



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CVMP achievements 2016

Highlights and reflections

2017 EMA Veterinary Medicines Info Day, London

Presented by David Murphy on 16 March 2017
Chair of the Committee for Medicinal Products for Veterinary Use (CVMP)

An agency of the European Union





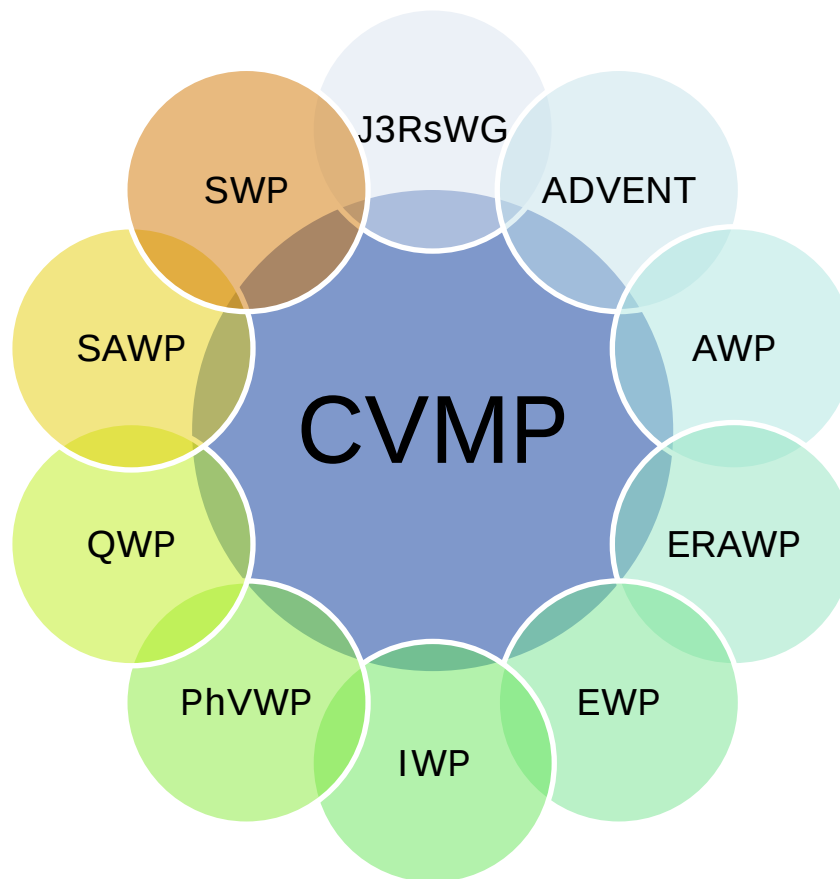
Presentation overview

- Work of the CVMP
- Significant outputs for 2016
 - Assessment related activity
 - Other activity
- 2017 CVMP Work Plan



CVMP responsibilities

- Assessment related activity
 - Assessment of MAAs submitted through the centralised procedure; post-authorisation activities; and, safety monitoring of those VMPs on the market.
 - Evaluation of veterinary medicines authorised at national level referred for a harmonised position across the EU.
 - Establishment of maximum residue limits.
- The CVMP and its working parties contribute to the development of veterinary medicines and medicine regulation, by:
 - Providing scientific advice;
 - Preparing scientific guidelines and regulatory guidance; and
 - Cooperating with international partners on the harmonisation of regulatory requirements.





2016 Outputs MAA (new/extension)

Pharmaceutical

- Positive opinion: **Bravecto**, **Draxxin**, Metacam, **Varromed**, Stronghold Plus, Equioxx
 - Generic: Sevocalm, Sedadex, Halagon, Cepedex,
- Negative opinion: Draxxin

Immunological

- Positive opinion: Evalon, **Letifend**, **Poulvac E. coli**, **Clynav**, **ERAVAC**, Coliprotec F4/F18
- Negative opinion: Respiporc FLUpan H1N1



2016 Outputs

- MRL opinions
 - New: hydrocortisone aceponate, aluminium salicylate, fluralaner
 - Extensions: monepantel, gamithromycin
- Scientific advice: 18

2016 Outputs – Referrals complete

- Article 33: CattleMarker IBR
- Article 34: None.
- Article 35: Colistin in combination with other AM(s); altrenogest; lincomycin/spectinomycin for oral use in pigs and/or poultry; Gentamicin soln for injection for cattle and pigs; Zinc Oxide for oral use in pigs
- Article 45 of Regulation 726/2004: Velactis (cabergoline)



2016 Outputs – PhV

- 174 VMPs authorised via the centralised procedure since 1995
- In 2016, a total of 18,413 adverse event reports relating to CAPs received:
 - 17,859 adverse events in animals and 554 adverse events in humans
 - Adverse event reports in dogs and cats accounting for 82% of the cases
 - (Focus group on promotion of PhV reporting for food animals).
- 147 periodic safety update reports reviewed (15 with recommendations for change)



2016 Outputs – MUMS

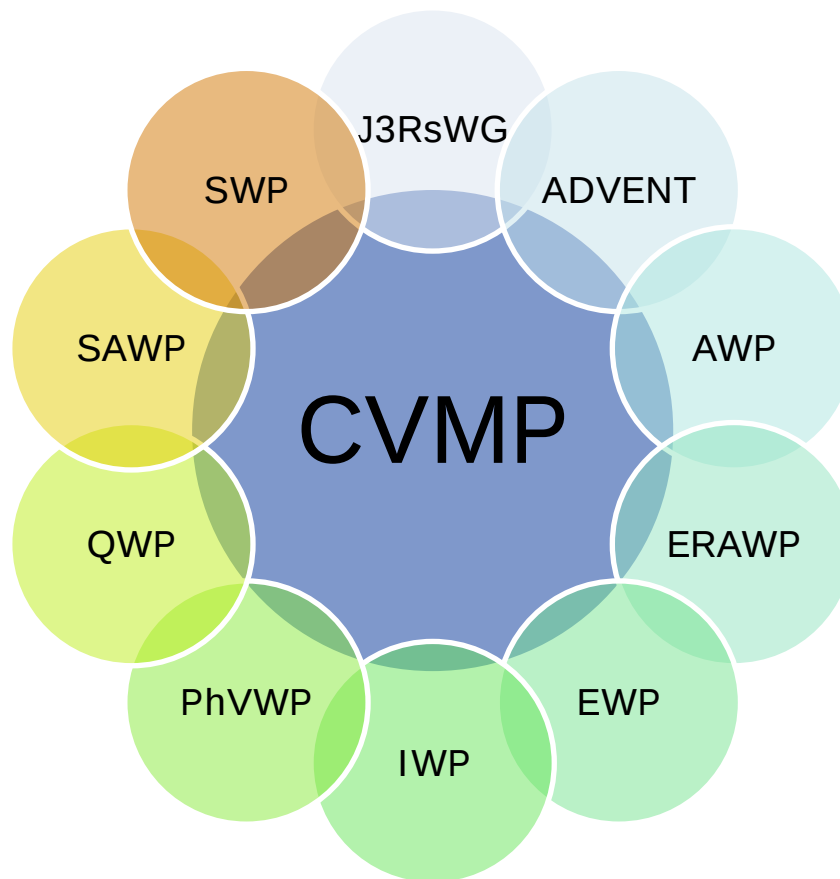
- Classification requests – overview
 - 25 MUMS requests received,
 - 18 classified and 4 reclassified as MUMS/limited market (88% in total).
 - Two product/indications recommended as eligible for financial incentives.
- MUMS related approvals: Letifend, Poulvac E. coli, Clynav, ERAVAC, Varromed
- Revised MUMS GLs adopted following close of consultation:
 - Quality
 - Safety and residues, and
 - Efficacy and target animal safety



2016 Outputs – MUMS

MUMS/limited market classification and reclassification								
Year	2009	2010	2011	2012	2013*	2014	2015	2016
MUMS classification with financial incentives	5	11	8	16	10	2	7	1
MUMS reclassification with financial incentives						0	1	1
MUMS classification without financial incentives	4	6	10	4	10	20	16	17
MUMS reclassification without financial incentives						0	0	3
Not MUMS	1	3	3	1	3	7	5	3
TOTAL	10	20	21	21	23	29	29	25

* Restriction of financial incentives to food producing animals only from 1 September 2013





2016 Outputs – Non-assessment activity

- Guidelines:
 - Finalised - 8
 - Released for consultation - 8
- Reflection papers
 - Finalised - 3
 - Released for consultation - 6
- Q+A documents (QWP x 7; ERAWP x 1; PhVWP x 1)
- Contributions to various VICH GLs

2016 Outputs – Guidelines finalised

- EWP: Revised GL on efficacy of VMPs containing AMs
- EWP: Revised GL on efficacy of substances for ticks and fleas in dogs and cats
- QWP: Revised GL on process validation for finished products
- IWP: Revised GL on the production and control of IVMPs
- J3RsWG: GL on the principles of regulatory acceptance of 3Rs testing approaches

- Revised MUMS GLs: Quality; Safety and residues; Efficacy and TAS



2016 Outputs – Guidelines released for consultation:

- EWP: Revised GL on efficacy studies for intra-mammary products
- QWP: GL on sterilisation of the product, active substance, excipient and primary container
- ERAWP: GL on plant testing strategy for VMPs
- SWP: GL on user safety of topically administered VMPs
- SWP: GL on approach towards harmonisation of withdrawal periods
- ERAWP: GL on higher tier testing of VMP effects on dung fauna (2017 Workshop planned)
- J3RsWG: GL for individual laboratories for transfer of quality control methods validated in collaborative trials with a view to implementing 3Rs.
- QWP: GL on the chemistry of active substances



2016 Outputs – Reflection Papers finalised

- ERAWP: Poorly extractable substances (relates to OECD TG 307)
- IWP: Risks that should be considered prior to the use of unauthorised vaccines in emergency situations
- IWP: Methods found suitable within the EU for demonstrating freedom from extraneous agents of the seeds used for the production of IVMPs

2016 Outputs – Reflection Papers released for consultation:

- ERAWP: Authorisation of VMPs containing potential PBTs/vPvB substances
- QWP: Chemical structure and properties criteria to be considered for the evaluation of NAS status of chemical substances
- QWP: Dissolution specification for generic oral release products
- EWP: Anthelmintic resistance (Focus Group meeting).
- J3RSWG: Overview of the current regulatory testing requirements for VMPs and opportunities for implementing the 3Rs
- PhVWP: Non-spontaneous adverse event reports



2016 Outputs – ADVENT

Problem statements released for public consultation:

- Monoclonal antibodies
 - Characterisation and specification setting
 - Target animal and reproductive safety
- Stem cells
 - Sterility
 - Extraneous agents
 - Tumorigenicity
 - Target animal safety



2016 Outputs – Antimicrobial resistance

- CVMP Strategy on AMs 2016-2020.
- AMEG: Updated advice on the use of colistin in animals
- Joint EMA and EFSA scientific opinion on measures to reduce the need to use AMs in food animals in the EU (RONAFA)



CVMP Vision Statement on antimicrobials 2016-2020

The CVMP's vision is the availability of effective antimicrobial medicines for the treatment of important infectious diseases of animals with, at the same time, minimum risks to animals or humans arising from their use.



6 October 2016
EMA/CVMP/209189/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP strategy on antimicrobials 2016-2020

Adoption by CVMP for release for consultation	6 November 2015
Start of public consultation	17 November 2015
End of consultation (deadline for comments)	29 February 2016
Adopted by CVMP	6 October 2016



CVMP Strategy on antimicrobials – Aims and Actions

Aim 1: To provide opinions for the authorisation of effective AM VMPs.

Aim 2: To consider and advise on the risk to public health that could arise from the use of antimicrobials in animals, and to balance this against the need to protect animal health. To provide advice in a One Health context.

Aim 3: To maintain the effectiveness of AMs that are already authorised as VMPs.

Aim 4: To encourage the development of new and existing AM VMPs.

Aim 5: To support the responsible use of AMs.

Aim 6: Recognising that AMR is a global problem, to work in partnership with all relevant stakeholders.

Other considerations of the CVMP strategy

One of the most effective measures to limit expansion of AMR is an **overall reduction in antimicrobial use**.

- This is best achieved through measures to prevent infections from establishing (husbandry, biosecurity, vaccination, etc) and more **targeted use** of antimicrobials where it is still necessary for animal health (e.g. by use of accurate diagnosis, evidence-based regional treatment guidelines and correct dosing regimens)

The CVMP will also **support the development of veterinary medicines which reduce the need for use of antimicrobials (“alternatives”)**, such as vaccines, and will facilitate the regulatory pathway for innovative products by contributing guidance through the Innovation Task Force (**ITF**) and the CVMP Ad Hoc Group on Veterinary Novel Therapies (**ADVENT**)

Measures to reduce the need to use antimicrobials in animal husbandry in the EU (RONAFA)

EC Request to the EMA and EFSA

1. Review the measures that have been, or are being taken, to reduce the use of antimicrobials in animal husbandry in the EU.
2. Assess the impact of such measures regarding the occurrence of antimicrobial resistance in bacteria from food-producing animals and food.
3. Possible alternatives to the use of antimicrobials in animal husbandry in the EU.
4. Impact of such alternative measures on the occurrence of antimicrobial resistance
5. Recommend options to reduce antimicrobial usage in animal husbandry in the EU



24 January 2017
EMA/CVMP/47873/2017
Media and Public Relations

Press release

It's time to reduce, replace and re-think the use of antimicrobials in animals

EMA - EFSA joint opinion on EU measures to reduce antimicrobials use in animals

Reducing the use of antimicrobials in food-producing animals, replacing them where possible and re-thinking the livestock production system is essential for the future of animal and public health. Antimicrobial resistance (AMR) is one of the world's most pressing public health issues and the use of antimicrobials in animals contributes to this problem, so limiting their use to the minimum necessary to treat infectious diseases in animals is crucial.

Recommendations to reduce antimicrobial use in food-producing animals

An integrated, multifaceted approach is needed:

- Control strategies that have been important drivers for change include setting of national targets to reduce antimicrobial use.
- Use should be reduced to the minimum that is necessary to treat infectious diseases.....their use to prevent such diseases should be phased out in favour of alternative measures.
- CIAs for human medicine should only be used in animals as a last resort.
- Consider alternatives to antimicrobials.
- Implementing farming practices that prevent the introduction and spread of the disease.
- Education and awareness.

Vaccine availability

Joint EMA and HMA action plan

- Aims to implement the conclusions of a joint EMA and HMA workshop on improving the availability of veterinary vaccines held in March 2015.
- Workshop objectives:
 - To improve availability while maintaining a high level of protection for animal and public health
 - To examine whether the authorisation requirements for vaccines are proportionate

Vaccine availability

Implementing the plan

- February 2016, HMA and EMA established a joint steering group to strategically oversee the plan's implementation.
- March 2016, the CVMP established an ad-hoc expert group on veterinary vaccine availability (CADVVA) to support the steering group in implementing the actions under CVMP responsibility
- December 2016, the joint steering group met with Industry representatives to discuss ongoing activities and next steps.



Conclusion on 2016

Much done,
.....more to do

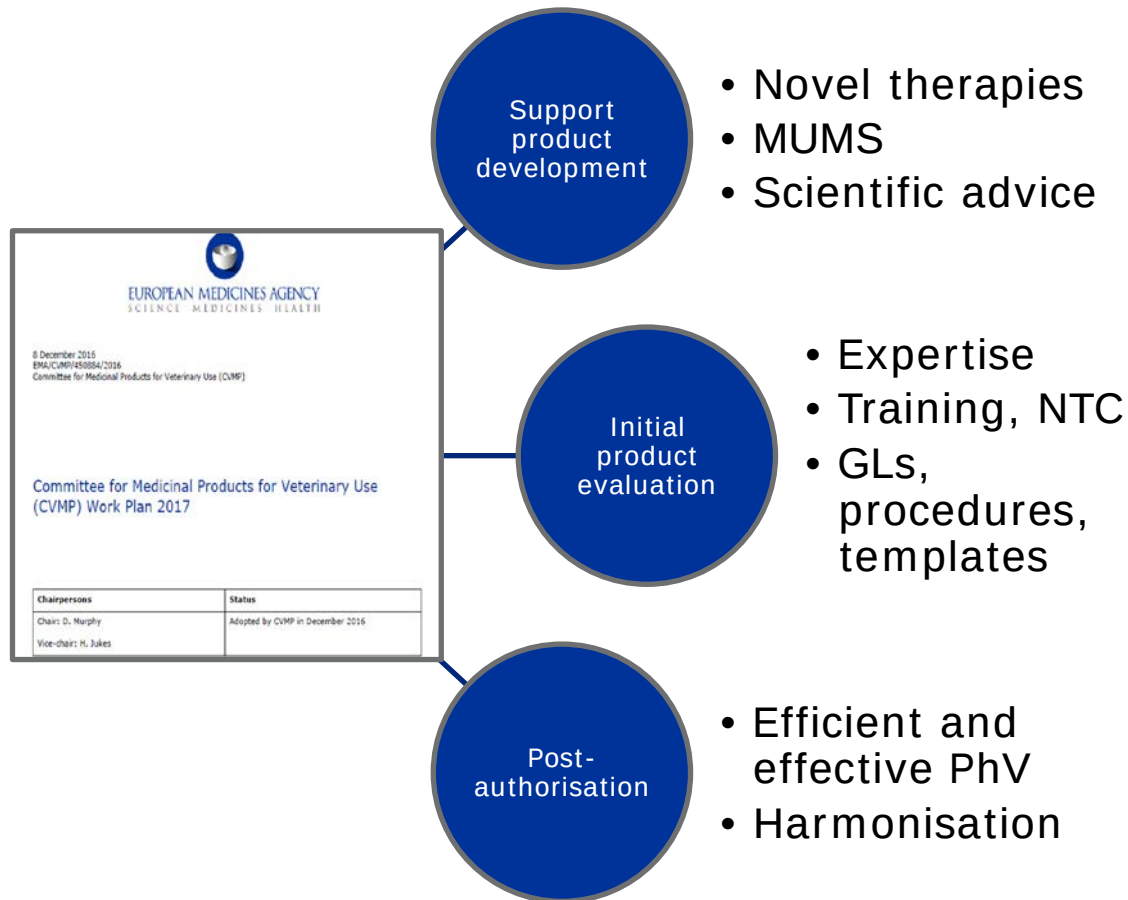


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8 December 2016
EMA/CVMP/450884/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use (CVMP) Work Plan 2017

Chairpersons	Status
Chair: D. Murphy Vice-chair: H. Jukes	Adopted by CVMP in December 2016



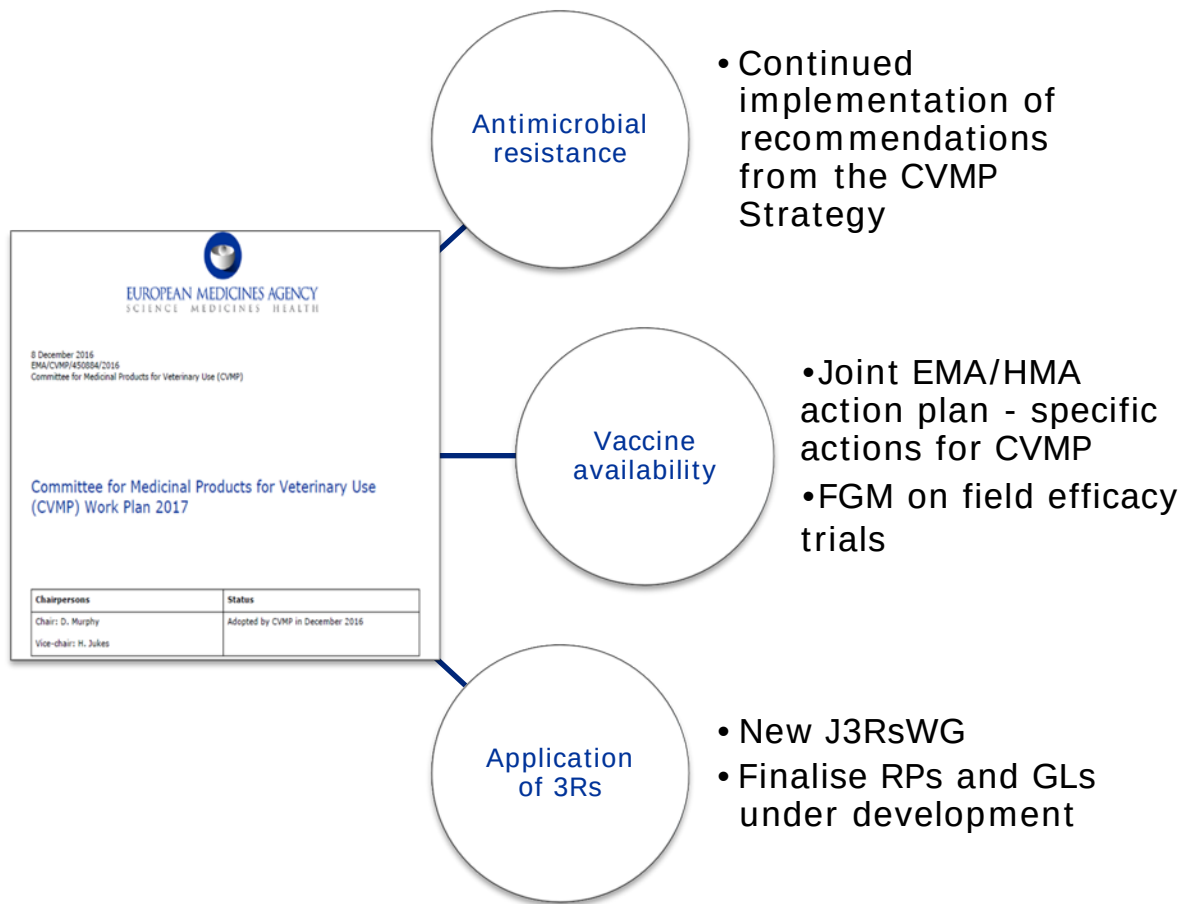


Specialised areas

- ERA
 - Reflection paper on PBT
 - Reflection paper on use of VMPs in aquaculture
- MRLs
 - Methodological principles for risk assessment and risk management

International harmonisation

- Contribute to VICH
- Harmonisation of scientific approaches on risk assessment





Thank you for your attention

Further information

www.ema.europa.eu

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