



**Národní organizace  
pro ověřování  
pravosti léčiv**

# **DOPADY FMD NA VÝROBCE NUTNÉ KROKY A POŽADAVKY**

Martin Mátl

# DŘÍVE NEŽ ZAČNEME ...

Výrobce

vs.

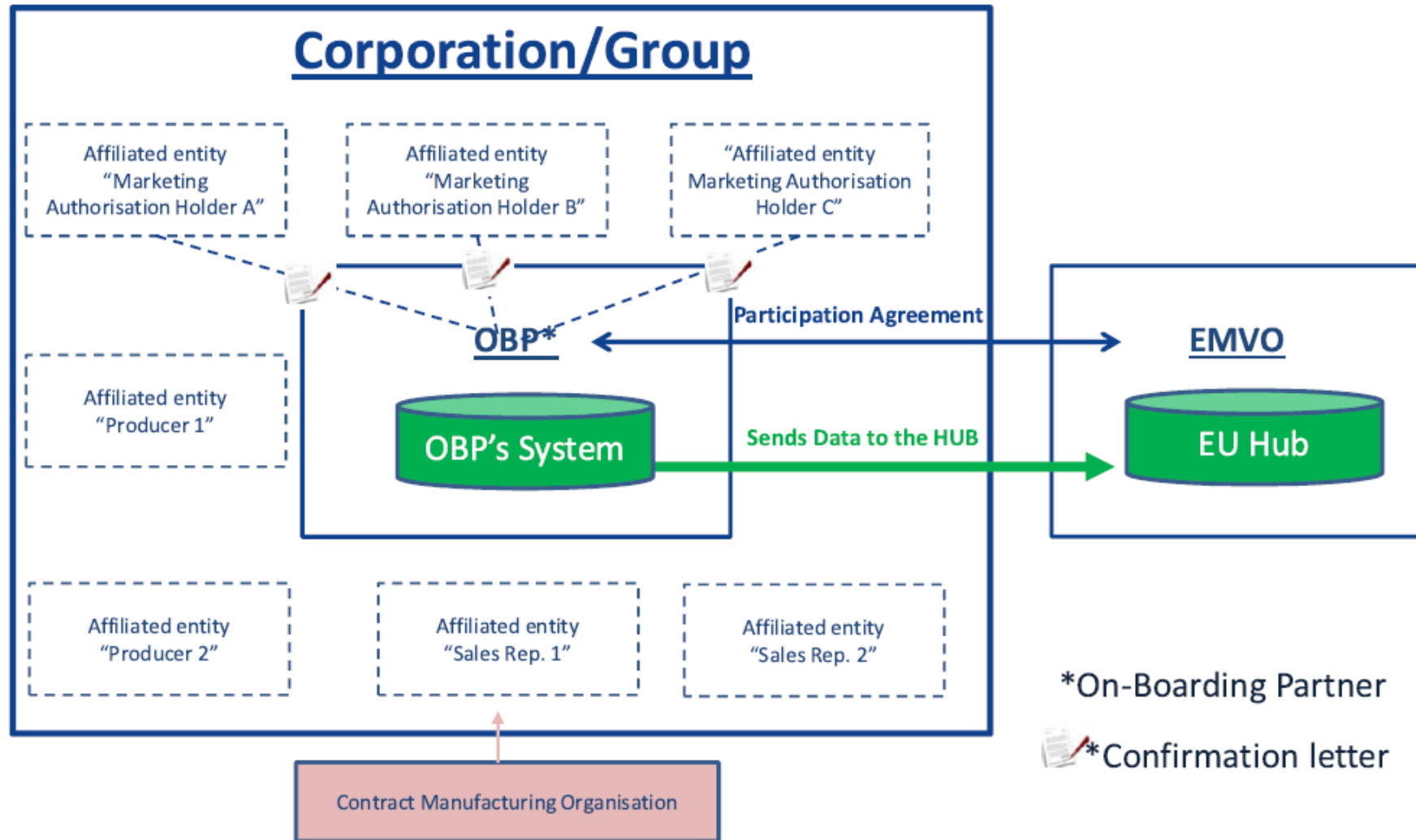
Držitel rozhodnutí o registraci

Marketing Authorisation Holder (MAH)



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# Relationship OBP\* and EMVO



# VÝROBCE – NUTNÉ KROKY

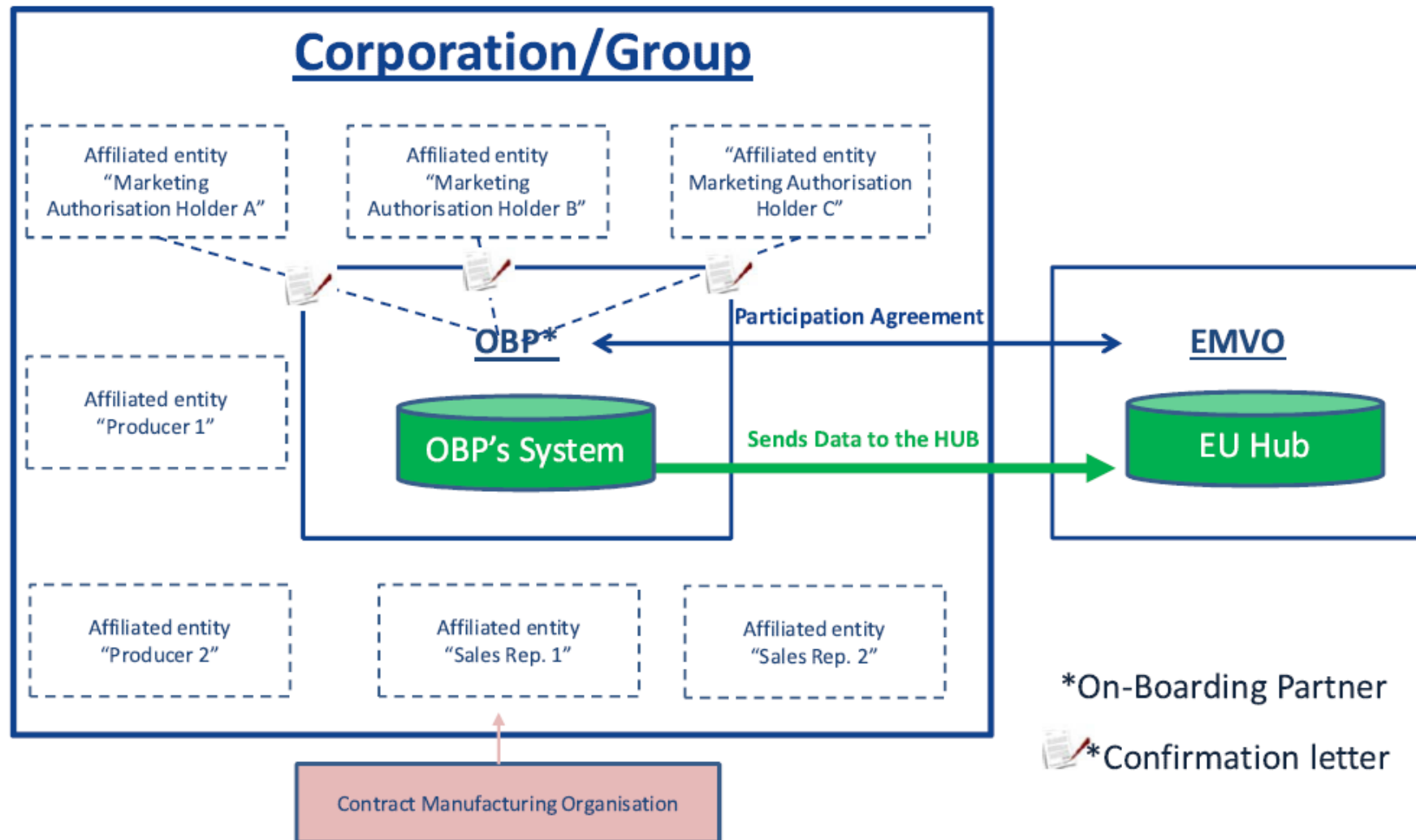
- Vybavení výrobní linky technologiemi pro OP
- Uvedení OP na obalech v souladu s registrací
- Připojení se na EU HUB (On-boarding)

## What is an “OBP”?

- OBP means On-Boarding Partner and is the contracting party of EMVO and concludes the non-disclosure agreement (NDA) and participation agreement (PA).
- The OBP is legally authorized to sign on behalf of a MAH/a group of MAHs.
- The OBP has to be affiliated (\*) to a MAH/a group of MAHs

(\*) 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).

# Relationship OBP\* and EMVO



# On-Boarding Process

*Managed and administered by EMVO's Commercial & Partner Management Team*

*Managed by EMVO's Operations Team*

**1) Participation Request**

- Initial Contact
- Portal registration
- Non-Disclosure Agreement (NDA)

**2) Legitimacy Check**

- Legitimacy check of organizations and person responsible
- Multi-stage procedure

**3) Contractual/ Commercial On-boarding**

- Participation Agreement (PA)
- On-boarding Fee payment

**4) Technical On-boarding**

- System Connection
- System Testing
- System Operation

# OBP Contracts with EMVO

## 1. Non-Disclosure Agreement (NDA)

- Covers **provision of Confidential Information** by EMVO, e.g. on
  - European Hub
  - Gateway
- Purpose: **Assessment of participation** in the EMVS project

## 2. Participation Agreement (PA)

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



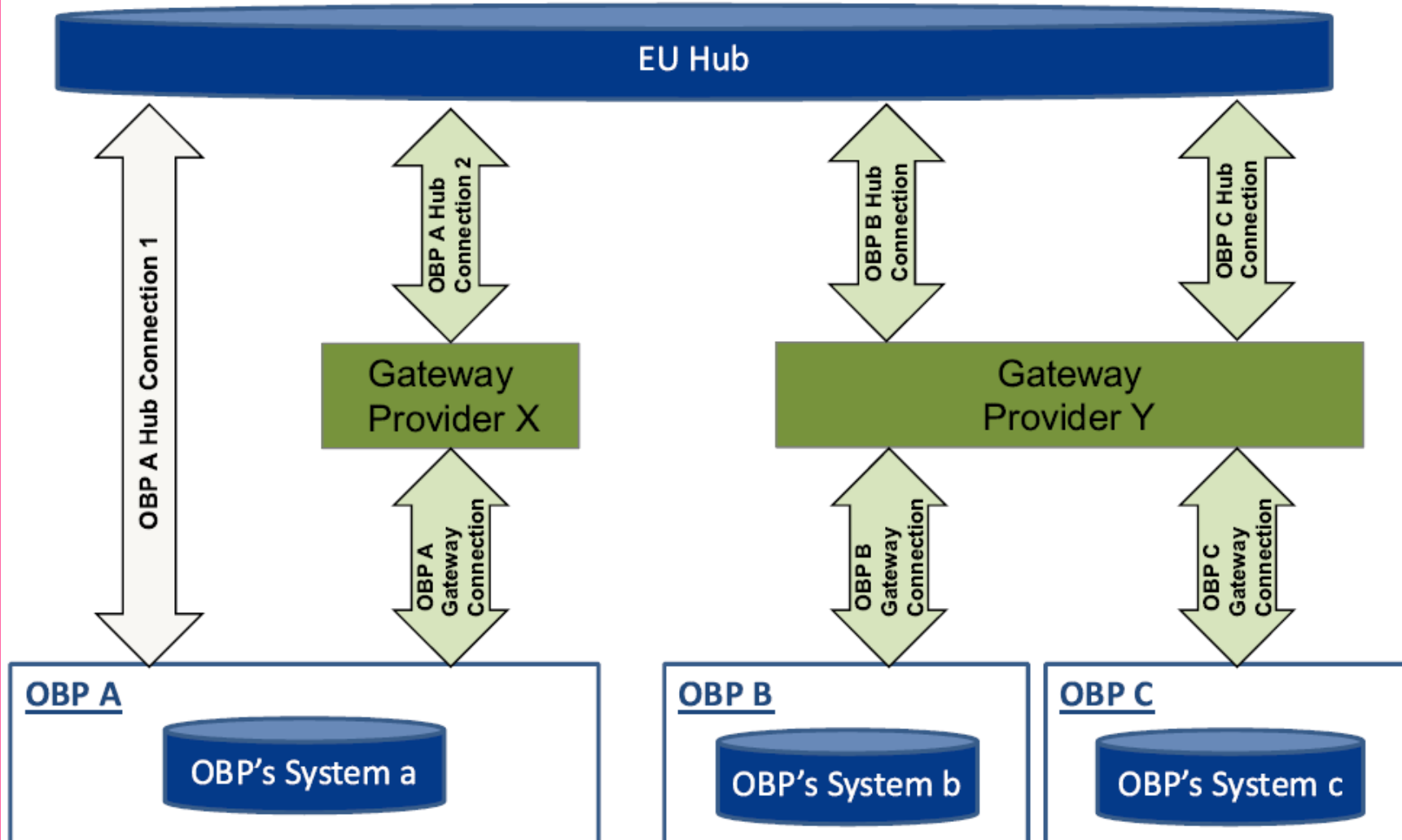
### One-Time Fee per OBP

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

## Technical On-boarding

- ❑ Starts when Participation Agreement is signed by EMVO
- ❑ OBPs will connect their system sequentially to:
  - the ITE environment to develop an interface
  - the IQE environment to certify the interface
  - The PRD environment to use the interface
- ❑ OBPs can choose to connect via
  - a Direct connection (data send from OBP's system straight to EU Hub)
  - a Gateway connection (Data sent first to a Gateway Provider. The Gateway Provider sends it through to the EU Hub)

# Connection Types





## OBP Portal

### Welcome to EMVO's On-boarding Partner Portal

In order to continue, you will need a valid email address. Once you complete the registration form, we'll send you an invitation email with instructions and next steps.

[Request to participate >](#)

**Děkuji za pozornost**