EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Integration of Agency Committees and Network into Delivery of the Strategy

EMA's Regulatory Science Response

Veterinary Stakeholders Workshop, 6th December 2018

Presented by David Murphy
Chair, CVMP

Europe Medicines Regulatory Network

HMA
Heads of Medicines Agencies

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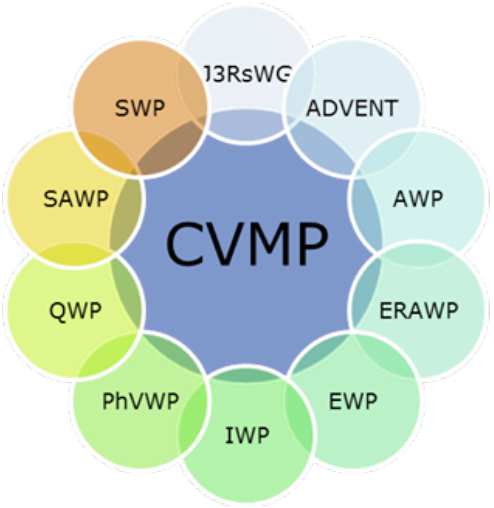
- Ensuring access to medicines that are safe, effective and of good quality.
- Providing a regulatory environment that facilitates and supports product development and innovation to promote and protect human and animal health.

CVMP role in the Network

- 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.

CVMP responsibilities



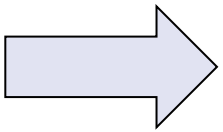
Responsible for the day-to-day business of providing product development scientific advice and MAA assessments.

Together with other Committees of the Agency, has a responsibility to engage with advances in regulatory science and translating that into the regulatory review environment.

Key role in delivery of the strategy.

Delivery of the strategy

- Strategic goals
  - Core recommendations
    - Underlying actions



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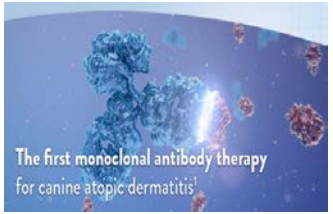
7 December 2017
EMA/CVMP/254946/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

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

Challenges – novel therapies

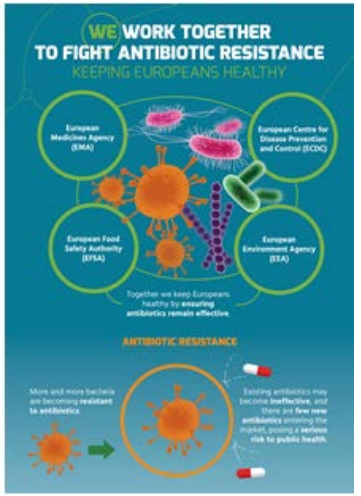


Novel therapies

- Biologicals
- Products aimed at herd management/increasing productivity
- Alternatives to antimicrobials

- Current regulatory paradigms poorly adapted to such medicines
- Limited expertise

Challenges – Dealing with risk



Challenges

- Limited resources
  - Compounded by Brexit
- Relocation of the EMA
  - Disruption to normal working party activity
- Implementation of the new veterinary regulation

Opportunities (1)

- identify emerging developments in science and technology that will impact on veterinary medicines development;
- Identify key priorities where enhanced engagement is essential;
- Develop expertise (increase collaboration with external experts);
- Prioritise use of resources.

Opportunities (2)

- Smart implementation of the new veterinary regulation
  - To support innovation and product development (flexibility to deal with the complex area of novel therapies)
  - 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


4 month old