**Checklist recommended by the State Agency of Medicines (SAM)**

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 in MS WORD format
* EM in English
* 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