Recommendations for agreement on the additional risk minimisation measures with the State Medicines Control Agency of Lithuania

Documents/information required for submission to SMCA

A. General information:

- Rationale for and objectives of the aRMM ☐
- For a new marketing authorisation, estimation date of introduction of the product to the market ☐
- The contact details of the marketing authorisation holder and, if applicable, another organisation to which it has subcontracted the submission (with the names and e-mail addresses of the contact persons) ☐
- Completed checklist ☐

B. Reference documents: ☐

- The regulatory procedure which has led to the need of the aRMM with supportive documents (e.g. European Commission decision, CHMP opinion, approved/updated risk management plan (RMP)) ☐
- The most recently approved summary of product characteristics (SmPC) and patient information leaflet (PIL) ☐
- RMP, reflecting the relevant aRMM ☐

C. Additional risk minimisation measures:

- Draft aRMM in text format (word) in the Lithuanian language ☐
- In case of a modification of aRMM: track-changed documents in text format (word) ☐
- Complete script of the video material, if applicable ☐
- Screenshots of the website where aRMM will be published online, as well as the URL (direct link) that will be used for this purpose ☐

D. Cover letter intended for HCPs in Lithuania ☐

E. Dissemination plan ☐

F. Follow-up activities ☐