EFTA COURT

Request for an Advisory Opinion from the EFTA Court by Fürstliches Obergericht dated 2 June 2020 in criminal proceedings against M and X AG

(Case E-7/20)

A request has been made to the EFTA Court dated 2 June 2020 from Fürstliches Obergericht (Princely Court of Appeal), which was received at the Court Registry on 10 June 2020, for an Advisory Opinion in criminal proceedings against M and X AG on the following questions:

1. **Must burnout infusions with the combination of substances determined here be qualified as "medicinal products" within the meaning of Article 1(2) of Directive 2001/83/EC?**

   (a) **If the answer to this question is in the affirmative: Does in the present case the manufacture, supply and administration of the burnout infusion constitute a placing on the market within the meaning of Article 2(1) of the Directive?**

   (b) **If the preceding questions are answered in the affirmative: Do the burnout infusions constitute medicinal products which, within the meaning of Article 2(1) of the Directive, are prepared industrially or manufactured by a method involving an industrial process?**

   (c) **Are the burnout infusions due to the method of their manufacture covered by the exception provided for in Article 3(2) of the Directive?**

2. **What must be understood under "wholesale distribution" within the meaning of Directive 2001/83/EC as amended by Directive 2011/62/EU and what criteria must be fulfilled for this?**

3. **In the event that the above Directives are, in principle, applicable to the present case:**

   Is it compatible with the freedom of establishment pursuant to Article 31 et seq. EEA and, moreover, must it be regarded as proportionate, if

commercial trading in medicinal products of the kind in question carried out from the State of residence of a natural or legal person within the EEA or between an EEA State and a third country, without these medicinal products coming in contact the territory of the State of residence, is subjected to a statutory authorisation obligation, whose infringement may be penalised as a misdemeanour by a custodial sentence of up to six months?

4. **Does it have an influence on the answer to the above questions if in another EEA State (here: EU Member Germany) the medicinal products in question do not require authorisation?**