EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CVMP work plan for 2016: Highlights and potential implications for new applications and developments

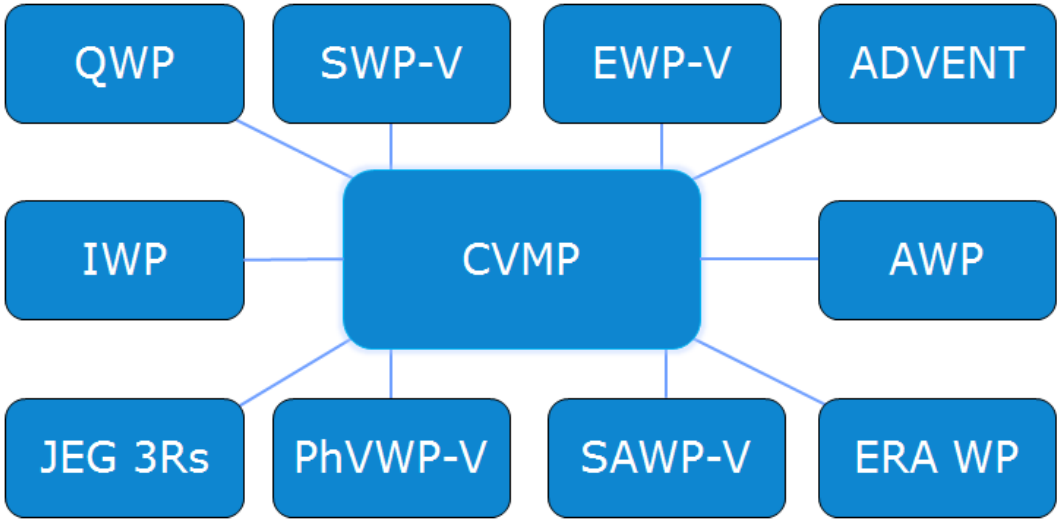
European Medicines Agency/IFAH-Europe Info Day 2016

Presented by Anja Holm on 17 March 2016
Chair of the Committee for Medicinal Products for Veterinary Use (CVMP)

Overview

CVMP Working Parties

- CVMP Quality WP
- CVMP Safety WP
- CVMP Efficacy WP
- CVMP Environmental Risk Assessment WP
- CVMP Antimicrobials WP
- CVMP Immunologicals WP
- CVMP Pharmacovigilance WP
- Joint Ad hoc Expert Group on 3Rs
- CVMP ADVENT – Novel therapies
- *CVMP Scientific Advice WP*



CVMP

- Core business
- Specific topics

1 CVMP work plan 2016; A. Holm

Joint CHMP/CVMP Quality Working Party (QWP) 1/2

Guideline on the selection of sterilisation processes for drug products, active substances and primary packaging (H/V)

- New draft guideline – just published for 6 months consultation until August 2016
- Intended to replace the Annex 'Decision trees for the selection of sterilisation methods' (EMEA/CVMP/065/99) of the Note for guidance on development pharmaceutics for veterinary medicinal products (EMEA/CVMP/315/98)
- Also replaces information on methods of sterilisation described in the Note for Guidance on manufacture of the finished dosage form (due for revision in 2016)

Joint CHMP/CVMP Quality Working Party (QWP) 2/2

- **Guideline on the manufacture of the finished dosage form (V)**

  Revised guideline being drafted – due for release for consultation in 2016

- **Guideline on the chemistry of active substances (V)**

  New guideline being drafted – due for release for consultation in 2016; to replace the Note for guidance on chemistry of new active substances (EMEA/CVMP/541/03/Final) and also Chemistry of active substances (3AQ5A)

CVMP Safety Working Party (SWP-V) 1/2

Measures regarding the methodological principles for risk assessment and risk management recommendations (will replace Volume 8 of The rules governing medicinal products in the EU)

- Commission requested CVMP input in relation to the development of the above measures; work to be led by a joint CVMP-SWP drafting group
- Use existing information on risk assessment (from Vol. 8 and Dir 2009/9/EC) but create a more succinct document (refer to published guidance); also consider whether new approaches need to be reflected, e.g.
  - should exposure modelling and food basket remain ‘as is’ or is there a case for change (look at JECFA and EFSA approaches)?
  - is more information needed on alternatives to the ADI?
- Risk management recommendations section will be new
- Commission requested input by end of year (ambitious deadline)

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CVMP Safety Working Party (SWP-V) 2/2

- **Guideline on user safety evaluation of topically applied veterinary medicinal products**

  Draft guidance being finalised – hope to publish next quarter

- **Guideline on limits for genotoxic impurities in veterinary medicinal products**

  Ongoing discussions in relation to approach to take for products for use in food producing animals. Aim to publish a draft GL this year

- **VICH MRK guideline on residue studies in honey (EU is topic leader)**

  Final Expert Working Group discussions expected in coming months – hope to sign off for public consultation during quarter 2 - 3

- **Note for guidance for determination of withdrawal periods for milk**

  Reviewing GL to consider including guidance relevant to dry cow products; SWP developing an alternative to current milk WP programme (MELK 14) (aim to publish draft GL towards end 2016)

CVMP Environmental Risk Assessment Working Party (ERAWP) 1/2

Reflection paper on the environmental risk assessment of veterinary medicinal products used in aquaculture

- Aim to address the potential environmental risks based on current aquaculture practices in the EU and discuss whether there is a need to develop further guidance.
- The paper will be developed following a 1-day workshop on the environmental risk assessment of VMPs with CVMP/ERAWP experts and leading specialists in the scientific and/or regulatory field in the EU.
  - ➢ Aim to identify challenges for assessors and applicants and gain a better understanding of the aquaculture practices in the EU and relevant legislative frameworks (EU and national frameworks).

CVMP Environmental Risk Assessment Working Party (ERAWP) 2/2

- **Guideline on scientific method for the risk assessment of veterinary medicinal products in groundwater** (with the CVMP Safety WP)

  Technical GL on how to conduct the assessment is being finalised. Discussion with the SWP on the approach to apply for VMP substances that are used also as PPP and/or biocides. Intention to publish in Q4 for consultation.

- **Guideline on testing strategy and risk assessment for plants**

  Draft GL is being finalised on recommendations on how/when would be considered appropriate to conduct additional plant studies in the phase II of the environmental risk assessment for veterinary medicinal products. Intention to be publish for public consultation in Q3.

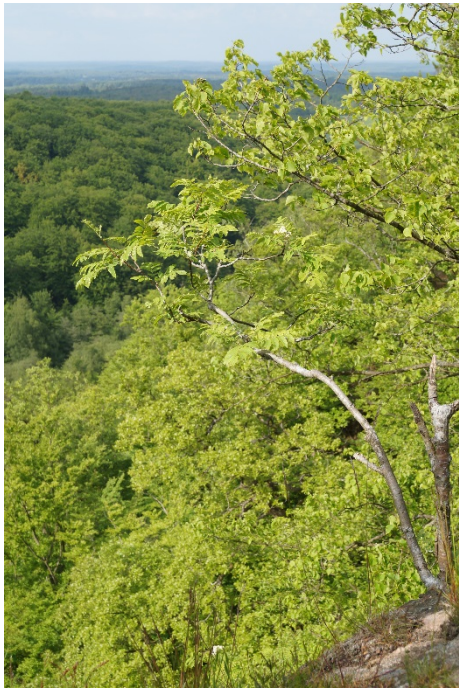
- **Guideline on higher tier testing of antiparasitic compounds to dung organisms**

  Draft GL is being finalised on recommendations on how/when would be considered appropriate to conduct field testing in situations where an effect on dung organisms is identified already in tier A of the ERA. Intention to be publish for public consultation in Q3

CVMP Efficacy Working Party (EWP-V) 1/2

Reflection paper (RP) on anthelmintic resistance

- Aim to publish for second consultation Q2 2016.
- Focus Group Meeting on 13 June with attendance of regulatory authorities, interested parties and academia.
- The document addresses the
  - Current resistance situation in Europe
  - Recommendations for actions for CVMP
  - Recommendations for actions for other groups (outside scope of CVMP)



CVMP Efficacy Working Party (EWP-V) 2/2

- **New: GL on data requirements for VMPs for prevention of transmission of dog and cat vector-borne diseases**

  Aim to publish draft GL in 2017. GL proposed as currently no guidance on studies available

- **Revision: Concept paper to revise the pharmacokinetics GL**

  Public consultation of CP currently on-going (until 30 April 2016)

  Frequently used GL, revision proposed in view of experience (e.g. pk-pd modelling) and 3Rs

- **Revision: Concept paper to revise the zootechnicals GL**

  Public consultation of CP foreseen later in 2016

  Revision proposed in view of recent product related inquiries, also considerations to include guidance on products in aid of herd management

CVMP Antimicrobials Working Party (AWP) 1/2

New mandate from the Commission to update the advice from the AMEG on colistin

- Recent discovery of the first mobile colistin resistance gene (*mcr-1*)
- CVMP requested to re-convene the AntiMicrobial advice ad-hoc Expert Group (AMEG), who prepared the 2013 advice – 5 AWP members are involved
- Call for scientific data for the update of advice: 29 February – 15 March 2016
- Consultation period: end of May – beginning of June 2016
- Deadline of the finalisation of the report: 30 June 2016

CVMP Antimicrobials Working Party (AWP) 2/2

- **Reflection paper on off-label use of antimicrobials in selected domestic animals**
- **Reflection paper on use of aminoglycosides in animals in the European Union**
- **Reflection paper on use of broad-spectrum penicillins in animals in the European Union**

The RPs will take into account the EMA advice to the EC on the impact on public health and animal health of the use of antibiotics in animals; CVMP will make recommendations on risk management measures in conjunction with AWP.

Planned to be published for consultation in 2016.

CVMP Immunologicals Working Party (IWP) 1/2

Guideline on requirements for the production & control of allergen products for use in animals

- Discussion by IWP of comments received from public consultation on concept paper
- GL will encompass quality, safety & efficacy issues, focus on dogs, cats & horses, therapeutic & diagnostic use, natural & recombinant allergens
- Revised draft GL to be released for consultation (Q4 2016/Q1 2017)

CVMP Immunologicals Working Party (IWP) 2/2

- **Guideline on requirements for the production and control of immunological veterinary products - Annex 2: The approach to demonstrate freedom from extraneous agents as part of the production and control of IVMPs for mammalian species and finfish**

  GL to be finalised – Q4 2016

- **Concept paper on DNA vaccines non-amplifiable in eukaryotic cells for veterinary use**

  Revision of existing note for guidance; concept paper to be released for consultation – Q2 2016

- **Concept paper on the use of adjuvanted veterinary vaccines**

  Revision of existing note for guidance; Concept paper to be released for consultation – Q3 2016

- **Concept paper to propose revision of guideline on data requirements for multi-strain dossiers for inactivated vaccines against Avian Influenza (AI), Blue Tongue (BT) and Foot and Mouth Disease (FMD)**

  Concept paper to be released for consultation – Q4 2016

CVMP Pharmacovigilance Working Party (PhVWP-V) 1/2

Recommendation on implementation of signal detection and pharmacovigilance surveillance for centrally authorised products

- Aiming to further link the signal detection activity to the analysis of PSURs.
- Reducing the overlap and aiming to use the best functionalities of both systems.
- Promoting collection of all data electronically, including non-serious adverse event reports.
- Aiming for better use of pharmacovigilance resources.
- Taking into account experience from pilot on electronic submission of PSUR line listing.
- Workshop with stakeholders to be held in May 2016

CVMP Pharmacovigilance Working Party (PhVWP-V) 2/2

- **Reflection paper on promotion of pharmacovigilance reporting**

  Revision of reflection paper to develop aspects on encouraging reporting on food producing animals and providing feedback to reporters; focus group meeting to initiate dialogue with stakeholders (to be held in November 2016)

- **New: Reflection paper on non-spontaneous adverse event reports**

  Release for consultation Q1-2 and subsequent reflection on need for further guidance

Joint CHMP/CVMP Expert Group on 3Rs in Regulatory Testing of Medicinal Products (JEG 3Rs) 1/2

Draft reflection paper on overview of animal testing requirements and opportunities for 3Rs implementation

- RP has been developed as a follow up to draft GL on regulatory acceptance of 3Rs testing approach – aim to adopt in Q2 2016
- Provides an overview of the main animal tests required for the regulatory testing of medicinal products for veterinary use (separate RP for human medicinal products)
- Tabular format with separate sections for each WP
- Lists current regulatory requirements and implemented 3Rs initiatives as well as identifying new opportunities for further implementation of 3Rs

Joint CHMP/CVMP Expert Group on 3Rs in Regulatory Testing of Medicinal Products (JEG 3Rs) 2/2

- **GL on regulatory acceptance of 3Rs testing approach**

  Ongoing revision of GL following public consultation that ended in Dec 2014. Aim to publish in Q3 2016.

  The GL will enable applicants developing veterinary products to utilise the scientific advice procedure to obtain CVMP view on acceptability of 3Rs tests.

- **Review of in process and final product batch testing requirements**

  Ongoing review of current and historical in-process and final product batch release testing for centralised veterinary vaccines to identify 3R opportunities.

- **GL on transferring methods validated in collaborative trials to a product/lab specific context**

  GL will clarify requirements for laboratory/product specific validation for laboratories and medicinal products included in large collaborative studies. Aim to publish in Q3 2016.

CVMP Ad-Hoc Group on Veterinary Novel Therapies (ADVENT) 1/2

Two problem statements released for 2-month public consultation (until 30.4.2016)

- Topics: **monoclonal antibodies** and **stem cell sterility in veterinary use**
- The consultation is used for identification of additional relevant questions to each particular topic.
- Comments to be taken into account for developing guidance in the form of Questions and Answers (Q&A).

CVMP Ad-Hoc Group on Veterinary Novel Therapies (ADVENT) 2/2

- **Further development of guidance on current priority topics**

  Cell-based products – stem cells: sterility, tumorigenicity and extraneous agents.

  Monoclonal antibodies – aspects to be agreed.

  Tumour vaccines – for consideration of whether guidance should and can be given.

- **ADVENT work plan to be updated, if considered necessary**

  Stakeholders are invited to submit their views on relevant novel therapy topics for which they consider guidance would be useful

CVMP - Committee for Medicinal Products for Veterinary Use – core business

- Applications: MRLs and medicinal products, incl. variations, renewals, pharmacovigilance
- Scientific advice
- Referrals
- Guidance documents: WPs
- International cooperation and harmonisation
- Regulatory topics for CAPs, MUMS-designations
- Organisational topics

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Minor uses/minor species (MUMS) and limited markets

Revised guidelines on data requirements for veterinary medicinal products intended for minor use - minor species (MUMS) on:

- Quality
- Safety and residue, including environmental
- Efficacy and target animal safety
- Immunologicals *(removal of Table 2 – 'Gap list')*

Currently out for consultation until July 2016

CVMP - Public work plan for 2016

- Reflection paper on PBTs (vPvBs), consultation ends in May
  - Persistent, Bioaccumulative and Toxic substances – RP discusses the approach to the assessment of (potential) PBT and vPvB substances in veterinary medicinal and other products (chemicals, biocides, plant protection products), and the need for new legal provisions.
- CVMP's Antimicrobial strategy for 2016-2020.
  - Update strategy after public consultation (29/2) and foster the implementation
- Vaccine availability initiative
  - Work ongoing after vaccine availability meeting in 2015 – reflections on CVMP's options
- Update of the Assessor's guideline
  - Important for consistency of reports.
  - Pharmaceuticals section finalised. Immunologicals section on-going.

Thank you for your attention

Questions?