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