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How implementation of the VMP regulation strengthens the European Medicine Regulatory Network ?

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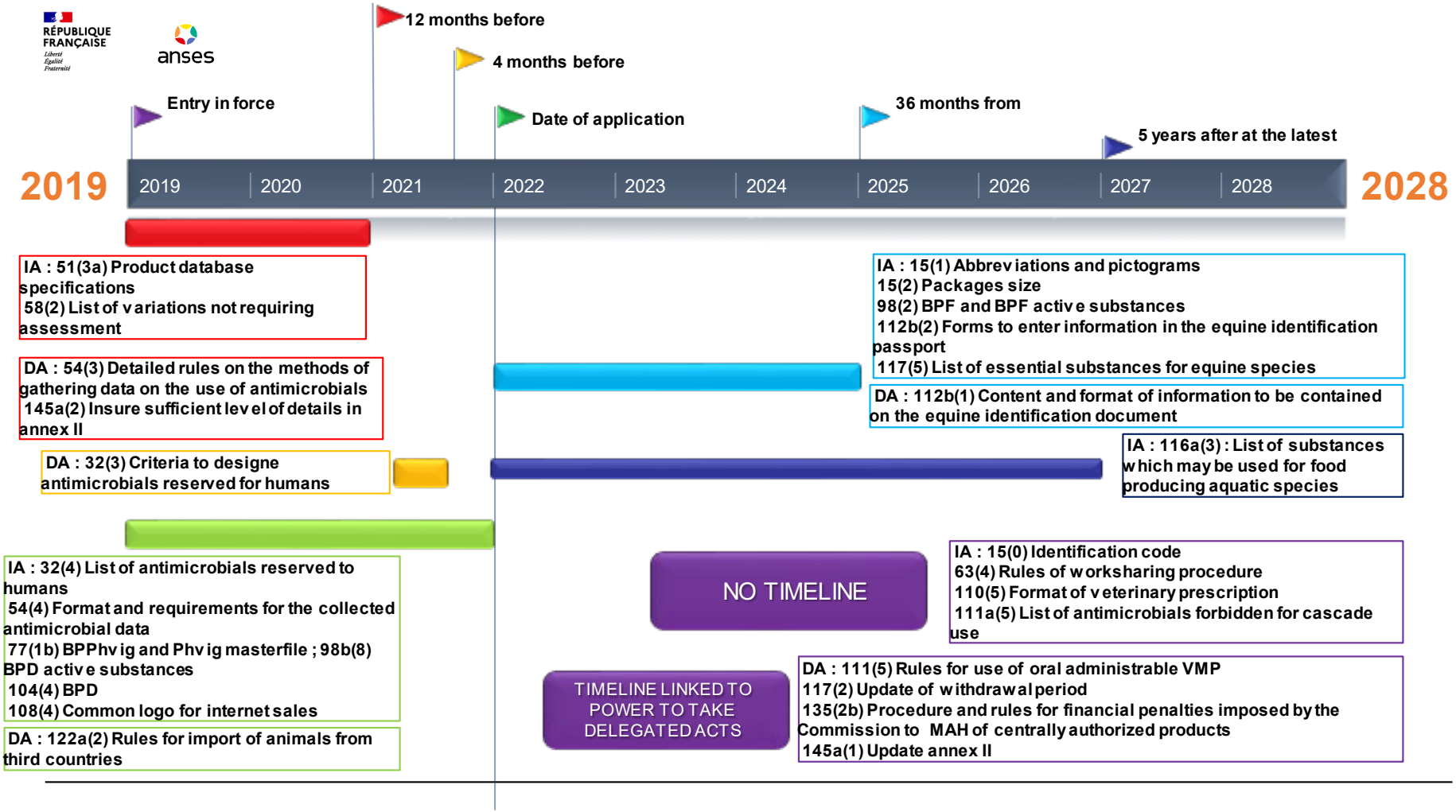
1. R2019/6 entered into force on 28/01/2019 : a real challenge

HMA Task Force for Coordination of Implementation of Vet regulation : TFCIVR

- Entered into application on 28/01/2019 : a **lot of challenges to face** in just 3 years in complex context : BREXIT and then COVID 19
- **Numerous DA and IA to adopt following a strict timeline :** 13 before 28/01/2022
- **Several databases to be developped**
  - 4 databases / UPD, EVVET3, MWD, ASU
  - No HR nor budget identified at the beginning
  - Take into consideration human databases : Product database based on SPOR and Lessons learned from CTIS development
- **New process to be developped :**
  - Signal detection
  - Harmonisation of SPC
  - Exceptionnal circumstances and limited market
  - VNRA directly managed in UPD
  - Novel therapies ….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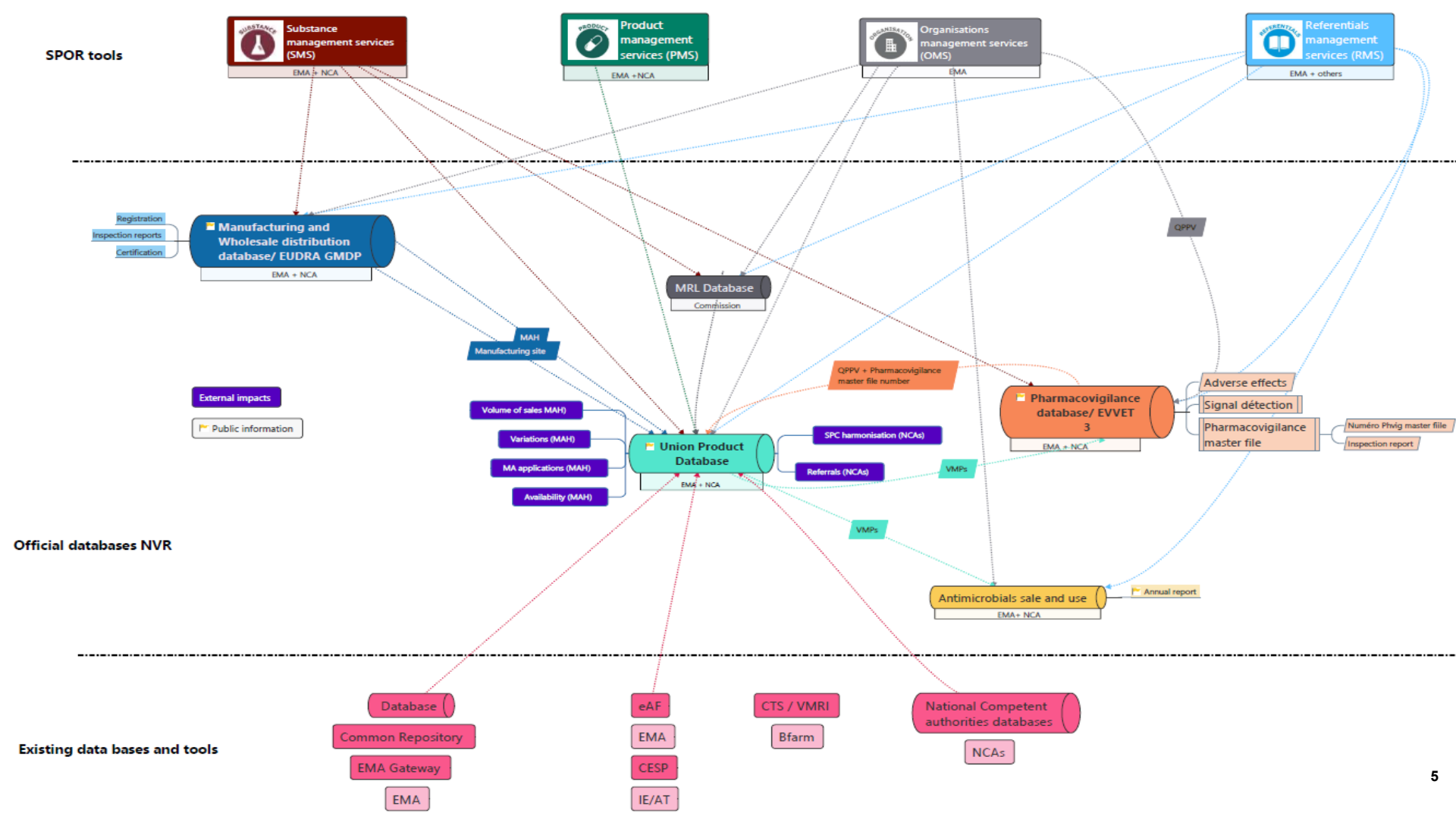
anses
12 months before
4 months before
Entry in force
Date of application
36 months from
5 years after at the latest
2019
2019
2020
2021
2022
2023
2024
2025
2026
2027
2028
2028
IA : 51(3a) Product database specifications
58(2) List of variations not requiring assessment
IA : 15(1) Abbreviations and pictograms
15(2) Packages size
98(2) BPF and BPF active substances
112b(2) Forms to enter information in the equine identification passport
117(5) List of essential substances for equine species
DA : 54(3) Detailed rules on the methods of gathering data on the use of antimicrobials
145a(2) Insure sufficient level of details in annex II
DA : 112b(1) Content and format of information to be contained on the equine identification document
DA : 32(3) Criteria to designe antimicrobials reserved for humans
IA : 116a(3) : List of substances which may be used for food producing aquatic species
IA : 32(4) List of antimicrobials reserved to humans
54(4) Format and requirements for the collected antimicrobial data
77(1b) BPPhvig and Phvig masterfile ; 98b(8) BPD active substances
104(4) BPD
108(4) Common logo for internet sales
NO TIMELINE
IA : 15(0) Identification code
63(4) Rules of worksharing procedure
110(5) Format of veterinary prescription
111a(5) List of antimicrobials forbidden for cascade use
DA : 122a(2) Rules for import of animals from third countries
TIMELINE LINKED TO POWER TO TAKE DELEGATED ACTS
DA : 111(5) Rules for use of oral administrable VMP
117(2) Update of withdrawal period
135(2b) Procedure and rules for financial penalties imposed by the Commission to MAH of centrally authorized products
145a(1) Update annex II


SPOR tools
Substance management services (SMS)
EMA + NCA
Product management services (PMS)
EMA +NCA
Organisations management services (OMS)
EMA
Referentials management services (RMS)
EMA + others
Registration
Inspection reports
Certification
Manufacturing and Wholesale distribution database/ EUDRA GMDP
EMA + NCA
MRL Database
Commission
QPPV
MAH
Manufacturing site
External impacts
Public information
Volume of sales MAH)
Variations (MAH)
MA applications (MAH)
Availability (MAH)
Union Product Database
EMA + NCA
QPPV + Pharmacovigilance master file number
SPC harmonisation (NCAs)
Referrals (NCAs)
VMPs
Pharmacovigilance database/ EVVET 3
EMA + NCA
Adverse effects
Signal détection
Pharmacovigilance master file
Numéro Phvig master fille
Inspection report
VMPs
Antimicrobials sale and use
EMA+ NCA
Annual report
Official databases NVR
Existing data bases and tools
Database
Common Repository
EMA Gateway
EMA
eAF
EMA
CESP
IE/AT
CTS / VMRI
Bfarm
National Competent authorities databases
NCAs

Databases

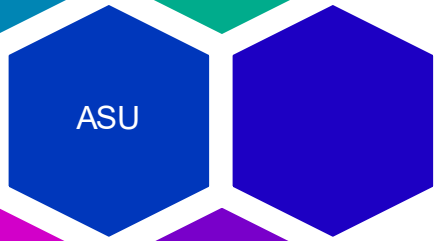
- Project Group
- Product Owner Group → Test
- Adaptation of national DB

Manufacture and Wholesale Distributors database

Wholesale Manufacturers and Distributors Database

Antimicrobial sales and use database

Collection of Antimicrobial Sales and Use data



Union Product Database

Database of veterinary medicinal products

Database on Pharmacovigilance of Veterinary Medicinal Products

Union Pharmacovigilance Database

2. Involvement of the network : TFCIVR and CMDv

HMA Task Force for the Coordination of the Implementation of Veterinary Regulation (TF CIVR)

- Mandate adopted in **June 2018** during 92nd HMA Meeting at Sofia (BG)
- 1st meeting in **September 2018** at Maisons –Alfort (FR),

- Task force within the Network of Heads of Agency (HMA) with the European Commission and EMA
- Discussion forum to make recommendations on common principles for the implementation of the new Regulation for delegated acts and enforcement in the areas of competence of the network of agencies
- Propose common designs via questionnaires circulated to CMDv
- Provide strategic guidance for the development of IT systems
- Prepare a mapping of network activities needed to implement the new Regulation
- Coordinate the work and timetable of all groups in the network and follow up on their action
- Be a force of proposals and develop EU Network Training content

HMA Task Force for Coordination of Implementation of Vet regulation : TFCIVR

- **Composition : → co-chairing HMA/EMA**
  - **All NCAs**
  - EMA representative
  - Commission representative

- **TC or F2F meeting** every 2-3 months depending of the progress of the work
  - 22 meetings since September 2018
  - In 2020, launch of Change Management meeting : 6 meetings
  - Dedicated meeting : IT, Pharmacovigilance (P-SMEG)…

- **Main discussion – common agenda :**
  - Impact of COVID : impact on NCAs.
  - Update from EMA on preparation of advices
  - Update from EC on the implemented/delegated acts : follow up of the packages
  - CMDv Report : feedback from the Legislation working group
  - Update on the work of EMA / CVMP / CMDv NVR Coordination Group
  - Update on VMP-Reg implementation programme : UPD, EVVET3, MWD, ASU
  - NCA Concerns

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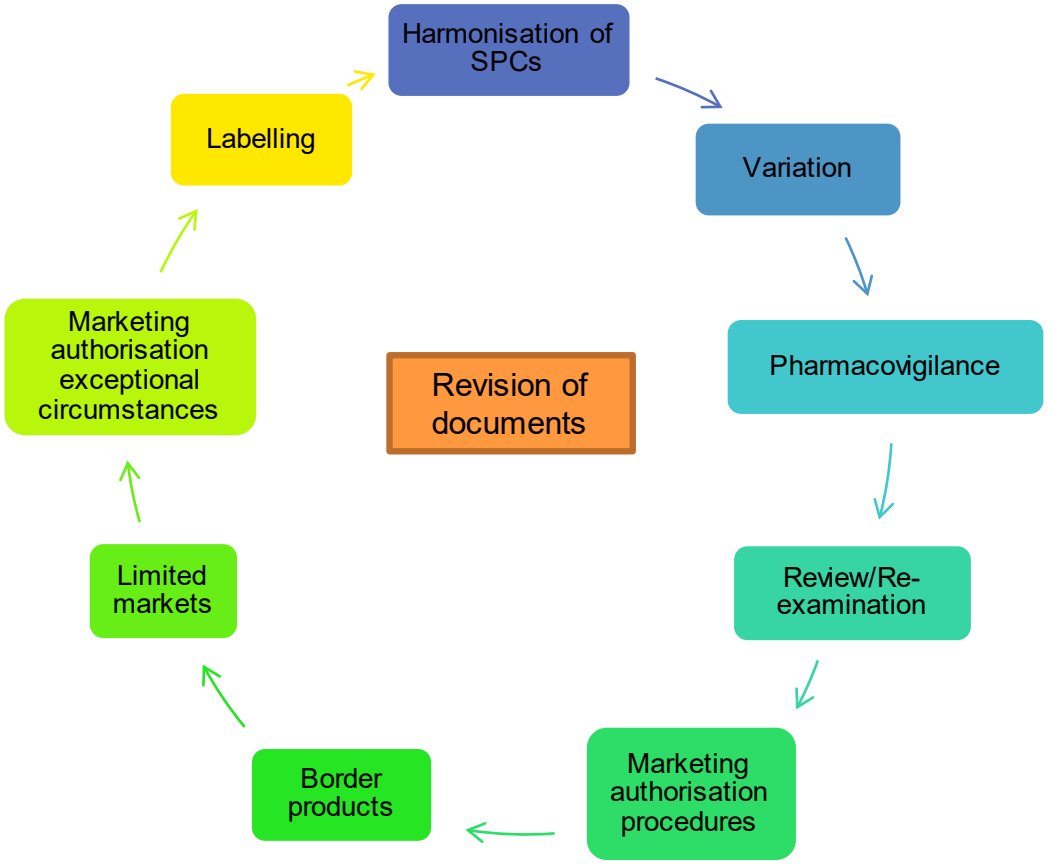
CMDv

Coordination Group for Mutual Recognition and Decentralised Procedures for Veterinary Medicinal Products

Implementation of the Regulation (EU) 2019/6 by National Competent Authorities : how the CMDv helped the network ?

CMDv Legislation working group

- WG EMA/CVMP with CMDv representatives
- EMA CVMP CMDv coordination group
- Collaboration with EMA on QRD templates
- Collaboration with CMDh for joint documents (ex: ASMF, variations…)
- Exchanges with EDQM and EMA for updating RMS/SPOR lists



- Public Consultation Organised for public documents
- A lot of questionnaires exchanged within CMDv to collect NCA's view on the implementation of specific articles
- Numerous exchanges with the European Commission : 31 letters Q&A exchanged

Update of CMDv documents

Objectives:

- Update existing guidance/templates taking into account the Regulation 2019/6/EC and its DA and IA.
- Drafting guidance/templates for new CMDv procedures/responsabilites

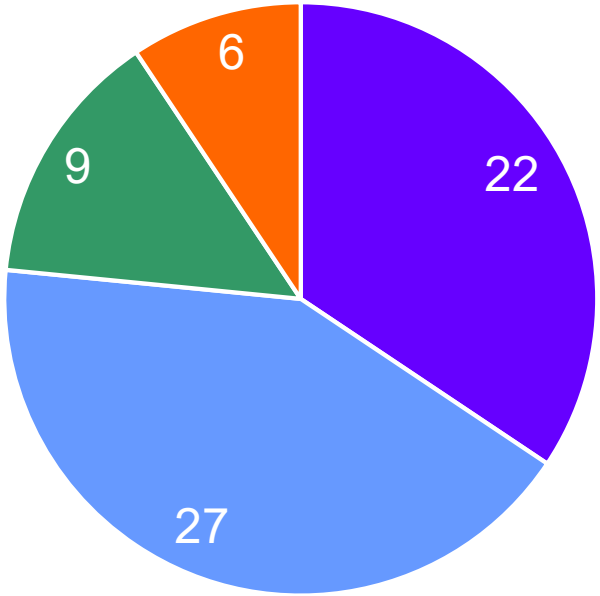
Dependencies:

- Commission interpretation of the legislation
- Some documents are applicable to NP/MRP/DCP and CP -> link with EMA (e.g. variations)
- Procedures with interactions with other groups (e.g. Pharmacovigilance)
- Impact on existing IT Tools (CTS) and dependency on development of new IT tools (UPD)
- Public consultations for BPGs/requests form industry to be involved

Impact:

- Almost all existing documents need to be amended
- Complete revision structure/content CMDv website
- Workload on rapporteurs/co-rapporteurs/CMDv members for revision!

Update of CMDv documents



- Best Practice Guides
- Guidance Documents/Position Paper
- SOP/SMP/ROP
- Other documents

3. Conclusion and next steps

Next steps for CMDv

All (nearly) documents are updated – but still a lot to do.

New tasks for CMDv :

- SPC harmonisation,
- New tasks in relation to pharmacovigilance,
- Recommendation on the classification of borderline products.

Update of new documents according to knowledge acquired : variations for instance.

UDP : learn to work with EU databases, improve handling MA procedures (including variations), publication of documents… according to business requirements.

Next steps for the network

- Excellent results obtained thanks to a good collaboration
- TFCIVR mandate extended to the end of 2022 → evolution for a permanent EMA-HMA WG – identified need to maintain a place for discussion
- Lots of work to finalize : DA and IA, GLs, report from the Commission…
- New process to be launched or to improve : signal management, harmonisation of SPC…
- Confident in the future success but still need an important involvement from all NCAs
- A milestone point would be useful in few years to assess the achievement of the objectives of the veterinary regulation, particularly on availability, reduction of administrative burden , fight against antimicrobial resistance

EMAN at Saint Malo