THE COMMON BALTIC PACKAGE PROCEDURE FOR VETERINARY MEDICINAL PRODUCTS

1. Aim and Scope

The Common Baltic Package Procedure for Veterinary Medicinal Products (hereinafter referred to as "Procedure") has been created by Estonian Agency of Medicines, Latvian Food and Veterinary Service and Lithuanian National Food and Veterinary Risk Assessment Institute (hereinafter referred to as "NCAs"), in order to facilitate the process of labelling harmonisation, which is a prerequisite for obtaining the common Baltic packages for veterinary medicinal products. This is an administrative procedure applicable in cases when harmonisation of labelling information is required for veterinary medicinal products, for which common Baltic package is intended to use.

2. Prerequisites

2.1. Provisions of the Guideline on Common Baltic Package for Veterinary Medicinal Products (hereinafter referred to as "Guideline") shall apply.

2.2. Proposed labelling text shall comply with annotated QRD template; common Baltic package specific guidance provided in the labelling template of the Guideline should be also respected when drawing up the proposed labelling text.

2.3. There is no ongoing variation procedure that could affect labelling.

2.4. There is no ongoing renewal procedure.

3. Procedure

3.1. MAH shall submit simultaneously to all participating Baltic States an identical application containing the following elements in electronic format (hard copies are not required):

- Cover letter
- Application Form (Annex 2)
- Proposed harmonised labelling text in English.

An application with accompanying documents can be sent via e-mail, Eudralink or CESP. Latvia shall accept submission via Eudralink or CESP only.

3.2. Within 7 calendar days following receipt of application, the concerned Baltic States shall agree on a Reference Baltic State (RBS); remaining state(s) will act as concerned Baltic State(s) (CBS).

3.3. The RBS shall inform CBS and the MAH about the start of the procedure (the procedure starts (Day 0) on the day when the RBS has been agreed.)

3.4. The RBS shall perform an assessment of the proposed English labelling text and send comments to the CBS within 7 calendar days from the start of the procedure.

3.5. CBS shall send comments or agreement on the proposed labelling text to the RBS and to other CBS within 7 calendar days.

3.6. CBS and RBS shall use their best endeavours to reach an agreement by Day 21.

3.7. On Day 22 of the procedure, the RBS shall forward the agreed labelling text to the MAH. The clock will be stopped until response from the MAH has been received. The clock stop shall not be longer than 7 calendar days.

3.8. On Day 30 of the procedure, the RBS shall forward the MAH's responses to CBS or close the procedure, if consensus has been reached.

3.9. The RBS shall evaluate the responses and send the final proposal to the CBS within 7 calendar days after receipt.

3.10. The CBS shall send additional comments to RBS and other CBS, if any, within 7 calendar days.

3.11. On the Day 45, the RBS shall close the procedure and send final agreed labelling text to the MAH and CBS.

3.12. Within 5 days after close of procedure, the Estonian State Agency of Medicines shall update the database of the Common Baltic Package Procedures. The database is intended for internal use only and will contain names of the veterinary medicinal products and dates of the start and end of the procedures. In case Estonia shall not be involved in the procedure, RBS shall contact the Estonian State Agency of Medicines and ask for relevant updates.

3.13. Within 15 calendar days after close of procedure, MAH shall submit national translation of labelling text to RBS and CBS.
3.14. Before launching the veterinary medicinal product, MAH shall submit mock-ups to RBS and CBS.

Annex 1

FLOW-CHART OF THE COMMON BALTIC PACKAGE PROCEDURE FOR VETERINARY MEDICINAL PRODUCTS

Pre-procedure	MAH submits application to all participating Baltic States. The participating Baltic States agree on a Reference Baltic State (RBS) within 7 calendar days.
Day 0	RBS starts the procedure.
Until Day 7	RBS sends comments on the proposed labelling text to CBS.
Until Day 14	CBS send their comments to RBS and other CBS.
Until Day 21*	Consultations between RBS and CBS.
Day 22	RBS sends consolidated comments to MAH and stops the procedure. If there are no comments, RBS closes the procedure and provides final labelling text to MAH.
Clock stop period	MAH sends responses / acceptance to RBS within 7 calendar days.
Day 23	The RBS restarts the procedure. If MAH accepts changes proposed by RBS and CBS, RBS closes the procedure.
Until Day 30	RBS forwards the MAHs responses to CBS.
Until Day 44*	The RBS and CBS send their final comments to each other and agree on the final labelling text.
Until Day 45	RBS closes the procedure and sends final English labelling text to MAH and CBS.
Within 5 days after close of procedure	The Estonian State Agency of Medicines updates the database of completed procedures.
Within 15 days after close of procedure	MAH submits national translations of labelling text to RBS and CBS.
Before launching	MAH submits mock-ups to RBS and CBS.

* if needed

Annex 2

APPLICATION FORM FOR THE COMMON BALTIC PACKAGE PROCEDURE

Concerned Baltic State(s)*

☐EE ☐LT ☐LV

* Chosen by MAH.

Name and address of the MAH:	Name and address of contact person: Telephone number: E-mail:

Veterinary medicinal product(s) concerned by this application

	Estonia	**Lithuania**	**Latvia**
(Invented) name			
Active substance(s)			
Strength**			
Pharmaceutical form			
MA number(s)			

** Several strengths may be included, if proposed labelling text is the same. In case of several strengths, this section should be duplicated.

Declaration of the applicant

I hereby submit an application for the common Baltic package procedure and I declare that (*please tick the appropriate declarations*):

- ☐ There are no other changes than those identified in this application.
- ☐ National fees have been paid (if applicable).
- ☐ This application has been submitted simultaneously to all participating Baltic States.
- ☐ There is no ongoing variation procedure that could affect labelling.
- ☐ There is no ongoing renewal procedure.

Signature

Signatory_____ Job title _____

Name _____ Date _____