ANNEX IV

CONDITIONS OF THE MARKETING AUTHORISATION

The National Competent Authorities, coordinated by the Reference Member State, shall ensure that the following conditions are fulfilled by the Marketing Authorisation Holders:

- Conduct a drug utilisation study (DUS) to monitor the effectiveness of the risk minimisation measures. The protocol and the timelines of the DUS should be provided to the RMS within one month of the commission decision concluding this referral procedure.

- Circulate the DHPC agreed upon with the CHMP, in accordance with the agreed communication plan.

- Shorten the PSUR cycle to an annual submission