AESGP
Association Européenne des Spécialités Pharmaceutiques Grand Public
Association of the European Self-Medication Industry
Europäischer Verband der Arzneimittel-Hersteller

AESGP comments on the EC Draft Template for the written confirmation for active substances imported into the European Union for medicinal products for human use

AESGP represents manufacturers of non-prescription medicines of either chemical or herbal origin at European level. It counts 29 national associations and 25 associate members. Through its national and associate members, it represents many small and medium-sized companies operating in the self-care sector.

AESGP appreciates the opportunity to take part in this consultation. We have the following remarks on the proposed template:

- The use of footnotes is generally unclear.
  - Footnote 1: we suggest replacing it by a short introductory paragraph at the beginning of the template putting the form into the context of the EU legislation and explaining its objective and essence.
  - Footnote 2: we believe it would be easier that the text be included between brackets next to the line "Manufacturer's license number"
  - Footnote 3: It cannot reasonably be expected that authorities will refer to the WHO certificate to know what needs to be indicated in these fields. In addition the WHO certificate seems to refer to medicinal products and not substances. Generally, having a clear indication as to what is expected under the column 'category(ies)' and 'activity(ies)' would be crucial.

- The way to express the active substance should be clearly indicated (INN).

- "*the issuing regulatory authority hereby confirms that: the standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU [….]":* we anticipate that some authorities will not be able to sign such statement due to legal considerations as the requirement is not enshrined in their legislation but in a foreign legislation which they have no obligation to abide by. It seems that in such cases the only possibility would be for the country to be added to the list of 'EU-GMP equivalent countries' referred to in Article 111b. This process may however take some time and it seems that some interim measures would be necessary in the interval.

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- "*The authenticity of this written confirmation may be verified with the issuing regulatory authority*": It seems unlikely that customs will have the time to check whether this form is genuine or not and a simple paper is quite easy to forge or falsified. Other systems (like a central database) would need to be put into place to guaranty the reliability of the written confirmation.

- What would the legal force of such written confirmation be? Would it be only for use by customs or also by EU national competent authorities?

- What happens in the case of imported active substances that may not accompanied by a written confirmation after July 2013? We are quite worried that not all third country Authorities are aware of this new requirement and may have a system in place to cope with it by the required deadline. As indicated above, our concerns also stem from the fact that some authorities may not be entitled to sign such confirmation due to their own rules. July 2013 is just a step away and we would urgently ask for transition measures to be considered to address the above cases and enable shipment of actives from third countries to the EU pending a system of written confirmation is properly set up in those exporting countries or that the country makes it to the EU list of 'equivalent countries'.

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