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Legislation

European Union

Brexit and medicinal products: New version of the EMA's Q&A document

The European Medicines Agency (EMA) has published a new version (Rev 04), dated 1 February 2019, of the "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", which can be found here: https://ec.europa.eu/info/sites/info/files/medicinal_products_for_human_and_veterinary_use-qa_en.pdf.

Requests for time-limited exemptions so as to continue batch testing medicinal products in the UK after the Brexit date

Although marketing authorisation holders must transfer to the EU, by the withdrawal date, the quality control testing of medicinal products performed in the UK, the European Commission and national authorities are aware that it may be difficult to do so. Thus, on 21 February, the European Commission, with the agreement of the Heads of Medicines Agencies (HMA), published recommendations in this respect (Withdrawal of the United Kingdom and EU rules for Batch testing of medicinal products,

https://ec.europa.eu/health/sites/health/files/files/documents/brexit_batchtesting_medicinalproducts_en.pdf)

The above provide that an exemption to rely on the quality control testing conducted in the UK for the time period strictly necessary and for the specific batches identified may be requested and granted. As recalled in Note MUH 5/2019 published on 5 March 2019 by the Spanish Medicines and Healthcare Products Regulatory Agency ("AEMPS") - entitled 'Requests for time-limited exemptions so as to continue batch testing medicinal products in the UK after the Brexit date' - the following requirements must be met: 1. A batch release site in the EU27/EE29 must be identified by the marketing authorisation holder by the withdrawal date. 2. The batch release site must be supervised by a qualified person established in the EU27 by the withdrawal date. 3. The establishment conducting the quality control testing must be verified by a competent authority of the EU27/EEE29, including on the spot checks. 4. All necessary steps must have been taken to prepare the transfer of the quality control testing site to the EU27/EEA29.

Requests for exemptions must have been submitted by 29 March 2019: centrally authorised medicinal products, to the European Medicines Agency; medicinal products authorised by the European mutual recognition and decentralised procedure, to the reference Member State; and medicinal products authorised by a purely national procedure, to the AEMPS.

Public consultation on the basic principles for the availability of authorised electronic product information ("ePI")

The Heads of Medicines Agencies, in a working group chaired by the Spanish Medicines and Healthcare Products Regulatory Agency, in which the European Medicines Agency and the European Commission participate, has drawn up some basic principles that electronic information of medicinal products for human use must meet as a way to improve the manner in which the information included in the summary of product characteristics and package leaflet reaches patients, carers and healthcare professionals.

The document with these principles, dated 31 January 2019, can be found at the following link: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/electronic-product-information-human-medicines-european-union-draft-key-principles_en.pdf. These principles are open to comments until 31 July 2019.

Entry into force of Commission Delegated Regulation (EU) 2016/161 laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use

On 9 February 2019, the verification of safety features of medicinal products for human use, in accordance with the provisions of Directive 2011/62/EU amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as supplemented by Commission Delegated Regulation (EU) 2016/161, has commenced. These texts set out a system that involves placing a unique identifier and an anti-tampering device on the packaging of medicinal products.

These features shall be included in all packaging of prescription medicinal products, except for those that are excluded because of their low risk. They may also appear on non-prescription medicinal products considering the risk of and the risk arising from falsification.

Commission Delegated Regulation (EU) 2016/161 requires manufacturers, wholesalers and community and hospital pharmacies supplying medicinal products to the public to immediately inform the competent authorities of any tampering or suspected falsification that they detect in the verification of safety features. In order to facilitate such notification, the AEMPS has published instructions drawn up in collaboration with the competent regional authorities, available at https://www.aemps.gob.es/industria/dispositivos_seguridad/notifica-sospechas-med-falsificados/home.htm

Report from the Commission on the application of the competition rules in the pharmaceutical sector (2009-2017)

On 28 January 2019, the European Commission presented to the Council and the European Parliament its Report on "Competition Enforcement in the Pharmaceutical Sector (2009-2017) - European competition authorities working together for affordable and innovative medicines [Document COM(2019) 17 final], available at http://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/report_en.pdf.

This Report provides an overview of how the Commission and the national competition authorities of the 28 Member States have enforced EU antitrust and merger rules in the pharmaceutical sector in 2009-2017.

Generic descriptors and nutrition and health claims on foods

1. According to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, any claim made which states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health is to be considered as a health claim and therefore must therefore comply with that Regulation.

   In addition, according to Article 1(3), a trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food which may be construed as a nutrition or health claim may be used without undergoing the authorisation procedures provided for in that Regulation, provided that it is accompanied by a related nutrition or health claim in that labelling, presentation or advertising which complies with the provisions of that Regulation.

   However, Article 1(4) provides for a possible exemption from the application of Article 1(3) for generic descriptors (denominations) which have traditionally been used to indicate a particularity of a class of foods or beverages that could imply an effect on human health.

2. Pursuant to the foregoing, Commission Regulation (EU) 2019/343 of 28 February 2019 providing derogations from Article 1(3) of Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on food for the use of certain generic descriptors (OJ L 62, 1.3.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0343&from=EN) has been adopted.

Processing of personal data in the framework of clinical trials

The European Commission's Directorate-General for Health and Food Safety ("DG SANTE") submitted to the European Data Protection Board ("EDPB") a request for consultation concerning a

document on "Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR)".

The simultaneous application of both regulations requires some clarification, which is what the document drafted by the European Commission and referred to in the EDPB's "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)" of 23 January 2019 purports to provide. In said Opinion, the EDPB suggests several modifications to the Commission's document in order to reflect alternative legal bases that the processing of personal data may have within the framework of clinical trials.

For more information, see my document "*Tratamiento de datos personales en el marco de ensayos clíni¬cos*", https://www.ga-p.com/wp-content/uploads/2019/02/Tratamiento-de-datos-personales-en-el-marco-de-ensayos-cl%C3%ADnicos.pdf.

Judgments and decisions

European Union

Carve-outs and patent law: generic medicinal product of a reference medicinal product with indications or dosages still patented

In its judgment of 14 February 2019, in Case C-423/17 (*Warner-Lambert Company*), the Court held that making use of the carve-out option (excluding from applications for marketing authorisation of generic medicinal products those indications or dosage forms that are still covered by patent law) the marketing authorisation applicant "thus limits the scope of his application and the competent national authority does not have any discretion in that respect" (para. 43). Furthermore, it is insisted that there must be a correlation between the medicinal product placed on the market and the authorised one, and if a subsequent *carve out* had no effect on the scope of a marketing authorisation for a medicinal product already granted, this would lead to a divergence between the authorised and the marketed version of a medicinal product.

More in depth in the document "El carve out y el Derecho de patentes: Generic drug of a reference drug with indications or dosages still patented", Pharmaceutical Analysis March 2019 (García Vidal).

Are plants obtained by an essentially biological process patentable? A European Patent Office ("EPO") decision reopens the debate

1. The Decision of the EPO's Enlarged Board of Appeal of 25 March 2015, in the cases of Broccoli II (G 2/13) and Tomatoes II (G 2/12), concluded that the exclusion of essentially biological processes for the production of plants in Article 53(b) of the European Patent Convention ("EPC") does not have a negative effect on the allowability of a product claim directed to plants or plant material. And according to the Decision, such a claim is allowable even if the only method available at the filing date for generating the claimed subject-matter is an essentially biological process, or if the claim takes the form of a *product-by-process* claim, and the process of obtaining the plant is essentially biological.

2. This Decision generated a considerable number of criticisms, including in the European Parliament resolution of 17 December 2015 on patents and plant breeders' rights (EP Resolution 2015/2981(RSP)), and in the subsequent Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological invention (Commission Notice 2016/C 411/03).

3. Following the aforementioned Commission Notice, the EPO's Administrative Council decided to exclude from patentability plants and animals obtained exclusively by means of an essentially biological process. To this end, Rules 27 and 28 of the Implementing Regulations to the EPC were amended with effect from 1 July 2017.

4. When the disputes appeared to have ended, the EPO's Technical Board of Appeal 3.3.04, in its written decision in case T 1063/18, decided that the new Rule 28(2), which excludes from patentability plants exclusively obtained by means of an essentially biological process, was in conflict with Article 53(b) EPC as interpreted by the Enlarged Board of Appeal in decisions G 2/12 and G 2/13. Therefore, such a patent cannot be refused.

The decision can be found at http://documents.epo.org/projects/babylon/eponet.nsf/0/426B74FD32463ACEC1258398003EA3F4/$File/T_1063-18_en.pdf

Supplementary protection certificate for a medicinal product and marketing authorisation for a new formulation, protected by a basic patent, of a previously authorised active ingredient

In its Judgment of 21 March 2019 (*Abraxis Bioscience*, C-443/17, EU:C:2019:238) the Court held that Article 3(d) 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, read in conjunction with Article 1(b) of that regulation, must be interpreted as meaning that the marketing authorisation referred to in Article 3(b) of that regulation, relied on in support of an

application for a supplementary protection certificate concerning a new formulation of an old active ingredient, cannot be regarded as being the first marketing authorisation for the product concerned as a medicinal product in the case where that active ingredient has already been the subject of a marketing authorisation as an active ingredient.

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