EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 December 2024
EMA/INS/GMP/574803/2024

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Director
Regulatory, Drug Development and Manufacturing
EFPIA (European Federation of Pharmaceutical Industries and Associations)

**Sent via e-mailEMA/INS/GMP/574803/2024**

Dear Par,

**Subject: GMP/GDP certificates validity date extension**

I am replying to your letter of 2th November with regards to the extended validity of GMP certificates. The GMDP IWG has considered and discussed the points raised in your letter during their plenary meeting of 25 – 27 November 2024.

The extension of the validity date of GMP Certificates was a temporary regulatory flexibility implemented by the GMDP IWG in 2021 during the public health emergency due to Covid-19. The GMDP IWG subsequently agreed to continue the extension of the validity dates of GMP Certificates until the end of 2024.

The IWG took into account that the national competent authorities have resumed the scheduling and conduct of on-site inspections and national competent authorities are extending EU GMP Certificates based on distant assessments and reliance upon information from international partners. These measures have had the effect that that backlogs have been reduced and are expected to be resolved in 2025.

Therefore, the GMDP IWG has agreed that there would be no further automatic extension of the validity date and that there is a return to the normal practice concerning the validity date of GMP Certificates that was in place before the onset of the public health emergency. National Competent Authorities will decide case by case whether any additional extension to a GMP certificate is applicable. This means that the issuing national competent authority should be consulted where there is any question concerning the content of a GMP certificate. This instruction is also included as a footer in the EUDRAGMDP Database.

The GMDP IWG does not anticipate that this measure will lead to shortages for the following reasons:

- The Qualified Person (QP) has the ultimate responsibility for ensuring that each batch of medicinal product is manufactured in accordance with GMP. The Qualified Person may take into consideration a GMP certificate issued by a national competent authority, however this should be only one element of the overall assessment undertaken by the QP. A Qualified Person can base their decision on other evidence of GMP compliance that are available to them, for example audits conducted by themselves or by third parties. Manufacturers should ensure that their risk based audit schedules take into account the validity date of GMP certificates so that there are up to date audits available.

- A Qualified Person should consult the issuing authority if the validity date of the GMP Certificate has passed. Issuing authorities will promptly deal with such consultations.

Marketing authorization holders are also advised to plan submission of variations for marketing authorisation of medicines imported into the EU/EEA that lead to a change of importer and consequentially to a change of the supervisory authority[1] (that may be different to the authority that has issued a GMP Certificate for the third country site(s)). The GMDP IWG would recommend that these planned changes to the importer are coordinated 2-3 months in advance with the authority that issued the last GMP certificate, and with the new supervisory authority so that any issues with the GMP certificate validity date can be resolved prior to submission of any variation. For centrally authorized products, the EMA Inspections Office may be consulted for this purpose.

In conclusion, we hope this information addresses the concerns of the interested parties and remain open to discuss should additional issues arise. I will write to you separately about the Interested Parties meeting for 2025.

[1] In the case of medicinal products imported from third countries, the supervisory authorities for imports shall be the competent authorities of the Member State or Member States that granted the authorisation provided for in Article 40(3) of Directive 2001/83/EC and Article 88 (1) (c) of Regulation 2019/6 to the importer, unless appropriate agreements have been made between the Union and the exporting country to ensure that those controls are carried out in the exporting country and that the manufacturer applies standards of good manufacturing practice at least equivalent to those laid down by the Union.

Yours sincerely,

Cuddy James Brendan

Digitally signed by Cuddy James Brendan
Date: 2024.12.09 16:37:21 +01'00'

Brendan Cuddy,

Chairman GMDP IWG.

Quality and Safety of Medicines Department

European Medicines Agency.

Cc

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Dr. Marie-Hélène Pinheiro
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Active Pharmaceutical Ingredients Committee (APIC), AnimalhealthEurope, European Compliance Academy, European QP Association (ECA/EQPA), European Federation of Pharmaceutical Industries and Associations (EFPIA), European Industrial Pharmacists Group (EIPG), International Plasma and Fractionation Association (IPFA), International Society for Pharmaceutical Engineering (ISPE), Medicines for Europe, Parenteral Drug Association (PDA), and Plasma Protein Therapeutics Association (PPTA).