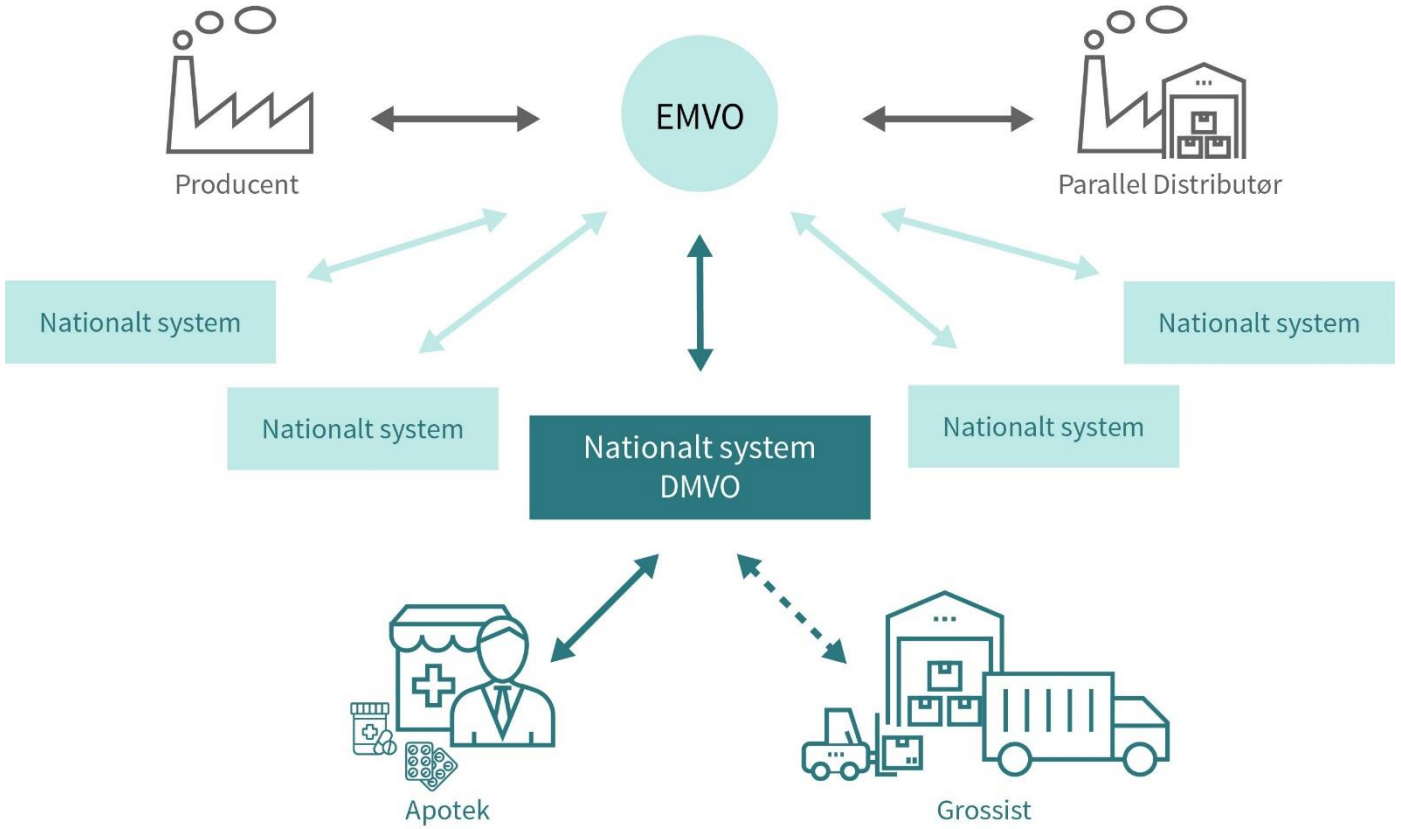
- Ny dato 1. marts 2018
- Pilotdeltagelse, tilmeldte
  - Grossister – TMJ og Nomeco – tidsplaner modtaget
  - Apotekernes IT leverandører – Cito IT
  - Sygehusapotekerne –
  - Producenter/parallelimportører – Orifarm, Roche A/S, Sandoz og Bayer (april 2018)
- Workshop 2 for pilotdeltagere - Ultimo November 2017
  - Kravspecifikation & tidsplan

Ramp-up - skala

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)		

DMVO Dansk Medicin Verifikation Organisation

Afslutning



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Den danske kontrakt- og betalingsmodel

Finansieringsmodel Danmark

Der er rundt om i Europa valgt forskellige finansieringsmodeller.

Det er for nogle lande en udfordring at få finansieret Ramp Up fasen.

I Danmark er der valgt en model, hvor ingen firmaer skal betale før systemet er oppe at køre. Der er en långiver (DLI), der får sit lån tilbage ved direktivets ikrafttrædelse primo 2019.

DMVO Dansk Medicin Verifikation Organisation

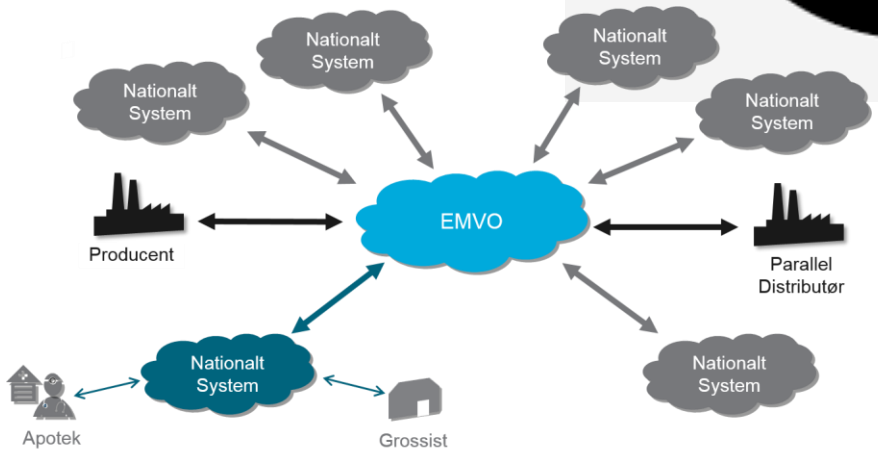
Hvem skal betale – hvad siger lovgivningen

LM-loven:

§ 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: ”Omkostningerne til datalagringssystemet afholdes af fremstillerne af lægemidler, der er forsynet med sikkerhedselementerne, jf. artikel 54a, stk. 2, litra e), i direktiv 2001/83/EF.”

Man skal derfor, hvis man vil have sit produkt på det danske marked pr. 9. februar 2019, betale et årligt verifikationsgebyr gældende fra 2019 pr. MAH’er(indehaver af en eller flere markedsføringstilladelser).



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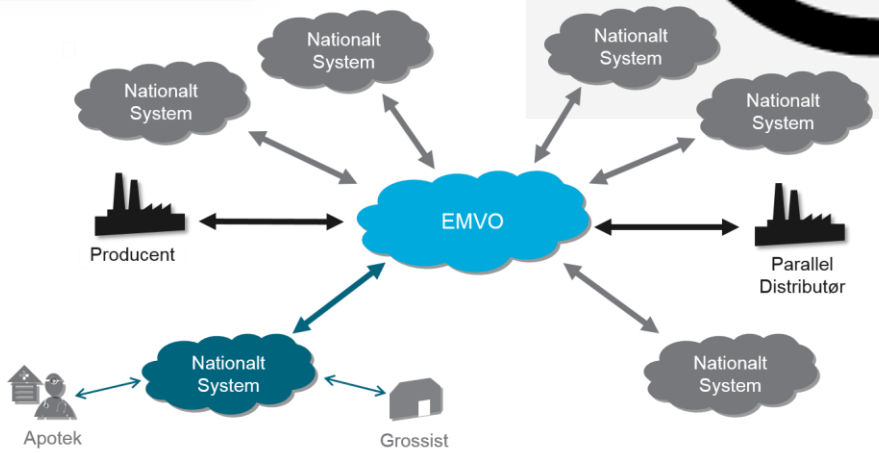
Hvem skal nu betale og hvor meget?

Reglerne:

§ 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-

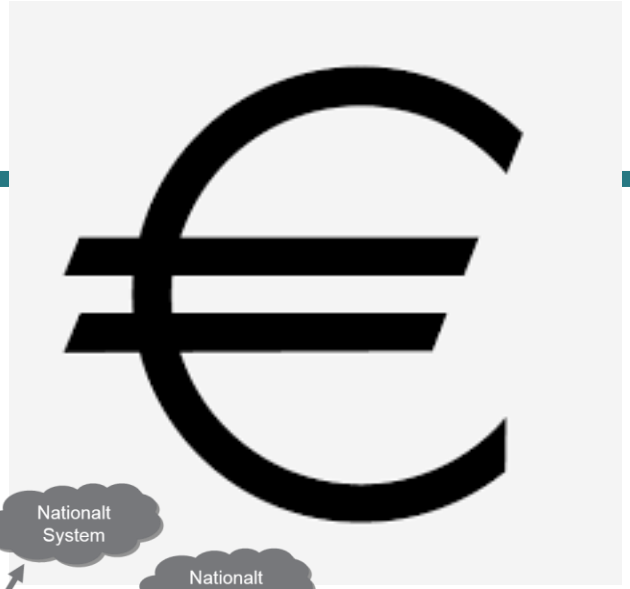
Bestyrelsen har på sit møde den 20. april 2017 besluttet, at startgebyret via en rabatordning gøres progressivt – jo tidligere indgåelse af kontrakt med DMVO des billigere

Bestyrelsen besluttede at det videre udredningsarbejde om antallet af MAH'er og fastsættelse af gebyrer, så vidt muligt skal ske i tæt dialog med Lægemiddelstyrelsen.



DMVO Dansk Medicin Verifikation Organisation

Hvem skal nu betale og hvor meget?

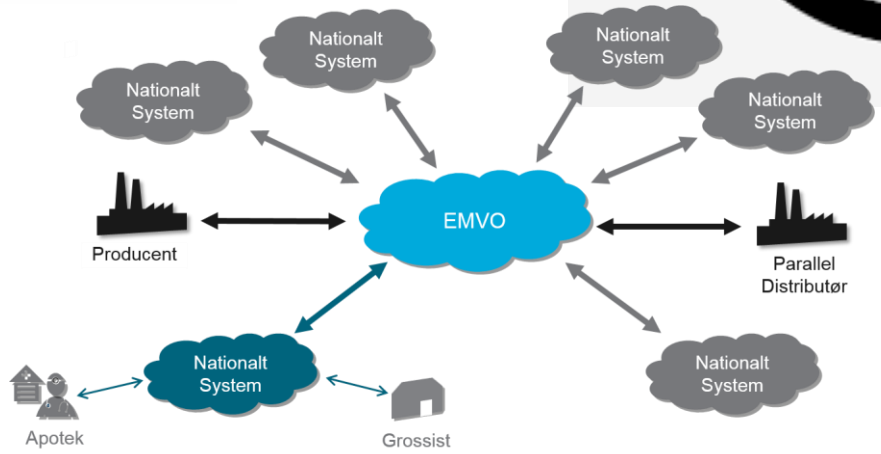


Reglerne:

§ 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-

Bestyrelsen har truffet beslutning om at der betales et one-off registration fee (startgebyr) og et annual fee (årligt gebyr), første gang i 2019.

Det er besluttet at one-off registration fee og annual fee for 2019 først skal forfalde til betaling i 2019, og at man i DK tager udgangspunkt i den model, som er valgt på europæisk plan, dvs. en flat fee struktur.



DMVO Dansk Medicin Verifikation Organisation

Grundlag for prissætning af gebyrer

Lægemiddelstyrelsen og DMVO har i fællesskab i juni 2017 udsendt skrivelse til en konsolideret bruttoliste over mulige MAH'er.

Der er efterflg. i september 2017 udsendt en påmindelse til de MAH'er, vi ikke har modtaget svar fra.

230 MAH'er er for nuværende registreret med deres kontaktoplysninger og vil modtage kontrakten direkte.

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Kontraktens udformning

Ved kontraktens udformning har DMVO valgt at lade sig inspirere af den belgiske og finske MAH kontrakt.

En IT advokat har stået for selve udformningen samt det juridiske indhold.

En mindre reviewgruppe har haft mulighed for at gennemse og kommentere på kontrakten, og indkomne kommentarer er indarbejdet.

Medlemmerne af DMVO bestyrelsen fra de betalende parter har godkendt hovedindhold og principper i den kontrakt- og betalingsmodel, som præsenteres i dag.

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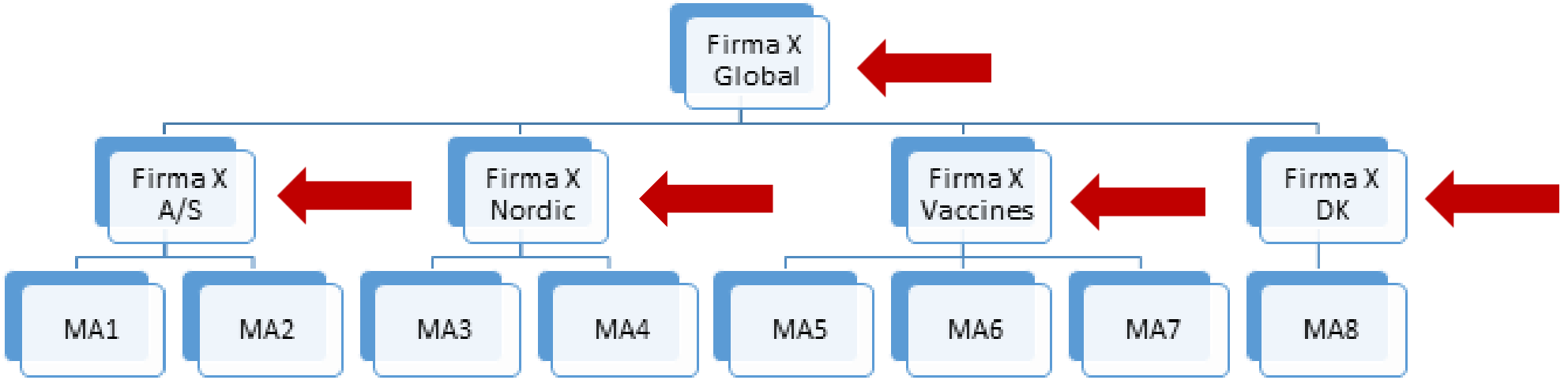
Kontrakten – hvem indgås kontrakten med?

Kontraktens udformning muliggør, at et moderselskab (Company) kan indgå kontrakt på vegne af flere MAH'er samt en MAH'er kan indgå kontrakten direkte med DMVO. Betaling sker pr. MAH uanset om kontrakten omfatter en eller flere MAH'er.



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Progessivt one-off registration fee (startgebyr)

Der er truffet beslutning om et progressivt startgebyr med opbakning fra bestyrelsen.

Betaling af startgebyret betales senest 31. januar 2019.

Efter 9. februar 2019, vil nye MAH'er også skulle betale et 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.					

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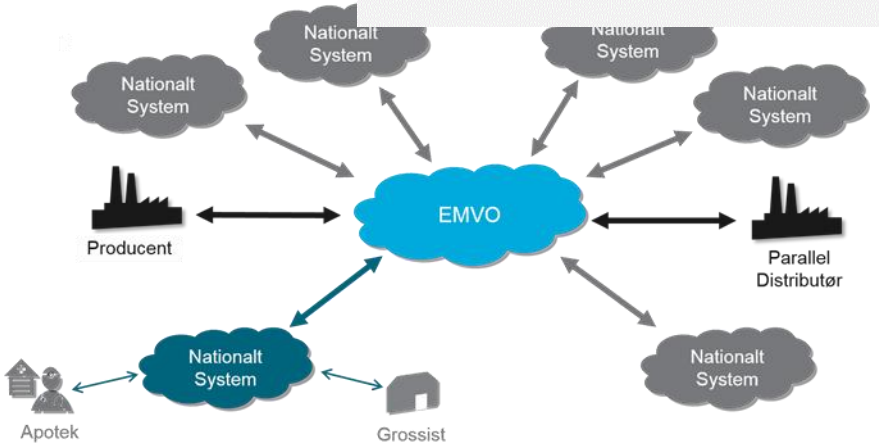
Hvad med det årlige verifikationsgebyr?

Det årlige verifikationsgebyr vedtages af bestyrelsen november 2018 og tager højde for antallet af MAH'er.

Det årlige verifikationsgebyr afregnes pr. MAH og baserer sig på faktiske omkostninger ved at drive DMVO og det dertilhørende verifikationssystem samt udgør en flat fee (samme gebyr for alle), svarende til den europæiske model.

Det årlige verifikationsgebyr vil første gang skulle betales senest 1. marts 2019. Efterfølgende hver den 15. januar 20XX.



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MAH'ere i Danmark

- Lægemiddelstyrelsen skønner
  - 750 MAH i systemet - skønsmæssigt 8% dubletter skal sorteres fra
  - 420 er aktive - skønsmæssigt 8% dubletter skal sorteres fra

- Ca. 230 repræsentanter med en omsætning i DK
- Tilsammen har repræsentanterne pt ca. 288 aktive MAH
- Alle MAH'ere skal on boarde før 9 februar 2019 for at kunne sælge receptpligtige lægemidler fremover
- Der er bygget en lille incitament ind i modellen, så jo før jo billigere

- DMVO har sammenholdt med lægemiddelstatistikken
  - 35 MAH er ikke registreret af lægemiddelstyrelsen, men har alligevel salg i dk
  - 2500 Drugids mangler(PI, Sygehusegenproduktion, SSI, etc.)
  - 751 MAH har Rx drug-id der opfylder betingelserne om verifikation
  - 288 MAH har haft Rx salg i 2015-2017
  - I praksis forventes et lidt lavere antal MAH'ere i 2019

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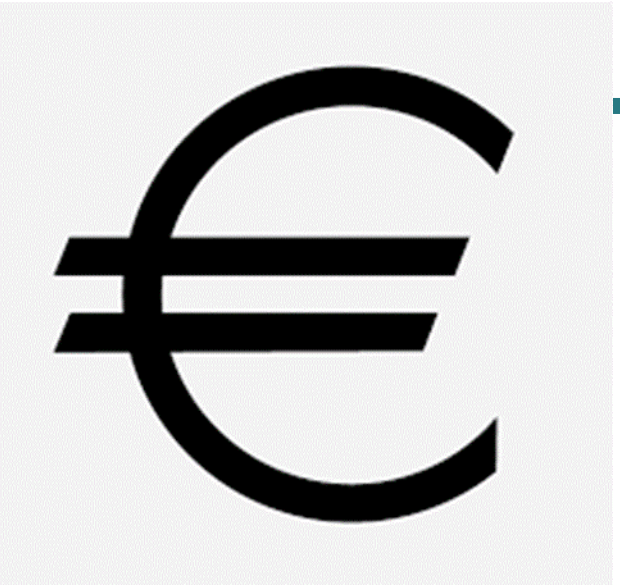
Eksempel på årligt fee ved 230 MAH



Udgangspunktet 230 MAH, DKK ca. 41.000 i årligt fee per MAH

- Stor Generika – 9 MAH, 9,5 mio pakninger, 325 brands, 670 mio i omsætning
  - pris per år DKK ca. 369.000
- Stor original, 5 MAH, 5,5 mio pakninger, 98 brands, 340 mio
  - pris per år DKK ca. 205.000
- Lille original, 1 MAH, 2200 pakninger, 5 brands, 1,2 mio i omsætning
  - pris per år DKK ca. 41.000

- Hvis dette setup giver et over/underskud opkræves/returneres dette via af det årlige fee. fremover
- Der er intet incitament til at vente til efter 2019 – man kommer til at betale on-boarding plus index regulering for alle nye MAH

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Processen herfra

Kontrakten vil blive udsendt direkte til alle MAH'er, som senest har ladet sig registrere hos DMVO 31. oktober 2017 i løbet af november 2017.

I forbindelse med kontrakten, vil det blive præciseret på hvilken måde kontrakten skal underskrives og returneres.

DMVO er for nuværende ved at undersøge muligheder for elektronisk underskrift og returnering af kontrakt. Oplysninger herom følger med kontrakten, ved dennes fremsendelse.

Spørgsmål kan endvidere rettes direkte til DMVO.

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DMVO Dansk Medicin Verifikation Organisation

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Dansk
Medicin
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Organisation

Backup

Hvad er definitionen på en MAH'er

MAH (indehaver af markedsføringstilladelsen) er den virksomhed som er indehaver af den udstedte markedsføringstilladelse for et lægemiddel.

Det vil oftest være den virksomhed. der har ansøgt om og fået godkendt en markedsføringstilladelse, men markedsføringstilladelsen kan godt overdrages til en anden virksomhed efter godkendelsen er udstedt.

Indehaveren af markedsføringstilladelsen er ansvarlig for markedsføringen af lægemidlet.

Udpegningen af en repræsentant fritager ikke indehaveren af markedsføringstilladelsen for dennes retlige ansvar.

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