

Dermoscent® Cosmetovigilance

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Agenda

Introduction

The methodologies used to measure the safety of Dermoscent® products

Procedures for reporting adverse reactions to ensure optimal management

Best practices for managing rare adverse reactions, including dos and don'ts



I. Introduction

What is cosmetovigilance?

- Pharmacovigilance → safety of medicines
- Cosmetovigilance → safety of cosmetic products

Cosmetovigilance is a system for monitoring and recording **undesirable effects** associated with the use of **cosmetics in humans**.

It covers any undesirable effect, serious or otherwise, which has occurred under normal or reasonably expected conditions of use of any cosmetic product on the market.

Regulation EC 1223/2009



Not mandatory for veterinary cosmetics



**Cosmetovigilance
procedure
since 2003**



Why have a cosmetovigilance procedure?



**Cosmetovigilance
procedure
since 2003**

To **ensure pets safety** by detecting, analyzing and preventing undesirable effects that may occur during the use of our dermo-cosmetic products.

- ✓ **Quality** of our products has always been essential
- ✓ **ISO 9001** quality certification → **customer satisfaction** & **continuous improvement** are fundamental



Who handles the cosmetovigilance procedure?

Contract with an independent expert (veterinary dermatologist) for specific cases

Marie CAUQUIL, PhD
R&D manager



Céline COCOLLOS, PharmD
Regulatory Affairs Manager



Email address for cosmetovigilance:

cosmetovigilance@dermoscent.com



II. Methodologies

Safety of Dermoscent® products

The safety of each Dermoscent® product has been **evaluated all along their development:**

- **Ingredients rigorously chosen and dosed** by specialists
- **Physiologic pH** for a better tolerance
- Developed in accordance with the regulations EC 1223/2009 (human cosmetics) to ensure safety in the defined conditions of use
- Formulations validated by **numerous tests from *in vitro* to clinic evaluations**

However, no matter how a product is considered safe,
as long as it contains active ingredients,
adverse reactions can happen.

WHY ?

Idiosyncrasic reactions, due to particular sensitivities of some pets.
Unfortunately, almost unpredictable.

→ Our cosmetovigilance procedure enables us to monitor products launched on the market to ensure that they are well tolerated in “real life conditions of use”.



How do we measure cosmetovigilance?

Updated
twice a
year

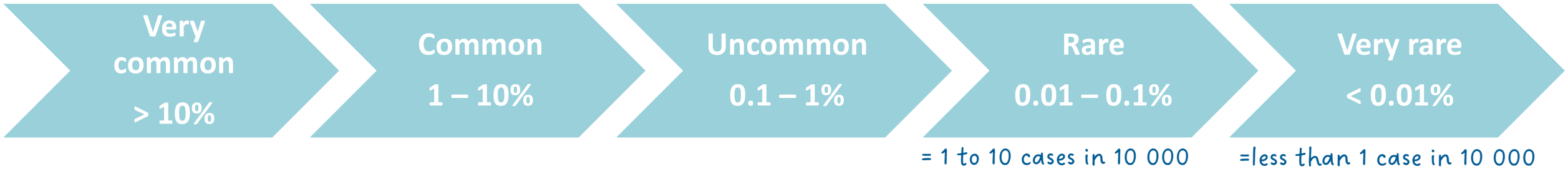
For each Dermoscent® product :

$$\text{Cosmetovigilance rate} = \frac{\text{Number of adverse reactions reported}}{\text{Number of units sold since the launch of this product}} \times 100$$

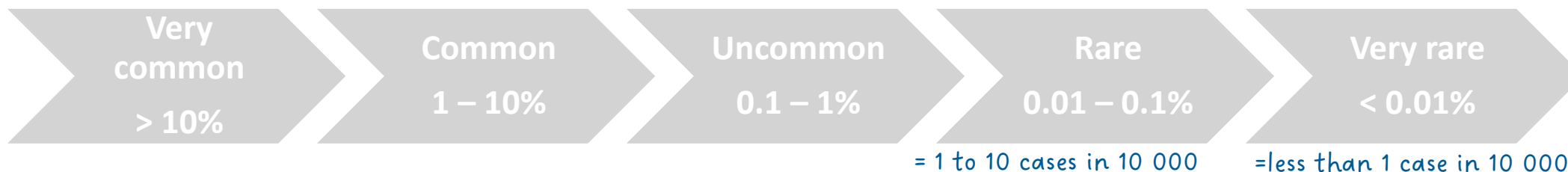


Adverse reaction rates

In medicine, **adverse reactions to drugs** are classified according to their **frequency of occurrence**:



Cosmetovigilance rates of some best-sellers



Product	Cosmetovigilance rate	Frequency
Dermoscent BIO BALM® for dogs	0.0014%	Very rare
Essential 6® spot-on for cats	0.0138%	Rare
Essential 6® spot-on for dogs and small mammals	0.0039%	Very rare
Essential Mousse for cats	0.0024%	Very rare
Essential Mousse for dogs	0.0013%	Very rare
PYOclean® Oto	0.0074%	Very rare
SunFREE	0.0288%	Rare
ATOP 7® spot-on	0.0617%	Rare
ATOP 7® spray	0.0174%	Rare



Cosmetovigilance analysis

- Although rare or very rare, reactions are more frequent:
 - With unrinsed products than with rinsed products
 - With ATOP 7® line than with other Dermoscent® lines



Expected because pets using ATOP 7® line have allergies, so they are more likely to be sensitive to substances contained in any product.

- Comparaison with adverse reaction rates of medicines for allergic patients:

- Oclacitinib (Apoquel®)

Very common (>1 animal / 10 animals treated):	pyoderma, skin lump, papilloma
Common (1 to 10 animals / 100 animals treated):	lethargy, lipoma, polydipsia, increased appetite nausea, vomiting, diarrhoea, anorexia histiocytoma, fungal skin infection, pododermatitis otitis lymphadenopathy cystitis aggression
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	anaemia, lymphoma, convulsion

data from summary of product characteristics

- Lokivetmab (Cytoint®)

Rare:

Hypersensitivity reactions (anaphylaxis, facial oedema, urticaria)
Vomiting and/or diarrhoea
Neurological signs (seizure, convulsion or ataxia)

Very rare:

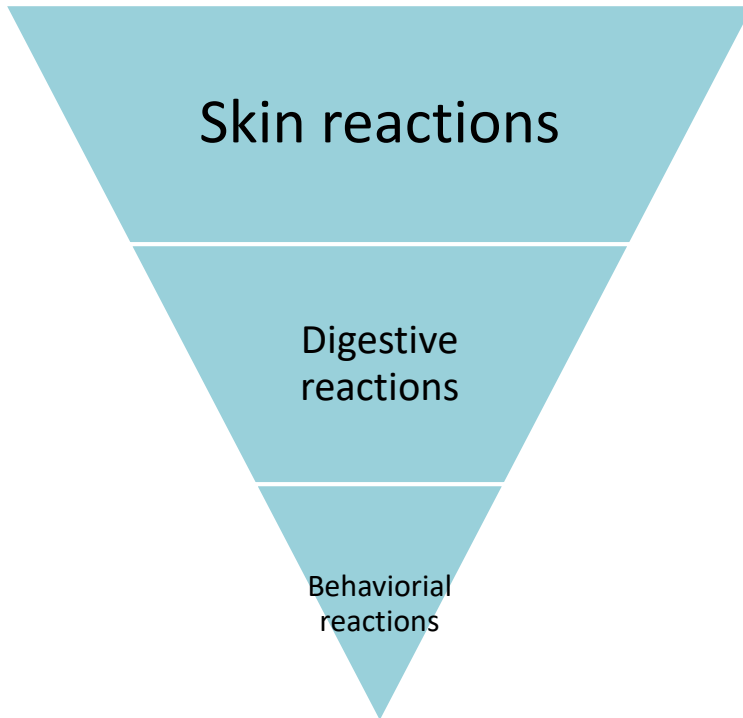
Application site disorders (injection site pain, injection site swelling)
Clinical signs of immune-mediated diseases, such as haemolytic anaemia or thrombocytopenia

data from summary of product characteristics

Reactions to placebos also occur!



Cosmetovigilance cases you may encounter



Example: reaction to spot-ons

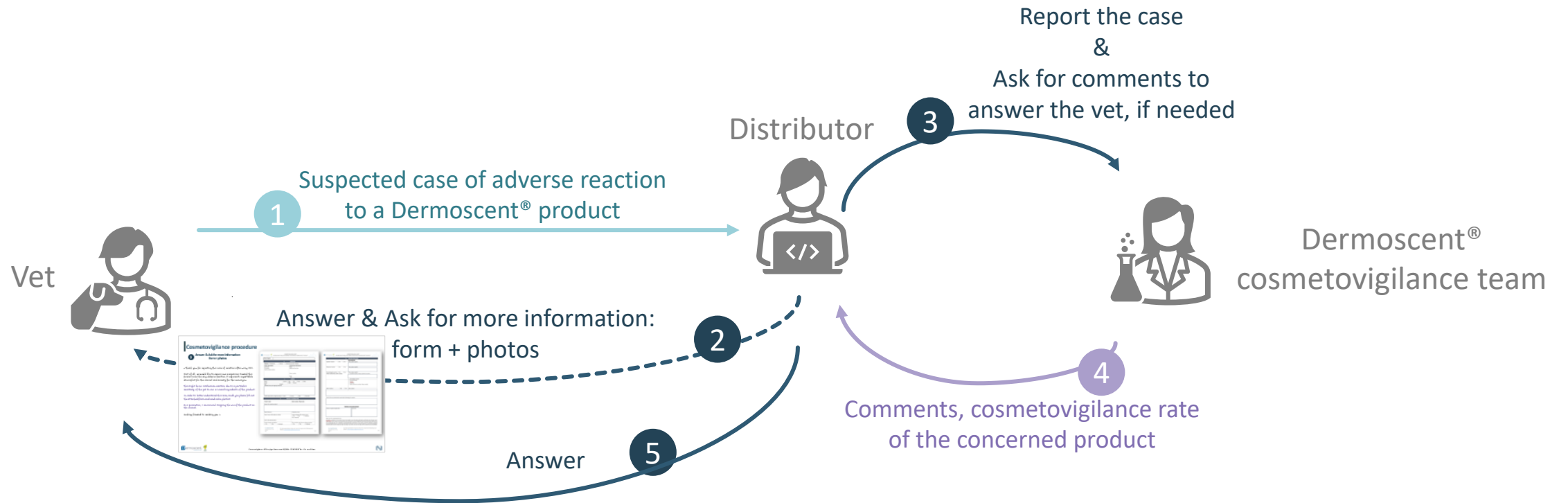
- Almost always localized to the application zone
- Often occur after the application of the 2nd or 3rd pipette
- Type of reaction:
 - Hair loss, sometimes without erythema (allergic reaction or not?)
 - Erythema
 - Pruritus



It can be challenging or even impossible to determine if the reaction reported is linked to the product or if it's just a coincidence. In any case, we record the reaction.

III. Procedures for reporting cosmetovigilance cases

Cosmetovigilance procedure



III. Best practices

Best practices for managing rare adverse reactions

DON'T	DO
Put the case on stand-by, without answering	Answer quickly, or at least notice you have well received the complaint
Overreact, say it's dramatic	Be reassuring, explain that even reactions can happen (rarely), the product remains safe
Minimize the problem or deny that the product could be involved in the reaction	Say (depending on the case): <ul style="list-style-type: none">- it seems the pet reacted to the product- it might be a reaction to the product- it seems unlikely to be a reaction of the product but we cannot exclude it
Keep the cases for yourselves	Report cases to Dermoscent® team (even if incomplete)



Best practices for managing rare adverse reactions

- If a link between the product and the reaction is likely, we recommend discontinuing the use of the product on this pet.
- Washing the pet (or at least the area of application) with a mild shampoo is in general a good idea to eliminate the source of intolerance.
- Specific cases: only if the vet asks for a refund, we propose to send them another product (they decide whether or not to reimburse the pet owner) → in such cases, please send the product to the vet and inform us, so we can replace the product for you on a future order



Conclusion

Take home message

- Adverse reactions to Dermoscent® products are rare to very rare
- But intolerance are possible, due to particular sensitivities of some pets.
- Dermoscent® has a cosmetovigilance procedure, as it exists for human cosmetics in Europe.
- If a vet suspect an adverse reaction, always report the reaction to:
cosmetovigilance@dermoscent.com and always answer to explain and reassure the veterinarian who reported the case



Thank you for your attention!
Any question?

