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2023 No. 36

Contents

Legislation and legislative proposals

European Union

The European Parliament adopts at first reading the proposal for a regulation on standards of quality and safety for substances of human origin intended for human application

The European Parliament introduced some amendments to the proposal for a regulation of the European Parliament and of the Council on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC.

It did so on 12 September 2023 by adopting at first reading its position on the regulation proposal[1] concerning substances of human origin ("SoHOs") (such as blood, tissues, cells or any other substance of human origin such as human breast milk and microbiota) intended for human application, SoHO preparations, products manufactured from SoHOs and intended for human application, SoHO donors and recipients, and offspring from donated sperm.

The changes introduced include, in addition to those emphasising the voluntary and unpaid nature of SoHO donations, the amendment concerning the exchange of information on SoHO availability and continuity of supply, which adds a new Article 34*a* providing that the competent authorities shall establish a digital communication channel through which they can exchange information on the availability of SoHOs in the national territory in a fast and efficient manner. Through this channel, competent authorities may, in specific situations of need, oblige national SoHO entities to provide information on the availability of a certain SoHO. They shall also take into account alerts sent by national SoHO entities concerning the availability of SoHOs and potential shortages.

Also relevant is the introduction by the European Parliament of a new Article 36*a* on authorisation and registry of SoHO clinical studies, according to which these studies shall be authorised by the competent authorities, after verification that the clinical study has been subject to a positive recommendation by a relevant ethics committee where necessary. In addition, the competent authorities will register each authorised clinical trial on the EU SoHO Platform. And, where a clinical study on substances of human origin involves more than one entity and those entities are located in different Member States, the clinical study shall only require the authorisation of one competent authority in the Union.

Transparency rules for clinical trials

The European Medicines Agency has adopted a new version of its transparency rules for the publication of information on clinical trials submitted

[1] ***Link***

through the Clinical Trials Information System (CTIS), 5 October, EMA/263067/2023][2].

This regulation seeks to strike a balance between transparency and the protection of trade secrets. The main changes include removing the deferral mechanism to delay the publication of certain data for up to seven years from the end of a trial.

Update to the Clinical Trials Information Document

On 29 September 2023 the European Commission published a new version (version 6.6) of the document on questions and answers concerning the regulation of clinical trials in Regulation (EU) No 536/2014 (*Clinical Trials Regulation (EU) No 536/2014- Questions & Answers*)[3].

Judgments, rulings and decisions

European Union

Wholesale distribution of medicinal products

The Court of Justice - in its judgment of 21 September 2023 (C-47/22, ECLI:EU:C:2023:691) - has held that "the holder of an authorisation for the wholesale distribution of medicinal products may not obtain medicinal products from other persons who, under national legislation, are authorised or entitled to supply medicinal products to the public, but who are themselves neither holders of such a distribution authorisation nor exempt from the requirement to obtain such an authorisation, even if the acquisition concerns only a minimal quantity, or if the medicinal products thus acquired are intended to be resold only to persons authorised or entitled to supply medicinal products to the public or to persons who themselves hold a wholesale distribution authorisation".

In addition, the personnel requirements to be met by a wholesale distributor of medicinal products "are fulfilled where, during an inspection, the responsible person designated by the wholesaler is not present on the premises, provided that he or she is contactable by telephone and that the members of staff present on the premises are able to provide directly to the inspection service the information requested by the latter about the procedures which fall within their sphere of competence. In order to assess whether a wholesaler has sufficient competent staff, it is necessary to take into account the activities that that wholesaler has, where applicable, outsourced and the number of staff members involved in those activities".

The right to obtain a copy of personal medical data

The Court of Justice, in its judgment of 26 October 2023 (C-307/22, ECLI:EU:C:2023:811), has clarified

[2] ***Link***

[3] ***Link***

what the right of access to data undergoing processing means in the case of data relating to the health of the data subject. Thus, according to the Court, in the context of a doctor-patient relationship, the right to obtain a copy of personal data undergoing processing:

1) Means that the data subject must be given a faithful and intelligible reproduction of all those data.

2) Entails the right to obtain a full copy of the documents included in his or her medical records and containing, inter alia, those data if the provision of such a copy is essential in order to enable the data subject to verify how accurate and exhaustive those data are, as well as to ensure they are intelligible.

3) Includes in any event the right to obtain a copy of the data in his or her medical records containing information such as diagnoses, examination results, assessments by treating physicians and any treatment or interventions provided to him or her.

Similarly, the Court also states that a piece of national legislation which, with a view to protecting the economic interests of the controller, makes the data subject bear the costs of a first copy of his or her personal data undergoing processing, does not comply with the General Data Protection Regulation.

COVID certificates and processing of personal data

The Court of Justice, in its judgment of 5 October 2023 (C-659/22, ECLI:EU:C:2023:745), has stated that the concept of *processing* personal data referred to in the General Data Protection Regulation must be interpreted as "including the verification, using a national mobile application, of the validity of interoperable COVID-19 vaccination, test and recovery certificates issued pursuant to Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic, and used by a Member State for national purposes".

Foods that affect children's health: the average consumer pays a higher level of attention

1. An application for the EU word mark Namlac to distinguish, inter alia, baby food; milk-based flours for babies; milk sugar for pharmaceutical use; lactose for pharmaceutical use; diet drinks for medical use; diet drinks for babies adapted for medical use ; diet foods for medical use; dietary substances for medical use; protein-based food supplements; nutritional supplements; glucose-based food supplements; enzyme-based food supplements; mineral food supplements; mineral supplements intended for use in food; health food supplements consisting mainly of minerals', was filed in opposition by the proprietor of the earlier Spanish figurative mark registered for 'milk for infants':

The European Intellectual Property Office (both its Opposition Division and the Board of Appeal) rejected the opposition on the grounds that there is no likelihood of confusion.

2. For its part, the General Court dismisses the action (Judgment of 6 September 2023, Case T-728/22, ECLI:EU:T:2023:511).

According to the General Court, the average consumer's attention is higher when purchasing food that may affect children's health: "parents of babies and young children pay a higher level of attention when purchasing baby products, given the importance they attach to the nutrition and health of babies (judgment of 16 September 2009, *Hipp & Co v OHIM - Laboratorios Ordesa (Bebimil)*, T221/06, not published, EU:T:2009:330, paragraph 40]. This case law applies *a fortiori* to goods such as 'milk for infants'. Even assuming, as the appellant submits, that the goods designated by the earlier mark are freely available in supermarkets, that does not alter the finding that the relevant consumer will show a high level of attention when it comes to foodstuffs which affect the health of children, and even more so of young children".

Therefore, the Court concludes that, "even taking into account the identity of some of the goods in question and the similarity of others, the slight similarities that the marks may have visually, phonetically and conceptually are not sufficient to conclude that there is a likelihood of confusion for the relevant consumer, notwithstanding the interdependence between various factors"'.

The Enlarged Board of Appeal of the European Patent Office makes a pronouncement on priority claims

The Enlarged Board of Appeal of the European Patent Office - in its decision of 10 October 2023, in consolidated cases G 1/22 and G 2/22 - has interpreted the regulation on priority claims in patent matters contained in the Convention on the Grant of European Patents.

As is well known, according to Article 87 of the Convention, anyone who has duly filed, in or for a State party to the Paris Convention for the Protection of Industrial Property or a member of the World Trade Organisation, an application for a patent, utility model or utility certificate, or his successors in title, shall enjoy, for the purpose of filing a European patent application in respect of the same invention, a right of priority during a period of twelve months from the date of filing of the first application.

Now, according to the Enlarged Board of Appeal, the European Patent Office is competent to assess whether the applicant is entitled to claim priority under this regulation. And there is a *rebuttable* presumption that the applicant claiming priority is entitled to do so.

Furthermore, this presumption also applies in situations where the European patent application derives from a PCT application (relating to the Patent Cooperation Treaty) or where the priority applicants are not identical with the subsequent applicants. Consequently, in a situation where a PCT application is jointly filed by parties A and B, with party A applying for a patent for one or more States and party B for one or more other States, party B may claim priority of the PCT application.

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