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Public consultation on EMA Regulatory Science to 2025

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* Name

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Introduction

The purpose of this public consultation is to seek views from EMA's stakeholders, partners and the general public on EMA's proposed strategy on Regulatory Science to 2025 and whether it meets stakeholders' needs. By highlighting where stakeholders see the need as greatest, you have the opportunity to jointly shape a vision for regulatory science that will in turn feed into the wider EU network strategy in the period 2020-25.

The views being sought on the proposed strategy refer both to the extent and nature of the broader strategic goals and core recommendations. We also seek your views on whether the specific underlying actions proposed are the most appropriate to achieve these goals.

The questionnaire will remain open until June 30, 2019. In case of any queries, please contact: RegulatoryScience2025@ema.europa.eu.

Completing the questionnaire

This questionnaire should be completed once you have read the draft strategy document. The survey is divided into two areas: proposals for human regulatory science and proposals for veterinary regulatory science. You are invited to complete the section which is most relevant to your area of interest or both areas as you prefer.

We thank you for taking the time to provide your input; your responses will help to shape and prioritise our future actions in the field of regulatory science.

Data Protection

By participating in this survey, your submission will be assessed by EMA. EMA collects and stores your personal data for the purpose of this survey and, in the interest of transparency, your submission will be made publicly available.
For more information about the processing of personal data by EMA, please read the privacy statement.

Questionnaire

Question 1: What stakeholder, partner or group do you represent:

- ○ Individual member of the public
- ○ Patient or Consumer Organisation
- ○ Healthcare professional organisation
- ○ Learned society
- ○ Farming and animal owner organisation
- ○ Academic researcher
- ○ Healthcare professional
- ○ Veterinarian
- ○ European research infrastructure
- ○ Research funder
- ○ Other scientific organisation
- ○ EU Regulatory partner / EU Institution
- ○ Health technology assessment body
- ○ Payer
- ◉ Pharmaceutical industry
- ○ Non-EU regulator / Non-EU regulatory body
- ○ Other

* ***Please specify:***

between 1 and 1 choices

- [ ] Individual company
- [x] Trade association
- [ ] SME

Name of organisation (if applicable):

EGGVP - European Group for Generic Veterinary Products

Question 2: Which part of the proposed strategy document are you commenting upon:

- ( ) Human
- (•) Veterinary
- ( ) Both

Question 3 (veterinary): What are your overall views about the strategy proposed in EMA's Regulatory Science to 2025?

Please note you will be asked to comment on the core recommendations and underlying actions in the subsequent questions.

Continuous Improvement initiatives to streamline and modernise the existing Regulatory processes and science within the EU are much welcome. The recommendations proposed by EMA in its strategy for Regulatory Science to 2025 are largely supported by EGGVP.

Question 4 (veterinary): Do you consider the strategic goals appropriate?

Strategic goal 1: Catalysing the integration of science and technology in medicines development (v)

- (•) Yes
- ( ) No

Strategic goal 2: Driving collaborative evidence generation – improving the scientific quality of evaluations (v)

- (•) Yes
- ( ) No

Strategic goal 3: Addressing emerging health threats and availability/therapeutic challenges (v)

- (•) Yes
- ( ) No

Strategic goal 4: Enabling and leveraging research and innovation in regulatory science (v)

- (•) Yes

No

Question 5 (veterinary): Please identify the top three core recommendations (in order of importance) that you believe will deliver the most significant change in the regulatory system over the next five years and why.

First choice (v)

Please note that veterinary goals start at no.32

32. Transform the regulatory framework for innovative veterinary medicines

1st choice (v): please comment on your choice, the underlying actions proposed and identify any additional actions you think might be needed to effect these changes.

It is expected that the regulatory landscape will have a medium to high impact on the animal health industry within the next 5-10 years (new VMPs and medicated feed regulations…).

Generic veterinary medicines do also need an appropriate regulatory environment for innovative VMPs because:
- Innovations are performed by generic veterinary companies themselves (i.e. hybrid applications)
- Generic veterinary industry shall most likely move to the 'prevention is better than cure' area of the business, with a slow and progressive decrease of the curative area of business. This will encompass some veterinary novel therapies aside from vaccines, or alternatives to antibiotics.

To encompass this, a pragmatic approach from the EMA towards emerging and new technologies would be welcome, to allow a quick reaction to innovations. The main challenge for EMA will be to be able to quickly adapt to new technologies and implement the appropriate Guidelines.

Regulatory strategy and developments to support that:
- Besides the basic EU legislation (i.e. new Veterinary Medicines regulation), to envisage for a side-by-side very flexible and rapid guideline system in place to allow quick reaction towards emerging and new technologies- so as not to depend on changes in the core regulations.
- Ensure communication, quick interaction and liaison with industry in order to develop and implement on a timely manner the required Regulatory guidelines that would be required for novel therapies.
- Ensure that science prevails over politics, and to work so as to increase public confidence.
- Continued support from the EMA to industry by providing scientific advice at the very early stage on innovative solutions on the animal health area (recommendations + predictability).

Not recommended - Avoid blocking
- do not set out detailed rules/standards in law
- do not apply rules developed for human medicines without considering applicability on the veterinary side

Second choice (v)

Please note that veterinary goals start at no.32

40. Continue to promote the responsible use of antimicrobials and their alternatives

2nd choice (v): please comment on your choice, the underlying actions proposed and identify any additional actions you think might be needed to effect these changes.

Raising awareness and communicating about the risks arising from the inappropriate use of veterinary medicines shall continue to be a top-1 priority, focusing on responsible use principles for both humans and animals under a One Health approach and with the final aim to preserve the efficacy of medicines and reduce resistance patterns.

The importance of veterinary medicines to be prescribed and administered according to their Summary of Product Characteristics, under a correct therapeutic regime and following an accurate examination and clinical diagnosis, supported by sensitivity testing whenever possible, shall be stressed.

A holistic One Health approach, addressing components like biosecurity, prevention and vaccination, animal husbandry/health care practices, and infection control will be required. Benchmarking of use data collected and analyzed by harmonized protocols at use level will be much more effective and motivating to make progress as compared to quantitative reduction targets. Quantitative reduction targets for veterinary antibiotics can be counterproductive as this might induce a shift to more potent compounds, often used in human medicine and/or classified as CIAs, and might result in compromised animal health and welfare and food safety and public health. Reductions in AMR-infections should be the primary endpoint. Additionally the general insights are absent whether quantitative reduction targets correspond to reductions in AMR and more specifically there is no knowledge on the actual level which should be achieved to avoid development of AMR.

Third choice (v)

Please note that veterinary goals start at no.32

35. Update Environmental Risk Assessments in line with the latest scientific knowledge

3rd choice (v): please comment on your choice, the underlying actions proposed and identify any additional actions you think might be needed to effect these changes.

Today a full ERA has to be carried out for each generic veterinary application, which is the major constraint for the generic veterinary industry in the decision-making of new product development. All the efforts in ERA generation up to date have been nonsense and in contradiction with the generic principle.

IN the long term - EGGVP is certainly in favour of a workable system to make a more efficient use of resources for both applicants and authorities. Monographs are considered a good solution.

In the short term, predictability of ERA requirements is the most urgent priority for the generic vet industry. EGGVP calls regulators to provide clear guidance to allow us predict when ERA's will be required for generics. The new Regulation mentions that ERA "may" be required to generic applications. Requirements should be clear before introducing a MA-application. It would be too late and provide serious damages if requirements pop-up during a procedure.

Question 6 (veterinary): Are there any significant elements missing in this strategy. Please elaborate which ones (v)

Some topics have not been identified to date as potential key trends in the future development of veterinary medicines. Topics such Biosimilars could possibly be extended as well to Animal Health (regulated similarly to biosimilars used for Human Health).

Question 7 (veterinary): The following is to allow more detailed feedback on prioritisation, which will also help shape the future application of resources.Your further input is therefore highly appreciated. Please choose for each row the option which most closely reflects your opinion. For areas outside your interest or experience, please leave blank.

Should you wish to comment on any of the core recommendations (and their underlying actions) there is an option to do so.

Strategic goal 1: Catalysing the integration of science and technology in medicines development (v)

	Very important	Important	Moderately important	Less important	Not important
32. Transform the regulatory framework for innovative veterinary medicines	◉	○	○	○	○
33. Reinforce and further embed application of the 3Rs principles	○	◉	○	○	○
34. Facilitate implementation of novel manufacturing models	◉	○	○	○	○

Please feel free to comment on any of the above core recommendations or their underlying actions. **Kindly indicate the number of the recommendation you are commenting on**:

32 - New rules for Protection of Technical Documentation in the veterinary medicines regulation 2019/6 will bring significant delays in the entrance in the market of generic VMPs in the near future. Implementation of supplementary guidelines to facilitate the registration and entrance of alternative generic veterinary medicines into the EU Market, and thus increase the availability and accessibility of veterinary medicines, is much needed.

34 - Cater for novel approaches to manufacture; Specifically QbD (Quality by Design) already makes it necessary to view dossiers in a different light, also in veterinary medicine (not only for human medicines). It would be expected that future trends such as digitalisation, increased use of modelling also in manufacturing, "batch size 1" and e.g. 3D printing of medicinal products will have a major impact on the "underlying" regulatory science.

Strategic goal 2: Driving collaborative evidence generation – improving the scientific quality of evaluations (v)

	Very important	Important	Moderately important	Less important	Not important
35. Update Environmental Risk Assessments in line with the latest scientific knowledge	◉	○	○	○	○
36. Apply the latest scientific principles to the assessment of the safety of residues of veterinary medicines	○	○	◉	○	○
37. Collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance	◉	○	○	○	○
38. Develop new and improved communication and engagement channels and methods to reach out to stakeholders	○	○	◉	○	○
39. Develop new approaches to improve the benefit-risk assessment of veterinary medicinal products	○	○	◉	○	○

Please feel free to comment on any of the above core recommendations or their underlying actions. **Kindly indicate the number of the recommendation you are commenting on**:

36- EGGVP does support the orientations and recommendations provided, although stress is missed on investments in special populations initiatives – i.e. the current safety guidelines for MUMS remain a challenge; developments are far lengthy and expensive, and as such further strategy and efforts would be welcome.

37 - EGGVP welcomes that stakeholders will continue to be involved in the development of future veterinary pharmacovigilance guidelines and rules.
The establishment of expert groups to access actual-use data is welcomed and is a good recommendation, but it should be noted as a point of attention that off-label use is in general rarely reported to MAHs unless adverse events are present.
Regarding the recommendation to facilitate development of methodology using new technology (e.g., mobile phone apps) to increase reporting rates of ADRs: EGGVP believes that first the format to report into the PhV DB should be simplified (user friendly, simple mask, time to enter the data should not exceed 20 minutes). Thereafter the adaption to mobile phones can be a second step.

38 - Fully supported with the aim to increase understanding from the public, but its extent should be carefully considered in order not to damage business interests of companies, because scientific information could be
- misinterpreted by the broad public (including press)
- or used by competitors (for example, as a tool to steer competitive developments).

Strategic goal 3: Addressing emerging health threats and availability/therapeutic challenges (v)

	Very important	Important	Moderately important	Less important	Not important
40. Continue to promote the responsible use of antimicrobials and their alternatives	◉	○	○	○	○

41. Coordinate Network activities to improve data collection on antimicrobial use in animals	◉	○	○	○	○
42. Engage with stakeholders to minimise the risks of antiparasitic resistance	◉	○	○	○	○
43. Promote and support development of veterinary vaccines	◉	○	○	○	○

Please feel free to comment on any of the above core recommendations or their underlying actions. **Kindly indicate the number of the recommendation you are commenting on**:

40 - EGGVP is of the opinion that implementing the methodology as described in the 'Reflection paper on dose optimisation of established veterinary antibiotics in the context of SPC harmonisation' (published by CVMP for consultation - not adopted yet) would allow keeping a broad arsenal of safe and effective veterinary treatment options available in the future.

41 - Fully supported. Standardised collection methods across the EU would definitely be an incentive for MAHs reporting. The current situation (ESVAC data collection from MAHs so disharmonised in the MS) involves huge and unnecessary administrative burden for companies.

Strategic goal 4: Enabling and leveraging research and innovation in regulatory science (v)

	Very important	Important	Moderately important	Less important	Not important
44. Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science	○	◉	○	○	○
45. Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions	◉	○	○	○	○
46. Identify and enable access to the best expertise across Europe and internationally	◉	○	○	○	○
47. Disseminate and share knowledge, expertise and innovation across the regulatory network and to its stakeholders	○	◉	○	○	○

Please feel free to comment on any of the above core recommendations or their underlying actions. **Kindly indicate the number of the recommendation you are commenting on**:

Thank you very much for completing the survey. We value your opinion and encourage you to inform others who you know would be interested.

Useful links

EMA website: Public consultation page (https://www.ema.europa.eu/en/regulatory-science-strategy-2025)

Background Documents

EMA Regulatory Science to 2025.pdf

Contact

RegulatoryScience2025@ema.europa.eu