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Legislation and legislative proposals

European Union

Harmonised standards on medical devices

According to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, and according also to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, 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 the Regulation covered by those standards or parts there of.

On that basis, the European Commission at the time requested the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) to review the existing harmonised standards on medical devices and on in vitro diagnostic medical devices drafted under the aegis of the earlier directives and to draft new standards on the basis of the regulation.

The references of these standards are now published in the Official Journal of the European Union, by means of:

(a) Commission Implementing Decision (EU) 2021/1182 of 16 July 2021 on the harmonised standards for medical devices drafted in support of Regulation (EU) 2017/745 of the European Parliament and of the Council (OJ L 256 of 19 July 2021[1]).

(b) Commission Implementing Decision (EU) 2021/1195 of 19 July 2021 on the harmonised standards for in vitro diagnostic medical devices drafted in support of Regulation (EU) 2017/746 of the European Parliament and of the Council [OJ L 258 of 20 July 2021[2]).

Parliament and Council reach agreement on the Health Technology Assessment Regulation

On 22 June, the European Parliament and the Council reached an agreement on the Health Technology Assessment Regulation, the proposal for which was presented in January 2018 by the Commission. The timeline and background

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021D1182&from=EN

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021D1195&from=EN

[3] https://www.consilium.europa.eu/en/policies/health-technology-assessment-post-2020/

[4] https://www.aemps.gob.es/informa/notasinformativas/productossanitarios/seguridad-3/2021/informacion-sobre-productos-sanitarios-en-base-al-acuerdo-de-reconocimiento-mutuo-mra-ue-suiza

information can be found in the link of the Council's press release[3].

Medical devices and the EU-Switzerland Mutual Recognition Agreement

The European Commission has published a notice on the status of the EU-Switzerland Mutual Recognition Agreement (MRA) for Medical Devices as from 26 May 2021, following the entry into application of the new Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. It recalls, among other things, that Swiss manufacturers will be treated like any other third country manufacturer intending to place their medical devices on the EU market.

Following this, the Spanish Medicines and Healthcare Products Regulatory Agency (AEMPS) published its own notice with information on medical devices based on the EU-Switzerland MRA[4], recalling the following:

— Distributors that are going to import products from Switzerland must previously request an import licence from the AEMPS.

— Spanish companies appointed as authorised representatives by a manufacturer of class I or custom-made medical devices from Switzerland or a third country must communicate their details and products to the AEMPS' Register of Responsible Persons.

— Companies marketing medical devices in Spain which, as a result of the MRA with Switzerland, have undergone a change in their labelling and/or instructions for use, must update their marketing communications to the AEMPS through the telematic application CCPS. Likewise, in cases where a valid CE marking certificate issued by an EU Notified Body (NB) is not available, they must deregister the communications. As for devices, Spanish manufacturers that manufacture devices that are certified by a Swiss NB must request a new certificate in accordance with the new regulation from an EU NB.

EMA Q&A document on medical devices

The European Medicines Agency (EMA) has published a new version of its Q&A document on medical devices: "Questions & answers for applicants, marketing authorisation holders of medicinal products and notified bodies with respect to the implementation of the medical devices and in vitro diagnostic medical devices regulations (EU) 2017/745 and (EU) 2017/746", dated 23 June 2021, which can be found in link of EMA's website overviewing medical devices legislation[5].

Pesticides in food

Two regulations on pesticides in food have been published:

(a) Commission Delegated Regulation (EU) 2021/1040 of 16 April 2021 amending Delegated Regulation (EU) 2016/128 as regards

[5] https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices#medical-devices-legislation-section

[6] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R1040&from=EN

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R1041&from=EN

[8] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020AR5525&from=EN

the requirements on pesticides in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children (OJ L 225 of 25 June 2021[6]).

(b) Commission Delegated Regulation (EU) 2021/1041 of 16 April 2021 amending Delegated Regulation (EU) 2016/127 as regards the requirements on pesticides in infant formula and follow-on formula (OJ L 225 of 25 June 2021[7]).

CoR opinion on a pharmaceutical strategy for Europe

The Official Journal of the European Union (2021/C 300/15 of 27 July 2021) publishes the "Opinion of the European Committee of the Regions - A pharmaceutical strategy for Europe and legislative proposal for changing the mandate of the European Medicines Agency (EMA)". In this document[8], the European Committee of the Regions (CoR) gives its opinion on the Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

Maximum levels of certain substances in foodstuffs

As regards the content of certain substances in foodstuffs, two pieces of legislation should be highlighted:

(a) Commission Regulation (EU) 2021/1317 of 9 August 2021 amending Regulation (EC) No 1881/2006 as regards maximum levels of lead in certain foodstuffs (OJ L 286 of 10 August 2021[9]).

(b) Commission Regulation (EU) 2021/1408 of 27 August amending Regulation (EC) No 1881/2006 as regards maximum levels of tropane alkaloids in certain foodstuffs (OJ L 304 of 30 August 2021[10]).

EU portal and database for clinical trials of medicinal products for human use

On 13 July 2021, the Commission adopted Decision (EU) 2021/1240 of 13 July 2021 on the compliance of the EU portal and the EU database for clinical trials of medicinal products for human use with the requirements referred to in Article 82(2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council (OJ L 275 of 31 July 2021[11]).

Good distribution practice for veterinary medicinal products

The European Commission has adopted Implementing Regulation (EU) 2021/1248 of 29 July 2021 as regards measures on good distribution practice for veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council.

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[9] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R1317&from=EN

[10] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R1408&from=EN

[11] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021D1240&from=EN

[12] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R1248&from=EN

[13] https://www.ga-p.com/publicaciones/nuevas-sentencias-del-tribunal-de-justicia-que-interpretan-la-directiva-sobre-medicamentos-para-uso-humano

The implementing regulation, published in the Official Journal of the European Union L 272 of 30 July 2021[12], applies to holders of a manufacturing authorisation performing wholesale distribution of the veterinary medicinal products covered by that manufacturing authorisation, as well as to holders of a wholesale distribution authorisation, including those established or operating under specific customs regimes, such as free zones or customs warehouses.

Judgments, rulings and decisions

European Union

Inaccurate health advice does not constitute a defective product

In its judgment of 10 June 2021 in case C 65/20, the Court of Justice has ruled that a copy of a printed newspaper that, concerning paramedical matters, gives inaccurate health advice relating to the use of a plant which, when followed, has proved injurious to the health of a reader of that newspaper, does not constitute a 'defective product' within the meaning of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

According to the Court, 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 "precludes a medicinal product which may be dispensed without a prescription in one Member State from also being regarded as a medicinal product which may be dispensed without a prescription in another Member State where the medicinal product in question does not have a marketing authorisation and has not been classified".

For a detailed analysis of this judgment, please refer to Ángel García Vidal, "*Nuevas sentencias del Tribunal de Justicia interpretando la Directiva sobre medicamentos para uso humano*", *Análisis farmacéutico*, GA_P, July 2021[13].

Marketing in a Member State of a medicinal product which has not been granted an MA in that Member State, but which has an MA in another Member State

In its judgment of 8 July in case C 178/20, the Court of Justice examined the placing in the market of a Member State of a medicinal product which has not been granted a marketing authorisation (MA) in that Member State, but which has an MA in another Member State, where it is dispensed without a prescription.

Prize competition linked to the purchase of a medicinal product

In its judgment of 15 July in case C-190/20, the Court of Justice examines a mail-order pharmacy's advertising by means of a prize competition. The Court states that Directive 2001/83/EC on the Community code relating to medicinal products for human use "must be interpreted as not applying to national legislation which prohibits a pharmacy which sells medicinal products by mail order from organising an advertising

campaign in the form of a prize competition allowing participants to win everyday items other than medicinal products, participation in that competition being subject to the submission of an order for a medicinal product for human use subject to a medical prescription, together with that prescription".

For a detailed analysis of this judgment, please refer to Ángel García Vidal, "*Nuevas sentencias del Tribunal de Justicia interpretando la Directiva sobre medicamentos para uso humano*", *Análisis farmacéutico*, GA_P, July 2021.

Biocidal action of an active substance

In Case C-29/20, as referred to the Court of Justice, the advocate general - in his Opinion of 20 May - has proposed to the court to rule that Article 3(1)(a) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products is to be interpreted as meaning that, where an active substance in a product has been approved by an implementing Regulation, the requirement of "otherwise exerting a controlling effect [...] by any means other than mere physical or mechanical action" is presumed to be satisfied. The Advocate General adds that "in the context of a legal action, such a presumption may be rebutted only if the biocidal action of the active substance can be excluded in respect of that product. However, such a presumption is irrebuttable if that product is composed of a single approved active substance or if its composition is identical to that of a biocidal product indicated as representative when the application for approval of the active substance was submitted".

International Law

EPO's EBoA establishes the prohibition on double patenting

The Enlarged Body of Appeal (EBoA) of the European Patent Office (EPO), in its decision of 22 June 2021 in case G-4/19, has resolved the problem of double patenting, i.e. whether it is possible for the same applicant to obtain two European patents on the same invention.

In the absence of express regulation in the Convention on the Grant of European Patents, the EPO has been issuing contradictory decisions. Hence the importance of the intervention of the EBoA, which rejects the possibility of double patenting, whether we are dealing with several applications filed independently on the same date, with an initial and a divisional application or with applications claiming the same priority.

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