EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES

Brussels, 27 April 2018

NOTICE TO STAKEHOLDERS

WITHDRAWAL OF THE UNITED KINGDOM AND EU LEGISLATION IN THE FIELD OF SUPPLEMENTARY PROTECTION CERTIFICATES FOR MEDICINAL PRODUCTS AND PLANT PROTECTION PRODUCTS

The United Kingdom submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. This means that, unless a ratified withdrawal agreement[1] establishes another date, all Union primary and secondary law will cease to apply to the United Kingdom from 30 March 2019, 00:00h (CET) ('the withdrawal date').[2] The United Kingdom will then become a 'third country'.[3]

Preparing for the withdrawal is not just a matter for EU and national authorities but also for private parties.

In view of the considerable uncertainties, in particular concerning the content of a possible withdrawal agreement, stakeholders are reminded of legal repercussions, which need to be considered when the United Kingdom becomes a third country.

Subject to any transitional arrangement that may be contained in a possible withdrawal agreement, as of the withdrawal date, Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products[4] and Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products[5] will no longer apply to the United Kingdom. This has in particular the following consequences.

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1 Negotiations are ongoing with the United Kingdom with a view to reaching a withdrawal agreement.

2 Furthermore, in accordance with Article 50(3) of the Treaty on European Union, the European Council, in agreement with the United Kingdom, may unanimously decide that the Treaties cease to apply at a later date.

3 A third country is a country not member of the EU.

4 Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, p. 1.

5 Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products, OJ L 198, 8.8.1996, p. 30.

1. CALCULATION OF DURATION OF SUPPLEMENTARY PROTECTION CERTIFICATES IN THE EU-27

Article 13 of Regulation (EC) No 469/2009 and Article 13 of Regulation (EC) No 1610/96 establish that the supplementary protection certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapses 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 European Union, reduced by a period of five years.[6] [7]

An authorisation to place the product on the market granted by a United Kingdom competent authority as of the withdrawal date will not be considered a first authorisation to place the product on the market in the European Union for the purposes of Article 13 of Regulation (EC) No 469/2009 and Article 13 of Regulation (EC) No 1610/96.

However, an authorisation to place the product on the market granted by a United Kingdom competent authority before the withdrawal date is to be considered as the first authorisation to place the product on the market in the European Union for the purposes of Article 13 of Regulation (EC) No 469/2009 and Article 13 of Regulation (EC) No 1610/96 on the duration of the certificate.[8]

2. APPLICATIONS FOR SUPPLEMENTARY PROTECTION CERTIFICATES AS OF THE WITHDRAWAL DATE IN THE UNITED KINGDOM

As of the withdrawal date, Regulation (EC) No 469/2009 and Regulation (EC) No 1610/96 no longer apply to the United Kingdom.[9]

The website of the Commission (https://ec.europa.eu/growth/industry/intellectual-property/patents/supplementary-protection-certificates_en) provides general information concerning supplementary protection certificates. This page will be updated with further information on the United Kingdom's withdrawal, where necessary.

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[6] They also state that, in any event, the duration of any certificate may not exceed five years from the date on which it takes effect.

[7] This duration of the certificate for medicinal products may be extended by six months in certain cases, in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use (OJ L 378, 27.12.2006, p. 1).

[8] Also for the purposes of Article 3(b) of Regulation (EC) No 469/2009, Article 3(1)(b) of Regulation (EC) No 1610/96 (valid authorisation has been granted), Article 8(a)(iv) (content of the application for a certificate), and Article 11(1)(e) (publication) of those Regulations.

[9] For applications for a supplementary protection certificate submitted before the withdrawal date, the EU is trying to agree solutions with the United Kingdom in the withdrawal agreement. The essential principles of the EU's position on Intellectual property rights are available here: https://ec.europa.eu/commission/publications/position-paper-intellectual-property-rights-including-geographical-indications_en.