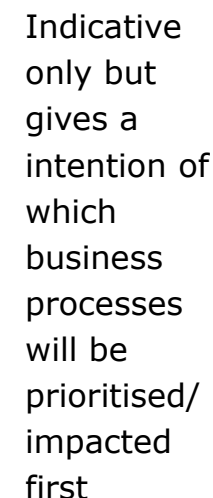




EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Substance, Product, Organisation and Referential (SPOR) Impacts on Processes

DRAFT



Art 57/xEVMPD (Auth P)

- Most discussions so far have been focused only on the Submission of Authorised product information under the Art 57 process hence this is the starting point of the diagram.
- EMA intends to enforce the pre-registration of R&O for Art57, xEVMPD (IMP), eAF and CT application regulatory processes around the same time. When this happens R & O data are registered once and reused across Art 57, IMPs, eAF, EudraCT.
- 6 months after the PMS go-live date, the Art57 system will no longer be used to submit/receive Authorised Medicinal Product information and it will be replaced by PMS.
- The Medicinal product information submission as requested by art57 of the Phv Legislation will be the first process where ISO IDMP format will be used.
- IDMP will not be enforced for Vet products as a consequence of PMS.

xEVMPD (IMP)

- Although the different transition stages are very similar to authorised products IDMP will not be enforced for IMPs as a consequence of PMS.

EV excel file publication

- Excel publication will not be discontinued when RMS/OMS are enforced but the intention is to discontinue it at some point. The timing of this is still to be discussed with Art 57 IWG.
- As there is ample time to prepare after RMS/OMS go-live the latest this process could be supported is SMS/PMS go live date, it will not be extended through transitional period.

eAF

- eAF already uses referential data from RMS and work is ongoing to see how/when eAF could also use OMS data.
- It is unclear if/how/when CESSP will replace eAF. We have assumed they will coexist for a period, particularly until all stages of CESSP are complete.

CESSP

- CESSP will use SPOR and IDMP compliant Products, This is how IDMP format could be enforced to the vet Industry.

EudraCT

- Industry/Sponsors will be asked to align with SPOR due to enforcement in xEVMPD (IMP).

EU DB/Portal

- The new CT portal will go live integrated with SOR but not with P. There are plans for subsequent IDMP implementation but as they have not been firmed up they are not reflected here.

Vets (EuPh Vet)

- NCAs may continue to submit product data to EudraPharm vet but some, particularly H&V, may choose to transition to IDMP which would support them integrating with CESSP. Although this can happen as soon as PMS goes live we have assumed the main driver would be CESSP var.