

December 2018 CMDh/351/2017, Rev.1

Labelling for multi-language packages

Some Member States/groups of Member States provide special guidance on multi-language packages. The CMDh has compiled links to the available information below.

Nordic packages:

 $\underline{https://lakemedelsverket.se/english/product/Medicinal-products/Applications-for-new-authorisations-variations-and-renewals/}$

Baltic packages:

http://www.ravimiamet.ee/en/baltic-package-procedure-0

Belgian packages:

https://www.famhp.be/sites/default/files/content/POST/MAH/155-en-exemptions.pdf