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Comments to
DRAFT TEMPLATE FOR THE WRITTEN CONFIRMATION FOR ACTIVE SUBSTANCES IMPORTED INTO THE EUROPEAN UNION FOR MEDICINAL PRODUCTS FOR HUMAN USE

1. **Principle problem in the draft written statement**

   According to Article 2.4 of TBT Agreement, where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations. As we all know, GMP guidelines on API established by The World Health Organization (WHO) is effective and appropriate for the fulfillment of the legitimate objectives pursued. EU should respect WHO effort in this regard but not require certifying the GMP level of the imported APIs only equivalent to that in the EU. The EU requirement is obviously against WTO/TBT agreement.

2. **Points need further explanations in the Draft**

   a) EU indicates that the draft template is based on, and in conformity with, the Model Certificate of Good Manufacturing Practices of WHO. Please give more details on where and how the EU colleagues have taken reference to the WHO model certificate.
   b) As for the specific content of the draft, the second item is *Manufacturer's License number*. Please make it clear which it is. Number of Manufacture License issued by China's SFDA, China's GMP Certificate number, or that of GMP Certificate issued by EMA?
   c) The draft does not specify whether the written statement is issued based on each consignment, product or just company.
   d) The draft does not mention about the period of validity of the written statement.
   e) EU has no clear explanation on which substances are included in the API. Does it include active substance in intermediate and food supplements? We suggest making it clear about the specific range of the said APIs.
   f) In practice, there are many chemical substances listed into the same Customs tariff code. As a result, it is difficult for the Customs officials to make correct judgment on which chemical substance should be supervised as APIs. We suggest EU colleagues take this point into consideration to make the draft more practical at the stage of Customs.