EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Development of veterinary novel therapies: Update

European Medicines Agency/IFAH-Europe Info Day 2016

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Focus of the presentation

Development of veterinary novel therapies:

Update since the INFO Day 2015

EU Medicines Agencies Network Strategy to 2020

Key theme in veterinary medicine:

- Animal health and human health in relation to **veterinary medicines,** by increasing the availability of veterinary medicines and minimising the risks that may arise from the use of antimicrobials in veterinary medicine.
- Four principle objectives:
  - **Objective 1: Increase availability of veterinary medicines and promote development of innovative medicines and new technologies**
    - The network will increase the availability of all types of veterinary medicine, giving particular attention to products indicated for minor use in major species and for minor species (MUMS), as well as smaller national markets, and for technologies that are new to the veterinary domain.

Support options for novel therapies

Several instruments available:

- Micro-, small- and medium-sized enterprise (SME) office and incentives.
- Innovation Task Force (ITF).
- Minor uses / minor species and limited markets (MUMS).
- Scientific Advice (CVMP SAWP-V).
- Pre-submission meetings.
- Guidance and guidelines on EMA website on procedural, regulatory and scientific issues.
- CVMP Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT).

Small and medium-sized enterprise (SME) office

Note: The company should **apply for SME status** to the Agency's SME office before requesting **financial incentives** or **administrative assistance** from the Agency.

SME register

- Public register – access through EMA website.
- Open to all SMEs registered in EMA.
- Currently 117 vet companies and 71 vet/human companies
- Objectives:
  - To facilitate and promote interaction, partnering and networking between SMEs.
  - To increase information available to SMEs and their stakeholders.
  - To provide a source of information for European Union (EU) institutions, agencies and Member States.
- Contact: sme@ema.europa.eu

Innovation Task Force (ITF)

A discussion platform for early dialogue with applicants to proactively identify scientific, legal and regulatory issues of emerging therapies and technologies.

The ITF holds **briefing meetings** with applicants covering regulatory, technical and scientific issues arising from the development of innovative medicines, new technologies and borderline products.

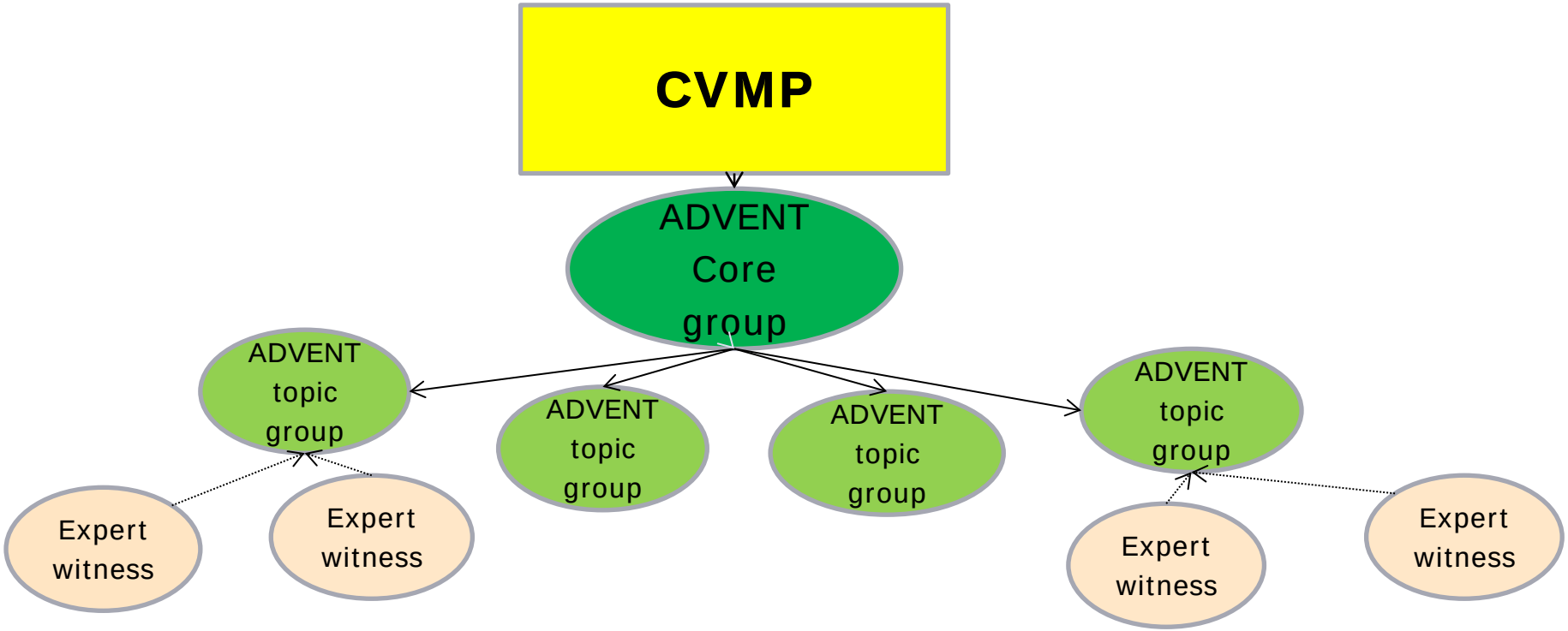
- 2 ITF briefing meetings in 2015
- 4 ITF briefing meetings are expected in 2016, the first in February

CVMP Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT)

ADVENT was established in 2014

- Provides guidance on the requirements for authorisation of novel veterinary medicines.
- The advice will be general in nature and will not be related to a particular application or product.
- The ADVENT's tasks include:
  - Providing advice on the requirements for authorisation of therapies that are new to the veterinary domain (novel therapies).
  - International cooperation on novel therapy related issues.
  - Advising, through the CVMP, to the European Commission.
  - Contributing to novel therapy related workshops and training.

ADVENT organisation



CVMP Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT)

ADVENT guidance is:

- Advisory in nature.
- Not legally binding.
- General in nature and not related to a particular application.
- In the form of ‘Question and Answer’.

Will be updated in line with subsequent scientific developments.

CVMP Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT)

Current priority topics in ADVENT Work plan 2016 include:

- Cell-based products – stem cells: sterility, tumorigenicity and extraneous agents.
- Monoclonal antibodies – aspects to be agreed.
- Tumour vaccines – for consideration of whether guidance should and can be given.

The work programme may be updated considering the progress made with the assigned tasks and in light of new topics that have been identified as priority topics.

The public are invited and encouraged on a continuous basis to submit their views on topics, relevant to novel therapies and related products for which they consider guidance would be useful.

CVMP Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT)

CVMP adopted two ADVENT problem statements in January 2016

- Basis for development of 'Question and Answer' documents.
  - Monoclonal antibodies in veterinary use.
  - Stem cell sterility.
- Published for comments in EMA website.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2016/03/news_detail_002482.jsp&mid=WC0b01ac058004d5c1

- Deadline for comments 15.5.2016.

ADVENT will continue the work with additional topics according to the work plan.

Thank you for your attention