EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CMDh
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

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Q&A on impact of EU-USA Mutual Recognition Agreement on marketing authorisation applications and relevant variations

Q1: How does the EU-USA Mutual Recognition Agreement (MRA) affect marketing authorisation applications or variations?

A1: To date all marketing authorisation applications that include a manufacturing site located in a third country with whom the European Union has a Mutual Recognition Agreement (MRA) or similar arrangement, must be accompanied by a GMP certificate issued by the authorities of the country in question. This also applies to variations relating to a change to add such manufacturers.

However, in the case of manufacturing sites located in the USA, a Certificate of Pharmaceutical Products (CPP) should be submitted. These export certificates are valid for 2 years once issued and conform to the format recommended by the World Health Organization's (WHO), Certificate of Pharmaceutical Product scheme.

The US exporter should apply to FDA for the Export Certificate and the EU marketing authorisation applicant or holder should ensure that a certificate is submitted for all US sites listed in the relevant EU submission.

Alternatively, if pre-existing GMP certificates issued by an EEA authority are available these can continue to be used. Certificates shall be regarded as valid for this purpose if, unless stated otherwise on the certificate, no more than three years have elapsed since the date of the inspection stated.

There is no change in the case of submissions pertaining to products out of the scope of the MRA or not yet included.

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Q2: I plan my submission, which includes manufacturing sites for the medicinal product located in the USA, before November 2017, when the Mutual Recognition Agreement is expected to become operational, but the submission will not be approved until after this date. What evidence am I expected to provide on the GMP status of these manufacturers?

A2: 1st November 2017* is the earliest date that the agreement enters into force. When it enters into force EU authorities can formally recognise Export Certificates issued by FDA for manufacturers located in the USA for products within the MRA scope. In the meantime, existing submission requirements continue to apply i.e. evidence that the medicinal product manufacturer is registered with FDA together with GMP certificates issued by an EEA authority.

If no EEA GMP certificate is available, applications will not be invalidated for that reason alone. During the assessment procedure a risk-based decision will be made on a case-by-case basis, taking account of the status of the MRA, whether a pre-authorisation inspection is triggered for other reasons and, if so, whether the inspection will be done by an EEA authority or FDA.

*Provided certain conditions are met as laid down in the agreement

Q3: Where can I find more information on the MRA?

A3: Further information can be found here and will be updated as major developments occur. In addition, submission guidance impacted by the MRA will be identified and updated as soon as possible.