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Legislation

European Union

New EU regulations on medical devices

1. At present, medical devices are regulated in the EU by three directives dating back to the 1990s: (a) Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC), (b) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; and (c) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

   Although the above directives have been the subject of subsequent amendments (notably, by way of Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007), the fact is that technological progress has highlighted the need for revision of current legislation. And to this we must add the existence of a number of scandals concerning medical devices, such as the faulty PIP breast implants.

2. Such being the state of things, the European Commission launched in 2012 a process to reform the regulatory framework for medical devices, introducing, on 26 September of that year, two legislative proposals together with a communication: (a) Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 [COM/2012/0542 final]; (b) Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices [COM/2012/0541 final]; and (c) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on "Safe, effective and innovative medical devices and in vitro diagnostic medical devices for the benefit of patients, consumers and healthcare professionals". [COM/2012/0540 final].

   One of the main stated objectives of the Commission is to revise the current legal regime in order to improve the safety of medical devices and facilitate their trade throughout the EU. It was argued that under the legislation in force there is a shortage of information and clinical trials proving that these products are safe and effective, and that it is not always possible to determine who is the manufacturer of the products sold in the Union; not to mention the existence of national electronic registers which are not always compatible with each other, or the existence of different rules which determine the scope of the checks carried out by the notified bodies.

   The Regulations have been published in the Official Journal of the European Union (L 117 of 5 May 2017) and entered into force on the twentieth day following said publication. However,

with the exception of some articles, the new rules will only apply after a transitional period so as to allow the industry to adapt to the new changes introduced. Namely, 3 years after entry into force for the Regulation on medical devices (spring 2020) and 5 years after entry into force (spring 2022) for the Regulation on in vitro diagnostic medical devices.

The separate regulation of active implantable medical devices has thus been brought to an end, replaced by a single legislative act applicable to all medical devices other than in vitro diagnostic medical devices.

Of course, the fact that the legislative instrument of a regulation has been used makes transposition into national laws unnecessary, which will prevent divergences in the interpretation by the Member States. The implementation of the regulations will not prevent States, however, from restricting the use of any particular type of product in relation to matters not covered by the same, as well as from regulating other aspects that the regulations do not address such as the organization, provision or financing of health services and medical care, including the requirement that certain products can be dispensed only on medical prescription, the requirement that only certain healthcare professionals or health centers may dispense or use certain products or that their use must be accompanied by specific professional advice.

3. The adopted regulations are considerably long and complex texts, with several annexes. For a detailed analysis, *vide* GARCÍA VIDAL, Á., "*Los nuevos reglamentos de la Unión Europea sobre productos sanitarios*", http://www.gomezacebo-pombo.com/media/k2/attachments/los-nuevos-reglamentos-de-la-union-europea-sobre-productos-sanitarios.pdf.

Good clinical practice inspection procedures

Commission Implementing Regulation (EU) 2017/556 of 24 March 2017 provides detailed arrangements for the good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014 of the European Parliament and of the Council. [OJ L 80, 25.3.2017, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0556&from=EN]

This Regulation will apply to inspections of: (a) clinical trials conducted in the Union, including clinical trial sites related to those trials but located outside the Union; (b) clinical trials referred to in the applications for clinical trial authorisations pursuant to art. 25(5) of Regulation (EU) No 536/2014; and (c) clinical trials conducted in third countries and referred to in marketing authorisation applications in the Union.

Multiannual control programme to ensure compliance with maximum residue levels of pesticides in or on food of plant and animal origin

Commission Implementing Regulation (EU) 2017/660 of 6 April 2017 concerning a coordinated multiannual control programme of the Union for 2018, 2019 and 2020 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin has been published in the Official Journal of the European Union, L 94, 7.4.2017 (http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0660&from=EN).

With this regulation it is intended that Member States monitor pesticides in or on food of plant and animal origin.

Controls and other official activities performed to ensure the implementation of legislation on food and feed standards and health and animal welfare, plant health and crop protection products

1. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products has been published in the Official Journal of the European Union, L 95, 7.4.2017 (http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0625&from=EN).

   This Regulation lays down rules for: (a) the performance of official controls and other official activities by the competent authorities of the Member States; (b) the financing of official controls; (c) the administrative assistance and cooperation between Member States in view of the correct application of the rules referred to in paragraph 2; (d) the performance of controls by the Commission in Member States and in third countries; (e) the adoption of conditions to be fulfilled with respect to animals and goods entering the Union from a third country; (f) the establishment of a computerised information system to manage information and data in relation to official controls.

2. OJ L 137, 24.5.2017, has published a corrigendum to this Regulation (http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0625R(01)&from=EN).

Classification, labelling and packaging of substances and mixtures

1. Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labeling and packaging of substances and mixtures has been amended by Commission Regulation (EU) 2017/776 of 4 May 2017 for the purposes of its adaptation to technical and scientific progress. [OJ L 116, 5.5.2017, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0776&from=EN].

2. Furthermore, OJ L 112, 28.04.2017, has published Commission Regulation (EU) 2017/735 of 14 February 2017 amending, for the purpose of its adaptation to technical progress, the Annex to Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0735&from=EN).

Judgments and decisions

European Union

Prohibitions on advertising in respect of oral and dental care devices and EU law

The Judgment of the Court of Justice of the European Union (Third Chamber) of 4 May 2017 in Case C-339/15, in response to a request for a preliminary ruling from the *Nederlandstalige rechtbank van eerste aanleg te Brussel, strafzaken* (Court of First Instance, Criminal Division, Brussels, Belgium) in criminal proceedings brought against Luc Vanderborght, has ruled that the Unfair Commercial Practices Directive (Directive 2005/29/EC) must be interpreted as not precluding a national provision, such as that at issue in the main proceedings, which protects public health and the dignity of the profession of dentist, first, by imposing a general and absolute prohibition of any advertising relating to the provision of oral and dental care services and, secondly, by establishing certain requirements of discretion with regard to signs of dental practices.

However, the Directive on electronic commerce (Directive 2000/31/EC) must be interpreted as precluding national legislation, such as that at issue in the main proceedings, which imposes a general and absolute prohibition of any advertising relating to the provision of oral and dental care services, inasmuch as it prohibits any form of electronic commercial communications, including by means of a website created by a dentist.

And also art. 56 TFEU must be interpreted as precluding national legislation, such as that at issue in the main proceedings, which imposes a general and absolute prohibition of any advertising relating to the provision of oral and dental care services.

The CJEU interprets Regulation (EC) No 273/2004, which establishes harmonised measures for the intra-Union control and monitoring of certain substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances:

1. Art. 1 of Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors establishes harmonised measures for the intra-Union control

and monitoring of certain substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances with a view to preventing the diversion of such substances. In this regard, art. 2(a) of this Regulation [following the amendment made by Regulation (EU) No 1258/2013] defines 'scheduled substance' as any substance listed in Annex I that can be used for the illicit manufacture of narcotic drugs or psychotropic substances, including mixtures and natural products containing such substances but excluding mixtures and natural products which contain scheduled substances and which are compounded in such a way that the scheduled substances cannot be easily used or extracted by readily applicable or economically viable means, medicinal products as defined in art. 1(2) 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 veterinary medicinal products as defined in art. 1(2) of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products.

2. Meanwhile, Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors, as amended by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013, lays down rules for the monitoring of trade between the Union and third countries in certain substances frequently used for the illicit manufacture of narcotic drugs and psychotropic substances for the purpose of preventing the diversion of such substances. It applies to imports, exports and intermediary activities.

   Art. 2(a) of Regulation (EC) No 273/2004 defines 'scheduled substance' as 'any substance listed in the Annex that can be used for the illicit manufacture of narcotic drugs or psychotropic substances, including mixtures and natural products containing such substances, but excluding mixtures and natural products which contain scheduled substances and which are compounded in such a way that the scheduled substances cannot be easily used or extracted by readily applicable or economically viable means, medicinal products as defined in point 2 of Article 1 of Directive [2001/83], and veterinary medicinal products as defined in point 2 of Article 1 of Directive [2001/82], except medicinal products and veterinary medicinal products listed in the Annex'.

3. Annex I to Regulation (EC) No 273/2004 contains the exhaustive list of 'scheduled substances', within the meaning of Article 2(a) of that regulation, which includes, under Category 1, ephedrine and pseudoephedrine. 12. At the same time, 'medicinal products and veterinary medicinal products containing ephedrine or its salts' and 'medicinal products and veterinary medicinal products containing pseudo-ephedrine or its salts' are included in category 4 of scheduled substances within the Annex to Council Regulation (EC) No 111/2005 since the entry into force of Regulation (EU) No 1259/2013.

4. The Order of the Court of Justice of the European Union (Eighth Chamber) of 2 March 2017 in Case C-497/16, *Juraj Sokáč*, addressed, in response to a request for preliminary ruling, the

question of whether "medicinal products", within the meaning of art. 1(2) of Directive 2001/83, which contain "scheduled substances", within the meaning of art. 2(a) of Regulation (EC) No 273/2004, such as ephedrine and pseudoephedrine, can be regarded as excluded from the scope of the latter regulation following the entry into force of Regulations (EU) Nos 1258/2013 and 1259/2013.

The CJEU has ruled that these medicinal products indeed remain excluded from the scope of Regulation (EC) No 273/2004 following the entry into force of Regulations (EU) Nos 1258/2013 and 1259/2013.

Liability for defective vaccines: proof of damage and the causal relationship between defect and damage. Advocate General's Opinion in Case C-621/15

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 states, in art. 4 thereof, that '[t]he injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage**'**.

In Case C-621/15, *W and Others v Sanofi Pasteur MSD SNC, Caisse primaire d'assurance maladie des Hauts-de-Seine and Caisse Carpimko*, the CJEU is referred a question on the interpretation of this article.

In the Opinion of Advocate General Bobek, delivered on 7 March 2017, it is proposed that the Court respond that said article 'does not in itself preclude, in the area of liability of pharmaceutical laboratories for the vaccines that they manufacture, a method by which the court ruling on the merits, in the exercise of its exclusive jurisdiction to appraise the facts, may consider that the facts relied on by the applicant constitute serious, specific and consistent presumptions capable of proving the defect in the vaccine and the existence of a causal relationship between it and the disease, notwithstanding the finding that general medical research does not establish a relationship between the vaccine and the occurrence of the disease, provided that such a method of proof does not effectively result in a reversal of the burden of proof of default, damage or causal link between those two**.**

In particular, such a method of proof may only involve presumptions that: **–** rely on evidence which is both relevant and sufficiently rigorous to sustain the inferences drawn; – are rebuttable; – do not unduly curtail free assessment of evidence by the national court, in particular by preventing the national judge, without prejudice to general national rules on admissibility of evidence, from taking account of relevant evidence, or requiring that specific pieces of evidence are treated as conclusive proof that one or more of the conditions of Article 4 are fulfilled, irrespective of what other evidence is presented; – do not prevent the national judges from giving due consideration

to any relevant medical research presented to the national court, without prejudice to rules on admissibility of evidence, or impose as an absolute requirement that medical research be presented in order to demonstrate defect or causal link.'

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