Pharmacovigilance

FAMHP

BRUSSELS

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Els Dewaele

famhp

federal agency for medicines and health products

.be

Content

- Introduction
- Actors with pharmacovigilance requirements
- Pharmacovigilance process
- Databases
- Adverse Events (AEs)
- Signal Management (SD)
- Pharmacovigilance systems: PSMF
- Parallel trade in VMPs

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Recitals referring to pharmacovigilance

Recital 21 – Pharmacovigilance as new task for CMDv

Recital 29 – Public Access to information (e.g. pharmacovigilance database)

Recital 38 – Unlimited period of time for MAA → renewal only by exception

Recital 55 – Pharmacovigilance rules are necessary for protection of public and animal health and environment. Collection of information on AE should contribute to good VMP use

Recital 56 – Environmental incidents after administration to an animal = AE

Recital 57 – CA, Agency and MAH should encourage and facilitate reporting of AE + facilitate feedback

Recital 58 – Measures to improve operation of Ph Vig system → consistent system, but consider changes due to definition, terminology, technology

Recitals referring to pharmacovigilance

Recital 59 – MAH responsible for continuous Ph Vig. Collect AE report for their VMPs, including outside MA

Recital 60 – Increase shared use of resources among authorities and enhance efficiency of Ph Vig system. Data collected to single reporting point

Recital 61 – Possibility to impose PA study obligation

Recital 62 – EU Ph Vig DB → improve detection of AE, facilitate Ph Vig surveillance and worksharing.
Exchange with national DB

Recital 63 – Procedures comply with measures in GVP.
Signal management is "gold standard"

Chapter IV: Post marketing authorisation measures/section 5

Article 73 – Union pharmacovigilance system

Article 74 – Union pharmacovigilance database

Article 75 – Access to the pharmacovigilance database

Article 76 – Reporting and recording of suspected adverse events

Article 77 – Pharmacovigilance responsibilities of the marketing authorisation holder

Article 78 – Qualified person responsible for pharmacovigilance

Article 79 – Pharmacovigilance responsibilities of competent authorities and the EMA

Article 80 – Delegation of tasks by competent authority

Article 81 – Signal management process

→ **Implementing acts on good pharmacovigilance practices + PSMF(art.77(6))**

Other articles including Ph Vig

Article 5 - Definitions

Article 8 - Data to be submitted with the application

Article 102 - Parallel trade in veterinary medicinal products

Article 126 - Pharmacovigilance inspections

Article 130 - Suspending, revoking, or varying the terms, of marketing authorisations

Article 139 - CVMP

5: The Committee shall establish a standing working party for pharmacovigilance with a remit including evaluating potential signals in pharmacovigilance arising from the Union pharmacovigilance system proposing the options for risk management referred to in Article 79 to the Committee and to the coordination group, and coordinating the communication about pharmacovigilance between the competent authorities and the Agency.

Article 144 - Tasks of the coordination group

Article 154 - Establishing the pharmacovigilance database and manufacturing and wholesale distribution database

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Actors with Ph Vig requirements

1. Agency (EMA)
2. National Competent Authority
3. MAH of a VMP
4. Registration holder of a homeopathic VMP (Art.2,5)
5. Parallel trader: wholesale distributor (Art.102,6)
6. (Vet/health care professional) → Specific requirements by CA possible (Art.79.2)

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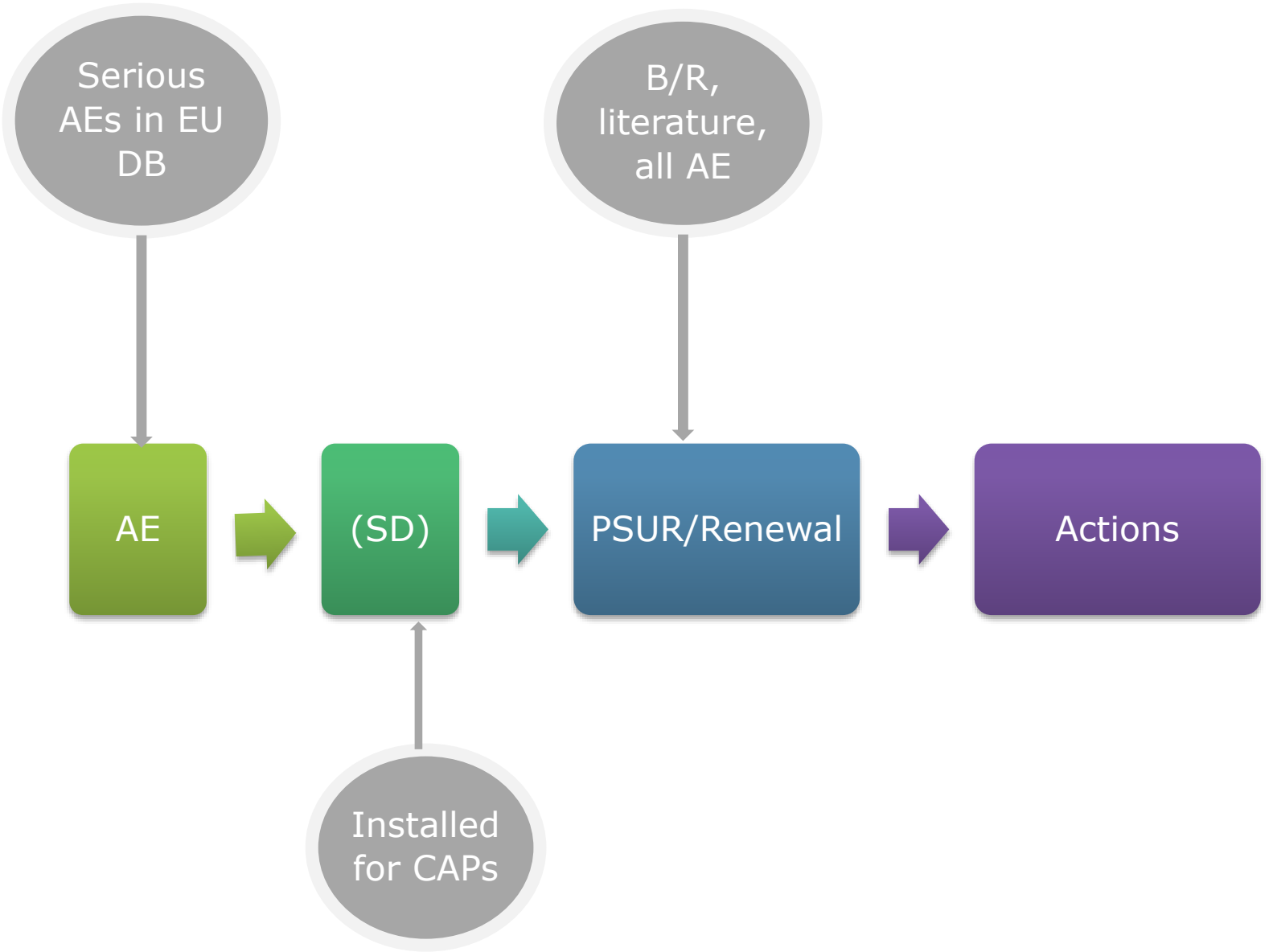
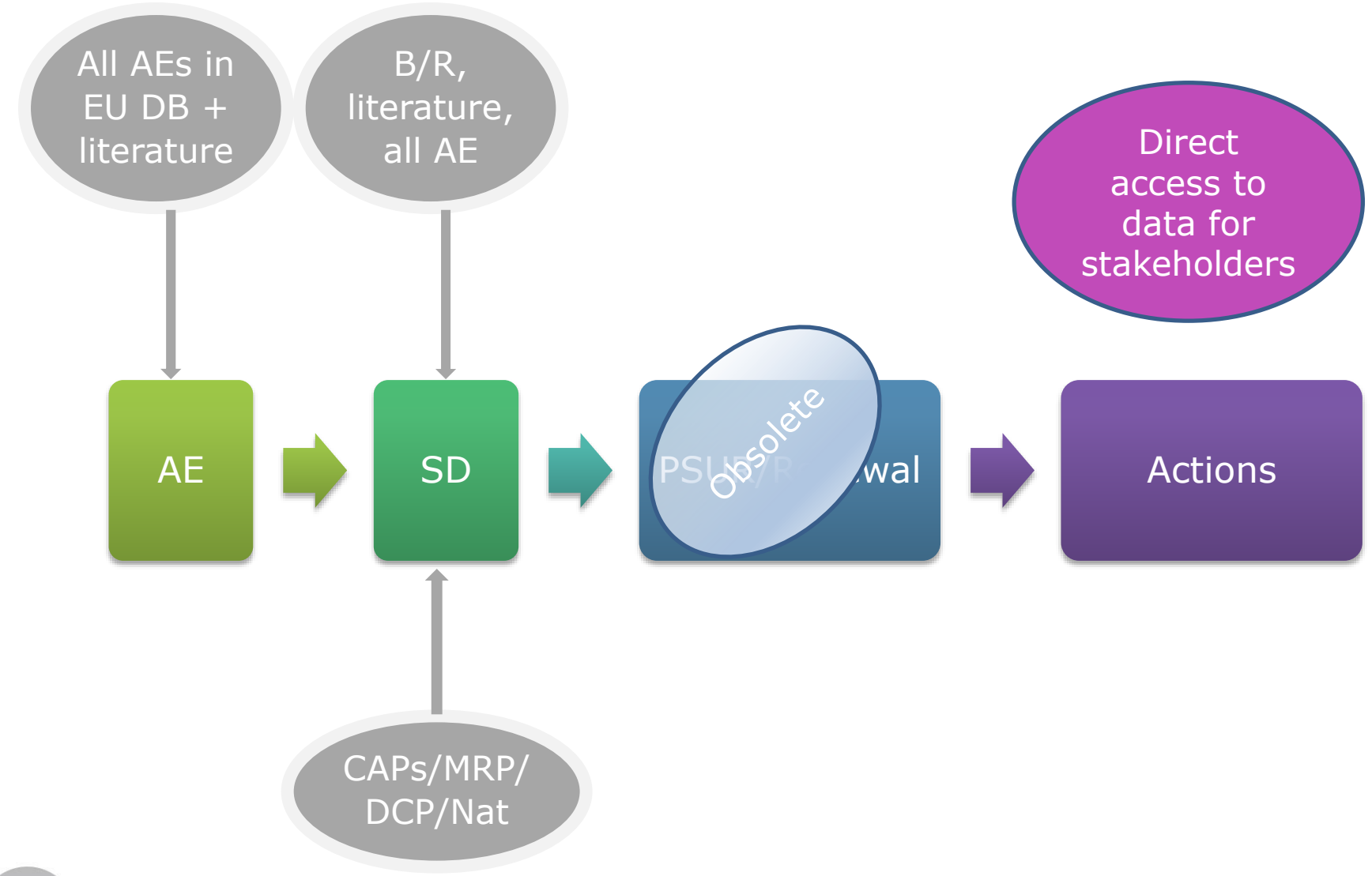
As is process of AEs



To be process of AEs



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Pharmacovigilance database (Art. 74 and 75)

Content

Reporting and recording suspected AE by CAs and MAHs

Information on QPPV

Reference number of PSMF

Results and outcomes of signal detection

Results of inspection

Functionality

Interconnected with product database

Functional specifications by Agency with CAs and Commission

Set up as a data-processing network with transmission of information (CAs, EMA, Commission, MAHs)

Access

Full access regulatory agencies

Access to their products for MAHs + non confidential information on other VMPs

Public access

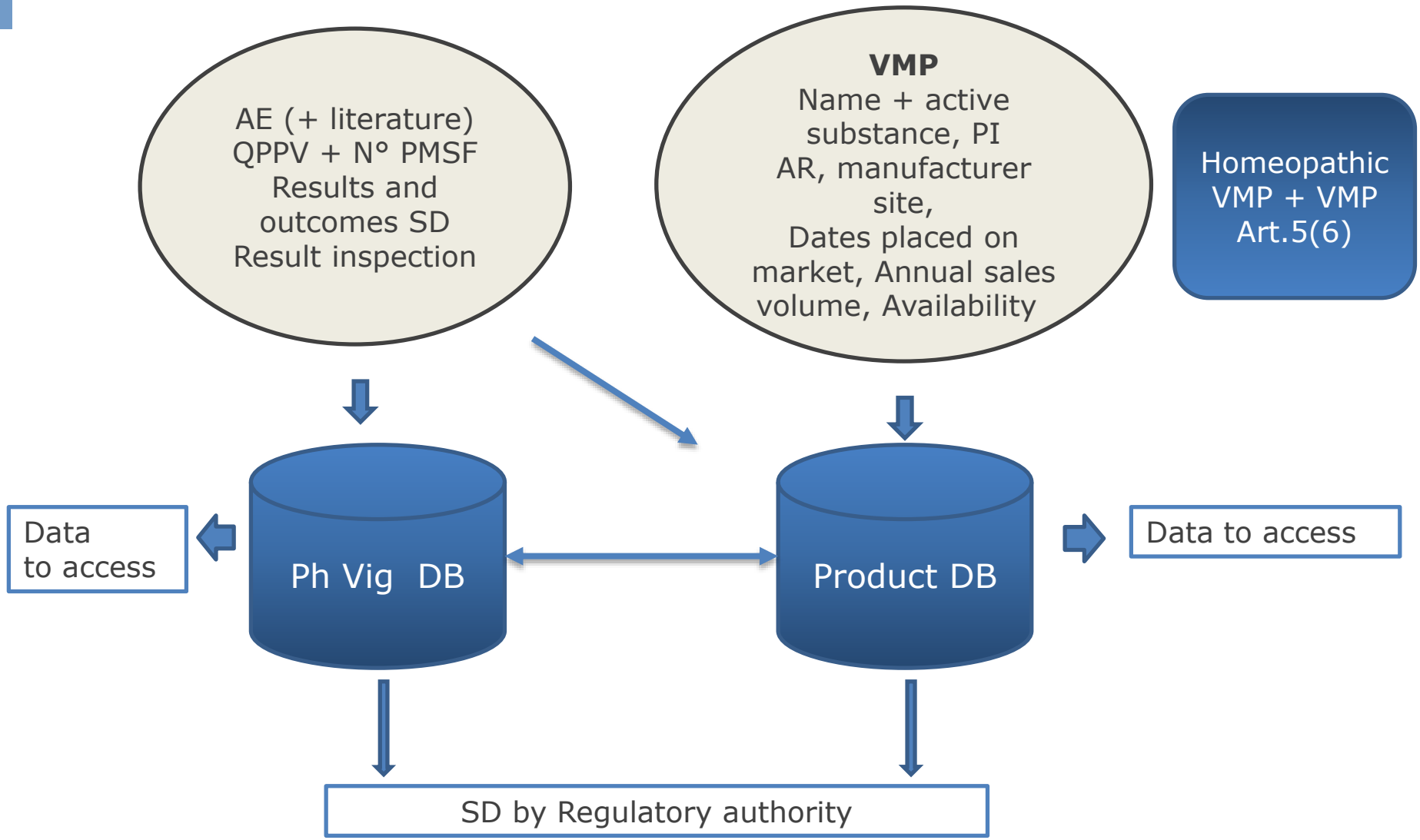
Number and Incidence broken down (2 years after application)

* By product
* By animal species
* By type of suspected adverse event

Results and outcomes of signal detection

* By MAHs
* For products or group of products

Pharmacovigilance Database



Question time

- Which way of providing sales would be preferable?

1. Once a year for all products. Asking additional data (e.g. Ph Vig) over the year?
2. Providing sales with DLP set for SM?
3. No preference

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AEs (Art. 76)

- Same objective and general scope for notification
- CA/MAH record all AEs reported to **them** in 30 days
- For MAH: reported AE that occurred in EU/3rd country or published in the **scientific literature** with regard to their authorised VMP
- All AEs = serious/non serious VMPs, animals reacting on MPs of human use
- CA/Agency can request to collect specific Ph Vig data or a post-marketing surveillance study
- In Ph Vig database

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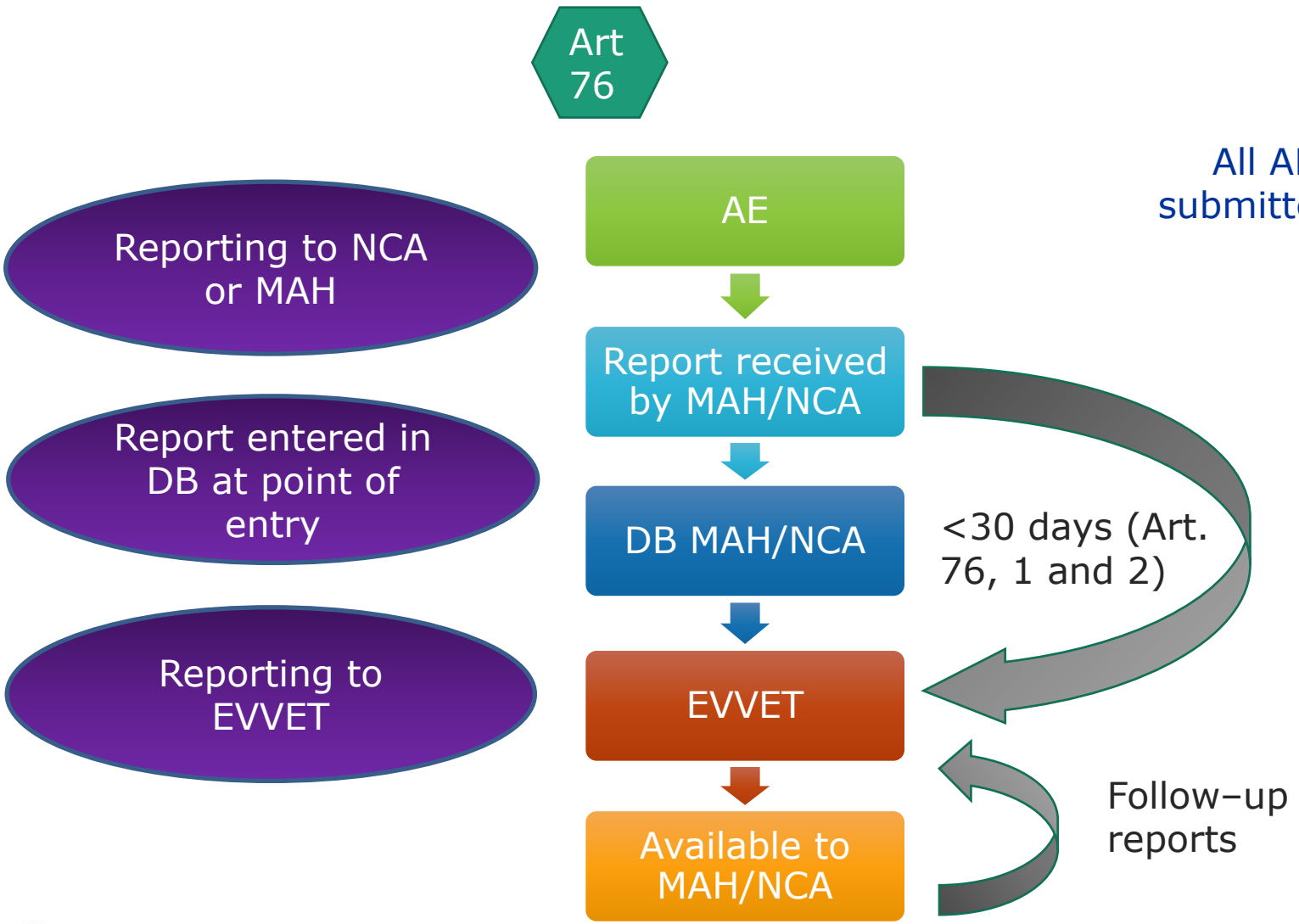
Handling of AEs today

- EVVET 2: maintenance
- Practices on coding (causality, VeDDRA) → assure quality!!!

For MAH

- Serious AEs in animals + all human ARs in the EEA to be reported by MAH within 15 days to NCA where AE occurred
- Serious and unexpected AEs in animals, all human ARs, suspected transmission of an infectious agent from third country to be reported by MAH within 15 days to EVVET DB
- Non serious EU AEs: included in PSUR. Some MAHs already send all their non-serious AEs to DB

Adverse Event (AE) process



All AEs will be submitted to EVVET

Question time

- Which action would reduce administrative burden the most in reporting of AEs by MAHs? Pick only one.

1. Simplified tool for reporting
2. Minimise certain coding practices
3. Reduction in number of follow-ups

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Signal Management (SD) (Art. 81)

MAH

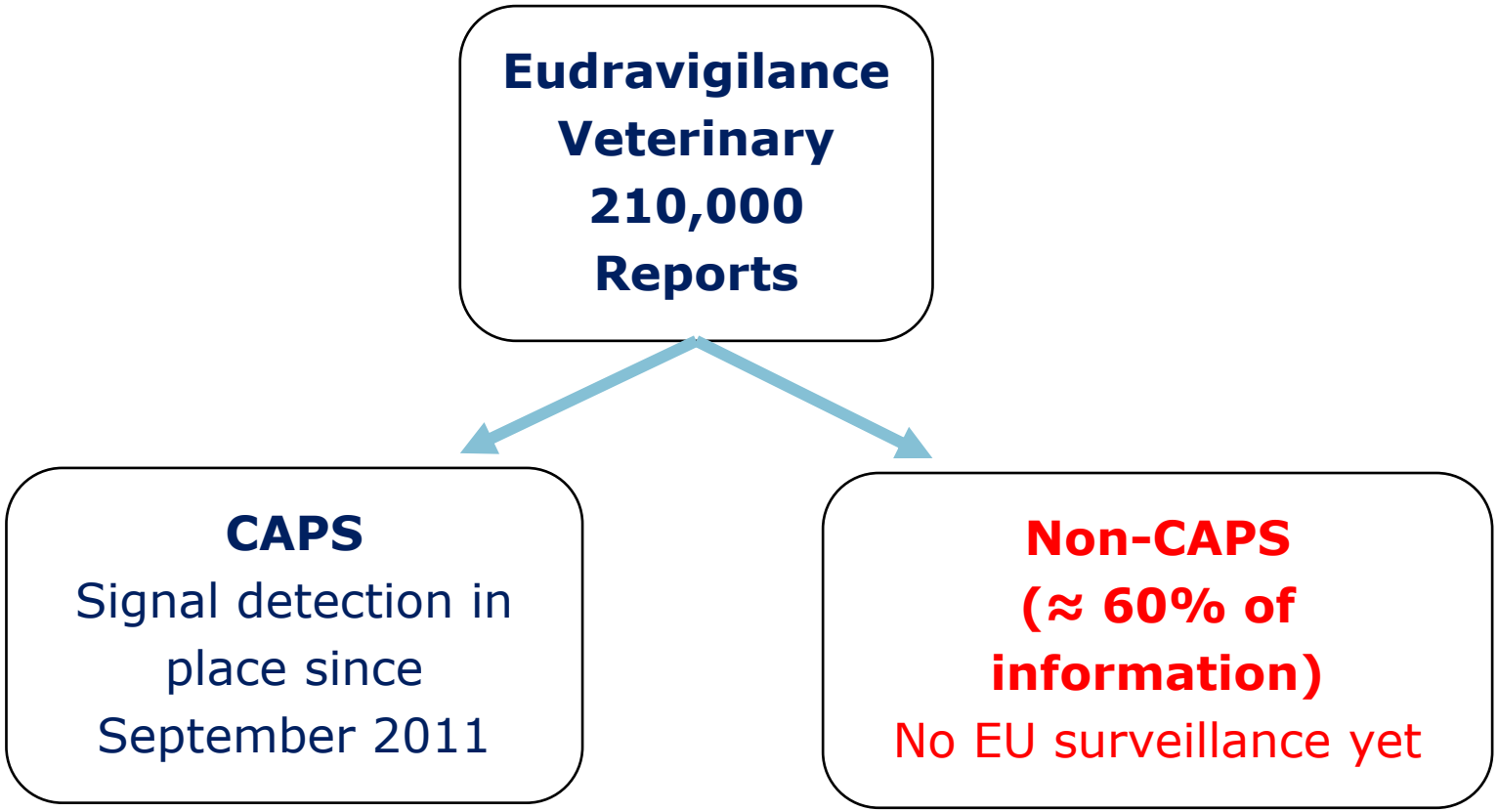
1. Perform SD + sales, literature, other Ph Vig data
2. Change in B/R or new risk → notify CA/Agency without delay (≤ 30 days) + take action
3. To record results and outcomes in Ph Vig DB at least annually

Signal Management (SD) (Art. 81)

CA/Agency

1. Decide on targeted signal management process on VMP/group of VMPs
2. Agency and coordination group shall share tasks + select a lead authority
3. In case of follow-up action → take appropriate measures

Signal Management today



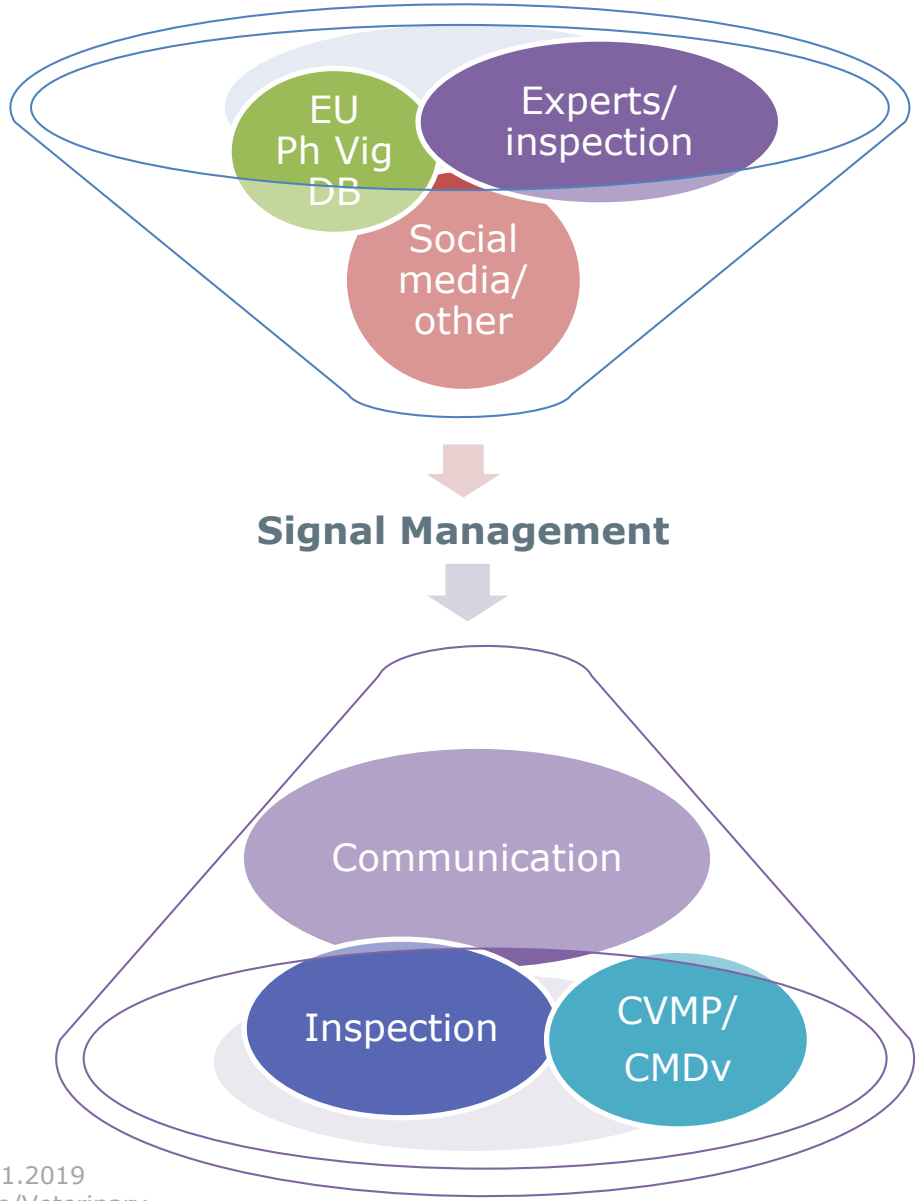
EMA - 2017

Signal Management today

- Procedure for CAPs
- Every 6 months/yearly
- Detecting and evaluation of signals
- In preparation of PSUR/requiring specific Ph Vig points to MAH
- Discussed in the Ph Vig WP → reported to CVMP
- NUI/RA for National products
- Signal management by MAHs = outcome?

Signal Management

To consider:



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PSMF (Art. 8)

- Summary of PSMF in MAA

PSMF (Art. 77)

For MAH

1. One or more PSMFs: 1 PSMF/VMP
2. Responsible for Ph Vig of their products + continuous evaluate B/R
3. Comply with Good Ph Vig Practices
4. Ph Vig tasks /QPPV contracted out by MAH → in PSMF
5. One or more QPPVs → Only 1 QPPV designated for every PSMF

PSMF (Art. 78)

For QPPV

1. Elaborating and maintaining PSMF
2. Allocate reference number to PSMF and communicate to Ph Vig DB for every product
3. Notify CA/Agency of place of operation
4. Monitoring the Ph Vig system and ensure CAPA
5. Contact point for Ph Vig inspection

PSMF (Art. 79 and 126)

For CA/Agency

1. CA verify by control and inspection Ph Vig compliance
2. Request at any time PSMF → to be given in 7days

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3. To check PSMF and Ph Vig system correctly applied
4. Carry out/coordinate inspections on Ph Vig system
5. Inspection by CA where PSMF is located
6. Worksharing possible
7. Result of Ph Vig inspection in Ph Vig DB

Ph Vig System today

- Ph Vig system described in the DDPS
- DPPS to be provided during each MAA (and Variations)
- DDPS can contain a product specific addendum
- Checked during inspection

Ph Vig System today

- To be considered a living, evolving document!
- Change triggers variations for all products
- Inspection planning

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Parallel trade in VMPs (Art. 102, 6)

Obligations of every wholesaler-distributor to parallel trade:

a) Submit a declaration to CA in the destination member state and take appropriate measures to ensure that the wholesale distributor in the source member state will keep it informed of any pharmacovigilance issues

e) Collect AEs and report them to the MAH of the parallel-traded VMP

Thank you for your attention.
Any question?

"Now! *That* should clear up
a few things around here!"

Contact

Federal Agency for Medicines and Health Products – FAMHP

Victor Hortaplein - Place Victor Horta 40/40
1060 BRUSSELS

tel. + 32 2 528 40 00
fax + 32 2 528 40 01
e-mail welcome@fagg-afmps.be

www.famhp.be

Follow the FAMHP on Facebook, Twitter and LinkedIn

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