EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 May 2022
EMA/INS/169000/2022
Human Medicines Division
Quality and Safety of Medicines Department

Public Consultation Concerning The Physical Attendance And The Location Of Personal Residency Of The Qualified Person

Consultation procedure: 13 May 2022 – 13 June 2022

1. Background

The COVID-19 pandemic required manufacturers and importers of medicinal products and regulatory authorities to operate under business continuity mode, impacting the standard way of working.

As a result it was necessary to publish guidance on regulatory expectations and flexibility during the COVID-19 pandemic to minimise risks of shortages while ensuring that the high standards of quality, safety and efficacy of medicines made available to patients in the EU were maintained. This guidance has been developed in cooperation between the European Commission, the Coordination group for Mutual recognition and Decentralised procedures – human ("CMDh"), the Inspectors Working Group, the Coordination group for Mutual recognition and Decentralised procedures – veterinary ("CMDv") and EMA. This guidance published by the European Commission is available here:

https://ec.europa.eu/health/system/files/2021-09/guidance_regulatory_covid19_en_0.pdf

and here for medicines for veterinary use:

https://ec.europa.eu/food/system/files/2021-11/ah_vet-med_covid-19_qandas.pdf

The guidance recognised that the work of the Qualified Person required adaptation, permitting remote batch certification when on site presence was not possible.

The GMDP Inspectors Working Group is currently reviewing the flexibilities concerning requirements for the QP's physical attendance at the authorised manufacturing site when performing batch certification or batch confirmation on a routine basis, outside of an emergency situation. A set of Question and Answers has been drafted reflecting on the conditions which should apply and the appropriate technical requirements to facilitate remote certification and confirmation. This set of Questions and Answers also addresses the location of personal residency of the QP.

The ultimate responsibility for the interpretation of EU legislation is vested on the European Court of Justice and therefore the content of this document is without prejudice to a different interpretation that may be issued by the European Court of Justice.

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2. Consultation procedure

The purpose of this consultation is to collect relevant information from stakeholders to help the GMP/GDP Inspectors Working Group to finalise this question and answer guidance on remote batch certification / confirmation by the QP on a routine basis.

Comments on the proposed text (see pages 3 and 4 of this document) should be submitted no later than 13 June 2022 by email to ADM-GMDP@ema.europa.eu.

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Questions & Answers Concerning The Physical Attendance And The Location Of Personal Residency Of The Qualified Person

These Questions & Answers apply to EU/EEA QP certification or QP confirmation, as described in EU GMP, and specifically in Annex 16. It is applicable to the manufacture and importation of human and veterinary medicinal products as well as investigational medicinal products.

Q1. Is remote batch certification / batch confirmation by the QP (i.e. when not at the authorised site address specified on the MIA) allowed on a routine basis?

A1. Remote batch certification / batch confirmation could be allowed if accepted by the national competent authority where the authorised site is located. Some competent authorities may have specific requirements regarding the location of QPs or the implementation of remote batch certification / batch confirmation on a routine basis. Manufacturers and QPs should ensure that they comply with any applicable local requirements.

Q2. Where remote QP certification / confirmation is allowed on a routine basis, what conditions should apply?

A2. The following points should be taken into consideration:

- It is a prerequisite that the QP certification/confirmation is carried out in full accordance with EU legislation and EU GMP guidelines
- QP Certification / Confirmation should take place within the EU/EEA in all cases.
- QPs are obliged to maintain their knowledge in relation to the products, manufacturing processes and pharmaceutical quality system. QPs also need to be satisfied that their ongoing reliance on the relevant pharmaceutical quality system is well founded. Therefore, the time spent by QPs at the authorised site should be commensurate with the risks related to the processes at the authorised site.
- Where remote QP certification is employed on a routine basis, it must be described and controlled within the pharmaceutical quality system and relevant detailed site procedures should be in place. In Member States where use of contract QPs is permitted, the technical agreement between the authorisation holder and the QP should also mention remote certification / confirmation, and specify the circumstances under which the QP must attend the site.
- The QP should have electronic access to all information, deemed necessary according to Annex 16, when making a decision on batch certification / confirmation. The QP should physically attend the manufacturing site where there are specific issues or cases which cannot be satisfactorily clarified or resolved through electronic means.
- The MIA holder should provide the required facilities to enable QPs to carry out their functions remotely. This includes the equipment, access to software

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applications (e.g. manufacturing executions systems, electronic batch record system, laboratory information systems etc.) and support required to enable electronic batch certification / confirmation and completion of the batch certification register remotely. IT systems used for remote batch release should comply with requirements of EU GMP Annex 11.

- All actions carried out by the QP at the remote location should be contemporaneously available for inspection by the competent authorities at the authorised batch release site. It is the responsibility of the MIA holder to guarantee that a) only the QP has access to the batch certification / confirmation function and batch register, b) that data being transferred (data in motion) are complete and unchanged and c) an appropriate system for electronic signatures is in place. The MIA holder should be able to demonstrate during inspection how often the QP is on site, and their active participation in monitoring the quality system. QPs must be able to demonstrate that they are fulfilling their wider duties in accordance with Annex 16.
- Compliance with the above points should be included as part of the Self Inspection process at the authorized manufacturing site where QP certification / confirmation takes place.

Q3. Is the QP required to be a resident in the Member State where the authorised site is located?

A3. Some Member States may have specific national requirements.

Q4. What are the technical requirements for the remote access and the signature used for batch certification / confirmation?

A4. The risk with regard to IT-security and data integrity for remote access is higher than for access within the controlled environment at the authorised site. Minimum requirements depend very much on the state of technology employed and should comply with the guidance in Annex 11. The following requirements should be adapted to reflect current technological developments. Technical and organisational solutions which are not listed below but result in an appropriate level of security may also be acceptable:

- Prior to transfer of any hardware off-site it should be identified and inventoried. It should be ensured that the hardware remains complete and up-to-date. The hard disk should be encrypted and any ports that are not required should be disabled.
- For QPs who may be using a virtual private network, security parameters on the network operating system, database and application level should be configured appropriately to avoid unauthorised access.
- Recognised industry standards should be used for authentication and authorisation (e.g. two-factor or multifactor authentication). There should be no use of shared authentication information, and automatic expiry of authentication information should be employed.
- Data in motion should be secured by strong transport encryption (e.g. TLS 1.2, https)
- The MIA holder is responsible for putting organisational controls (e.g. assignment of individual privileges) and technical controls in place to ensure that only the QP is able to perform remote batch certification / confirmation.