European Commission
DG Sanco/Pharmaceuticals
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April, 20th 2012

Response of the Bogin, the Netherlands
To the CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION
Sanco.ddg1.d.6(2012)73176
DELEGATED ACT ON THE PRINCIPLES AND GUIDELINES OF GOOD MANUFACTURING PRACTICE FOR ACTIVE SUBSTANCES IN MEDICINAL PRODUCTS FOR HUMAN USE.

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

- The Bogin supports the extension of the scope of Directive 2003/94/EC to active substances as a means
  - to enhance coherence of the regulatory setting and
  - to emphasise the need for Good Manufacturing Practices (GMP) to apply to both medicinal products and active substances in a similar fashion

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

- For the sake of clarity, the Bogin recommends that GMP for active substances and medicinal products is addressed in separate chapters, even if it triggers the repetition of some part of the text.

Justification: It would facilitate enforcement by avoiding the definition of duties and responsibilities of API manufacturers and suppliers to be defined positively rather than as exceptions to the duties and responsibilities applying to FP manufacturers.

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

- Atypical actives and active substances used in pharmaceutical development (laboratory work) should be specifically excluded of the scope of this directive and clarification that the importation requirements, as introduced in art 46b2, should not apply.

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

- The Bogin supports the inclusion of obligations for API manufacturers
  - To allow MAH/medicines manufacturer to take full responsibility for the medicinal product and the quality and quality control of the active substances
    - e.g. QP declaration requirements (art 8.3ha)
    - e.g. API supply chain management (EU GMP guide – Chapter 5 – Production - ongoing revision)
    - e.g. API outsourced activities (EU GMP guide – Chapter 7 – outsourced activities – ongoing revision)

- To ensure that where applicable, active substances shall only be exported to the EU
  - when EU importation rules are met (art 46b2) and;
  - when EU importers are officially registered in the EU competent authorities registry (art 52a).

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.

The Delegated Act should not create any new requirement which would introduce differences in the rules for API GMP which have been harmonised with other regions through ICH efforts (ICHQ7A).