EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on ADVENT and progress on Q&A documents: experience with pre-drafting consultations

EMA Veterinary Medicines Info Day 16-17 March 2017, London

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Contents

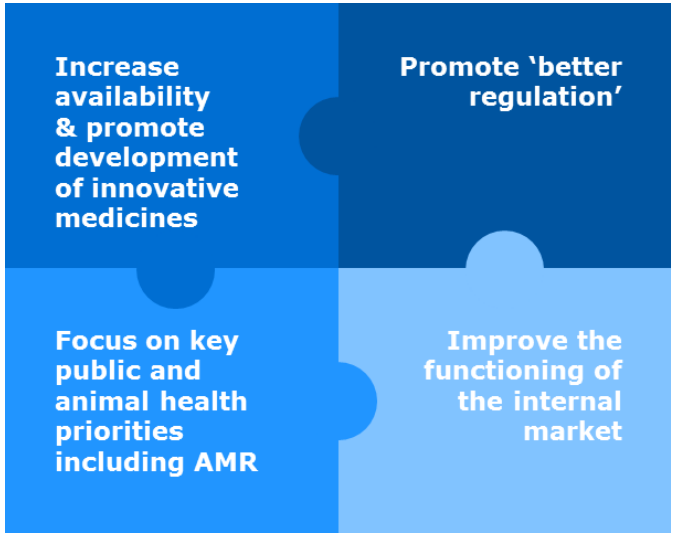
Background

Steps in development of ADVENT Q&A documents

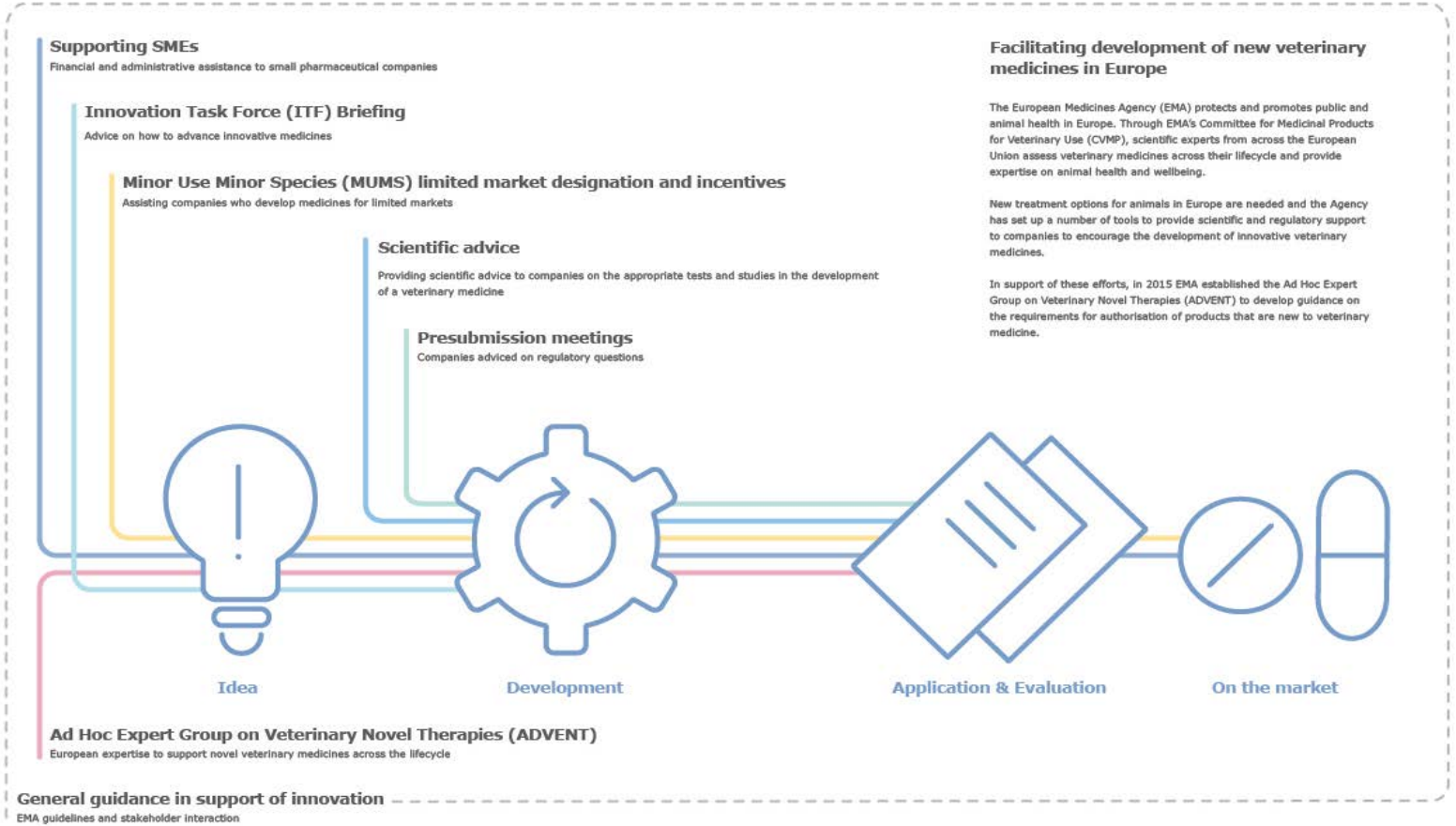
Current situation

Lessons learned

EU Medicines Agencies Network Strategy to 2020: Theme 2: Contributing to animal health and human health in relation to veterinary medicines



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**.


Supporting SMEs
Financial and administrative assistance to small pharmaceutical companies
Innovation Task Force (ITF) Briefing
Advice on how to advance innovative medicines
Minor Use Minor Species (MUMS) limited market designation and incentives
Assisting companies who develop medicines for limited markets
Scientific advice
Providing scientific advice to companies on the appropriate tests and studies in the development of a veterinary medicine
Presubmission meetings
Companies adviced on regulatory questions
Facilitating development of new veterinary medicines in Europe
The European Medicines Agency (EMA) protects and promotes public and animal health in Europe. Through EMA's Committee for Medicinal Products for Veterinary Use (CVMP), scientific experts from across the European Union assess veterinary medicines across their lifecycle and provide expertise on animal health and wellbeing.
New treatment options for animals in Europe are needed and the Agency has set up a number of tools to provide scientific and regulatory support to companies to encourage the development of innovative veterinary medicines.
In support of these efforts, in 2015 EMA established the Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT) to develop guidance on the requirements for authorisation of products that are new to veterinary medicine.
Idea
Development
Application & Evaluation
On the market
Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT)
European expertise to support novel veterinary medicines across the lifecycle
General guidance in support of innovation
EMA guidelines and stakeholder interaction

Steps in development of ADVENT Q&A documents

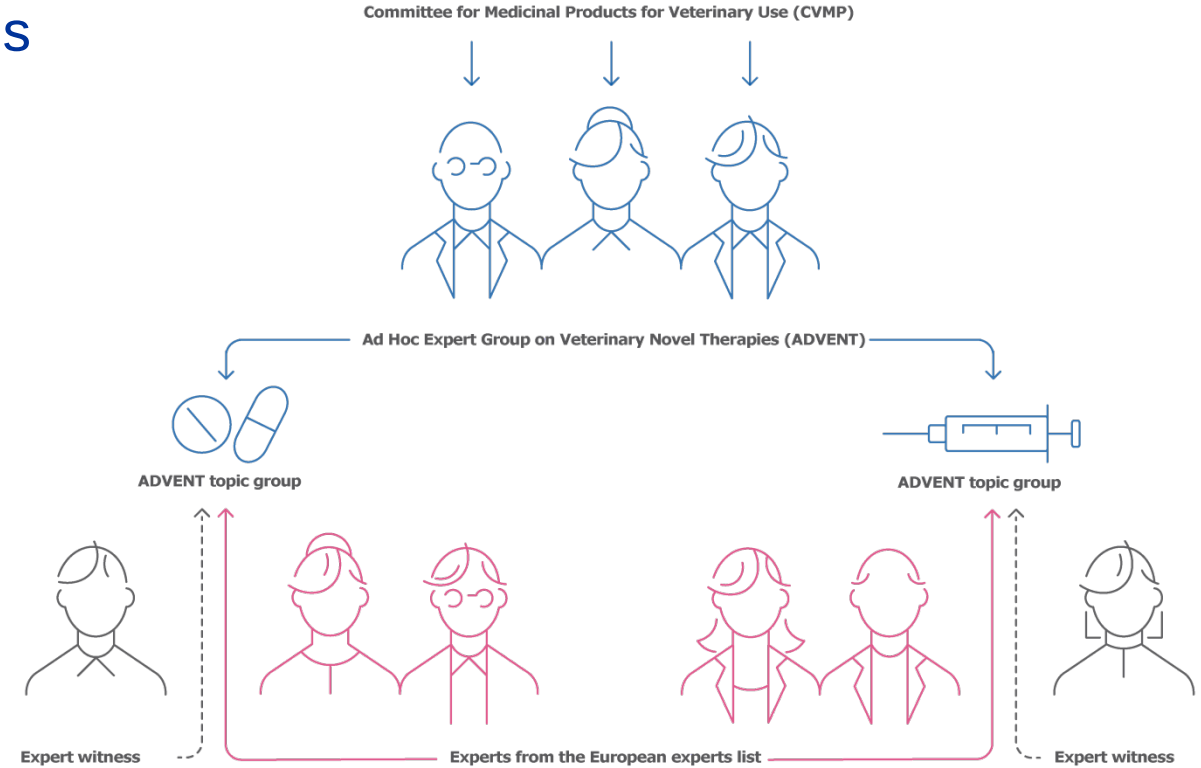
Five problem statements published for consultation in 2016

- One related to monoclonal antibodies in veterinary use
- Four related stem cells
  - Stem cell sterility
  - Extraneous agents
  - Tumorigenicity
  - Target animal safety
- Target to gain stakeholder views on issues and questions relevant to novel therapy developers
  - ”To be able to answer to right questions”

Steps in development of ADVENT Q&A documents

Total number of comments received	19
• Mostly detailed, but also some general comments regarding the use of novel therapies as VMPs were made	
• Comments received mostly from industry, few from NCAs and clinicians	
• Monoclonal antibodies in veterinary use	6
• Stem cells	13
➢ Stem cell sterility	8
➢ Extraneous agents	2
➢ Tumorigenicity	2
➢ Target animal safety	1

Four ADVENT topic groups were established to prepare Q&A documents



Lessons learned

Guidance in the area of novel therapies is needed.

A timely and effective communication on publication of problem statements and possibility to provide comments is essential

Relevant and useful comments received to enlighten stakeholder views and issues that need to be addressed

Not all stakeholders are willing to provide comments in case they have specific knowledge or plans in specific areas

Thank you for your attention

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