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Legislation

European Union

SPC Manufacturing Waiver Amendment

On 14 May 2019, the Council of the European Union approved the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products, text that had previously been approved by the European Parliament in its legislative resolution of 17 April 2019. On 20 May 2019, the President of the European Parliament and the President of the Council jointly signed the final text of the legislative proposal and, at the time of writing, only publication in the Official Journal is pending for final adoption.

Regulation (EC) No 469/2009 has thus been amended to introduce a provision according to which a supplementary protection certificate shall not confer protection against: (i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries; (ii) any related act that is strictly necessary for the making, in the Union, referred to in point (i), or for the actual export; (iii) the making, no earlier than six months before the expiry of the certificate, of a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate; or (iv) any related act that is strictly necessary for the making, in the Union, referred to in point (iii), or for the actual storing, provided that such related act is carried out no earlier than six months before the expiry of the certificate.

Amended version of the Q&A document on the interplay between the Clinical Trials Regulation and the General Data Protection Regulation

On 10 April 2019, the European Commission's Directorate-General for Health and Food Safety published an amended version of the Question and Answer document on the interplay between Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data: https://ec.europa.eu/health/sites/health/files/files/documents/qa_clinicaltrials_gdpr_en.pdf

The European Commission takes into account "Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b))" adopted by the European Data Protection Board on 23 January 2019 (Vid. García Vidal, Á., "Tratamiento de datos personales en el marco de ensayos clínicos", & Análisis Farmacéutico, February 2019, https://www.ga-p.com/wp-content/uploads/2019/02/Tratamiento-de-datos-personales-en-el-marco-de-ensayos-cl%C3%ADnicos-1.pdf).

Inclusion of the Republic of Korea in the list of third countries with a regulatory framework applicable to active substances for medicinal products for human use and the respective control and enforcement activities ensuring a level of protection of public health equivalent to that in the Union

In accordance with Article 111b(1) of Directive 2001/83/EC a third country may request the Commission to assess whether its regulatory framework applicable to active substances exported to the Union and the respective control and enforcement activities ensure a level of protection of public health equivalent to that of the Union in order to be included in a list of third countries ensuring an equivalent level of protection of public health.

The Republic of Korea has been included in that list. The inclusion has been made by means of Commission Implementing Decision (EU) 2019/769 of 14 May 2019 amending Implementing Decision 2012/715/EU establishing a list of third countries with a regulatory framework applicable to active substances for medicinal products for human use and the respective control and enforcement activities ensuring a level of protection of public health equivalent to that in the Union. [OJ L 126/70 of 15.5.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D0769&from=EN]

As a result, the list of third countries consists of Australia, Brazil, Israel, Japan, Republic of Korea, Switzerland and the United States of America.

Amendment to the regulation on classification, labelling and packaging of substances and mixtures

OJ L 86 of 28.3.2019 publishes Commission Regulation (EU) 2019/521 of 27 March 2019 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0521&from=EN.

Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State

Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008 (OJ L 91/1 of 29.3.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0515&from=EN) aims to strengthen the functioning of the internal market by improving the application of the principle of mutual recognition and by removing unjustified barriers to trade.

To that end, the Regulation, which applies to goods of any type, lays down rules and procedures concerning the application by Member States of the principle of mutual recognition in individual cases in relation to goods which are subject to Article 34 TFEU and which are lawfully marketed in another Member State, having regard to Article 36 TFEU and the case-law of the Court of Justice of the European Union.

The Regulation also provides for the establishment and maintenance of Product Contact Points in Member States and for cooperation and exchange of information in the context of the principle of mutual recognition.

Amendments to the regulation on cosmetic products

A number of regulations amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products have been adopted. These are the following regulations:

(*a*) Commission Regulation (EU) 2019/681 of 30 April 2019 amending Annex II to Regulation (EC) No 1223/2009, OJ L 115/5 of 2.5.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0681&from=EN

(*b*) Commission Regulation (EU) 2019/680 of 30 April 2019 amending Annex VI to Regulation (EC) No 1223/2009, OJ L 115/3 of 2.5.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0680&from=GA

(*c*) Commission Regulation (EU) 2019/698 of 30 April 2019 amending Annexes III and V to Regulation (EC) No 1223/2009, OJ L 119 of 7.5.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0698&from=EN

(*d*) Commission Regulation (EU) 2019/831 of 22 May 2019 amending Annexes II, III and V to Regulation (EC) No 1223/2009, OJ L 137 of 23.5.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0831&from=EN

Protective measures against pests of plants and temporary derogations in view of official testing, scientific or educational purposes, trials, varietal selections, or breeding

According to Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, Member States may, on application, temporarily authorise the introduction into, the movement within, and the holding and multiplication in their territory of certain pests for official testing, scientific or educational purposes, trials, varietal selections, or breeding. Moreover, Member States may, on application, authorise temporarily the introduction into, and the movement within, their territory of plants, plant products and other objects used for official testing, scientific or educational purposes, trials, varietal selection or breeding.

In this context, the European Commission has adopted Delegated Regulation (EU) 2019/829 of 14 March 2019 supplementing Regulation (EU) 2016/2031 of the European Parliament and of the Council on protective measures against pests of plants, authorising Member States to provide for temporary derogations in view of official testing, scientific or educational purposes, trials, varietal selections, or breeding. This Regulation has been published in OJ L 137/15 of 23.5.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0829&from=EN.

Coordinated control plan with a view to establishing the prevalence of certain substances migrating from materials and articles intended to come into contact with food

The European Commission has adopted Recommendation (EU) 2019/794 of 15 May 2019 on a coordinated control plan with a view to establishing the prevalence of certain substances migrating from materials and articles intended to come into contact with food (notified under document C(2019) 3519). [OJ L 129/37 of 17.5.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019H0794&from=EN]

Judgments and decisions

European Union

Question referred for a preliminary ruling on third party SPCs

The England and Wales High Court (Patents Court) has referred a question to the Court of Justice of the European Union (CJEU) for a preliminary ruling as to whether Regulation (EC) No 469/2009

precludes the grant of a supplementary protection certificate to the proprietor of a basic patent in respect of a medicinal product which is the subject of a marketing authorisation held by a third party without that party's consent. The CJEU will thus give a preliminary ruling on the controversial problem of "third party SPCs". The aforementioned decision of the Patents Court, in Eli Lilly And Company v Genentech, Inc., can be found at: https://www.bailii.org/ew/cases/EWHC/Patents/2019/388.html

Impartiality of the Committee for Medicinal Products for Human Use

In its judgment of 27 March 2019, in Case C-680/16 P, the Court (Fourth Chamber) concludes that the objective impartiality of the Committee for Medicinal Products for Human Use may be jeopardised by the appointment as chief rapporteur in a procedure relating to the application to renew the marketing authorisation for a medicinal product of an employee of the national authority that had previously rejected said application and referred the matter to the Committee.

Referral to the Enlarged Board of Appeal related to plant patentability

Following recent decisions of the Technical Boards of Appeal reported in previous issues of this Newsletter and in a step to restore legal certainty in respect of the patentability of plants and animals exclusively obtained by means of an essentially biological process, on 5 April 2019 the President of the European Patent Office submitted questions to the Enlarged Board of Appeal to clarify the applicable legal framework.

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