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Adoption of the amendment to the SPC Regulation: the 'manufacturing waiver' and the 'day 1 launch'

Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products has been adopted and published (OJ L 153, 11.6.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0933&from=EN).

Under the approved amendment, a supplementary protection certificate (SPC) will not provide protection against certain acts against which the basic patent conferred protection, namely acts comprising the making of a product, or medicinal product containing that product, for the exclusive purpose of export to third countries or any related act strictly necessary for that making or for the actual export. This exception to the protection conferred by an SPC is known as the 'manufacturing waiver'.

In addition, it also facilitates the production of medicines so that they can be placed on the market in the State of protection of the certificate on the day following expiry of the certificate (the so-called 'day 1 launch'). The making - no earlier than six months before the expiry of the SPC - of a product or a medicinal product containing that product for the purpose of storing it in the Member State of making, in order to place that product, or medicinal product containing that product, on the market of Member States after the expiry of the corresponding SPC, and any related act strictly necessary for the making, in the Union, referred to above, or for actual storing, is thus permitted.

In order to benefit from these exceptions, manufacturers have to fulfil an obligation to provide certain information to the designated authority granting SPCs in the Member State of making.

Issuing entities designated to operate a system for the assignment of UDIs in the field of medical devices

Both Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices each establish a Unique Device Identification system (UDI system) for certain medical devices falling within their scope.

In this regard, before devices to which the UDI system applies are placed on the market, the manufacturer is required to assign a Unique Device Identifier (UDI) to the device, and the UDI has to be one that was created in compliance with the rules of an issuing entity designated by the Commission to operate a system for the assignment of UDIs.

To this end, Commission Implementing Decision (EU) 2019/939 of 6 June 2019 designating issuing entities designated to operate a system for the assignment of Unique Device Identifiers (UDIs) in the field of medical devices has been published (OJ L 149, 7.6.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D0939&from=EN).

POPs Regulation

Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants has been adopted (OJ L 169, 25.6.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1021&from=en).

As provided for in Article 1 thereof, the objective of this Regulation is to protect human health and the environment from persistent organic pollutants (POPs) by prohibiting, phasing out as soon as possible, or restricting the manufacturing, placing on the market and use of substances subject to the Stockholm Convention on Persistent Organic Pollutants, or the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants, by minimising, with a view to eliminating where feasible as soon as possible, releases of such substances, and by establishing provisions regarding waste consisting of, containing or contaminated by any of those substances.

Where appropriate, Member States may apply stricter requirements than those laid down in this Regulation, in accordance with the Treaty on the Functioning of the European Union.

New edition of the Manual on Borderline Medical Devices

A new version, number 22, was published on 22/05/2019 of the Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices, prepared by the Medical Devices Expert Group, a working group formed by the European Commission, representatives of all the Member States of the European Union, EFTA and other stakeholders. The Manual, which is not legally binding and is merely a tool to facilitate the application of EU legislation on medical devices, can be found at the following address: https://ec.europa.eu/docsroom/documents/35582?locale=en.

Publication of clinical trial result summaries

The European Commission, the European Medicines Agency and the Heads of Medicines Agencies have jointly produced a letter reminding sponsors about their obligation for the reporting of clinical trial summaries in the EU Clinical Trials Database (EudraCT).

The letter, dated June 2019 and entitled "Letter to stakeholders regarding the requirements to provide results for authorised clinical trials in EUDRACT", can be found at the following link: https://www.ema.europa.eu/en/documents/other/joint-letter-european-commission-ema-hma-stakeholders-regarding-requirements-provide-results_en.pdf.

Procedure for designation of the 'AEMPS' as a notified body in accordance with the Medical Devices Regulation

On 28 June 2019, the Spanish Medicines and Healthcare Products Regulatory Agency (AEMPS) applied to the Ministry of Health, Consumer Affairs and Social Welfare to be designated as a Notified Body in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Guidance on shortages of medicinal products

The task force set up by the Heads of Medicines Agencies and the European Medicines Agency has recently published the following documents:

a) Guidance for marketing authorisation holders on reporting of shortages in the EU (Document EMA/674304/2018 of 1 July 2019), available at https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-detection-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs_en.pdf. This document provides guidance to the pharmaceutical industry on resolving shortages, including a form for marketing authorisation holders to report shortages to the competent authorities.

b) Good practice guidance for communication to the public on medicines' availability issues (Document EMA/632473/2018 of 4 July 2019), available at https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/good-practice-guidance-communication-public-medicines-availability-issues_en.pdf. This document is addressed to the competent authorities and the European Medicines Agency.

Reprocessing of single-use medical devices

According to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, any natural or legal person who reprocesses a single-use device to make

it suitable for further use within the Union shall be considered to be the manufacturer of the re-processed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation. By way of derogation from the foregoing, as regards single-use devices that are reprocessed and used within a health institution, Member States may decide not to apply all of the rules relating to manufacturers' obligations laid down in this Regulation.

Based on the above, on 23 July 2019, the European Commission published a draft Commission Implementing Regulation regarding 'Common Specifications for the reprocessing of single-use medical devices', available here: https://ec.europa.eu/info/law/better-regulation/initiative/11888/publication/5715706/attachment/090166e5c601ed28_en.

New European Commission factsheets and questions and answers on medical device regulations

1. The European Commission is preparing a series of factsheets and questions and answers to disseminate the content of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices. The most recent are from June 2019, "Factsheet for healthcare professionals and health institutions" and from August 2019, "Unique Device Identification (UDI) System - FAQs".

2. As for the rest, all the Fact Sheets and guidance have been included for greater dissemination on the website of the Spanish Medicines and Healthcare Products Regulatory Agency, (https://www.aemps.gob.es/en/legislacion/espana/productosSanitarios/prodSanitarios.htm) as follows:

    — FAQ – MDR Transitional provisions

    — Factsheet for Manufacturers of Medical Devices

    — Step by step implementation model for medical devices Regulation

    — Factsheet for Authorised Representatives, Importers and Distributors of Medical Devices and in vitro Diagnostic Medical Devices

    — Factsheet for the Procurement Ecosystem of Medical Devices and in vitro Diagnostic Medical Devices

    — Factsheet for Authorities in non-EU/EEA States on Medical Devices and in vitro Diagnostic Medical Devices

    — Factsheet for healthcare professionals and health institutions

    — Unique Device Identification (UDI) System - FAQs

Regulation (EU) 2019/1020 on market surveillance and compliance of products

Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1020&from=EN) shall apply to products that are subject to the Union harmonisation legislation listed in Annex I concerning manufactured products. These products include cosmetic and biocidal products. However, food, feed, medicinal products for human and veterinary use, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction are excluded.

Judgments and decisions

European Union

Parallel import of medicinal products

In its judgment of 3 July 2019, in Case C-387/18, the Court (Fifth Chamber) has ruled that Articles 34 and 36 TFEU must be interpreted as precluding the legislation of a Member State, such as that at issue in the main proceedings, which requires, for the issue of a parallel import licence for a medicinal product, that that medicinal product and the medicinal product which has been granted a marketing authorisation in that Member State are both reference medicinal products or both generic medicinal products and which, therefore, prohibits the issue of any parallel import licence for a medicinal product where it is a generic medicinal product whereas the medicinal product previously authorised in that Member State is a reference medicinal product.

Orphan medicinal products and the requirement of significant benefit

Regulation (EC) No 141/2000 on orphan medicinal products provides (Art. 3(1)) that a medicinal product shall be designated as an orphan medicinal product if its sponsor can establish: (a) that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the Community when the application is made, or that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the Community and that without incentives it is unlikely that the marketing of the medicinal product in the Community would generate sufficient return to justify the necessary investment; and (b) that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been

authorised in the Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition.

And according to Commission Regulation (EC) No 847/2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts 'similar medicinal product' and 'clinical superiority', 'significant benefit' means a clinically relevant advantage or a major contribution to patient care.

Now, in its judgment of 16 May 2019, in Case T-733/17, the General Court (Seventh Chamber) considers that the fact that a medicinal product may be authorised at EU level does not permit the conclusion or even the presumption that it will be of significant benefit, in comparison with the reference product, on the sole ground that the latter is authorised in only one Member State. Among other reasons, because no provision either in Regulation No 141/2000 or Regulation No 847/2000 provides that a marketing authorisation at EU level for an orphan medicinal product constitutes per se a significant benefit in comparison with treatment based on an existing medicinal product, which is as effective and already authorised, albeit in only one Member State.

Burden of mandatory use of a pharmaceutical trademark and clinical trials

1. In the Newsletter of January 2019 we reported on the Opinion of the Advocate General in Case C-668/17 P. This case is interesting because therein it is discussed whether using a disputed trademark to distinguish a medicinal product in a clinical trial may constitute genuine use of the trademark for a medicinal product and whether the fact that the medicinal product is subject to a clinical trial is a proper reason for non-use.

2. In the judgment under appeal, the General Court had pointed out that the use of the disputed trademark in a clinical trial could not be equated with marketing or even a direct preparatory act, but had to be regarded as an internal use, since it had taken place without competition, in a restricted circle of participants and without the objective of obtaining or maintaining a market share. Thus, the General Court did not rule out the possibility that there may be genuine use of a Community trademark where the designated products have not yet been marketed and such marketing is imminent, but it understood that no proof of that had been provided.

   The General Court also held that the carrying out of a clinical trial could constitute a proper reason for non-use of a trademark, but held that the acts of the trademark proprietor were within its sphere of influence and fell within its sphere of responsibility and could therefore not be regarded as obstacles beyond its control.

3. And so, in the judgment of 3 July 2019 in the referred case, the Court (Fourth Chamber) affirms the interpretation of the General Court. The Court points out that the application for a clinical trial was submitted more than three years after registration of the disputed trademark and that registration of the trademark was requested on the applicant's own initiative and not because

it was legally required to do so, whereas there was great uncertainty both as to the date and as to the possibility of marketing the product designated by that trademark in so far as that product was at the clinical trial stage. It cannot therefore be held that there is a proper reason for non-use and the General Court "did not err in law in considering that the passage of time between, on the one hand, the dates of application and registration of the disputed trademark and, on the other hand, the date of commencement of the clinical trial, as well as the duration of the trial and the financial resources provided for its rapid completion, were, in principle, the responsibility of the proprietor of that trademark and could therefore not be regarded as being beyond the proprietor's control".

Advertising of medicinal products by celebrities: celebrity can derive from the number of followers

The ASA CAP Code, UK self-regulatory rule book for non-broadcast advertisements, sales promotions and direct marketing communications, provides in rule 12.18 that "[m]arketers must not use health professionals or celebrities to endorse medicines".

In this regard, the Advertising Standards Authority (ASA), in a ruling of 3 July 2019 (available here: https://www.asa.org.uk/rulings/sanofi-uk-A19-557609.html), has concluded that a social network user who has 30,000 or more followers must be considered a celebrity for the purposes of rule 12.18 and thus cannot endorse medicines.

Orphan medicinal product and existence of a prior marketing authorisation for the same medicinal product

According to Art. 5 of Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, in order to obtain the designation of a medicinal product as an orphan medicinal product, the sponsor shall submit an application to the Agency at any stage of the development of the medicinal product before the application for marketing authorisation is made.

Traditionally, the European Medicines Agency has understood that applications for the aforementioned designation should be rejected when the sponsor has already submitted a marketing authorisation application for a medicinal product containing the same active substance.

However, the Court of Justice, in its judgment of 29 July 2019 (C-359/18 P), has confirmed the interpretation held by the General Court that new medicinal products containing the same active substance as existing orphan medicinal products should be entitled to an additional period of orphan exclusivity if they fulfil the criteria for orphan designation under Article 3(1) of Regulation No 141/2000.

Cross-border healthcare: the recognition of prescriptions does not extend to order forms intended to ensure that doctors (or institutions) have available a supply of medicinal products with a view to their being used subsequently in the course of their activities

The Advocate General Yves Bot, in his Opinion in Case C-222/18 (VIPA), proposed that the Court should reply that Art. 3(k) and Art. 11(1) of 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 must be interpreted as meaning that the obligation imposed by Article 11(1) to recognise prescriptions only applies to prescriptions that name the patient for whom the medicinal product prescribed is intended, for the purposes of individual treatment. Art. 11(1) therefore does not apply to order forms intended to ensure that doctors (or institutions) have available a supply of medicinal products with a view to their being used subsequently in the course of their activities

In addition, according to the Advocate General, "Articles 34 and 36 TFEU must be interpreted as not precluding national legislation, such as that at issue in the main proceedings, that does not authorise the dispensing of prescription-only medicinal products on the basis of order forms drawn up by healthcare professionals qualified to draw up prescriptions who practise in a different Member State, since such legislation is justified by an objective of protecting public health and is appropriate for the purpose of achieving that objective".

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