EMA Veterinary Awareness Day 13 September 2023

Contribution of EMA and the EU network to veterinary medicines science and regulation

CVMP role and responsibilities

Frida Wikström
Vice-chair of CVMP

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Committee for Veterinary Medicinal Products

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

- Scientific committee of the EMA
- All EU member states + Norway and Iceland
- 5 members based on expertise

Role of the CVMP

Evaluating applications for medicines

Safe and effective medicines for animals

Evaluating residue limits

Safety for humans

Contribute to development of medicines

Stimulating innovation

Role of the CVMP

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

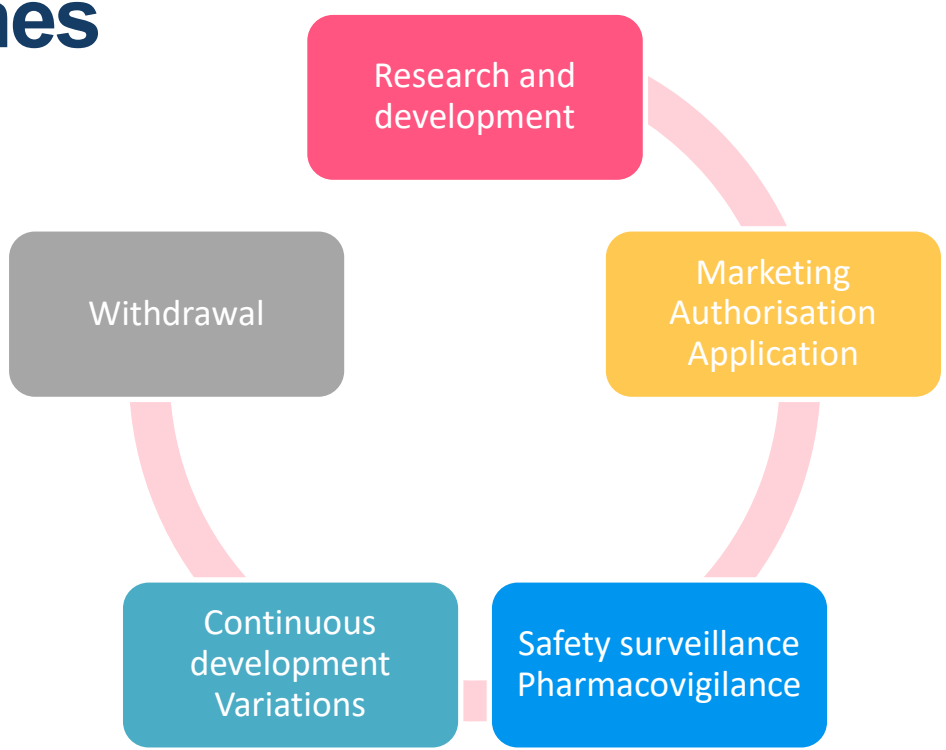
- Independent from industry
- Do not perform any studies
- Medical companies and the production of medicines are controlled by inspections

CVMP Working parties

- Scientific groups with expertise in specific fields
- Members from the network
- Draft guidance documents and support CVMP on scientific matters

Life cycle of medicines

The CVMP is involved in all stages of the life cycle of a veterinary medicinal product

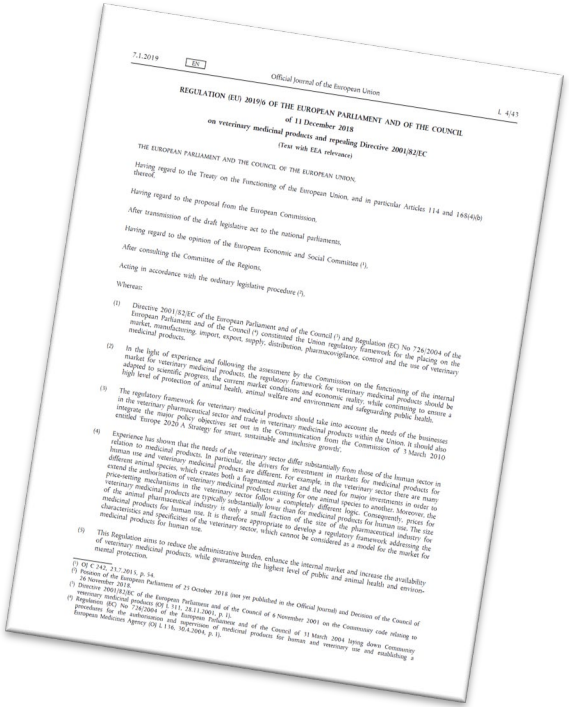


Research and development

CVMP and the EMA provide support to companies developing medicines through

- **Scientific advice**
  - Scientific Advice Working Party
  - Specific questions concerning development of a product
- **Innovation Task Force** (ITF)
  - Discussion platform at early stages of product development
- Development of **guidance** (scientific and regulatory)

New applications for medicines



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.

(2) In the light of experience and following the assessment by the Commission on the functioning of the internal market for veterinary medicinal products, the regulatory framework for veterinary medicinal products should be adapted to scientific progress, the current market conditions and economic reality, while continuing to ensure a high level of protection of animal health, animal welfare and environment and safeguarding public health.

(3) The regulatory framework for veterinary medicinal products should take into account the needs of the businesses in the veterinary pharmaceutical sector and trade in veterinary medicinal products within the Union. It should also integrate the major policy objectives set out in the Communication from the Commission of 3 March 2010 entitled 'Europe 2020 A Strategy for smart, sustainable and inclusive growth'.

(4) Experience has shown that the needs of the veterinary sector differ substantially from those of the human sector in relation to medicinal products. In particular, the drivers for investment in markets for medicinal products for human use and veterinary medicinal products are different. For example, in the veterinary sector there are many different animal species, which creates both a fragmented market and the need for major investments in order to extend the authorisation of veterinary medicinal products existing for one animal species to another. Moreover, the price-setting mechanisms in the veterinary sector follow a completely different logic. Consequently, prices for veterinary medicinal products are typically substantially lower than for medicinal products for human use. The size of the animal pharmaceutical industry is only a small fraction of the size of the pharmaceutical industry for medicinal products for human use. It is therefore appropriate to develop a regulatory framework addressing the characteristics and specificities of the veterinary sector which cannot be considered as a model for the market for medicinal products for human use.

(5) This Regulation aims to reduce the administrative burden, enhance the internal market and increase the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection.

(1) OJ C 242, 23.7.2015, p. 14.
(2) Position of the European Parliament of 25 October 2018 (not yet published in the Official Journal) and Decision of the Council of 26 November 2018.
(3) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).
(4) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

- Regulation (EU) 2019/6 describes content and format
- Same structure and principles as for human medicines
- The applicant provides data
- 210 days of assessment + clock stops

The MA procedure

Submission by Applicant

CVMP appoints Rapporteurs

Rapporteurs assessment report;
Peer Review
CVMP comments
Discussion by CVMP

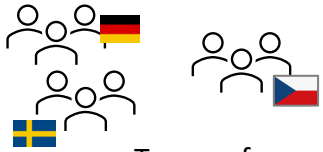
Questions to Applicant
Agreed and adopted by CVMP

Responses to questions from Applicant

Rapporteurs assessment report
Peer Review
CVMP comments
Discussion by CVMP

CVMP Opinion

European Commission
Commission decision



Teams of experts
Multinational assessment teams

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Clock stop

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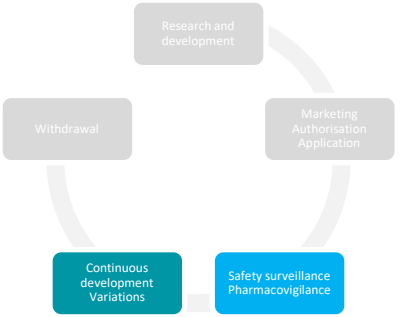
Benefit-risk balance

Post-authorisation



Everything that happens after authorisation

- **Variations** - changes to the authorisation
- **Referrals** - to resolve issues for example:
  - concerns over the safety or benefit-risk balance
  - disagreements among Member States on the use of the medicine

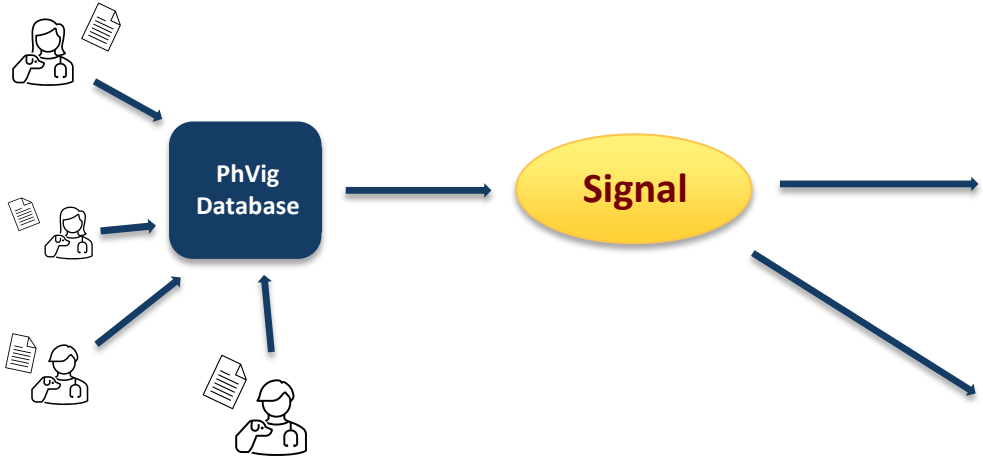
Post-authorisation

Pharmacovigilance

Changes in Regulation (EU) 2019/6 – new roles, processes and systems

- Continuous monitoring of **safety of medicines**
- Use of medicines in practice in larger numbers of animals makes it possible to detect rare events that are not seen in studies in the application
- **Adverse event reports** is the primary information source

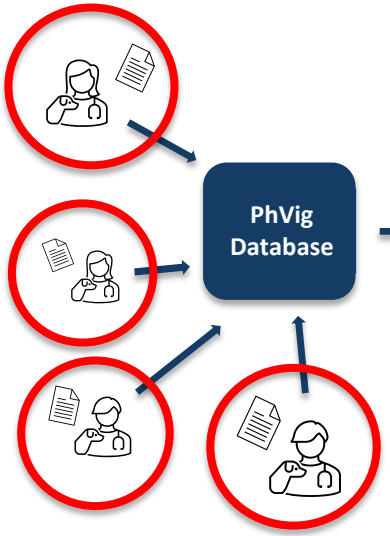
Signal Management



Potential outcomes
-Changes to Product Information
-Risk Management Measures
-Close monitoring
-Post-marketing surveillance study
-Communication of information to veterinarians

Adverse Event reports

Signal Management



Adverse Event reports

PhVig Database

Signal

Positive benefit-risk balance

MAH
-Assessment of signal
-Proposal for action
-To CVMP via variation

EMA/NCA
-Targeted Signal Management
-CVMP/PhVWP assesses and decides on action

Potential outcomes
-Changes to Product Information
-Risk Management Measures
-Close monitoring
-Post-marketing surveillance study
-Communication of information to veterinarians

The CVMP provides guidance

- To help companies developing medicines
- To help assessors and harmonise evaluations
- Working Parties draft guidance → Discussion and adoption by CVMP
- Operational Expert Groups address certain topics requiring specific expertise, e.g. bacteriophage guideline

Wider collaborations and contributions

EMA and the CVMP collaborates with and contributes to the work of a number of European and international actors

Wider collaborations and contributions

Guidance documents and scientific recommendations relating to the implementation of Regulation (EU) 2019/6

- List of antimicrobials reserved for humans
- Collection of data on antimicrobials used in animals

Wider collaborations and contributions

Ref. Ares(2022)5104497 - 13/07/2022

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate G – Crisis preparedness in food, animals and plants
Unit G2 - Animal Health
Head of Unit

Brussels,
SANTE/G2/IDC/rk(2022)5027908

Subject: Request for a scientific opinion on vaccination against highly pathogenic avian influenza

Dear Dr Ernesto Liebana Criado,

I would like to submit a formal request to EFSA for a scientific opinion on vaccination against highly pathogenic avian influenza (HPAI).

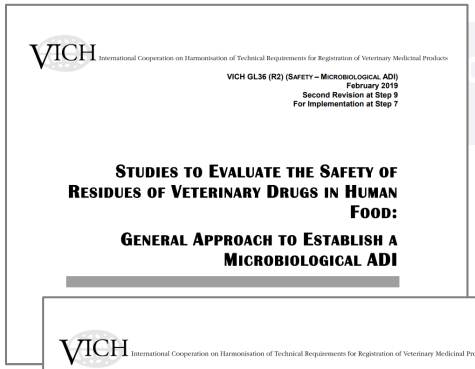
HPAI viruses in wild birds pose a significant challenge to risk managers taking into account the recurrent high risk of infection for poultry, correlated to the migration season of the migratory wild birds. In the recent years, the HPAI epidemic seasons in the EU have constantly increased in duration and severity. The number of wild birds and wild bird species found infected with HPAI viruses increased and therefore, the capacity to protect poultry from infection with HPAI virus became more and more challenging.

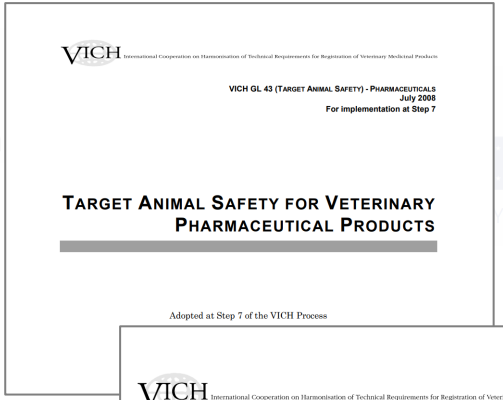
EUROPEAN FOOD SAFETY AUTHORITY

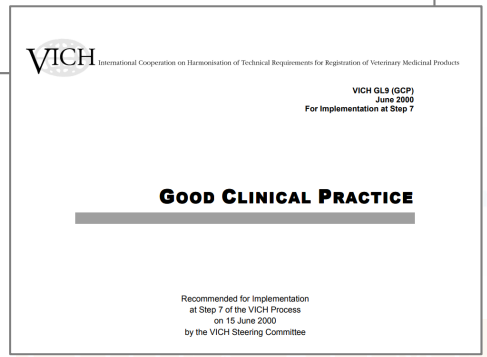
Taking part in expert panels

- Scientific opinion on vaccination against highly pathogenic avian influenza

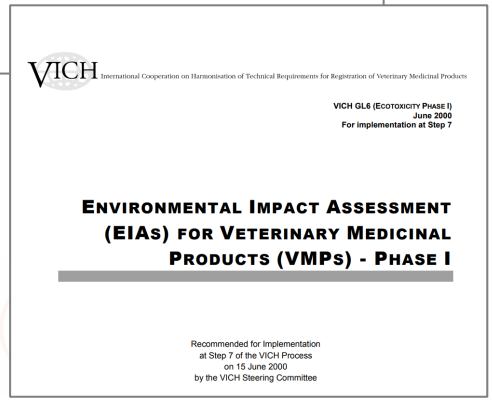
Wider collaborations and contributions



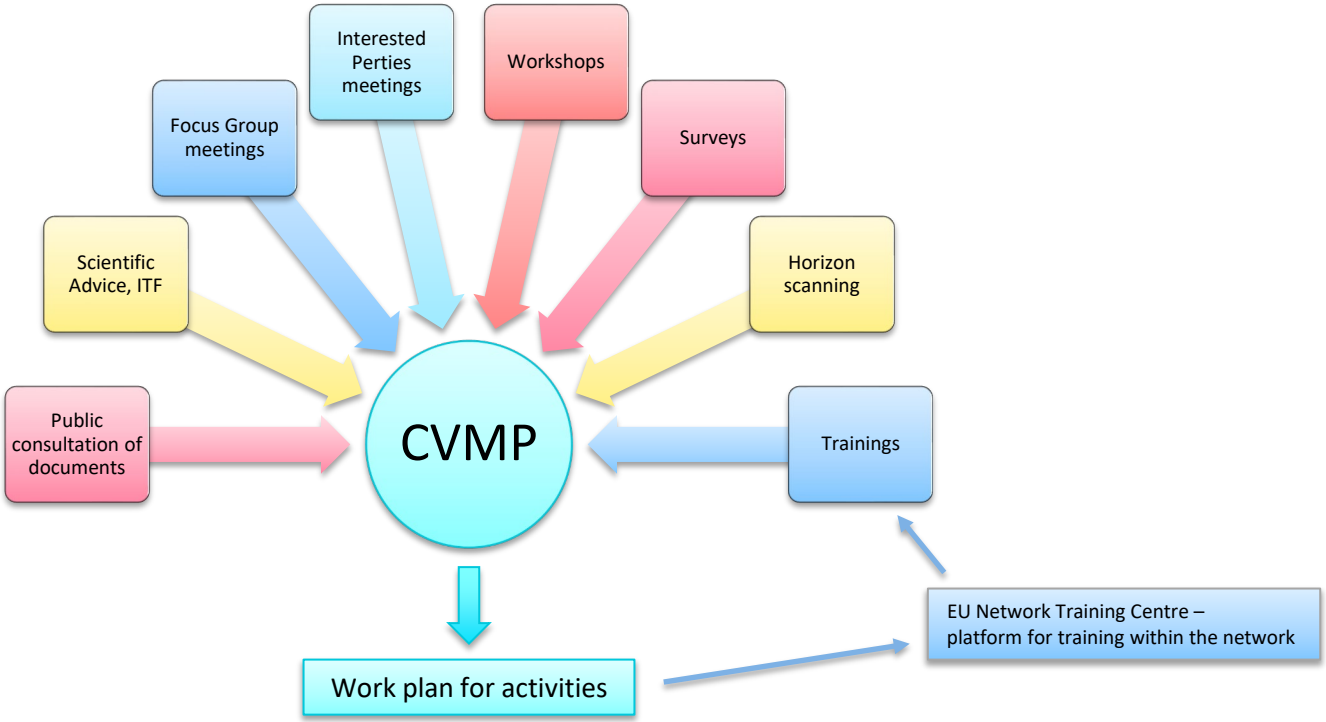




Development of international scientific guidance for veterinary medicines



Keeping our knowledge up to date




We are part of a network
– collaboration is our strength


Thank you
for your
attention
Any questions?