ESTONIAN STATE AGENCY OF MEDICINES
LATVIAN STATE AGENCY OF MEDICINES
LITHUANIAN STATE MEDICINES CONTROL AGENCY

COMMON BALTIC PACKAGE GUIDANCE

Combined EE/LV/LT package is acceptable only if (invented) name of medicinal product as referred in Article 1(20) of the directive 2001/83/EC as amended is the same in all Member States involved. In case of doubt, CHMP Guideline on the acceptability of invented names for human medicinal products processed through the centralised procedure should be consulted.

For combined EE/LV/LT packages, requirements of the Directive 2001/83/EC as amended and Commission Guideline on the readability of the label and package leaflet of medicinal products for human use does apply.

Labelling and package leaflet shall comply with relevant EU/EMEA/QRD published guidance documents, especially QRD templates with explanatory notes.

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.

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

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

{MM/YYYY}
Words "Expiry date" are endorsed to appear in all national languages. Otherwise, digits indicating month and year may appear without any further references.

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

Should not be translated
Only name of the Member State should appear in national language.

12. MARKETING AUTHORISATION NUMBER(S)

13. MANUFACTURER'S BATCH NUMBER

Word "Batch" is endorsed to appear in all national languages. Otherwise, batch number may appear without any further references.

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

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

3. EXPIRY DATE

{MM/YYYY}
Digits indicating month and year may appear without any further references.

4. BATCH NUMBER

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

{MM/YYYY}
Digits indicating month and year may appear without any further references.

4. BATCH NUMBER

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

Done at Vilnius, 03 August 2009

Riga 10.08.2009.

For the Lithuanian State Medicines Control Agency	For the Estonian State Agency of Medicines	For the Latvian State Agency of Medicines
Director	Director General	Director
Gintautas Bareys	Kristin Raudsepp	Inguna Adovica

18 August 2009