

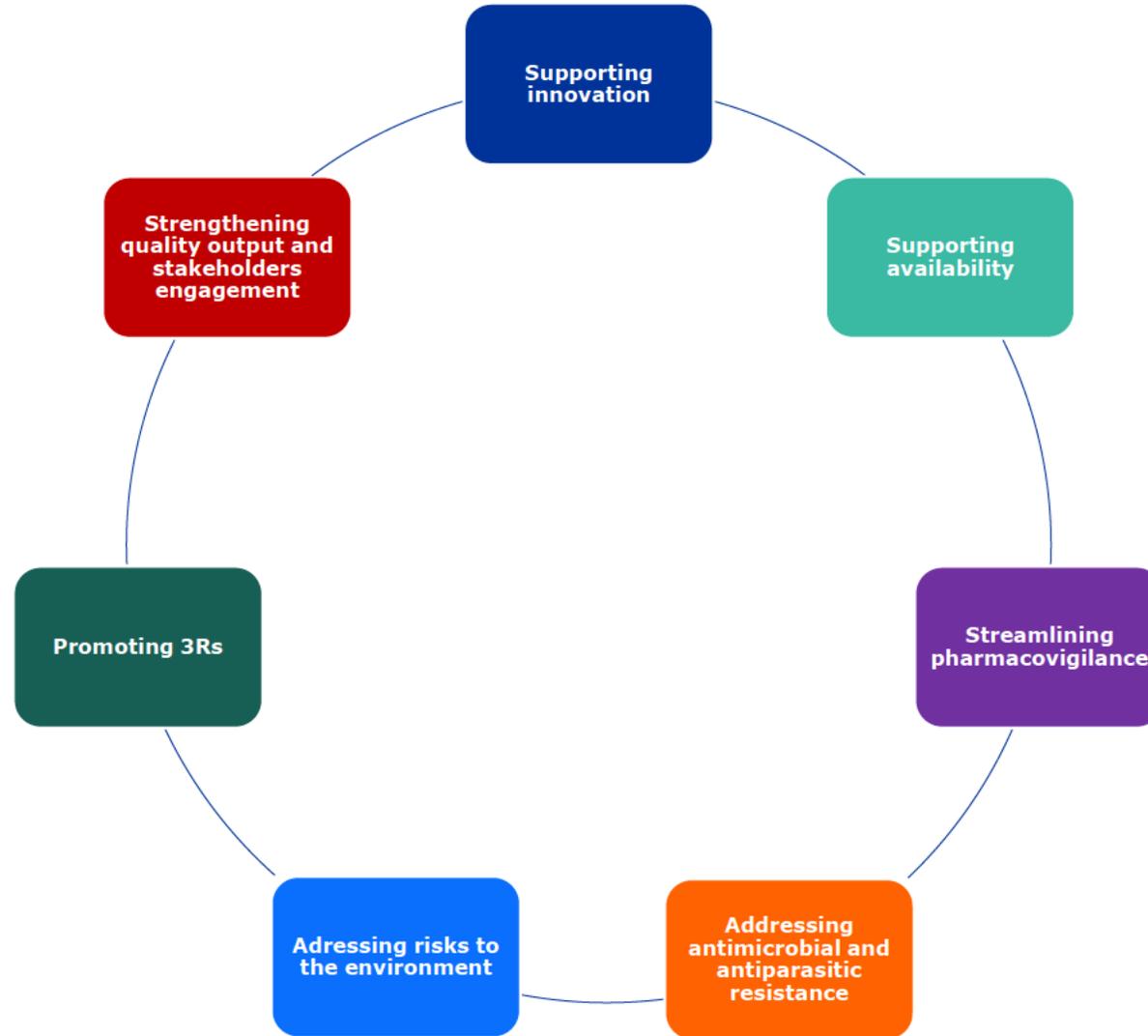
EMA Veterinary Info Day 2026

CVMP workplan for 2026 and beyond

Johan Schefferlie, Chair of the Committee for
Veterinary Medicinal Products (CVMP)

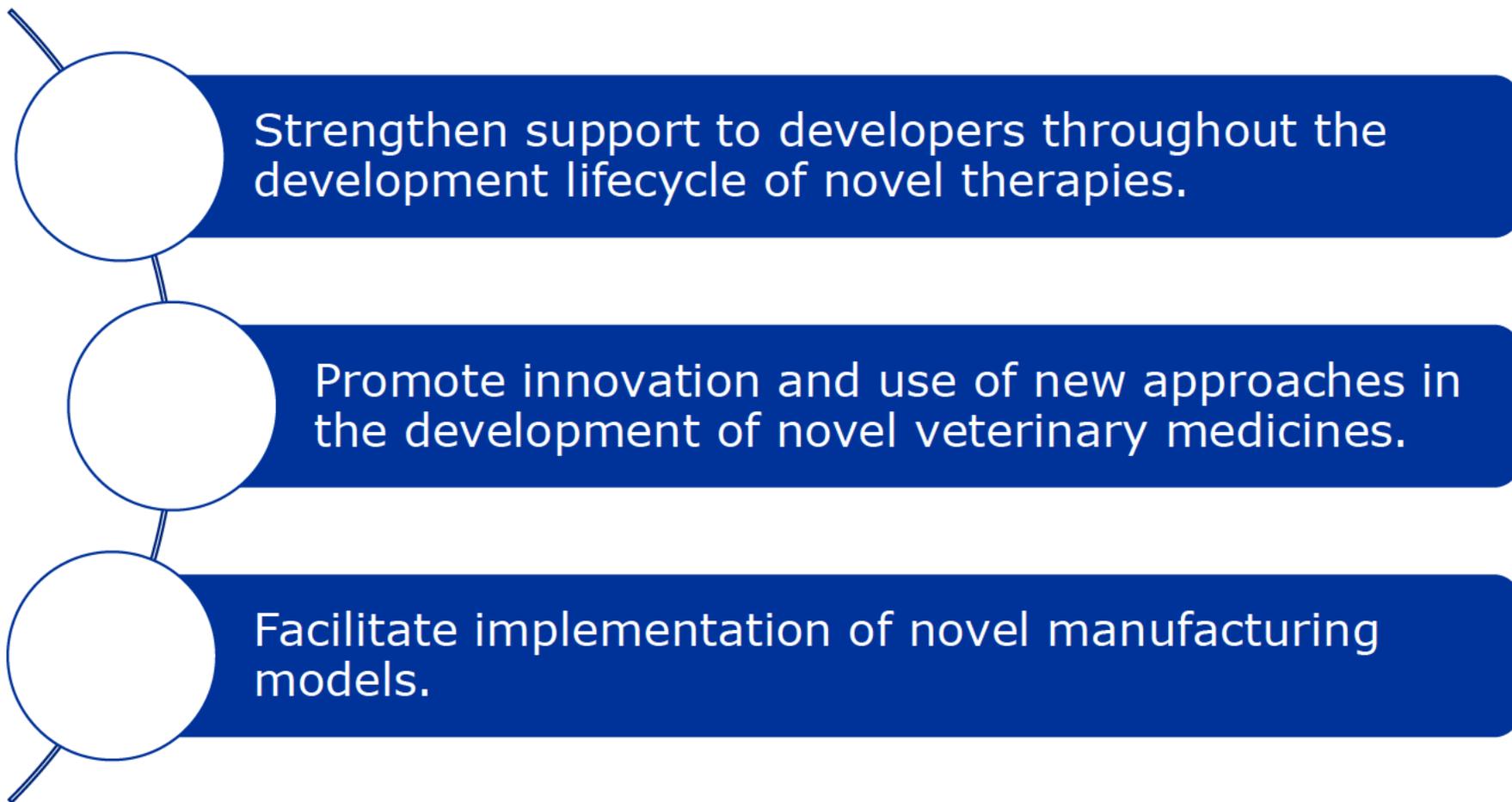


Strategic goals



Supporting innovation

Supporting innovation and new product development



Supporting innovation and new product development

- Set up specific Operational Expert Groups of Working Parties to provide guidance on new technologies.
- Set up a European Expert Community on new technologies.
- Provide scientific advice and contribute to Innovation Task Force meetings.
- Support applicants in obtaining classification of VMPs, e.g. biological immunological.
- Continue promotion of availability of veterinary medicinal products, especially vaccines, by e.g. implementation of approaches and facilitating applications under exceptional circumstances, vaccine antigen master files, vaccine platform technology master files and multi-strain dossiers.
- Develop guidance for veterinary biosimilar VMPs. For this task, the CVMP has established a temporary Drafting Group (tDG) to deal with procedural aspects and the development of relevant guidelines.
- In collaboration with the Quality Innovation Group (QIG), advance key areas for technical developments, including novel/advanced manufacturing approaches.

Supporting innovation and new product development

- **Set up specific Operational Expert Groups of Working Parties to provide guidance on new technologies.**

- Set up a European Expert Community on new technologies

Safety of nanoparticles

- Provide support to the Risk Force meetings

- Support application of the CVMP for high-priority medicinal products

RNA interference and RNA antisense therapies

- Continue promotion of the implementation of approaches and facilitating applications under exceptional circumstances, vaccine antigen manufacturing

Quality aspects of secretomes as VMPs

- Develop guidance for a temporary Drafting Group (tDG) to deal with procedural aspects and the development of relevant guidelines

- In collaboration with the Quality Innovation Group (QIG) advance key areas for technical developments including novel/advanced manufacturing approaches

Supporting innovation and new product development

- Set up specific Operational Expert Groups of Working Parties to provide guidance on new technologies
- **Set up a European Expert Community on new technologies.**
- Provide scientific advice and contribute to Innovation Task Force meetings
- Support applicants in obtaining marketing authorizations
- Continue promotion of a **European Expert Community on new technologies** by e.g. implementation of approaches and facilitating applications under exceptional circumstances, vaccine antigen master files, vaccine platform technology master files and multi-strain dossiers
- Develop guidance for veterinary biosimilar VMPs. For this task the CVMP has established a temporary Drafting Group (tDG) to deal with procedural aspects and the development of relevant guidelines
- In collaboration with the Quality Innovation Group (QIG) advance key areas for technical developments including novel/advanced manufacturing approaches

In progress 

Supporting innovation and new product development

- Set up specific Operational Expert Groups of Working Parties to provide guidance on new technologies.
- Set up a European Expert Community on new technologies.
- **Provide scientific advice and contribute to Innovation Task Force meetings.**
- Support applicants in obtaining classification of VMPs, e.g. biological immunological.
- Continue promotion of a **Continuous process** implementation of approach e.g. vaccine antigen master files, processes, dossiers.
- Develop guidance for veterinary biosimilar VMPs. For this task, the CVMP has established a temporary Drafting Group (tDG) to deal with procedural aspects and the development of relevant guidelines.
- In collaboration with the Quality Innovation Group (QIG), advance key areas for technical developments, including novel/advanced manufacturing approaches.

Supporting innovation and new product development

- Set up specific Operational Expert Groups of Working Parties to provide guidance on new technologies.
- Set up a European Expert Community on new technologies.
- Provide scientific advice and contribute to Innovation Task Force meetings.
- **Support applicants in obtaining classification of VMPs, e.g. biological immunological.**
- Continue promotion of availability of veterinary medicinal products, especially vaccines, by e.g. implementation of approaches and facilitating applications under exceptional circumstances, vaccine antigen master files, and vaccine master files for biologics.
- Develop guidance for veterinary medicinal products, including a temporary Drafting Group (TDG) to deal with procedural aspects and the development of relevant guidelines.
- In collaboration with the Quality Innovation Group (QIG), advance key areas for technical developments, including novel/advanced manufacturing approaches.

Continuous process



Supporting innovation and new product development

- Set up specific Operational technologies.
- Set up a European Expert - 7 exceptional circumstances in 2025 (BTV, HPAI, EHD)
- Existing PTMF used → facilitated fast approval!
- Provide scientific advice a
- Support applicants in obtaining classification of VMPs, e.g. biological immunological.
- **Continue promotion of availability of veterinary medicinal products, especially vaccines, by e.g. implementation of approaches and facilitating applications under exceptional circumstances, vaccine antigen master files, vaccine platform technology master files and multi-strain dossiers.**
- Develop guidance for veterinary biosimilar VMPs. For this task the CVMP has established a temporary Drafting Group relevant guidelines
- In collaboration with the C developments including novel/advanced manufacturing approaches

Continuous process



Supporting innovation and new product development

- Set up specific Operational Expert Groups of Working Parties to provide guidance on new technologies.
- Set up a European Expert Community on new technologies.
- Provide scientific advice and contribute to Innovation Task Force meetings.
- Support applicants in obtaining classification of VMPs, e.g. biological immunological.
- Continue promotion and implementation of a vaccine antigen mask, by e.g. instances, in dossiers.
- **Develop guidance for veterinary biosimilar VMPs. For this task, the CVMP has established a temporary Drafting Group (tDG) to deal with procedural aspects and the development of relevant guidelines.**
- In collaboration with the Quality Innovation Group (QIG) advance key areas for technical developments, including novel/advanced manufacturing approaches.

In progress 

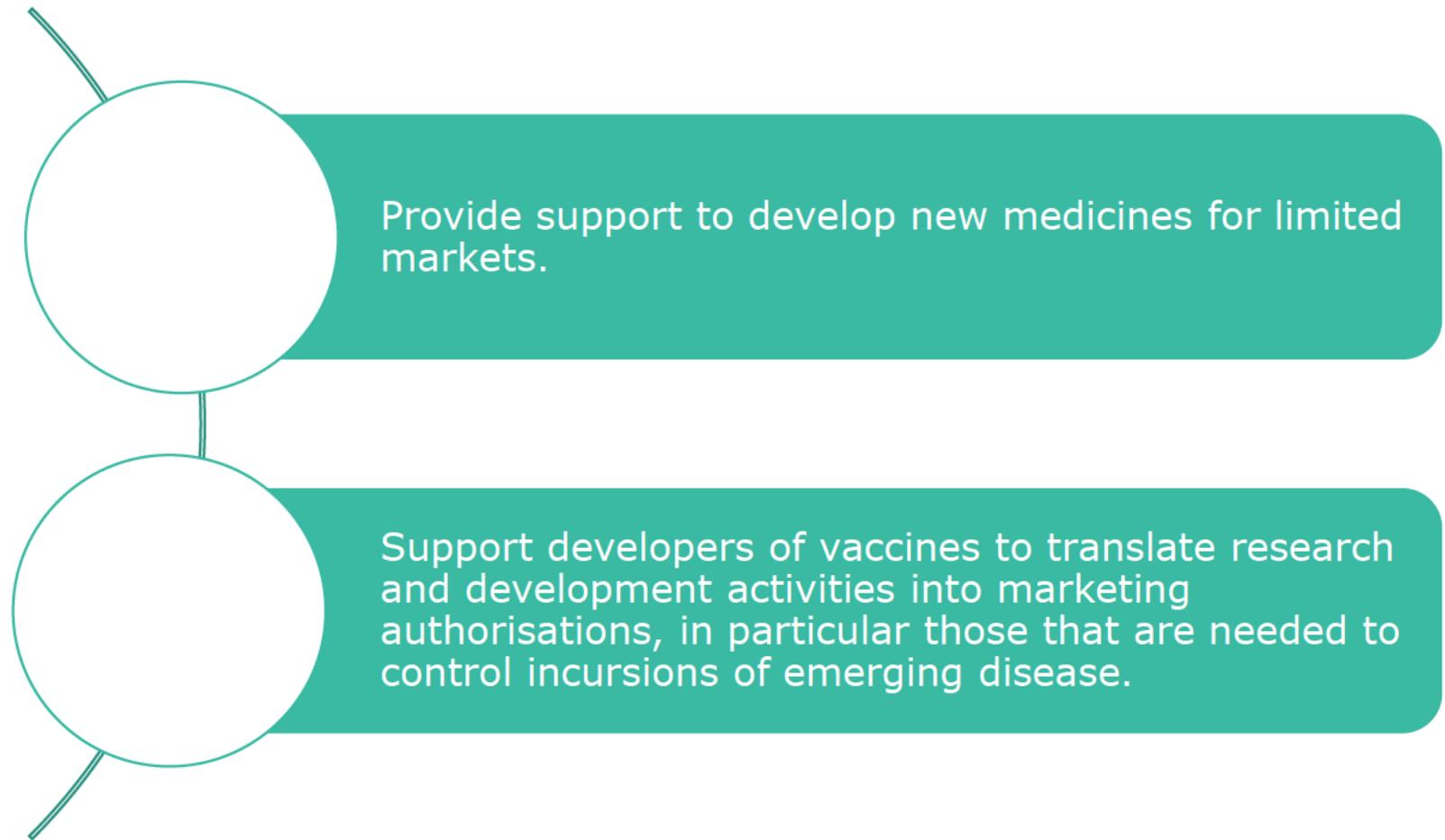
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- Set up a European Expert Community on new technologies.
- Provide scientific advice and contribute to Innovation Task Force meetings.
- Support applicants in obtaining classification of VMPs, e.g. biological immunological.
- Continue promotion of availability of veterinary medicinal products, especially vaccines, by e.g. implementation of approaches and facilitating applications under exceptional circumstances, vaccine antigen master files, vaccine platform technology master files and multi-strain dossiers.
- Develop guidance on the use of temporary Draft Marketing Authorisations (DMAs) and establish a Department of relevant guidelines.
- **In collaboration with the Quality Innovation Group (QIG) advance key areas for technical developments, including novel/advanced manufacturing approaches.**

Continuous process 

Supporting availability

Improving veterinary medicines availability, in particular vaccine availability and products for limited markets

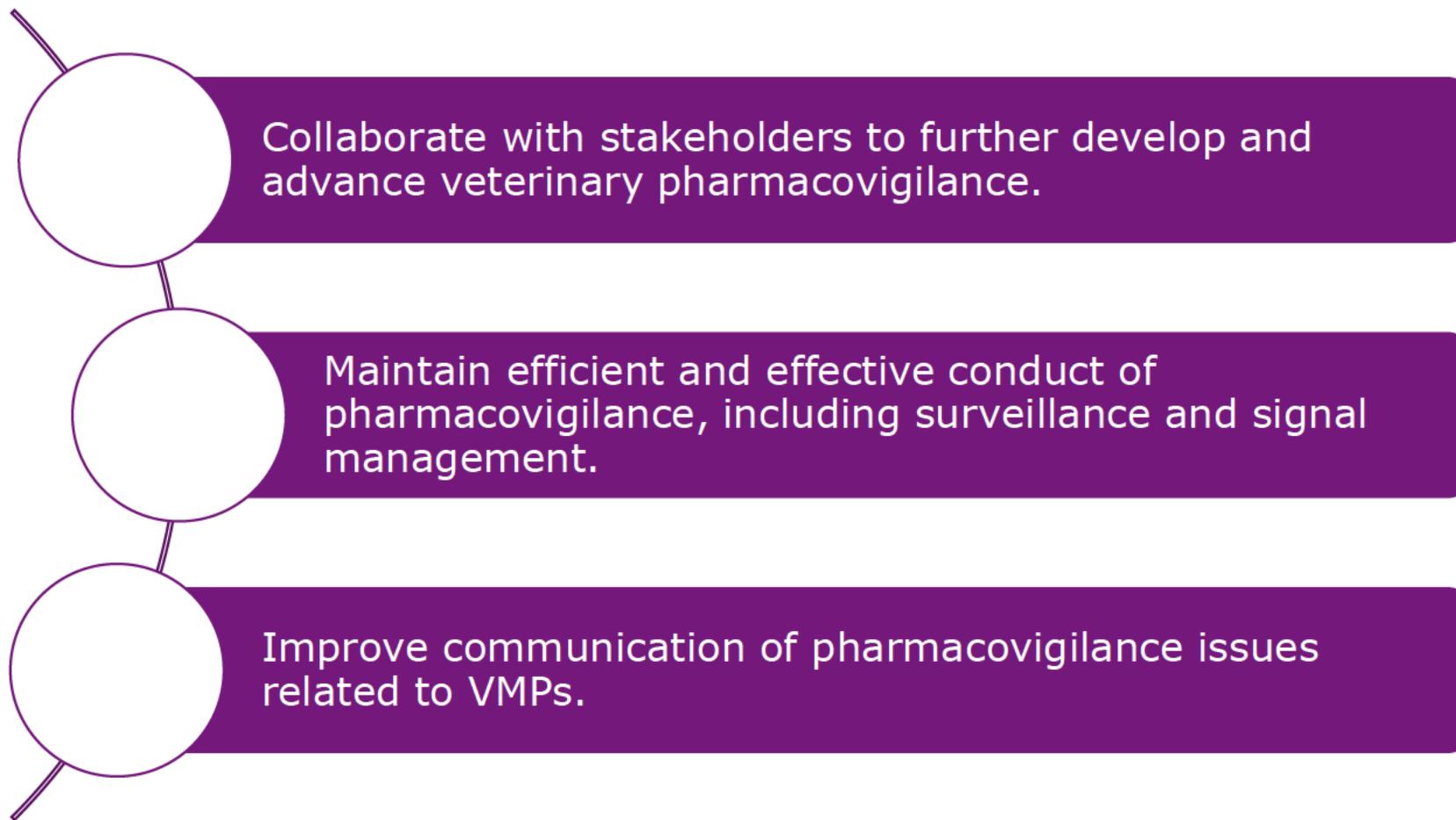


Improving veterinary medicines availability, in particular vaccine availability and products for limited markets

- Provide a Q&A on eligibility criteria for limited markets for stakeholders.
- Streamline working practices for the assessment of limited market applications.
- Provide recommendations to applicants on the classification of products as limited markets and eligibility under Article 23.

Streamlining pharmacovigilance

Streamlining post-authorisation monitoring



Streamlining post-authorisation monitoring

- Provide oversight for the continued implementation of efficient and effective methodology and procedures for post-authorisation surveillance following their implementation in 2025.
- *Further details in PhVWP workplan.*
- Concept paper for revision of VGVP module: Signal management.

Streamlining post-authorisation monitoring

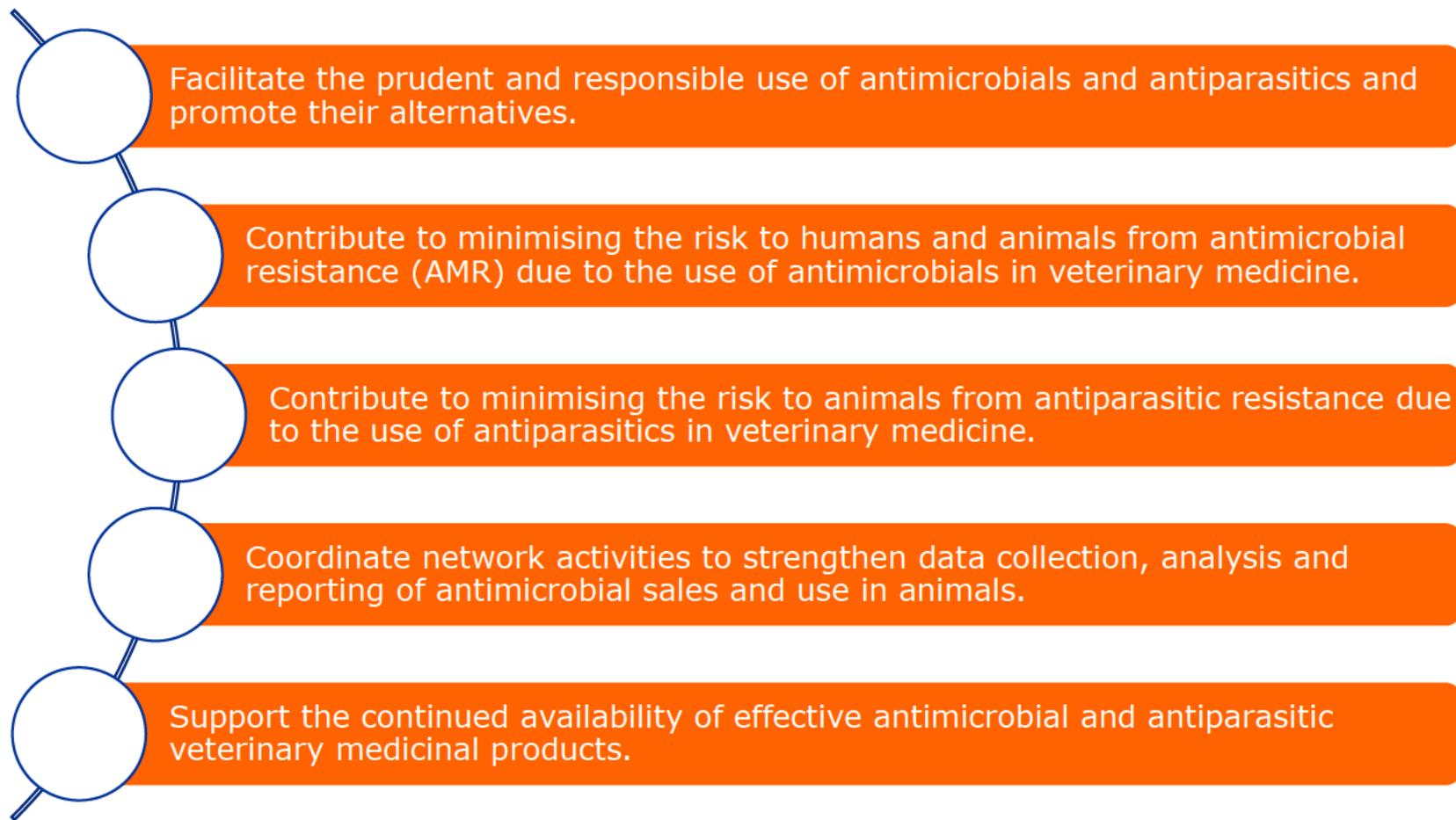
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- Further details in PhVWP workplan
- **Concept paper for revision of VGVP module: Signal management**



Released for public consultation

Addressing antimicrobial and antiparasitic resistance

Addressing the public and animal health threat associated with antimicrobial resistance and the risk of antiparasitic resistance



Addressing the public and animal health threat associated with antimicrobial resistance and the risk of antiparasitic resistance

- Provide scientific opinions on existing antibiotics, focusing on the review of the posology.
- Promote responsible use in partnership with other EU Agencies, regulators and international bodies.
- Contribute to the 5th JIACRA report in collaboration with EFSA and ECDC.
- Provide pre-authorisation support (e.g. via early pre-submission discussions, scientific advice) to develop and obtain marketing authorisations for new VMPs that can assist in the reduction of use of antimicrobials, initiating development of scientific guidance, as appropriate.
- Promote the responsible use of antiparasitic medicines.
- See workplan of the Antimicrobials Working Party.

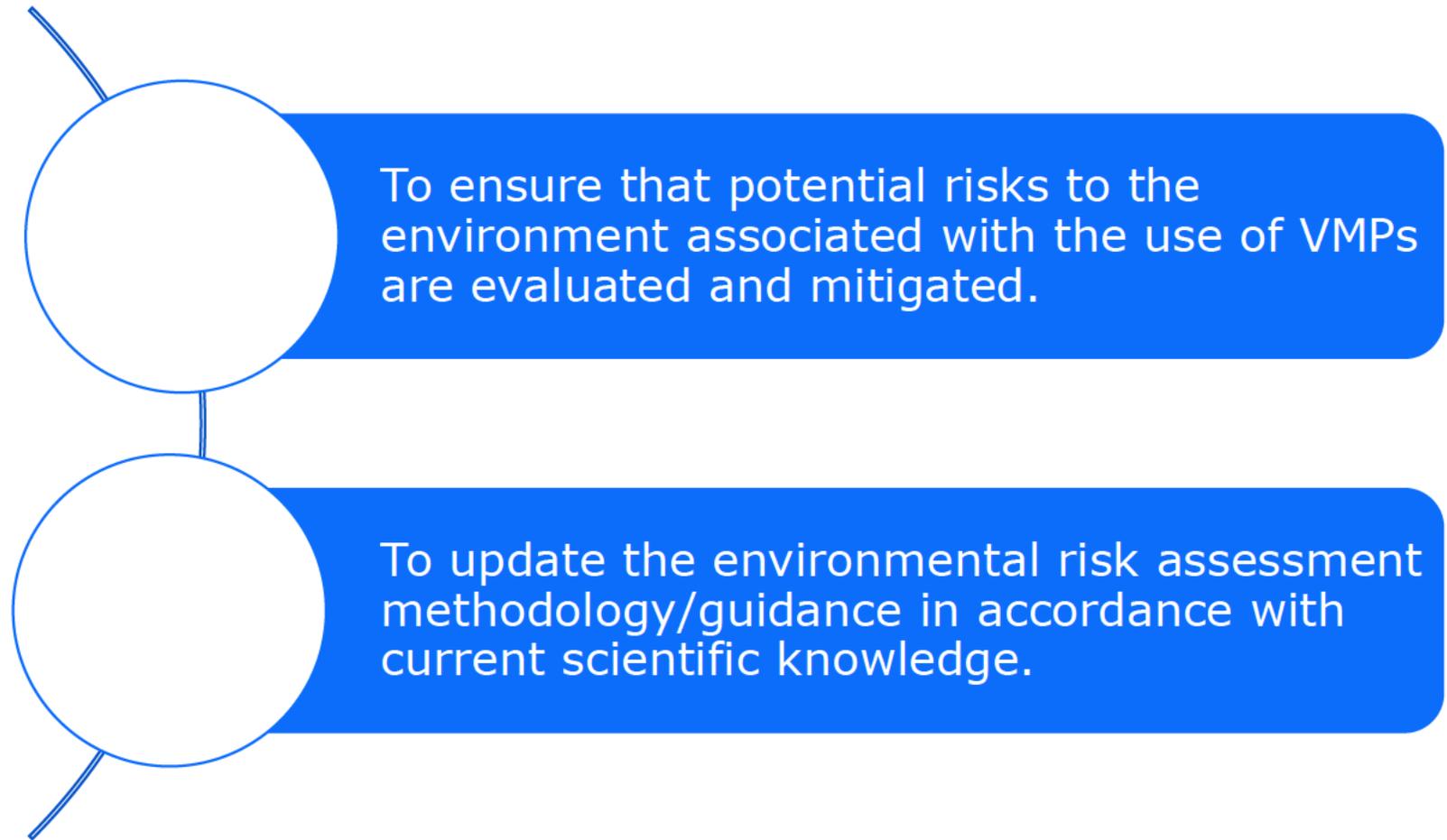
ADRA

Addressing the public and animal health threat associated with antimicrobial resistance and the risk of antiparasitic resistance

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- Promote responsible use in partnership with other EU Agencies and regulators and international bodies
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- Provide pre-authorisation support (e.g. via early pre-submission discussions, scientific advice) to develop and obtain marketing authorisations for new VMPs that can assist in the reduction of use of antimicrobials, initiating development of scientific guidance, as appropriate
- Promote the responsible use of antiparasitic medicines
- **See workplan of the Antimicrobials Working Party**

Addressing risks to the environment

Addressing the risks associated with veterinary pharmaceuticals in the environment



Addressing the risks associated with veterinary pharmaceuticals in the environment

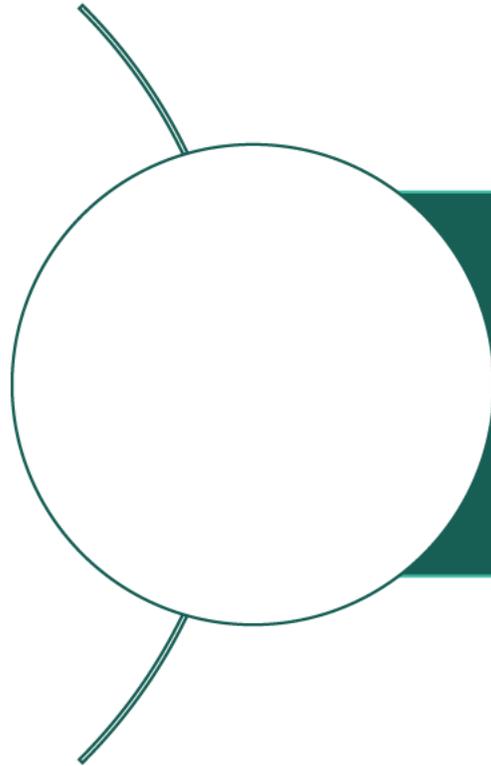
- Consider the comments from the Concept Paper on the environmental risk assessment for specific groups of companion animal products and discuss the next steps

Focus Group Meeting in June

- *See the work plan of the Environmental Risk Assessment Working Party.*

Promoting 3Rs

Application of 3Rs in the regulatory testing of medicinal products



Support and promote the development and application of 3Rs-compliant methods in the regulatory testing of veterinary medicinal products.

Application of 3Rs in the regulatory testing of medicinal products

- Support the international regulatory acceptance of 3Rs-compliant methods through promoting those in the context of the development of VICH guidelines.
- See EMA's 3Rs Working Party work plan.

Application of 3Rs in the regulatory testing of medicinal products

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- **See EMA's 3Rs Working Party work plan**

Own stakeholder meetings

**Strengthening
quality output and
stakeholders
engagement**

Strengthening quality output and stakeholders engagement



Strengthening quality output and stakeholders engagement

- In collaboration with EU Network Training Centre, contribute to the training of assessors on regulatory scientific topics and guidelines for the network.
- Work to increase capability in modelling, simulation and extrapolation within the European Regulatory Network.
- Consider the need to establish European specialised expert communities (ESECs) in more scientific areas related to veterinary medicinal product development.
- Together with HMA and VSFG, analyse the current gaps in, and future needs for capacity and capability, in order to ensure sustainable scientific support for the CVMP.
- Streamline evaluation processes to enable more efficient use of resources.
- Liaison with the CHMP Methodological Working Party for scientific advice and potentially during MAAs/variations.
- Collaboration with the CHMP Infectious Diseases Working Party on the development of future guidance documents.
- Organisation of a Veterinary Medicines Info Day, Interested Parties Meeting, Focus Group Meetings.
- Reviewing the content of CVMP agendas and minutes to increase transparency.



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Thank you

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