



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CVMP work plan for 2015: Highlights and potential implications for new applications and developments

EMA/IFAH-Europe Info Day 2015



Presented by Anja Holm on 12 March 2015

Chair of the Committee for Medicinal Products for Veterinary Use (CVMP)

An agency of the European Union

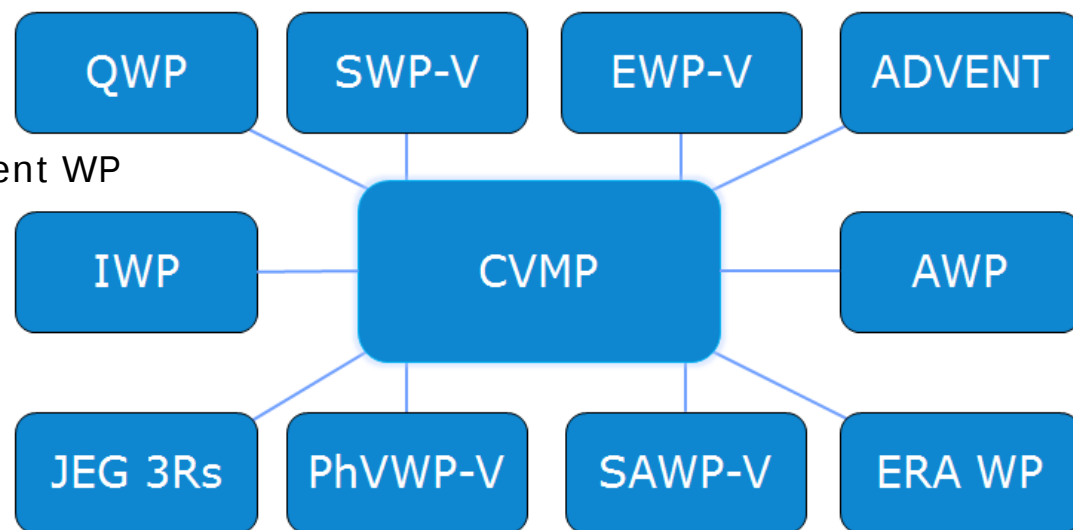




Overview

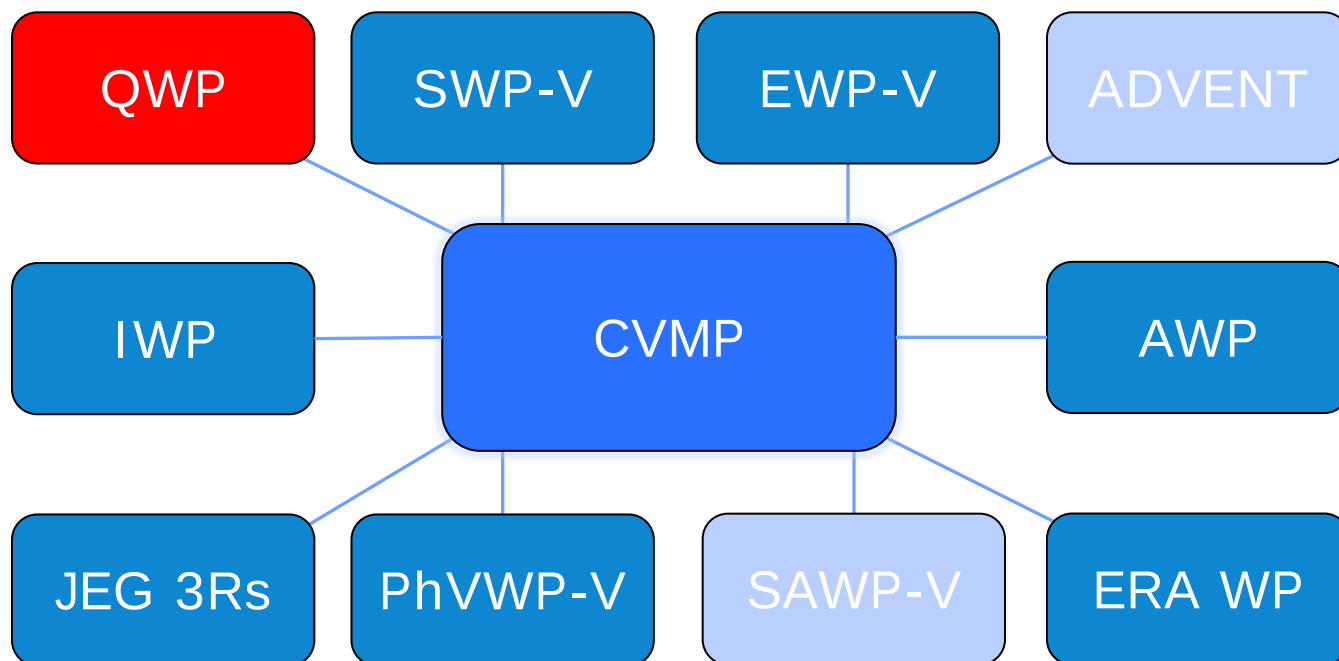
CVMP Working Parties

- 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 Scientific Advice WP*
- *CVMP ADVENT – Novel therapies*



CVMP

- Core business
- Specific topics





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

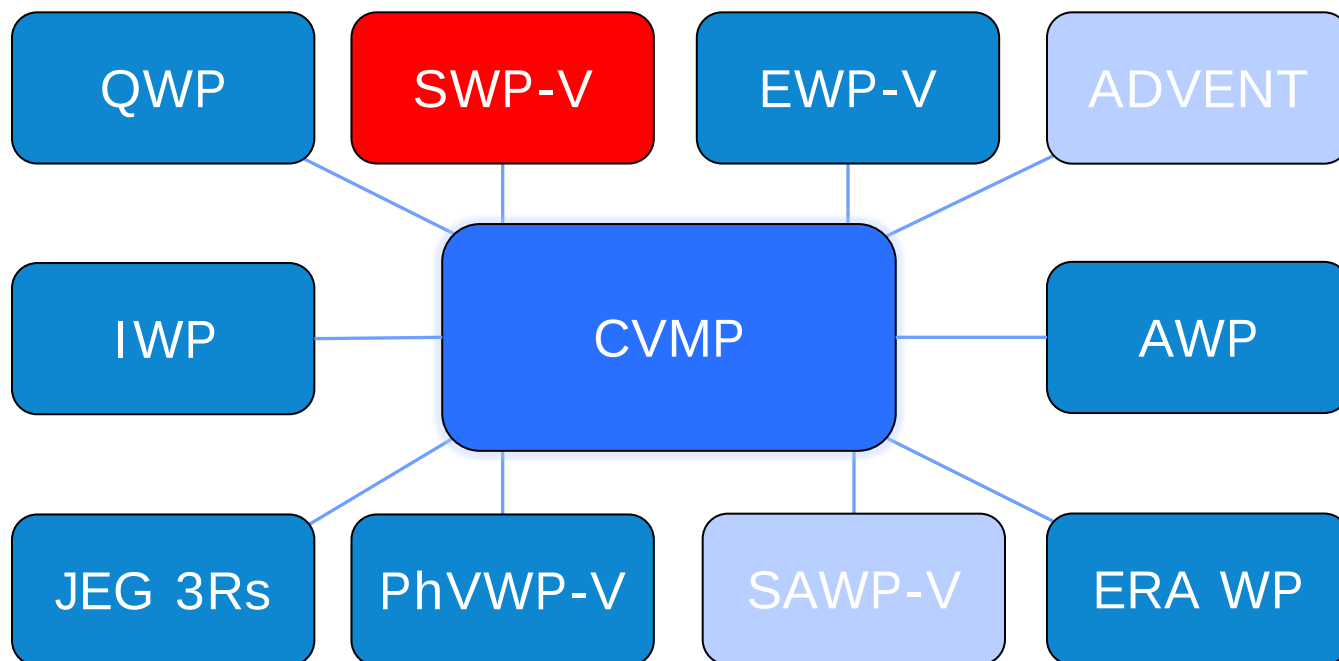
V Guideline on the Chemistry of active substances

- Initiative for bridged revision of relevant H Guidelines (currently “Note for guidance on chemistry of new active substances” (CPMP/QWP/130/96, Rev 1) and “Chemistry of active substances” (3AQ5a)).
- Draft Human Guideline almost finalised, now update Vet guidance.
- For Vet products no Guideline yet on genotoxic impurities and no equivalent Vet Guidelines to ICH M7, Q11 and Q8-10.
- Revised Vet Guideline will need to cover these differences, NTA structure and references to CVMP guidelines.



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

- **H/V Guideline on the selection of sterilisation processes for drug products, active substances and primary packaging**
 - New guideline
- **V Guideline on the manufacture of the finished dosage form**
 - Revision
- **V Guidance on quality data requirements for veterinary medicinal products intended for use in minor uses or minor species**
 - Review of, and revision if necessary





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

User safety evaluation of topically applied veterinary medicinal products (hope to publish draft in Q3-Q4 2015)

- There has been an increased number of applications for topically administered products in recent years, particularly in relation to companion animals
- Existing user safety guideline provides general guidance but more detailed guidance on considerations relevant to topically applied products would be valuable for industry and assessors, as it would encourage consistent and predictable decisions
- The GL will include guidance on:
 - direct exposure scenarios (eg, contact arising from spillage) as well as more indirect exposure of household members (eg exposure of children resulting from contact with treated animal),
 - evaluating acute exposure as well as (sub)chronic exposure
 - points to consider in relation to wipe tests
- Development will consider existing EPA (2012) guidance as well as guidance in use by EU member states



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

Guideline on risk characterisation and assessment of maximum residue limits for biocides

Final guideline published. Relates specifically to biocidal substances used in animal husbandry

Note for guidance for determination of withdrawal periods for milk

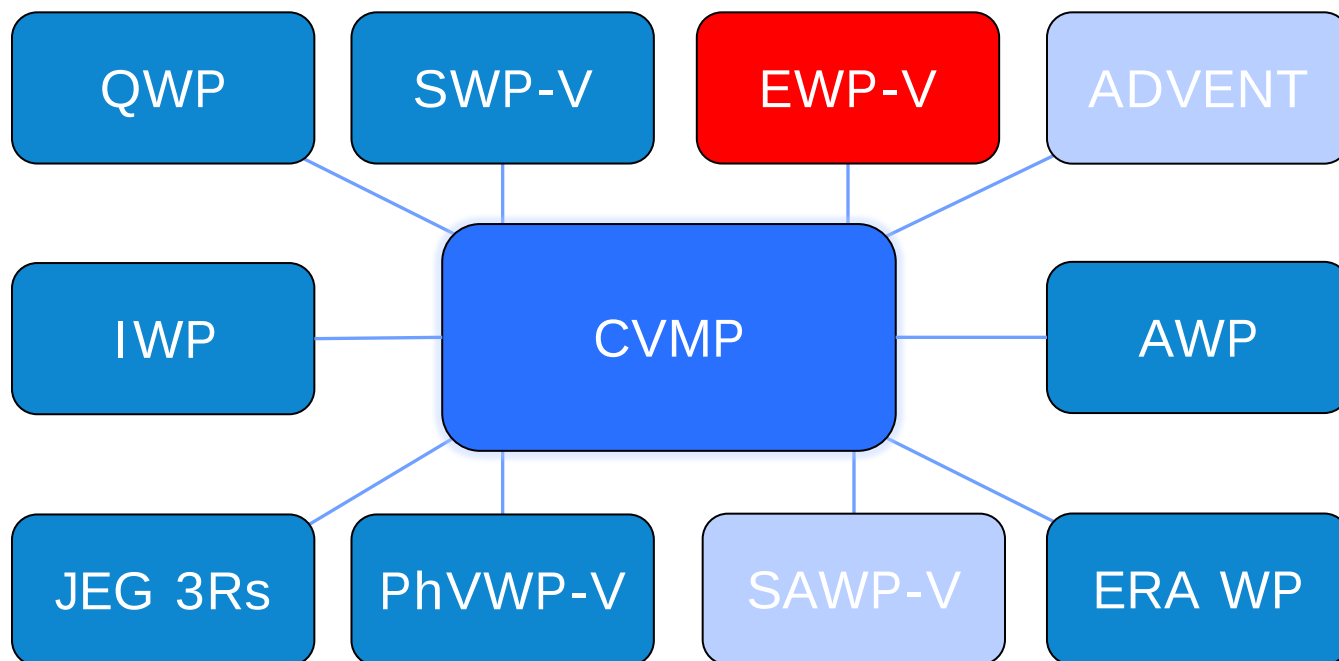
Reviewing GL to consider including guidance relevant to dry cow products. SWP considering alternative to current WP programme (MELK 14) (hope to publish draft GL in Q 4 2015)

Guideline on genotoxic impurities in VMPs

Development of an approach for agreeing limits for genotoxic impurities in VMPs (hope to publish draft GL in Q3-4 2015)

Guidance on the toxicological risk to humans and the environment of VMPs in groundwater

Concept paper published in 2013 but further work was put on hold pending finalisation of the consultation of the revision to the groundwater directive. SWP/ERAWP now working on this further (hope to publish draft GL in Q2-3 2015)





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

Guideline on the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances (EMA / CVMP / 627 / 01) – Revision

- Following publication for comments and focus-group-meeting (Dec 2013), CVMP adopted revised GL for second round of consultation (deadline: 31 May 2015)
- In collaboration with AWP
- Main changes:
 - More detailed information on metaphylaxis claims
 - More detailed information on “products which according to official guidance should be reserved for certain situations only”
 - Revised glossary / definitions

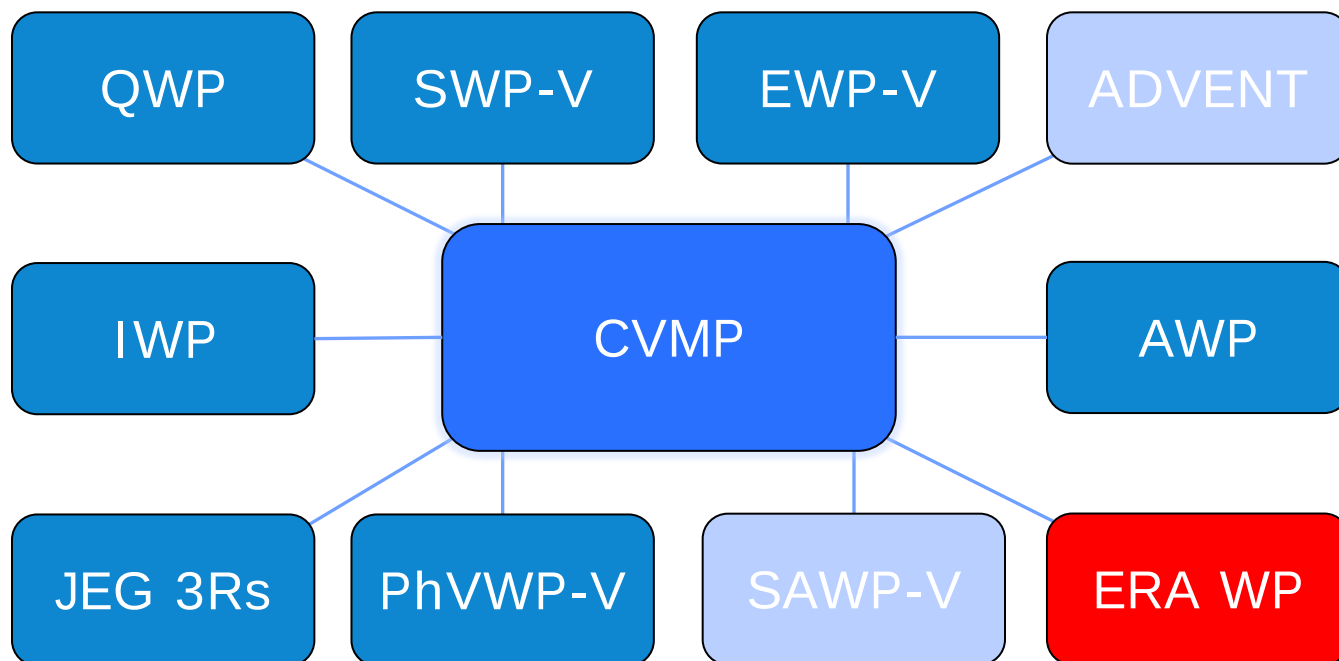


CVMP Efficacy Working Party (EWP-V) 2/2

Another focus in work plan 2015: “Antiparasitics”

- **GL on the testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats** (EMA/CVMP/005/00) (Revision)
Revised GL soon to be published for 6-months consultation (publication exp. following April CVMP).
- **GL on data requirements for veterinary medicinal products for the prevention of transmission of canine and feline vector-borne diseases** (New)
End of public consultation of concept paper: 28 Feb 2015
- **Reflection paper - ectoparasitic resistance** (New)
In preparation (publication exp. mid/end 2015)
- **Reflection paper - anthelmintic resistance** (New)
Revised RP in preparation (following end of public consultation: 31 Jul 2014) incl. recommendations

Focus group meeting (anthelmintic resistance) – planned for mid/end 2015





CVMP Environmental Risk Assessment Working Party (ERA WP) 1/2

Guideline on the 'Assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicines'

- Guideline published for the 1st public consultation: 2013
 - Technical guideline based on PBT identification according to REACH Annex XIII
- Inclusion in GL of 'Part 2. Assessment of products containing a PBT substance'
- Guideline published for a 2nd public consultation: 11/2014 – 01/2015
 - **Part 1:** PBT identification according to REACH Annex XIII
 - **Part 2 (New):** Assessment of VMPs containing a PBT substance: describing general principles on how VMPs containing a substance that have been identified as PBT should be further assessed within the context of a marketing authorisation application.
- Guideline to be finalised by Q3 2015



CVMP Environmental Risk Assessment Working Party (ERA WP) 2/2

Reflection paper on ‘poorly extractable and/or non-radiolabelled substances’

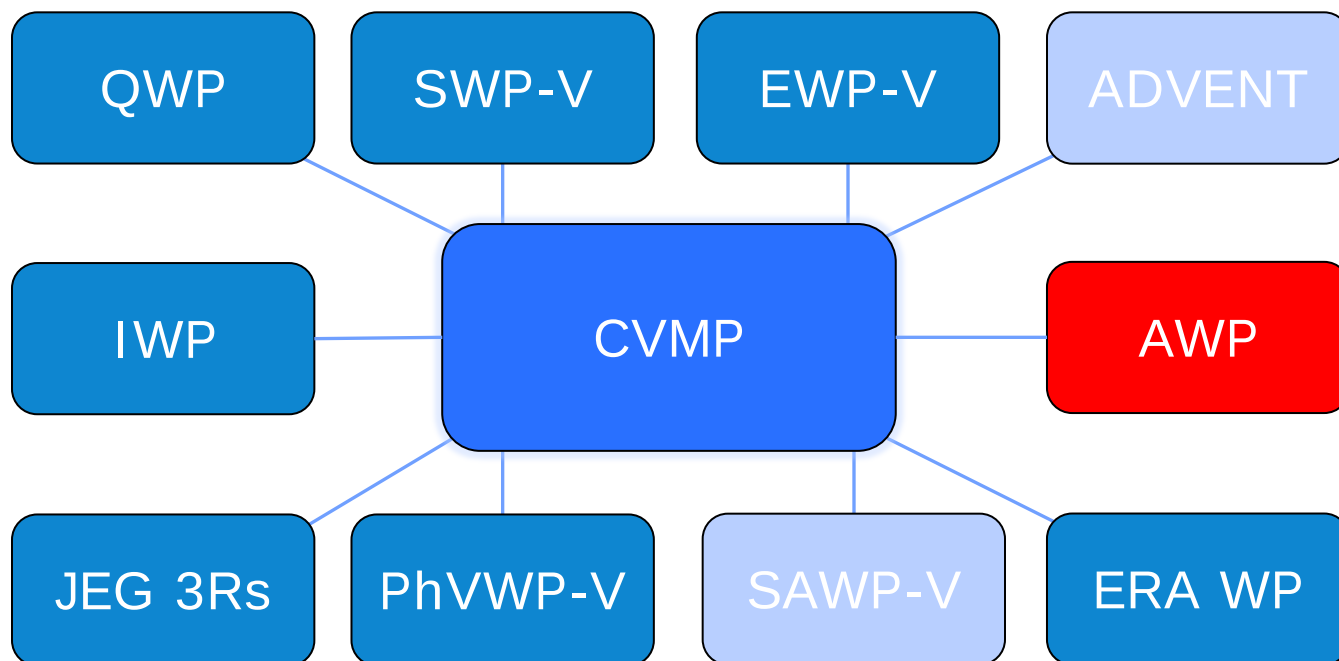
- How poorly extractable and/or non-radiolabelled substances should be assessed when they do not meet the quality criteria on recovery rates according to guideline OECD 307

Antimicrobial resistance (AMR) due to presence of veterinary antimicrobials in the environment

- Reflection paper in collaboration with AWP

Higher tier testing of antiparasitic compounds to dung organisms

- Guideline on recommendations on how and 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.





CVMP Antimicrobials Working Party (AWP) 1/2

Guideline on antimicrobial resistance risk assessment

Scope: VMPs intended for food producing species and transmission of AMR by the foodborne route or through direct contact with treated animals.

Guideline structured into:

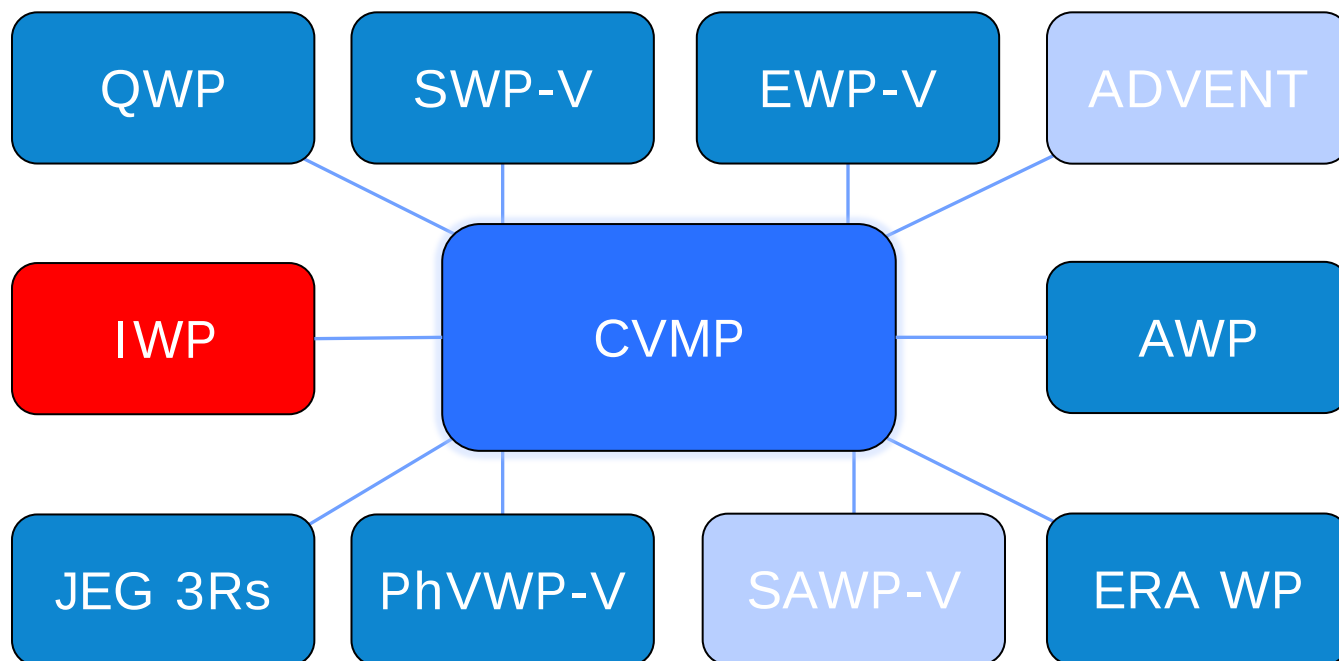
- Hazard identification
- Release assessment
- Exposure assessment
- Consequence assessment

End of consultation: 31 August 2015



CVMP Antimicrobials Working Party (AWP) 2/2

- Guidance on **data requirements for new veterinary medicinal products for companion animals with respect to antimicrobial resistance**
- Reflection paper **on use of aminoglycosides in animals in the European Union**
- Reflection paper on **off-label use of antimicrobials in selected domestic animals**
- Concept paper on **use of broad-spectrum penicillins in animals in the European Union**





CVMP Immunologicals Working Party (IWP)

1/2

Testing of immunological veterinary medicinal products (IVMPs) for freedom from extraneous agents (EAs)

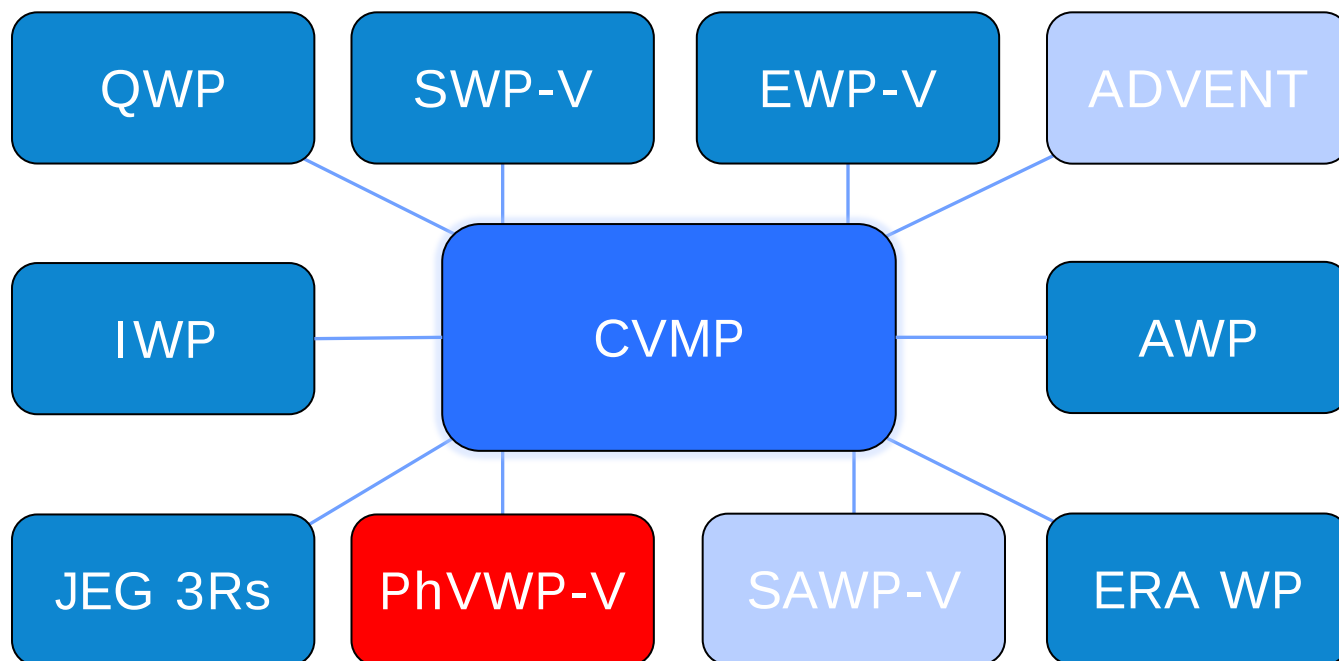
- **Proposal:** Split the existing 'Table of extraneous agents to be tested for in relation to general and species specific guidelines on production and control of mammalian veterinary vaccines' (7BIm10a)
- **Current situation:** CVMP discussion document on approach to updating EU guidance on testing of IVMPs for freedom from EAs (to be endorsed by CVMP in March 2015)
- **Timeline:** release for public consultation (Q3/Q4 2015)



CVMP Immunologicals Working Party (IWP)

2/2

- **Guidance on the replacement of cell lines used for the production of immunological veterinary medicinal products** – published for consultation
- **Guidance on the use of heat treatment to inactivate retrovirus RD114 in live immunological veterinary medicinal products (IVMPs)** – published for consultation
- **Guideline on data requirements for IVMPs intended for MUMS/limited markets** - to be released for consultation (2015)





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

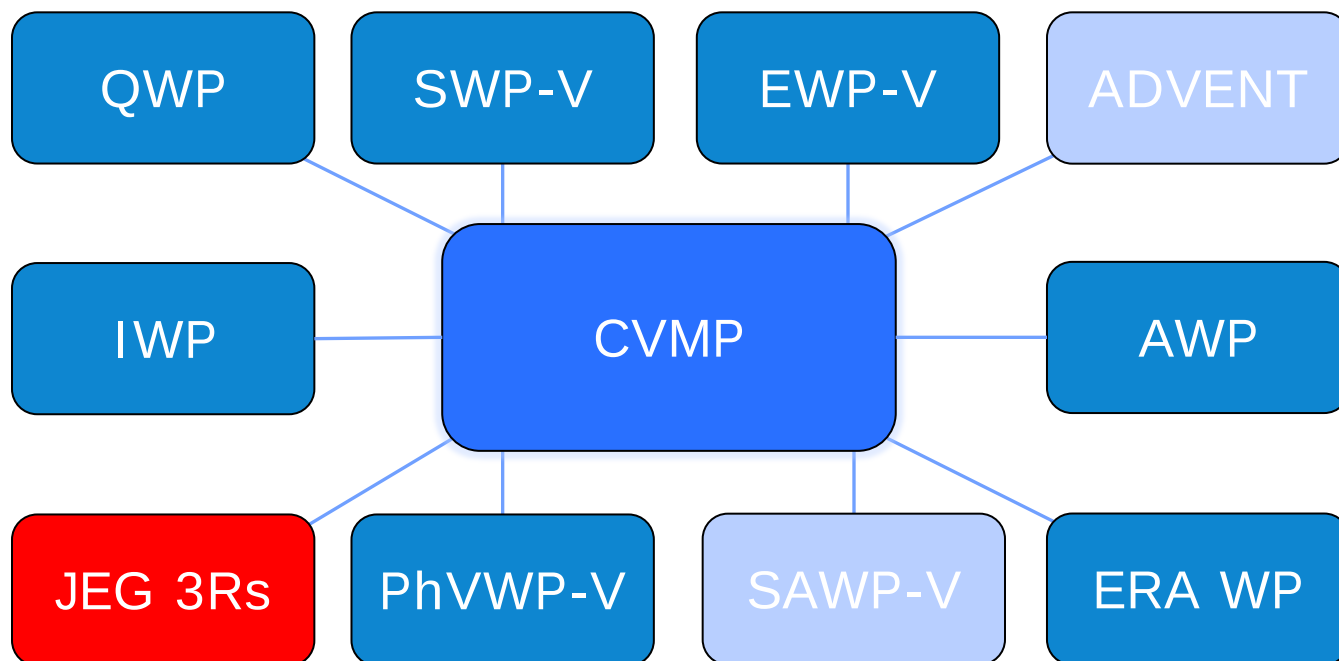
Finalisation of the recommendation on pharmacovigilance surveillance and signal detection of veterinary medicinal products

- Following public consultation (ended June 2014)
- Focus group meeting on signal detection held in 2014
- Status to date: 159 CAPs for surveillance in EVVet with more than 350 surveillance reports during 2014
- Nearly 12,000 AEs reported 2014, a substantial increase in number



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

- 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
- 23 September 2015
- Reflect on **practical integration of PSUR and signal detection for post-marketing surveillance** of veterinary medicinal products in the EU
- Develop reflection paper to harmonise the approach to pharmacovigilance information coming from **social media**





JEG on 3Rs in Regulatory Testing of Medicinal Products (JEG 3Rs) 1/2

Guidance on transferring quality control methods validated in collaborative trials to a product/laboratory specific context

- Aim is to facilitate and encourage use of QC methods that have been validated and included in regulatory publications (eg, Ph Eur) but which still need to undergo product/laboratory specific validation
- BWP/IWP/JEG 3Rs is reviewing collaborative study reports to determine what relevant information is available and what would be of use
- Considerable work required, including liaison with EDQM and EURL ECVAM
- Publication of draft expected in second half of 2016



JEG on 3Rs in Regulatory Testing of Medicinal Products (JEG 3Rs) 2/2

Review and update of CXMP guidelines to ensure that these reflect best 3Rs practice

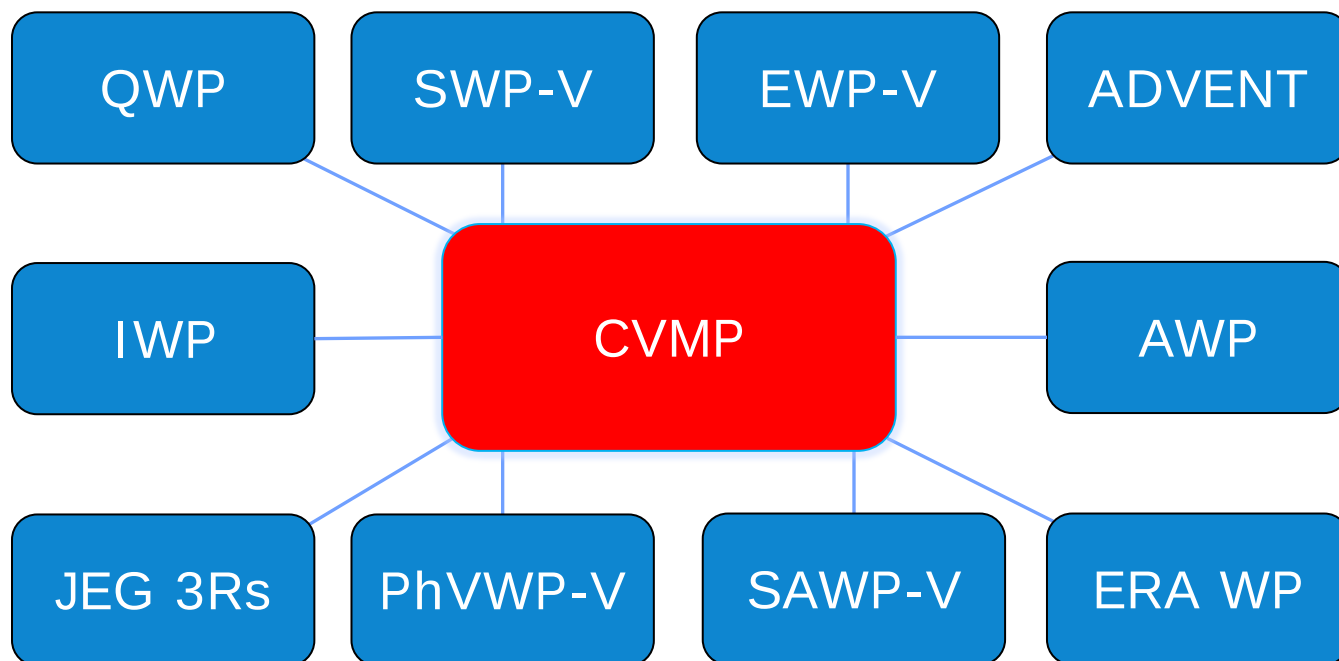
- Relevant working parties: QWP, SWP, SWP-V, BWP, IWP, VWP & EWP-V GLs. Some have reviewed GLs and are in process of incorporating updates – others are still reviewing. Hope to complete project by end Q1 2016
- Related to this, aim to publish a document outlining the main animal tests required and highlighting 3Rs options

GL on regulatory acceptance of 3Rs testing approach

- Finalise draft GL following public consultation. Draft GL highlights possibility of using scientific advice to obtain EMA view on acceptability of 3Rs tests.

Review of final product batch testing requirements

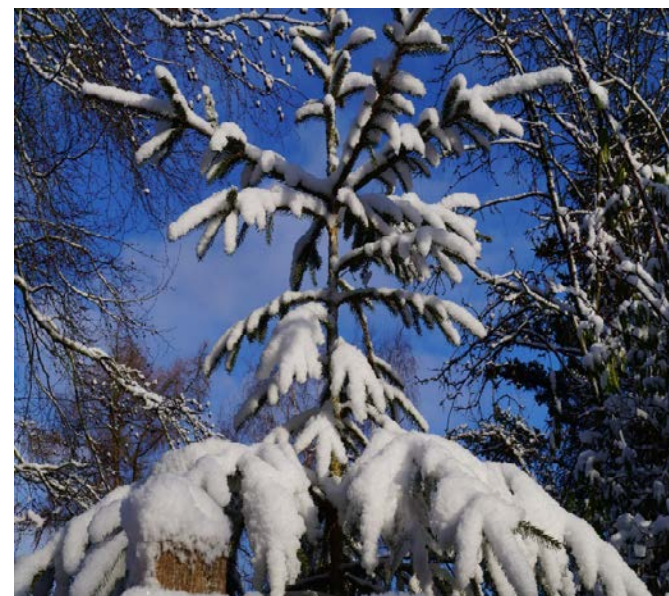
- Review of batch release testing for centralised veterinary vaccines and compliance with 3Rs options in PhEur. Ongoing work.





Committee for Medicinal Products for Veterinary Use (CVMP) – core business

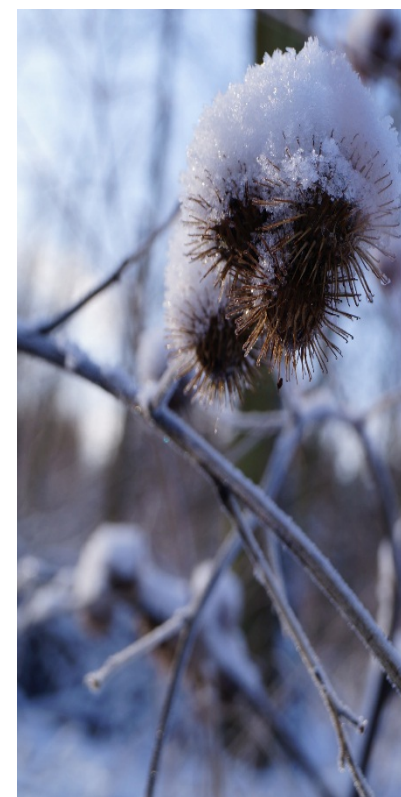
- Applications: MRLs and medicinal products, incl. variations, renewals, pharmacovigilance
- Scientific advice
- Referrals
- Guidance documents: WPs
- International cooperation and harmonisation
- Regulatory topics for CAPs, MUMS-designations
- Organisational topics





Committee for Medicinal Products for Veterinary Use (CVMP) – specific topics

- Antimicrobial resistance
- MUMS guideline: data requirements review and short-list
- Novel therapies: early discussion and stepwise guidance
- Vaccines: registration requirements workshop
- Aquaculture: availability of medicines and environmental issues
- Multinational assessment teams





Thank you for your attention!
Questions?

