Luxembourg, 15 July 2021

**PRESS RELEASE 10/2021**

**Judgment in Case E-7/20 *Criminal proceedings against M and X AG***

# DEFINITION OF MEDICINAL PRODUCT AND AUTHORISATION REQUIREMENT FOR WHOLESALE DISTRIBUTION

In a judgment delivered today, the Court answered questions referred by the Princely Court of Appeal (*Fürstliches Obergericht*) regarding the interpretation of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ("the Directive").

The case in the main proceedings concerns criminal proceedings against M and X AG, who were sentenced for having traded in medicinal products abroad without the requisite national authorisation.

The referring court sought guidance on the interpretation of "medicinal product" and of "wholesale distribution of medicinal products" within the meaning of the Directive. Furthermore, the referring court asked for guidance on the compatibility of the national legislation with Article 31 EEA et seq. and whether it is of relevance if the product in question does not require authorisation in another EEA State.

The Court held that the determination of whether a product is a "medicinal product" must be made on a case-by-case basis, taking into account the factors set out in point 2 of Article 1 of the Directive, such as the product's presentation or pharmacological, immunological or metabolic properties. Furthermore, the Court held that where a medicinal product has been sold at the wholesale and/or retail level in EEA States, it must be considered as having been intended to be placed on the market in EEA States for the purposes of the Directive. The Court further held that a medicinal product is prepared industrially or manufactured by a method involving an industrial process if its preparation or manufacture involves an industrial process characterised, in general, by a succession of operations, which may be mechanical or chemical, in order to obtain a significant quantity of a standardised product. As to the definition of "wholesale distribution of medicinal products" within the meaning of point 17 of Article 1 of the Directive, the Court found that the activity of procuring, supplying and exporting medicinal products came within the scope of that definition even though a wholesale distributor has not physically handled those products.

With regard to a national measure subjecting the activity of wholesale distribution of medicinal products to an authorisation requirement in conformity with Article 77(1), the Court found this to be compatible with EEA law. Regarding the difference in classification as a medicinal product between EEA States, the Court held that the fact that a product is not classified in one EEA State as a medicinal product does not have an influence on whether the competent authorities of another EEA State may classify it as a medicinal product in accordance with the Directive.

The full text of the judgment may be found on the Court's website: www.eftacourt.int.