EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CVMP work plan 2014

Highlights and potential implications for new applications and developments

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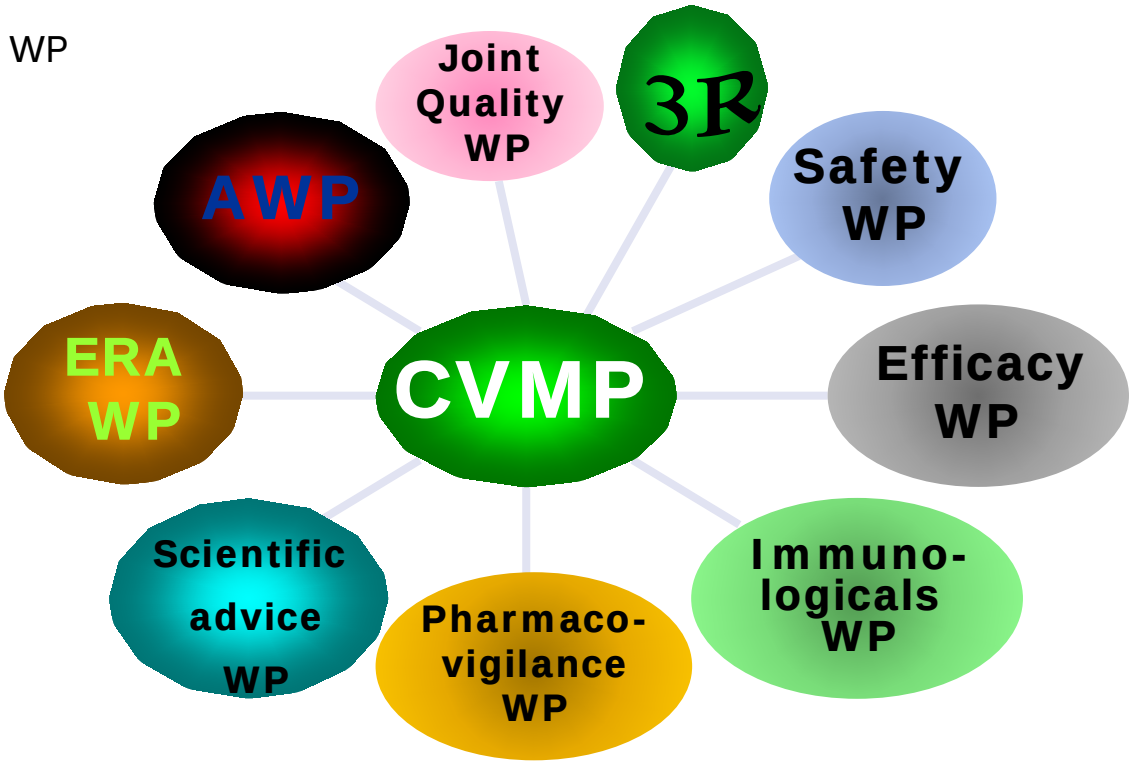
Overview

- **Key topics of the ongoing work of the CVMP Working Parties**
  - Joint CHMP/CVMP Quality WP
  - Safety WP
  - Environmental Risk Assessment WP
  - Efficacy WP
  - Antimicrobials WP
  - Immunologicals WP
  - Pharmacovigilance WP
  - Joint Ad Hoc Expert Group on application of 3Rs
  - (Scientific advice WP)
- **CVMP work**
  - Core business
  - Specific topics



Joint CHMP/CVMP Quality Working Party

Priority revised guidelines (all are Joint CHMP/CVMP GLs):

- GL on **Stability** Testing for Applications for Variations to a MA
- GL on **Near Infrared Spectroscopy**
- GL on **Process Validation** for finished products

Also:

- **QP Declaration guidance** notes and template, near finalisation

CVMP Safety Working Party

- **Development of guidance on limits of genotoxic impurities in veterinary medicinal products**
  - draft guideline to be published for consultation Q3/4 (multidisciplinary project involving EWP and QWP)
- **Development of guidance on user safety evaluation of topically applied veterinary medicinal products**
  - concept paper to be published for consultation Q1 - 2
- Further development of guidance on **setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities** (contribution to guidance developed by CHMP SWP)

CVMP Safety Working Party

- **Finalisation of guidance on risk characterisation and assessment of MRLs for biocides following consultation**
  - ongoing
- **Revision of guidance on determination of withdrawal periods for milk**
  - draft revision to be published for consultation in Q3
- **Support EU regulatory experts at VICH on safety and residues topics**
  - Guideline on the Acute Reference Dose
  - Metabolism and residues kinetics guidelines on residue studies in fish and honey
- **Preparation of comments on draft Codex MRLs**

CVMP Environmental Risk Assessment Working Party

- **Assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicine**
  - Finalisation of the guideline following the close of the public consultation
- **Antimicrobial resistance (AMR) due to presence of veterinary medicines with antimicrobial properties in the environment**
  - Development of an overview document on the current knowledge of AMR in the environment

CVMP Environmental Risk Assessment Working Party

- **Problem statement on poorly extractable non-radiolabelled substances that do not meet the quality criteria on recovery rates during the OECD 307 study**
  - Development of guidance on how to consider those cases
- **Assessor training on environmental risk assessment: Assessing the fate of veterinary medicinal products in the environment**
  - Date: 18-19 June 2014
  - Main topics: determination of physico-chemical parameters (e.g. lipophilicity, sorption), degradation in soil, FOCUS modelling

CVMP Efficacy Working Party

- Antiparasitics
  - Efficacy of antiparasitic substances for treatment and prevention of **tick and flea** infestations in dogs and cats:
    Revised GL expected to be released for consultation Q2-3 2014
  - **Anthelmintic** resistance: New reflection paper under development.
  - VICH anthelmintic GLs: Involvement in proposed Task Force and revision
  - Fixed combinations of antiparasitics: Considerations on benefit-risk
- Antimicrobials GL
  - Revised GL: **Efficacy studies for antimicrobials**
    Revision (together with AWP) now started, following FGM in Dec 2013, presentation later today

CVMP Efficacy Working Party

- VICH - **Fixed combinations** guidance
  - Support of EU expert involved in VICH Task Force (to develop CP)
- VICH – **Bioequivalence** guidance
  - Support of EU expert, after end of public consultation (July 2014)
- Revised GL: Efficacy studies for **NSAIDs** (Adopted at January CVMP)
- New GL: **Palatability** of veterinary medicinal products
  - Mainly for pet products, but also for generics for group treatment
    Final GL expected to be adopted Q2 2014
- Revised GL: Efficacy studies for **intramammary** cattle products
  - New section on generics (and other changes)
    End of public consultation 30 April 2014

CVMP Antimicrobials Working Party

- **Request for scientific advice on the impact on public health and animal health of the use of antibiotics in animals**
  - Support AMEG in the preparation of the responses to the request from the Commission
- **Data requirement for new veterinary medicinal products for companion animals with respect to antimicrobial resistance**
  - Revision of reflection paper after close of the public consultation
- **Concept paper on use of aminoglycosides in veterinary medicines**
  - To be drafted for release for consultation

CVMP Antimicrobials Working Party

- **AMR risks related to off label use of antimicrobials in veterinary medicine**
  - Initial reflections for consideration by CVMP

CVMP Immunologicals Working Party

- **Table of extraneous agents to be tested for in relation to the guideline on requirements for the production and control of IVMPs** (EMA/CVMP/IWP/354949/2010)
  - Intensive work with IFAH-Europe on the possibility to introduce a chapter on methods considered acceptable for the purpose of extraneous agents detection in suitably experienced laboratories

- **Guideline on the compliance of authorised equine influenza vaccines with OIE recommendations**
  - Following consultation a revised version is expected to be published mid 2014 for coming into effect in 2015

CVMP Immunologicals Working Party

- **Guideline on indications for veterinary vaccines**
  - Challenge to provide a useful reflection of the assessment while still presenting the data without “overloading” the product information with statistical results

- **Recommendation of considerations of the risk associated with the use of unauthorised vaccines in emerging situations**
  - Ongoing discussions on a document intended for decision makers in governments who are faced with the decision on the potential use of unauthorised vaccines in emergency situations

CVMP Pharmacovigilance Working Party

- Finalisation of the recommendation on **pharmacovigilance surveillance and signal detection** of veterinary medicinal products
  - End of public consultation 30 June 2014
- Develop a reflection paper on **promotion of pharmacovigilance reporting**, particularly with regard to food-producing animals
- Develop a reflection paper on potential approach to **causality assessment** as part of the procedure for surveillance of veterinary medicinal products, taking into account recent developments within veterinary pharmacovigilance
- PhVWP-V **Interested Parties** meeting

Joint Ad Hoc Expert Group on application of 3Rs

- **Review and update of CXMP guidelines for compliance with 3Rs principles** (in conjunction with relevant working parties)
  - Concept paper published for consultation in February 2014; JEG 3Rs and Working Parties currently reviewing guidelines
- **Guideline on regulatory acceptance of 3Rs testing approaches** (multidisciplinary project involving relevant working parties)
  - Draft guideline to be published for consultation Q2-3 2014
- **Development of guidance to support product specific validation of 3Rs tests used for batch release purposes** (multidisciplinary project involving IWP and BWP)
  - Concept paper to be published Q2 2014

Joint Ad Hoc Expert Group on application of 3Rs

- **Review of final product batch testing requirements for centrally authorised products**
  - Work to proceed looking at products authorised on a year by year basis, starting with 2013

- **Preliminary analysis of regulatory relevance of new alternative methods (PARERE)**
  - Continue to comment on EURL ECVAM draft recommendations

CVMP

Core business

- **Applications**; MRLs and veterinary medicinal products
- **Scientific Advice**
- **Referrals**
- Guidance documents
- International cooperation and harmonisation
- Input to the Commission

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CVMP

- **Work planning**: intended submission date should be realistic to avoid delays; necessary for resource planning for rapporteurs and their assessor teams, Agency
  - new rules for when Rapporteurs are appointed
  - Rap-meetings later in procedure

- **ITF (Innovation Task Force)**: *presentation tomorrow*
  - more help in the very early stage
- More emphasis on **scientific advice**:
  - ensures agreement on your development plans from CVMP

CVMP

- MUMS (Minor Use and Minor Species) policy
  - Policy and fee incentives revised, *presentation tomorrow*
  - CVMP considers updating the MUMS guidelines
- Referrals
  - Antimicrobial resistance is high on the community agenda
  - Harmonisation of SPCs can be expected for some antimicrobials
- Tailored environmental risk assessments
  - e.g. hormonal substances


Thank you for your attention
Questions?