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Corrigenda to EU regulations on medical devices: more than corrections, an extension of the time limit for conformity with Regulation (EU) 2017/745

1. OJ L 334 of 27.12.2019 contains corrigenda to recent EU regulations, namely:

   (a) Corrigendum to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745R(02)&from=EN.

   (b) Corrigendum to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746R(03)&from=EN.

2. Rather than a correction, the corrigendum to Regulation (EU) 2017/745 introduces an amendment to the original content of the Regulation, because it extends the time limit for the continued marketing of certain medical devices that meet the requirements of the previous legislation. Thus, the first wording of Art. 120(3) of the Regulation stated that

> "By way of derogation from Article 5 of this Regulation, a device *with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation* it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives."

Now, the following is provided instead:

> "By way of derogation from Article 5 of this Regulation, a device *which is a class I device pursuant to Directive 93/42/EEC, for which the declaration of conformity was drawn up prior to 26 May 2020 and for which the conformity assessment procedure pursuant*

to this Regulation requires the involvement of a notified body, or which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2020 it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives."

Good manufacturing practice for investigational medicinal products for human use and arrangements for inspections; corrigendum to Commission Delegated Regulation (EU) 2017/1569

A corrigendum to Commission Delegated Regulation (EU) 2017/1569 of 23 May 2017 supplementing Regulation (EU) No 536/2014 of the European Parliament and of the Council by specifying principles of and guidelines for good manufacturing practice for investigational medicinal products for human use and arrangements for inspections has been published in OJ L 285 of 6.11.2019, https://www.boe.es/buscar/doc.php?id=DOUE-L-2019-81717.

Use of pharmacologically active substances or their residues in veterinary medicinal products or as feed additives

OJ L 317 of 9.12.2019 has published Commission Delegated Regulation (EU) 2019/2090 of 19 June 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and Council regarding cases of suspected or established non-compliance with Union rules applicable to the use or residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives or with Union rules applicable to the use or residues of prohibited or unauthorised pharmacologically active substances, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R2090&from=EN.

As indicated in its first article, the new Regulation lays down rules on specific requirements for official controls and applicable measures for cases of non- compliance or suspected non-compliance with Union rules applicable to the use of authorised, unauthorised or prohibited pharmacologically active substances on food-producing animals and to their residues.

Reference points for action for non-allowed pharmacologically active substances present in food of animal origin

Commission Regulation (EU) 2019/1871 of 7 November 2019 on reference points for action for non-allowed pharmacologically active substances present in food of animal origin and repealing Decision 2005/34/EC has been adopted and published. OJ L 289 of 8.11.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1871&from=EN).

As provided in Art. 1, the Regulation lays down: (a) rules for the establishment of reference points for action for residues of pharmacologically actives substances, for which no maximum residue limit has been laid down in accordance with Regulation (EC) No 470/2009; (b) methodological principles and scientific methods for the risk assessment of the safety of reference points for action; (c) reference points for action for residues from certain pharmacologically active substances for which no maximum residue limit has been laid down in accordance with Regulation (EC) No 470/2009; and (d) specific rules on action to be taken in the case of a confirmed presence of a residue of a prohibited or non-allowed substance at levels above, equal to or below the reference point for action.

Authorisation of products containing, consisting of, or produced from genetically modified maize

OJ L 316 of 6.12.2019 has published Commission Implementing Decision (EU) 2019/2087 of 28 November 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 and genetically modified maize combining two, three, four or five of the single events Bt11, MIR162, MIR604, 1507, 5307 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2019) 8428) (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D2087&from=EN).

Foods and food ingredients containing, consisting of, or produced from the above-mentioned genetically modified maize, feed containing, consisting of, or produced from the above-mentioned genetically modified maize and products containing or consisting of the above-mentioned genetically modified maize are authorised for any use other than cultivation, are authorised. It is also laid down that the 'name of the organism' on the labelling shall be 'maize'.

Classification, labelling and packaging of substances and mixtures as regards information relating to emergency health response

Commission Delegated Regulation (EU) 2020/11 of 29 October 2019 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and

packaging of substances and mixtures as regards information relating to emergency health response has been adopted.

This Commission Delegated Regulation has been published in OJ L 6 of 10.1.2020, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0011&from=EN.

Production and labelling of organic products

Commission Implementing Regulation (EU) 2019/2164 of 17 December 2019 amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control has been adopted. [OJ L 328 of 18.12.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R2164&from=EN].

A Corrigendum to Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 has also been published. [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0848R(04)&from=EN]

Cosmetic products

A number of amendments and corrigenda to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products have been published:

(a) Commission Regulation (EU) 2019/1857 of 6 November 2019 amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, OJ L 286 of 7.11.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1857&from=EN.

(b) Commission Regulation (EU) 2019/1858 of 6 November 2019 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, OJ L 286 of 7.11.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1858&from=EN.

(c) Corrigendum to Commission Regulation (EU) 2019/1966 of 27 November 2019 amending and correcting Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 324 of 13.12.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1966R(01)&from=EN).

Temporary animal health requirements for consignments of products of animal origin for human consumption

OJ L 317 of 9.12.2019 publishes Commission Implementing Decision (EU) 2019/2098 of 28 November 2019 on temporary animal health requirements for consignments of products of animal origin for human consumption originating in and returning to the Union following a refusal of entry by a third country (notified under document C(2019)8092), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D2098&from=EN.

This Decision shall apply from 14 December 2019 to 21 April 2021, as Regulation (EU) 2016/429 and the Commission Delegated Regulation on animal health rules for the entry into the Union, movement and handling after the entry of certain animals, germinal products and products of animal origin from third countries or territories apply from that date.

Use of chia seeds (*Salvia hispanica*) as a novel food

Commission Implementing Regulation (EU) 2020/24 of 13 January 2020 authorising an extension of use of chia seeds (Salvia hispanica) as a novel food and the change of the conditions of use and the specific labelling requirements of chia seeds (Salvia hispanica) under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 has been published in the OJ L 8 of 14.1.2020, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0024&from=EN.

Safety features appearing on the packaging of medicinal products for human use

On 18 October 2019, the European Commission published an Aide memoire on good practices in the distribution of medicines in relation to Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use ("Aide memoire for GDP inspection of wholesalers compliance with Commission Delegated Regulation (EU) 2016/161 for safety features", https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/inspection_gdp_aidememoire_en.pdf).

Clinical trials on medicinal products for human use: new draft version of the European Commission's Q&A document

The European Commission has published, in November 2019, a new draft version of the Q&A document on Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April

2014 on clinical trials on medicinal products for human use: 'Clinical Trials Regulation (EU) No 536/2014 Draft Questions & Answers Version 2.3', available at https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/regulation5362014_qa_en.pdf.

Cybersecurity for medical devices

The Medical Device Coordination Group has prepared the document 'MDCG 2019-16 Guidance on Cybersecurity for medical devices' of December 2019, https://ec.europa.eu/docsroom/documents/38941, which provides manufacturers, as well as other operators, with guidance on how to fulfil all the relevant essential requirements of the European Union legislation on medical devices with regard to cyber security. In addition, an annex provides a description of other pieces of legislation relevant to the domain of cybersecurity for medical devices.

Guide for manufacturers of Class I medical devices

The Medical Device Coordination Group has prepared the document 'MDCG 2019-15 Guidance notes for manufacturers of class I medical devices' of December 2019, https://ec.europa.eu/docsroom/documents/38787.

This document provides guidance to manufacturers of Class I medical devices who place on the Union market medical devices under their name or trademark. This guidance also applies to situations where an importer, distributor or any other legal person assumes the obligations incumbent on manufacturers.

Conformity assessment of technical documentation for medical device selected on a representative basis

The Medical Device Coordination Group has prepared the document 'MDCG 2019-13 Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation' of December 2019, https://ec.europa.eu/docsroom/documents/38669.

This guidance defines and elaborates on the sampling criteria and use of such criteria for drawing up and maintaining a sampling plan and clarifies the tasks to be performed by the notified body, including the extent of the technical documentation assessment.

Guidance on the presentation, content and validation of the summary of safety and clinical performance (SSCP) for medical devices

The Medical Device Coordination Group has produced the document 'MDCG 2019-9 Summary of safety and clinical performance. A guide for manufacturers and notified bodies' of August 2019, https://ec.europa.eu/docsroom/documents/37285.

Judgments and decisions

European Union

Access to documents held by the EMA in the context of an MA authorisation

As reported in a previous issue of this newsletter, on 5 February 2018, the General Court delivered three judgments examining the issue of third-party access to documents incorporated in the marketing authorisation application for medicinal products submitted to the European Medicines Agency.

These judgments were handed down in the following cases: a) case T 718/15, regarding an application for access to a clinical study report in the marketing authorisation ('MA') application dossier for a medicinal product; b) case T 235/15, regarding an application for access to an assessment report Committee for Medicinal Products for Human Use (CHMP) on the clinical superiority of an orphan medicinal product to another previously authorised, as well as on the similarity of both medicinal products; and c) case T-729/15, regarding access to toxicology test reports belonging to a file relating to a veterinary medicinal product.

In these, the General Court notes that the prevailing principle is that of public access to information and that the exceptions to that principle relate to those referred to in Art. 4(2) of Regulation No 1049/2001, including the exception relating to commercially confidential information. However, the General Court finds that in the cases in question the confidentiality of the documents to which the European Medicines Agency has given access to the public has not been proved. It also states that the fact that the period of data exclusivity is in force does not preclude the disclosure of the documents in which such data are contained.

The judgments of the General Court in case T-718/15 and case T-729/15 were appealed (respectively, cases C-175/18 P y C-178/18 P).

On 11 September the Advocate General Hogan delivered his opinion in both cases, proposing that the Court should set aside the judgments under appeal, believing that the General Court erred in law in so far as it concluded that there was no general presumption that CSRs should not be disclosed by reference to the first indent Art. 4(2) of Regulation No 1049/2001. In any event, I also consider that the General Court erred in law insofar as it concluded that the disclosure of the report at issue would not compromise the appellant's commercial interests for the purposes of the first indent of Art. 4(2) of Regulation No 1049/2001.

Well, the Court of Justice of the European Union ('CJEU'), in its Judgment of 22 January 2020, C175/18 P, EU:C:202023, dismisses the appeal and rejects the opinion of the Advocate General, pointing out, inter alia, (a) that a general presumption of confidentiality is merely an option for the EU institution, body, office or agency concerned and the latter always retains the possibility of carrying out a specific and individual examination of the documents in question to determine whether they are protected, in whole or in part, by one or more of the exceptions laid down in Art. 4 of Regulation No 1049/2001; and (b) although Art. 39(3) of the TRIPS Agreement requires members of the TRIPS Agreement to protect undisclosed test or other data, the origination of which involves a considerable effort, against unfair commercial use, that fact does not, in itself, mean that the data contained in a clinical study report, such as the report at issue, must be viewed as data whose disclosure is likely to undermine the commercial interests of the person who produced them.

And, in the same vein, the CJEU also dismisses the appeal in Case C178/18 P, in its judgment of 22 January 2020, EU:C:2020:24

Pay-for-delay in the pharmaceutical field

According to the CJEU (judgment of 30 January 2020, C307/18, EU:C:2020:52), Art. 101(1) TFEU must be interpreted as meaning that a settlement agreement with respect to pending court proceedings between a manufacturer of originator medicines and a manufacturer of generic medicines, who are potential competitors, concerning whether a process patent (for the manufacture of an active ingredient of an originator medicine that is in the public domain) held by the manufacturer of originator medicines is valid and whether a generic version of that medicine infringes the patent, whereby that manufacturer of generic medicines undertakes not to enter the market of the medicine containing that active ingredient and not to pursue its action for the revocation of that patent for the duration of that agreement, in return for transfers of value in its favour by the manufacturer of originator medicines, constitutes an agreement which has as its object the prevention, restriction or distortion of competition: if it is clear from all the information available that the net gain from the transfers of value by the manufacturer of originator medicines in favour of the manufacturer of generic medicines can have no explanation other than the commercial interest of the parties to the agreement not to engage in competition on the merits; unless the settlement agreement concerned is accompanied by proven pro-competitive effects capable of giving rise to a reasonable doubt that it causes a sufficient degree of harm to competition.

Moreover, where a dominant undertaking holder of a process patent for the production of an active ingredient that is in the public domain concludes a set of settlement agreements which have the effect of keeping temporarily outside the market potential competitors who manufacture generic medicines using the said active ingredient, such agreements constitute an abuse of a dominant position within the meaning of Art. 102 TFEU if – according to the referring court – they have the capacity to restrict competition and, in particular, to have exclusionary effects, going beyond the specific anticompetitive effects of each of the settlement agreements.

The CJEU provides a summary of the main criteria in its case law on the conditions for the granting of marketing authorisation

The company holding in the United States a marketing authorisation for the medicinal product Fanaptum, containing the active substance iloperidone, submitted to the European Medicines Agency an application for an MA for the medicinal product Fanaptum, which was refused by way of Implementing Decision C(2018) 252 final.

An appeal against this refusal was lodged with but dismissed by the General Court in its judgment of 19 December 2019, *Vanda Pharmaceuticals Ltd*, T211/18, EU:T:2019:892. The judgment is interesting because it provides an excellent summary of the main case law criteria on the conditions for granting an MA. Among them, for instance, it is recalled that: (a) "it is not for the authority responsible for the examination of an MA to prove that a product is not safe, but rather for the MA applicant to establish that the medicinal product in question has a favourable risk-benefit balance"; (b) "the decision whether or not to grant an MA, which must be founded on a high standard of public health protection, must be taken solely on the basis of the criteria of safety and efficacy arising from the relevant provisions of EU law. While it cannot be excluded that an MA applicant may rely on pre- and post-marketing data concerning third countries, no argument can be inferred, in absolute terms, from the fact that an MA has been granted in those countries"; (c) "the conditions for granting an MA must be interpreted in accordance with the general principle that can be identified from case-law that the protection of public health must unquestionably take precedence over economic considerations"; or (d) "as regards judicial review of the CHMP opinion — and by extension of its assessment report — the Court cannot substitute its own assessment for that of the CHMP".

Genuine use of an earlier mark and opposition to an EU trademark application

An application for registration of the word sign INTAS, as an EU trademark, in respect of pharmaceutical goods (Classes 5 and 10 of the Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks), is opposed by the proprietor of an earlier EU and national registered figurative mark.

The EUIPO upholds the opposition and rejects the mark, both the Opposition Division and the Board of Appeal. For its part, the judgment of the General Court of 7 November 2019, *Intas Pharmaceuticals Ltd*, T 380/18, EU:T:2019:782, dismisses the action brought and concludes that the Board of Appeal did not err in finding t that proof of genuine use of the earlier trade marks at issue had been furnished and that there was a likelihood of confusion. And said judgment recalls, in this regard, that it "must be held that use of an earlier EU trade mark in one Member State is capable of producing effects on the internal market by, for example, ensuring that the goods are known — in a commercially relevant manner — by participants in a market that is larger than that corresponding to the territory where the mark is used (Opinion of Advocate General Sharpston in *Leno Merken*, C 149/11, EU:C:2012:422, point 54)".

The CJEU rules on the scope of protection of intellectual property rights conferred by a plant variety right

The CJEU has just given an important judgment, dated 19 December 2019, in case C-176/18, in which it addresses some central problems on the scope of protection of intellectual property rights conferred by a plant variety right.

The judgment is given in response to the questions referred by the Spanish Supreme Court in a dispute in which the holder of a Community plant variety right in respect of a mandarin tree variety sued a farmer who, in the time between publication of the application for a Community plant variety right and grant thereof, had purchased plants belonging to the variety from a nursery that was open to the public and planted them. In such circumstances, the main problem lies in determining whether the act of planting the trees and putting them into production violates the breeder's right.

The Court rules that:

(a) Art. 13(2)(a) and (3) of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights must be interpreted as meaning that the activity of planting a protected variety and harvesting the fruit thereof, which is not likely to be used as propagating material, requires the authorisation of the holder of the Community plant variety right relating to that plant variety where the conditions laid down in Art. 13(3) of that regulation are fulfilled.

(b) Art. 13(3) of Regulation No 2100/94 must be interpreted as meaning that the fruit of a plant variety , which is not likely to be used as propagating material, may not be regarded as having been obtained through the 'unauthorised use of variety constituents' of that plant variety, within the meaning of that provision, where those variety constituents were propagated and sold to a farmer by a nursery in the period between the publication of the application for a Community plant variety right in relation to that plant variety and the grant thereof. Where, after such

protection has been granted, those variety constituents were propagated and sold without the authorisation of the right holder, the latter may assert his or her right under Art. 13(2)(a) and (3) of that regulation in respect of that fruit, unless he or she had reasonable opportunity to exercise his or her right in relation to those variety constituents.

For a more detailed analysis of the judgment and its repercussion: García Vidal, Á., 'In which cases does planting trees and harvesting their fruit infringe a plant variety right?' https://www.ga-p.com/wp-content/uploads/2020/01/En-qu%C3%A9-casos-infringe-el-derecho-de-obtenci%C3%B3n-vegetal_eng.pdf

Farmer's privilege: the CJEU delimits the right of the holder of a Community plant variety right to request information from an official body

Art. 14 of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights provides for the so-called farmer's privilege, according to which farmers are authorized to use for propagating purposes in the field, on their own holding the product of the harvest which they have obtained by planting, on their own holding, propagating material of a variety other than a hybrid or synthetic variety, which is covered by a Community plant variety right, if certain conditions laid down in implementing rule are met.

This implementing rules are found in Commission Regulation No. 1768/1995, which, among other provisions, provides for the possibility of a holder addressing to official bodies a "request for information on the actual use of material, by planting, of specific species or varieties, or on the results of such use" (Art. 11(1)), with a view to having information on the use of the variety in order to be able to claim the equitable remuneration established for making use of the farmer's privilege.

In its judgment of 17 October 2019 in Case C-239/18, *Saatgut-Treuhandverwaltungs GmbH v* EU:C:2019:869, the CJEU held that said Art. 11(1) must be interpreted as not providing the possibility for the holder of the Community plant variety right to request information from an official body on the use of material of species, without such a request defining the specific protected variety for which that information is requested.

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