Written comments from the Ministry of Health of the Republic of Latvia on concept paper submitted for public consultation: Delegated act on the principles and guidelines of good manufacturing practice for active substances in medicinal products for human use

Ministry of Health of the Republic of Latvia welcomes and supports the proposal of Commission regarding implementing measures on EU-wide rules for the importation of active substances.

Consultation item No. 1 – We agree, that EU rules of GMP (Eudralex Vol. 4, Part II of GMP guidelines) should be taken into account.

Consultation item No. 2 –We agree with the Commission's proposal.

Consultation item No. 3 – We agree with the Commission's proposal. But we would like to note, that communication channels for suspension/withdrawal of authorizations in third countries should be established as from consultation document. Currently it is not clear whether it will be communicated through Rapid Alert system or by alternative means.

Consultation item No. 4 – We agree with the proposal to use existing mechanisms in order to optimally use available resources and to avoid duplication.

Consultation item No. 5 – We would like to take the opportunity to raise our concerns regarding interpretation of requirements of Article 46b(2) of Directive 2001/83/EC, particularly wording „active substances shall only be imported if, *inter alia*, the active substances are accompanied by a written confirmation from the competent authority of the exporting third country which, as regards the plant manufacturing the exported active substance, confirms that the standards of good manufacturing practice and control of the plant are equivalent to those in the Union". Currently it is not clear, what information should be provided in written confirmation with regards to proper identification of „active substance [manufacturing] plant" and how detailed this information should be – site address, building/workshop numbers, equipment as it is possible for some third country plants to have several manufacturing workshops/lines with different degree of compliance. It would be advisable to provide guidance or clarification regarding level of detail of information to be included in this confirmation.