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Legislation and legislative proposals

European Union

Changes to the dates of application of certain provisions of Regulation (EU) 2017/745 on medical devices

The serious health crisis situation throughout the European Union has shown that neither health institutions nor economic operators are in a position to implement Regulation (EU) 2017/745 on medical devices on the provided dates, and this has led to an extension of the period of application of certain (but not all) provisions of the regulation, by way of Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (OJ L 130 of 24 April, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0561&from=EN)

In addition to the purpose of deferring the application of certain provisions of Regulation (EU) 2017/745, Regulation (EU) 2020/561 aims at allowing the extension to the territory of the Union the validity of the national derogations under Directive 90/385/EEC and 93/42/EEC. Furthermore, as the previous legislation remains in force, the application of the provisions repealing Directives 90/385/EEC and 93/42/EEC is also deferred.

Renewal of the designation of notified bodies

As a consequence of the deferment of the application of certain provisions of Regulation (EU) 2017/74, Notified Bodies designated under Directives 90/385/EEC and 93/42/EEC concerning medical devices may certify medical devices for one more year, until 25 May 2021. In connection with this, it is necessary to renew the designation of Notified Bodies, which is done by Commission Implementing Regulation (EU) 2020/666 of 18 May 2020 amending Implementing Regulation (EU) No 920/2013 as regards the renewal of designations and the surveillance and monitoring of notified bodies (OJ L 156 of 19 May 2020, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0666&from=EN).

Union-wide derogations for medical devices

Both Directives 90/385/EEC and 93/42/EEC and Regulation (EU) 2017/745 provide that before placing a medical device on the market, manufacturers shall carry out a conformity assessment of

that device. Similarly, these texts allow national competent authorities to authorise, on request, the placing on the market of medical devices that have not been subject to an assessment, where it is in the interest of public health or patient safety or health. These are the so-called national derogations. Regulation (EU) 2017/745 also allows the Commission, in exceptional cases, to extend the validity of a national derogation to the territory of the Union for a limited period of time ("Union-wide exemption").

However, in order to be able to respond to possible shortages of medical devices across the Union that are essential for the fight against COVID-19, Regulation (EU) 2020/561 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions, has already allowed the implementation of the derogations at Union level.

On that basis, OJ L 171 of 19 May published the Communication from the Commission - Guidelines on the adoption of Union-wide derogations for medical devices in accordance with Article 59 of Regulation (EU) 2017/745 (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX-:52020XC0519(01)&from=EN).

Trade in counterfeit pharmaceutical products

The European Intellectual Property Office, through the European Observatory on Infringements of Intellectual Property Rights, and in collaboration with the OECD, has published a study entitled "Trade in Counterfeit Pharmaceutical Products" (https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/Trade_in_Counterfeit_Pharmaceutical_Products/Trade_in_Counterfeit_Pharmaceutical_Products_en.pdf) The study includes data for the years 2014-2016 and, in addition to alerting on this problem, emphasizes that the sanctions are insufficient to deter such conduct. Attention is also paid to e-commerce and the sending of small packages as one of the challenges to be faced.

COVID-19 and cross-border healthcare cooperation

The European Commission has prepared a Communication on "Guidelines on EU Emergency Assistance in Cross-Border Cooperation in Healthcare related to the COVID-19 crisis", published in OJ L 111 of 3 April, at https://ec.europa.eu/info/sites/info/files/guidelines_on_eu_emergency_assistance_in_cross-bordercooperationin_heathcare_related_to_the_covid-19_crisis.pdf.

Authorisation for the exportation of certain protective equipment

Based on Commission Implementing Regulation (EU) 2020/402 of 14 March 2020, Commission Implementing Regulation (EU) 2020/568 of 23 April 2020 makes the exportation of certain protective devices (detailed in the Annex to the Regulation) subject to the production of an export authorisation. Commission Implementing Regulation (EU) 2020/568 was published in OJ L 129 of 24 April (https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32020R0568&from=EN).

Guidance on in vitro diagnostic tests for COVID-19 and their performance

The European Commission presented on 15 April 2020 (Document C/2020/2391 final) a Communication with "Guidelines on COVID-19 in vitro diagnostic tests and their performance". These can be found at the following link: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX-:52020XC0415(04)&from=EN.

Commission guidelines on the supply of medicinal products

The 'Guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak' (2020/C 116 I/01) drawn up by the European Commission (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC0408(03)&from=ES) are published in the Official Journal of 8 April 2020.

Commission guidelines on the free movement of health professionals

A Commission Communication containing a "Guidance on free movement of health professionals and minimum harmonisation of training in relation to emergency measures - recommendations regarding Directive 2005/36/EC" is published in OJ L 156 of 8 May (https://ec.europa.eu/info/sites/info/files/guidance-movement-health-professionals-harmonisation-training-covid19_en.pdf).

Harmonised standards for personal protective equipment

OJ L 156 of 19 May publishes Commission Implementing Decision (EU) 2020/668 of 18 May 2020 on the harmonised standards for personal protective equipment drafted in support of Regulation

(EU) 2016/425 of the European Parliament and of the Council (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020D0668&from=EN).

COVID-19 and Competition Law

In relation to the application of competition law in the context of the Corona crisis, the following documents and actions are relevant:

a) The Joint statement by the European Competition Network (ECN) on application of competition law during the Corona crisis (https://ec.europa.eu/competition/ecn/202003_joint-statement_ecn_corona-crisis.pdf)

b) The Commission's Communication "Temporary Framework for assessing antitrust issues related to business cooperation in response to situations of urgency stemming from the current COVID-19 outbreak, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC0408(04)&from=ES). This Communication covers possible forms of cooperation between undertakings in order to ensure the supply and adequate distribution of essential scarce products and services during the COVID-19 outbreak. The Communication sets out "the main criteria that the Commission will follow in assessing these possible cooperation projects aimed at addressing the shortage of essential products and services during the COVID-19 outbreak, and in setting its enforcement priorities during this crisis".

c) The Complaints and Consultation Tray related to the application of competition rules in the context of the pandemic, launched by the Spanish Markets and Competition Authority on 31 March.

Rogue traders during the COVID-19 outbreak

The Consumer Protection Cooperation Network has adopted a common position on rogue traders during the COVID-19 outbreak. It can be found at this link https://ec.europa.eu/info/live-work-travel-eu/consumers/enforcement-consumer-protection/scams-related-covid-19.

Relief from import duties and VAT exemption on importation granted for goods needed to combat the effects of the COVID-19 outbreak

OJ L 103 of 3 April publishes Commission Decision (EU) 2020/491 of 3 April 2020 on relief from import duties and VAT exemption on importation granted for goods needed to combat the effects

of the COVID-19 outbreak during 2020 (notified under document C/2020/2146), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020D0491&from=EN.

Guidance on medical devices in the context of the COVID-19 pandemic

The European Commission has published a question and answer document on medical devices in the context of the COVID-19 pandemic ("Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context"). The document is dated 3 April and can be viewed at the following link: https://ec.europa.eu/docsroom/documents/40607?locale=en.

COVID-19 and clinical trials

A third version, dated 28 April, of the document prepared by the European Medicines Agency and the Heads of Medicines Agencies, "Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic", https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/guidanceclinicaltrials_covid19_en.pdf.

COVID-19 and the use of health data for research purposes

The European Data Protection Board has published Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak, adopted on 21 April 2020: https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_guidelines_202003_healthdatascientificresearchcovid19_en.pdf.

COVID-19 and the use of location data and contact tracing tools

The European Data Protection Board has issued guidelines on the use of location data and contact tracing tools in the context of the COVID-19 outbreak. This is the document "Guidelines 04/2020 on the use of location data and contact tracing tools in the context of the COVID-19 outbreak", dated 21 April and available at this link: https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_guidelines_20200420_contact_tracing_covid_with_annex_en.pdf.

Also of interest in this respect:

a) the Communication from the Commission with 'Guidelines on Apps supporting the fight against COVID 19 pandemic in relation to data protection' (https://ec.europa.eu/info/sites/info/files/5_en_act_part1_v3.pdf).

b) Commission Recommendation of 8.4.2020 on a common Union toolbox for the use of technology and data to combat and exit from the COVID-19 crisis, in particular concerning mobile applications and the use of anonymised mobility data (C(2020) 2296 final), https://ec.europa.eu/info/sites/info/files/recommendation_on_apps_for_contact_tracing_4.pdf; and

c) the eHealth Network document entitled "Mobile applications to support contact tracing in the EU's fight against COVID-19 - Common EU Toolbox for Member States", https://www.huntonprivacyblog.com/wp-content/uploads/sites/28/2020/04/covid-19_apps_en.pdf

Q&A on regulatory expectations for medicinal products for human use during the COVID-19 pandemic

The European Commission, the European Medicines Agency and the Heads of Medicines Agencies have prepared a Q&A document on regulatory issues related to the COVID-19 pandemic ("Questions and answers on regulatory expectations for medicinal products for human use during the COVID-19 pandemic", 10 April). The document is available at the following link: https://ec.europa.eu/health/sites/health/files/human-use/docs/guidance_regulatory_covid19_en.pdf.

Computerised systems used to manage clinical trial data

The European Medicines Agency has published, on 7 April, a "Notice to sponsors on validation and qualification of computerised systems used in clinical trials". It is available at the following link: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/notice-sponsors-validation-qualification-computerised-systems-used-clinical-trials_en.pdf.

Maximum residue levels of pesticides in and on food of plant and animal origin

OJ L 135 of 29 April published the Commission Implementing Regulation (EU) 2020/585 of 27 April 2020 concerning a coordinated multiannual control programme of the Union for 2021, 2022 and 2023 to ensure compliance with maximum residue levels of pesticides and to assess the con-

sumer exposure to pesticide residues in and on food of plant and animal origin (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0585&from=EN).

Use of animals for scientific purposes

OJ L 129 of 24 April published Commission Implementing Decision (EU) 2020/569 of 16 April 2020 establishing a common format and information content for the submission of the information to be reported by Member States pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes and repealing Commission Implementing Decision 2012/707/EU (notified under document C(2020) 2179) (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020D0569&from=EN)

Draft Agreement between the EU and the United Kingdom

The Draft Agreement between the European Union and the United Kingdom to regulate their new relationship (Draft text of the Agreement on the New Partnership with the United Kingdom, published on 18 March and available here: https://ec.europa.eu/info/sites/info/files/200318-draft-agreement-gen.pdf) contains several articles of interest in the field of intellectual property and life sciences. In this regard, Article 39 is devoted to patents and public health, Article 40 to the extension of the period of protection conferred by patents on medicines and Article 41 to the extension of the period of protection conferred by patents on plant protection products, so that the parties are obliged to grant additional protection, which in the European Union is established by means of supplementary protection certificates.

In addition, there are also several articles on the protection of trade secrets.

Judgments and decisions

European Union

Supplementary protection certificate and product protected by a basic patent in force

The Court of the European Union, in its judgment of 30 April 2020, *Royalty Pharma,* C650/17, EU:C:2020:327, has stated that "Article 3(a) 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 must be interpreted as meaning that a product is protected by a basic patent in force, within the meaning of that provision, if it corresponds to a general functional definition used by one of the claims of the basic patent and necessarily comes within the scope of the invention covered by that patent, but is not otherwise indicated in individualised form as a specific embodiment of the method of that patent, provided that it is specifically identifiable, in the light of all the information disclosed by that patent, by a person skilled in the art, based on that person's general knowledge in the relevant field at the filing date or priority date of the basic patent and on the prior art at that date".

Furthermore, according to the Court, "a product is not protected by a basic patent in force, within the meaning of that provision, if, although it is covered by the functional definition given in the claims of that patent, it was developed after the filing date of the application for the basic patent, following an independent inventive step".

Indication concerning the dosage of homeopathic medicinal products

Article 69 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 lays down a number of particulars which must appear on the labelling and, where appropriate, on the package leaflet of homeopathic medicinal products. In the Judgment of the Court of the European Union of 23 April 2020, *Deutsche Homöopathie-Union,* Joined Cases C-101/19 and C-102/19, it is held that that directive precludes the package leaflet referred to in Article 69 thereof from including information other than that listed in that provision, in particular dosage schedules for homeopathic medicinal products covered by that provision.

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