EudraGMDP

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Welcome to EudraGMDP

EudraGMDP is the name for the Union database referred to in article 111(6) of Directive 2001/83/EC and article 80(6) of Directive 2001/82/EC. It contains the following information:

- Manufacturing and import authorisations
- Good Manufacturing Practice (GMP) certificates.
- Statements of non-compliance with GMP
- GMP inspection planning in third countries

In addition the following new information is required in the database for the first time in 2013. As data transfer from national systems can be complex, it will take several months for all the National Competent Authorities to complete the uploading of this data.

- Wholesale Distribution Authorisations
- Good Distribution Certificates (GDP)
- Statements of non-compliance with GDP
- Registration of manufacturers, importers and distributors of active substances for human use located in the EEA

Almost all information uploaded into the database is available to the general public. National Competent Authorities are able to exclude some information from public view. This includes information of a commercially sensitive or personal nature, inspection planning and information that may need to be restricted in the interests of security.

Read-only access to EudraGMDP

Users are advised that since inspections of manufacturers of active substances are based on risk, some active substance manufacturers may not be in possession of a GMP certificate issued by an EEA authority. The absence of a GMP certificate should not be understood as meaning that the active substance manufacturer in question does not comply with GMP.

EMA is not responsible for the contents of the database. Any questions on its content should be addressed to the relevant National Competent Authority.

Digitally signed by Moraru Grigore
Date: 2023.10.09 09:19:35 EEST
Reason: MoldSign Signature
Location: Moldova

The EudraGMDP database is maintained and operated by the EMA. Access to the general public is granted in order to enhance availability of information related to the EMA mandate. The content of the database is provided by the National Competent Authorities (NCA) of the EEA. For this reason, the EMA accepts no responsibility or liability whatsoever (including but not limited to any direct or consequential loss or damage it might occur to you and/or any other third party) arising out of or in connection with the information on this database. Any questions about the content should be addressed to the relevant NCA. Please click here to get list of NCA's.

Due to the restrictions caused by COVID-19, the period of validity GMP and GDP certificates issued by EEA authorities is automatically extended until the end of 2023, except where clarifying remarks in the document state otherwise. Manufacturers, and importers and distributors must continue to comply with GMP/GDP and all other legal obligations. On-site inspections are conducted where and when possible. Competent authorities reserve the right to perform risk based supervision of sites by either on-site inspections or distant assessments and, based on the outcome, may continue to issue, withdraw or restrict GMP certificates, as appropriate.

For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI.

Documents issued by UK authorities up to and including 31 December 2020 remain available for consultation in EudraGMDP. However, they are no longer included or updated from 1 January 2021, with the exception of the documents pertaining to sites located in Northern Ireland.

As of 28 January 2022, the source of organisational data will change. Additional information and instructions are available on EMA's website