# AGREEMENT ON THE COMMON BALTIC PACKAGE LABELLING

State Agency of Medicines of the Republic of Estonia, represented for the purposes of the signature of this Agreement by Kristin Raudsepp, Director General,

State Agency of Medicines of the Republic of Latvia, represented for the purposes of the signature of this Agreement by Inguna Adoviča, Director,

State Medicines Control Agency of the Republic of Lithuania, represented for the purposes of the signature of this Agreement by Gintautas Barcys, Director,

All hereinafter referred to as the "Party (-ies)",

AFFIRMING their wish to promote the relations between the State Agency of Medicines of the Republic of Estonia, State Agency of Medicines of the Republic of Latvia, State Medicines Control Agency of the Republic of Lithuania,

STATING their commitment to support joint efforts to provide efficacious and safe medicinal products to their respective populations,

CONFIRMING the need for cooperation to minimize impact of medicinal products shortages,

SUPPORTING the objective to enforce bilateral cooperation on field of medicinal products,

HEREBY ADOPT the following Cooperation Agreement:

## ARTICLE 1

The Parties shall develop and enhance cooperation in the area of medicinal products for human use as set out in this Cooperation Agreement.

## ARTICLE 2

The cooperation, referred to in Article 1, shall consist of the cooperation in the area of the labelling of the medicinal products. Particulars of the cooperation shall be agreed upon by the Parties in the annexes to this Agreement.

## ARTICLE 3

1. This Protocol shall enter into force on the day of its signature and shall be valid for the period of three years.

2. If none of the Parties terminates the Agreement by means of the written notification, three months prior to its expiration, the Agreement shall be automatically extended for the next three years period.

3. The Agreement might be prolonged for the longer period than referred to in point 2 of this Article upon the written agreement of all the Parties.

4. Each Party has the right to initiate an amendment, the revision or termination of the Agreement at any time. Proposed amendments and revisions are discussed by all the Parties. In case of the common consent, the new version of the annexes of this Agreement shall be signed. It is recommended to notify the other Party (-ies) 1 (one) month prior the desired termination term.

## ARTICLE 4

1. The Agreement contains 3 Annexes:
   a) Annex 1: Common Baltic Package Procedure;
   b) Annex 2: Application Form for the Common Baltic Package Procedure;
   c) Annex 3: Flow-Chart of the Common Baltic Package Procedure.
2. All the annexes of this Agreement are part of this Agreement.

## ARTICLE 5

The present Agreement is drawn and signed in 3 (three) copies. Each Party shall receive one copy. Each of the copies has the same legal effect.

Signed in Vilnius on 03 sept 2015.

| For the Estonian State Agency of Medicines | For the Latvian State Agency of Medicines | For the Lithuanian State Medicines Control Agency |
|---|---|---|
| Kristin Raudsepp | Inguna Adoviča | Gintautas Barcys |
| Director | Director | Director |

VALSTYBINĖ VAISTŲ KONTROLĖS TARNYBA PRIE LIETUVOS RESPUBLIKOS SVEIKATOS APSAUGOS MINISTERIJOS

# COMMON BALTIC PACKAGE PROCEDURE

## 1. Scope

1.1. This is a voluntary procedure applicable to the changes of the labeling referred to in the Article 61(3) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, including all the amendments (thereinafter referred to as Directive 2001/83/EC).

1.2. Combined Baltic package is acceptable only if invented name of THE medicinal product as referred in Article 1(20) of the Directive 2001/83/EC, is the same in Estonia, Latvia and Lithuania involved. In case of disagreement on invented names, Guideline on the acceptability of invented names for human medicinal products processed through the centralized procedure should be consulted.

## 2. Prerequisites that are obligatory for the common procedure

2.1. Summary of product characteristics cannot contain any differences that prelude harmonization of the labeling.

2.2. Name of the medicinal product is the same in all Baltic States.

2.3. Requirements of the Directive 2001/83/EC as amended, Commission Guideline on the readability of the label and package leaflet of medicinal products for human use and Common Baltic Guideline shall apply.

2.4. The labeling shall comply with the relevant EMA guidance documents, especially QRD templates with explanatory notes.

2.5. There is no ongoing variation procedure that could affect the labeling in either Estonia, Latvia or Lithuania.

2.6. There is no renewal procedure ongoing in either Estonia, Latvia or Lithuania.

## 3. Procedure

3.1. Marketing Authorization Holder (thereinafter referred to as MAH) shall submit an identical application (annex 2 of the Agreement) accompanied by the labeling text in English and national translations in Microsoft Word format to all the participating Baltic states. The application and labeling text shall be submitted electronically, hard copies are not required. In case of changing language of active substances and excipient (s) from national to Latin, application form would not be required, only a request sent by e-mail would be acceptable.

3.2. The Baltic States shall agree on a Reference Baltic State (thereinafter referred to as RBS).

3.3. The RBS shall inform Concerned Baltic state(s) (thereinafter referred to as CBS(s)) and MAH about the start of the procedure perform an assessment of the English text and send the proposal on the labeling to the CBS(s) within 14 calendar days. The days are set according to flow chart (annex 3 of the Agreement).

3.4. CBS(s) shall send comments or agreement on the labeling text to RBS within 7 calendar days.

3.5. In case of different opinions, the both states shall use their best endeavors to reach an agreement.

3.6. The RBS shall forward the agreed proposals on changes to the MAH. The clock will be stopped until responses received from the MAH. The clock stop shall not be longer than 14 calendar days.
3.7. The RBS shall evaluate the responses and send the final proposal to the CBS(s) within 7 calendar days.
3.8. The CBS(s) shall send additional comments, if any, within 7 calendar days.
3.9. In case of agreement, the RBS shall close the procedure and send final labelling text to the MAH and CBS(s).
3.10. MAH shall submit mock-ups to RBS and CBS(s) within 15 calendar days.
3.11. The Estonian state Agency of Medicines shall be responsible for updating the database on agreed Baltic packages. In initial phase, the database is intended to be merely for internal use. It will contain names of the medicinal products and dates of the end of the procedures.

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING**

**{NATURE/TYPE}**

## 1. NAME OF THE MEDICINAL PRODUCT

*{(Invented) name, strength and pharmaceutical form}*
*{Active substance (s)}*

*European Pharmacopoeia full standard term should be used for pharmaceutical form.*

*Name of active substance should appear in all national languages or Latin without any brackets or further explanations. Latin should never be combined with any another language.*

## 2. STATEMENT OF ACTIVE SUBSTANCE(S)

*Statement of active substance should be in national languages. In case of 3 and more active substances Latin may be used.*

## 3. LIST OF EXCIPIENTS

*Should appear in all national languages or Latin.*
*Latin should never be combined with any another language.*
*Express qualitatively only those excipients known to have a recognised action or effect and included in guideline on "Excipients in the Label and Package Leaflet of Medicinal Products for Human Use" (The rules governing medicinal products in the European Union, Volume 3B). However, if the medicinal product is a parenteral, a topical or an eye preparation or if used for inhalation, all excipients must be stated.*

## 4. PHARMACEUTICAL FORM AND CONTENTS

*European Pharmacopoeia short standard term may be used for pharmaceutical form if space on the package is not sufficient.*

## 5. METHOD AND ROUTE(S) OF ADMINISTRATION

*European Pharmacopoeia standard term should be used.*

Read the package leaflet before use.

## 6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT SHOULD BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

## 7. OTHER SPECIAL WARNING(S), IF NECESSARY

**8. EXPIRY DATE**

*Words "Expiry date" are endorsed to appear in all national languages.*

For terms on Expiry date see Appendix IV on the European Medicines Agency website

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf

**9. SPECIAL STORAGE CONDITIONS**

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

*{Name and address}*
*<{tel}>*
*<{fax}>*
*<{e-mail}>*
*Should not be translated.*
*Only name of the Member State should appear in national language.*

**12. MARKETING AUTHORISATION NUMBER(S)**

**13. BATCH NUMBER**

*Word "Batch" is endorsed to appear in all national languages.*

For terms on Batch number see Appendix IV on the European Medicines Agency website

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf

**14. GENERAL CLASSIFICATION FOR SUPPLY**

*<Medicinal product subject to medical prescription.>*
*<Medicinal product not subject to medical prescription.>*

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

*<Justification for not including Braille accepted>*

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**{NATURE/TYPE}**

## 1. NAME OF THE MEDICINAL PRODUCT

*{(Invented) name strength pharmaceutical form}*
*{Active substance (s)}*

*European Pharmacopoeia short standard term may be used for pharmaceutical form if space on the package is not enough.*

*Name of active substance should appear in all national languages or Latin without any brackets or further explanations. Latin should never be combined with any another language.*

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

*{Name}*

## 3. EXPIRY DATE

For terms on Expiry date see Appendix IV on the European Medicines Agency website
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf
Otherwise, digits indicating month and year may appear without any further references.

## 4. BATCH NUMBER

For terms on Batch number see Appendix IV on the European Medicines Agency website
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf

Otherwise, batch number may appear without any further references.

## 5. OTHER

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**{NATURE/TYPE}**

## 1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

*{(Invented) name strength pharmaceutical form}*
*{Active substance (s)}*
*<Route of administration>*

*European Pharmacopoeia short standard term may be used for pharmaceutical form.*

*Name of active substance should appear in all national languages or Latin without any brackets or further explanations. Latin should never be combined with any another language.*

*European Pharmacopoeia standard term should be used for route of administration.*

## 2. METHOD OF ADMINISTRATION

## 3. EXPIRY DATE

For terms on Expiry date see Appendix IV on the European Medicines Agency website http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf

Otherwise, digits indicating month and year may appear without any further references.

## 4. BATCH NUMBER

For terms on Batch number see Appendix IV on the European Medicines Agency website http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf

Otherwise, batch number may appear without any further references.

## 5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

*European Pharmacopoeia short standard term may be used for pharmaceutical form.*

## 6. OTHER

Annex 2

## APPLICATION FORM FOR THE COMMON BALTIC PACKAGE PROCEDURE

### 1. Baltic States

| Participating Baltic States * | Reference Baltic State ** |
|---|---|
| ☐EE ☐LT ☐LV | ☐EE ☐LT ☐LV |

*Chosen by MAH.

** Agreed by Baltic States.

### 2. Medicinal product(s) concerned by this application *

| | Estonia | Lithuania | Latvia |
|---|---|---|---|
| (Invented) name | | | |
| Strength(s)* | | | |
| Pharmaceutical form | | | |
| Marketing authorisation number(-s) | | | |
| Active substance(s) | | | |
| Marketing authorisation holder | | | |
| name | | | |
| address | | | |
| Contact person | | | |
| name | | | |
| address | | | |
| e-mail | | | |
| phone | | | |
| Therapeutic indications ** | | | |
| Posology and method of administration *** | | | |

* All strengths may be included if proposed labelling text is the same.

** For non-prescription medicinal only: please provide English translations of section 4.1 of SPS approved by RBS and CBS(s).

*** For non-prescription medicinal only: please provide English translations of section 4.2 of SPS approved by RBS and CBS(s).

### 3. Declaration of the applicant

I hereby submit an application for the common Baltic package in accordance with the proposals given above. 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 other ongoing variation procedure that could affect the labelling.
- ☐ The renewal procedure is not ongoing.

### 4. Signature

**Signatory**_____ Job title _____

Name _____ Date _____

# FLOW-CHART OF THE COMMON BALTIC PACKAGE PROCEDURE

| | |
|---|---|
| Day 0 | Marketing authorization holder (thereinafter referred to as MAH) submits application accompanied by proposed labeling text to the Baltic States. |
| Day 14 | Reference Baltic state ((thereinafter referred to as RBS) sends texts of the proposed labeling with comments and tracked changes to Concerned Baltic states (thereinafter referred to as CBS(s)). |
| Until Day 21 | CBS(s) send their comments to RBS. |
| Until Day 28* | Consultation between the Baltic states involved in the procedure. |
| Day 29 | RBS sends comments to the MAH, if there are any and stops the procedure. If there are no comments, RBS closes the procedure. |
| Day 30 | MAH sends response to the Baltic states. If MAH accepts changes proposed by Baltic states, RBS closes the procedure. |
| Day 37* | The RBS evaluates the response and sends the final proposal to the CBS(s). |
| Until Day 44* | Consultation between RBS, CBS (s) and MAH. |
| Day 45 | RBS closes the procedure and sends final labelling texts in English. |
| Until Day 50 | The Estonian Agency updates the database of Baltic packages. |
| Until Day 60 | MAH submits mock-ups to RBS and CBS(s). |
| | RBS and CBS(s) perform review of the mock-ups and reach an agreement with MAH. Consultation between the RBS and CBS(s). |

*if needed