MINISTERIO
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E IGUALDAD

agencia española de
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DIRECCIÓN DE LA
AGENCIA ESPAÑOLA
DE MEDICAMENTOS Y
PRODUCTOS SANITARIOS

COMMENTS TO THE DRAFT TEMPLATE FOR THE WRITTEN CONFIRMATION FOR ACTIVE SUBSTANCES IMPORTED INTO THE EUROPEAN UNION FOR MEDICINAL PRODUCTS FOR HUMAN USE PUBLIC

SUBMITTED BY THE AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS (AEMPS), SPAIN

We welcome this initiative from the European Commission that might help the implementation of these new controls on active substances importation.

Entry into force of Article 46b(2) may bring with it supply problems if the exporting countries fail to fulfill the requirement of issuing the written confirmation accompanying each active substance. This is particularly important because countries that are major exporters to the EU, namely China and India, are not currently in a position as to be included in the list elaborated by the Commission in accordance with Article 111b of Directive 2001/83/EC.

We would like to point out our concerns about the possibility that these countries do not accept to issue these written confirmations, which would lead to a great increase in the performance of international inspections that will be very difficult to deal with, considering the current inspection resources of National Competent Authorities (NCA) that are also facing other additional tasks arisen from this Directive.

Thus we consider very appropriate this initiative from the Commission, as it may contribute to reduce the potential negative impact of the Article 46b(2) in the supply of active substances.

Having said that, AEMPS would like to submit the following comments for consideration:

- **Site address:** regarding to point (1) of the annex, we think that sometimes it could be important to provide a more detailed information about the manufacturing plant, including the identification the building in which the active substance is manufactured. We have recently received a non GMP compliance certificate affecting only to one building of one site but not to the others which had the same address.
- **Categories and activities:** in relation with the categories, we consider that a list should be elaborated according to the active substance manufacturing process (sterile/non sterile/biological origin /chemical synthesis...) from which the issuing authority could select the appropriate term. Similarly, another list should be prepared for the activities performed in the site.
- The sentences about the commitment of the issuing authorities to inform EU authorities comes from the text of the Directive. In relation with the third sentence *('In the event of findings...)* it does not cover other cases not strictly related to non-compliance e.g. cases were the plant has ceased all or part of its activities, or the regulatory surveillance on this site is no longer taking place so we propose to add a sentence to this paragraph:

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU. ***If the activity of the plant ceases completely or partially (regarding some of the active substances listed above), this information will be supplied to the EU.***

- **Issuing authorities:** in some third countries it is not clear who is the regulatory authority competent to issue such written confirmation (e.g. in China, India inspections can be

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performed by local/district, regional or national authorities), and a list of competent authorities per country would be very helpful with regard to the verifications of the validity of written confirmation.

- **Validity of the written confirmation:** this document confirms that the site is subject to regular inspections, including the active substances listed in the table. However, it not should be relied upon the validity of such statement (and of the written confirmation) indefinitely. This confirmation should bear a validity period, so that the issuing authority can renew the confirmation in all its terms. Also it could be very useful having the date of the last inspection.

One last organizational comment. With regard to the verifications of the authenticity of these written confirmations maybe it would be helpful to organize some coordination at EU level in order to avoid the repetition of the same document verifications on the 27 NCA.

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