Notes on Marketing Authorisation Procedures During the COVID-19 Pandemic

The COVID-19 pandemic affects all areas of life. For this reason, medicines authorities in the EU and the pharmaceutical industry will have to adjust their working processes and regulatory activities to the new requirements. The European Commission (EC), the European Medicines Agency (EMA), and the heads of the European agencies (HMA) have assessed the situation and agreed on modes of action to advance regulatory flexibility. Regulatory procedures for medicines designed to treat COVID-19 patients will be simplified and accelerated to react efficiently to the new developments.

In addition to the joint EC/EMA/HMA document „Questions and answers on regulatory expectations for medicinal products for human use during the COVID-19 pandemic" the Co-ordination Group (CMDh) for Mutual Recognition Procedures (MRP) and Decentralised Marketing Procedures (DCP) for human medicines has adopted a Practical Guidance Document containing answers and questions that supplements the notes from the European Commission. The arrangements of the Practical Guidance shall also be applicable for purely nationally authorised medicines within the responsibility of the Paul-Ehrlich-Institut subject to Directive 2001/83/EC.

An "Exceptional Change Management Process (ECMP)" is described in the Guidance in No. 4 for medicines, which are rated as essential for the treatment of COVID-19 patients. In addition, for these medicines, reference is made to the possibility that these products may be marketed without national translations of the product information texts, if necessary (cf. No. 6) or to perform expedited MRP or RUP procedures (cf. No. 7).

Questions concerning these arrangements will be answered by Unit EU Co-operation Biomedicinal Products atf the Paul-Ehrlich-Institut.

Adopting exceptional rules and expediting procedures on a case-to-case basis is possible based on the Act for the protection of the population in an epidemic situation of national extent (G*esetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite*)" of 27 March 2020 and the Regulation governing the guarantee of products for medical care during the epidemic caused by the corona virus SARS-CoV-2 *(Verordnung zur Sicherstellung der Versorgung der Bevölkerung mit Produkten des medizinischen Bedarfs bei der durch das Coronavirus SARS-CoV-2 verursachten Epidemie*, MedBVSV). This can also concern medicines not subject to Directive 2001/83/EC such as blood components for the transfusion and haematopoetic stem cell preparations. The MedBVSV is expected to come into force soon.

Contact

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Further informationen

- European Commission, EMA, HMA: Notice to Stakeholders: Questions and Answers on Regulatory Expectations for Medical Products for Humane Use During the COVID-19 Pandemic
- CMDh: Procedural guidance during COVID-19 pandemic
- Act for the protection of the population in the event of a pandemic situation of national extent (German only)
- BMG Regulation governing the guarantee of products for medical care (German only)