Unit SANCO/D/6,
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Brussels

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BY POST AND EMAIL TO SANCO-PHARMACEUTICALS-D6@EC.EUROPA.EU

UK comments on the European Commission's draft template for the written confirmation for active substances imported into the European Union

Dear Sir, Madam,

Please find below the United Kingdom's response to the consultation on the "draft template for the written confirmation for active substances imported into the European Union for medicinal products for human use." In summary, our views are that:

- It is not clear from the draft template or the consultation document how the specific active substances will be identified (for example by the use of common names, IUPAC nomenclature, CAS identifiers, InChI).

- Annex 5 of the WHO Technical Report Series, No. 908, 2003, recommends that GMP certificates have a defined period of validity, becoming invalid if site activities change or the site is no longer considered to be GMP compliant. We suggest that the same principle is applied to the draft template, and offer the following text for consideration:

  > "This written confirmation remains valid until *[date]*. It becomes invalid if the activities and/or categories referred herein are changed or if the site is no longer considered to be in compliance with GMP."

- We notice that the draft template specifically refers to regular, repeated inspection of active substance manufacturers. Since Member States will not be required to subject active substance manufacturers on their territory to regular and repeated inspection, we have concerns that Article 46b(2)(ii) places a substantially greater duty on third country Competent Authorities than that placed on Member States through Article 111(1)(1b).

I would also like to take this opportunity to again express the UK's concerns about the potential consequences of the new requirements for verification of compliance with GMP for active substances imported from third countries which is currently an obligation placed on holders of manufacturing authorisations. The new EU legislation places requirements on competent authorities of third countries to confirm that sites manufacturing active substances comply with GMP. In recent discussions with

third country regulators it has become evident to the UK that these regulators either have little or no knowledge of these new requirements or have indicated that they have no plans to comply. We have very serious concerns about the impact that this state of affairs could have for availability of suitably certificated active substances imported into the EU from July 2013. This in turn will impact significantly on the availability of medicines across the EU.

Whilst the UK has concerns about a number or countries, we have specific concerns about India where the regulatory framework is fragmented and contacts with the regulatory authorities are limited. To illustrate our concerns, over one third of UK Marketing Authorisations name an active substance manufacturer in India. If the Indian regulatory system fails to issue the required statements a huge number of products will be denied access to the EU market and to patients which would have a major impact on the supply of medicines and public health.

In summary, it seems clear on current evidence that third countries are not intending to put mechanisms in place that will provide the necessary certification for each manufacturing site, nor are they prepared to apply to the Commission for inclusion on the “list”. In these circumstances the UK believes it is necessary for the Commission to take stock of the likely implications of this issue for continued supplies of medicines within the EU and propose a course of action on behalf of the Union as a whole. I urge the Commission to come up with a practical solution.

Yours sincerely,

Jonathan Mogford
Director of Policy