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

Brussels, 15 June 2020
REV2 – replaces the notice (REV1)
dated 27 April 2018

NOTICE TO STAKEHOLDERS

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

Since 1 February 2020, the United Kingdom has withdrawn from the European Union and has become a "third country".[1] The Withdrawal Agreement[2] provides for a transition period ending on 31 December 2020.[3] Until that date, EU law in its entirety applies to and in the United Kingdom.[4]

During the transition period, the EU and the United Kingdom will negotiate an agreement on a new partnership, providing notably for a free trade area. However, it is not certain whether such an agreement will be concluded and will enter into force at the end of the transition period. In any event, such an agreement would create a relationship which in terms of market access conditions will be very different from the United Kingdom's participation in the internal market,[5] in the EU Customs Union, and in the VAT and excise duty area.

Moreover, after the end of the transition period the United Kingdom will be a third country as regards the implementation and application of EU law in the EU Member States.

Therefore, all interested parties, and especially economic operators, are reminded of the legal situation after the end of the transition period (Part A below). This notice also

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

2 Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, OJ L 29, 31.1.2020, p. 7 ("Withdrawal Agreement").

3 The transition period may, before 1 July 2020, be extended once for up to 1 or 2 years (Article 132(1) of the Withdrawal Agreement). The UK government has so far ruled out such an extension.

4 Subject to certain exceptions provided for in Article 127 of the Withdrawal Agreement, none of which is relevant in the context of this notice.

5 In particular, a free trade agreement does not provide for internal market concepts (in the area of goods and services) such as mutual recognition, the "country of origin principle", and harmonisation. Nor does a free trade agreement remove customs formalities and controls, including those concerning the origin of goods and their input, as well as prohibitions and restrictions for imports and exports.

explains certain relevant separation provisions of the Withdrawal Agreement (Part B below).

Advice to stakeholders:

To address the consequences set out in this notice, stakeholders are in particular advised to assess the consequences of the end of the transition period in view of this notice.

Please note:

This notice does not address the EU rules on

- medicinal products for human use and veterinary medicinal products;
- plant protection products;
- intellectual property, including aspects of exhaustion of intellectual property rights.

For these aspects, other notices are in preparation or have been published.[6]

A. LEGAL SITUATION AFTER THE END OF THE TRANSITION PERIOD

After the end of the transition period, 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[7] 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[8], no longer apply to the United Kingdom. This has in particular the following consequences:

1. CALCULATION OF DURATION OF SUPPLEMENTARY PROTECTION CERTIFICATES IN THE EUROPEAN UNION

Article 13 of Regulation (EC) No 469/2009 and Article 13 of Regulation (EC) No 1610/96 establish that the supplementary protection certificate is to 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

6 https://ec.europa.eu/info/european-union-and-united-kingdom-forging-new-partnership/future-partnership/preparing-end-transition-period_en

7 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.

8 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.

the date of the first authorisation to place the product on the market in the European Union, reduced by a period of five years.[9] [10]

An authorisation to place the product on the market granted by a United Kingdom competent authority after the end of the transition period 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 end of the transition period 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.[11]

2. APPLICATIONS FOR SUPPLEMENTARY PROTECTION CERTIFICATES SUBMITTED IN THE UNITED KINGDOM AFTER THE END OF THE TRANSITION PERIOD

After the end of the transition period, Regulation (EC) No 469/2009 and Regulation (EC) No 1610/96 no longer apply to the United Kingdom (except as described for in Part B).

B. RELEVANT SEPARATION PROVISIONS OF THE WITHDRAWAL AGREEMENT

Article 60 of the Withdrawal Agreement provides that, after the end of the transition period, Regulation (EC) No 469/2009 and Regulation (EC) No 1610/96 continue to apply in the United Kingdom in respect of pending applications for supplementary protection certificates for medicinal products and for plant protection products (as well as for the extension of the duration of such certificates). Therefore, such pending applications must continue to be processed by the relevant authority in the United Kingdom in accordance with those Regulations.

Pending applications are those submitted to an authority in the United Kingdom before the end of the transition period while the administrative procedure for the grant of the certificate concerned or of the extension of its duration is ongoing at the end of the transition period.

Article 60 of the Withdrawal Agreement also provides that any certificate granted by the United Kingdom following those applications is to provide for the same level of protection as that provided for in Regulation (EC) No 1610/96 or Regulation (EC) No 469/2009.

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[9] 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.

[10] 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).

[11] 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(1)(a)(iv) (content of the application for a certificate), and Article 11(1)(e) (publication) of those Regulations.

The website of the Commission on EU rules on intellectual property (https://ec.europa.eu/growth/industry/intellectual-property/patents/supplementary-protection-certificates_en) provides general information concerning EU legislation applicable to Supplementary protection certificates. These pages will be updated with further information, where necessary.

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