



*Path to marketing  
authorisation: SMEs'  
experiences and peer-  
to-peer considerations*

Dr Susan Kennedy  
28-October-2021

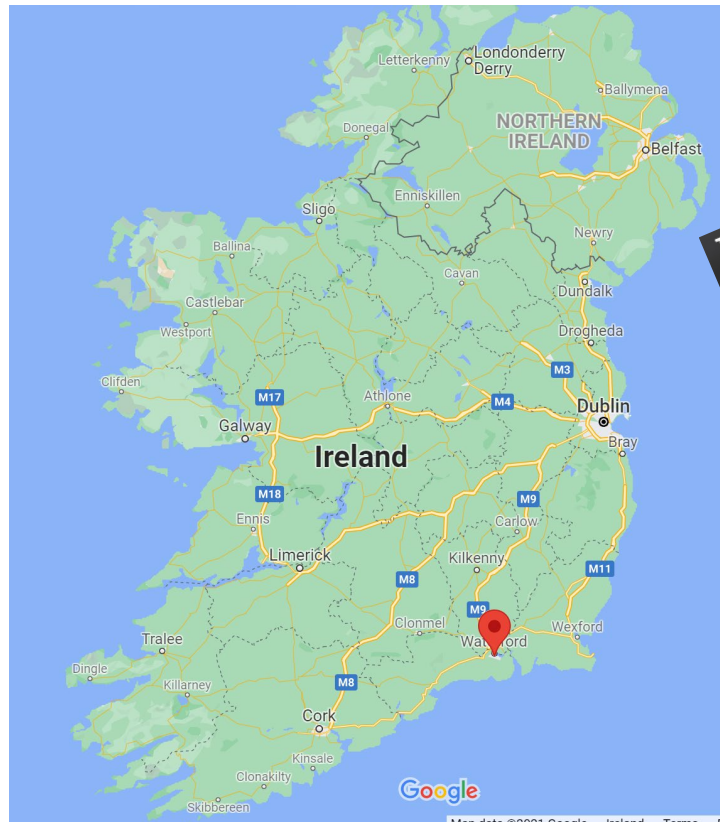


*Bridging the treatment gaps in veterinary healthcare for companion animals*





# Location



Best Place to Live in Ireland 2021:  
Why Waterford city won





## OUR WHY?

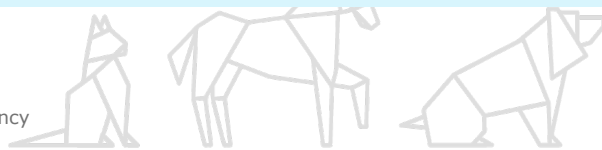
**To bridge the treatment gaps in veterinary healthcare for companion animals**

## OUR MISSION

**At TriviumVet our mission is to deliver innovative healthcare solutions for companion animals**

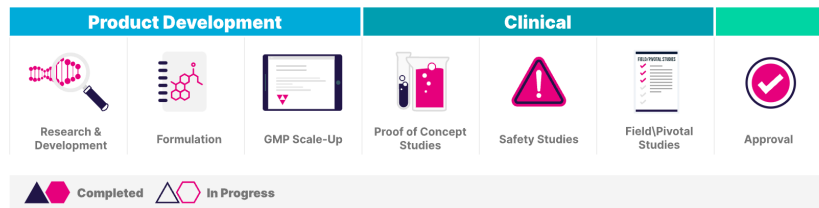
## OUR VISION

**The TriviumVet vision is to have a valuable impact on global pet healthcare**





# Pipeline



**OmepraVet™** Canine Gastric Ulcer Disease



**Felycin™** Feline Cardiomyopathy



**RapaVet™** Canine Cardiac Disease



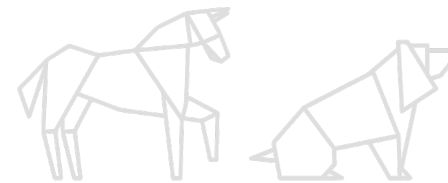
**IntegralVet™** Canine Diagnostic



**Syrandol™** Canine Neuropathic Pain



**TRIV-209L** Feline Chronic Kidney Disease





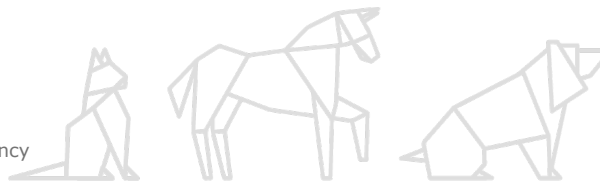
# Why Request Scientific Advice?

SA can be requested for any VMP (Directive 2001/82/EC and Regulation (EU) 2019/6)

SAWP-V advises applicants on the conduct of various tests and trials to demonstrate the **quality**, **safety**, and **efficacy** of medicinal products

Advice received is valid throughout EU, irrespective of authorisation route

Advice given by the Agency is not binding





# Scientific Advice Process

- When to request?
- Timing

## Calendar for CVMP meetings in 2022-2024

Meeting dates

Month	2022	2023	2024
January	18, 19, 20	17, 18, 19	16, 17, 18
February	15, 16, 17	14, 15, 16	13, 14, 15
March	15, 16, 17	21, 22, 23	12, 13, 14
April	11, 12, 13 <sup>1</sup>	18, 19, 20	16, 17, 18
May	10, 11, 12	15, 16, 17 <sup>2</sup>	21, 22, 23
June	14, 15, 16	13, 14, 15	18, 19, 20
July	12, 13, 14	11, 12, 13	16, 17, 18
August	No meeting foreseen	No meeting foreseen	No meeting foreseen
September	6, 7, 8	5, 6, 7	10, 11, 12
October	4, 5, 6	3, 4, 5	8, 9, 10
November	8, 9, 10	7, 8, 9	5, 6, 7
December	6, 7, 8	5, 6, 7	3, 4, 5





# Scientific Advice Process

- When to request?
- Timing
- Structure of request



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

Date:   
EMA/279341/2012  
Veterinary Medicines Division

## Letter of intent for request of Scientific Advice (SA)

Please fill all the predefined fields as accurately as possible<sup>1</sup>

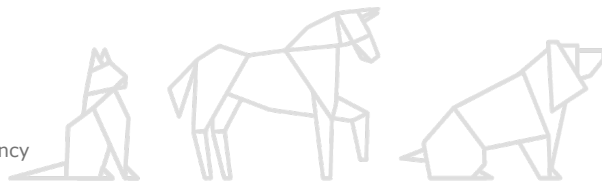
<b>INN</b> (if available)	<input type="text"/>
<b>Invented name</b> (if available)	<input type="text"/>
<b>Company product code</b>	<input type="text"/>
<b>Description of the product</b>	<input type="text"/>





# Scientific Advice Content

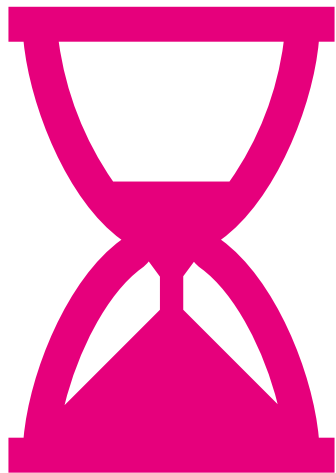
*Questions posed should be as precise  
and clear as possible*



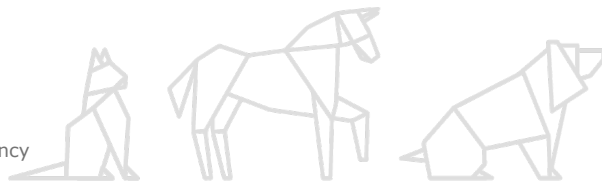




# Scientific Advice Review Period



**60 or 90 days**





# Scientific Advice Case Study 1



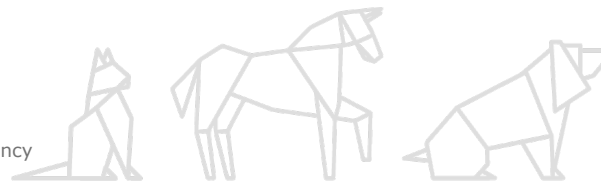
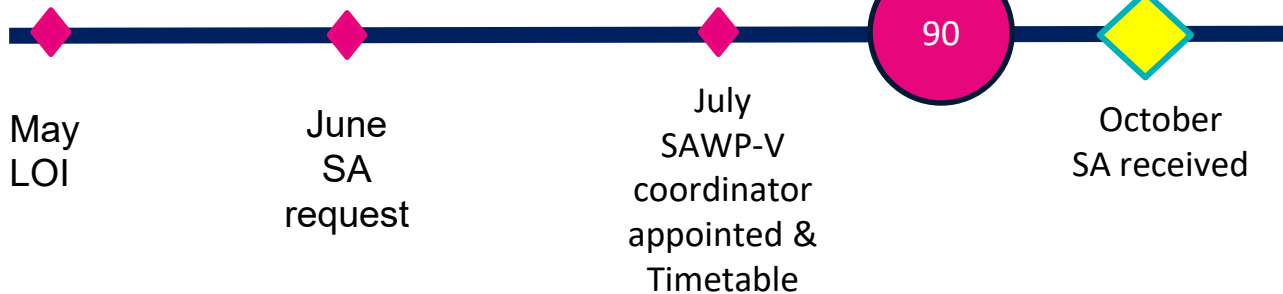
European Medicines Agency  
Veterinary Medicines and Inspections

London, 22 September 2008  
Doc. Ref. EMEA/CVMP/VICH/393388/2006

VICH Topic GL43

Step 7

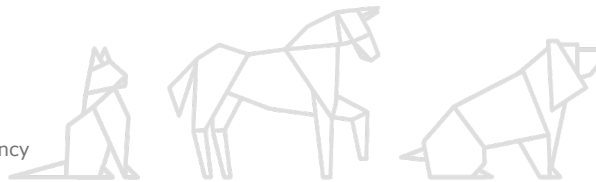
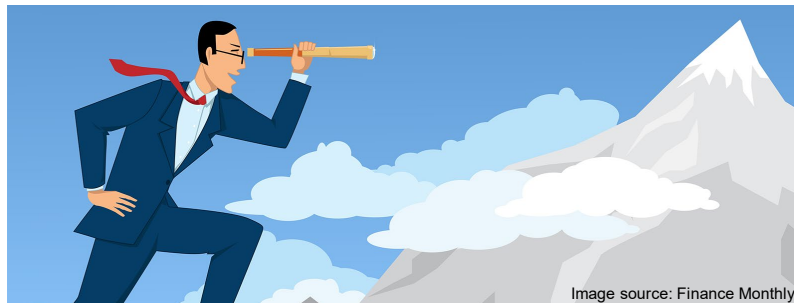
GUIDELINE ON TARGET ANIMAL SAFETY FOR VETERINARY PHARMACEUTICAL  
PRODUCTS





# Scientific Advice Case Study 2

## Part 3



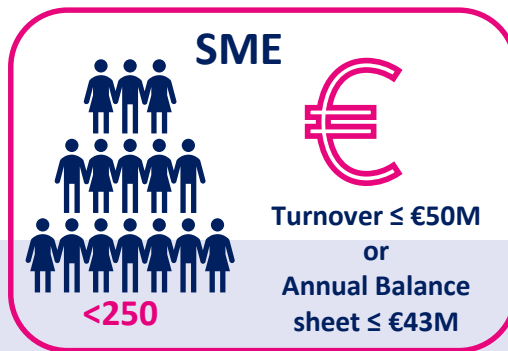


# Scientific Advice Fees

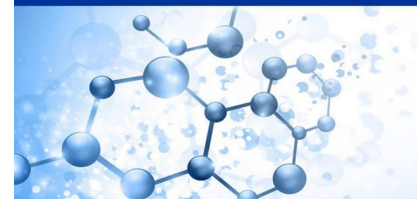
## 4. Exemptions from payment of fees for veterinary medicinal products for limited markets

A 50% reduction of the applicable fee for scientific advice shall apply for veterinary medicinal products classified as eligible for consideration under Article 23 as referred to in Annex II section 8.1 of these Rules.

*Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures  
EMA/MB/52454/2021*



Scientific advice



**90%** reduction to the total applicable fee for non-orphan medicinal products

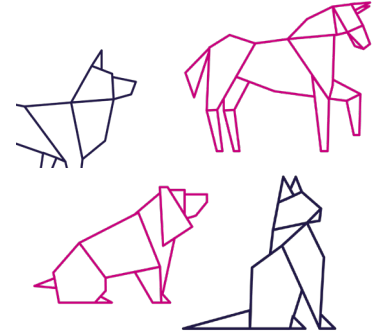
**100%** reduction to the total applicable fee for designated orphan medicinal products (see section 5.2.3)

**100%** reduction to the total applicable fee for products eligible to the PRIME scheme<sup>a</sup>

**90%** reduction to the total applicable fee for veterinary medicinal products

# Experience of SA as an SME

- Beneficial in product development and dossier compilation
- Relevance of timing
- Fee reduction is critical for SME
- Valuable guidance and templates online
- Reach out to SME Office







*Thank  
You!*