Comments on the Draft Template for the Written Confirmation for Active Substances Imported into the European Union for Medicinal Products for Human Use.
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Consultation Item	Comment / Rationale	Proposal
General Comments	Since co-existence of multiple formats for the written confirmations to be issued by the various non-EU API exporting countries would be a source of highly undesirable administrative work and possibly a source of delays and misunderstanding, EFCG basically welcomes the planned implementation of a *harmonised* EU template. In general, however, EFCG believes that the written confirmation as to Article 46b(2)(b) does, by far, *not* constitute the best solution to ensure GMP compliance of active substances imported into the EU, especially originating from certain Asian countries. Doubts are deemed justified how such confirmations can be issued by authorities of third countries which themselves do not fulfill the prerequisites to be included on the list of equivalent countries as to Article 111b ? While the European Commission has in the meantime issued a concept paper on the "*Requirements for the Assessment of the Regulatory Framework*" of non-EU API exporting countries, this consultation paper on the written confirmations does not at all describe the requirements to be complied with by the third country authority issuing such written confirmations stating compliance with the EU GMPs for APIs (!). Having said this, the detailed comments on the draft template further below shall be considered as EFCG's view on the "third-best" solution. As to EFCG's known position the actual "waiver", Article 46b(4), would constitute the desirable option (or best alternative to the Article 111b list) whereas the written statements should be used in exceptional cases only (e.g. in case of Asian sites/affiliates of EU API manufacturers that are run according to global company standards complying with the EU GMPs).	Early discussion of the template as well as its use in practice between the EU and the concerned third countries is strongly recommended.

Annex	EFCG considers the draft template annexed to the Commission consultation paper as substantially appropriate, both as to form and content, in connection with the provisions of Article 46b(2)(b) of Directive 2001/33/EC. **<u>Applicability of the template</u>** The term "**category(ies)**" in the table is not self-explaining. In the template (second paragraph of confirmations), "unannounced inspections" are mentioned. Since such inspections are not normally carried out by the EU Competent Authorities, and in any case, the EU Inspectorates have the right to accede the premises, we suggest this to be removed. It is stated that findings related to non-compliance should be supplied by the exporting third countries to the EU. There should be a clear procedure how such information will be communicated, and in particular it should be clarified which person/organisation in the EU would have to be contacted. "*The authenticity of this written confirmation may be verified with the issuing regulatory authority*": there should be clarification as to when and how this verification may be carried out, to reduce the risk of unforeseen delays or impediments to the importation of active substances. **<u>Functioning of the written confirmation process</u>** There is the possibility that a significant percentage of active substance used by European manufacturers of medicinal products would be subject to the written confirmation procedure. Therefore, it is in the best interest of the Community that there is a transparent and functional implementation of the legislative requirements for this procedure. For instance, - It is not clear if this template is meant to be completed only once for each production site or to be renewed for each shipment and/or batch? - If intended for single use only, can copies of the written confirmation be used, or should each shipment contain originals? The latter situation would not adequately work in practice for high volume products. - In case the written confirmation may be used for multiple batches or shipments, there should be a certain period of validity, as per the WHO Model Certificate. To require a	A definition of "**category(ies)**" should be given. Delete "and unannounced". Establish detailed procedure on provision of non-compliance findings by exporting third country. The Commission should describe precise details and procedures as to how the written confirmation process should work. Include clarification on single/multiple use of the written confirmation and the use of copies. It is suggested that the original written confirmation have a validity of at least three years from inspection, a

	repeated issuance of a new confirmation by the third country authority for each and every shipment is not only in contrast with the WHO Model, but will inevitably lead to problems unrelated to quality of the active substance. - There may be situations in which the exported APIs can be (or will be) used for both human and veterinary use, but that this is not yet known when exporting the drug substance. Active substance exported to the EU should be accompanied by the written confirmation. EFCG is most concerned about the manner in which the written confirmations may be subjected to control. What the Falsified Medicines Directive was *not* intended to do was create a barrier to entry of active substances into the EU, by creation of a bureaucratic process which would substantially delay product importation for reasons completely unrelated to GMP. We would like to suggest, in fact, that there is a risk that customs officials might not have the necessary means for being able to determine (i) whether or not the goods being imported are an active substance, (ii) if they are coming from a country not on the list of GMP equivalency, and (iii), whether or not the confirmation letter has all necessary elements and applies to the particular active substance and exporter. Furthermore, there are EFCG members with API manufacturing sites in several countries, including China. EFCG is specifically concerned with the implementation of this draft template in China. It is EFCG's concern that manufacturing sites in China do not have the authority to require Chinese authorities to provide the necessary written confirmation, regardless of the specific template used, in order to comply with the import of APIs into Europe. **<u>Exceptions</u>** Because of the close relationship between Articles 46b(2)(b) and 46b(4) of the Directive, it is appropriate that the latter also be commented on in this public consultation, and dealt with by appropriate instruments. So as to maintain a common economic treatment throughout the EU, we would propose that any waiver made by a Member State be automatically applicable in all Member States.	term reflected in the same WHO Model Certificate. Please clarify how to handle this situation? In order to assist with such verifications and to minimize the possibility of counterfeit written confirmations, we suggest that the written confirmations be evaluated and authenticated by a competent EU authority and stored in a database, allowing access to the appropriate authorities for the written confirmation procedure. The list of confirmed manufacturing sites and active substances will be generated based on these documents and should be available to the competent authorities so that it will be unnecessary to attach the documents to every shipment to be checked at entry into the EU. Hence the Article 46b(2)(b) provisions could be fulfilled even more efficiently by having each shipment accompanied by a reference (number) in respect of the confirmation stored in the aforementioned database.

	Furthermore, we would like to suggest that the spirit and objectives of the Directive would be met by having the waiver of Article 46b(4) apply not only in cases where a Member State has carried out a GMP inspection, but also where other competent authorities have done so. We believe that the waiver option could be dealt with in a more flexible manner, with possible acceptance of GMP certificates from MRA partner countries, also when the MRA does not include APIs, from countries included in the Article 111b list, and maybe also GMP Certificates from PIC/S member countries. Such a solution would allow continued availability of medicinal products even when the time and available resources of Member State inspection authorities might not have allowed this.	