swissmedic

Guidance document

Switzerland-United Kingdom Regulatory Cooperation: Guidance on Veterinary Medicines Simultaneous Reviews

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1 Purpose and introduction

The purpose of this document is to outline the process for the simultaneous review of veterinary medicine submissions by Switzerland's Swissmedic and the United Kingdom's (UK) Veterinary Medicines Directorate.

Note that guidance documents are administrative instruments not having the force of law.

Simultaneous reviews offer the following benefits without compromising domestic standards and scientific rigour:

- Simultaneous access to two major markets for veterinary medicine manufacturers
- More choices for animal owners and food producers by supporting faster access and expanding the number of treatment options available
- A stronger global review community that allows regulators to work across jurisdictions to share knowledge and expertise
- Independent, sovereign decision-making by each regulator while striving for harmonisation

What is a simultaneous review

Simultaneous reviews permit manufacturers to submit a dossier to both regulators at the same time. The evaluation is conducted independently by each country in parallel, with the objective of issuing regulatory decisions at the same time. Submissions also must meet all applicable national requirements.

2 Eligible products

Submissions may be for new veterinary medicinal products, or for new uses of existing products that already hold marketing authorisations in both countries provided they have not been subject to relevant or significant safety-related regulatory action in either country.

The product must be identical in formulation and manufacturing including the source of the active ingredient. There may be differences in product labels. Currently, this opportunity is only open to applications which are based on a full dossier, that is containing all applicable technical information for safety, efficacy and quality.

Submissions for medicines for minor uses/minor species (MUMS) are especially encouraged.

Immunologicals and generics are not eligible for review under this pathway at the present time. Veterinary medicines and products exempted from authorisation in the UK are not eligible, nor those authorised using the Swiss notification procedure.

3 Phases of a simultaneous review

3.1 Pre-submission phase

3.1.1 Expression of Interest

Early interactions by industry with the regulators are important and will assist in the process to assess the feasibility and admissibility of a submission. Applicants are encouraged to contact the VMD and Swissmedic to learn more about this process and initiate dialogue with the regulators. Applicants may signal their interest by sending an expression of interest to both regulators at the earliest opportunity.

The expression of interest should also include a request for a pre-submission discussion. The request should as a minimum provide basic information on the proposed product and indicate the scientific disciplines that the applicant wishes to discuss as well as any specific issues/questions to be addressed by the regulators, although questions concerning scientific advice would be considered outside of this process. The regulators will then jointly work with the applicant to schedule these discussions.

The expression of interest should also include authorisation from the applicant to the regulators to permit the exchange of relevant information.

3.1.2 Pre-submission discussions

Pre-submission discussions are required to inform a decision on admissibility. This meeting is of a scoping/exploratory nature. The purpose of a pre-submission discussion where presentations are made by the applicant to the regulators is to introduce their new medicinal product and to discuss whether it is a good candidate for this process.

Joint pre-submissions are strongly recommended. These meetings should involve the applicant, including its representatives in both countries, and both regulators at the same time. If not possible, applicants may also have pre-submission meetings with each country individually.

Discussions can confirm and clarify data requirements and product testing, address submission formatting, and provide feedback from regulators on study protocols proposed by applicants. The discussions are also an opportunity to clarify any national requirements.

The applicant is responsible for proposing an agenda in advance of the meeting, recording the meeting notes and seeking any comments, clarifications or corrections from meeting participants in a timely manner; revised and finalised meeting notes should be shared with the regulators for approval and future reference.

3.1.3 Decision on admissibility

If a submission is deemed to be an appropriate candidate, the regulators will request a formal letter from the applicant seeking a collaborative review.

Based on the information gathered through the pre-submission discussions and the formal request from the applicant, the regulators will consider a variety of factors before deciding to proceed. The regulators will communicate the decision on admissibility to the applicant via formal letters.

3.1.4 Timelines for review

Both regulators will aim to reach a final decision to approve or refuse within 210 days of the date it is accepted into review.

Timelines should be confirmed with the regulators prior to filing but upon successful completion of validation, your assessment procedure will progress in accordance with the following table:

Phase	Timetable
Initial Assessment	Assessment Day 0-110 Swissmedic and VMD Assessment Reports and Lists of Questions sent to applicant.
Co Response 1	90 days – clock stop (can be increased to 180 days upon request)

Second Assessment	Assessment Day 111-150 Swissmedic and VMD assess responses and further lists of questions sent to applicant (in Switzerland in form of the preliminary decision).
Co Response 2	60 days – clock stop
Third Assessment	Assessment Day 151-180 Swissmedic and VMD assess responses and further lists of questions sent to applicant.
Co Response 3	30 days – clock stop
Sign-off	By Assessment Day 210 VMD and Swissmedic will make national sovereign decision to approve or refuse.

Your application will progress into a national phase, where VMD and Swissmedic undertake independent activities to issue authorisations / registrations.

3.2 Submission filing phase

3.2.1 Coordinated filing

Applicants must file separate submissions to both regulators independently and simultaneously. Applicants are to file their submission to each country:

- Switzerland via the Swissmedic Portal
- UK via the VMD Digital Service

All submissions must meet all applicable national regulatory and administrative requirements.

The content of the submissions should be the same, including nation-specific technical requirements. There may also be national-specific administrative documentation or fees payable, as per national regulatory requirements, policies or processes. Applicants are encouraged to confirm applicable fees with both regulators prior to submission.

Applicants are to submit in the NtA format to both countries, as set out in Volume 6b of the European Notice to Applicants.

To enable the review process, data and other information (including confidential business information) provided by the applicant will be discussed by the regulators. Applicants are asked to provide a letter authorising this exchange of information.

3.2.2 Submission completeness check (validation)

Each regulator will perform a validation of the submission to ensure that the submission can be accepted for review. If the regulators have questions about the content of the submission during screening/validation, they will send it to the applicant with a copy to the other regulator.

It is the applicant's responsibility to ensure that both regulators have an updated consolidated dossier at the end of validation so both countries are working on identical dossiers and no data are missing.

At the end of validation, each regulator will send a communication to the applicant informing them of the acceptability of the submission for review.

3.3 Submission review phase

Regulators will meet to discuss the submission, including lists of questions, also referred to as clarification requests. Regulators will also meet throughout the submission process.

Lists of questions from both regulators may be combined or issued separately. Applicants will be provided with an established amount of time in which to submit completed responses which should be confirmed with the regulators. Applicants are expected to share their responses to all questions with both regulators.

Opportunities to harmonise and align labelling will be considered.

If the applicant is seeking to meet with one regulator at any point during the submission review process, it is incumbent upon them to inform and invite the other regulator to participate.

3.4 Sovereign decision

Each regulator makes its own sovereign decision in accordance with relevant national legislation. Each regulator will undertake the necessary national administrative and/or legal steps relating to the issuance of a market authorisation or negative decision. To the extent possible, regulators will synchronise the timing and communication related the issuance of decisions.

In the event of a negative decision by one or both regulators the applicant is encouraged to discuss available options and the administrative process to address deficiencies with the regulator(s) based on their regulatory frameworks. Note that relevant national reconsideration/procedural fairness and appeals processes apply.

4 Additional considerations

Should an applicant wish to withdraw a submission from review, they are encouraged to contact both regulators at the earliest opportunity prior to cancellation to discuss any concerns and regulatory considerations.

Once a product has received market authorisation, it is the responsibility of the applicant to adhere to all applicable national post-market regulatory requirements. Regulators will continue to collaborate and exchange information to support post-market monitoring, risk assessment and risk management activities, as appropriate.

5 Contact information

For more information contact:

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Change history

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1.1	Chapter 3.1.4: Phase “Co Response 3” added	lac
1.0	New document	lac