G A _ P

Gómez-Acebo & Pombo

Pharma & Healthcare

Ángel García Vidal

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

'Academic Counsel', Gómez-Acebo & Pombo

2024 No. 38

Contents

Legislation and legislative proposals

European Union

EU reference laboratories in the area of public health

Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health establishes a network of European Union reference laboratories in the area of public health. It provides that the Commission may, by means of implementing acts, designate EU reference laboratories to support national reference laboratories in order to promote good practice and alignment by Member States on a voluntary basis on diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States.

On that basis, Commission Implementing Regulation (EU) 2024/892 of 22 March designating European Union reference laboratories for certain specific areas of public health[1] has been adopted. In particular, reference laboratories are designated in the following areas: antimicrobial resistance (AMR) in bacteria; vector-borne viral pathogens; emerging, rodent-borne and zoonotic viral pathogens; high-risk, emerging and zoonotic bacterial pathogens; legionella; and diphtheria and pertussis.

Harmonised standards on in vitrodiagnostic medical devices

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices provides in Article 8 that devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements of that Regulation covered by those standards or parts thereof.

As that regulation repealed Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices, the European Commission, in its Implementing Decision C (2021) 2406, requested the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation to review the existing harmonised standards on in vitro diagnostic medical devices drafted in support of said directive and to draft new harmonised standards in support of Regulation (EU) 2017/746. This resulted in Commission Implementing Decision (EU) 2021/1195 including the references of the harmonised standards drafted in support of said regulation.

However, two amendments to the above-mentioned Implementing Decision (EU) 2021/1195 have just been adopted:

a) Commission Implementing Decision (EU) 2024/815 of 6 March 2024 amending Implementing Decision (EU) 2021/1182 as regards

[1] Official Journal of the European Union (OJEU) No. 892 of 25 March 2024; see in this ***link.***

harmonised standards for medical gloves for single use, biological evaluation of medical devices, sterilization of health care products, packaging for terminally sterilized medical devices and processing of health care products[2].

b) Commission Implementing Decision (EU) 2024/817 of 6 March 2024 amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for sterilisation of health care products and packaging for terminally sterilised medical devices[3].

Covid, GMOs and medicinal products: end of the temporary derogation

1. In order to make COVID19 vaccines and treatments available to the public, Regulation (EU) 2020/1043 of the European Parliament and of the Council of 15 July on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19), established a temporary derogation from Union legislation on genetically modified organisms (GMOs) to ensure that the conduct of clinical trials in the territory of several Member States with investigational medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19 is not delayed. Thus, Article 2 provides, inter alia, as follows:

> All operations related to the conduct of clinical trials, including packaging and labelling, storage, transport, destruction, disposal, distribution, supply, administration or use of investigational medicinal products for human use containing or consisting of GMOs intended to treat or prevent COVID-19, with the exception of the manufacturing of the investigational medicinal products, shall not require a prior environmental risk assessment or consent in accordance with Articles 6 to 11 of Directive 2001/18/EC or Articles 4 to 13 of Directive 2009/41/EC when these operations relate to the conduct of a clinical trial authorised in accordance with Directive 2001/20/EC.

2. Now that the pandemic is over, the European Commission has declared, in the "Notice from the Commission on the fulfilment of the conditions for the application of Regulation (EU) 2020/1043 of the European Parliament and of the Council on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19)"[4], that the "conditions for the application of Regulation (EU) 2020/1043 are no longer fulfilled".

Commission Notice - Guidance to Applicants - Veterinary Medicinal Products

The European Commission has published guidance on the regulation of veterinary medici-

[2] OJEU No. 815 of 8 March 2024; see in this ***link***.

[3] OJEU No. 817 of 8 March 2024; see in this ***link***.

[4] OJEU No. 1960 of 6 March 2024; see in this ***link***.

nal products by way of a Notice titled "Guidance to Applicants - Veterinary Medicinal Products"[5].

This is a very useful document, setting out various matters of interest concerning Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and its interpretation. The Commission's guidance has been drawn up in consultation with the competent authorities of the Member States and the European Medicines Agency in order to "assist stakeholders in complying with their obligations under the Regulation. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law".

Although it is not possible at this stage to analyse all the issues addressed in the guidelines, we can highlight, for example, the clarifications concerning the distinction between veterinary medicinal products by function or by presentation. Thus, according to the Commission, "a product is 'presented for treating or preventing disease' when it is expressly 'indicated' or 'recommended' as such, possibly by means such as labels, leaflets and/or oral representation. A product is also considered as 'presented for treating or preventing disease' whenever any averagely well-informed consumer gains the impression that the product in question should, having regard to its presentation, have the properties of a medicinal product. the external form given to a product, although it may serve as strong evidence of the seller's or manufacturer's intention to market that product as a veterinary medicinal product, cannot be the sole or conclusive evidence, since otherwise certain food products which are traditionally presented in a similar form to medicinal products would also be covered and fall in the scope of the definition of a medicinal product".

Guide for micro-, small and medium-sized enterprises operating in the pharmaceutical sector

The European Medicines Agency has published a new version of its guide for micro-, small and medium-sized enterprises (SMEs) operating in the pharmaceutical sector: "User guide for micro, small and medium-sized enterprises. On the administrative and procedural aspects of the provisions laid down in Regulation (EC) No 726/2004 and Regulation (EU) 2019/6, that are of particular relevance to SMEs"[6].

The aim of this guide is to facilitate understanding of the main aspects of medicinal product legislation. The guide is structured to follow the stages of developing a medicinal product, paying particular attention to the requirements for obtaining a market authorisation.

Gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain in vitro diagnostic medical devices

The European Commission has submitted a Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain in vitro diag-

[5] OJEU No. 1443 of 14 February 2024; see in this ***link***.

[6] See in this ***link***.

nostic medical devices (Document COM(2024), 43 final)[7].

This amendment aims to give manufacturers more time to comply with the requirements for *in vitro* diagnostic medical devices. As highlighted in the explanatory memorandum:

> The need for additional time is most acute for mitigating shortages of class D devices. They constitute about 4% of the market16 but their conformity assessment is intensive due to the requirement for individual technical documentation assessment and, where relevant, involvement of the scientific bodies (expert panel and EU reference laboratories). With only 12 notified bodies currently designated, capacity in the system to perform the required third party assessments remains limited, so an extension of the transitional period for class D IVDs should be combined with a shift in the transition deadlines for the other device groups as well to avoid a bottleneck in the certification process and to prevent shortages of these devices too. Class C and class B are large device groups (representing 26% and 49% of the market, respectively), and some of them are also subject to special requirements such as individual technical documentation assessment. It is also logical from the perspective of protection of public health that higher risk classes should be subject to the more stringent rules earlier than lower risk classes.

The proposed regulation also aims to enable a gradual implementation of individual Eudamed (European database on medical devices) modules once they have been audited and declared functional, as well as to impose an obligation on manufacturers to inform their relevant competent authority and health institutions before they cease, temporarily or permanently, the supply of a critical device.

Report on competition enforcement in the pharmaceutical sector

The European Commission has published a report entitled "Update on Competition Enforcement in the Pharmaceutical Sector (2018-2022)" and addressed to the Council and the European Parliament[8].

This report provides an overview of how the Commission and the national competition authorities of the EU Member States have enforced EU antitrust and merger rules concerning medicines and certain other medical products in the period 2018-2022.

Public consultation on the Implementing Regulation of Regulation (EU) 2021/2282 on health technology assessment

The European Commission has launched a public consultation on the draft Implementing Regulation of Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment,

[7] See in this ***link***.

[8] See in this ***link***.

which sets out procedural rules regarding certain aspects of joint clinical assessments and the format and the templates of submission and report documents[9].

Judgments, rulings and decisions

European Union

Preference for scientific advisory groups over ad hoc expert groups

The Court of Justice - in its Judgment of 14 March 2024, C-291/22 P, ECLI:EU:C:2024:228 has stated that the convening, in a therapeutic area for which a scientific advisory group ('SAG') is established, of an ad hoc expert group cannot, without undermining the useful effect of the establishment of SAGs, the commitments made by the European Medicines Agency in point 6.1 of the guidelines on the re-examination procedure and consistency in the processing of marketing authorisation applications, be accepted on the basis of the Committee for Medicinal Products for Human Use's consideration that an ad hoc expert group would be better able to answer its questions than the SAG established, where appropriate reinforced by additional experts.

E-platforms and the sale of medicinal products

The Court of Justice - in its judgment of 29 February 2024, C-606/21, ECLI:EU:C:2024:179 - has held that "a service provided on a website consisting in connecting pharmacists and customers for the sale, via the websites of pharmacies which have subscribed to that service, of medicinal products not subject to medical prescription falls within the concept of an 'information society service'" within the meaning of Article 85c of 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, and that "Member States may, on the basis of that provision, prohibit the provision of a service consisting in connecting, via a website, pharmacists and customers for the sale, from the websites of pharmacies which have subscribed to that service, of medicinal products not subject to medical prescription, if it transpires, having regard to the characteristics of that service, that the provider of that service is itself selling such medicinal products without being authorised or entitled to do so under the law of the Member State in whose territory it is established".

Thus, this judgment recognises the possibility of providing online intermediation services between pharmacies and customers, provided that, in view of the specific conditions of the application, it is clear that the sale of medicinal products is not carried out by the person responsible for the application.

[9] For more information and the possibility of participating in the public consultation, see in this ***link***.

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