VMRF Group
Veterinary Mutual Recognition Facilitation Group

VMRF/038/99-Rev.1-Final

VETERINARY MUTUAL RECOGNITION FACILITATION GROUP (VMRF)

PARALLEL APPLICATIONS

MS - SOP

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« MS-SOP »

This document was produced by the VMRFG in order to facilitate and harmonise the practical application of Article 21 paragraph 2 of Directive 2001/82/EC by competent national Authorities.

Prerequisite: extracts from European legislation and Commission Communication

1- Article 21 paragraph 2 of Directive 2001/82/EC. "Where a Member state notes that an application for authorisation submitted is already under active examination in another Member State in respect of that veterinary medicinal product, the Member State concerned may decide to suspend the detailed examination of the application in order to await the assessment report prepared by the other Member State in accordance with Article 25(4)."
"The Member State concerned shall inform the other Member State and the applicant of its decision to suspend detailed examination of the application in question. As soon as it has completed the examination of the application and reached a decision, the other Member State shall forward a copy of its assessment report to the Member State concerned."

Article 22 2nd subparagraph of Directive 2001/82/EC "Within 90 days of receipt of the assessment report, the Member State concerned shall either recognise the decision of the first Member State and the summary of the product characteristics as approved by it, or, if it considers that there are grounds for supposing that the authorisation of the veterinary medicinal product concerned may present a risk to human or aninal health or the environment[1], it shall apply the procedures set out in Articles 33 to 38 of this Directive.

2- Commission Communication C98/2016 of 16 July 1998. (OJEC, 98/C229/03, 22 July 98). "Article 8 paragraph 2 of Directive 81/851/EEC[2] offers Member States the possibility to start a mutual recognition procedure, where an application lodged in one Member State is already under active examination in another Member State.
This provision explicitly covers only cases in which identical applications are pending in different Member States and in which an earlier authorisation was not yet granted in another Member State. Cases in which a marketing authorisation has already been issued in another Member State are not covered by this Article. In such cases Article 8a of Directive 81/851/EEC[3] applies.

The wording "may" in Article 8 paragraph 2[2] implies that the concerned Member State has an option to choose whether to suspend the authorisation procedure and await the assessment report prepared by the other Member State or to proceed with the application. This provision is applicable and remains applicable for all applications submitted after 1.1.1995. The entering into force of Article 8a[3] on 1.1.1998 has no direct effect on the applicability of this provision. Different Member States "may" therefore go in

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[1] **The expression « risk to human or animal health or the environment » refers to the quality, safety and efficacy of the veterinary medicinal product**
[2] **Article 21 paragraph 2 of Directive 2001/82/EC**
[3] **Article 22 of Directive 2001/82/EC**

parallel with simultaneous and identical applications under Article 8 paragraph 2[2] even after 1.1.1998. However, this possibility is only theoretical, because as soon as one of the two Member States actually grants a marketing authorisation, Article 8a of Directive 81/851/EEC[3] becomes applicable and the Member State which has not yet granted an authorisation must start a mutual recognition in accordance with this Article.

Since the application must be under active examination in the other Member State, this mechanism requires Member States to actively co-operate. Having determined that the application is under active examination, the Member State which has suspended its evaluation informs the other (Reference) Member State and the applicant of its decision to suspend detailed examination of the application in question.

Usual Procedure

1. Situation

A Member State receive a national application and is informed usually in Part IA, section 4, that the application has been submitted simultaneously in (an)other Member State(s). An earlier authorisation was not yet granted in another Member State. This application is not a so called "line extension" of a product authorised nationally or a so called "bibliographical application" according to Article 13(1)(a) ii) of Directive 2001/82/EC.

2. First phase

The Member State where the application is made "may" choose to suspend the authorisation process if the application is under active examination in another Member State. Therefore, the first step of the procedure should be to exchange information on the evaluation status in the different Member State(s) where the application has been submitted (cf draft letter no 1).

Letter no 1

To: .....(Member States where the application was submitted)
Cc : ….…..…..(Other Member States for information)
From: .....(contact persons)

Re:

Name/pharmaceutical form	
Active substance(s) + strength	
Species	
Proposed therapeutic indication	
Applicant	

Dear Colleagues,

The above application was submitted nationally on ...(Date). However, it has come to our attention that the same application was submitted in your country. As far as we know, an earlier authorisation was not yet granted in another Member State.

Could you please check:

1)	*if the above application was submitted in your country*	*□yes*	*□no*
2)	*if yes, whether the application is at present under active examination*	*□yes*	*□no*
3)	*if you intend to suspend your national evaluation in case the application is under active examination in another Member State*	*□yes*	*□no*

In order to avoid duplication of work, we would propose then to find a co-operative agreement at the next VMRFG meeting.

Thank you for your prompt reply,

Yours sincerely,

3. Second phase

- Scenario 1: the application is under active examination in another Member State. After the co-operative discussion with the other Member States involved, if the Member State chooses to suspend its examination, it should inform the applicant, the (reference) Member State and the other Member States involved of its decision (cf. letter no 2).

Letter no 2

To: .....(applicant)
.....(future reference Member State)
Cc:.....(Member States where the application was submitted)

From: .....(contact persons)
Re:

Name /strength /pharmaceutical form	

Dear Mr...(applicant),

The above application was submitted nationally on ....However, it has come to our attention that the same application is pending in another Member State(....) and that an earlier authorisation was not granted in any of the Member States yet.
As your application is under active examination in another Member State (…), we would like to inform you that we have decided to suspend the national procedure according to Article 21, paragraph 2 of Directive 2001/82/EC in order to initiate a mutual recognition procedure as soon as an authorisation is granted in the reference Member State (ref. Commission Communication, OJEC, 98/C229/03, 22 July 98, chapter 5 related to Article 8a of Directive 81/851/EEC).

Yours sincerely,

- Scenario 2: the application is or is not under active examination in another Member State and a Member State decides to proceed actively with the application. After the co-operative discussion with the other Member State(s) involved, it should formally inform the applicant and the other Member States involved of its decision (cf. letter no 3).

Letter no 3

To: .....(applicant) *Cc:.....(Member States where the application was submitted)* *From: .....(contact persons)* *Re:*

Name /strength /pharmaceutical form	

Dear Mr...(applicant),

The above application was submitted nationally on .... However, it has come to our attention that the same application is pending in another Member State(....) and that an earlier authorisation was not granted in any of the Member States yet.
We would like to inform you that we have decided to proceed with the active examination of the above application.

Yours sincerely,

4. Third phase

- scenario 1: a marketing authorisation is granted in the (reference) Member State

The reference Member State should inform immediately the Member State(s) where the examination was suspended that a marketing authorisation is granted, then Article 22 of Directive 2001/82/EC becomes automatically applicable in the Member States where the same application was submitted. The reference Member State should provide an assessment report to the involved Member States.

- scenario 2: a negative opinion is given in the (reference) Member State

The reference Member State should inform immediately the Member State(s) where the examination was suspended that a negative opinion is adopted. Then, as soon as the Member State(s) where the examination was suspended is informed that the (reference) Member State has rejected the application, it should automatically proceed with the active examination of the application. In case several Member States have suspended their active examination, the procedure described in the present « MS-SOP » could be reconsidered. The Member State where a negative opinion was given should provide an assessment report to the involved Member States.

- scenario 3: the application is withdrawn in the (reference) Member State

The reference Member State should inform immediately the Member State(s) where the examination was suspended that the application was withdrawn by the applicant before an opinion can be adopted. Then, as soon as the Member State(s) where the examination was suspended is informed that the application is withdrawn in the (reference) Member State, it should automatically proceed with the active examination of the application. In case several Member States have suspended their active examination, the procedure described in the present « MS-SOP » could be reconsidered. The Member State where the application is withdrawn may provide an assessment report to the involved Member States