Mr. Brendan Cuddy
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EMA
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The Netherlands

Aligned with and support by AnimalhealthEurope and

European Industrial Pharmacists Group (EIPG)

Letter on behalf of GMDP IWG from 9 December 2024 to interested parties

09 January 2025

Dear Mr. Cuddy

We appreciate and would like to express our thanks for the letter of 9 December sent to the interested parties by the inspectors working group on the risks related to potentially expiring GMP certificates by the end of 2024.
The letter of 9 December is intended to address the import of finished or partially manufactured medicinal products from third country manufacturers with "date-lapsed" GMP certificates.

The validity of GMP certificates will not be automatically extended beyond the end of 2024. The source for valid GMP certificates is the EUDRA GMDP data base which to our understanding makes publicly available current and valid GMP certificates. To avoid repeated enquiries would it not be preferable for GMP certificates, which the supervisory authorities believe cannot be extended in their validity or be replaced by a new one to be removed by 1 January 2025 to avoid any misinterpretation?

Under current marketing authorisation procedures, a "valid" GMP certificate is a pre-requisite for the granting of a Marketing Authorisation or variation to add a new medicinal product manufacturer. Valid GMP certificates in addition are required for customs clearance and physical importation of medicinal products managed under the responsibility of the MAH or MIAH.

We are pleased to have confirmation that a "valid" GMP certificate is not a pre-requisite for demonstrating the ongoing compliance status of a site and that information from suitable audits is equally appropriate for the purpose.

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We seek clarification on the above with regard to veterinary medicinal products as art. 94(5) of Regulation (EU) 2019/6 appears to be explicit and inflexible on this point.

We nevertheless consider that the use of audits cannot override the withdrawal of a GMP certificate or any specific restrictions placed on a GMP certificate. We consequently agree that the status of GMP certificates must be monitored using the EUDRA GMDP database.

We are concerned that the wording of the letter of 9 December, which details specific tasks for the Qualified Person in person as this could add to misunderstanding of the role of the Qualified Person and their responsibilities. It would have been more appropriate to address all of the mentioned tasks directed to the Qualified Person, in particular those highlighted with bullet points, to the Manufacturing/Import Authorisation Holder who holds overall responsibility by way of art. 46f of Directive 2001/83/EC.

We acknowledge that the Qualified Person acts as an agent for the Manufacturing/Import Authorisation Holder in securing compliance with GMP and should therefore among many things ensure that the status of GMP certificates and audit outcomes are monitored to prevent the certification of batches when a certificate has been withdrawn, or where certification would be contrary to any specific restrictions on a GMP certificate, or contrary to audit findings.

To avoid questions about the validity of a marketing authorisation we believe it is the responsibility of the Marketing Authorisation Holder to engage in dialogue with the relevant supervisory authority regarding the validity of relevant GMP certificates and plans for re-inspection.

Thank you very much for taking our comments into consideration. We would be very happy to receive a reply from GMDP IWG.

Your´s sincerely

Ulrich Kissel

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