Quadripartite initiative on availability of antimicrobials (AMs) and alternatives to their use (ATAMs)

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How did it all start?

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The joint initiative on availability of AMs and ATAMs

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The founding team









Joint action (IE, FR, PT, SP) on availability of AM and alternatives

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Identify the therapeutic gaps and recognise the reasons for those gaps.

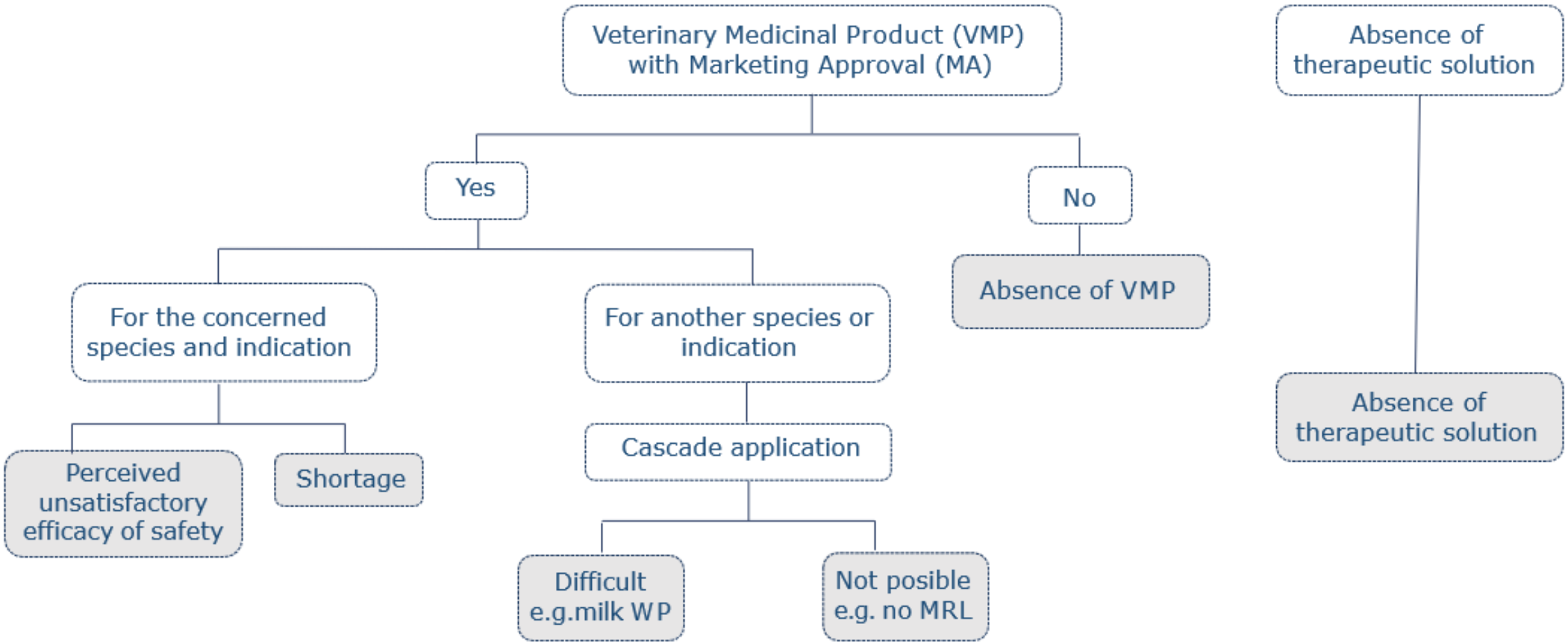
IDENTIFICATION AND REASONS



Prioritise the therapeutic gaps

PRIORISATION

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Veterinary Medicinal Product (VMP) with Marketing Approval (MA)
Yes
No
Absence of VMP
For the concerned species and indication
For another species or indication
Perceived unsatisfactory efficacy of safety
Shortage
Cascade application
Difficult e.g.milk WP
Not posible e.g. no MRL
Absence of therapeutic solution
Absence of therapeutic solution

2024: 1st report of the Quadripartite



- Identifies key therapeutic gaps in veterinary medicine and their root causes.
- Explores potential alternatives to address unmet animal health needs.
- Emphasizes vaccines as a key alternative to antibiotics in tackling antimicrobial resistance (AMR).
- https://www.resistenciaantibioticos.es/sites/default/files/2024-09/Availability_of_antimicrobial_medicinal_products_and_alternatives_to_their_use.pdf

The joint initiative on availability of AMs and ATAMs

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The team today













Steps

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Identify the therapeutic gaps and recognise the reasons for those gaps.

IDENTIFICATION AND REASONS



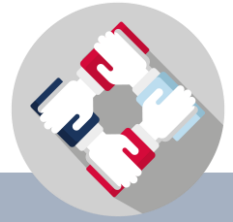
Prioritise the therapeutic gaps

PRIORISATION



Establish ways of collaboration between countries to address common problems

COLLABORATION



Extend this initiative to other EU Member States and promote collaboration

EXTEND THE COLLABORATION



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Guidance on Improving Availability of Antimicrobials and Alternatives to Antimicrobials for EU Therapeutic Gaps

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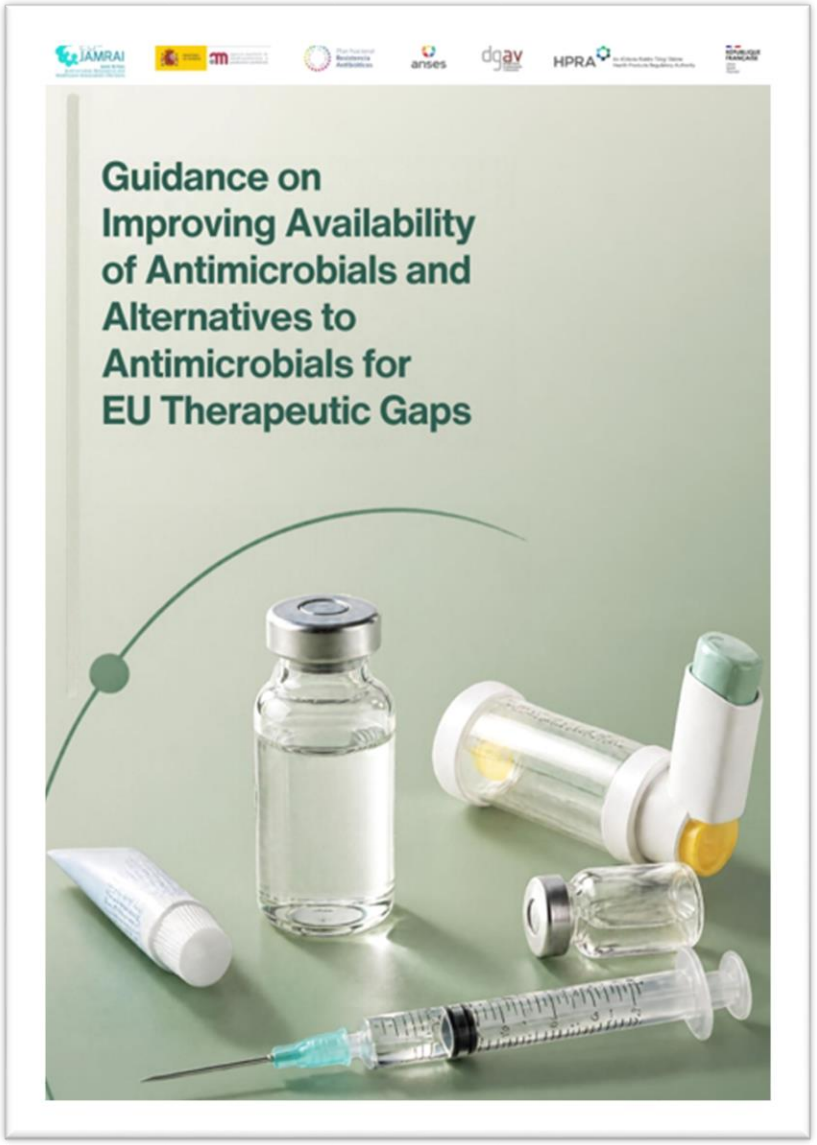


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The guidance is intended to assist National Competent Authorities (NCAs), in identifying situations where regulatory cooperation may improve access to authorised products.

- support the availability of AMs and ATAMs across the EU;
- facilitate cooperation between stakeholders;
- promote prudent antimicrobial use;
- support alternatives to antimicrobials and antimicrobial stewardship objectives;
- ensure transparent and proportionate decision-making.

Regulatoy tools

- Mutual Recognition Procedures (MRP);
- Subsequent Recognition Procedures (SRP);
- Accelerated or day-0 MRP/SRP where justified;
- Variations to existing marketing authorisations;
- Limited market authorisations;
- Authorisations under exceptional circumstances;
- Use of existing import mechanisms.

Action Plan

1. Identify a therapeutical gap
2. Assess the market context: VMPs authorised and available in another EU MS
3. Meet the prioritisation criteria, reduction of the need for/ used of antimicrobial use in the use of category B antibiotics (quinolones, 3rd- 4th-gen cephalosporins, polymyxins)
4. Consider regulatory action

Practical considerations for Zero-Day MRP

- Availability of the dossier in English where possible
- Consistency of product information between Member States
- Awareness of ongoing variations affecting the dossier
- Coordination between RMS and CMS before submission
- Verification that administrative processes allow rapid implementation

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Timeline for Zero-Day MRP

Pre-submission phase (no fixed regulatory timeline)

- Reference MS (RMS) and Concerned MS (CMS)
- agreement
- Applicant discuss with CMS product specific issues

Submission: request zero-day MR procedure

Validation phase (up to 14 days): CMS performs validation check

Mutual recognition phase

RMS starts MRP >> CMS accepts existing RMS assessment >> procedure starts and end on the same day

tional phase after day 0: national marketing authorization is issued

Pilot project: quadripartite results to date

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Alternatives to antimicrobials

1. GRIPORK :Inactivated vaccine against swine influenza. National procedure: conversion to zero-day MRP

2. DINDORAL: Vaccine against haemorrhagic enteritis in turkeys: SRP zero-day procedure

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Ophtalmological product

Antimicrobials

CROTAX 8 mg/ml eye drops

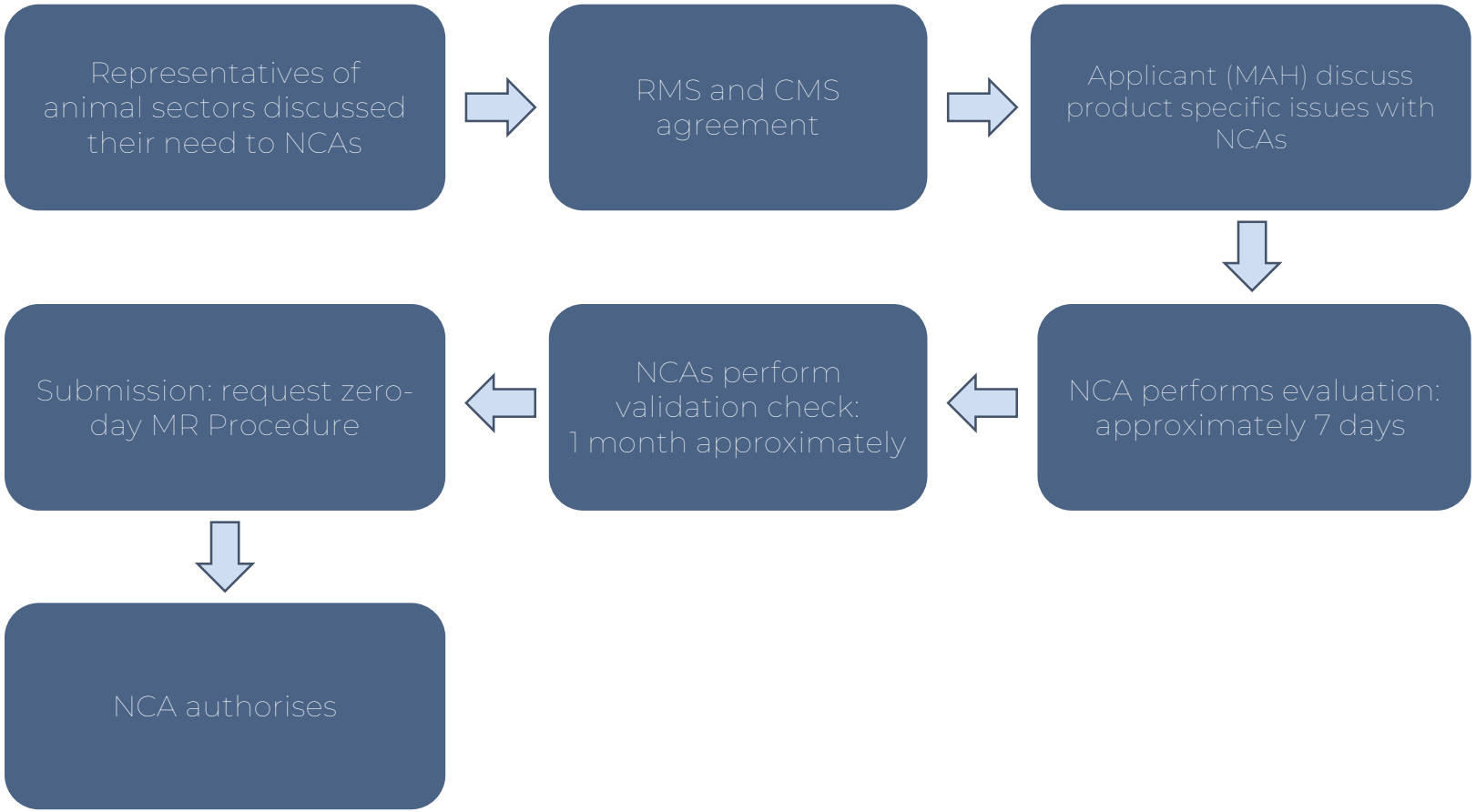
Solution for dogs, cats and non-food producing horses

Chloramphenicol

Authorised and available in Portugal but not in Spain

- ✓ Met the required criteria for selecting VMP for the zero-0 MRP
- ✓ Procedure by MAH in Portugal with support of DGAV and AEMPS

Example of intervention: steps



What is next in the action plan?





- Ongoing work to address therapeutic gaps in minor food-producing species, particularly in the rabbit and small ruminant sectors (sheep and goats)

- Continued collaboration with animal sector representatives and FVE to address remaining therapeutic gaps

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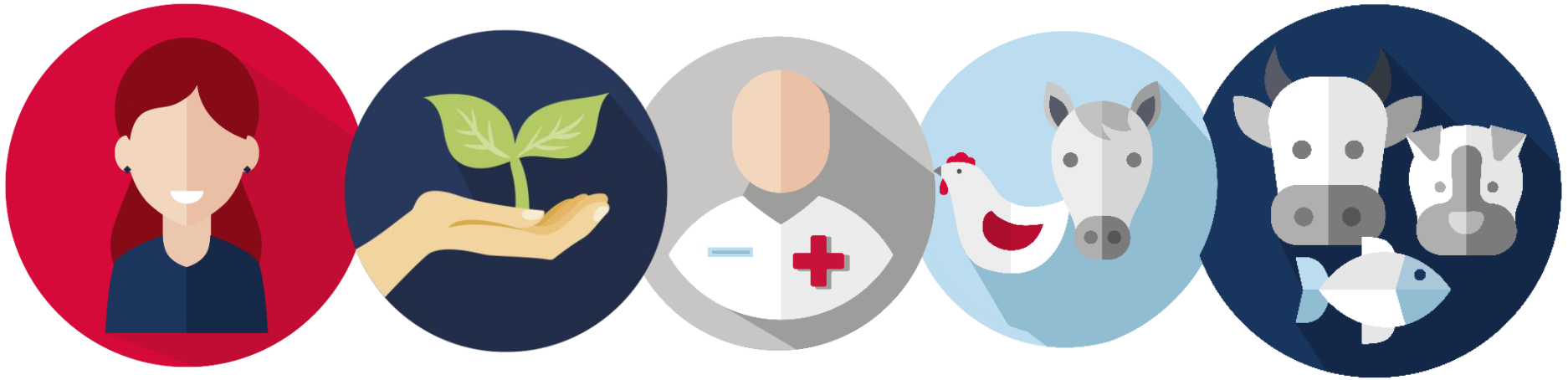
Conclusion

- Time for action is now
- Working together might prove more beneficial than an individual initiatives
- This could be a model that is resilient, scalable and fosters EU regulatory harmony

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Gracias por vuestra atención.



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