European Commission
DG Sanco/Pharmaceuticals
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Response of the Ministry of Health, Welfare and Sport, 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.

Directive 2011/62/EU ("Falsified Medicines Directive") of 08 June 2011 introduces a number of requirements aimed at strengthening the supply chain for medicinal products. This may lead to EU-specific requirements relating to Good Manufacturing Practice (GMP) for Active Pharmaceutical Ingredients (API). There is a concern that creation of standards other than those already in GMP part II and ICH Q7A would add confusion to API management expectations across regions.

Our view is that the GMP and storage and distribution principles for APIs already established in EU GMP Guide Part II, and consistent with ICH Q7A should be formally adopted by the European Commission as currently written as the basis for GMP under the Delegated Act required under Article 1(7). As regards storage and distribution principles for APIs as described in the Falsified Medicines Directive Article 1(7), these are adequately covered under the part II guidance set out in the GMP rules and those elements of that guidance should be adopted as the guidelines required under Article 1(7).

If it is considered that the standards for API GMP and storage and distribution principles need strengthening, we propose that this should be achieved through the ICH process so as to ensure that the standards across the ICH regions remain aligned. It is recognised however that this may be a lengthy process and could lead to delays in implementing the Falsified Medicines Directive proposals, consequently adoption of the Part II requirements for GMP, storage and distribution is recommended, at least initially.

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

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

Consultation item No 4: Do you agree with this specific point? Do you consider that

other provisions specific to active substances should be added?

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.

In line with the transposition timeline in Directive 2003/94/EC, the time limit for transposition would be 6 months after publication of the delegated act at the latest. The date of *application* of the delegated act and the national laws transposing it would be set later than the date of transposition at nine months after publication of the delegated act.

Is it possible to provide adequate transition periods in consultation with stakeholders?