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Amendment to the regulation on classification, labelling and packaging of substances and mixtures

OJ L 115 of 4 May 2018 publishes Commission Regulation (EU) 2018/669 of 16 April 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0669&from=EN

Judgments and decisions

European union

Decentralised procedure for marketing authorisation for a medicinal product and review of the point in time from which the exclusivity period starts to run

1. The Court of Justice (Second Chamber), in its judgment of 14 March 2018 in Case C-557/16, *Astellas Pharma GmbH v Helm AG and Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA)*, has interpreted 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, as amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012.

2. According to the Court, arts. 28 and 29(1) of Directive 2001/83, as amended by Directive 2012/26, must be interpreted as meaning that, in a decentralised marketing-authorisation procedure for a generic medicinal product, the competent authority of a Member State concerned by that procedure cannot itself determine the point in time from which the data exclusivity period for the reference medicinal product starts to run when adopting, under art. 28(5) of that directive, its decision on the placing on the market of that generic medicinal product in that Member State.

3. Similarly, art. 10 of the same directive, read in conjunction with art. 47 of the Charter of Fundamental Rights of the European Union, must be interpreted as meaning that a court of a Member State

involved in a decentralised procedure for marketing authorisations, hearing an action brought by the holder of the marketing authorisation for the reference medicinal product against the marketing-authorisation decision for a generic medicinal product in that Member State taken by its competent authority, has jurisdiction to review the determination of the point in time from which the data exclusivity period for the reference medicinal product starts to run. By contrast, that court does not have jurisdiction to review whether the initial marketing authorisation for the reference medicinal product granted in another Member State was granted in accordance with that directive.

National legislation limiting the right to retail, use and administer veterinary medicinal, anti-parasitic and organic products to veterinary practitioners

The Court of Justice (Third Chamber), in its judgment of 1 March 2018 in Case C 297/16, *Colegiul Medicilor Veterinari din România (CMVRO) and Autoritatea Națională Sanitară Veterinară Veterinară şi pentru Siguranța Alimentelor, intervening Asociația Națională a Distribuitorilor de Produse de Uz Veterinar din România,* has ruled that

1) Article 15 of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market is to be interpreted as not precluding national legislation, such as that at issue in the main proceedings, under which veterinary practitioners have an exclusive right to retail and use organic products, special purpose anti-parasitic products and veterinary medicinal products.

2) Article 15 of Directive 2006/123 is to be interpreted as precluding national legislation, such as that at issue in the main proceedings, under which shares in establishments retailing veterinary medicinal products must be owned exclusively by one or more veterinary practitioners.

Application for internal review of decisions authorising the placing on the market of genetically modified soybeans

1. An application was made to the European Commission to carry out an internal review of Implementing Decisions (EU) Nos 2015/686, 2015/696 and 2015/698, regarding the marketing authorisation for the genetically modified soybeans MON 87769, MON 87705 and 305423.

The application was submitted pursuant to art. 10 of Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies.

As the General Court points out in the judgment below, the application claimed that "(i) there was a lack of guidance from EFSA concerning the health impact of genetically modified crops

with significantly altered nutritional content; (ii) the lack of guidance resulted in an inadequate and inconsistent assessment of nutritional risks which did not meet legal requirements; (iii) the lack of guidance resulted in infringement of the provisions on labelling; (iv) the lack of guidance resulted in inadequate and inconsistent post-marketing monitoring proposals; (v) there was a failure to consider herbicide residues when examining the impact of the consumption of genetically modified food and feed on health as regards the MON 87705 and 305423 soybeans, and (vi) as regards the MON 87705 soybean, the assessment of the unintended effects of ribonucleic acid interference was inadequate".

However, the Commission refused the application for review on the ground that the first five complaints and part of the sixth complaint, described in paragraph 14 above, did not fall within the scope of Article 10 of Regulation No 1367/2006 and that the remainder of the sixth complaint concerning the environmental risk assessment did 'not justify the need to amend Decision 2015/696'.

2. The General Court (Seventh Chamber), in its judgment of 14 March 2018 in Case T 33/16, *TestBioTech eV v European Commission, supported by Monsanto Europe, Monsanto Company, Pioneer Overseas Corp. and Pioneer Hi-Bred International, Inc.*, annuls the letter of the Commissioner for Health and Food Safety of 16 November 2015, bearing the reference Ares(2015) 5145741, concerning a request for internal review, based on Article 10 of Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies, of the implementing decisions authorising the placing on the market of the genetically modified soybeans MON 87769, MON 87705 and 305423.

The Commission will therefore have to take a fresh decision on the request.

Importer of a medical device to which it affixes an additional label: no exception to the exhaustion of trade mark rights

1. The Court of Justice (Fifth Chamber), in its judgment of 17 May 2018 in Case C 642/16, *Junek Europ-Vertrieb GmbH v Lohmann & Rauscher International GmbH & Co KG*, has again addressed the issue of exhaustion of the rights conferred by a trade mark and the relabelling of products under a trade mark. The judgment was given in relation to Article 13 (2) of Council Regulation (EC) No 207/2009 of 26 February 2009 on the European Union trade mark, but the interpretation is equally applicable to the current Regulation (EU) 2017/1001, which continues to regulate the exhaustion of the rights conferred by a trade mark in similar terms, providing in its Article 15 as follows:

"1. An EU trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the European Economic Area under that trade mark by the proprietor or with his consent.

2. Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialisation of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market".

2. According to the Court, "the proprietor of a mark cannot oppose the further commercialisation, by a parallel importer, of a medical device in its original internal and external packaging where an additional label, such as that at issue in the case in the main proceedings, has been added by the importer, which, by its content, function, size, presentation and placement, does not give rise to a risk to the guarantee of origin of the medical device bearing the mark".

In the specific case, the packaging of the product was modified by including the indication on the bottom left

, as can be seen in this magnification:

Assessment of the safety of cosmetic products

The Court of Justice (Sixth Chamber), in its judgment of 12 April 2018 in Case C 13/17, *Fédération des entreprises de la beauté v Ministre des Affaires sociales, de la Santé et des Droits des femmes, Ministre de l'Éducation nationale, de l'Enseignement supérieur et de la Recherche and Ministre de l'Économie et des Finances (formerly Ministre de l'Économie, de l'Industrie et du Numérique)*, has interpreted art. 10(2) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

Art. 10 of the above Regulation regulates safety assessments and provides that the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up in accordance with Annex I. And according to art. 10(2), "[t]he cosmetic product safety assessment, as set out in Part B of Annex I, shall be carried out by a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognised as equivalent by a Member State".

According to the Court, art. 10(2) of Regulation No 1223/2009 must be interpreted as conferring on each Member State the power to determine disciplines that are 'similar' to pharmacy, toxicology or medicine, as well as levels of qualification satisfying the requirements of that regulation, on condition that it complies with the objectives laid down by that regulation, consisting, in particular, in guaranteeing that the person entrusted with the assessment of the safety of cosmetic products has a qualification that enables him to ensure a high level of protection of human health.

Relevant circles for the purposes of determining whether a pharmaceutical trade mark has become a generic term

1. The General Court, in its judgment of 18 May 2018 in Case T 419/17, *Mendes SA v European Union Intellectual Property Office (EUIPO)*, set out to determine which circle is to be taken into account when deciding whether a pharmaceutical trade mark has become a revocable generic term.

According to the General Court, in cases where intermediaries participate in the distribution to the consumer or the end user of a product which is the subject of a registered trade mark, the relevant classes of persons whose views fall to be taken into account in determining whether that trade mark has become the common name in the trade for the product in question comprise all consumers and end users and, depending on the features of the market concerned, all those in the trade who deal with that product commercially. The perception of pharmacists and doctors, both general practitioners and specialists, must therefore also be taken into account. However, "the scientific community is not part of the relevant circles, playing no part at all in

the communication process between the vendor, on the one hand, and the purchaser, on the other. It has, in consequence, no influence over end consumers' decision to purchase".

2. Furthermore, the judgment has also made it clear, in relation to the revocation of a trade mark by conversion into a misleading sign, that the revocation of a trade mark for that reason occurs only when the public, in view of the trade mark, expects intrinsic characteristics from the product, taking into account the message conveyed by the trade mark. But it "is in no way intended to impose on the proprietor of a mark the obligation to ensure a certain level of quality, except where the mark conveys such a message".

3. For a more detailed examination of this ruling, please refer to our Pharmaceutical Analysis document for the month of May 2018.

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