EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Role of ADVENT in innovation support

Session 3: Interactions with Stakeholders

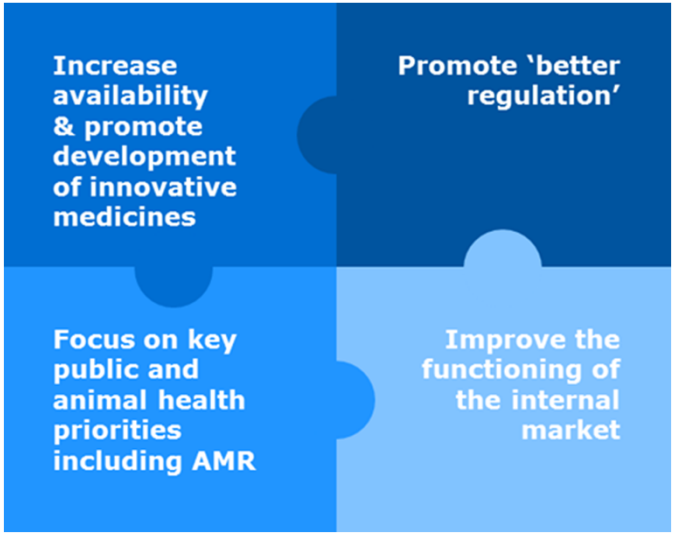
EMA veterinary medicines innovation day

Presented by Dr Esther Werner, 19 April 2018
CVMP, ADVENT, IWP Chair

Agenda

- EU Medicines Agencies Network Strategy to 2020
- CVMP Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT)
- Development of ADVENT Q&A documents
- ADVENT Questions and answers documents
- Further activities

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**.

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

ADVENT was established in 2014 – under the CVMP

- Provides guidance on requirements for authorisation of novel veterinary medicines.
- Advice will be general in nature and not be related to a particular application or product.
- *EMA Management Board*:
  June 2014: Preliminary mandate for two years endorsed.
  December 2016: Group's continued activity endorsed for an additional 3 years.
- *Core group*: 6 experts selected by CVMP (members of CVMP, its Working Parties or national experts).
- *Specialist expert groups* (topic groups) used when generating advice on a particular novel therapy question, usually 4-6 additional experts, with specialist knowledge of the therapy concerned.

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

ADVENT's tasks include:

- Providing advice on requirements for authorisation of therapies that are new to the veterinary domain (novel therapies*).
- Supporting dossier evaluation and referrals for 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.

* ***Novel therapies*** *are therapies entirely new to veterinary medicine either because they are genuinely novel and have not been previously used in the context of a medicine, or new only to the veterinary domain, although well known in terms of research, and possibly in the context of human medicine.*

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', starting with problem statements.

Will be updated in line with subsequent scientific developments.

Mandate, objectives and rules of procedure *for the CVMP Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT)*

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/12/WC500179063.pdf

Development of ADVENT Q&A documents

Five problem statements published for consultation in 2016.

- One related to monoclonal antibodies in veterinary use.
- Four related to 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”

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

ADVENT Questions and answers documents

Q & A on allogenic mesenchymal stem cell-based products for veterinary use:

- Specific questions on tumorigenicity, published 21/11/2017.
- Specific questions on extraneous agents, published 27/07/2017.
- Specific questions on sterility, published 23/06/2017.
- Specific questions on target animal safety, under finalisation.

ADVENT Questions and answers documents

Q & A on monoclonal antibodies for veterinary use, published 11/12/2017**.**

- General principles in characterisation/specification setting for veterinary monoclonal antibodies.
- Quality control needed for potential contaminants.
- Required stability testing for veterinary mAb.
- Reproductive safety studies needed for the target animal safety evaluation of mAbs.
- Safety data for use of mAb in breeding/pregnant animals, what would be considered adequate to characterize the risk.
- Safety of mAbs for the target animal, what data need to be generated to characterise the potential for indirect effects.

Further activities

- Reflect need of new guidance topics based on questions raised and lines taken by CVMP during recent scientific advice and marketing authorisation assessment procedures of cell-based products.
- Reflect principles in classification of novel therapy products (pharmaceutical or immunological product) and consider the most appropriate format of dossier structure for these products reflecting initially stem cell or mAb products.
- Review the pharmacodynamic, pharmacokinetic and toxicological properties of biological substances relevant in the field of veterinary medicines (cytokines, stem cells and mAb) and considering how they impact on whether or not MRL evaluations would be necessary for substances that fall into those classes.
- (Consideration of regulatory and data requirements of bacteriophage products.)

Further activities

- Exchanges with the US Food and Drug Administration (FDA), when appropriate, in the context of the confidentiality arrangement that exists between the EMA and FDA, and/or other regulatory authorities outside the EU.
- Contact on an advisory basis with parties concerned with the manufacture and control of veterinary novel therapies.
- When considered appropriate, oral or written presentations by interested parties can be made or may be invited during the development of advice.

Further activities

- ADVENT welcomes suggestions on novel therapy related subject areas that would benefit from the provision of scientific guidance. Please send contributions to advent@ema.europa.eu.
- When ADVENT releases problem statements for public consultation in order to identify further questions please send your comments.

Thank you for listening.

Any questions?