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Legislation

European Union

Brexit and Pharmas

1. On 2 May 2017, the European Commission and the European Medicines Agency (EMA) published a "Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use", which was updated on 29 January 2018 and made available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/05/WC500226603.pdf

This guidance document acts as a reminder that EU law requires that marketing authorisation holders are established in the EU (or EEA) and that some activities must be performed in the EU (or EEA), related for example to pharmacovigilance, batch release, etc. In addition, the Commission and the EMA expect marketing authorisation holders to prepare and proactively screen authorisations they hold for the need for any changes and recalls that the necessary transfer or variation requests will need to be submitted in due time, considering the procedural timelines provided in the regulatory framework. In its readiness to support marketing authorisation holders, the Commission and the EMA also announced the preparation of a series of Q&A.

In fulfilment of the foregoing, the document "Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure" was prepared and published on 31 May 2017. An updated version, published on 23 January 2018, is available at https://ec.europa.eu/health/sites/health/files/files/documents/qa_on_brexit.pdf

2. Also relevant is the fact that on 28 November 2017 the EMA published procedural guidance to help pharmaceutical companies prepare for the United Kingdom's (UK) withdrawal from the European Union (EU). An updated version, published on 29 January 2018, is available at http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/11/WC500239369.pdf

Q&A on Safety Features for Medicinal Products for Human Use

On 30 November 2017, AEMPS published on its website (https://www.aemps.gob.es/ca/industria/dispositivos_seguridad/docs/Q-A-safetyfeatures.pdf) an unofficial translation of the questions and answers document regarding the implementation of the rules on the safety features for medicinal products for human use (Version 8) published by the European Commission earlier

in the month and available at https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/qa_safetyfeature_v8_0.pdf

Judgments and decisions

European Union

Supplementary Protection Certificates and Marketing Authorisations

The Court (Seventh Chamber), in its judgment of 7 December 2017 in Case C-567/16, in response to a request for a preliminary ruling from the High Court of Justice (England and Wales, Chancery Division, Patents Court) in proceedings between Merck Sharp & Dohme Corporation and the Comptroller General of Patents, Designs and Trademarks, has interpreted Article 3(b) of 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 (the SPC Regulation), which provides that a supplementary protection certificate (SPC) is to be granted if, in the Member State in which the application is submitted and at the date of that application, a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (Directive 2001/83).

According to the Court, Article 3(b) of the SPC Regulation is to be interpreted as meaning that an end of procedure notice issued by the reference Member State in accordance with Article 28(4) of Directive 2001/83/EC, before the expiry of the basic patent, as defined in Article 1(c) of Regulation No 469/2009, may not be treated as equivalent to a marketing authorisation within the meaning of Article 3(b) of that regulation, with the result that a SPC may not be obtained on the basis of such a notice.

In addition, Article 10(3) of Regulation No 469/2009 is to be interpreted as meaning that the fact that no marketing authorisation has been granted by the Member State concerned at the time the SPC application is lodged in that Member State does not constitute an irregularity that can be cured under that provision.

Rectification of the Date of Expiry of a Supplementary Protection Certificate

The Court (Second Chamber), in its judgment of 20 December 2017 in Case C-492/16, in response to a request for a preliminary ruling from the Fővárosi Törvényszék (Budapest High Court, Hungary) in proceedings between Incyte Corporation and Szellemi Tulajdon Nemzeti Hivatala, has ruled that:

(1) Article 18 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate (SPC) for medicinal products, read in the light of Article 17(2) of Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a SPC for plant protection products, must be interpreted as meaning that the date of the first authorisation to place the product on the market, as stated in an application for a SPC, on the basis of which the national authority competent for granting such a certificate calculated the duration of the certificate, is incorrect in a situation, such as that at issue in the main proceedings, where the date led to a method for calculating the duration of the certificate which does not comply with the requirements of Article 13(1) of Regulation No 469/2009, as interpreted by a subsequent judgment of the Court.

(2) Article 18 of Regulation No 469/2009, read in the light of recital 17 and of Article 17(2) of Regulation No 1610/96, must be interpreted as meaning that, in a situation such as that set out in point 1 of this operative part, the holder of a supplementary protection certificate may, under Article 18 of Regulation No 469/2009, bring an appeal for rectification of the duration stated in the certificate, provided that that certificate has not expired.

Concerted Practices in the Pharmaceutical Field

The Court (Grand Chamber), in its judgment of 23 January 2018 in Case C-179/16, in response to a request for a preliminary ruling from the Consiglio di Stato (Council of State, Italy) in proceedings between F. Hoffmann-La Roche Ltd, Roche SpA, Novartis AG, Novartis Farma SpA and Autorità Garante della Concorrenza e del Mercato, has interpreted Article 101 of the Treaty on the Functioning of the European Union (TFEU) which, as is well known, prohibits anti-competitive or concerted practices. And it has done so in relation to various issues concerning the pharmaceutical market. Thus, according to the Court, Article 101 TFEU must be interpreted as follows:

(1) A national competition authority may include in the relevant market, in addition to the medicinal products authorised for the treatment of the diseases concerned, another medicinal product whose marketing authorisation does not cover that treatment but which is used for that purpose and is thus actually substitutable with the former. In order to determine whether such a relationship of substitutability exists, the competition authority must, in so far as conformity of the product at issue with the applicable provisions governing the manufacture

or the marketing of that product has been examined by the competent authorities or courts, take account of the outcome of that examination by assessing any effects it may have on the structure of supply and demand.

(2) An arrangement put in place between the parties to a licensing agreement regarding the exploitation of a medicinal product[1] does not fall outside the application of that provision on the ground that the arrangement is ancillary to that agreement.

An arrangement put in place between two undertakings marketing two competing products, which concerns the dissemination to the European Medicines Agency, healthcare professionals and the general public of misleading information relating to adverse reactions resulting from the use of one of those medicinal products for the treatment of diseases not covered by the marketing authorisation of that product, with a view to reducing the competitive pressure resulting from such use on the use of the other product, constitutes a restriction of competition 'by object' for the purposes of that provision.

[1] Concerted practice aimed at reducing competitive pressure on the use of that product for the treatment of given diseases and which is designed to restrict the conduct of third parties promoting the use of another medicinal product for the treatment of those diseases.

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