EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CVMP update on activities relating to Regulation 2019/6

Veterinary Medicines Info Day 2021

Presented by David Murphy on 25 March 2021
Chair of the Committee for Medicinal Products for Veterinary use (CVMP)

Role of the CVMP

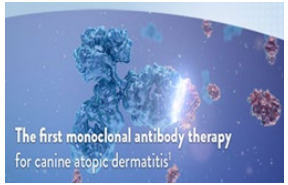
Article 57, Regulation (EC) No. 726/2004

1. The Agency shall provide the Member States and the institutions of the Community with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use which is referred to it in accordance with the provisions of Community legislation relating to medicinal products.

To this end, the Agency, acting particularly through its committees, shall undertake the following tasks:

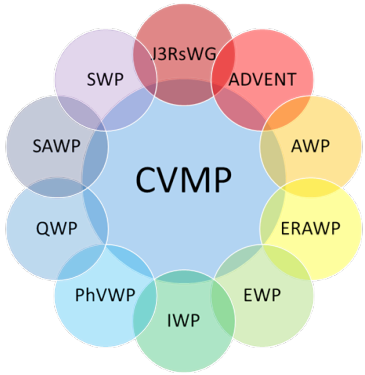
(a) coordination of the scientific evaluation of ……...

Role of the CVMP



- Assessment-related activities:
  - Authorisation, and life-cycle management, of VMPs via the centralised procedure
  - Evaluates VMPs authorised at national level referred for a harmonised position
  - Establishment of maximum residue limits

- Contribute to the development of VMPs and VMP regulation, by:
  - providing scientific advice;
  - preparing scientific guidelines and regulatory guidance;
  - cooperating with international partners on the harmonisation of regulatory requirements.



Assessment-related activities (concluded)

Year	New/Extn MA*	New/Extn MRL	Referrals	Scientific advice
2018	18	3	4	23
2019	17	2	5	21
2020	20	5	7	28

*3 negative opinions, one of which went positive following re-examination

Referrals concluded (2018-2020) – potential serious risk issues

Legal basis	Article 33	Article 34	Article 35	Article 13	Article 30	Article 45
Number	1	2	9	1	2	1
Concern	Consumer safety	SPC harmonisation	• Consumer safety x 7, • Indications/ dose x 2	Inadequate efficacy	• Consumer safety, • TAS	PRRS MLV

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20 January 2021
EMA/CVMP/553776/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use (CVMP) Work Plan 2021

REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 December 2018

on veterinary medicinal products and repealing Directive 2001/82/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 168(4)(b) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) Directive 2001/82/EC of the European Parliament and of the Council [3] and Regulation (EC) No 726/2004 of the European Parliament and of the Council [4] constituted the Union regulatory framework for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and the use of veterinary medicinal products.

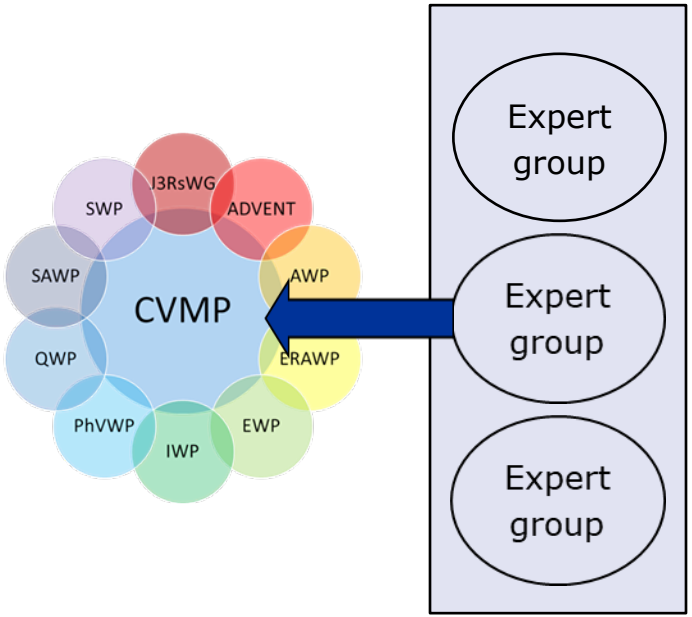
Impact on the EMA

Explicit requirements

- Provide scientific advice on request to the European Commission as part of consultation in drawing up **delegated and implementing act**s specified in the regulation

Implicit requirements

- Endorse **new and revised guidanc**e which involve CVMP and its working parties
- **Provide scientific advice** to the EC on other obligations in the new veterinary regulation (e.g. in relation to ERA)



Objectives of the new veterinary regulation

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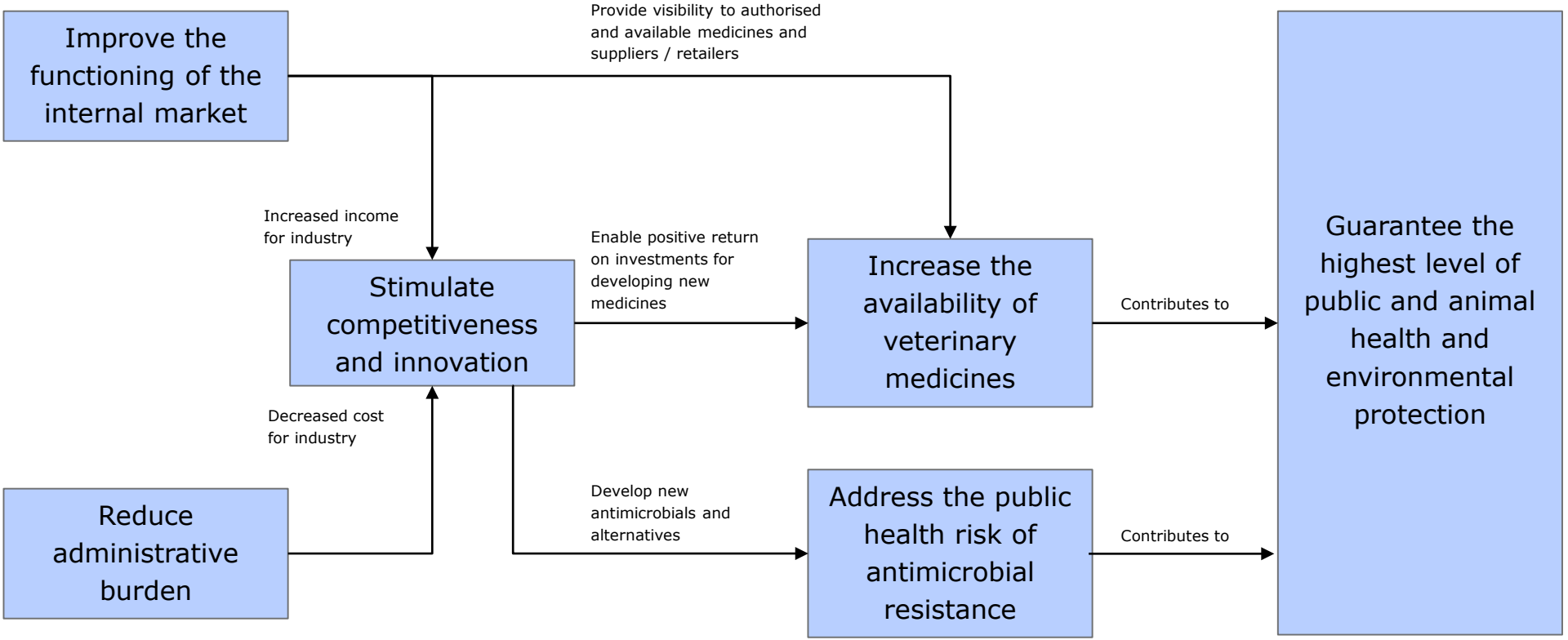

"These objectives are not only complementary, but also interlinked, as innovation will provide new and better medicines to treat and prevent diseases in animals, while avoiding damage to the environment." (Preamble) "It is critically important to have a single market for veterinary medicinal products as the veterinary pharmaceutical sector is driven by commercial returns obtained through the sales of veterinary medicinal products on the resources spent. The current confined and fragmented markets do not allow the pharmaceutical sector to have a positive return on investments for developing new products for certain animal species. The ambition to improve the availability of medicines in the Union and the functioning of the internal market and market competition can only be carried out at EU level. Ultimately, this would benefit animal and human health across the Union." (Grounds for the proposal/initiative)

Other considerations:

- Promote the appropriate application of the 3Rs,
- Liaise with CMDv on topics of common interest to ensure consistency of approach

- In relation to assessment activity, the CVMP is committed to
  - Strengthening the quality of the scientific review process
  - Ensuring consistency of outputs
  - Reviewing assessment procedures, with a view to process improvement

Activities to support for product development and innovation

- Scientific recommendation on the revision of Annex II (✓ 30 Aug 2019)
- Generation of guidance to support Annex II:
  - Data requirements for vaccine antigen master file,
  - Data requirements for vaccine platform technology master file,
  - Data requirements for multi-strain dossiers (GL revision)
  - Requirements for field efficacy data for veterinary vaccines (GL revision)

Concept papers out for consultation **31/03/2021**

  - Consider what, if any, new guidance is required in the area of novel therapies

Finalise by Jan 2022

Activities to support for product development and innovation

Article 40

Prolongation and additional periods of the protection of technical documentation

5. *If a variation to the terms of the marketing authorisation approved in accordance with Article 67 involves a change to the pharmaceutical form, administration route or dosage, which is assessed by the Agency or the competent authorities referred to in Article 66 to have demonstrated:*

(a) a reduction in the antimicrobial or antiparasitic resistance; or

(b) an improvement of the benefit-risk balance of the veterinary medicinal product,

the results of the concerned pre-clinical studies or clinical trials shall benefit from four years protection.

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16 July 2020
EMA/CVMP/340959/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Concept paper for the development of a reflection paper on criteria for the application of Article 40(5) of Regulation (EU) 2019/6

Agreed by CVMP Drafting Group on Article 40(5) of Regulation (EU) 2019/6	1 July 2020
Adopted by CVMP for release for consultation	16 July 2020
Start of public consultation	20 July 2020
End of consultation (deadline for comments)	21 September 2020

Finalise by – July 2021

Activities to support availability – limited markets

Update: The **eligibility criteria** and guidelines on **reduced data requirements** that will apply under the Regulation are available for **public consultation:**

- Classification of a product as intended for a limited market and eligibility for authorisation under Article 23 of Regulation (EU) 2019/6 (Applications for limited markets)
- Safety and residue data requirements for the establishment of maximum residue limits in minor species
- Safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6
- Data requirements for applications for immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6
- Efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6

These guidelines will supersede the currently applicable guidelines under EMA's MUMS / limited market policy on 28 January 2022.

Stakeholders should send their comments to vet-guidelines@ema.europa.eu by 15 May 2021 using the form linked within the guidelines.

Focus group meeting 30/03/2021
Finalise by July 2021

Activities to support availability – exceptional circumstances

Article 25

Applications in exceptional circumstances

By way of derogation from point (b) of Article 8(1), in exceptional circumstances related to animal or public health, an applicant may submit an application which does not meet all requirements of that point, for which the benefit of the immediate availability on the market of the veterinary medicinal product concerned to the animal or public health outweighs the risk inherent in the fact that certain quality, safety or efficacy documentation has not been provided. In such a case, the applicant shall be required to demonstrate that for objective and verifiable reasons certain quality, safety or efficacy documentation required in accordance with Annex II cannot be provided.

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20 January 2021
EMA/CVMP/IWP/630533/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Concept paper for the development of a guideline on data requirements for authorisation of immunological veterinary medicinal products under exceptional circumstances

Agreed by Immunologicals Working Party	17 December 2020
Adopted by CVMP for release for consultation	20 January 2021
Start of public consultation	29 January 2021
End of consultation (deadline for comments)	31 March 2021

Finalise by Jan 2022

Activities relating to pharmacovigilance

EMA scientific recommendations

- Good pharmacovigilance practice
- Format and content of PSMF

✓ 29 May 2020

Committee for Medicinal Products for Veterinary Use (CVMP) Work Plan 2021

Key objectives

- Maintain efficient and effective conduct of pharmacovigilance, including surveillance and signal management, while preparing for the future system by providing the necessary guidance, systems, and refining processes;
- Improve communication of urgent pharmacovigilance issues related to VMPs and provide regular updates on emerging and topical issues.

Activity

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Develop guidance following on from the scientific recommendations on the implementing acts, with a focus on the following topics: - Signal management process; - PSMF and PhV inspections; – Communication on post-authorisation safety issues.	PhVWP	1	Ongoing	Yes	July 2021
2.	Establish processes for work sharing procedures for post-marketing surveillance based on signal detection for all VMPs authorised in the EU.	Dedicated Expert group in consultation with EMA and CMDv/HMA	1	Ongoing	No	Jan 2022

Activities relating to antimicrobial resistance

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SCIENCE MEDICINES HEALTH

20 January 2021
EMA/CVMP/179874/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP strategy on antimicrobials 2021-2025

Adopted by CVMP for release for consultation	18 June 2020
Start of public consultation	1 July 2020
End of consultation (deadline for comments)	30 September 2020
Adoption by CVMP	20 January 2021

Mission statement on antimicrobials

The CVMP's mission is to ensure the availability of effective antimicrobial medicines for the treatment of infectious diseases of animals while, at the same time, minimising the risks to animals, humans and the environment arising from their use.

Activities relating to antimicrobial resistance

EMA scientific recommendations

- ✓ Requirements for collection of data on AMs
- ✓ Format for the collection of data on AMs
- ✓ Criteria for AMs reserved for human use
- × List of 'reserved' AMs
- × List of AMs 'restricted' when used under 'cascade'

- Guideline on risk assessment of AM VMPs (finalise by April 2021)
- Art. 107(3) - Elaborate criteria for determining 'exceptional cases' when AM prophylaxis would be accepted (Jan 2022)
- Art. 57: Develop guidance, data reporting protocols and templates following the scientific recommendations on the IA and DA on collection of AM use data (Dec 2021)
- Reflection paper on promoting alternatives to AMs (June 2021)

Activities relating to environmental risk

- Reflection paper on AMR due to the presence of veterinary AMs in the environment (✓ Feb 2021)
- Article 18(7) – establish criteria for requesting ERA data for generic applications (finalise by Dec 2021)
- Article 37(2)(j) (Decisions refusing marketing authorisations) - Establish principles to demonstrate that a persistent, bioaccumulative and toxic substance is essential to prevent or control a serious risk to animal health (finalise by Jan 2022)
- Elaborate concept paper for a GL on ERA of products used in aquaculture (finalise by Dec 2021)

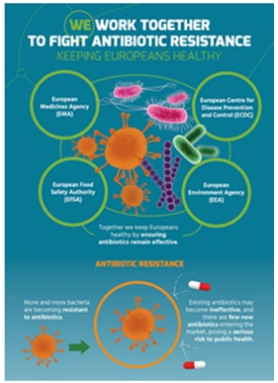
Activities- selected other

- Article 42 – Scope of the centralised procedure
  - Establish clear rules on eligibility,
  - Ensure effective/efficient procedures to process (an increase in) applications
- Contribute to any tasks arising from revision of the QRD template, as requested (released for consultation March 2021)

- Further to a request from the Commission, finalise a recommendation for a joint EMA/EFSA approach on exposure assessment methodologies for residues from VMPs, feed additives and pesticides residues in food of animal origin (finalise by Nov 2022)

Challenges for the CVMP

- Realising the primary objectives of Regulation 2019/6 (supporting new products, improving availability, reducing burden, ….) in the face of increasing demands to protect public health and the environment (….and animal health)



Challenges for the CVMP

- Delivering on commitments
- Ensuring quality of scientific output
- Dealing with unplanned activities
- Dealing with novel therapies, access to appropriate expertise, increased external scrutiny……..

- Limited resources

Reinforce the scientific and regulatory capacity and capability of the network

Key objectives

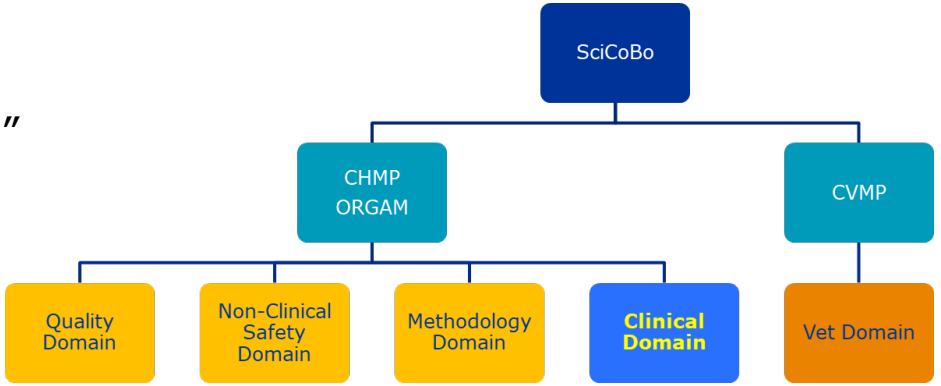
- Strengthen the quality of the scientific review process by developing available expertise;
- Ensure optimal organisation of the available expertise within the network for services provided to EMA.

Activity

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	In collaboration with EU network training centre, contribute to the training of assessors on regulatory scientific topics and guidelines for the network (with a focus on training updates relating to the Regulation (EU) 2019/6).	Veterinary training coordination group	1	Ongoing	No	All 2021
2.	Implement the recommendations of the EMA Management Board Task Force on Working Parties	Veterinary Domain (SPG)	1	Ongoing	No	All 2021

Management Board review

- Reorganise in five principal "Domains"



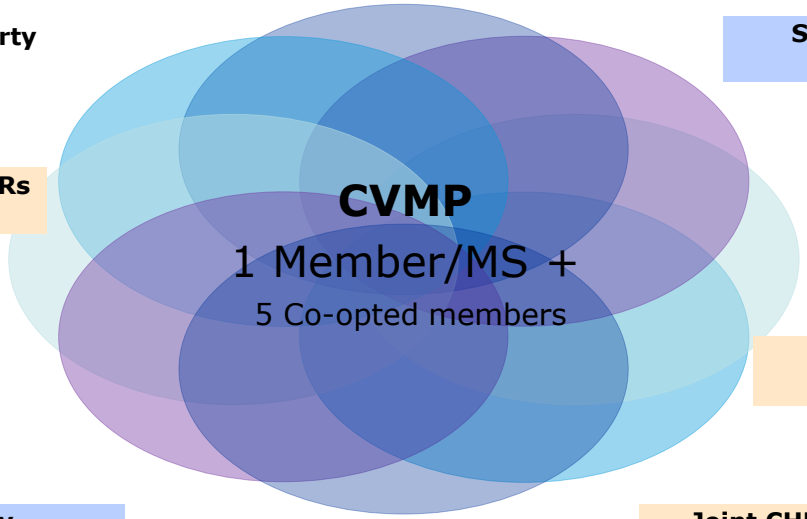
- Reconfirm the need for all working parties and renew/refresh their mandates
- For those WPs confirmed, renew membership by criteria of proven expertise
- Introduce systematic and structured stakeholder engagement at domain level to underpin strategic priority planning and individual GL generation/revision

Immunologicals Working Party
12 Members

Pharmacovigilance Working Party
1 Member/MS

Safety Working Party
12 Members

Joint CVMP/CHMP working group on 3Rs
TBD



Scientific Advice Working Party
15 Members

Environmental Risk Assessment Working Party
12 Members

Novel Therapies Working Party
6-8 Members

Efficacy Working Party
12 Members

Antimicrobials Working Party
10 Members

Joint CHMP/CVMP Quality Working Party
TBD

Conclusion

- Ambitious work programme for 2021,
- Numerous challenges to implementation on Regulation 2019/6,
- But, focus must be on the opportunities and realising meaningful benefits:
  - To support innovation, product development and availability
  - To increase efficiency of regulatory processes
  - To adopt a more effective risk-based approach to activities/decision-making
  - To foster proportionate decision making

  While promoting and protecting animal and public health
- There is a need for continued active stakeholders engagement

Any questions?

Further information

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