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Newsletter

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Good manufacturing practices for active substances used as starting materials in veterinary medicinal products

Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products, establishes (Art. 93(1)(j)) that veterinary medicinal products manufactured in the Union, including those intended for export, as well as those imported into the Union, must comply with good manufacturing practice for veterinary medicinal products and use as starting materials only active substances which have been manufactured in accordance with good manufacturing practice for active substances. On that basis, the aforementioned regulation entrusts the Commission with the adoption of measures relating to such good practices.

On that regulatory basis, Commission Implementing Regulation (EU) 2025/2154 of 17 October 2025 laying down good manufacturing practice for active substances used as starting materials in veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council[1] has been adopted.

This implementing regulation, which seeks to align manufacturing requirements with existing European standards for medicinal products for human use, will enter into force on 16 November 2025 and will apply from 16 July 2026.

Procedural rules for the preparation and update of joint clinical assessments of medical devices and in vitro diagnostic medical devices

Commission Implementing Regulation (EU) 2025/2086 of 17 October has been approved and published, laying down, pursuant to Regulation (EU) 2021/2282 on health technology assessment, procedural rules for the interaction during, exchange of information on, and participation in, the preparation and update of joint clinical assessments of medical devices and in vitro diagnostic medical devices at Union level, as well as templates for those joint clinical assessments[2].

[1] OJ L 2025/2154 of 27.10.2025, see this *link*.

[2] OJ L 2025/2086 of 20.10.2025, see this *link*.

Commission guidelines on variations to marketing authorisations

Variations to marketing authorisations for medicinal products are governed by Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products. Article 4 thereof requires the Commission to draw up guidelines on the details of the various categories of variations, on the application of the procedures laid down in Chapters II, III and IV of the Regulation itself, and on the documentation to be submitted pursuant to those procedures.

In compliance with that mandate, the Commission has drawn up the 'Guidelines on the details of the various categories of variation, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use, and on the documentation to be submitted pursuant to those procedures'[3]. With this document, the Commission seeks to facilitate the interpretation and application of the variations regulation, as well as to provide details on the application of the relevant procedures, including the steps to be taken (from the submission of a notification or an application for a variation to the final outcome of the procedure).

Council approves the Regulation of the European Parliament and of the Council on compulsory licensing for crisis management

On 27 October 2025, the Council approved the Regulation of the European Parliament and of the Council on compulsory licensing for crisis management, which aims to lay down rules on the conditions and the procedure for granting a Union compulsory licence for intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States in the context of a crisis or emergency mode. The regulation still needs to be approved by the European Parliament in plenary.

The main feature of this regulation currently being pushed through is that, as compulsory licences are set up as Union licences, they will not be granted by national patent authorities, but by the European Commission, which will only be able to do so in response to a crisis or emergency mode.

By centralising the granting of compulsory licences, the aim is to avoid the lack of uniformity that could arise if a particular patent were subject to a compulsory licence in one Member State and not in another, or if the conditions of the licences in several States were divergent. The aim is for the Commission's decision to apply in all Member States where a particular technology (necessary to deal with the crisis or emergency) is protected, and for this to be done under the same conditions, with the proviso that the granting of the licence by the Commission must be preceded by the opportunity for third parties to submit comments, as well as by an opinion from the advisory body responsible for the crisis or emergency mechanism in question (or, in the absence of a competent advisory body, from an ad hoc body set up by the Commission composed of one representative of each Member State).

[3] OJ C 223/1 of 2.8.2013, see this *link*.

However, the limitation of the cases in which compulsory licences may be granted by the Union means that national authorities will still be able to grant compulsory licences when these are not granted in response to any of the crises or emergencies referred to above.

Judgments, rulings and decisions

European Union

Concerted practices through a patent agreement

In its judgment of 18 October 2023, Teva Pharmaceutical Industries and Cephalon v Commission (T-74/21, EU:T:2023:651), the General Court dismissed the action for annulment of European Commission Decision C(2020) 8153 final of 26 November 2020 (Case AT.39686-Cephalon), in which the Commission found that the agreement between a patent-holding pharmaceutical company and a generic company whereby the latter undertook not to market its generic product or challenge the patents constituted a concerted practice contrary to competition law.

However, the Court of Justice, in its judgment of 23 October 2025, C-2/24 P, ECLI:EU:C:2025:825, has dismissed the appeal against that judgment of the General Court and, in doing so, recalls its previous case law in cases such as that decided in the judgment of 27 June 2024, *Servier and Others v Commission* (C-201/19, EU:C:2024:552), emphasising that "settlement agreements whereby a manufacturer of generic medicines that is seeking to enter a market recognises, at least temporarily, the validity of a patent held by a manufacturer of originator medicines and gives an undertaking, as a result, no longer to challenge that patent and not to enter that market are liable to have effects that restrict competition, since challenges to the validity and scope of a patent are part of normal competition in the sectors where there exist exclusive rights in relation to technology".

Accordingly, "settlement agreements, such as the settlement agreement in the present case, must be classified as restrictions of competition by object where it is plain from examining them that the transfers of value made by the manufacturer of the originator medicine to the manufacturer of the generic medicine can ultimately have as their sole explanation the commercial interest of those operators not to engage in competition on the merits".

Cross-border healthcare

In its judgment of 4 September 2025, C-489/23 (ECLI:EU:C:2025:651), the Court of Justice has ruled that Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, read in the light of Article 56 of the Treaty on the Functioning of the European Union (TFEU), must be interpreted as precluding national legislation which makes reimbursement of the costs of cross-border healthcare incurred by an insured person in the Member State of affiliation subject to a medical assessment, carried out by a health professional belonging to the public health insurance system of that State, which has given rise to the issuing, by that health professional, of a document authorising the hospitalisation of that insured person.

On the other hand, Regulation (EC) No 883/ /2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems, read in the light of Article 56 TFEU, "must be interpreted as not precluding national legislation pursuant to which, where an insured person has, justifiably, been refused the prior authorisation required in order to receive certain cross-border healthcare, the amount of reimbursement of the costs of that healthcare by the Member State of affiliation is limited to the amount provided for by the health insurance scheme of that State, applying, to that end, a calculation method which significantly limits the amount of that reimbursement as compared with the costs actually incurred by the insured person in the Member State where he or she was provided with that healthcare, provided that that calculation method is based on objective, non-discriminatory and transparent criteria. Nevertheless, if, for reasons relating to his or her state of health or to the need to receive urgent treatment in a hospital, that person was prevented from applying for such a prior authorisation or was not able to wait for the decision of the competent institution on the application for authorisation submitted, he or she is entitled to obtain reimbursement, from the competent institution, of an amount equivalent to that which would ordinarily have been assumed by that institution if he or she had had such an authorisation".

Standard of judicial review of European Medicines Agency (EMA) decisions

The General Court, in its judgment of 24 September 2025, T-483/22, ECLI:EU:T:2025:912, has referred to the standard of judicial review of decisions by which the European Commission decides whether or not a medicinal product is to be granted a marketing authorisation or whether or not it constitutes an orphan medicinal product.

To that end, the court draws a distinction between the review that the EU judicature may be called upon to carry out of the formal legality of the scientific opinions of the EMA's committees and of the Commission's exercise of its discretion.

With regard to the review of scientific opinions, "the Court cannot substitute its own assessment for that of those committees. Only the proper functioning of the committee, the internal consistency of the opinion and the statement of reasons contained in it can be subject to judicial review. As regards the latter aspect, the review consists of examining whether those documents contain a statement of reasons from which it is possible to ascertain the considerations on which they are based and whether they establish a comprehensible link between

the medical or scientific findings and the conclusions".

As regards the Commission's exercise of its discretion, the General Court recalls its case law, according to which "where the EU authorities have a broad discretion, in particular as to the assessment of highly complex scientific and technical facts in order to determine the nature and scope of the measures which they adopt, review by the EU judicature is limited to verifying whether there has been a manifest error of assessment or a misuse of powers, or whether those authorities have manifestly exceeded the limits of their discretion". Therefore, the EU judicature cannot substitute its assessment of scientific and technical facts for that of the EMA.

Telemedicine and the e-commerce directive

As is well known, Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce), provides in Article 3(1) that each "Member State shall ensure that the information society services provided by a service provider established on its territory comply with the national provisions applicable in the Member State in question which fall within the coordinated field", the coordinated field being understood to mean (Article 2) "requirements laid down in Member States' legal systems applicable to information society service providers or information society services, regardless of whether they are of a general nature or specifically designed for them".

On that basis, the Court of Justice, in its judgment of 11 September 2025, C-115/24, ECLI:EU:C:2025:694— that Article 3(1) of the Directive on electronic commerce must be interpreted as meaning that telemedicine services must be provided in accordance with the legislation of the Member State in which the provider is established. And in the same vein, Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, when it provides (Article 3(d)) that "in the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established".

Furthermore, and in relation to Directive 2011/24/EU, the Court of Justice states that the aforementioned article must be interpreted as meaning that "the concept of cross-border healthcare provided in the case of telemedicine, for the purposes of that article, corresponds solely to healthcare provided, exclusively via information and communication technologies, to a patient by a healthcare provider established in a Member State other than that patient's Member State of affiliation, at a distance and therefore without that patient and that provider being simultaneously physically present in the same location".

Borderline products and the precedence of medicinal product legislation

In its judgment of 4 September 2025, Kwizda Pharma II (C-451/24, ECLI:EU:C:2025:663), the Court of Justice has interpreted Article 2(2) 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, which provides that in "cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other

Community legislation the provisions of this Directive shall apply".

In addition to emphasising that the rule of precedence referred to above is based on public health considerations, "by reason of the higher requirements deriving from the legislation relating to medicinal products for the placing on the market of products", the Court of Justice states that the provision does not apply when it is clear that a given product does not fall within the legal definition of those other regulated products.

Finally, the Court of Justice concludes that it is not possible for a given product to be considered both a medicinal product and another type of regulated product, because "a product which is unequivocally a medicinal product must be subject only to the rules relating to medicinal products" and, consequently, "a product may be covered by other legislation only if it is not considered to be a medicinal product".

Having established the above interpretative guidelines, the Court of Justice examines whether, in cases where a national authority responsible for authorising the marketing of a type of regulated product other than medicinal products refuses to grant authorisation (on the grounds that the product in question does not fall within the legal definition of that regulated product, but is a medicinal product), it may prohibit its marketing.

According to the Court, it is for national law to establish whether the authority responsible for authorising the marketing of medicinal products must be the same as the authority responsible for authorising those other products. On that basis, there may be different national authorities or agencies depending on the type of product. That being so, "if an administrative authority of a Member State, which does not have jurisdiction to apply the legislation on medicinal products, considers that a product which is the subject of a procedure before it is a medicinal product which was placed on the market without having the authorisation required by that legislation, it must immediately inform the competent authority thereof. Only in that way can that competent authority take the necessary measures as quickly as possible to guarantee the protection of public health".

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