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Life Sciences Newsletter

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Legislation and legislative proposals

European Union

Harmonised standards for medical devices

Several Commission implementing decisions on harmonised standards for medical devices have been published in March 2020. These are as follows:

a) Commission Implementing Decision (EU) 2020/437 of 24 March 2020 on the harmonised standards for medical devices drafted in support of Council Directive 93/42/EEC, OJ L 90I, 25.3.2020, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020D0437&from=EN.

b) Commission Implementing Decision (EU) 2020/438 of 24 March 2020 on the harmonised standards for active implantable medical devices drafted in support of Council Directive 90/385/EEC, OJ L 90I, 25.3.2020, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020D0438&from=EN.

c) Commission Implementing Decision (EU) 2020/439 of 24 March 2020 on the harmonised standards for in vitro diagnostic medical devices drafted in support of Directive 98/79/EC of the European Parliament and of the Council, OJ L 90I, 25.3.2020, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020D0439.

Impact of Brexit

The European Medicines Agency and the European Commission have presented a new version, dated 13 March, of the document on the impact of Brexit on rules for medicines ("Notice to stakeholders. Withdrawal of the United Kingdom and EU rules for medicinal products for human use and veterinary medicinal products", https://ec.europa.eu/info/sites/info/files/notice_to_stakeholders_medicinal_products.pdf).

New documents from the European Commission's Medical Device Coordination Group

The Medical Device Coordination Group of the European Commission has produced the following documents:

a) Joint Implementation/preparedness plan on the new Medical Devices Regulation 2017/745 (MDR), 11 March 2020 https://ec.europa.eu/docsroom/documents/40286?locale=en.

b) MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD, 16 March 2020 https://ec.europa.eu/docsroom/documents/40301?locale=en.

c) MDCG 2020-2 Class I Transitional provisions under Article 120 (3 and 4) – (MDR). 17 de marzo, https://ec.europa.eu/docsroom/documents/40324?locale=en.

d) MDCG 2020-1 Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software, de 17 de marzo https://ec.europa.eu/docsroom/documents/40323?locale=en.

e) MDCG 2018-1 v3 Guidance on BASIC UDI-DI and changes to UDI-DI, 17 March 2020, https://ec.europa.eu/docsroom/documents/40322?locale=en.

f) MDCG 2019-8 v2: Guidance document Implant Card relating to the application of Article 18 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices March 2020. Puede consultarse en el siguiente enlace: https://ec.europa.eu/docsroom/documents/40321.

Organic products

OJ L 87 of 23 March 2020 publishes Commission Delegated Regulation (EU) 2020/427 of 13 January 2020 amending Annex II to Regulation (EU) 2018/848 of the European Parliament and of the Council as regards certain detailed production rules for organic products (https://www.boe.es/buscar/doc.php?id=DOUE-L-2020-80435).

Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat

In the context of the serious health crisis generated by the COVID-19 virus, the European Commission issued Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat (OJ L 79I of 16 March 2020, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020H0403&from=EN.

As stated in the first paragraph of the Recommendation "with the objective to ensure availability of PPE and medical devices for adequate protection in the COVID-19 outbreak, the Commission invites all economic operators throughout the supply chain, as well as notified bodies and market surveillance authorities to deploy all the measures at their disposal to support the efforts aimed at ensuring that the supply of PPE and medical devices throughout the EU market will match the continuously increasing demand. Such measures should nevertheless not have a detrimental effect

on the overall level of health and safety and all relevant stakeholders should ensure that any PPE or medical devices, which is being placed on the EU market, continues to provide an adequate level of protection of the users' health and safety".

Prior export licence for certain products

Commission Implementing Regulation (EU) 2020/402 of 14 March 2020 making the exportation of certain products subject to the production of an export authorisation. The products are protective spectacles and visors, mouth-nose protection equipment, protective garments, gloves and face shields.

Medical stockpiling rescEU capacities

OJ L 82 of 19 March 2020 publishes Commission Implementing Decision (EU) 2020/414 of 19 March 2020 amending Implementing Decision (EU) 2019/570 as regards medical stockpiling rescEU capacities (notified under document number C(2020) 1827), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020D0414&from=GA.

As recalled in the Decision, "rescEU is a reserve of capacities at Union level aiming to provide assistance in overwhelming situations where overall existing capacities at national level and those committed by Member States to the European Civil Protection Pool are not able to ensure an effective response to natural and man-made disasters".

Clinical trials during the COVID-19 pandemic

The European Medicines Agency approved Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic, Version 2, March 27 (https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/guidanceclinicaltrials_covid19_en.pdf).

COVID- 19 and free circulation of substances of human origin

The European Commission has clarified to national authorities that Substances of Human Origin (SoHO) are considered essential goods/services for which free circulation within the EU is crucial. It has done so in its Note "COVID-19 and Substances of Human Origin Cross-Border shipments of SoHO as essential goods and services", https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/2020_soho_crossbordershipments_en.pdf.

In particular, shipments of organs for transplant, bone marrow or cord blood for transplantation (haematopoetic stem cells), blood for transfusion, plasma for transfusion and plasma for manufacturing medicinal products are considered essential.

Key principles to guide the development and use of electronic product information for medicines

The European Medicines Agency, the Heads of Medicines Agencies and the European Commission published key principles to guide the development and use of electronic product information (ePI) for human medicines in the EU, such as the package leaflet or the technical file. See, in this respect, the document prepared by the Spanish Medicines and Healthcare Products Regulatory Agency, which collaborated in the process (Reference: AEMPS, 3/2020, https://www.aemps.gob.es/informa/notasinformativas/laaemps/2020-laaemps/publicacion-de-los-principios-basicos-para-el-desarrollo-y-uso-de-informacion-en-formato-electronico-de-medicamentos-de-uso-humano/).

Composition of certain in vitro diagnostic medical devices

Commission Delegated Directive (EU) 2020/366 of 17 December 2019 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabiliser in polyvinyl chloride used in certain in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases was published in OJ L 67 of 5 March 2020, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020L0366&from=EN.

Self-diagnosis products

OJ L 63 of 3 March 2020 published Commission Implementing Decision (EU) 2020/350 of 28 February 2020 amending Decision 2002/364/EC as regards definitions of first–line assays and confirmatory assays, requirements for devices for self-testing and requirements for HIV and HCV rapid tests, confirmatory and supplementary assays (notified under document C(2020) 1086), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020D0350&from=EN.

Big data *in* the medical field

The European Medicines Agency and the Heads of Medicines Agencies have drawn up a report on the use of big data in the medical field. This is the "HMA-EMA Joint Big Data Taskforce Phase II report: 'Evolving Data-Driven Regulation'".

The Report includes ten recommendations, including the creation of an EU-wide platform for accessing and analysing healthcare data (*Data Analysis and Real World Interrogation Network,* or DARWIN), establishing methods to enable the detection and extraction of data critical to policy decisions, and ensuring ethical and secure data management and analysis.

Statements on the plan to encourage the use of market-regulating drugs

On 4 February 2020, the CEFI Foundation presented its arguments for the action plan to promote the use of market-regulating medicines in the Spanish Health System. They can be viewed at the following link: https://cefi.es/en/cefi-foundations-statements-on-the-action-plan-to-promote-the-use-of-drugs-regulating-the-market-in-the-national-health-system/.

Judgments and Decisions

European Union

Medical advice by phone and VAT

The Court of Justice, in its judgment of 5 March, *X-GmbH and Finanzamt Z*, C48/19 , EU:C:2020:169, interpreted Article 132(1)(c) of Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax, according to which Member States are to exempt the following transactions "(b) hospital and medical care and closely related activities undertaken by bodies governed by public law or, under social conditions comparable with those applicable to bodies governed by public law, by hospitals, centres for medical treatment or diagnosis and other duly recognised establishments of a similar nature; (c) the provision of medical care in the exercise of the medical and paramedical professions as defined by the Member State concerned.

According to the Court, services provided by telephone, consisting of advice on health and illness, may fall within the exemption provided for by that provision, provided that they pursue a therapeutic purpose, which it is for the referring court to ascertain.

Furthermore, Article 132(1)(c) of Directive 2006/112 must be interpreted as not requiring nurses and paramedics who provide assistance to natural persons by telephone to be subject to additional conditions of professional qualification in order to benefit from the exemption provided for in that provision, provided that they can be regarded as being of a quality equivalent to that of the services provided by other providers using the same means of communication, which is for the referring court to ascertain.

Reference to general and non-nutrient-specific benefits of a nutrient or food: conditions of legality

In its judgment of 30 January 2020, C-524/18, *Dr Willmar Schwabe,* EU:C:2020:60, the Court of Justice has interpreted Article 10(3) of 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.

According to the Court of Justice, the requirement laid down in that Article that any reference to general, non-specific benefits of the nutrient or food must be accompanied by a specific health claim included in the lists provided for in Articles 13 or 14 of that regulation, is not satisfied where the packaging of a food supplement contains a reference to general, non-specific health benefits of a nutrient or food on the front of the packaging, whereas the specific health claim intended to accompany it appears only on the back of that packaging and there is no clear reference, such as an asterisk, between the two.

In addition, references to general, non-specific benefits of a nutrient or food for overall good health or health-related well-being must be justified by scientific evidence within the meaning of Articles 5(1)(a) and 6(1) of that regulation. To that end, it suffices for such references to be accompanied by specific health claims included in the lists provided for in Article 13 or Article 14 of that regulation.

In more detail, García Vidal, "Las declaraciones generales de propiedades saludables de los alimentos", Análisis Farmacéutico Febrero 2020, https://www.ga-p.com/publicaciones/las-declaraciones-generales-de-propiedades-saludables-de-los-alimentos/.

Distribution of free drug samples to pharmacists

The Advocate General Mr. Giovanni Pitruzzella, in his Opinion of 30 January 2020, in case C 786/18, *ratiopharm GmbH v Novartis Consumer Health GmbH,* EU:C:202057, proposed that the Court of Justice should reply that Article 96(1) 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 'must be interpreted as meaning that pharmaceutical companies may distribute free samples of medicinal products, on the conditions laid down by that article, only to persons qualified to prescribe them'. Consequently, pharmaceutical companies would not be able to distribute free finished medicinal products to pharmacists, if their packaging is labelled "for demonstration purposes", the medicinal products are used by the pharmacist to test the product and there is no risk of further distribution (of the unopened product) to end users.

Online and cross-border sale of medicines

In Case C-649/18, the Advocate General's Opinion was delivered on 27 February 2020 (EU:C:2020:134), in which he proposed that the Court of Justice should reply that:

a) Article 34 TFEU does not preclude legislation of a Member State which prohibits advertising of online sales services for medicinal products provided by a pharmacy established in another Member State by means of large-scale mailings of advertising leaflets, including them, as the case may be, in packages from trading partners operating in the online sale of everyday consumer goods, and in offering discounts on the order price where that price exceeds a certain amount, in so far as such rules are necessary and proportionate to achieve the objective of protecting the dignity of the profession of pharmacist, which is for the referring court to ascertain.

b) Article 3(4)(b) of Directive 2000/31/EC ('Directive on electronic commerce) precludes the Member State of destination of an online sales service for medicinal products from applying to the provider of that service, established in another Member State: a measure prohibiting promotions, advertised on the internet site of that service provider, consisting of offering price discounts where the order exceeds a certain amount; a measure prohibiting the use of paid services for referencing in search engines and price comparators, and a measure making the validation of the first order for medicinal products on the internet site of that service provider subject to the prior completion of a health questionnaire by the patient, provided that the first Member State has not notified the second Member State and the European Commission of its intention to apply the measure in question to that same service provider, which is for the referring court to verify.

   Where such measures have been notified, Article 3(4)(a) of Directive 2000/31 does not preclude the Member State concerned from applying them to a provider of an online sales service for medicinal products established in another Member State, provided that they are appropriate and necessary for the protection of public health, which is for the referring court to ascertain.

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