



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Submission of legacy data - Veterinary

June 2018



- Conclusions below reviewed and agreed at Vet expert group, PMS workshop, EUNDB
- **1st Conclusion:** NCAs to send legacy data to populate PMS, so no migration from EudraPharm to PMS
=> However, until PMS operational, Eudrapharm still in use and NCAs to still send data for Pharmacovigilance purpose.
- **2nd Conclusion:**
- Minimum set of core **mandatory** fields taken from vet use cases identified, Recommended to be used by NCAs to map legacy data (Pending NVR relevant implementing acts) **Please start mapping R&O for these fields in local database** (of course more fields can be submitted if they are available, + SmPC)
- Note: for new data, more mandatory fields should be expected, but no more than what currently required from eAF
- Other essential data (QPPV, Master file, sales related info) to be submitted later
- Note: **NS** – non standardised data (free text field)
- **S** – standardised, i.e. mapped against OMS/RMS and coded

What mandatory fields?



	PMS Iteration 1	Use cases data fields	Core data set
Medicinal Product	Name (Med. Product)	Full presentation name	NS
Medicinal Product	Invented Name Part	Product short name	NS
Medicinal Product	Classification System	ATC vet code	S
Medicinal Product	Classification System	Legal basis	S
Medicinal Product	Classification System Value	ATC vet code	S
Authorization	Marketing Authorisation Number	Authorisation number	NS
Authorization	Country	Authorisation country	S
Authorization	Legal Status of Supply	Legal Status	S
Authorization	Authorisation Status	Authorisation status	S
Authorization	Date of First Authorisation	Date	S
Authorization	Procedure Identifier/Number (e.g. MRP number)	Procedure number	NS
Authorization	Procedure Type (e.g. MRP/DCP)	Authorisation procedure	S
Pharmaceutical Product and Device	Administrable Dose Form	Dosage form	S
Pharmaceutical Product and Device	Route of Administration	Route of administration	S
Substance	Substance	Active Substance	S
Substance	Strength Range (Presentation)	Strength value + Unit	NS / S
Substance	Strength Range (Concentration)	Strength value + Unit	NS / S
Authorization MAH organisation	Identifier	MAH organisation details	S
Packaged Medicinal Product	Package Description	Pack sizes	NS
Veterinary specification	Withdrawal period description	Withdrawal period and tissue	NS/ S - conditional
Veterinary specification	Target Species	Target Species	S

- Full presentation name: NS so might be in the national language
- Product short name: NS
- ATC vet code (classification system): S
- Legal basis: S – **Proposal**: new umbrella term will be created to reflect national legal basis for legacy data and to be used by all NCAs – **to be endorsed by CMDx**
- ATC vet code (value) : S
- Authorisation number: NS
- Authorisation country: S
- Legal status of supply: S – **currently 5 /6 values available, but there are national variances – EMA to contact NCAs to discuss inclusion of them in the list**



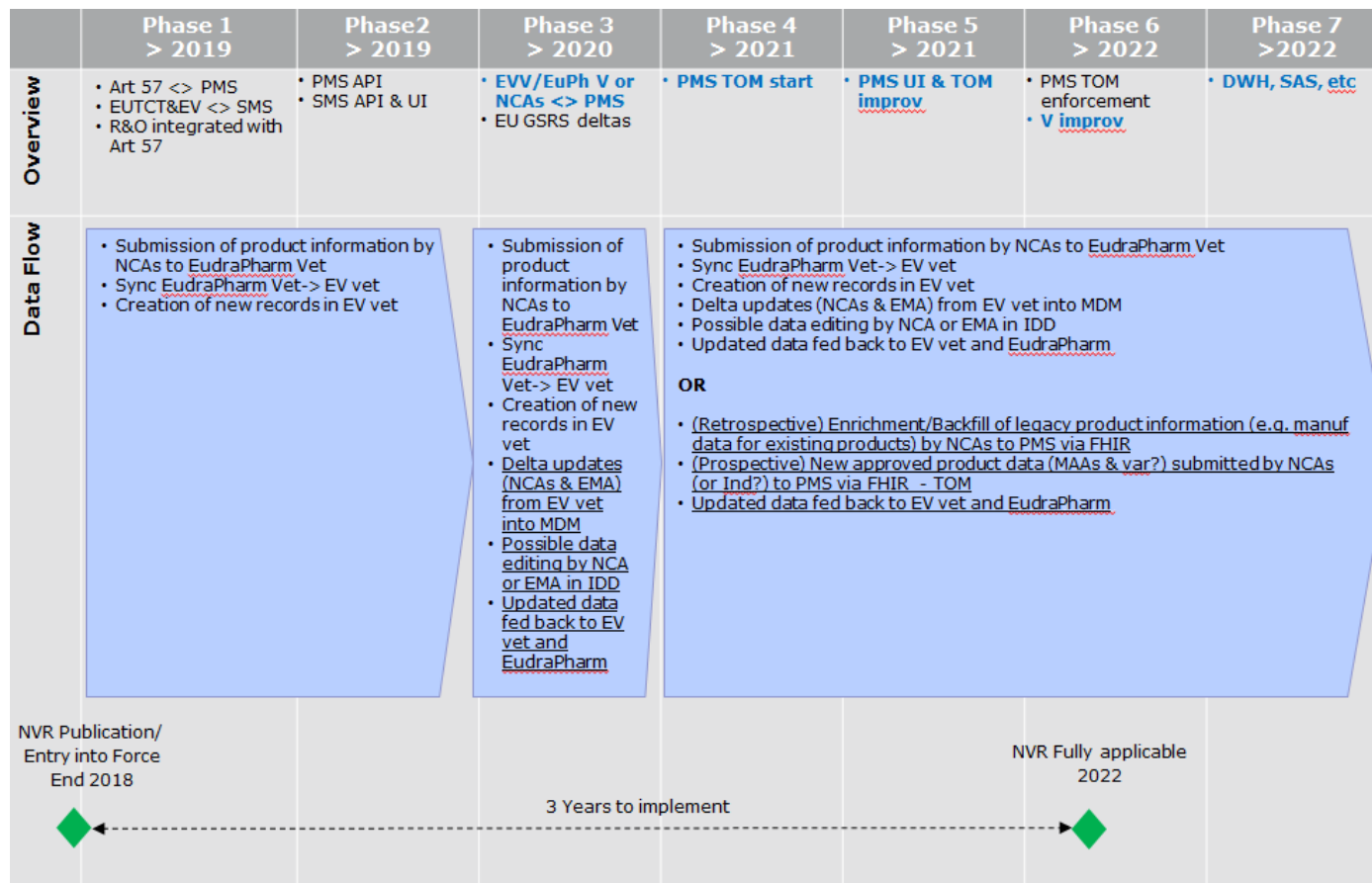
- Authorisation status: S
- Date of first authorisation: S
- Procedure number: NS – proposal to have only the stem number that would enable to compare same product in different countries – to be further discussed
- Authorisation procedure: S
- Route of administration: S
- Active substance: S
- Strength range : mandatory to have but can be either for presentation or concentration, and can be either S or NS. **Make sure antibiotics requirements taken into account**
- Identifier: S: MAH from OMS – manufacturers will come after. **(maybe by the time NCAs send data, manufacturer's data will be included)**



- Package description: NS – to be provided for each presentation separately
 - to note: text could be in national language
- Manufactured dose form: S
- Withdrawal period description: NS – Conditional – to exclude target species that would not require it (dogs, cats, + agree a dummy term “for horses with no withdrawal period necessary”)
- Target species: S

- Update the SPOR phase 3 and subsequent phases to reflect Conclusion 1, i.e. NCAs to send legacy data to PMS, no migration from EudraPharm
 - Investigate further about how to do the switch between EV vet and PMS
 - Proposal to re-instate meetings with NCAs about Eudrapharm to have overview of current situation
- With regards to Conclusion 2 (mandatory set of data identified for legacy data), the following points should be communicated:
 - This set of data is a draft work until implementation act of the New Vet Regulation (NVR) is endorsed and provide final input
 - The task force that will be created to implement the NVR should take those proposals into account

V Products data flow





Implementation guide (IG)

- Drafting of EU IG ongoing on the Human side
- Similar chapters for intro, message format, API/UI specifications, pre-registration requirements, maintenance activities,..
- Chapter on “initial submission” should be vet specific: description of the convention and how info is provided in each data field
- Vet expert group to work on this document with leadership from NCAs – to be discussed



Enriching data in addition to mandatory fields

- Who: NCAs vs Industry?
- What: Manufacturers, etc.
- How: In one go? In Blocks/Phases? With applications?



Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555

Send a question via our website www.ema.europa.eu/contact

Follow us on  **@EMA_News**