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Legislation and legislative proposals

European Union

Provisional agreement on proposal for a regulation on the European Health Data Space

In March 2024, the European Parliament and the Council of the European Union reached a provisional agreement on a proposal for a regulation on the European Health Data Space, an important piece of legislation that will facilitate access to personal electronic health data. The provisional agreement still needs to be ratified by both institutions.

Orally administered veterinary medicinal products

Commission Delegated Regulation (EU) 2024/1159 of 7 February 2024[1] supplements Regulation (EU) 2019/6 of the European Parliament and of the Council by laying down rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal handler to food-producing animals.

Delegated Regulation (EU) 2024/1159 applies to authorised and prescribed veterinary medicinal products administered orally in drinking water, mixed into feed, or administered on the surface of feed immediately prior to feeding and administered by the animal keeper to food-producing animals. However, it does not apply to the use of medicated feed manufactured in accordance with Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed.

Procedural rules for the interaction during, exchange of information on, and participation in, the preparation and update of joint clinical assessments of medicinal products for human use at Union level

Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment provides in Article 15 for the adoption by the Commission of detailed procedural rules for joint clinical assessments. Pursuant to this, Commission Implementing Regulation (EU) 2024/1381 of 23 May 2024 laying down procedural rules for the interaction during, exchange of information on, and participation in, the preparation and update of joint clinical assessments of medicinal products for human use at Union level, as well as templates for those joint clinical assessments[2] has been adopted and published.

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[1] OJEU No. 1159 of 19 April 2024. See this ***link.***

[2] OJEU No. 1381 of 24 May 2024. See this ***link.***

As set out in its first article, this new regulation lays down detailed procedural rules for joint clinical assessments of medicinal products at Union level as regards the following:

a) cooperation, in particular by exchange of information, with the European Medicines Agency on the preparation and update of joint clinical assessments of medicinal products;

b) interaction, including the timing thereof, with and between the Coordination Group established under Article 3 of Regulation (EU) 2021/2282, its subgroups and health technology developers, patients, clinical experts and other relevant experts during joint clinical assessments of medicinal products and their updates;

c) general procedural rules on the selection and consultation of stakeholder organisations and patients, clinical experts, and other relevant experts in joint clinical assessments at Union level;

d) the format and templates for dossiers with information, data, analyses and other evidence to be provided by health technology developers for joint clinical assessments;

e) the format and templates for joint clinical assessment reports and summary joint clinical assessment reports.

Final materials as used in products that come into contact with water intended for human consumption

The European Commission has adopted two implementing decisions in application of Directive (EU) 2020/2184 of the European Parliament and of the Council as regards the procedures and methods for testing and accepting final materials as used in products that come into contact with water intended for human consumption. These are Implementing Decision (EU) 2024/367[3] and Implementing Decision (EU) 2024/368[4], both of 23 January 2024.

Clinical audits of medical radiological practices

The European Commission has published Commission Recommendation (EU) 2024/1112 of 18 April 2024 on clinical audits of medical radiological practices carried out pursuant to Council Directive 2013/59/Euratom[5], which aims to harmonise the provisions applicable in the Member States regarding the implementation of the provisions of Directive 2013/59/Euratom, in order to promote a more harmonised approach at Community level.

[3] OJEU No. 367 of 23 April 2024; see this ***link***.

[4] OJEU No. 368, 23 April 2024; see this ***link***.

[5] OJEU No. 1112 of 22 April 2024. See this ***link***.

Judgments, rulings and decisions

European Union

Suspension, revocation or variation of a marketing authorisation where the risk-benefit balance is not favourable

According to the first paragraph of Article 116 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, the competent authorities are to suspend, revoke or vary a marketing authorisation if the view is taken that the medicinal product is harmful, that it lacks therapeutic efficacy, that the risk-benefit balance is not favourable or that the medicinal product's qualitative and quantitative composition is not as declared.

However, the General Court - in its Judgment of 15 May 2024, T-416/22, ECLI:EU:T:2024:316 - has interpreted the concept of *risk-benefit balance*, defined in Article 1(28a) of Directive 2001/83, as amended, as 'an evaluation of the positive therapeutic effects of the medicinal product in relation to the risks as defined in point 28, first indent' of Article 1 of said directive, which defines the concept of 'risks related to use of the medicinal product' as 'any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health'.

On that basis, the General Court states that a literal interpretation, according to the context and in the light of the objective pursued by Article 116 of Directive 2011/83, as amended, must lead to the understanding that the concept of *benefit-risk balance* also covers the risks associated with the off-label use of a medicinal product.

In that regard, the General Court states that 'the competent authorities must be able to take into account information relating to all the risks that a medicinal product poses to public health, including those associated with off-label use. The off-label use of a medicinal product may pose risks to public health similar to those associated with its on-label use. Off-label use of a medicinal product is not uncommon. It is a professional decision taken by a medical practitioner who assesses the benefits and risks involved. That practitioner must therefore be informed as fully as possible'.

An infringement of the General Data Protection Regulation may result in an act of unfair competition

In his Opinion of 25 April 2024 (C-21/23, ECLI:EU:C:2024:354), Advocate General Szpunar, on the question of the application of unfair competition rules as a reaction to an infringement of the rules governing personal data, proposes that the Court of Justice should rule that the General Data Protection Regulation does not preclude national rules which afford undertakings the right to rely, on the basis of the prohibition of acts of unfair competition, on infringements of the substantive provisions of that regulation which are alleged to be committed by their competitors.

Data of customers of a pharmacist and data concerning health

In his Opinion of 25 April 2024 (C-21/23, ECLI:EU:C:2024:354), Advocate General Szpunar takes

the view that the data of the customers of a pharmacist which are transmitted when an order is placed on an online sales platform for pharmacy-only but non-prescription medicines do not constitute 'data concerning health', 'in so far as only hypothetical or imprecise conclusions as to the health status of the person placing the online order may be drawn, which it is for the referring court to verify'.

The Advocate General bases his reasoning on the fact: that non-prescription medicine may be used to treat everyday diseases that may be encountered by anyone and are not symptomatic of a specific pathology or health status; that it may happen that the person placing the order is not the person who will use the medicine; and that 'a person may place an order via the internet without being required to provide precise data about his or her identity, in particular where the product is delivered not to the data subject's address but via a collection point, and where no other information is required for billing purposes'.

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