

The State Agency of Medicines (SAM) recommended checklist* – Addendum No. 1

Preparation of the educational material (EM) document package for agreement

Documents necessary for submission to SAM

- Copies of documents basing on which the educational materials are prepared and submitted
 - EC decision and the relevant annexes of the decision
 - CHMP documents
 - RMP version reflecting the planned appropriate risk minimisation measures
- EM draft in Latvian
- EM in English
- Updated version of the summary of Product Characteristics and Package Leaflet
- Cover letter

Information to be indicated in the cover letter:

- Justification of EM preparation and submission
- List of documents included in the EM package
- EM target audience
- EM distribution plan in Latvia
- Contact information (e-mail address, phone number) of the EM submitter (contact person for pharmacovigilance issues at national level, marketing authorisation holder or authorised person)
- List of documents attached to the cover letter

* The checklist is intended for the facilitation of the preparation of educational material document package, it is not necessary to submit the checklist itself to SAM.