EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CVMP update on activities relating to Regulation 2019/6

EMA Veterinary Medicines Info Day

Presented by David Murphy on 30 November 2021
Chair of the Committee for Medicinal Products for Veterinary use (CVMP)

Role of the CVMP

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

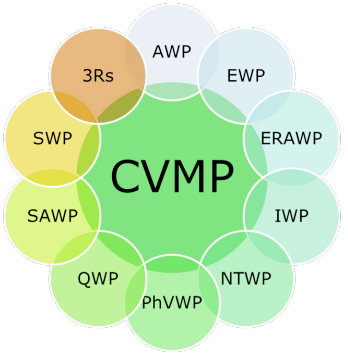
1. The Agency shall provide the Member States and the institutions of the Community with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use which is referred to it in accordance with the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



Role of the CVMP

Article 141.1, Regulation (EC) 2019/6 (Tasks of the Committee)

The Committee shall have the following tasks:

(a) carry out the tasks conferred on it under this Regulation and Regulation (EC) No 726/2004;
(b) prepare scientific opinions of the Agency on questions relating to the evaluation and use of VMPs;
(c) prepare opinions on scientific matters concerning the evaluation and use of VMPs on the request of the Executive Director of the Agency or the Commission;
(d) prepare opinions of the EMA on questions concerning the admissibility of applications submitted via the centralised procedure, and on granting, varying, suspending or revoking MAs for centrally authorised VMPs;
(e) take due account of any request made by Member States for scientific opinions;
(f) provide guidance on important questions and issues of general scientific nature;
(g) give a scientific opinion, in the context of cooperation with the World Organisation for Animal Health, concerning the evaluation of certain veterinary medicinal products intended exclusively for markets outside the Union;
(h) advise on the maximum limits for residues of veterinary medicinal products and biocidal products used in animal husbandry which may be accepted in foodstuffs of animal origin in accordance with Regulation (EC) No 470/2009;
(i) provide scientific advice on the use of antimicrobials and **antiparasitics in animals in order to minimise the occurrence of resistance in the Union**, and update that advice when needed;
(j) provide objective scientific opinions to the Member States on the questions which are referred to the Committee.

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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

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SCIENCE MEDICINES HEALTH

~~October~~ November 2021
EMA/CVMP/~~xxxxxx~~476954/~~20202~~2021
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products (CVMP) Work Plan 2022

7.1.2019 EN Official Journal of the European Union L 4/43

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.

Objectives of the new veterinary regulation

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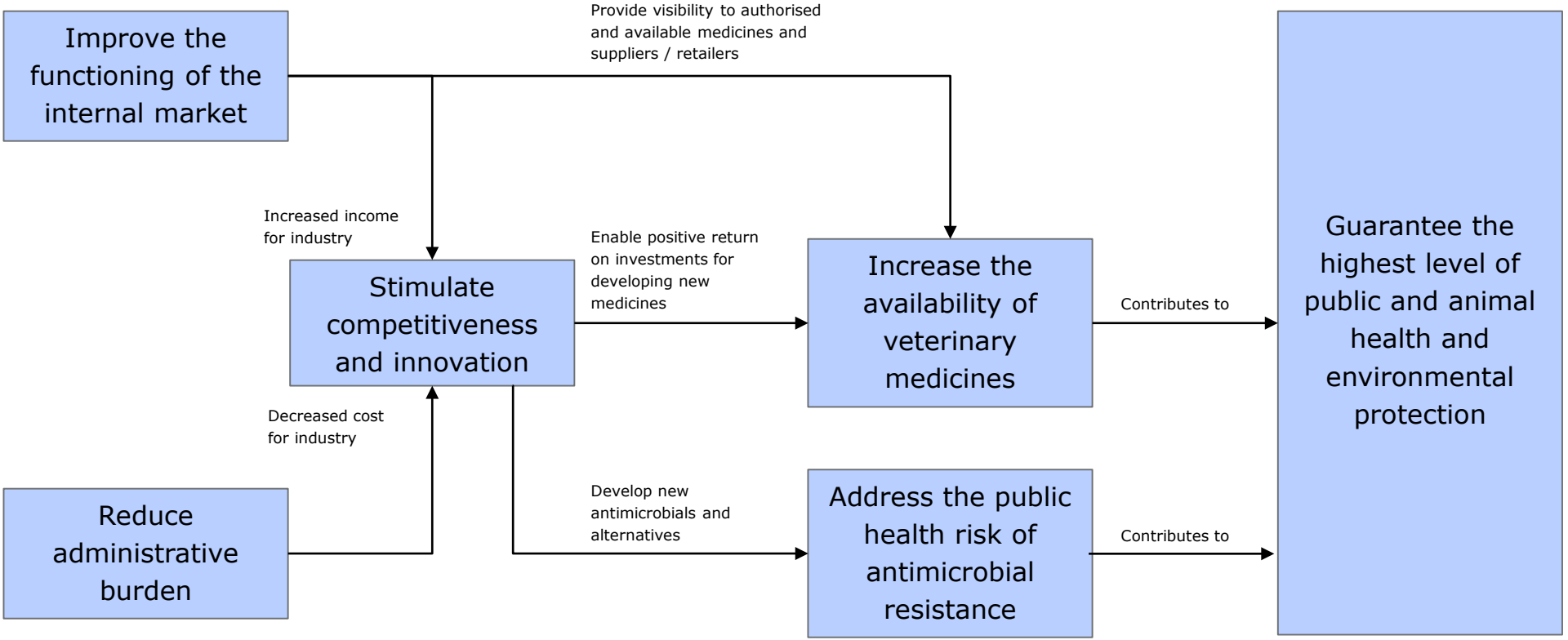

"These objectives are not only complementary, but also interlinked, as innovation will provide new and better medicines to treat and prevent diseases in animals, while avoiding damage to the environment." (Preamble) "It is critically important to have a single market for veterinary medicinal products 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

- Establishment of the Novel Therapies and Technologies Working Party

Generation of guidance to support Annex II:

1. Contribute to VICH guidance on target animal safety evaluation for veterinary monoclonal antibody products
2. Develop guidance on efficacy of cell therapies: mechanism of action, potency and clinical effects
3. Develop guidance on quality, safety and efficacy of bacteriophages as veterinary medicines

Activities to support for product development and innovation

- 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)

Post-consultation
Adoption of final GLs:
Q1 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 – Ju[redacted]21 May 2022

Activities to support availability – limited markets

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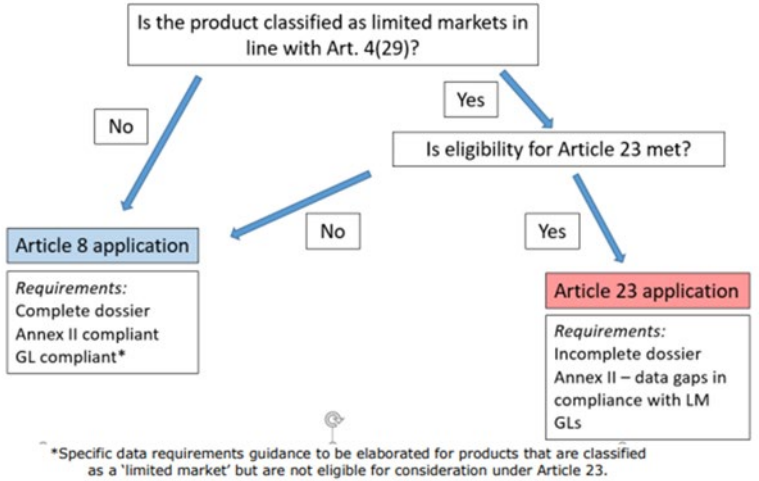
23 July 2021
EMA/CVMP/235292/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Reflection paper on classification of a product as intended for a limited market according to Article 4(29) and/or eligibility for authorisation according to Article 23 (Applications for limited markets)

Adopted by the Committee for Medicinal Products for Veterinary Use (CVMP) for release for consultation	17 February 2021
Start of public consultation	25 February 2021
End of consultation (deadline for comments)	15 May 2021
Adopted by CVMP	15 July 2021
Date for coming into effect	28 January 2022



Activities to support availability – limited markets

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23 July 2021
EMA/CVMP/59531/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6

Adopted by the Committee for Medicinal Products for Veterinary Use (CVMP) for release for consultation	17 February 2021
Start of public consultation	25 February 2021
End of consultation (deadline for comments)	15 May 2021
Adopted by CVMP	15 July 2021
Date for coming into effect	28 January 2022

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23 July 2021
EMA/CVMP/345237/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Guideline on 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

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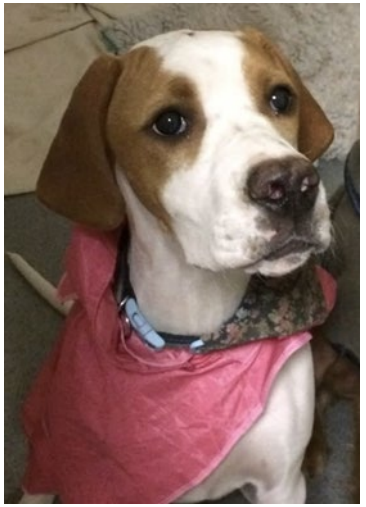
23 July 2021
EMA/CVMP/52665/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6

Activities to support availability – limited markets



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15 October 2021
EMA/CVMP/435071/2021
Committee for Medicinal Products for Veterinary Use (CVMP)

Concept paper on scientific guidelines for limited market products deemed not eligible for authorisation under Article 23 of Regulation 2019/6

Draft

Adopted by CVMP for release for consultation	7 October 2021
Start of public consultation	15 October 2021
End of consultation (deadline for comments)	15 December 2021

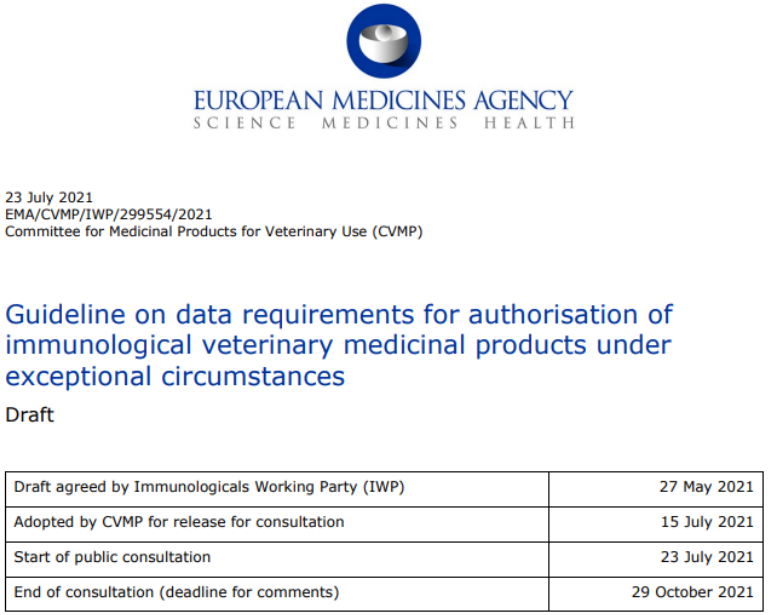
Finalise by – Jan 2023

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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23 July 2021
EMA/CVMP/IWP/299554/2021
Committee for Medicinal Products for Veterinary Use (CVMP)

Guideline on data requirements for authorisation of immunological veterinary medicinal products under exceptional circumstances

Draft

Draft agreed by Immunologicals Working Party (IWP)	27 May 2021
Adopted by CVMP for release for consultation	15 July 2021
Start of public consultation	23 July 2021
End of consultation (deadline for comments)	29 October 2021

Finalise by Q1 2022

Activities to support product authorisation

Committee for Veterinary Medicinal Products (CVMP) Work Plan 2022

Key objective

- Efficient procedures to support the authorisation of safe and effective veterinary medicines of good quality.
- Ensure a consistent approach to benefit/risk assessment and taking decisions on classification.

Activity

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Art. 42 (Scope of the centralised procedure): Ongoing review of procedures for the processing of generic applications submitted to the EMA to ensure efficiency of process.	EMA/CVMP	1	Ongoing	No	December 2022
2.	Revise the CVMP recommendation on the evaluation of the benefit-risk balance of VMPs (EMEA/CVMP/248499/2007).	CVMP	2	Ongoing	Yes	December 2023
3.	Art. 34 (Classification of VMPs): guidance on the application of Article 34 establishing criteria for determining the prescription status of centrally-authorised marketing authorisations.	EMA/CVMP	2	Jan 2022	Yes	December 2022

Concept paper on the revision of the CVMP Recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products (EMEA/CVMP/248499/2007)

Adopted by CVMP for release for consultation	4 November 2021
Start of public consultation	12 November 2021
End of consultation (deadline for comments)	28 February 2022

Activities relating to pharmacovigilance

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

Committee for Veterinary Medicinal Products (CVMP) Work Plan 2022

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.	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
2.	Ongoing review of signal management work sharing to ensure efficiency of process.	PhVWP	1	Ongoing	No	December 2022

Activities relating to antimicrobial resistance

EUROPEAN MEDICINES AGENCY
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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 recommendation: List of 'reserved' AMs
- ✗ EMA scientific recommendation: List of AMs 'restricted' when used under 'cascade'
- ✗ Guideline on risk assessment of AM VMPs (finalise by Apr 2021) Q2 2022
- ✓ Finalise SPC GL for VMPs containing AMs (June 2021)
- ✓ Art. 107(3) - Elaborate criteria for determining 'exceptional cases' when AM prophylaxis would be accepted (Jan 2022) Q2 2022
  - Review indications for existing AM CAP products and determine the approach to ensuring that they are aligned with the GL (June 2022)
  - Review the intramammary and AM efficacy GLs and revise as appropriate (Dec 2022)
- ✓ Reflection paper on promoting alternatives to AMs (June 2021)
  - Develop a concept paper on data requirements and potential claims for alternatives to AMs (Dec 2022)

Activities relating to environmental risk

- Article 18(7) – establish criteria for requesting ERA data for generic applications (finalise by Dec 2021) Q1 2022
- 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 (Jan 2022) June 2022
- Elaborate concept paper for a GL on ERA of products used in aquaculture (finalise by Dec 2021) Q1 2022
  - Development of a GL on ERA of VMPs used in aquaculture

Selected other 2022 activities

- 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)
- Consider the ongoing work of the EMA on the risk of nitrosamine formation or presence during the manufacture of human medicines and the implications of this activity for the quality evaluation of VMPs.

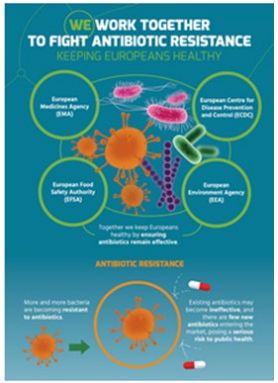
Other possible activities

- Feasibility study under Article 156 (active-substance-based review system ('monographs') and possible alternatives)
  - Report commissioned - contractor Fraunhofer ITEM
  - Extensive consultation – regulatory authority, industry, others ….
  - Final study report due by end of September 2021
  - Commission to draft a report to the EP and to the Council by 28/01/2022

- EU Commission request to evaluate the impact of the removal of titanium dioxide from the list of authorised food additives on medicinal products (EMA feedback delivered Sept 2021).

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

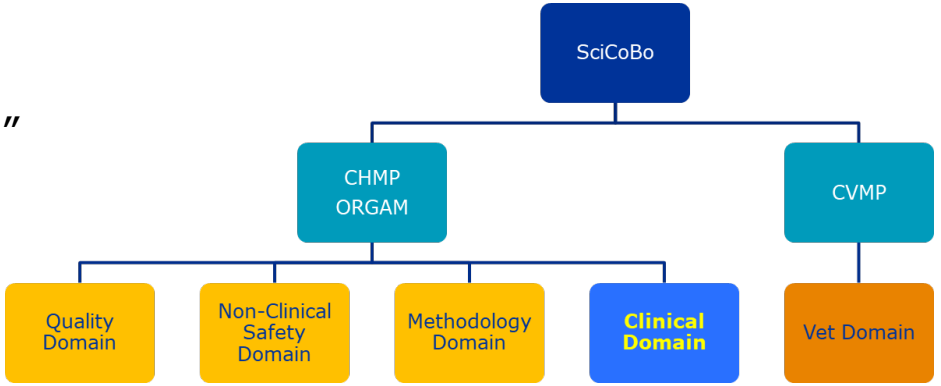
- Strengthen the quality of the scientific review process by developing available expertise;
- Ensure optimal organisation of the available expertise within the network for services provided to EMA.

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 Domain	1	Ongoing	No	All 2022
2.	Implement the recommendations of the EMA Management Board Task Force on Working Parties with a focus on: - Establishment of ESECs, - Stakeholder engagement	Veterinary Domain	2	Ongoing		All 2022

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

Conclusion

- Significant progress on delivery of 2021 CVMP work plan,
- Ambitious work programme for 2022,
- 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 stakeholder engagement

Any questions?

Further information

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