

APPLICATION FORM FOR THE COMMON BALTIC PACKAGE PROCEDURE

1. Baltic States

Participating Baltic States * <input type="checkbox"/> EE <input type="checkbox"/> LT <input type="checkbox"/> LV	Reference Baltic State ** <input type="checkbox"/> EE <input type="checkbox"/> LT <input type="checkbox"/> LV
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*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 _____