VDC

Association of Firms engaged in Wholesale and Foreign Trade in Drugs and Chemicals

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EU Commission
Unit SANCO/D/6
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Hamburg, 29th May 2012

Public consultation procedure opened 16th April 2012 on the "Draft template for the written confirmation for active substances imported into the European Union for medicinal products for human use"

Ladies and Gentlemen,

the VDC/Drug and Chemical Association is the branch association of specialized and well experienced companies particularly engaged in the importation of active pharmaceutical ingredients into the Community, based in Hamburg/Germany. Our member companies, most of them SMEs, are important suppliers of API to the relevant pharmaceutical industries in the EU.

Our comments and proposals are as follows:

1. Our members **highly appreciate and support** the approach taken by the EU Commission to create a uniform model GMP certificate required for the importation of active pharmaceutical ingredients into the EU. We trust that such a harmonized specimen binding for importers and competent authorities in all EU Member States, will essentially contribute to an increased legal certainty and will promote equal import conditions with a view to all relevant competitors in the EU.

Further on, we believe that the content provided in the a.m. draft document seems to be formally in line with the requirements outlined under Article 46 (2) lit. b (i) to (iii) of Directive No 2001/83/EC as amended by Directive No. 2011/62/EU.

2. **Nevertheless we would like to clearly express our serious concern** that many exporting/ producing countries might probably **not be willing or unable** to issue such written confirmations in the manner stipulated by Art. 46b (2) and reflected in the draft document. In this case, API importation into the Community might be seriously **jeopardized.**

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Against this background, **we strongly recommend and appeal** to the EU Commission

a.) to **make every effort to ensure** in bilateral negotiations that third countries affected by this legislation are duly informed about the relevant Community requirements , and that competent government authorities in the API exporting/producing countries accept to issue such written confirmations beginning with the implementation date mentioned under Art. 2 (2)lit a of Directive No 2011/62/EU, i.e. **2nd July 2013;**

b.) in such negotiations, **to appeal to and encourage** the relevant governments particularly in important API producing countries such as **India and PR China**, to urgently working towards procedural rules and national regulations which allow a smooth issuance of such new GMP certificates/ written confirmations by the local inspection authorities;

c.) to already now **consider a postponement** of the implementation date if the progress of such negotiations should not be sufficiently promising.

From the view of our importing members, this is an issue of **highest practical concern.** As to our present knowledge based on the information received from our member companies which are in close and regular contact with their suppliers/API manufacturers in the countries of origin, there are obviously **no current preparation measures /implementation efforts** giving rise to assume that the system might work by 2nd July 2013!

3. In context with the new GMP certification scheme there are further problems of high practical importance which need to be considered and resolved **in due time before entry into force** of the new system**.** Particularly we would like to draw your attention to the fact that

a.) there may be third country government authorities such as FDA which are reported **not to issue** GMP certificates in the scheme provided for by Directive 2011/62/EU , so a procedure should be in place to allow further importation of API , particularly considering that the alternative procedure (list of third countries to be established under new Article 111b of Directive 2001/83/EC) , with a view to these third countries concerned, will most probably not be implemented before 2nd July 2013;

b.) there should be a clear signal from the Commission that well- established standards of Good Manufacturing Practice applied in third countries , such as e.g. " Schedule M" in India , are accepted as " **at least equivalent**" in the meaning of the new GMP certificate form even if their requirements may not be fully identical with the EU GMP Standards for the production of API;

c.) the Commission should consider an adequate validity date /expiry date of the GMP certificate, reflecting the needs of practice. It must be taken into consideration that e.g. in PR China, as one of the most important API production countries, GMP certificates regularly will not be re-issued before the expiry of a **five years** validity period;

d.) difficulties for importing companies will arise in the particular case of **herbal substances and herbal preparations** including essential oils if due to an advanced production step after primary processing, the substance is no longer under the relevant Guidelines on Good Agricultural and Collection Practice but already under GMP production rules. Particularly due to the large number of local producers in the third countries of origin it must be **seriously doubted** whether local authorities will be able to adequately inspect such sites and to issue GMP certificates as requested under Art. 46 b (2) of Directive 2001/83/EC. Thus we appeal to the Commission to

consider specific solutions on this issue in order to **allow further importation** of plant material qualifying as active substance for use in pharmaceutical products.

4. In practice, GMP certificates (and this will consequently also apply to the new format of written confirmations once issued after due inspection of the production site), are regularly issued by the competent authority as one **signed original certificate** handed to the producing company. On the other hand (this at least is being practiced in Germany where GMP certificates for API have to be presented at the border inspection since several years) **copies** are only accepted if attested/authenticated by a relevant public authority or body in the country of origin. In order to avoid any costly and over-bureaucratic procedure, it should be assured that – for the purpose of importation into the Community- **a simple copy of the written confirmation will be accepted** by the customs authorities in the EU Member States.

5. GD SANCO is kindly asked to take our concerns and suggestions into consideration. Our association is of course willing to **support the Commission with all required information** and would of course **highly appreciate to present our concerns in a personal dialogue** with representatives of the EU Commission.

Yours sincerely,

Lutz Düshop

Managing Director

DRUG - AND CHEMICALS ASSOCIATION /
DROGEN -UND CHEMIKALIENVEREIN