European Commission
DG Sanco/Pharmaceuticals
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March, 23th 2012

Response of the Ministry of Health, Welfare and Sport, The Netherlands
To the CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION
SANCO/D3/(2011)ddg1.d3. 1438409
IMPLEMENTING ACT ON THE REQUIREMENTS FOR THE ASSESSMENT OF THE REGULATORY
FRAMEWORK APPLICABLE TO THE MANUFACTURING OF ACTIVE SUBSTANCES OF
MEDICINAL PRODUCTS FOR HUMAN USE

Dear Sir or Madam,

We welcome the concept paper submitted for public consultation on the implementing act on the requirements for the assessment of the regulatory framework applicable to the manufacturing of active substances of medicinal products for human use, and would like to thank you for the opportunity to comment.

Herewith our comment on the public consultation.

We agree with the consultation items but we would like to ask your attention by introducing this particular Directive on behalf of the patients who are dependent on the availability of drugs. When the rules are strictly introduced in July 2013 it might be possible that there will be a shortage of certain drugs. What will happen with Active Pharmaceutical Ingredients (APIs) from countries who are not on the EU list of equivalent countries? A great number of products has an API coming from the so called third countries. If the required documentation will not be available in time this will cause production problems. As these

products are already on the market in the EU, I would ask you to consider whether it is possible to introduce a transitional waiver to those APIs coming from third countries that cannot supply the requested documents in time but can establish on a history of good compliance with GMP.

Kind regards,

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