

AMRFV

Training

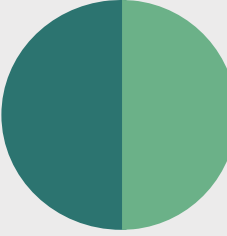


IRELAND

24 JUNE 2025



Funded by
the European Union



Introduction to overall EU regulatory framework: focus on veterinary medicinal products Regulation.

Hands-on Training for Farmers and Veterinarians: New measures to fight antimicrobial resistance

IRELAND, 24 JUNE 2025



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**Regulation (EU) 2019/6 on Veterinary
Medicinal Products**

**Regulation (EU) 2019/4 on
Medicated Feed**

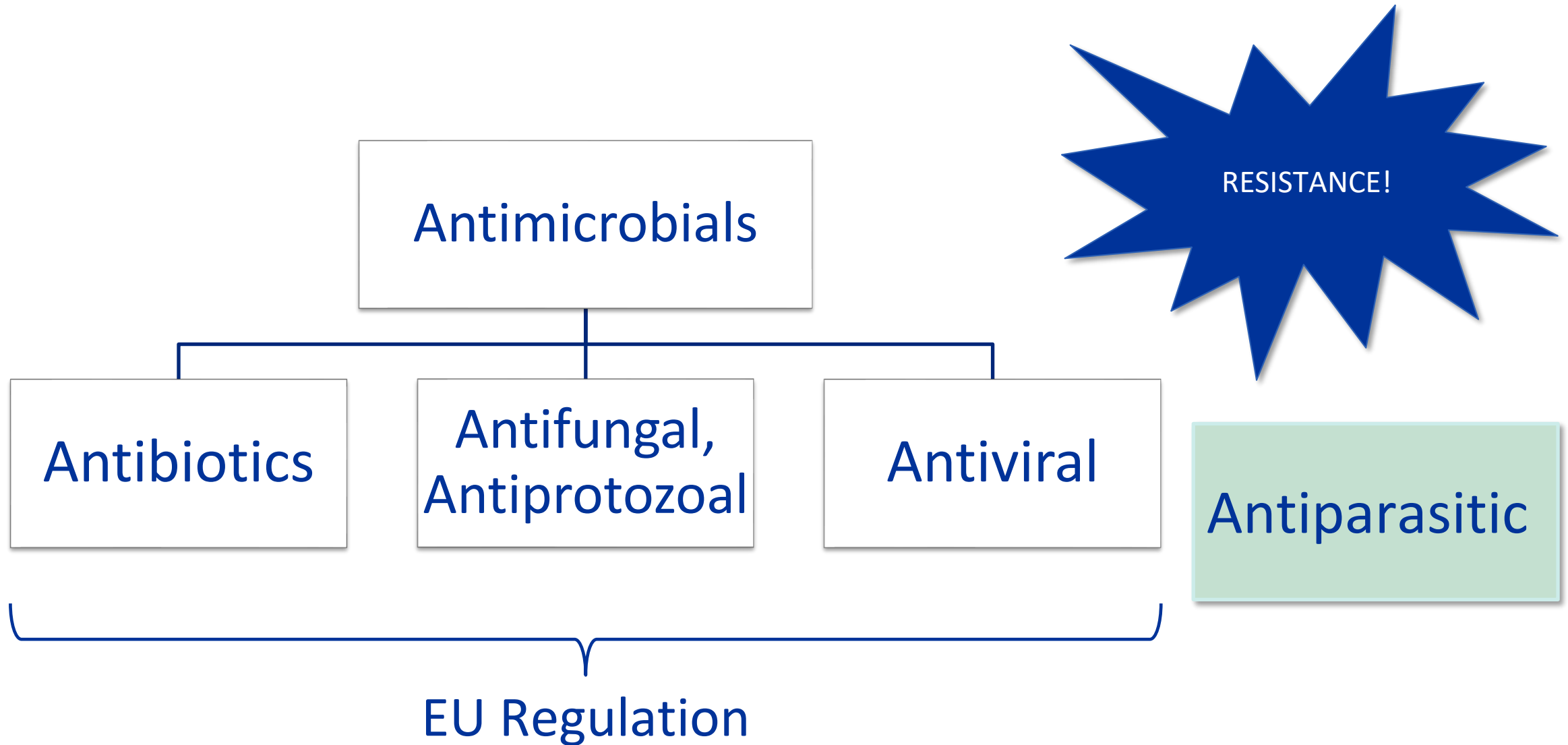
Definitions and general principles

'veterinary prescription' means a document issued by a veterinarian for a veterinary medicinal product or a medicinal product for human use for its use in animals.

'antimicrobial' means any substance with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, antifungals and anti-protozoals

Antimicrobial veterinary medicinal products must only be available on veterinary prescription.

ANTIMICROBIAL VERSUS ANTIBIOTICS



Common rules – Veterinary prescription

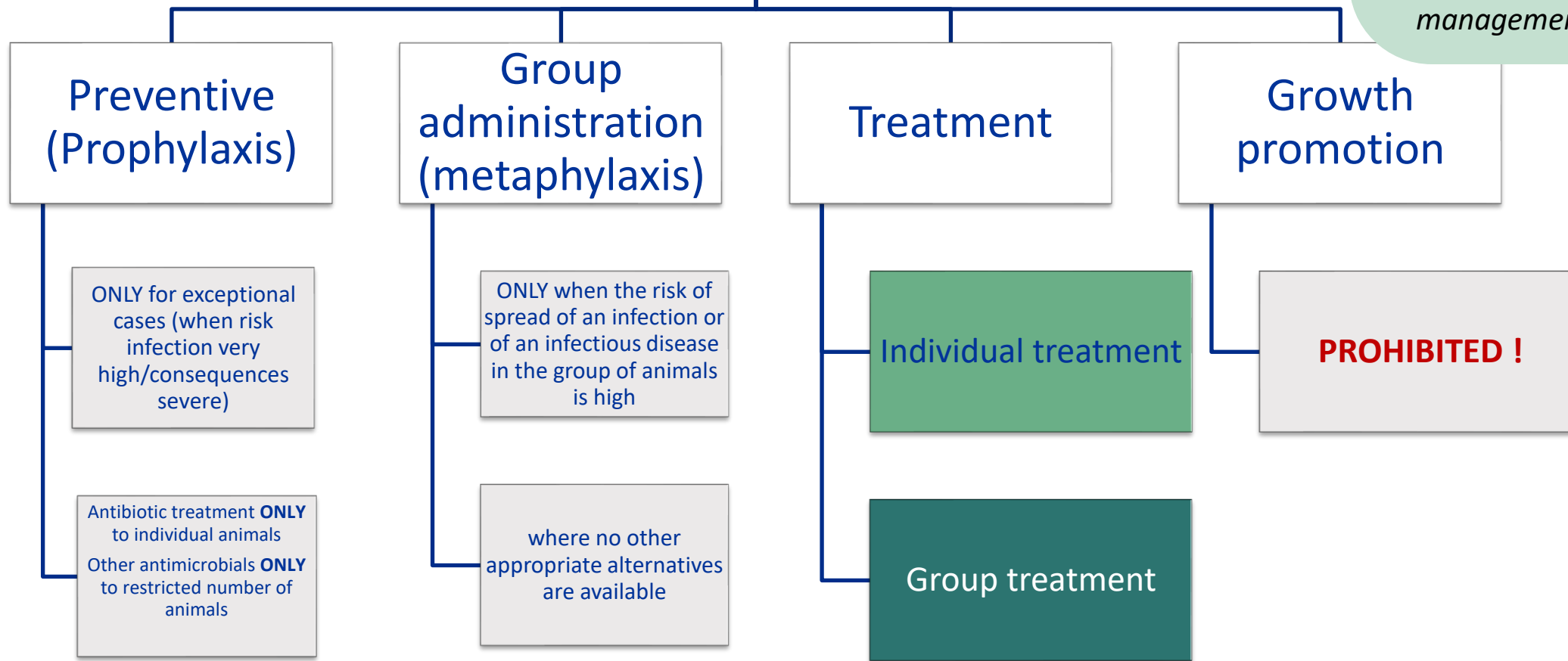
Some medicines are subject to veterinary prescription for reasons of safety (for animals and people!), efficacy & potential resistance, and possible misuse.

- (a) narcotic drugs or psychotropic substances
- (b) medicines for food-producing animals
- (c) **antimicrobials**
- (d) if a prior diagnosis is needed
- (e) euthanasia products
- (f) new active substances (< 5 yr)
- (g) vaccines
- (h) hormones or thyrostatics or beta-agonists



Common rules – Veterinary prescription

Ways of antimicrobial use



- shall **NOT** be applied **routinely**
- shall **NOT** be used to **compensate** for poor hygiene, inadequate animal husbandry, lack of care or poor farm management.

Uses of antimicrobials other than to treat sick animals

Prophylaxis

- When antimicrobials are administered to animals at risk of an infection or disease
- A measure taken to maintain health and prevent infection or disease from occurring

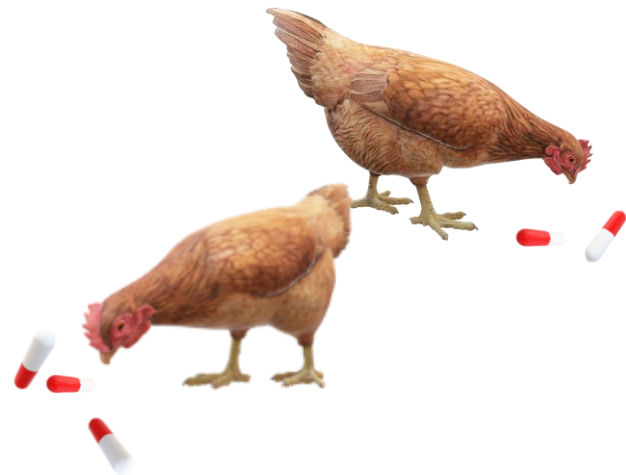
Metaphylaxis

- When antimicrobials are administered to animals with clinical signs and to clinically healthy animals belonging to the same flock or pen
- Some of the infections are treated before their clinical appearance

HEALTH

Start of the infectious disease

DISEASE



Preventive



early

Curative treatment / control



conventional

No symptoms

symptoms



4. EU framework on veterinary medicinal products and medicated feed



Regulation (EU) 2019/6 on Veterinary Medicinal Products (VMP Regulation)



Prophylaxis

Only in exceptional cases, for the administration to an individual animal (antibiotics) or a restricted number of animals (other antimicrobials) when the risk of an infection or of an infectious disease is very high and the consequences are likely to be severe.

Metaphylaxis

Only when the risk of spread of an infection or of an infectious disease in the group of animals is high and where no other appropriate alternatives are available.

Member States may provide guidance regarding such other appropriate alternatives and shall actively support the development and application of guidelines which promote the understanding of risk factors associated with metaphylaxis and include criteria for its initiation.

4. EU framework on veterinary medicinal products and medicated feed



General principles of the Veterinary Medicinal Products Regulation

Veterinary medicinal products shall be used in accordance with the **terms of the marketing authorization**.

All veterinary **prescriptions** should be **based on a clinical examination** or other proper assessment by a veterinarian

List of antimicrobials **reserved for humans only***

Obligation for Member States to **collect data on sale and use of antimicrobials**



VETERINARY PRESCRIPTIONS



Article 105

- The veterinarian can issue a veterinary prescription only after he or she has made a clinical examination or any other proper assessment of the health status of the animal or group of animals
- The veterinarian can issue a veterinary prescription for an antimicrobial only after he or she has diagnosed an infectious disease
- The veterinarian has to be able to provide justification for the prescription of an antimicrobial, especially for preventive (prophylaxis) and group (metaphylaxis) administration

Common rules – Veterinary prescription



Record keeping

Reg.(EU) 2019/6 (VPM)

Article 108

OBLIGATIONS



Article 108

Record-keeping by owners and keepers of food-producing animals

1. Owners or, where the animals are not kept by the owners, keepers of food-producing animals shall keep records of the medicinal products they use and, if applicable, a copy of the veterinary prescription.
2. Records referred to in paragraph 1 shall include:
 - (a) date of the first administration of the medicinal product to the animals;
 - (b) name of the medicinal product;
 - (c) quantity of the medicinal product administered;
 - (d) name or company name and permanent address or registered place of business of the supplier;
 - (e) evidence of acquisition of the medicinal products they use;
 - (f) identification of the animal or group of animals treated;
 - (g) name and contact details of the prescribing veterinarian, if applicable;
 - (h) withdrawal period even if such period is zero;
 - (i) duration of treatment.

Common rules – Veterinary prescription



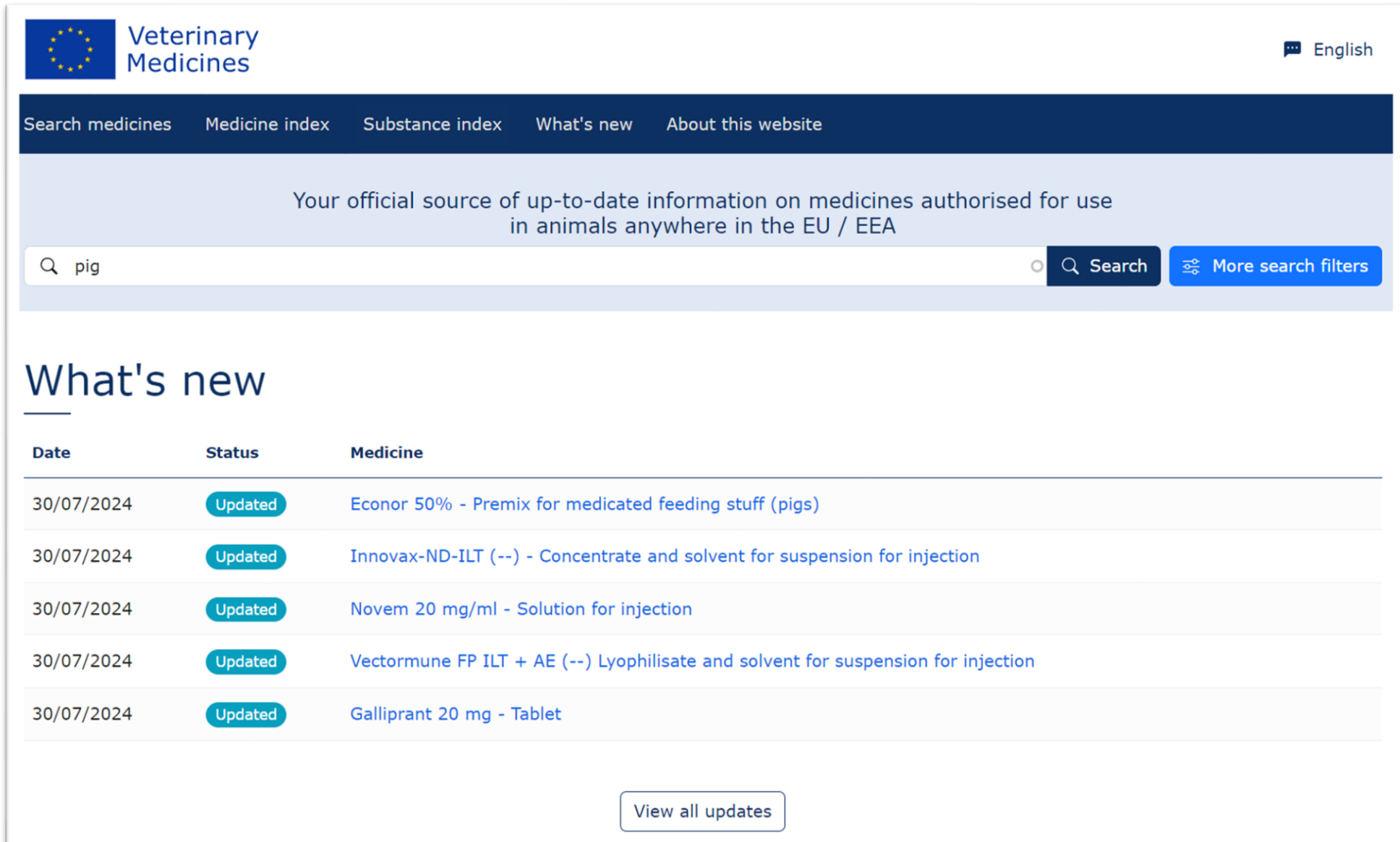
Marketing Authorisation

Reg.(EU) 2019/6 (VPM)

Principle Rule
Veterinary medicines must be used according to the marketing authorisation (SPC/leaflet)

You need to use a veterinary medicine for the indication, species and dosage regime detailed in the SPC/leaflet. If there is no veterinary product authorized for a certain indication/species or there is a shortage -> you can use the rules of Art. 112-114

You can consult the EU database with all authorised veterinary medicines: <https://medicines.health.europa.eu/veterinary/>



The screenshot shows the homepage of the EU Veterinary Medicines website. At the top left is the European Union flag and the text 'Veterinary Medicines'. At the top right is a language selector set to 'English'. Below this is a dark blue navigation bar with links: 'Search medicines', 'Medicine index', 'Substance index', 'What's new', and 'About this website'. A central banner reads 'Your official source of up-to-date information on medicines authorised for use in animals anywhere in the EU / EEA'. Below the banner is a search bar containing the text 'pig', a 'Search' button, and a 'More search filters' button. The main content area is titled 'What's new' and features a table of updates.

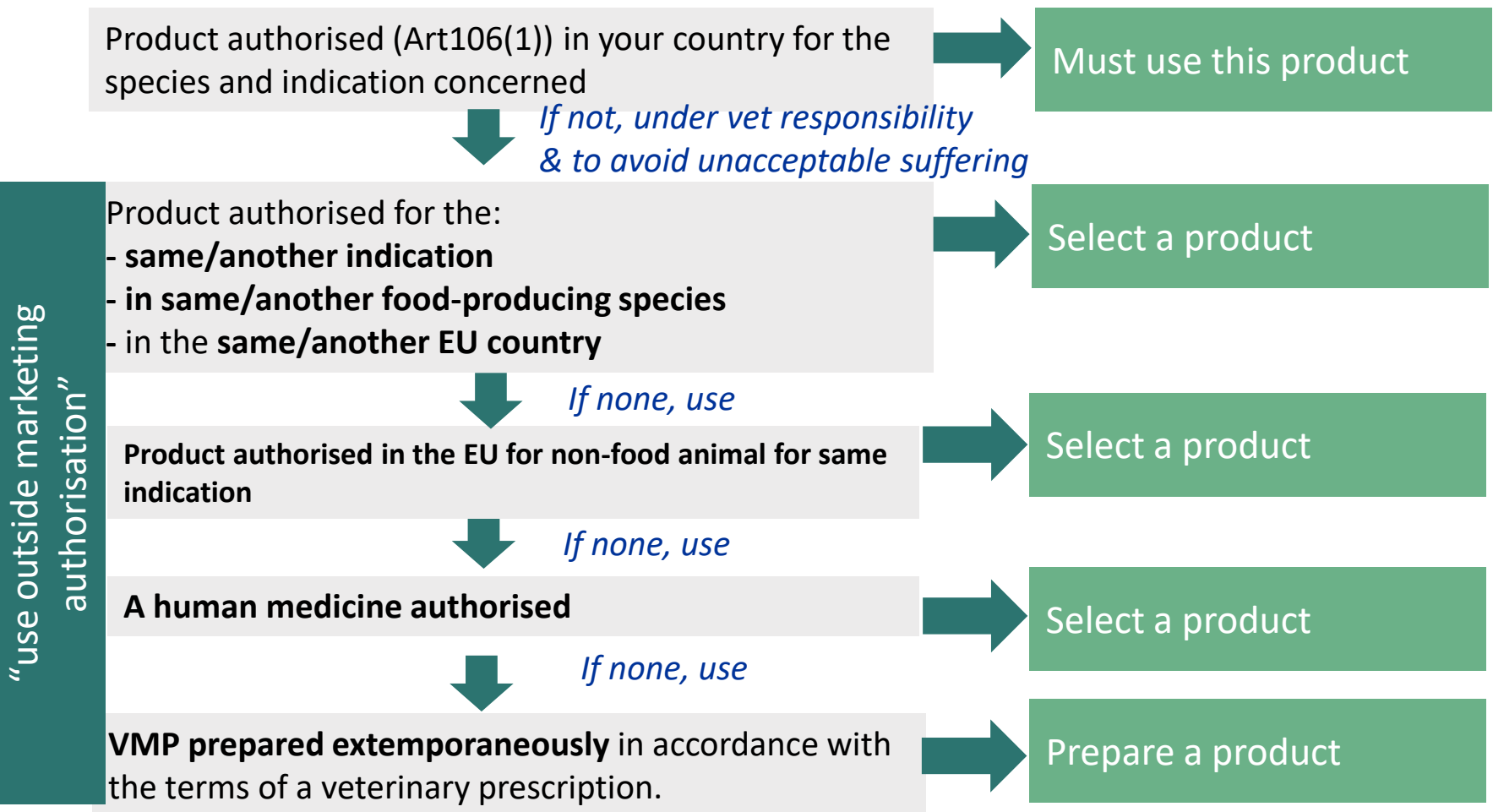
Date	Status	Medicine
30/07/2024	Updated	Econor 50% - Premix for medicated feeding stuff (pigs)
30/07/2024	Updated	Innovax-ND-ILT (--)- Concentrate and solvent for suspension for injection
30/07/2024	Updated	Novem 20 mg/ml - Solution for injection
30/07/2024	Updated	Vectormune FP ILT + AE (--)- Lyophilisate and solvent for suspension for injection
30/07/2024	Updated	Galliprant 20 mg - Tablet

[View all updates](#)

Common rules – Use of veterinary medicinal products outside the terms of the marketing authorisation

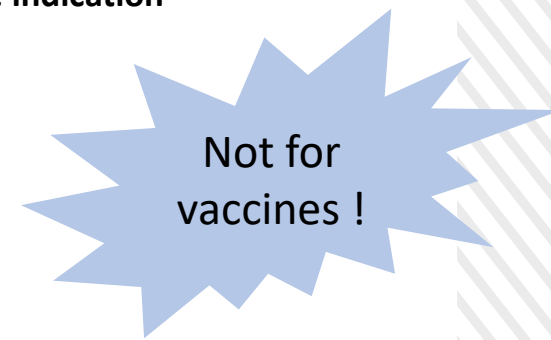


When no medicine authorised for food-producing animals or authorized ones are not available



3rd country products :

In cases where none of the foregoing options are available → use a VMP authorised in a **third country for the same animal species and the same indication**



Use of medicinal products outside the terms of the marketing authorisation in food-producing terrestrial animals



Product authorised in **your own country** for the **species** and **indication**



If none, under vet's responsibility & to avoid unacceptable suffering

a) Product authorised in **your own country or another EU Member State** for the **same or another food-producing terrestrial animal species**, for the **same or another indication**.



If none, use

b) Product authorised in **your own country** for use in **non-food-producing animal** for the **same indication**.



If none, use

c) Product authorised for **human use**.



If none, use

d) Product **prepared extemporaneously**.



If none, use

e) Product authorised in **a third country** for the **same animal species** and the **same indication** (not for vaccines!)

Don't forget special withdrawal periods

Common rules – Use of Veterinary Medicinal Products



When no authorized medicine is available for food-producing aquatic animals or authorized ones are not available

“cascade use of AM”

Product authorised in your country for the aquatic animal species and indication concerned

Must use this product



If not, use

Product authorised for the:
- same/another indication
- in same/another food-producing aquatic species
- in the same/another EU country

Select a product



If not, use

Product authorised in the EU for **food-producing terrestrial species** (substance list under development)

Select a product



If not, use

A **human medicine** authorised (substance list under development)

Select a product



If not, use

VMP prepared extemporaneously in accordance with the terms of a veterinary prescription

Prepare a product

3rd country products :

In cases where none of the foregoing options are available
→ use a VMP authorised in a **third country for the same animal species and the same indication**



Use of medicinal products outside the terms of the marketing authorisation in food-producing aquatic animals



Product authorised in **your own country** for the **species** and **indication**

↓ *If none, under vet's responsibility & to avoid unacceptable suffering*

a) Product authorised in **your own country** or **another EU Member State** for the **same** or **another food-producing aquatic species**, for the **same** or **another indication**.

↓ *If none, use*

b) Product authorised in **your own country** or **another EU Member State** for use in **food-producing terrestrial animal***

↓ *If none, use*

c) Product authorised for **human use***

↓ *If none, use*

d) Product **prepared extemporaneously**.

↓ *If none, use*

e) Product authorised in **a third country** for the **same animal species** and the **same indication**. (not for vaccines!)

Don't forget special withdrawal periods

Is there an authorised veterinary medicine for this species and indication?

When there is no medicine authorised for food-producing animals or authorised ones are not available



For details on specific precautions, veterinary responsibilities, and withdrawal periods, please refer to pages 10-11.

! *Restrictions to the use of antimicrobials and concerning maximum residue limit (MRL) status may apply



Under exceptional circumstances and in particular to avoid unacceptable suffering the veterinarian is allowed to use the Cascade. Is this the case?

YES

Is there a veterinary medicine for another **food-producing** species /condition in your or in another Member State?

YES

Use this authorised veterinary medicine*

NO

Is there a veterinary medicine authorised in the relevant Member State for use in a **non-food-producing** animal species for the same indication?

YES

Use this authorised veterinary medicine*

NO

Is there a medicinal product for human use authorised in your country or another EU Member State?

YES

Use this authorised product*

NO

Is it possible to extemporaneously prepare a product?

YES

Prepare extemporaneously*

YES

Use this authorised veterinary medicine **

NO

Is there a veterinary medicine product authorised in a third country for the same species and same indication?

No treatment with a medicinal product possible

NO

NO

YES



Is there an authorised veterinary medicine for this species and indication?



Under exceptional circumstances and in particular to avoid unacceptable suffering the veterinarian is allowed to use the Cascade. Is this the case?

For details on specific precautions, veterinary responsibilities, and withdrawal periods, please refer to pages 10-11.

! *Restrictions to the use of antimicrobials and concerning maximum residue limit (MRL) status may apply

Please note that a list under Article 114(3) ('Aquatic List') is currently being developed. Changes may occur once the list is finalized and becomes available



NO ↓

YES ↓

YES →

Is there a veterinary medicine authorised for same/another aquatic species /condition in your or another Member State?

YES →

Use this authorised veterinary medicine*

Use this authorised veterinary medicine*

NO ↓

Is there a veterinary medicine product authorised for use in food-producing terrestrial species in your or in another Member State?

YES →

Use this authorised veterinary medicine*

NO ↓

Is there a medicinal product for human use authorised in your country or another EU Member State?

YES →

Use this authorised product*

NO ↓

Is it possible to extemporaneously prepare a product?

YES →

Prepare extemporaneously*

YES →

Is there a veterinary medicine product authorised in a third country for the same species and same indication?

Use this authorised veterinary medicine **

NO ↓

No treatment with a medicinal product possible



EU Commission Implementing Regulation (EU) 2024/1973 of 18 July 2024

Establishing a list of antimicrobials which shall not be used in accordance with Articles 112 and 113 of Regulation (EU) 2019/6 of the European Parliament and of the Council or which shall only be used in accordance with those Articles subject to certain conditions.

It shall apply from 8 August 2026.

Commission Implementing Regulation (EU) 2024/1973
Applies from 8 August 2026

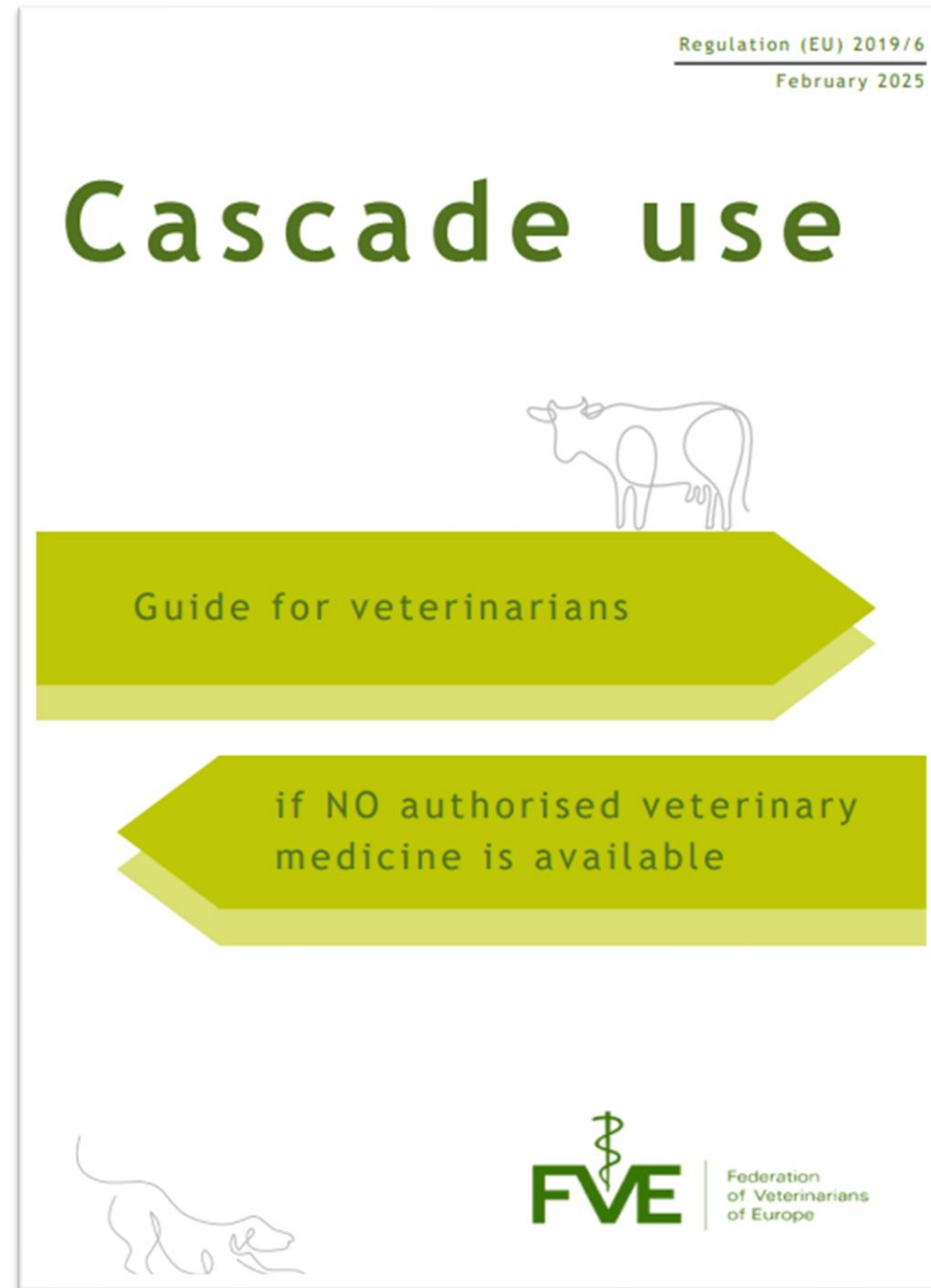
List of antimicrobials which shall only be used under restrictions in cascade

Conditions on the use of antimicrobials	Target pathogen identification and AST	Restricted around certain indications	Restricted to use for certain indications only	Restricted from use in certain species	Use in individual animals only	Restriction on route of administration	HMPs only for use in individual animals
Aminopenicillin- BLI combinations	✓			🐔			
3rd & 4th gen. cephalosporins	✓	Salmonella		🐔	✓		
Polymyxins	✓	Salmonella				✓	✓
Amphenicols	✓						
(Fluoro)quinolones	✓	Salmonella				✓	✓
Rifamycins (excl. EU-VMPs)	✓	Prophylaxis R. equi	Mycobacteria MDR Staph		✓		
TB drugs	✓				✓		
Riminofenazines	✓				✓		
Pseudemonic acids	✓	Not for decolonisation	MRSA/P		✓	Topical only	
Remdesivir			FIP only				
Echinocandins	✓	Last resort			✓		
Amphotericin B		Last resort					

More details:

check out the FVE
cascade Brochure

<https://fve.org/cms/wp-content/uploads/Cascade-1.pdf>



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Training



Thank you!

