EFTA COURT

Request for an Advisory Opinion from the EFTA Court by Oslo tingrett dated 16 June 2014 in the case of Pharmaq AS v Intervet International BV

(Case E-16/14)

A request has been made to the EFTA Court by a letter dated 17 July 2014 from Oslo tingrett (Oslo District Court), which was received at the Court Registry on 23 July 2014, for an Advisory Opinion in the case of Pharmaq AS v Intervet International BV, on the following questions:

1. **Concerning Article 2 of the SPC Regulation, has a product been placed on the market as a medicinal product in the EEA before it has been granted marketing authorisation in accordance with the procedure for administrative authorisation laid down in Directive 81/851/EEC (or Directive 2001/82 EEC) when delivery of the product has taken place in accordance with**
   - **(i) "special approval exemptions" granted by the State Medicines Agency to veterinarians and fish health biologists pursuant to Section 3-6 or 3-7 of the Norwegian Regulation of 22 December 1999, alternatively Sections 2-6 or 2-7 of the Norwegian Regulation of 18 December 2009, or**
   - **(ii) what are known as "AR 16 licences" granted by the Irish Department of Agriculture, Food and the Marine pursuant to the Irish Statutory Instrument No 144/2007 European Communities (Animal Remedies) Regulations 2007 part III "Exceptional authorisation", point 16?**

2. **If question 1 is answered in the affirmative, is such a product outside the scope of the SPC Regulation and is an SPC granted on the basis of such a product therefore invalid?**

3. **Concerning the interpretation of Article 2 of the SPC Regulation, should a marketing authorisation granted for a veterinary medicinal product pursuant to Article 26(3) of Directive 2001/82 be deemed to constitute an administrative authorisation pursuant to Directive 81/851 (or Directive 2001/82) within the meaning of Article 2?**

4.
   - **(a) Do special approval exemptions pursuant to Section 3-6 or 3-7 of the Norwegian Medicines Regulations of 1999 (FOR-199-12-22-1559) or Section 2-6 or 2-7 of the Norwegian Medicines Regulations of 2009 (FOR-2009-12-18-1839) constitute valid authorisation to place the product on the market as a medicinal product within the meaning of Article 3(b)?**

(b) **Do special approval exemptions pursuant to Section 3-6 or 3-7 of the Norwegian Medicines Regulations of 1999 (FOR-199-12-22-1559) or Section 2-6 or 2-7 of the Norwegian Medicines Regulations of 2009 (FOR-2009-12-18-1839) constitute a first authorisation to place the product on the market as a medicinal product in Norway within the meaning of Article 3(d)?**

5. **When the medicinal product is a virus vaccine, can the scope of protection under the SPC cover not only the specific strain of the virus that is included in the medicinal product and covered by the basic patent, but also other strains of the virus that are covered by the basic patent?**

   In answering this question, is it of significance whether

   a) **such other strains have an equivalent therapeutic effect to the virus strain included in the medicinal product or whether the therapeutic effect is not immediately equivalent?**
   b) **a medicinal product based on such other strain will have to be the subject of a separate marketing authorisation with requirements for documentation of safety and effect?**

6. **If an SPC has been granted with a product definition that is not strictly limited to the specific strain of the virus authorised to be placed on the market as a medicinal product,**

   a) will such an SPC be valid, or
   b) will the SPC be valid; such, however, that the scope of protection pursuant to Article 4 does not extend beyond the specific virus strain authorised to be placed on the market as a medicinal product?