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Gómez-Acebo & Pombo

Pharma & Healthcare

Ángel García Vidal

Professor of Corporate & Commercial Law, University of Santiago de Compostela

'Academic Counsel', Gómez-Acebo & Pombo

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Legislation and legislative proposals

European Union

Amendments to the regulations on medical devices and on in vitro diagnostic medical devices

Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June[1] amends Regulation (EU) 2017/745 of 5 April on medical devices and Regulation (EU) 2017/746 of 5 April on in vitro diagnostic medical devices.

Firstly, the changes concern the gradual roll-out of Eudamed by extending the deadline for compliance with the obligations and requirements that relate to this database, as the development of the electronic system on clinical investigations and performance studies has been considerably delayed.

Changes are also introduced in relation to the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices.

Similarly, Regulation (EU) 2024/1860 also further extends the transitional periods laid down in Regulation (EU) 2017/746 for devices covered by certificates issued by notified bodies in accordance with Directive 98/79/EC and for devices which are to undergo conformity assessment involving a notified body for the first time under Regulation (EU) 2017/746.

General product safety and health risks

The European Commission has adopted Implementing Regulation (EU) 2024/1740 of 21 June laying down the rules for the application of Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May on general product safety. In particular, the new implementing regulation deals with the modalities for consumers and other interested parties to inform the Commission of products that might present a risk to the health and safety of consumers and for the transmission of such information to the national authorities concerned.

In this respect, it is provided that the Commission will design the Safety Gate Portal to allow consumers and other interested parties to inform the Commission of products that might present a risk to the health and safety of consumers and to provide, among other information, elements identifying the products that might be presenting a risk to the health and safety of consumers; any available data on the supply chain of the product concerned, in particular the economic operator or the provider of an online marketplace through which they have purchased the product and the country of establishment of this economic operator or provider of an online marketplace, and the responsible person for the product; and elements supporting the suspected risk to the health and safety of consumers posed by the product, including where relevant the description and the

[1] *Official Journal of the European Union* no. 1860 of 9 July 2024 (see this ***link)***.

circumstances of the accident and the description of injuries or other harm that have occurred.

Examination of variations to the terms of marketing authorisations for medicinal products for human use

Commission Delegated Regulation (EU) 2024/1701 of 11 March amends Regulation (EC) No 1234/2008 as regards the examination of variations to the terms of marketing authorisations for medicinal products for human use[2].

The objective of the amending regulation is to achieve "a simpler, clearer and more flexible legal framework, while guaranteeing the same level of public health protection". To this end, among the main amendments, it regulates the submission of a single submission of variations to the terms of more than one marketing authorisation ("super-grouping of variations") so as to, as stated in the explanatory notes, "enable marketing authorisation holders to include their purely national marketing authorisation in the super-grouping of variations and to harmonise their purely national marketing authorisations in different Member States".

It also provides for the introduction of variations to change the composition of vaccines in situations of public health emergency, so that where a public health emergency at Union level is recognised, the relevant authorities - or, in the case of centralised marketing authorisations, the Commission - may, where certain pharmaceutical, non-clinical or clinical data are missing, exceptionally and temporarily accept a variation to the terms of a marketing authorisation for a vaccine pertaining to the pathogen causing the public health emergency.

Standards of quality and safety for all substances of human origin intended for human application

Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC[3] provides, as expressly stated in its first Article, for "measures that set high standards of quality and safety for all substances of human origin (SoHO) intended for human application and for activities related to those substances. It ensures a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring from medically assisted reproduction, including by strengthening the continuity of supply of critical SoHO".

Off-label use of veterinary medicinal products

Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December on veterinary medicinal products regulates both the use of medicinal products outside the terms of the marketing authorisation in non-food-producing animal species (Art. 112) and in food-producing terrestrial animal species (Art. 113).

On that basis, Commission Implementing Regulation (EU) 2024/1973 of 18 July 2024 establishing a list of antimicrobials which shall not be used in accordance with Articles 112 and 113 of

[2] *Official Journal of the European Union* no. 1701 of 17 June 2024 (see this ***link***).

[3] *Official Journal of the European Union* no. 1938 of 17 July 2024 (see this ***link***).

Regulation (EU) 2019/6 of the European Parliament and of the Council or which shall only be used in accordance with those Articles subject to certain conditions[4] has been adopted.

UDIs in the field of medical devices: renewal of issuing authorities

Commission Implementing Decision (EU) 2024/2120 of 30 July renews the designation of issuing entities designated to operate a system for the assignment of Unique Device Identifiers in the field of medical devices[5]. Thereby, the designation of the four entities listed in the previous Commission Implementing Decision (EU) 2019/939 is renewed.

International law

WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge

The World Intellectual Property Organisation (WIPO) - at the Diplomatic Conference from 13 to 24 May 2024 - has adopted the "WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge".

This treaty provides that where the claimed invention in a patent application is based on genetic resources, each contracting party shall require applicants to disclose the country of origin of the genetic resources or, if not known to the applicants, the source of the genetic resources. Likewise, where the claimed invention in a patent application is based on traditional knowledge associated with genetic resources, each contracting party shall require applicants to disclose the indigenous peoples or local community, as appropriate, who provided the traditional knowledge associated with genetic resources or, if not known to the applicants, the source of the traditional knowledge associated with genetic resources.

It also provides that contracting parties shall not place an obligation on offices to verify the authenticity of the disclosure, but that each contracting party shall make the information disclosed available in accordance with patent procedures, without prejudice to the protection of confidential information.

Judgments, rulings and decisions

European Union

Pay-for-delay agreements

On 27 June 2024, the Court of Justice handed down nine judgments related to different pay-for-delay agreements. As is well known, in this type of agreement, holders of pharmaceutical patents that have already expired pay manufacturers of generic medicines to delay the launch of generic versions of the patent-expired medicines or reach agreements so that the generic

[4] *Official Journal of the European Union* no. 1973 of 19 July 2024 (see this ***link***).

[5] *Official Journal of the European Union* no. 2120 of 1 August 2024 (see this ***link***).

companies do not challenge the validity of those patents.

The judgments delivered by the Court of Justice were in Cases C-144/19 P, Lupin v Commission; C-151/19 P, Commission v Krka; C-164/19 P, Niche Generics v Commission; C-166/19 P, Unichem Laboratories v Commission; C-176/19 P, Servier and Others v Commission v; C-197/19 P, Mylan Laboratories and Mylan v Commission; C-198/19 P, Teva UK and Others v Commission; C-201/19 P, Servier and Others v Commission; and C-207/19 P, Biogaran v Commission.

The judgments refer to a series of agreements reached in relation to generic medicines of the patented active ingredient perindopril, which the Commission considered to be contrary to competition law. For its part, the General Court upheld the existence of practices restricting competition, although it considered that there was no abuse of a dominant position by the company holding the patent. Now, for its part, the Court of Justice - without prejudice to the different nuances in each of the cases analysed - confirms the existence of practices restricting competition by object, although it qualifies the *modus operandi* of the General Court.

Thus, for example, in the judgment in Case C-201/19P, the Court of Justice emphasised that, "in order to determine whether a collusive practice may be classified as a restriction of competition by object, it is necessary to examine its content, its origin and its economic and legal context, in particular the specific characteristics of the market in which its effects will actually occur". However, in the Court of Justice's view, the General Court focused its analysis on the form and legal characteristics of such agreements, instead of concentrating on examining their actual relationship to competition. In so doing, it infringed the principles governing the application and interpretation of Article 101(1) of the Treaty on the Functioning of the European Union.

SPCs for medicinal products: the requirement that the products be protected by a basic patent

In his Opinion of 6 June 2024 in Joined Cases C119/22 and C149/22 (ECLI:EU:C:2024:472), the Advocate General has proposed in respect 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 that the Court of Justice rule that:

a) Article 3(a) must be interpreted as meaning that, in order to be regarded as 'protected by a basic patent' within the meaning of that provision, a 'product' must not only be expressly mentioned or at least be 'specifically identifiable' in the claims, but must also fall under the invention which is the subject matter of that patent.

b) Article 3(c) must be interpreted as meaning that it does not preclude the grant of a supplementary protection certificate (SPC) for a combination of active ingredients where a previous SPC had been granted for one of those ingredients; the concepts of 'core inventive advance' and 'subject matter of the invention' are irrelevant for the purposes of the assessment of the condition laid down in that provision.

International

Nutritional benefits and 'second medical use' patents

According to the Convention on the Grant of European Patents (Article 53(c)), European patents shall not be granted for methods for treatment of the human or animal body by surgery or therapy and "diagnostic methods practised on the human

or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods". In turn, according to Article 54 of this convention, "any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art", is patentable and is understood to meet the novelty requirement. In other words, the principle of patentability of substances or compositions that are already known, but for which a first therapeutic use is identified, is included. The same applies when second or subsequent therapeutic indications are identified, in accordance with Article 54(5) of the Convention, according to which "the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art" shall not be excluded.

Well, the Technical Board of Appeal of the European Patent Office - in its decision of 23 April 2024, in case T 0815/22 (ECLI:EP:BA:2024:T081522.20240423) - has declared that a patent claim related to the use of a substance (an infant formula) for promoting, in an infant, a postnatal growth trajectory or body development towards a growth trajectory or body development similar to those observed in human milk fed infants, is not a therapeutic use and therefore does not fit within the aforementioned provisions.

Consequently, the nutritional benefits of an infant formula to prophylactically reduce the risk of metabolic disease cannot be considered "a therapeutic use" in a second medical use claim.

If you have any questions regarding the contents of this document, please contact any one of the following GA_P lawyers:

Irene Fernández Puyol
Tel.: (+34) 91 582 91 00
ifernandez@ga-p.com

Estibaliz Aranburu Uribarri
Tel.: (+34) 91 582 91 00
earanburu@ga-p.com

Jesús Muñoz-Delgado
Tel.: (+34) 91 582 91 00
jmunoz@ga-p.com

Eduardo Gómez de la Cruz
Tel.: (+34) 91 582 91 00
e.gomez@ga-p.com