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SCIENCE MEDICINES HEALTH

SPOR impact on Veterinary stakeholders

Feedback from webinar with NCAs and Industry

Veterinary EMA

Objectives of the meeting

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- To have a common understanding of SPOR: What is SPOR? Why being involved?
- To provide a status update on main features of SPOR from the Veterinary domain point of view
- To listen to Veterinary stakeholders and list the concerns from NCAs and Industry side
- To agree next steps

SPOR Timelines & Outcomes

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2017

- **Q2:** P&SMS project started
- **Q2:** RMS & OMS live
- **Q2:** RMS & OMS Target Operating Model (TOM)
- **Q4:** Integrate OMS with eAF; RMS already integrated with eAF

2018

- **Q3:** CAP & NAP Manufacturers
- **Q3:** Integrate RMS & OMS with CESSP (MAA)
- **Q4: (**Draft) EU IG available

> 2019

- EU Substance list is available
- Substances TOM
- PMS API UAT
- (Final) EU IG is available

> 2020-2021

- **H&V Products (TOM):**
  - PMS starts to collect product data submitted via eAF/CESSP (not more data than eAF!) – ISO IDMP compatible format
  - Assessment/validation solely the responsibility of NCAs
  - EMA acts as custodian

> 2020-2021

- Legacy data will be transmitted by NCAs to Eudrapharm/PMS (NVR Art 51)?

> 2021-2022

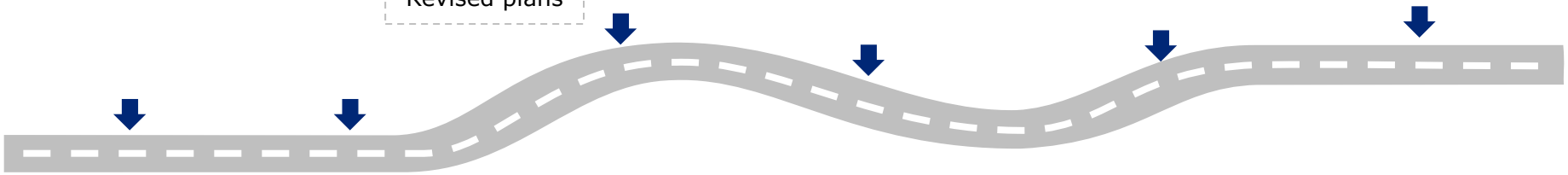
- Human Products TOM Enforcement

TBD

Veterinary Products Target Operating Model Enforcement ???

Agency Relocation

2018-2019: Revised plans



2018: RMS & OMS integrated with business processes

2018-2019: Documentation produced enables vet Industry to be aware of developments and prepare for future process

2020: P&SMS TOM ensures only **trusted data** is available for use in reg processes

The current plan **does not require Industry to backfill details on already approved products** (the provisions of pharmacovigilance Art.57 do not apply to veterinary medicines~~)~~

What will SPOR deliver? SPOR operating model

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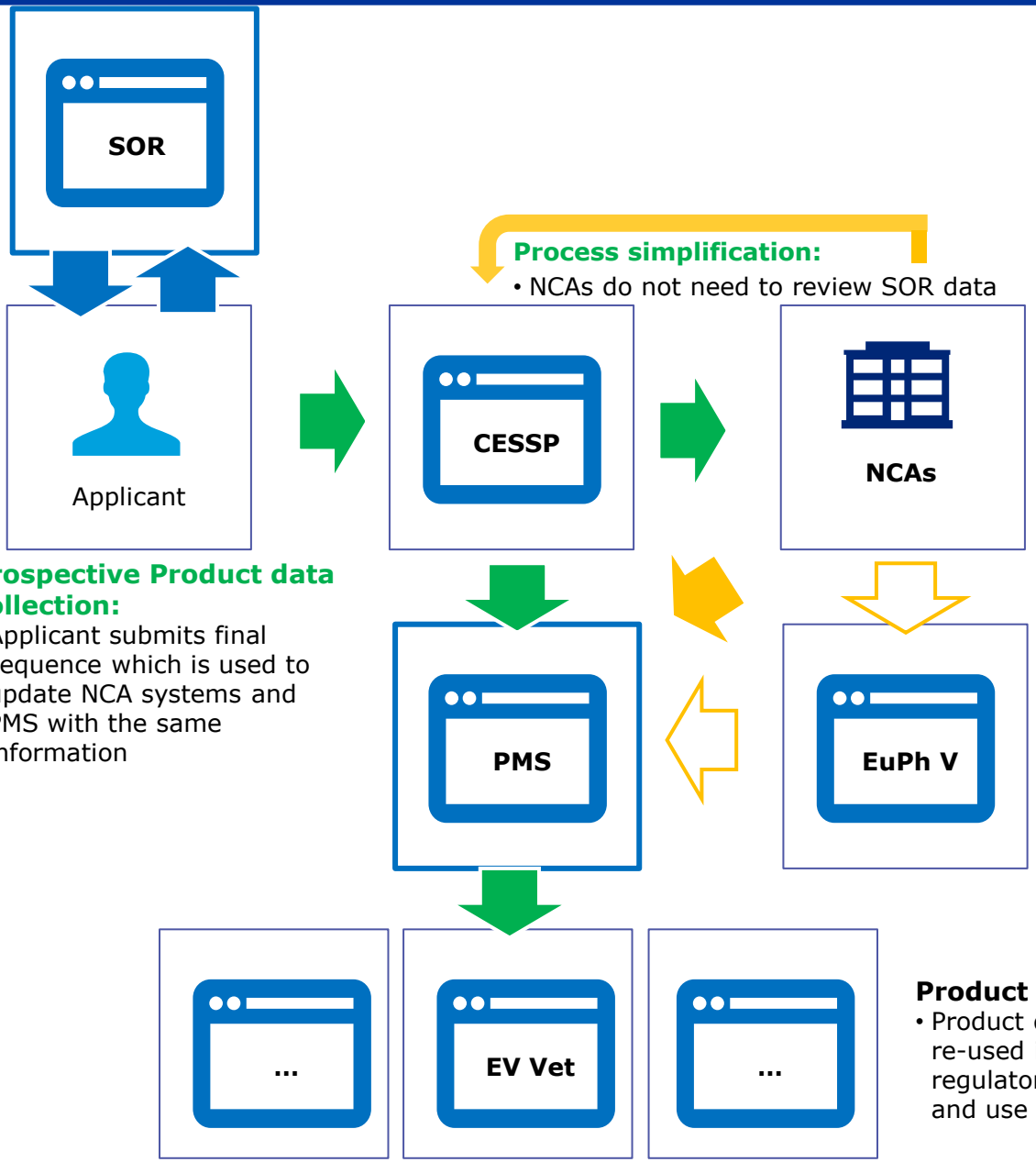
SOR pre-registration:
- Applicant requests new/updated SOR data before regulatory applications



SPOR within the Telematics Governance

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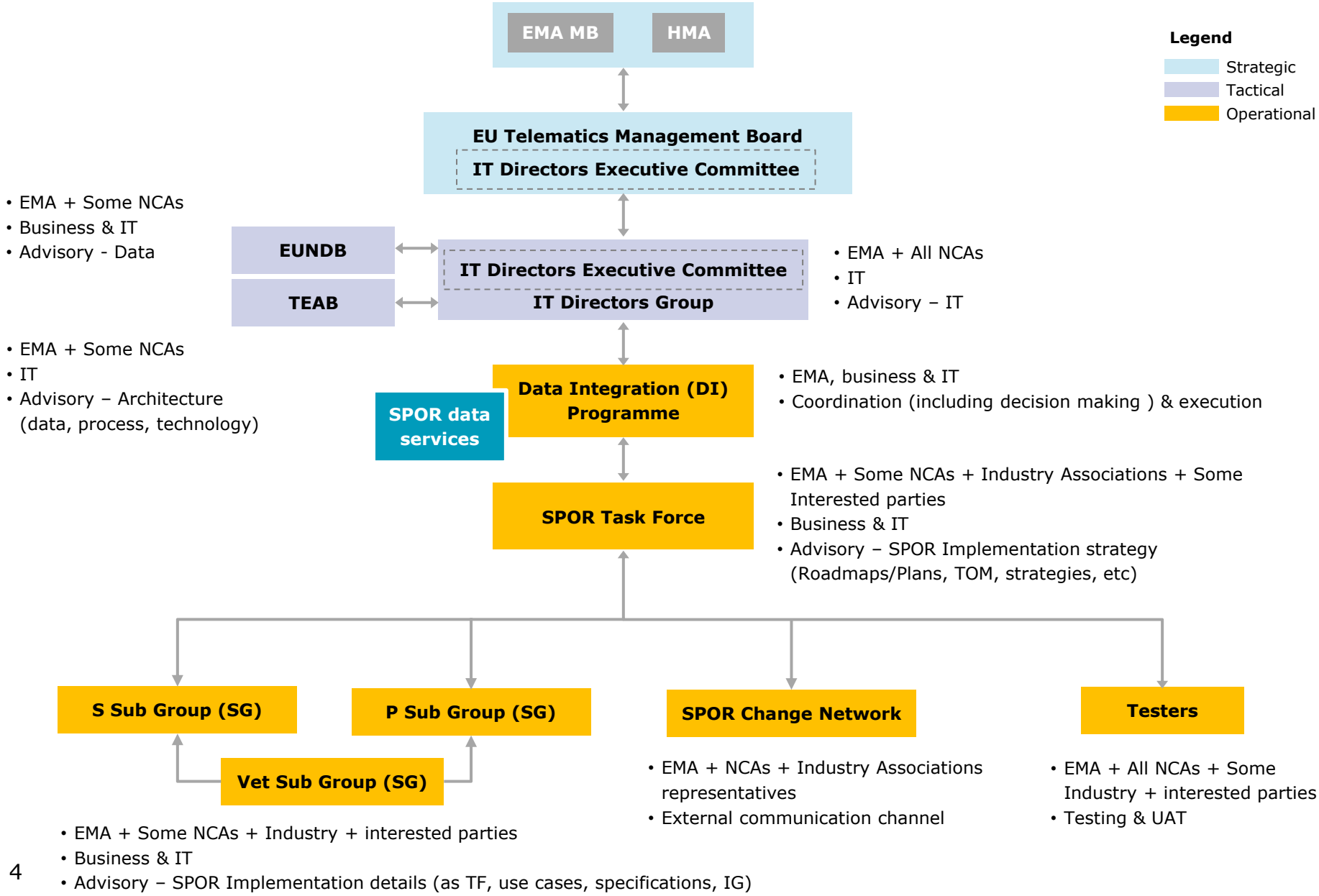

Communications / events 2018 (draft)

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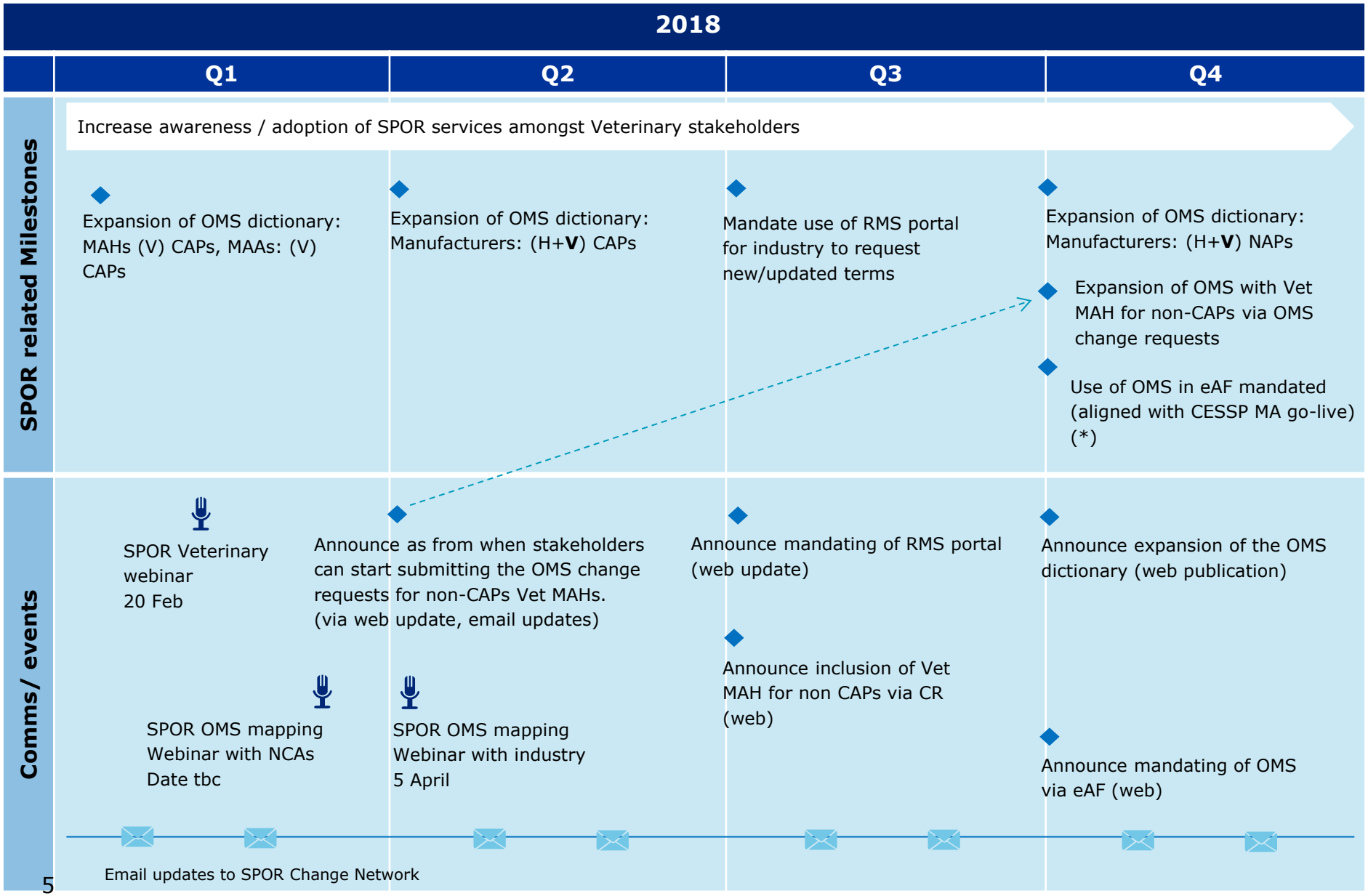

(*) – subject to planning

Key messages

S&O&R:

- **One stop shop** for data required in regulatory submissions
- Not more structured information than required today
- **Process simplification:** NCAs do not need to review SOR data

Products:

- **Same data model used across human & veterinary** domains to bring regulatory efficiencies
  - not all fields/ rules will be applicable to the veterinary domain (Use case analysis finalised 2016)
- **Legacy data** will be transmitted by **NCAs**
- Applicant submits **final sequence** which is used to **update NCA systems (RMS & CMS) and PMS with the same information**

Post-meeting note: it was clarified that no final sequence will be applicable for Vet, and updated dossier will be submitted at the stage of LoQ/LoOI.

- **Solution still being defined!** This is the moment to **adapt it to veterinary needs**

Presentation from NCAs

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Presentation from Veterinary/Human NCA (AGES)

- Explanation how they implement a phased approach for OMS integration with their own system (PHAROS)
- Mapping then automated data synchronisation
- What challenges they are faced with

Presentation from Veterinary NCA (ANSES-ANMV)

- Participation at many different meetings or groups to gather information => sometimes burden
- Concrete example how they mapped RMS lists
- Challenges identifed to adapt their national database and process for PMS
- SPOR API and user interface (website) seen as positive points

Presentation from Veterinary Industry

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On behalf of AnimalhealthEurope and EGGVP

They support:

- The current plan does not require veterinary Industry to backfill details on already approved products (the provisions of PhV Art.57 do not apply to veterinary medicines)
- Current draft TOM for PMS

They are concerned by:

- Future substance repository (EU G-SRS)
- Mandatory use of OMS by Q4 2018
- Large number of documents available and level of relevance

List of actions arising from webinar

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Organisations Management Services (OMS) – 1/2

Action 1 - EMA: Communicate the updated OMS data release plan to stakeholders.

- MAHs for non-CAPs Veterinary will be included via Change Requests.
- The timing to be announced by the end of Q1 2018.

Action 2 - EMA: Clarify the responsibility of submitting OMS change requests and potential impact on manufacturers.

- Any registered SPOR user can submit an OMS change request.
- The requests are validated and processed by EMA Data Stewards.
- The OMS portal will not prevent a registered SPOR User from submitting a request for their own organisation or any other organisation.

List of actions arising from webinar

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OMS - 2/2

Action 3 - eAF/CESSP maintenance group: "Is it possible to postpone planned mandatory use of OMS in eAF/CESSP from Q4 2018 to Q4 2019 (1 year?) or have a **phased mandatory use of OMS**, for instance for some specific organisation dataset at a time, and not all at the same time?"

- This question has been referred to eAF/CESSP maintenance group.

Action 4 - EMA: OMS data quality.

- Proposal from SPOR team to set up a key user group for OMS. (to go through practical aspects of data management of non-standard cases and recommend solutions).
- In the meantime SPOR team to increase awareness of OMS guidance related to data quality standards applied in OMS.

List of actions arising from webinar

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Product Management Services (PMS)

- **TOM -** general principle: data coming from what has been filled in in the eAF by Industry – no more, no less - and confirmation would be required from NCAs, that they have the same data. Process forward could be similar to the human side and be based on a "final sequence" submitted by Industry and confirmed by NCAs or simply be submitted by NCAs – TBC.

A definition of "final sequence" is needed.

Action 5 – NCAs reviewing TOM: Understand what is the implication of the final sequence, in the TOM, for Veterinary stakeholders. *Post-meeting note: it was clarified that no final sequence will be applicable for Vet, and updated dossier will be submitted at the stage of LoQ/LoOI.*

- **Veterinary Logical Data Model (LDM):** concerns were raised about what fields will be mandatory or optional.

Action 6 – EMA: work done on the Vet LDM and Vet use cases analysis to be taken into account. **Need to decide who will be involved in defining mandatory /optional fields, timeline for when this will happen, and process (how).** These questions will need to be covered this year to have a planning ready for Phase 3.

List of actions arising from webinar

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Referentials Management Services (RMS)

The biggest workload is on the NCAs, EMA needs to continue supporting with the mapping (for instance "legal basis") and submission of change requests. **No specific action was raised**.

Substance Management Services (SMS)

Questions related to the topic of **EU G-SRS** were **referred to the CBG-MEB Netherlands** who lead the project.

List of actions arising from webinar

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SPOR communications

Action 7 – EMA: Documents sections on the SPOR portal will be re-organised.

- This section will include the RMS and OMS system specific documents such as user guides, templates, manuals, and technical documentation.
- Documents such as slide decks from the webinars, or documentation related to implementation of SPOR services will be removed from the portal and maintained on the EMA corporate web under SPOR.
- The team will also work to improve existing SPOR related content on the corporate web e.g. include links to training material, review of the existing SPOR documents and identify opportunities for updates.

List of actions arising from webinar

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Participation in meetings

- Participation of NCAs and Industry stakeholders in all groups is recognised as time/resource consuming. However, the importance of attending and providing feedback during these meetings is also acknowledged, as recommendations made by these groups are escalated for decision making at the SPOR Programme /Telematics governance level.

Action 8 – Industry Associations / NCAs stakeholders asked to review participation in the SPOR implementation sub-groups as described in the Governance model, and ensure relevant representation in each group is achieved.

List of actions arising from webinar

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Measuring progress of SPOR implementation

- Next SPOR implementation questionnaire will be issued to NCAs (via the Change Liaisons) by the end of March 2018. The survey typically covers 4 areas: awareness, planning, mobilisation and mapping.

Action 9 – EMA: ensure relevant questions related to Veterinary domain are asked.

Action 10 - EMA: issue a survey to Industry Change Liaisons on the roll-out of SPOR data services / integration with eAF and first impressions.

- New veterinary regulation: possible adoption by end of 2018, then 2 to 3 years until implementation. However, already, there is a need to identify what type of systems will be needed to implement the NVR, especially for small NCAs.

Action 11 – EMA Veterinary: organise a survey for NCAs (vet + joint) about details of the operating model, and which tracking systems will need to be adapted (i.e. CTS, etc).

- 64 participants in total, from Industry and NCAs
- Slides available on EMA website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2018/02/event_detail_001606.jsp&mid=WC0b01ac058004d5c3

Thank you for your attention

Further information

Please send any queries regarding the IDMP/SPOR to:
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