



# Pharma & Healthcare

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Ángel García Vidal

Professor of Corporate & Commercial Law, University of Santiago de Compostela  
'Academic Counsel', Gómez-Acebo & Pombo

# Contents

## Legislation and legislative proposals..... 3

### • European Union ..... 3

- Use of artificial intelligence for the development, regulation and use of medicines ..... 3
- Amendment of the UPC Agreement regarding central division sections: new section in Milan and reallocation of competences between the seat and sections..... 3
- Transitional provisions for certain products without an intended medical purpose to which the medical device regulation applies ..... 3
- Brexit and the marketing of medicines in Northern Ireland under EU law ..... 4
- EU-US: extension to veterinary medicines of the Sectoral Annex on GMPs ..... 4

- Global digital health certification network ..... 5

- Proposal for a Regulation on plants obtained by certain new genomic techniques ..... 5

## Judgments, rulings and decisions ..... 6

### • European Union ..... 6

- The concept of a 'pharmaceutical company' in the EMA's policy on handling competing interests of scientific committee members and experts..... 6
- Legal standing to bring an action for annulment of a decision of the EMA ..... 7
- Conditionally authorised vaccines and national legislation requiring vaccination of healthcare workers ..... 7

# Legislation and legislative proposals

## European Union

### Use of artificial intelligence for the development, regulation and use of medicines

In July 2023, the European Medicines Agency published and submitted for public consultation a draft document on the use of artificial intelligence in the development, regulation and use of veterinary and human medicines. The document is entitled “Draft reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle”<sup>1</sup> and runs parallel to the one published by the U.S. Food and Drug Administration in May this year under the title “Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products”.

### Amendment of the UPC Agreement regarding central division sections: new section in Milan and reallocation of competences between the seat and sections

Previous issues of this newsletter have reported on the negotiations to create in Milan the central division section of the Unified Patent Court (UPC) initially established in London, city that could no longer host the section after Brexit.

It should be recalled that the UPC Agreement - which entered into force on 1 June 2023 - is an international treaty that, together with Regulation (EU) No. 1257/2012 implementing en-

hanced cooperation in the area of the creation of unitary patent protection and Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements, forms an essential part of the *unitary patent package*. The UPC is, in the words of Article 1 of the Agreement, “a court common to the Contracting Member States and thus subject to the same obligations under Union law as any national court of the Contracting Member States”, with competence to settle disputes relating not only to European patents with unitary effect, but also to any type of European patent.

At its meeting of 26 June 2023, the Administrative Committee of the UPC amended the text of the Agreement, on the basis of Article 87(2) thereof, to establish the heretofore London Section of the Central Division in the city of Milan (which will become operational in June 2024). The reallocation of competences of the central divisions has also been amended to give the Munich section competence for patents in the field of chemistry and metallurgy (initially held by the London section). In addition, competence for supplementary certificates is now assigned to the Paris Section.

### Transitional provisions for certain products without an intended medical purpose to which the medical device regulation applies

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<sup>1</sup> <https://www.ema.europa.eu/en/use-artificial-intelligence-ai-medicinal-product-lifecycle#current-version-section>

Commission Implementing Regulation (EU) 2023/1194 of 20 June 2023<sup>2</sup> has amended Commission Implementing Regulation (EU) 2022/2346 as regards the transitional provisions for certain products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council. Among other measures, it provides that the transitional provisions in Commission Implementing Regulation (EU) 2022/2346 for products for which clinical investigations are performed or for which a notified body has to be involved in the conformity assessment procedure are extended by 18 and 30 months, respectively.

### **Brexit and the marketing of medicines in Northern Ireland under EU law**

Despite Brexit, certain provisions of European Union law continue to apply in Northern Ireland by virtue of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community. Those laws which continue to apply include 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, as well as Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

With things standing the way they are, medicinal products placed on the market in Northern Ireland must comply with the above legislation and, on that basis, Regulation (EU) 2023/1182 of the European Parliament and of the Council of 14 June on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC<sup>3</sup> has been adopted.

### **EU-US: extension to veterinary medicines of the Sectoral Annex on GMPs**

The European Union and the United States have agreed in the EU-US Trade and Technology Council to extend the Sectoral Annex on Pharmaceutical Good Manufacturing Practices (GMPs) of the Agreement on Mutual Recognition between the European Community and the United States of America to veterinary medicinal products.

Accordingly, the EU recognises the inspections carried out by the Food and Drug Administration in relation to manufacturers of veterinary products, and the US Food and Drug Administration recognises the national competent authorities of the Member States (having so far recognised more than a dozen of these authorities, with the others still to be recognised according to a timetable set until July 2024).

This is set out in Decision No. 2536/2023 of the Joint Sectoral Committee established under Article 14 of the US-EU amended Sectoral Annex for pharmaceutical good manufacturing practices (GMPs) (the 'Annex') on including veterinary

<sup>2</sup> *Official Journal of the European Union*, No. 158, 21 June 2023, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R1194&qid=1696560095810>.

<sup>3</sup> *Official Journal of the European Union*, No. 157, 20 June 2023, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R1182&qid=1696560884787>.

products within the product coverage of the Annex of 11 May 2023 [2023/1044]<sup>4</sup>.

## Global digital health certification network

The Council of the European Union adopted Recommendation (EU) 2023/1339 of 27 June on joining the global digital health certification network established by the World Health Organization and on temporary arrangements to facilitate international travel in view of the expiry of Regulation (EU) 2021/953 of the European Parliament and of the Council<sup>5</sup>.

Following the COVID-19 pandemic, and with it the EU Digital COVID Certificate introduced by Regulation (EU) 2021/953, the Council recommends that Member States join the global digital health certification network. As indicated in the recommendation itself, the global network will initially include COVID-19 certificates; at a later stage, certification of other documents, such as routine immunisation records and the International Certificate of Vaccination or Prophylaxis, may also be added for the purposes of international travel and continuity of care.

## Proposal for a Regulation on plants obtained by certain new genomic techniques

The development of new gene editing techniques, such as CRISPR, which involve mutagenesis rather than transgenesis, has raised questions about the application of EU legislation on

genetically modified organisms to organisms resulting from the use of these techniques (in particular Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

In that regard, the Court of Justice, in its Grand Chamber Judgment of 25 July 2018, C-528/16, held that Directive 2001/18/EC must be interpreted as meaning that organisms obtained by means of techniques/methods of mutagenesis constitute genetically modified organisms and are therefore subject to that legislation. Only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of that directive.

In response to the numerous criticisms regarding this solution, on 5 July 2023 the European Commission presented a proposal for a new regulation on plants obtained by certain new genomic techniques [Document COM(2023)]<sup>6</sup>. In essence, it is now proposed that plants resulting from the application of these new techniques, which could also occur naturally or be produced by conventional breeding, should be exempted from the requirements of the legislation on genetically modified organisms and be subject to a verification procedure based on the criteria set out in the proposal. Other plants will remain subject to an authorisation procedure and risk assessment requirements.

<sup>4</sup> *Official Journal of the European Union*, No. 140, 30 May 2023, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:2023D1044&qid=1696561002079>.

<sup>5</sup> *Official Journal of the European Union*, No. 166, 30 June 2023, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023H1339>.

<sup>6</sup> [https://food.ec.europa.eu/document/download/c03805a6-4dcc-42ce-959c-e4d609010fa3\\_en?filename=gmo\\_biotech\\_ngt\\_proposal.pdf](https://food.ec.europa.eu/document/download/c03805a6-4dcc-42ce-959c-e4d609010fa3_en?filename=gmo_biotech_ngt_proposal.pdf)

# Judgments, rulings and decisions

## European Union

### The concept of a ‘pharmaceutical company’ in the EMA’s policy on handling competing interests of scientific committee members and experts

1. The European Medicines Agency’s policy (“EMA policy”) on the handling of competing interests of scientific committees’ members and experts, in the version of 6 October 2016, section 3.2.2, defines the concept of ‘pharmaceutical company’ as follows:

“Pharmaceutical company” shall mean: any legal or natural person whose focus is to research, develop, manufacture, market and/or distribute medicinal products. For the purpose of this policy, the definition includes companies to which activities relating to the research, development, manufacturing, marketing and maintenance of medicinal products (which might also be carried out in house) are outsourced on a contract basis.

In this regard CROs [clinical research organisations] or consultancy companies providing advice or services relating to the above activities, fall under the definition of a pharmaceutical company.

Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant pharmaceutical company), (ii) are controlled by or (iii) are under common control

of a pharmaceutical company, shall be considered as pharmaceutical companies for the purposes of this policy.

Independent researchers and research organisations including universities and learned societies are excluded from the scope of the present definition.

2. The Court of Justice - in its Judgment of 22 June 2023, C-6/21 P and -C16/21 P, ECLI:EU:C:2023:502 - has stated that “an overall exclusion of university hospital experts from participation in the EMA’s scientific opinions on the ground that such hospitals have, within them, one or more entities capable of constituting pharmaceutical companies, within the meaning of section 3.2.2 of the EMA policy, risks creating a shortage of experts with detailed medical knowledge in certain scientific fields, in particular in relation to orphan medicinal products and advanced medicinal products”.

However, the exclusion from the scope of the concept of ‘pharmaceutical company’, defined in point 3.2.2 of the EMA policy, provided for in the fourth paragraph of that definition, does not, however, apply to entities controlled by a university hospital which themselves satisfy the criteria of a ‘pharmaceutical company’ within the meaning of the first paragraph of that definition. “Consequently, individuals employed by an entity controlled by a university hospital or who, more broadly, collaborate with that entity cannot be led to express a scientific opinion for the EMA, if that entity meets the criteria of the concept of ‘pharmaceutical company’, as defined in section 3.2.2 of the EMA policy”.

## Legal standing to bring an action for annulment of a decision of the EMA

Following the publication by the European Medicines Agency of a call for expressions of interest for experts to become members of the Agency's scientific advisory groups, an action is brought before the General Court for failure to include the scientific advisory group on psychiatry ("Psychiatry SAG") in that call. The General Court dismissed the action for lack of locus standi, a decision upheld by the Court of Justice in its judgment of 13 July 2023, C-136/22 P, *Debrégeas*, ECLI:EU:C:2023:572.

The Court of Justice considers that the appellant cannot rely, for the purposes of establishing an interest in bringing proceedings, on the mere possibility that it might in the future submit an application for a marketing authorisation in respect of a pharmaceutical product intended for psychiatric use, an application in relation to which, according to the appellant, the Psychiatry SAG ought to be consulted. According to the Court, "a vested and current interest cannot arise from such a future and hypothetical situation".

Nor is it considered sufficient to confer standing to bring proceedings on the appellant on the ground that judicial proceedings are pending concerning the marketing authorisation applied

for by the appellant in respect of a psychiatric medicinal product, because an upholding of the appeal would not affect the earlier proceedings.

## Conditionally authorised vaccines and national legislation requiring vaccination of healthcare workers

In its judgment of 13 July, C-765/21 (ECLI:EU:C:2023:566), the Court of Justice held inadmissible a series of questions referred for a preliminary ruling in which it was asked, inter alia, whether EU law complies with national legislation which requires healthcare workers to be vaccinated using vaccines whose marketing has been conditionally authorised by the Commission, within the meaning and for the purposes of Regulation No 507/2006 on conditional marketing authorisation for medicinal products for human use which fall within the scope of Regulation (EC) No 726/2004.

The Court considers, inter alia, that the national court has not explained the reasons for the question as to the validity of the conditional marketing authorisations or as to the relationship which may exist between the validity of those authorisations and the obligation to vaccinate against COVID-19 laid down in the Italian national legislation at issue.

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

### Jesús Muñoz-Delgado

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