



CMDh developments regarding marketing authorisations processed through decentralised procedures

Minutes of the CMDh meetings of 25-27 January 2022

On 18 March 2022, the amended minutes of the CMDh meetings held in January 2022 were published. In these meetings, the CMDh discussed, among other issues, a case regarding an appeal against a Dutch marketing authorisation (MA) which had been processed through a decentralised procedure (DCP) with Netherlands as Reference Member State (RMS). The minutes include some fairly interesting remarks.

National MAs processed through DCPs

MAs granted by national agencies, even when processed through a DCP, are considered national administrative acts and, as such, are subject to the rules of the country that granted the MA. According to the CMDh, if the MA granted in the RMS is challenged and annulled, this does not automatically entail the annulment of the MAs granted in the Concerned Member States (CMS). The outcome of a judicial procedure against a MA granted by a given Member State (even if it is the RMS) shall only affect the MA of this Member State; and such outcome shall not automatically impact on the MAs granted in other Member States.

Applications filed by regulatory consultants

Another hot topic regarding this matter is how to handle cases where a regulatory consultant firm applies for a MA with the aim of subsequently transferring it to a pharmaceutical company, which will ultimately market the product as the MA holder (MAH). The CMDh understands that these entities must not be

considered the same company as the future MAH for the purposes of Article 8(3)(l) of Directive 2001/83/EC. According to this provision, any applicant of a MA must report on other applications, approvals and refusals that the same applicant has dealt with in other Member States. The applicant is not required to provide information on approvals and applications made by other entities.

The European Commission has issued several guidelines regarding how to interpret the term "same applicant". According to these, companies of the same group and/or licensees should be considered the "same applicant". The position of the CMDh is that regulatory consultant firms should not be considered the "same applicant" as the ulterior MAH.

Locus standi to appeal against MAs in the Netherlands

It follows from the minutes of the CMDh that a third party challenged the Dutch MA. In the Netherlands, competitors have locus standi to challenge third party's MAs and affected parties may request to be considered as an interested party in the administrative procedure for the granting of the MA.