EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Early support to innovation

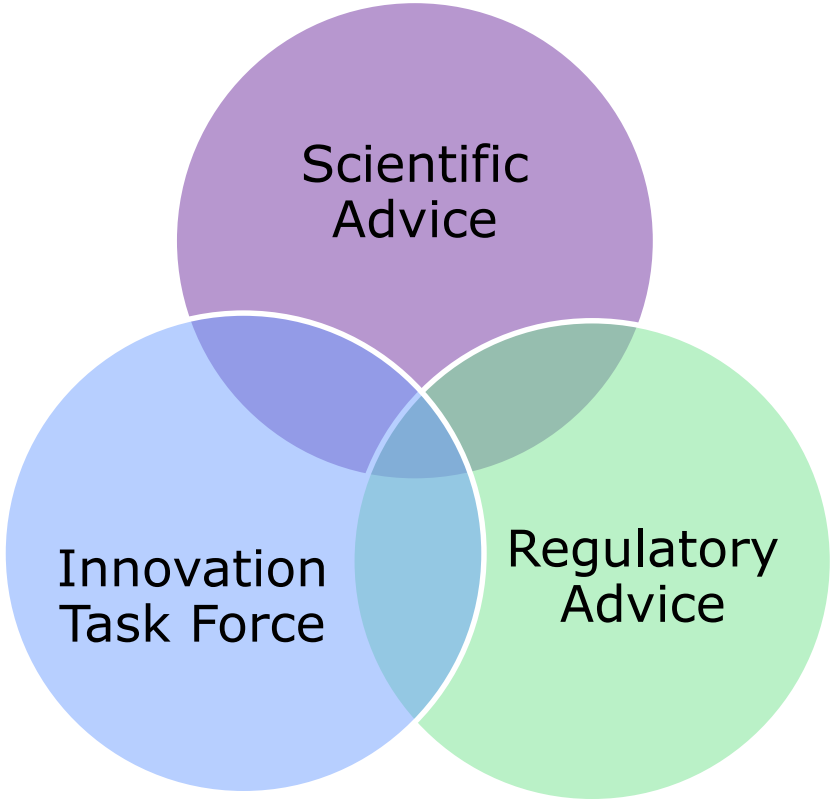
Session 1: EMA's support for SMEs developing innovative veterinary medicines

Veterinary Info Day for micro, small and medium-sized enterprises (SMEs): EMA support for SMEs under the new Veterinary Medicinal Products Regulation

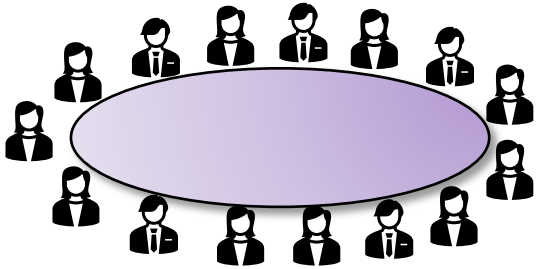
Presented by Frida Wikström on 28 October 2021
Chair of SAWP-v, CVMP member

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

EMA's support for SMEs developing innovative veterinary medicines



Scientific Advice Working Party (vet)



Working party to CVMP

15 members including chair and vice-chair, 13 also members/alternates of CVMP

Expertise to cover most areas

Meetings every month (except Aug) in the margins of CVMP meetings

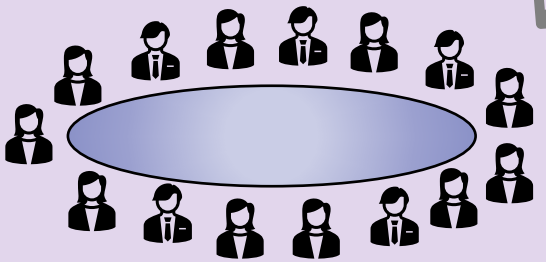
Provides recommendations to the CVMP on all matters relating directly or indirectly to all scientific aspects of veterinary medicinal products, including maximum residue limits (MRLs) and on questions of a more general scientific nature (including minor use minor species (MUMS) applications) pertaining to veterinary medicinal products

EMA

SA Request to EMA → Validation

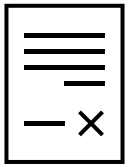
SAWP-v

Appointment of rapporteur → 

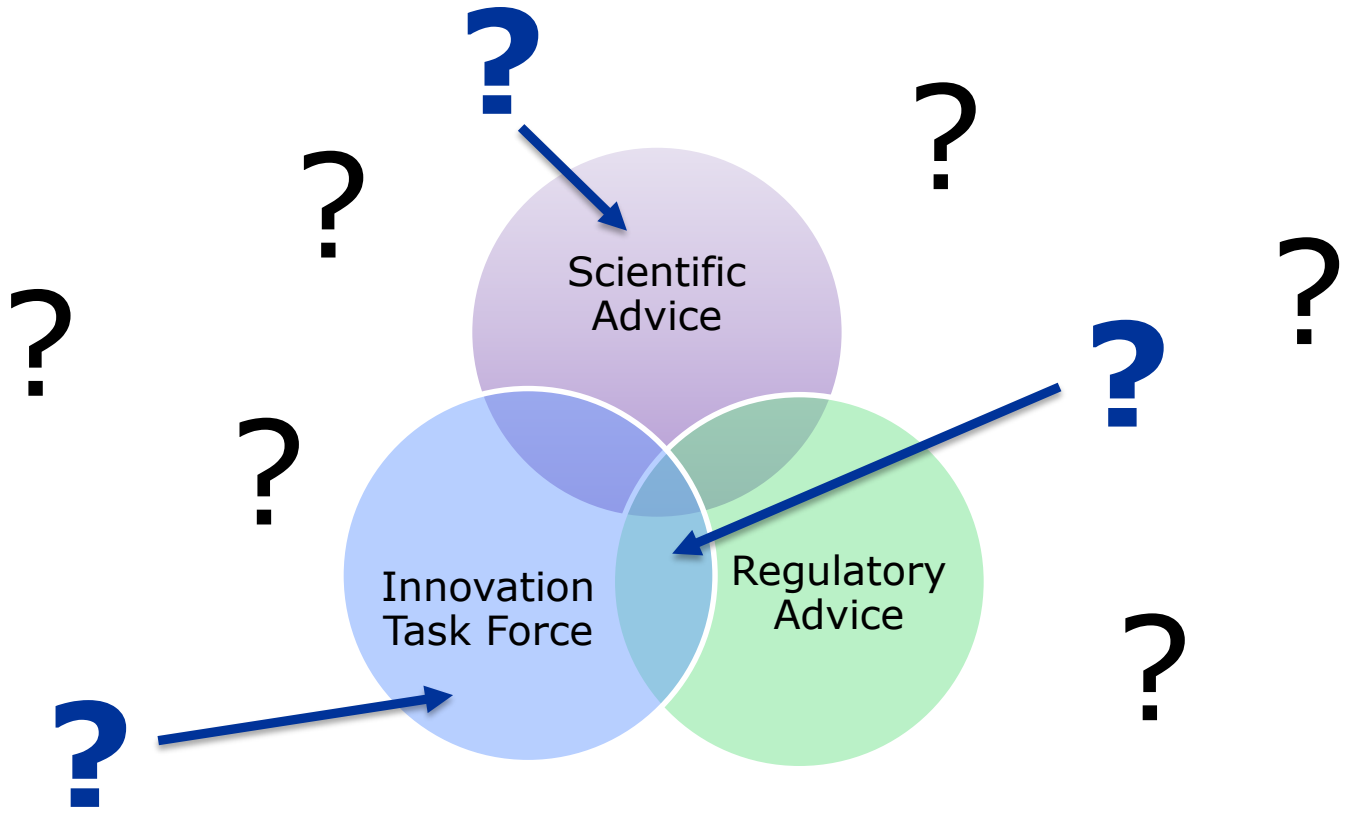


60 – 90 days

CVMP



Adoption



Example

The product is a cell therapy intended for treatment of dogs. A preliminary dose determination study and a pivotal field trial are planned (protocols provided). Will the planned studies be appropriate to address efficacy?

Scientific Advice

Scientific discussion on study design and data requirements for an upcoming application for marketing authorisation. Possibility to discuss aspects not addressed in guidance and make recommendations on e.g.

- Study groups – control group, number and size of groups, doses
- Endpoints, tested parameters
- Specific issues for product type and indication
- 3Rs

Example

The product is a new live vaccine against a zoonotic viral disease. How should safety be addressed, is there a possibility to make a theoretical assessment of risk of reassortment or is proprietary data necessary?

Scientific Advice

Scientific discussion on the specific risks for the vaccine and how these should be addressed in an application for marketing authorisation.

Example

The active substance is of biological origin and the mechanism of action is by non-specific immunomodulation. What data (dossier structure) will be required for safety and efficacy in an application for marketing authorisation?

Regulatory Advice

Data requirements, type of studies and dossier structure differ depending on classification of the product as immunological or biological

Classification requests are **regulatory issues** – to be addressed by EMA/CVMP

Example

The product is of biological origin and is similar to an already authorised product in the EU. Is a hybrid application appropriate?

Regulatory Advice

Legal basis of the application is a **regulatory issue** – to be addressed by EMA

However...

Questions relating to how similarity should be demonstrated and data requirements for the product are **scientific issues** – to be addressed by Scientific Advice

Example

Innovation Task Force

A product with a protein as active substance is under development. One point for consideration and discussion concerns the use of novel bioassays (anti-drug antibodies (ADAs), potency, stability) to fully characterise the protein.

Questions during early product development to aid in strategic decisions

Discussion forum with experts

Opinions expressed are those of experts, not of CVMP

How to phrase questions in Scientific Advice requests

Clear and specific

Provide relevant background information (summarised and in annexes)

SAWP-v/CVMP **cannot assess and conclude on data within the scope of a Scientific Advice**, this is done in the context of an application for marketing authorisation where the full data set is presented in the dossier

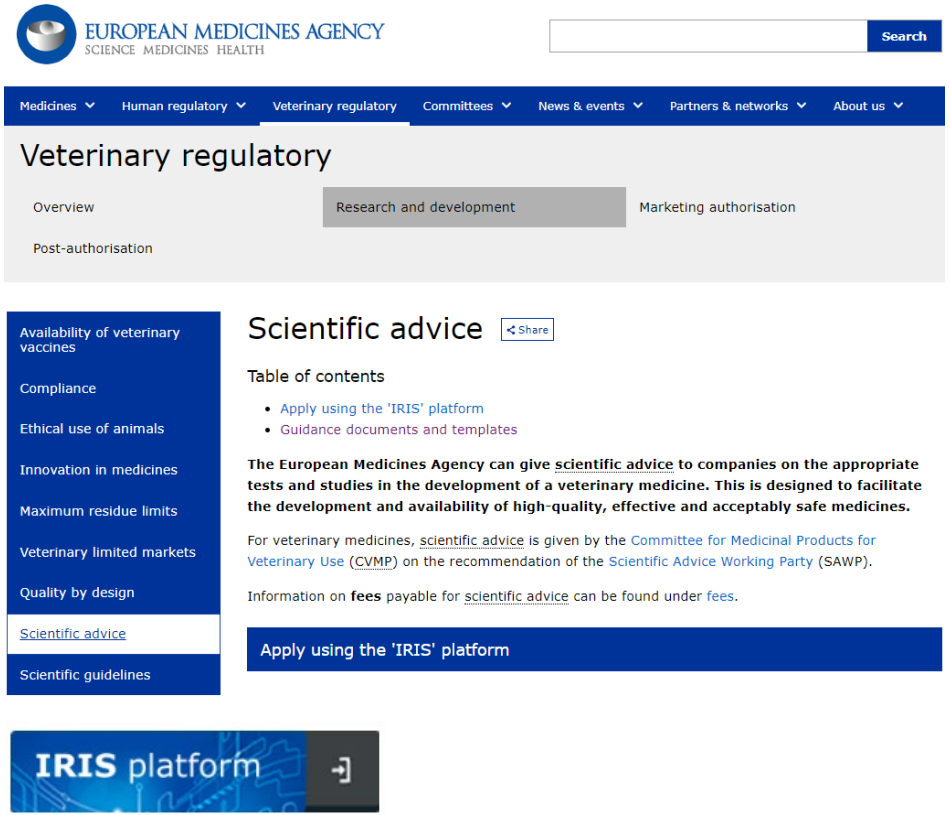
Further information

www.ema.europa.eu

IRIS – technical platform for submission of requests

Dates for submission

Guidance documents and templates



Any questions?

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