To: Concerned Person at EDQM/EU

Subject:

Comment on ' written confirmation for active substances imported into the European Union(EU) for medicinal products for human use in accordance with article 46b(2)(b) of directive 2001/83/EC'

Dear Sir,

We have gone through the recent draft guidelines on the above issue. We have following comments to make –

1. Many companies who are already supplying to EU have WHO certification. Therefore having one more additional certification will add to more paper work.
2. There are already many certification and declaration. This is an additional burden on the company. Companies already have regular audit from regulatory agencies/customer to verify the GMP compliance.
3. Is this declaration required only once for a product? Or is it required during every consignment?
4. There are many controlling competent authorities in each country. It should be specified who is the signing authority.
5. This certification should be exempted for companies/products which already have CEP/EU GMP/USFDA certification.
6. In view of all the above, we feel this is unnecessary certification for an API/active substance to be shipped to EU. Therefore we request you to reconsider this decision of mandatory certification. You can instead consider customer audit compliance/WHO GMP certification as a requirement for shipping the material to EU.

Thanking you

Yours truly

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