CIRCULAR ON THE DATE OF THE AUTORISATION TO PLACE THE PRODUCT ON THE MARKET

This circular establishes the rules applicable before the Intellectual Property Office for determining the date of the authorisation to place a medicinal product or a plant protection product on the market. The purpose of this circular is to simplify and harmonize the different authorization regimes. As from 01/06/2016, these provisions apply to all current and future SPC applications.

The concept of 'the date of the authorisation to place the product on the market' occurs in Articles 7 and 13 of the Regulation (EC) n° 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products and in Articles 7 and 13 of the Regulation (EC) n°1610/96 of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products.

Article 7, §1, stipulates that: « The application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market [as a medicinal product] [as a plant protection product] was granted. ».

Article 13, § 1, stipulates that: « The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years. ».

The date taken into account for the different authorisations to place the product on the market (MA) is the following:

1. **Date of MA for a medicinal product granted by the European Commission**

   The date of the MA is the date of notification of the decision granting the marketing authorisation. This date is published in the Official Journal of the European Union.

2. **Date of MA for a medicinal product granted by the Federal Agency for medicines and health products (FAMHP)**

   The date of the MA is either the starting date of the validity period of the marketing authorisation, or the date of signature of the MA, if this date is later.
3. Date of MA for a plant protection product granted by the Federal Public Service Health

The date of the MA is either the starting date of the validity period of the marketing authorisation, or the date of signature of the MA, if this date is later.

The circular of 22 September 2003 on the SPC grant procedures for medicinal products and for plant protection products is repealed at the date of 1 June 2016.

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