DELEGATED ACT ON THE PRINCIPLES AND GUIDELINES OF GMP FOR ACTIVE SUBSTANCES IN MEDICINAL PRODUCTS FOR HUMAN USE

Response of the Czech Republic to the Concept Paper submitted for public consultation

1. Extension of the Directive on GMP for medicinal products to active substances

Consultation item No 1: Do you agree with this appraisal and approach? Please comment.

Yes, we agree that Directive 2003/94/EC should be amended and extended to active substances; however, we assume that detailed guidance will continue to be provided through the Commission guideline in Eudralex – Volume 4, Part II (ICH Q7).

2. Adaptation of regulatory requirements of Directive 2003/94/EC to active substances

Consultation item No 2: Are there other aspects which should be considered? Please comment.

For the active substance manufacturers it would be appropriate to define requirements for education and practice of a person authorised to release intermediates and API mentioned in 2.18 of the Eudralex guideline – Volume 4, Part II (by analogy to qualified person).

Consultation item No 3: Do you consider this list complete? Please comment.

No additional comments.

Consultation item No 4: Do you agree with this specific point? Do you consider that other provisions specific to active substances should be added?

Under point 16 a new obligation is proposed for API manufacturers "to make ensure that the starting material is sourced from the premises claimed by the manufacturer of the starting material". However, there is no further clarification as to how this obligation should be fulfilled. We assume that the only option is to perform an audit at the manufacturing site of the starting material, which would result in a considerable burden for the API manufacturer. It is therefore proposed to limit this obligation only to important starting materials; the importance should be assessed in line with a formalised risk management system.

3. Other issues

Consultation item No 5: Please comment on section 3. Please raise any other issues or add any other comments you wish to make which have not been addressed in the consultation items set out above.

Taking into account the average duration of legislative process on the national level we consider the proposed periods too short and we propose extension of time limits to 12 months for transposition and 18 months for application of the delegated act.