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ESTONIAN STATE AGENCY OF MEDICINES
LATVIAN FOOD AND VETERINARY SERVICE
LITHUANIAN NATIONAL FOOD AND VETERINARY RISK ASSESSMENT INSTITUTE

GUIDELINE ON COMMON BALTIC PACKAGE FOR VETERINARY MEDICINAL PRODUCTS

Introduction

The national competent authorities (NCAs) for veterinary medicinal products in the three Baltic States have agreed to publish this document to assist Applicants / Marketing Authorisation Holders in creating common Baltic packages for veterinary medicinal products. While the NCAs are committed to assist Applicants and Marketing Authorisation Holders in their goal to achieve common Baltic packages for their products, it must be emphasised that labelling cannot be reduced or abbreviated to such an extent that safety is compromised. This guideline is applicable for veterinary medicinal products undergoing an authorisation procedure or authorised via national procedure, decentralised procedure (DCP) or mutual recognition procedure (MRP). The NCAs will update this document as needed.

What is a common Baltic package of a veterinary medicinal product?

There is no legal definition of a Baltic package. Traditionally, "Baltic" refers to the three Baltic States – Estonia, Latvia and Lithuania. As each of the Baltic States is often considered to be a small market or a very small market, the pharmaceutical industry has expressed its interest in the manufacturing of trilingual Baltic packages. In practice the term "Baltic package" usually refers to trilingual (EE/LV/LT) package used for at least one component of the packaging material (carton, label, blister, combined labelling-package leaflet) of veterinary medicinal product. However, this guideline shall also apply to bilingual packages, when only 2 out of 3 Baltic States (e.g. LV/LT or EE/LV) are involved. It should be noted that Baltic package does not prevent the combination of a Baltic country and a non-Baltic country, should the marketing authorisation holder so prefer.

Legal basis

Directive 2001/82/EC, as amended, lays down the basic rules concerning labelling. Each of the Baltic States has implemented the relevant legislation and follows relevant EU guidelines, including QRD template. Therefore, there are basically the same rules concerning labelling in all three Baltic States, except package 'blue-box' requirements and additional information on labelling/package leaflet that may be required or permitted nationally (relevant document is available on CMDv website).

Conditions/requirements to be met

A common (bilingual/trilingual) Baltic package can be obtained only if the particulars of the approved labelling text (including combined labelling-package leaflet) are the same in all languages covered by the package. Package "blue box" requirements that apply in certain Baltic States do not prevent the printing of Baltic package. Any other differences in the labelling text (including combined labelling-package leaflet) should be notified simultaneously to all NCAs involved in the future package. Harmonised labelling may be obtained via common Baltic Package Procedure for Veterinary Medicinal Products. However, in certain cases submission of variation may be requested.

Furthermore, the multilingual package is only possible if the readability is not compromised by adding 2 or more languages to the labelling elements, e.g. too small font size.

If Baltic package is planned for new products (DCP/MRP), Applicants should ensure that common product name is proposed for all concerned countries. Any issues related to the name should be solved

during the MA procedure (preferably by Day 106 in DCP and Day 65 in MRP), in order to avoid variation. Besides, Applicants should be convinced that it would be possible to display all particulars of the proposed labelling text in all languages on the multilingual package. It is recommended that Applicants only propose labelling text which is required by the annotated QRD template.
The omission of some particulars of labelling text should be justified. The shortened text will be evaluated and approved during DC/MR procedure.

The template for presentation of labelling text to appear on the outer and/or immediate Baltic package is provided below. This template does not replace or supersede the requirements laid down in the annotated QRD template, but provides additional guidance that should be followed in case of common (bilingual/trilingual) Baltic package. Furthermore, some of this additional guidance allows saving space, which may be compromised by placing information in two or three different languages. Guidance text applicable to Baltic package only is indicated in blue colour.

Once the Common Baltic Package Procedure for Veterinary Medicinal Products have been used, any further corrections in the approved common labelling text (including combined labelling-package leaflet) shall be notified simultaneously to all NCAs involved in initial Baltic Package Procedure. Further discussions could be done within variation procedure or via new Common Baltic Package Procedure once again, if necessary.

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Name, strength (if applicable) and pharmaceutical form of the veterinary medicinal product, as well as target species (if applicable), should be expressed identically in all languages.

For fixed-combination products: The names of the active substances should be presented separated by a "/", unless agreed differently during MR/DC procedure.

In case of space limitation name(s) of active substance(s) to appear under the name of the veterinary medicinal product may be stated in Latin (when Estonia is involved) or English (when Estonia is not involved) without any brackets or further explanations. Combination of Latin/English name(s) with national ones should be avoided.

In case of space limitation internationally agreed units might be used without translation (decided on a case by case basis).

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition of the veterinary medicinal product should be expressed identically in all languages.

*In case of space limitation name(s) of active substance(s) and, where applicable, excipients may be stated in Latin (when Estonia is involved) or English (when Estonia is not involved), except for the outer package of **OTC** products.*

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

In case of space limitation the abbreviation "EXP" may be used to replace national terms. "EXP" should not be used in combination with national terms. For immediate package only: It is also acceptable, if expiry date is stated without any abbreviation.

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For immediate package only: In case of space limitation Latin term "Ad us. vet." may be used to replace national terms (decided on a case by case basis). "Ad us. vet." should not be used in combination with national terms.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

The name of the country should be written in a full name in the national languages.

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

In case of space limitation the abbreviation "Lot" may be used to replace national terms. "Lot" should not be used in combination with national terms. For immediate package only: It is also acceptable, if batch number is stated without any abbreviation.

MINIMUM PARTICULARS TO SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

In case of space limitation name of active substance to appear under the name of the veterinary medicinal product may be in Latin (when Estonia is involved) or English (when Estonia is not involved) without any brackets or further explanations. Combination of Latin/English name(s) with national ones should be avoided.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

In case of space limitation name(s) of active substance(s) may be stated in Latin (when Estonia is involved) or English (when Estonia is not involved. Combination of Latin/English name(s) with national ones should be avoided.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

In case of space limitation the abbreviation "Lot" may be used to replace national terms. "Lot" should not be used in combination with national terms. It is also acceptable, if batch number is stated without any abbreviation.

7. EXPIRY DATE

In case of space limitation the abbreviation "EXP" may be used to replace national terms. "EXP" should not be used in combination with national terms. It is also acceptable, if expiry date is stated without any abbreviation.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

In case of space limitation Latin term "Ad us. vet." may be used to replace national terms (decided on a case by case basis). "Ad us. vet." should not be used in combination with national terms.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

In case of space limitation name of active substance to appear under the name of the veterinary medicinal product may be in Latin (when Estonia is involved) or English (when Estonia is not involved) without any brackets or further explanations. Combination of Latin/English name(s) with national ones should be avoided.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

3. EXPIRY DATE

In case of space limitation the abbreviation "EXP" may be used to replace national terms. "EXP" should not be used in combination with national terms. It is also acceptable, if expiry date is stated without any abbreviation.

4. BATCH NUMBER

In case of space limitation the abbreviation "Lot" may be used to replace national terms. "Lot" should not be used in combination with national terms. It is also acceptable, if batch number is stated without any abbreviation.

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

In case of space limitation Latin term "Ad us. vet." may be used to replace national terms (decided on a case by case basis). "Ad us. vet." should not be used in combination with national terms.