FVE
Federation of Veterinarians of Europe



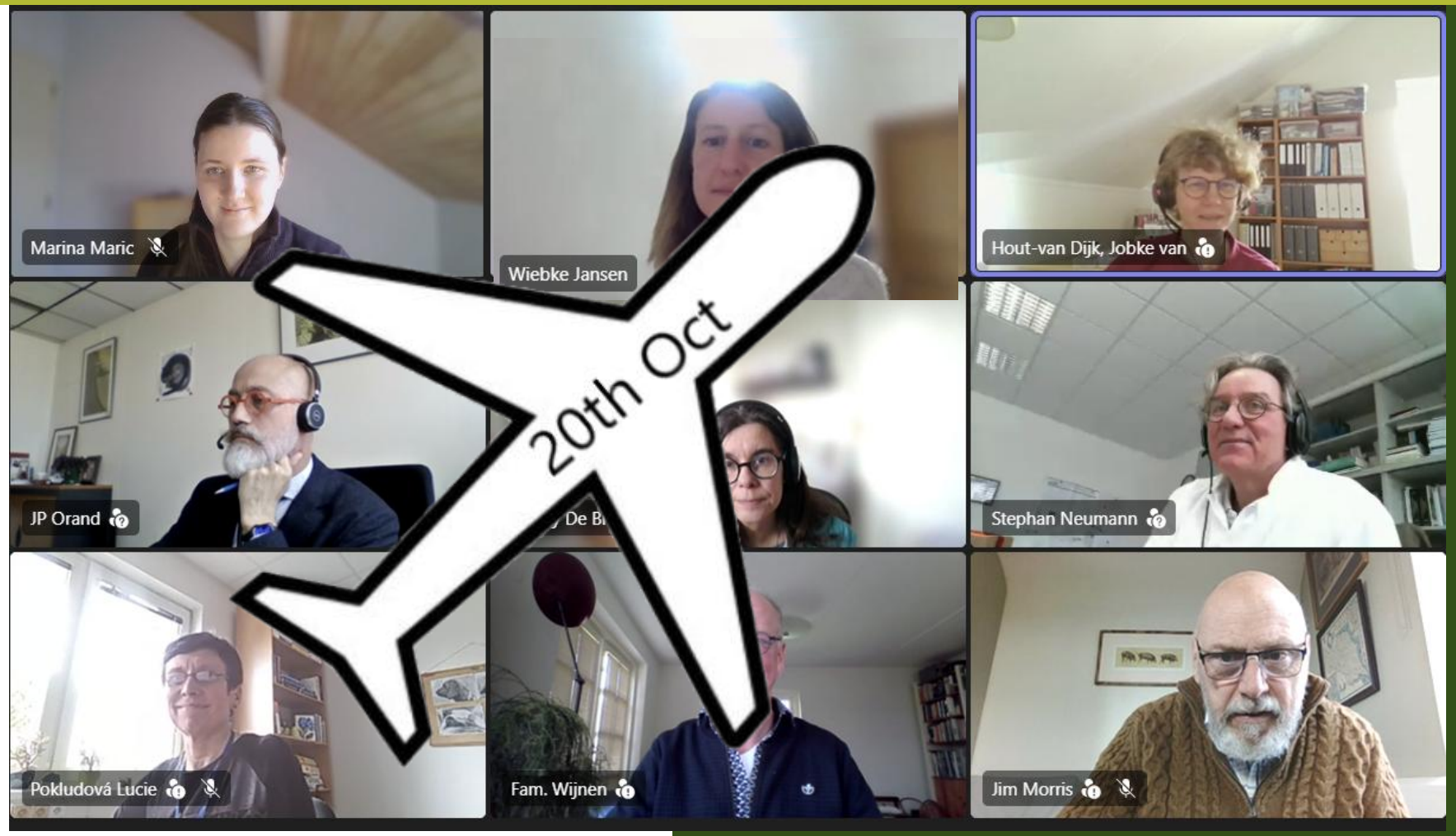
Medicine Working Group

Visegrad meeting October 2026

FVE/UEVP Medicines Working Group - new composition



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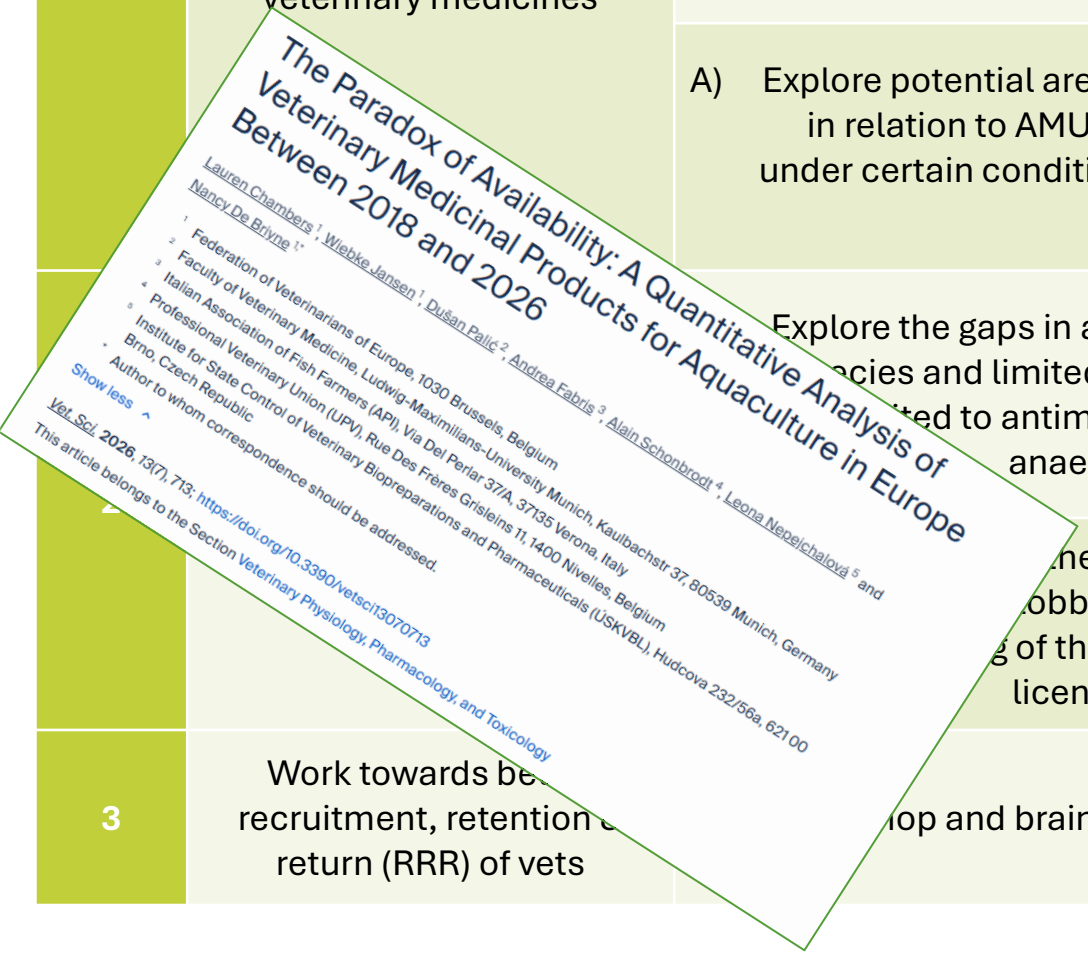
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The Paradox of Availability: A Quantitative Analysis of Veterinary Medicinal Products for Aquaculture in Europe Between 2018 and 2026

Lauren Chambers [1], Wiebke Jansen [1], Dušan Palić [2], Andrea Fabris [3], Alain Schonbrodt [4], Leona Nepejchalová [5] and Nancy De Bruyne [1]*

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[2] Faculty of Veterinary Medicine, Ludwig-Maximilians-University Munich, Kaulbachstr 37, 80539 Munich, Germany
[3] Italian Association of Fish Farmers (API), Via Del Perlar 37/A, 37135 Verona, Italy
[4] Professional Veterinary Union (UPV), Rue Des Frères Grisleins 11, 1400 Nivelles, Belgium
[5] Institute for State Control of Veterinary Biopreparations and Pharmaceuticals (ÚSKVBL), Hudcova 232/56a, 621 00 Brno, Czech Republic
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This article belongs to the Section Veterinary Physiology, Pharmacology, and Toxicology

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Art. 106(1) – The SPC Issue

- April 24th EC & Member States & FVE
  - **concrete recommendations for practitioners and Member States on how to interpret and apply the interplay between Article 106(1) and the cascade provisions (Art 112-114)**

This achievement only possible thanks to:
- **strong scientific input,**
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- **united efforts from across the profession**

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Interpretation recommendations aligning Art 106.1 with 112-114

1. The cascade **aims at** addressing specific animal health/welfare needs where a suitable veterinary medicinal product is not available (**"unmet clinical need"**). However, cascade use **is not aimed** at addressing widespread **lack of efficacy** or safety concerns from the use of a veterinary medicinal product **in accordance authorisation**
2. The cascade use includes cases where there is **no veterinary medicinal product** authorised to treat the relevant condition or target species, or when that veterinary medicinal product **is not available**. It also covers cases where a **specific clinical setting** is not addressed under the terms of the marketing authorisation.
3. Individual responses may vary to treatment. **If**, after initiating treatment, the **treated animal does not adequately respond** or if it experiences adverse events, **cascade use is justified**. Lack of efficacy or adverse events should be **reported**.
4. Cascade use may also be necessary to comply with **legal/regulatory requirements.**
5. Other clinical circumstances exist where the cascade use may be justified, if no suitable veterinary medicinal product is authorised/available & the vet considers that such use is **in the best interest of the animal.**

Interpretation recommendations aligning Art 106.1 with 112-114

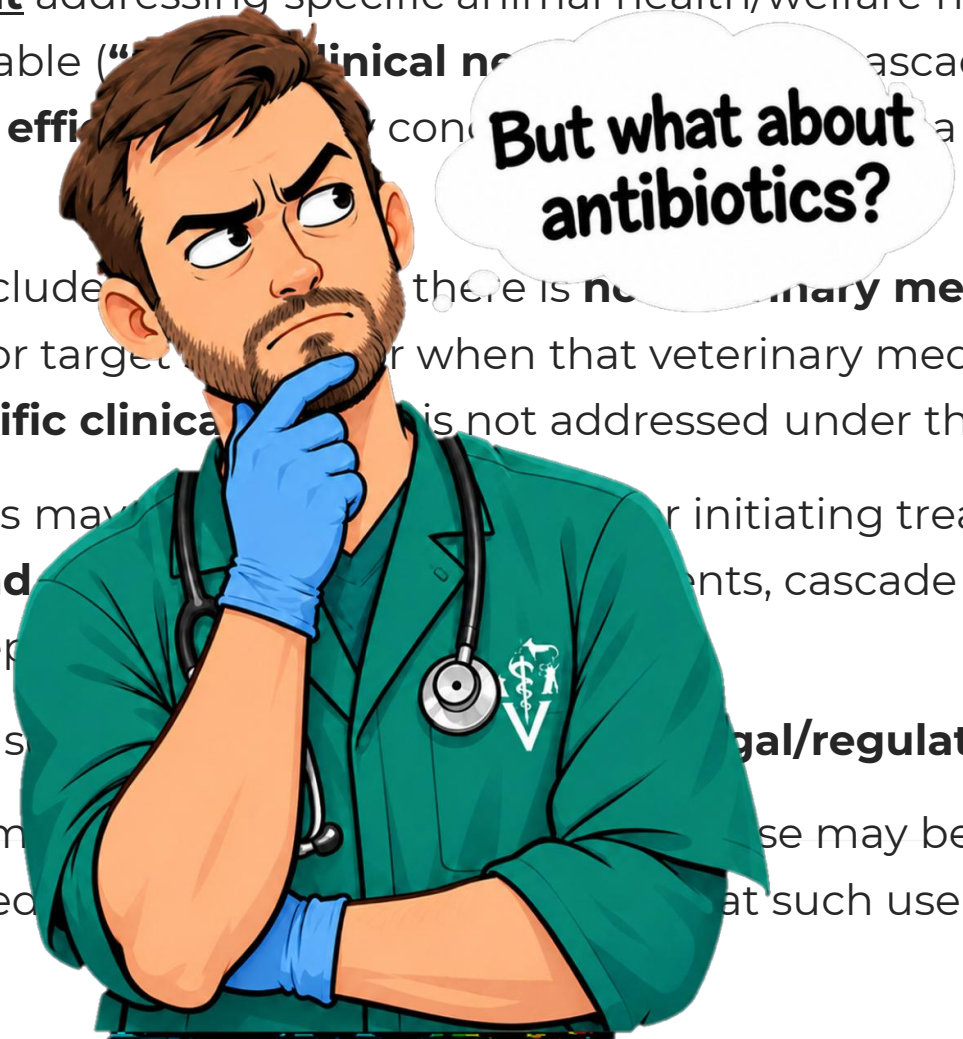
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Scenarios of unmet clinical need	Cascade use allowed?
Specific animal subset not covered by the terms of the marketing authorisation (*e.g.* pregnant animal, newborn, very old animal).	Yes
Underlying health conditions not covered by the terms of the marketing authorisation *(e.g.* renal impairment, gastrointestinal ulcer, hypersensitivity).	Yes
Concomitant use with other VMPs, not addressed in marketing authorisation.	Yes
Animal does not adequately respond to treatment (lack of efficacy).	Yes. Event should be reported.
Treated animal suffers from adverse events which require clinical response.	Yes. Event should be reported.
The specific clinical setting is contraindicated.	Only if an alternative VMP covering the clinical needs is not available.
More severe condition than the one foreseen in the marketing authorisation *(e.g.* advanced staged disease state).	Only if alternative VMP covering more severe condition is not available.
Route of administration not covered by the marketing authorisation is necessary to address the specific clinical need of the animal.	Only if alternative VMP with required route of administration is not available.
A specific vaccination schedule not covered by the marketing authorisation is required to comply with legal/regulatory requirements	Only if alternative VMP with required vaccination schedule is not available





Next step finding a solution in relation to Art 106.1 and antimicrobials

EC narration so far:

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Industry must update SPCs

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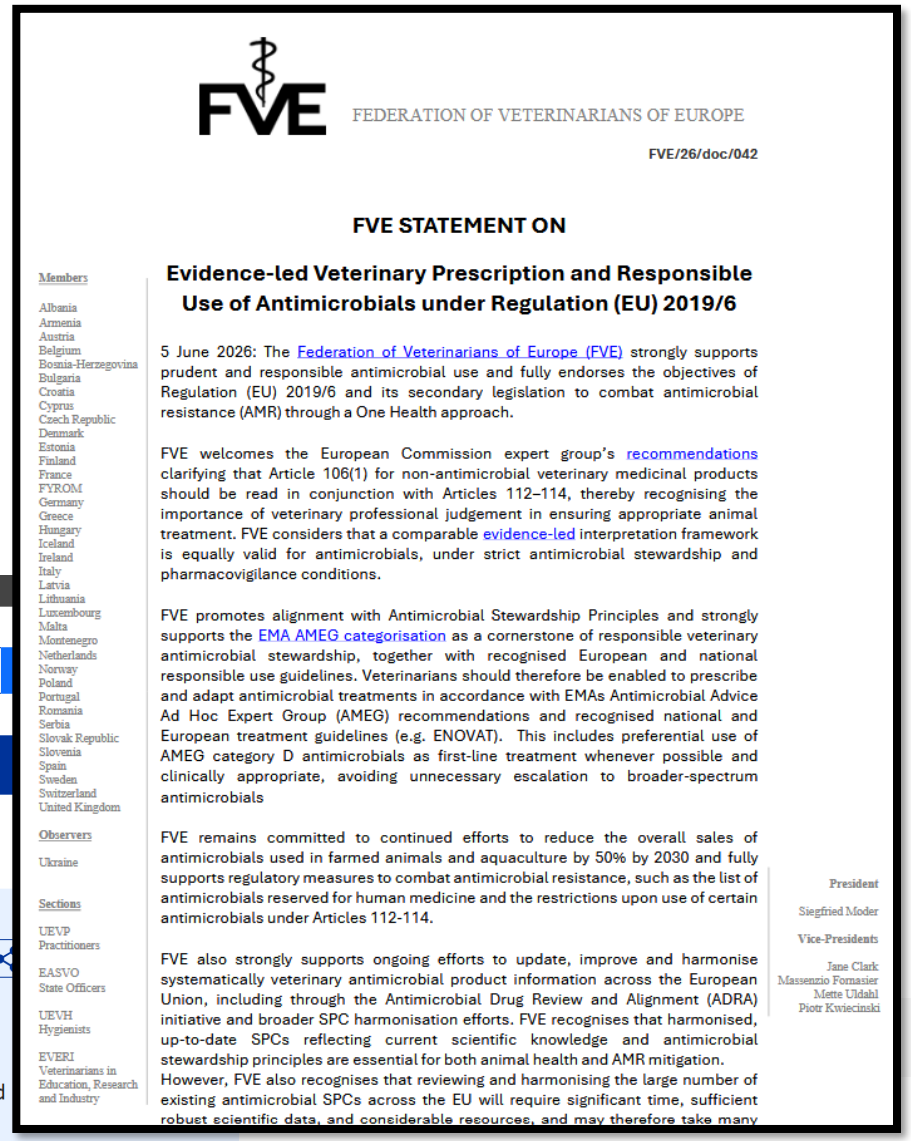
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FEDERATION OF VETERINARIANS OF EUROPE

FVE/26/doc/042

FVE STATEMENT ON

Evidence-led Veterinary Prescription and Responsible Use of Antimicrobials under Regulation (EU) 2019/6

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Cyprus
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Spain
Sweden
Switzerland
United Kingdom

Observers

Ukraine

Sections

UEVP Practitioners
EASVO State Officers
UEVH Hygienists
EVERI Veterinarians in Education, Research and Industry

5 June 2026: The Federation of Veterinarians of Europe (FVE) strongly supports prudent and responsible antimicrobial use and fully endorses the objectives of Regulation (EU) 2019/6 and its secondary legislation to combat antimicrobial resistance (AMR) through a One Health approach.

FVE welcomes the European Commission expert group's recommendations clarifying that Article 106(1) for non-antimicrobial veterinary medicinal products should be read in conjunction with Articles 112–114, thereby recognising the importance of veterinary professional judgement in ensuring appropriate animal treatment. FVE considers that a comparable evidence-led interpretation framework is equally valid for antimicrobials, under strict antimicrobial stewardship and pharmacovigilance conditions.

FVE promotes alignment with Antimicrobial Stewardship Principles and strongly supports the EMA AMEG categorisation as a cornerstone of responsible veterinary antimicrobial stewardship, together with recognised European and national responsible use guidelines. Veterinarians should therefore be enabled to prescribe and adapt antimicrobial treatments in accordance with EMAs Antimicrobial Advice Ad Hoc Expert Group (AMEG) recommendations and recognised national and European treatment guidelines (e.g. ENOVAT). This includes preferential use of AMEG category D antimicrobials as first-line treatment whenever possible and clinically appropriate, avoiding unnecessary escalation to broader-spectrum antimicrobials

FVE remains committed to continued efforts to reduce the overall sales of antimicrobials used in farmed animals and aquaculture by 50% by 2030 and fully supports regulatory measures to combat antimicrobial resistance, such as the list of antimicrobials reserved for human medicine and the restrictions upon use of certain antimicrobials under Articles 112-114.

FVE also strongly supports ongoing efforts to update, improve and harmonise systematically veterinary antimicrobial product information across the European Union, including through the Antimicrobial Drug Review and Alignment (ADRA) initiative and broader SPC harmonisation efforts. FVE recognises that harmonised, up-to-date SPCs reflecting current scientific knowledge and antimicrobial stewardship principles are essential for both animal health and AMR mitigation.
However, FVE also recognises that reviewing and harmonising the large number of existing antimicrobial SPCs across the EU will require significant time, sufficient robust scientific data, and considerable resources, and may therefore take many

President
Siegfried Moder
Vice-Presidents
Jane Clark
Massenzio Fornasier
Mette Uldahl
Piotr Kwiecinski

But let's not forget Art 104 and 105

Article 104

Retail of veterinary medicinal products at a distance

1. Persons permitted to supply veterinary medicinal products in accordance with Article 103(1) of this Regulation may offer veterinary medicinal products by means of information society services in the meaning of Directive (EU) 2015/1535 of the European Parliament and of the Council ([25]) to natural or legal persons established in the Union provided that those veterinary medicinal products are not subject to a veterinary prescription pursuant to Article 34 of this Regulation and that they comply with this Regulation and applicable law of the Member State in which the veterinary products are retailed.

But let's not forget Art 104 and 105

2. By way of derogation from paragraph 1 of this Article, a Member State may allow persons permitted to supply veterinary medicinal products in accordance with Article 103(1) to offer veterinary medicinal products subject to a veterinary prescription pursuant to Article 34 by means of information society services, provided that the Member State has provided a secure system for such supplies. Such permission shall only be granted to persons established in their territory and supply shall only occur within the territory of that Member State.

But let's not forget Art 104 and 105

Yes, the Regulation allows for derogation, but:

- is there a SECURE system provided by the state
- is it in compliance with national regulations (are there any)?
- is there a set of rules and possible penalties?
- were EC and MS notifed

But let's not forget Art 104 and 105

Article 105

Veterinary prescriptions

5. A veterinary prescription shall contain at least the following elements:

(a) identification of the animal or groups of animals to be treated;

(b) full name and contact details of the animal owner or keeper;

(c) issue date;

(d) full name and contact details of the veterinarian including, if available, the professional number;

(e) signature or an equivalent electronic form of identification of the veterinarian;

(f) name of the prescribed medicinal product, including its active substances;

(g) pharmaceutical form and strength;

(h) quantity prescribed, or the number of packs, including pack size;

(i) dosage regimen;

(j) for food-producing animal species, withdrawal period even if such period is zero;

(k) any warnings necessary to ensure the proper use including, where relevant, to ensure prudent use of antimicrobials;

(l) if a medicinal product is prescribed in accordance with Articles 112, 113 and 114, a statement to that effect;

(m) if a medicinal product is prescribed in accordance with Article 107(3) and (4), a statement to that effect.

FVE updated the ‘Cascade leaflet‘

Visual guide with:

- Flow charts on different treatment choices
- Information on withdrawal times, record keeping
- Available in



FVE updated the ‘Cascade leaflet‘

Visual guide with:

- Flow charts on different treatment choices
- Information on withdrawal times, record keeping
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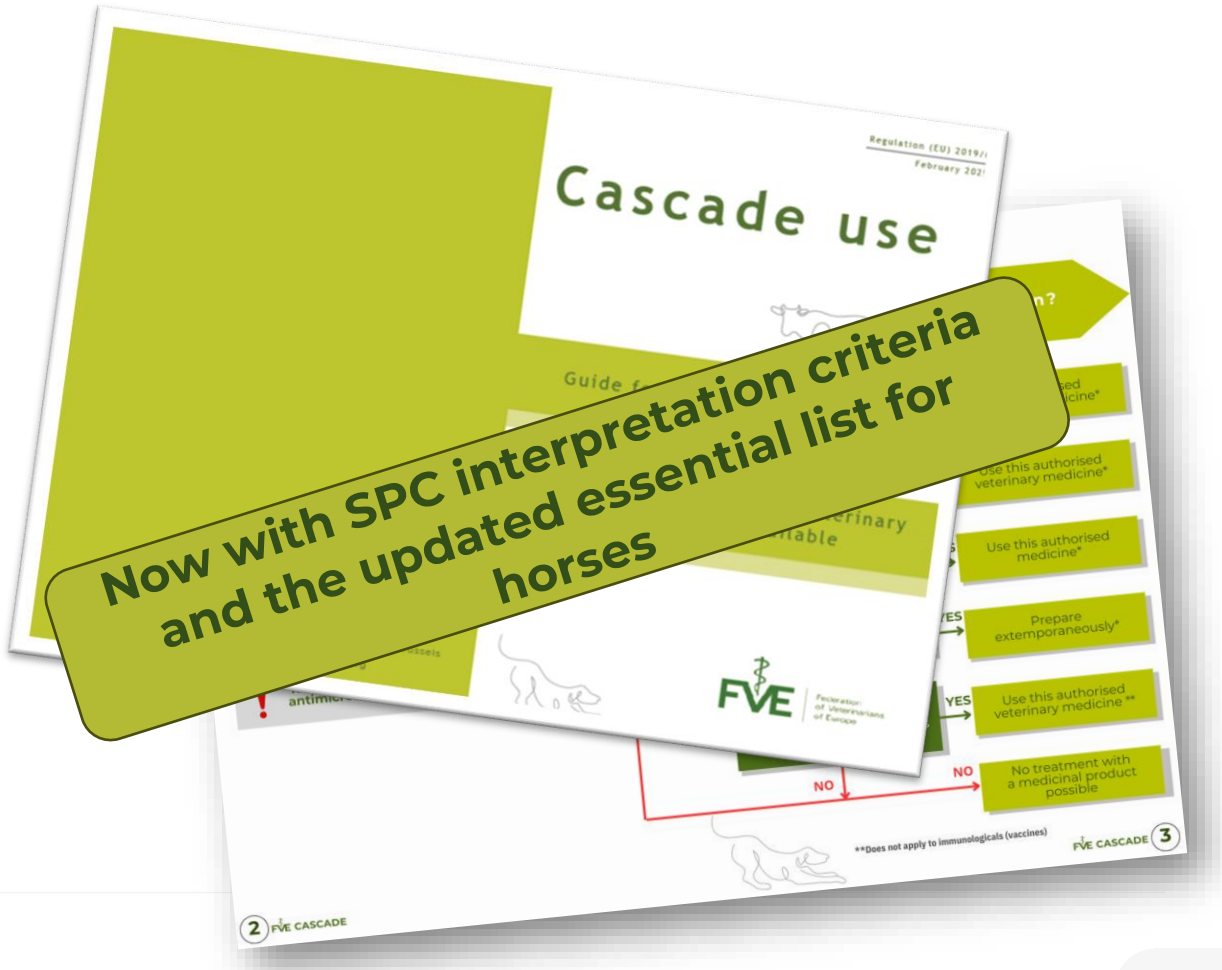
Want it in your language? Contact us!

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Want it in your language? Contact us!

FVE's VetMed+ Coalition



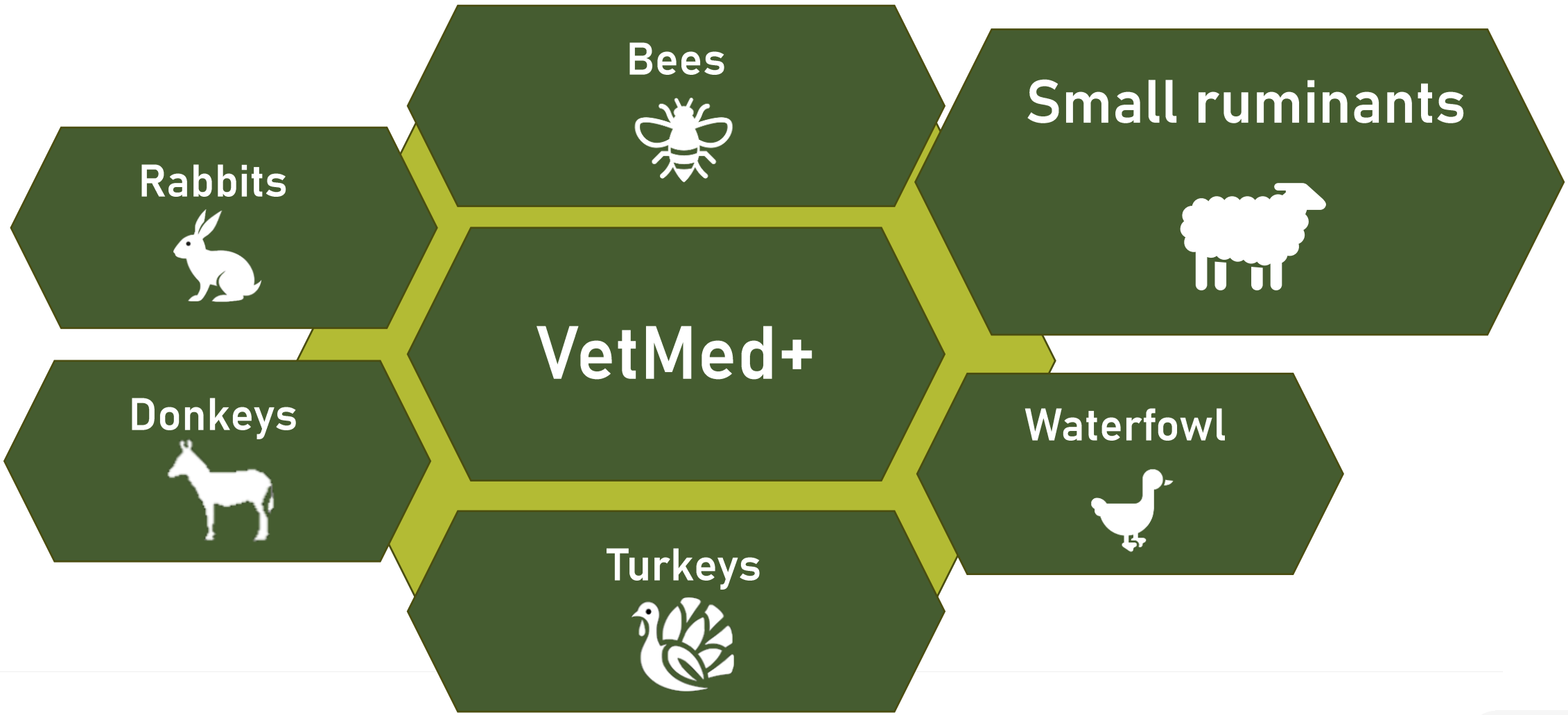
European Veterinary Medicines Gaps & Needs Compass

- better availability of medicines for **minor species**.
- VetMed+ steering task force and species-specific subgroups

→

1. **list of lacking priority VMPs and unmet needs**
2. **the root cause for the lack**
3. **potential alternatives or remedies**

- **Spanish National Action Plan On AMR (PRAN)**
- **Spanish Agency Of Medicine And Medical Devices (AEMPS)**
- **French Agency For Veterinary Medicinal Products (ANMV)**
- **Portuguese Directorate General Of Food And Veterinary (DGAV)**
- **Irish Health Products Regulatory Authority (HPRA)**


Bees
Small ruminants
Rabbits
VetMed+
Donkeys
Waterfowl
Turkeys

Only limited VMPs available for sheep and goats
Severe unmet needs = cascade

≈ 1/3

Products reported as available on the market

Sheep: 29% (1,415 / 4,895)
Goats: 33% (703 / 2,151)

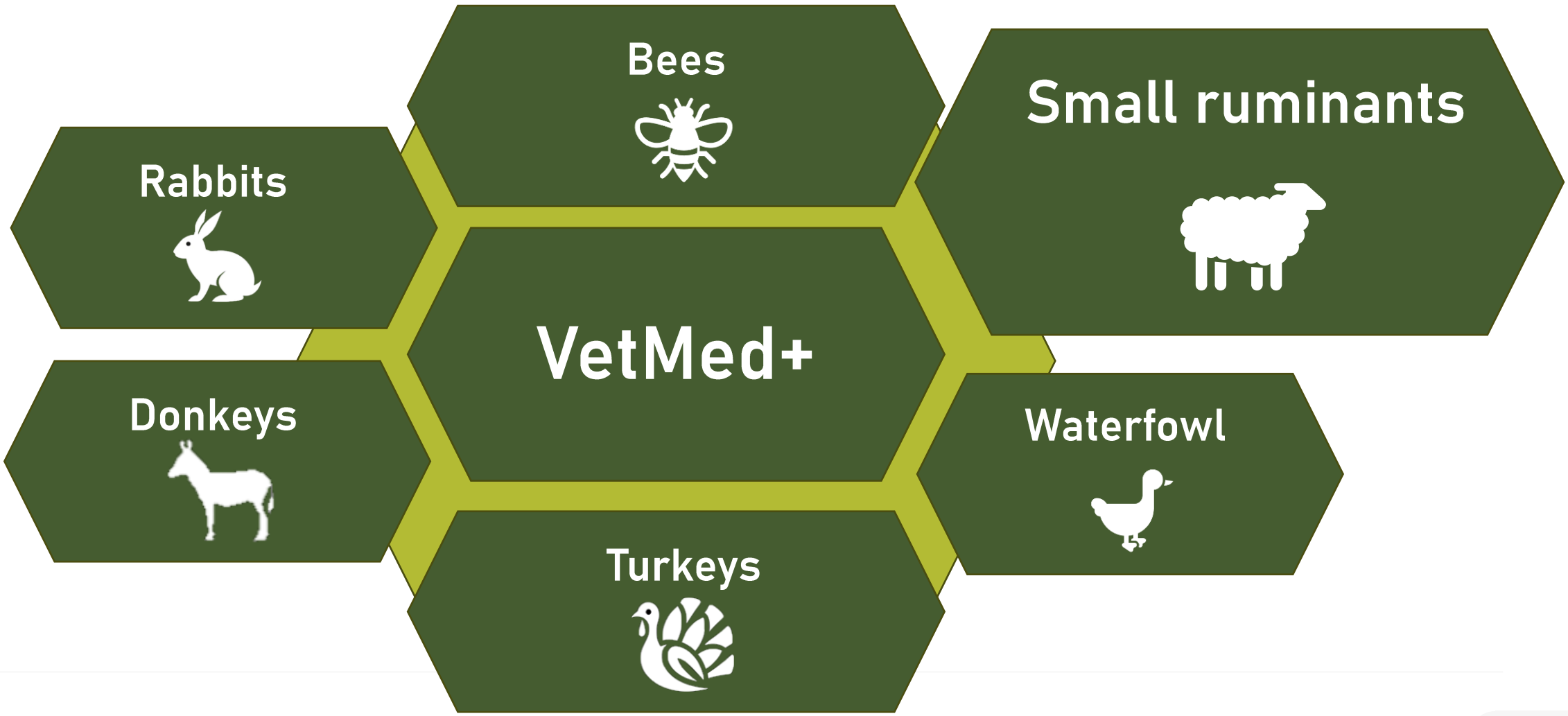


Full publication:
https://www.mdpi.com/2306-7381/13/3/297

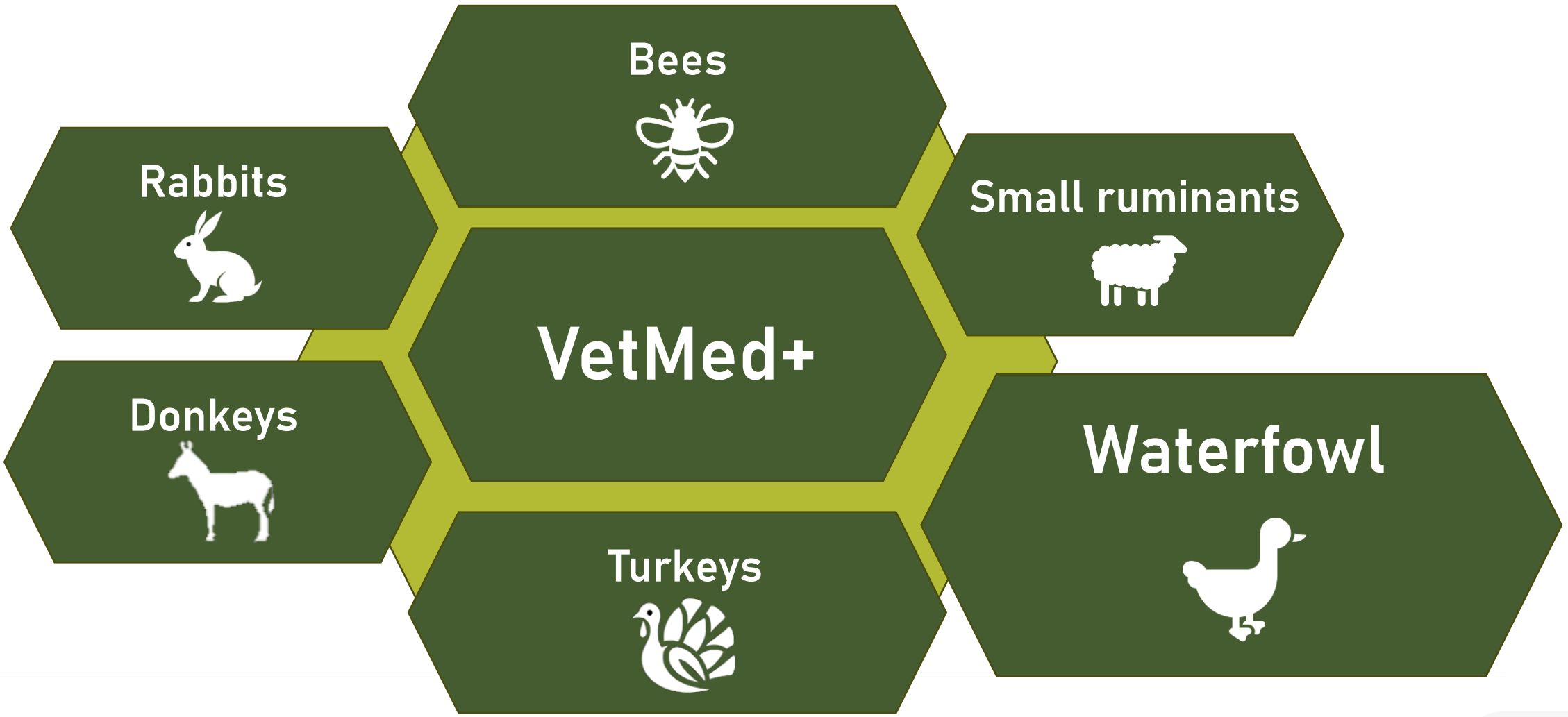
Example of gaps:

- **NSAIDs (nonsteroidal anti-inflammatory drugs)**
- **Anthelmintics**
- **mono-valent vaccines against listeria, coccidiosis, pasteurella, etc**




Bees
Small ruminants
Rabbits
VetMed+
Donkeys
Waterfowl
Turkeys




Bees
Rabbits
Small ruminants
VetMed+
Donkeys
Waterfowl
Turkeys

Bees

Rabbits

Donkeys



Small ruminants

Waterfowl

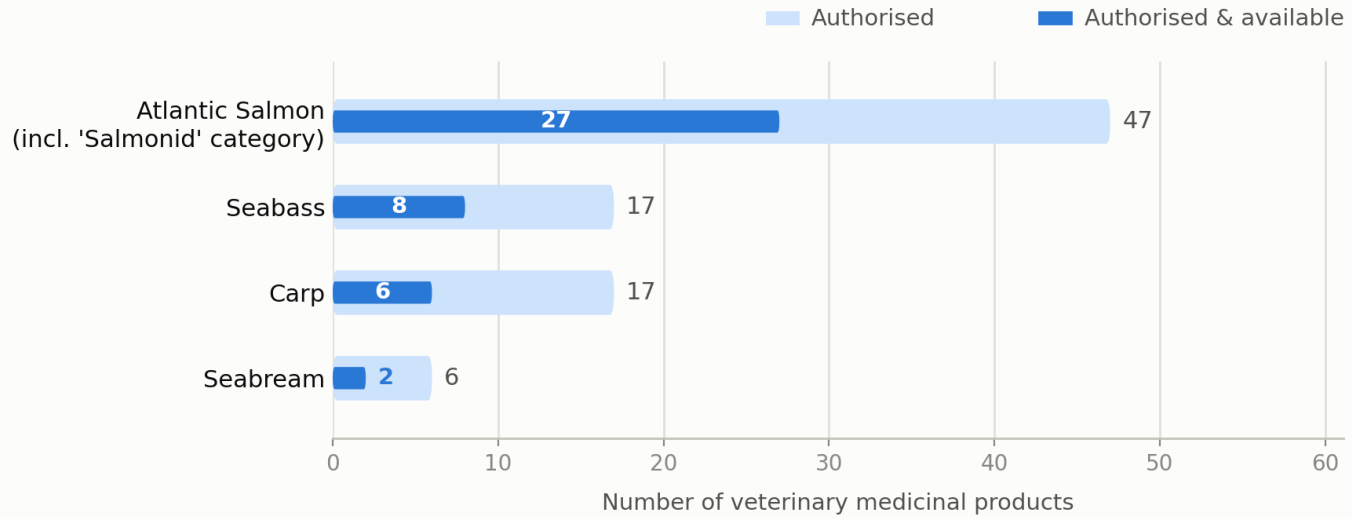
Even bigger gap concerning finfish

≈ 1/4

Products reported as available on the market
332

Products available on the market
88

Authorised veterinary medicinal products for farmed fish species outnumber those actually available on the EU market



Example of gaps:

- ectoparasites
- endoparasites
- *Aeromonas* spp. infections
- Fungal infections

etc…

CONTACT US

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FVE Federation of Veterinarians of Europe