



REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Multilingual Packaging

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Multilingual packages: way forward

- ...Common Baltic Labelling (1999)
- ...Nordic labelling
- ...Regional combinations

- CMDh new approach to multilingual packaging

Best Practice Guide

Availability of medicines!

Multilingual packages: way forward

- Intended for MRP/DCP and national procedures
- Early identification the need for MLP
- Key principles
 - Harmonised PI
 - The same invented name and strength
 - The same legal status

CMDh Best Practice Guide

**SINGLE
ASSESSMENT**
Harmonised text

```
graph TD; A["SINGLE ASSESSMENT  
Harmonised text"] --- B["Full text"]; A --- C["Reduced text"]
```

Full text

Reduced text

Multilingual packages: way forward

- Revise your product list
- Identify the possible candidates
- Contact the NCA



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Aitäh!

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