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Newsletter

PHARMA & HEALTHCARE

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Legislation and legislative proposals

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Harmonised standards on medical devices

1. According to Article 8 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April on medical devices, devices that are in conformity with the relevant harmonised standards or with the relevant parts of those standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof. An equivalent provision is found in Article 8 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April on in vitro diagnostic medical devices.

   On that basis, 'Commission Implementing Decision (EU) 2021/1182 of 16 July 2021 on the harmonised standards for medical devices drafted in support of Regulation (EU) 2017/745 of the European Parliament and of the Council' and 'Commission Implementing Decision (EU) 2021/1195 of 19 July 2021 on the harmonised standards for in vitro diagnostic medical devices drafted in support of Regulation (EU) 2017/746 of the European Parliament and of the Council' were adopted back in the day.

2. Now, these decisions have been adopted:

   a) Commission Implementing Decision (EU) 2025/681 of 8 April amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for medical gloves for single use, sterilization of medical devices and patient handling equipment used in ambulances[1]; after the Commission had made a request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation for the revision of existing harmonised standards on medical devices developed in support of Directives 90/385/EEC and 93/42/EEC, and for the drafting of new harmonised standards in support of Regulation (EU) 2017/745.

   b) Commission Implementing Decision (EU) 2025/679 of 8 April amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for

[1] Official Journal of the European Union, No. 681, 9 April 2025. See at this *link*.

sterilisation of medical devices[2], after the Commission had made a request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation for the revision of existing harmonised standards on in vitro diagnostic medical devices developed in support of Directive 98/79/EC and for the drafting of new harmonised standards in support of Regulation (EU) 2017/746.

Judgments, rulings and decisions

European Union

Advertising with health claims relating to botanical substances

Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December on nutrition and health claims made on foods, as amended by Regulation (EC) No 109/2008 of the European Parliament and of the Council of 15 January, provides in Article 10(1) that health claims shall be prohibited unless they comply with the requirements in the Regulation and are authorised in accordance with the Regulation and included in the lists of authorised claims provided for in Articles 13 and 14. And Article 10(3) adds that references to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14.

In Case C-386/23, the *Bundesgerichtshof* (Federal Court of Justice) asks the Court of Justice whether "plant or herbal substances ("[botanical substances]") [may] be advertised with health claims (Article 10(1) of Regulation No 1924/2006) or with references to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being (Article 10(3) of Regulation No 1924/2006) without those claims being authorised under that regulation and included in the list of authorised claims pursuant to Articles 13 and 14 of [that regulation] (Article 10(1) of [Regulation No 1924/2006]) or without those references being accompanied by a specific health claim contained in one of the lists referred to in Articles 13 or 14 of [that regulation] (Article 10(3) of [Regulation No 1924/2006]), pending completion of the evaluation by [EFSA] and the examination by the Commission of the inclusion of the claims notified

[2] Official Journal of the European Union, No. 679, 10 April 2025. See at this *link*.

in respect of "[botanical substances]" in the Community lists referred to in Articles 13 and 14 of Regulation No 1924/2006".

In its judgment of 30 April 2025 (ECLI:EU:C:2025:304), the Fifth Chamber of the Court of Justice ruled that Regulation (EC) No 1924/2006 must be interpreted as follows:

> in the context of commercial advertising of a food supplement composed of 'botanical substances' within the meaning of Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health, as meaning that it is not permitted, until the European Commission has completed its examination of health claims relating to botanical substances for the purposes of their inclusion in the lists of authorised health claims provided for in Articles 13 and 14 of Regulation No 1924/2006, as amended, to use specific health claims relating to such substances and describing or referring to psychological or behavioural functions, or to make reference to the general, non-specific benefits of such a substance for overall good health and health-related well-being without that reference being accompanied by a specific health claim included in those lists, unless the use of such claims is permitted under Article 28(6) of that regulation.

Unified Patent Court

The UPC rules on the infringement of a second medical use claim

The Unified Patent Court ('UPC') has delivered its first decision on the infringement of a second medical use claim, specifically in the Düsseldorf Local Division Decision of the Court of First Instance of the Unified Patent Court of 13 May 2025 (UPC_CFI_505/2024). In it, the Court starts from the principle that in "finding a balance between a fair protection for the patent proprietor and a reasonable degree of legal certainty for third parties, a limitation of the scope of protection to cases where the product is already or actually being used for the claimed therapeutic purposes would unduly limit the protection of the patent proprietor".

Therefore, "for a finding of infringement of a second medical use claim, the alleged infringer must offer or place the medical product on the market in such way that it leads or may lead to the claimed therapeutic use of which the alleged infringer knows or reasonably should have known that it does".

In this regard, the "requirements of such behaviour cannot be defined in an abstract manner but require an analysis of all the relevant facts and circumstances of the case at hand. Starting from the construction of the patent claim in question, relevant facts may include: the extent or significance of the allegedly infringing use; the relevant market including what is customary on that market; the market share of the claimed use compared to other uses; what actions the

alleged infringer has taken to influence the respective market, either "positively", de facto encouraging the patented use, or "negatively" by taking measures to prevent the product from being used for patented use.

In this regard, the "manufacturing of the product and in particular the package insert and the SmPC of a pharmaceutical product can be important. However, they are not always the only decisive factor to be taken into account in assessing whether the alleged infringer is in the end liable for patent infringement. Additionally, the extent to which the alleged infringer knows or should have known that the product will be used for the claimed purpose is of relevance".

The UPC rules on the imminent infringement of pharmaceutical patents

The Court of First Instance of the Unified Patent Court, in its Lisbon Local Division Order of 8 May 2025 (UPC_CFI_41/2025), has interpreted Article 62 of the Agreement on a Unified Patent Court ('UPCA'), according to which the court may grant injunctions to prevent any imminent infringement, in relation to pharmaceutical patents and measures taken by the generic pharmaceutical industry.

The Court starts from a general consideration that the pharmaceutical market "operates in a highly regulated field that constantly requires interaction with administrative entities. Before being placed on the market, a medicine must undergo several successive administrative steps, including the application for an MA, sales price determination, and reimbursement negotiations with health authorities. Furthermore, public tenders or public procurements may also be conducted". However, although administrative procedures, legislation and their interaction with market access vary depending on the Contracting Member State, it is held that the Court must assess imminent infringement independently, solely based on the interpretation of the UPCA, and not on national legislation.

The Court further notes that the risk of infringement cannot be established through an abstract assessment. Rather, it must be established on a case-by-case basis that the potential infringer has carried out acts that make it more likely than not that it intends to offer or place the product on the market before the patent expires: "Imminent infringement must then be assessed from the point of view of the concrete likelihood that, in light of the circumstances of the case, the Defendant is more likely than not to commit an act of infringement".

In the present case, the Court considers that, even though the defendant has obtained marketing authorisation for the medicinal product and the price determination and reimbursement negotiation procedure has been concluded, this alone is not sufficient to establish a risk of imminent infringement. According to the Court, "if the Defendant has not taken any other steps that indicate it will market the medicine, the administrative steps alone taken by the Defendant do not establish a risk of imminent infringement". In short, "the risk of infringement must arise directly from the conduct of the potential infringer. If the potential infringer's conduct does not constitute a risk of infringement, it cannot be asserted that such a risk was thereby created". On that basis, although in the case at hand the defendant had obtained marketing authorisation and price and reimbursement determinations, the Court considers that it has not been established that the defendant's conduct makes the infringement more likely than not.

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