Checklist for EM submission recommended by the State Agency of Medicines (SAM)

Documents required for submission to the State Agency of Medicines (SAM)

1. **Copies of documents justifying EM preparation and distribution:**
   - EC decision and relevant appendices of the decision ☐
   - CHMP documents ☐
   - RMP version, reflecting the relevant risk minimisation measures ☐

   EM in Latvian in MS WORD format:
   - All of the EMs intended for healthcare professionals ☐
   - All of the EMs intended for patients ☐
   - If an updated of a previously approved EM is submitted, only partially amending the previously approved EM, the EM sections amended as a result of the regulatory procedure must be submitted separately ☐

2. **EM in English** ☐

3. **Cover letter** ☐

The cover letter must include the following information:

4. **Justification for EM preparation and distribution (naming the justifying documents)** ☐
5. **List of documents included in the EM package, indicating version numbers** ☐
   - If an update of a previously approved EM is submitted, indicate a list of documents with version numbers amended as a result of the regulatory procedure, as well as a list of the remaining unamended EMs with version numbers, ☐
6. **Target audience and distribution plan for EM in Latvia** ☐
7. **E-mail address, phone number of EM submitter (MAH's national level contact person for pharmacovigilance issues)** ☐