GÓMEZ-ACEBO & POMBO

Newsletter

Life Sciences

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Legislation

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Refusal to authorise a health claim made on foods and referring to the reduction of disease risk

As scientific evidence is insufficient to establish a cause and effect relationship between the consumption of Anxiofit-1 and the reduction of subthreshold and mild anxiety, Commission Regulation (EU) 2017/236 of 10 February 2017 refusing to authorise a health claim made on foods and referring to the reduction of disease risk [OJ L 36, 11.2.2017, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0236&from=EN] refuses to include in the Union list of permitted claims the following claim: "Anxiofit-1 has been shown to ameliorate subthreshold and mild anxiety. Subthreshold and mild anxiety are risk factors in the development of anxiety disorders and depression".

Procedures for the notification of alerts as part of the EWRS established in relation to serious cross-border threats to health

The Early Warning and Response System ('EWRS'), as a permanent communication network between the Commission and the competent public health authorities in each Member State, for the prevention and control of certain categories of communicable diseases, was provided for by Decision No 2119/98/EC of the European Parliament and of the Council, Decision that was subsequently repealed and replaced by Decision No 1082/2013/EU of the European Parliament and of the Council, which, inter alia, laid down rules on epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health.

It is in the above context that Commission Implementing Decision (EU) 2017/253 of 13 February 2017 laying down procedures for the notification of alerts as part of the early warning and response system established in relation to serious cross-border threats to health and for the information exchange, consultation and coordination of responses to such threats pursuant to Decision No 1082/2013/EU of the European Parliament and of the Council has been adopted.

The Decision was published in OJ L 37, 14.2.2017, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017D0253&from=EN

Amendment of the US-EC MRA Pharmaceutical Good Manufacturing Practices Annex

The Agreement on Mutual Recognition between the European Community and the United States of America (MRA) signed in 1998 contains a Sectoral Annex for Pharmaceutical Good Manufacturing Practices that has been amended by Decision No 1/2017 of 1 March 2017 of

the Joint Committee established under Article 14 of the Agreement on Mutual Recognition between the European Community and the United States of America, amending the Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs) [2017/382]. [OJ L 58, 4.3.2017, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:22017D0382&from=EN].

As stated in Article 2, the purpose of this Annex is to facilitate the exchange of official GMPs documents between the parties and reliance on the factual findings in such documents, as well as to facilitate trade and benefit public health by allowing each party to leverage and to reallocate its inspection resources, including by avoiding duplication of inspections, so as to improve oversight of manufacturing facilities and better address quality risk and prevent adverse health consequences.

Release from the obligation of applying directives on the marketing of certain species or material

Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 1999/105/EC, 2002/54/EC, 2002/55/EC and 2002/57/EC regulate the marketing of, respectively, fodder plant seed, cereal seed, material for the vegetative propagation of the vine, forest reproductive material, beet seed, vegetable seed and seed of oil and fibre plants. However, insofar that the seed of some species is not reproduced or marketed in all the Member States and there are States of the European Union where the propagation of vine and the marketing of propagation material are of minor economic importance, the aforementioned Directives also provide that, subject to certain conditions, Member States may be wholly or partially released from the obligation to apply those Directives in respect of certain species or material.

And that is what the Commission did in Decision 2010/680/EU, now repealed and replaced by Commission Implementing Decision (EU) 2017/478 of 16 March 2017 [OJ L 75, 21.3.2017, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017D0478&from=EN], releasing certain Member States from the obligation to apply to certain species Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 1999/105/EC, 2002/54/EC, 2002/55/EC and 2002/57/EC

Judgments and decisions

European Union

Liability of the notified body appointed by a manufacturer to check on the conformity of medical devices

The judgment of the Court of Justice of the European Union (First Chamber) of 16 February 2017 in Case C-219/15, in response to a request for a preliminary ruling from the

Bundesgerichtshof (Federal Court of Justice, Germany) in proceedings between Elisabeth Schmitt and TÜV Rheinland LGA Products GmbH, has interpreted Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003.

This judgment was given on referral of a number of questions raised in the course of proceedings concerning a female citizen who, having had breast implants manufactured in France fitted in Germany, years later had them removed after the competent French authority established that the manufacturer in question had produced breast implants using industrial silicone which did not comply with quality standards.

The concerned party brought an action for damages against the notified body appointed to assess the manufacturer's quality system, arguing that an inspection of the delivery notes and invoices would have enabled this body to ascertain that the manufacturer had not used an approved form of silicone.

Having the action failed at first instance and on appeal, the German Supreme Court asked the CJEU whether it is the purpose and intention of Directive 93/42 that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance should act in order to protect all potential patients and may therefore, in the event of a culpable infringement of an obligation, have direct and unrestricted liability towards the patients concerned, if it is subject to a general obligation to examine devices, or at least to examine them where there is due cause, and if it is subject to a general obligation to examine the manufacturer's business records and/or to carry out unannounced inspections, or at least to do so where there is due cause.

According to the CJEU, the notified body is not under a general obligation to carry out unannounced inspections, to examine devices and/or to examine the manufacturer's business records. However, in the face of evidence indicating that a medical device may not comply with the requirements laid down in Directive 93/42, as amended by Regulation (EC) No 1882/2003, the notified body must take all the steps necessary to ensure that it fulfils its obligations.

Moreover, it is also held in the judgment that in the procedure relating to the EC declaration of conformity, the purpose of the notified body's involvement is to protect the end users of medical devices. The conditions under which culpable failure by that body to fulfil its obligations under the directive in connection with that procedure may give rise to liability on its part vis-à-vis those end users are governed by national law, subject to the principles of equivalence and effectiveness.

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