Submission rules before mandatory use:

- There is **no change** to the existing submission rules for submissions to NCAs
- Submission to PSUR Repository is recommended for all PSURs (also non pilot products/supplementary information)

CAPs:

- To the European Medicines Agency – submission through eSubmission Gateway/ Web Client including XML delivery file created in the PSUR Repository user interface
- Follow CAP Dossier Requirements document for NCA submissions for countries not yet using the Common Repository

Submission rules:

NAPs:

Mixed CAP/NAP PSUSA procedure:

- To all Member States in which the medicinal product has been authorised - (refer to Requirements for submissions for Periodic Safety Update Reports (PSUR) for MRP, DCP and National Products (NAPs))
- To the PRAC Rapporteur (refer to Requirements for submissions for Periodic Safety Update Reports (PSUR) for MRP, DCP and National Products (NAPs)
- To the European Medicines Agency – submission through eSubmission Gateway/ Web Client including XML delivery file created in the PSUR Repository user interface.

Submission rules:

NAPs:

NAP/NAP PSUSA procedure:

- To all Member States in which the medicinal product has been authorised - (refer to Requirements for submissions for Periodic Safety Update Reports (PSUR) for MRP, DCP and National Products (NAPs))
- Lead Member State appointed for the procedure (even if the product is not authorised in that Member State) (refer to Requirements for submissions for Periodic Safety Update Reports (PSUR) for MRP, DCP and National Products (NAPs))
- To the European Medicines Agency – submission through eSubmission Gateway/ Web Client including XML delivery file created in the PSUR Repository user interface.