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Calculation of the SPC-term Clarification by CJEU

Calculation of the SPC-term – referral to CJEU

In accordance with Article 13 of the SPC-Regulation, the term of an SPC is calculated based on the “date of the first authorization” to place a product on the market.

Up until recently, the calculation was based on the actual decision date of the authorization. In November 2013, UKIPO changed this practice relying on the date of notification (which typically takes place a few days later).

In light of the discrepant approaches, the Higher District Court in Vienna has now referred the case to the CJEU with the following questions:

1. Is the date of the first authorization to place the product on the market in the Community under Article 13(1) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6th May 2009 concerning the supplementary protection certificate for medicinal products determined under Community law, or does the Regulation refer to the date on which the authorization takes effect according to the law of the respective member state?

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2. If the CJEU affirms that the date under question 1 is determined under Community law: which is the relevant date – that of the authorization or that of the notification?

Should the CJEU confirm the position of the UKIPO, then the term of an SPC for a centrally approved product may be expected to be modestly increased by a few days.

A positive decision should also affect the calculation of the deadline for applying for an SPC as provided for in Article 7 of the SPC-Regulation.