IDENTIFICATION & AUTHENTICATION OF MEDICINES IN EUROPE: “OPPORTUNITIES AND CHALLENGES TO COMPLY WITH EU LEGISLATION”

CHINA/EU PHARMACEUTICAL FORUM 2018
16TH APRIL 2018
BASEL, SWITZERLAND

Andreas Walter
(General Manager)
AGENDA

FMD/DR

EMVO/EMVS

Status Implementation

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

305:14:59:01
DAYS  HOURS  MINUTES  SECONDS
FMD LEGISLATION AND DELELEGATED ACT

- Connect approx. 2,291 companies to the EMVS
- Establish National Systems in 32 countries
- Connect many thousand Pharmacies and Wholesalers
- Serialise all affected pharmaceutical packs (10.5bn)
THE DELEGATED REGULATION MANDATES RULES FOR MEDICINES VERIFICATION

Serialization by manufacturer
Risk based verification by Wholesalers
Verification and check-out at point of dispense

Safety features:
Code ('unique identifier')
+ Tamper evidence

System set up and governed by manufacturers and marketing auth. holders in consultation with other stakeholders. Oversight by competent authorities

Product #: 09876543210982
S/N: 12345AZRQF1234567890
Batch: A1C2E3G4I5
Expiry: 140531
AGENDA

16th April 2018
EFPIA-CPIA WORKSHOP

FMD/DR

EMVO/EMVS

Status Implementation

Achievements & Challenges
SYSTEM LANDSCAPE
**SYSTEM LANDSCAPE**

**OBP**: On-boarding Partner

**NMVS**: National Medicines Verification System

**NMVO**: National Medicines Verification Organisation

- Marketing authorization holder(s) parallel activity
- System owner = OBP

**European Hub**

- **OBP Interface**
- **Nat. Blueprint Interface**

- **NMVS**
  - **NMVO**
  - **Pharm. Interf.**
  - **Wholes. Interf.**

- **Interface**
  - **Pharmacy System**
    - System owner = Pharmacist
  - **Wholesaler System**
    - System owner = Wholesaler

EFPIA-CPIA WORKSHOP

European Medicines Verification Organisation

NMVO: National Medicines Verification Organisation
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)

16th April 2018
EFPIA-CPIA WORKSHOP

Tel. Helpdesk
+372 611 90 44
FIRSYT LINE SUPPORT: EMVO SERVICE CENTRE (Tallinn)
Agenda

1. FMD/DR
2. EMVO/EMVS
3. Status Implementation
4. Achievements & Challenges
NMVO Incorporated (all stakeholders)
NMVO Incorporated (stakeholder missing)
No NMVO
Non EU Countries

16th April 2018
EFPIA-CPIA WORKSHOP
BLUEPRINT TENDENCY

16th April 2018
EFPIA-CPIA WORKSHOP
### DR-COMPLIANCE 02/2019: VERY LATE COUNTRIES

<table>
<thead>
<tr>
<th></th>
<th>Governance</th>
<th>Technical</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Align MoU Stat NMVO</td>
<td>PM ProvC ProvS Contr</td>
</tr>
<tr>
<td>13</td>
<td>Hungary</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Liechtenstein</td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Malta</td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>Poland</td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>Portugal</td>
<td></td>
</tr>
<tr>
<td>31</td>
<td>Switzerland</td>
<td></td>
</tr>
<tr>
<td>32</td>
<td>U. Kingdom</td>
<td></td>
</tr>
</tbody>
</table>

- **Align** = Stakeholder Alignment
- **MoU** = MoU signed
- **Stat** = NMVO Statutes signed
- **NMVO** = NMVO implemented
- **PM** = Project Manager assigned
- **ProvC** = Provider Contacts established
- **ProvS** = Provider selected
- **Contr** = Provider Contract signed

Green = Complete Stakeholder Participation

- **B** = Incomplete Stakeholder Participation

- **R**

Greece and Italy not heading for 2019

---

16th April 2018
EFPIA-CPIA WORKSHOP
Above Target

Below Target

Actual Target 100%

16th April 2018
EFPIA-CPIA WORKSHOP
SIGNED PARTICIPATION AGREEMENT BY OBP\s PER COUNTRY

Additional PA signed by OBP\s in non-european countries:

- 2 OBPs
- 2 OBPs
- 1 OBP
STATUS ON-BOARDING

Target figure: 2291

Number

0 100 200 300 400 500 600

Earlier May-17 Jun-17 Jul-17 Aug-17 Sep-17 Oct-17 Nov-17 Dec-17 Janv-18 Feb-18 Mar-18

Signed Participation Agreements Legitimacy check passed OBPs connected to Hub V2 (PRD)

16th April 2018 EFPIA-CPIA WORKSHOP
NMVS READINESS

16th April 2018
EFPIA-CPIA WORKSHOP
END USER READINESS

Not yet activated

Above Target
Below Target
AGENDA

FMD/DR

EMVO/EMVS

Status Implementation

Achievements & Challenges
CHALLENGES & ACHIEVEMENTS ON EUROPEAN LEVEL

Challenges

- Set-up EMVO & EU Hub
- NMVO incorporated & NMVS selected (provider contract signed)
- Connect approx. 2,291 On-boarding Partners (OBPs) to the EU Hub
- Connect 27 (+5) NMVS to the EU Hub

EU Hub:
- Cooperation Agreement (CA) signed
- NMVS assessments & technical on-boarding
- On-boarding/certification of connection providers

Achievements

- EMVO incorporated & EU Hub upgraded 2.0 (but limited resources)
- 29 NMVOs (>75%) founded,
- 30 countries choose Blueprint
- 656 OBPs in Portal, 545 PA signed, 13 in PRD. Scheduled: 1,900 end of Q4 2017
- 21 CA signed
- Only Germany connected to EU Hub (PRD)
CHALLENGES & ACHIEVEMENTS ON NATIONAL LEVEL: HOSPITALS

Limited knowledge of FMD in health (and social) care

Limited involvement of hospital expertise in NMVOs

Limited cross-information between MS on issues and solutions

Defining a communication strategy (including NCAs!) to increase awareness in member states at all levels

Defining a strategy to get the involvement of hospital expertise in NMVOs

Updating HOPE/EAHP mapping exercise with current situation including:
- Governance indicators
- Awareness indicators
- Technical indicators

NCAs/NMVOs TO ACT

- Collecting of case studies/ national pilots;
- Gathering a consensus on issues and solutions
CHALLENGES & ACHIEVEMENTS ON NATIONAL LEVEL: INVOLVEMENT NCAs

Challenges:

- NCAs in several countries not involved reg. operations (awareness raising of end users and national manufacturers/MAHs)
- Nearly no support of NCAs reg. hospital integration in almost all countries (ownership, budgeting, awareness, etc.)
- Access to data by NCAs: Extended reporting requested

Achievements:

- Slow progress and low feedback (despite EMVO circular)
- No progress or feedback (despite EMVO circular)
- Constructive dialogue NCAs (WG II)/EMVO in order to harmonise access to data/reporting throughout Europe. Common position possible.

NCAs/EMVO/NMVOs TO ACT

16th April 2018
EFPIA-CPIA WORKSHOP
CONCLUSION: EUROPE CAN BE READY, IF…..

There is strong involvement, commitment and cooperation of all supply chain stakeholders on European and national level: It is a European, not only a national project!

NCAs play their role: Raising awareness, supporting the implementation process, hospitals, coding requirements, voluntary use of the safety features, regulatory pathway to implement the Safety Features, art work requirements, etc. Without support, the timely implementation could be at risk!

COM supports the implementation process and clarifies the legislation (awareness, Q&A, etc.)
o EMVO Website
  • Process Description for Pharmaceutical Companies & OBP Portal
    https://emvo-medicines.eu/pharmaceutical-companies/
  • Knowledge Database & Documents Overview

o Documentation
  • On-boarding Checklist
    https://youtu.be/SvmHYSEOBdI
  • Presentation, Guideline, Master Data Guide