Dear Sir/Madam,

Please find enclosed Ranbaxy's comments on the consultation paper DRAFT TEMPLATE FOR THE WRITTEN CONFIRMATION FOR ACTIVE SUBSTANCES IMPORTED INTO THE EUROPEAN UNION FOR MEDICINAL PRODUCTS FOR HUMAN USE.

1. What will be the validity of this certificate [issued by Local authority]?
2. Whether batch no. of API required to be mentioned or only API name is sufficient ?
3. Can this statement be issued for multiple APIs ? If new API is to be added, whether this can be added in the same certificate or new certificate will be required ?
4. Whenever product moves from in-house status to Ph. Eur. status, whether certification needs be reissued by local authority ?
5. Point 2 of statement should be changed from "Manufacturer's licence number" to Manufacturer's licence number/Authorisation for manufacture reference" as initially instead of manufacturing license, other approvals are given by local agencies as per the procedures.
6. The sentence "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" should be changed to "In the event of critical findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU".
7. If there are more than one manufacturing license available from the same manufacturing site (as different APIs can be made at the same site), whether certification can be clubbed in the single certificate mentioning manufacturing license number against Active Substance name.
8. Whether this certificate is applicable for Excipients also being exported to EU Market. If yes, then category will be mentioned as "Not Applicable".

We remain at your disposal for any additional information.

KR

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EU Regulatory Affairs Director

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