European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

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Strasbourg, 17/04/2012

Dear sirs,

Please find hereunder EDQM's comments to 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"

Consultation item N° 1
Extension of the Directive on GMP for medicinal products to active substances: Based on EDQM's experience in the assessment of applications for Certificates of suitability to the monographs of the European Pharmacopoeia and related GMP inspections, we fully support the appraisal and approach described in the concept paper.

Consultation item N° 2
Adaptation of regulatory requirements of Directive 2003/94/EC to active substances: From our point of view, there are no other aspects that would need to be considered.

Consultation item N°3
Provisions in Directive 2003/94/EC that would need to be amended: We fully agree that both articles 1 and 2 of Dir. 2003/94/EC need to be amended. In addition, the following other provisions specific to active substances need to be amended:

- article 3(2): reference to EU GMP for active substances
- article 5 "Compliance with marketing authorisation" should be reworded to take account of active substances
- article 10(3): the need to validate new manufacture or important modifications of a manufacturing process should also apply to active substances
- article 11(4): keeping samples should also apply to active substances
- article 13 complaints/product recall should also apply to active substance

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Consultation item N°4

Other provisions on active substances that could be added to Directive 2003/94/EC : Regarding the proposal to add obligation that the active substance manufacturer has to verify that the starting material is indeed produced on the premises claimed by its manufacturer: this specific requirement is important and it would be worth to broaden it, underlining the need that compliance with the approved specification, approved route of synthesis and manufacturing site are checked by the customer (including accuracy and veracity of data/information provided). It would also be worth extending the word "starting material" to "intermediate", with a need to provide a definition for the latter. More generally, an increased awareness of their respective responsibility is a key element for the manufacturer of API and their customers that would merit being emphasised in the Directive.

Consultation item N°5

Date of application of the delegated act: nine months after publication: The proposed application date provides manufacturers of active substances and medicinal products with sufficient time to implement any new or amended provisions of the Directive.

Yours sincerely,

Dr Susanne KEITEL
Director