**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 [ ]