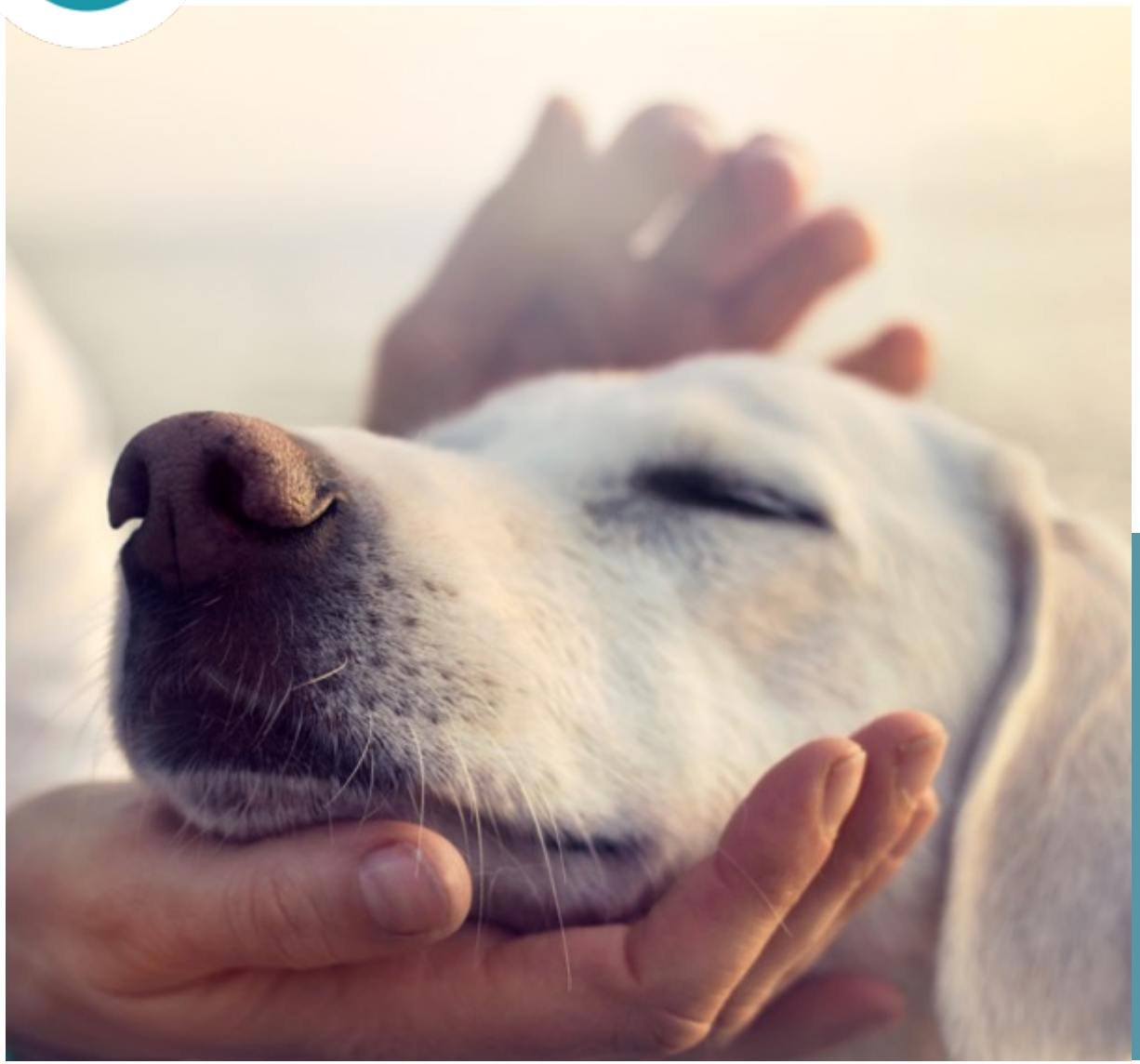

SPOR impact on Veterinary stakeholders

20th February 2018

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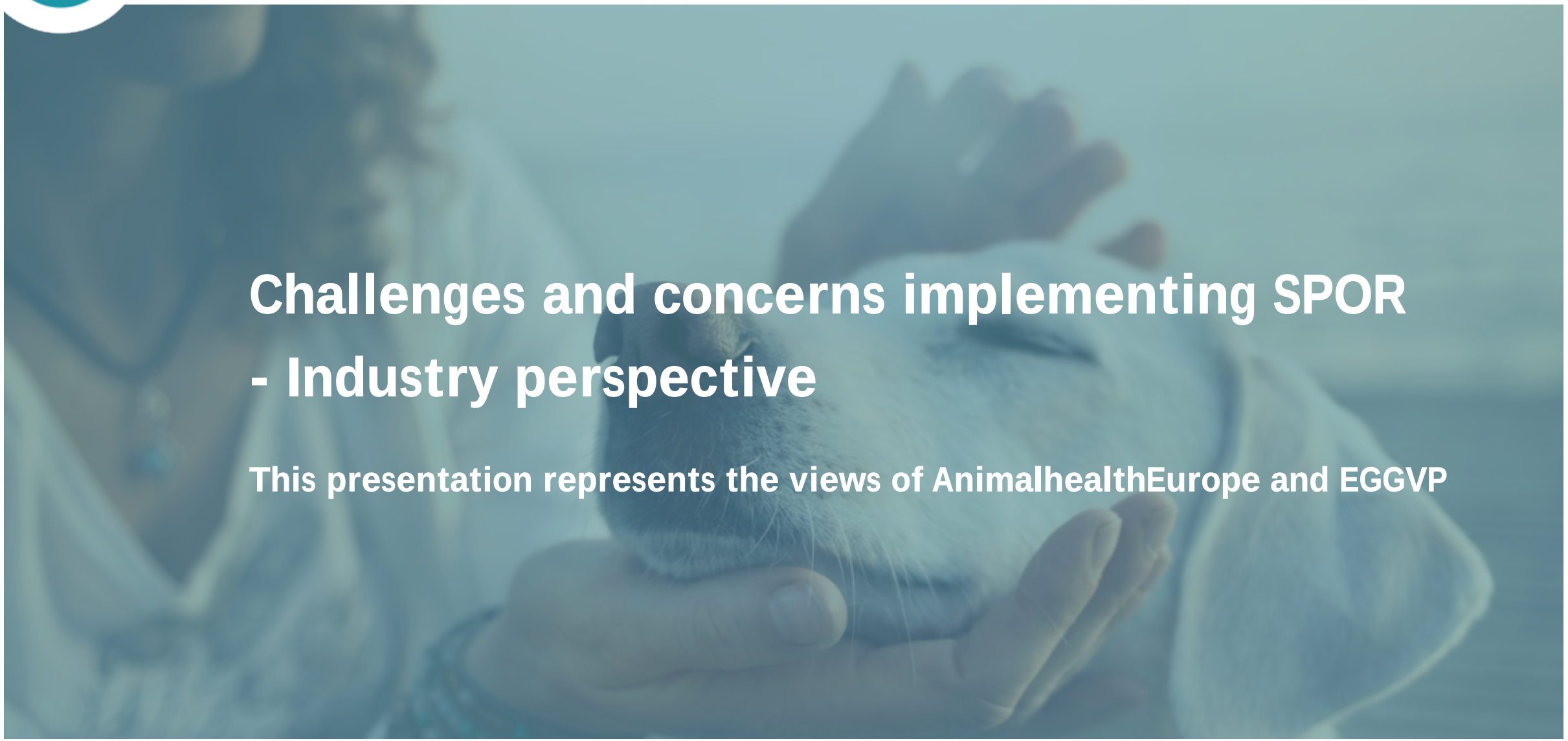
EGGVP European Group for Generic Veterinary Products



Challenges and concerns implementing SPOR - Industry perspective

This presentation represents the views of AnimalhealthEurope and EGGVP

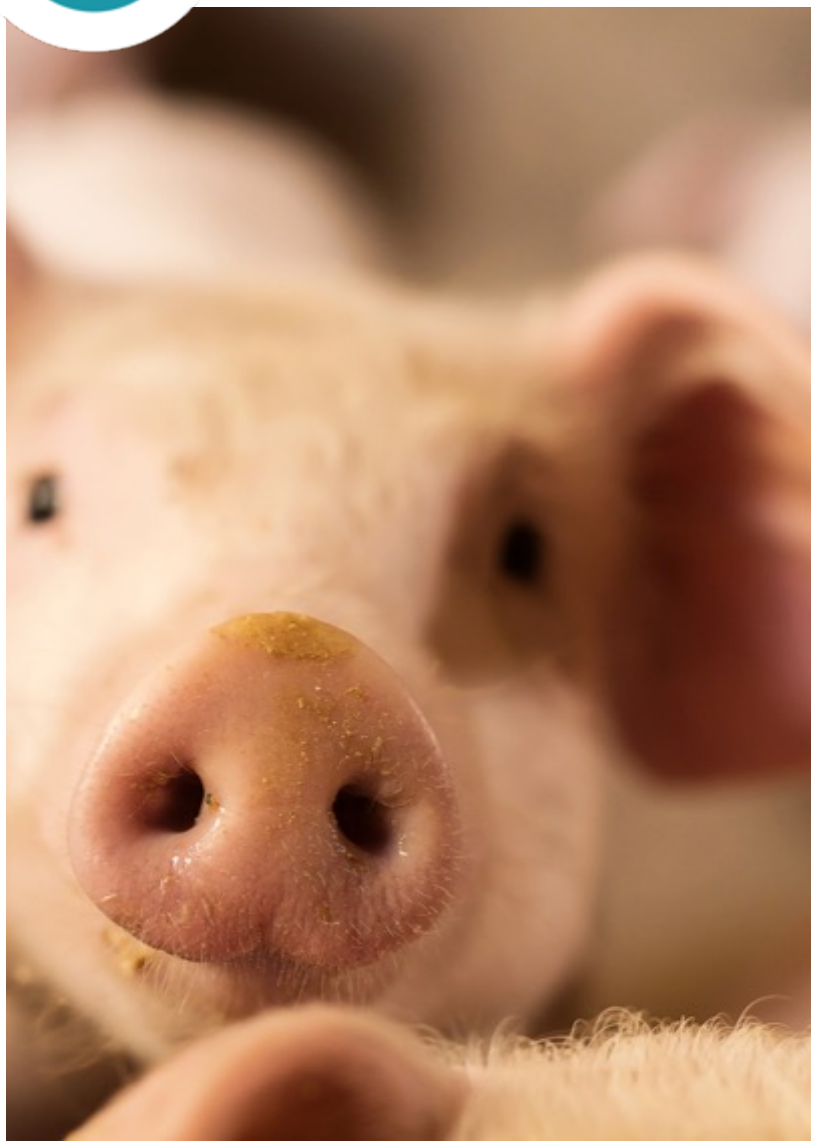
Veterinary Industry acknowledges and supports:

1. **"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)"**

   → *cf. EMA's PowerPoint communication on PMS & SMS, 25.01.2018*

2. **"Not all fields/ rules from IDMP will be applicable to the veterinary domain"**

   → *cf. EMA's PowerPoint presentation at the 2017 TOPRA veterinary Annual Symposium, 3.10.2017*



Veterinary Industry acknowledges and supports:

3. Current draft TOM for PMS foresees:

- Provision of data for legacy products by NCAs;
- Collection of data for new products and data updates via eAF/CESSP

➢ Integration of CESSP with PMS is KEY

Veterinary Industry has concerns with

1. mid-term:

   the objective to build a central ISO IDMP-compliant substance repository, covering also veterinary substances (EU G-SRS);

2. short-term:

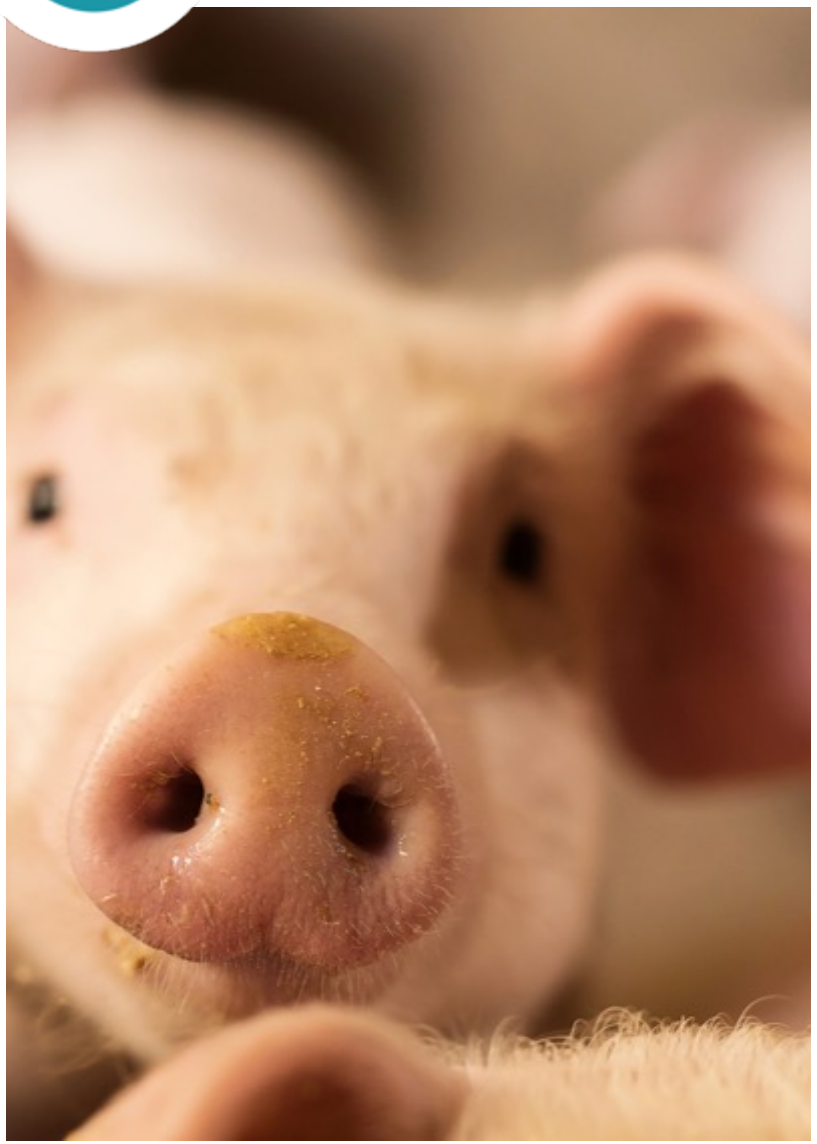
   the announced mandatory use of OMS Q4 2018

Concerns with EU G-SRS (1/2)

- Sufficient active involvement of veterinary-only agencies has to be assured during all phases of the project;
- A proportionate approach for the veterinary sector needs to be followed, considering low sector resources;
- Data gathering should be risk-based, due to workload related to a full EU G-SRS implementation;
- EU G-SRS & SMS must not increase regulatory hurdles for MA applicants by requesting data which are not required for the well-established benefit/risk assessment performed during the MA evaluation of VMPs.

Concerns with EU G-SRS (2/2)

- Risk for increasing administrative burden and distracting resources urgently needed for core activities in the veterinary area;
- Such impact would contradict the goals of the new Veterinary Regulation;
- Level of implementation should be driven by clear veterinary business cases and not merely by demands of the IDMP data model.
- There should be no impact on SPC/label/package leaflets as these are intended to veterinarians/animal owners



Concerns with OMS mandatory use by Q4 2018

An initial MAA eAF/CESSP data set requires Org data on:

- MA applicant - **Available by end 2018***
- Person authorised for communication (Consultancies) ?
- Manufacturers - **Available by end 2018****
- OMCL for batch release ?
- Contract companies for clinical trials ?
  (if bioavailability/bioequivalence studies)
- Billing details when different from applicant ?

*decision on applicants data for vet non-CAPs pending

**data sourced from EudraGMDP

Concerns with OMS mandatory use by Q4 2018

MA applicant /holder data for vet non-CAPs: communication on strategy needed in Q1/2018

CROs data still to be prioritised, but needed

Any plan for RA consultancy organisations ?

Potentially more CRs due to data related to billing address/entity

Concerns with OMS mandatory use by Q4 2018

Fine-tuning of mastered Org. data may be needed as they are being released

- **e.g. Frankfurt Am Main vs. Frankfurt am Main**
- **Inconsistent use of Latin Extended Character (e.g. Österreich vs. Oesterreich in DE)**
- **Are different versions of the same address for a single localised language needed ?**
- **County information added in e.g. BE, FR, AT when it does not appear on the regulatory ‚proof of establishment'**

Assurance needed such differences between OMS and NCA Dbases/official documents ⇨ no validation comments.

Contract manufacture / API supply

- Are MA applicants legally allowed to act on behalf the 3rd party for OMS updates ?
- If so, in a multi-customer setting, where does the responsibility for updating OMS lie ?
- Potential high administrative burden at CMO/API manufacturer due to requests from costumers
  - ➢ Does EMA plan any communication towards associations of such 3rd parties ?
- Process in case OMS data is changed by a 3rd party during an on-going regulatory procedure ?

Concerns with OMS mandatory use by Q4 2018

- Because of the above
- considering additional exceptional circumstances (Brexit and EMA relocation)
  - ➢ a 1-year transition period after Q4 2018 is being requested

Challenges in communication

- SPOR-related information located under „Human>Regulatory“ of EMA corporate website
- SPOR contains a lot of documents – can the most important ones be highlighted ?
- “must-read” OMS/RMS documents could be visible on the welcome page for the sake of visibility & user friendliness
- As well as a link to the @youtube training videos
- Training material on IAM may be helpful too

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Thank you!