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THE EUROPEAN COMMISSION PUBLISHES PROPOSALS FOR A NEW PHARMACEUTICAL PACKAGE

European Law | 30/06/23 | François Pochart

LIFE SCIENCES & HEALTHCARE

On April 26th, 2023, the European Commission (EC) published a set of proposals[1] aimed at revising pharmaceutical legislation to achieve objectives such as:

- Making sure that all patients across the EU have timely and equitable access to safe, effective and affordable medicines;
- Enhancing the security of supply and ensuring that medicines are always available to patients, regardless of where they live in the EU;
- Offering an attractive, innovation- and competitiveness friendly environment for research, development, and production of medicines in Europe;
- Making medicines more environmentally sustainable:
- Addressing antimicrobial resistance (AMR).

More specifically, the EC proposes simplifying and harmonizing Community legislation in this area through a new directive and a new regulation replacing Directive 2001/83/EC and Regulations (EC) 141/2000, (EC) 726/2004 and (EC) 1901/2006, as well as a Council recommendation on AMR.

The EC points to a number of causes of shortages of medicines, including increased dependence on third countries for supplies of active ingredients and excipients, and the commercial strategies of manufacturers who choose whether or not to launch a drug based on the price negotiated with national authorities.

To counter these practices, the EC proposes - among other measures - to reduce the regulatory protection period to 8 years (6 years of regulatory data protection + 2 years of market protection instead of the current 8+2). However, companies will be able to benefit from additional periods of regulatory protection, bringing the total duration of protection to a maximum of 12 years, compared with the current maximum of 11, under the following conditions:

- + 2 years of regulatory data protection if the company launches the medicine in all Member States continuously and in sufficient quantity within two years of marketing authorization, or within three years for small and medium-sized enterprises;
- + 6 months if the medicine addresses unmet medical needs;
- + 6 months if comparative clinical trials are conducted;
- + 1 year of regulatory data protection if the medicine can also treat other disease(s).

The EC also proposes to increase the period of regulatory protection from 10 to 13 years for so-called orphan medicines meeting unmet needs, and to grant 4 years of data protection for the repurposing (new therapeutic uses) of existing medicines that have not already benefited from a period of data protection.

Other proposals have been made, including:

- reducing the administrative burden and expediting the administrative procedures for the delivery of a marketing authorization (including for generic medicines);
- eliminating the obligation to renew a marketing authorization;
- setting up “regulatory sandboxes” enabling innovative drugs to be tested within a more flexible regulatory framework.

The EC also proposes establishing a list of critical medicines in respect of which the European Medicines Agency (EMA) will issue recommendations to reduce vulnerabilities in the supply chain. Holders of marketing authorizations will have to make every effort to follow these recommendations. The EC hopes in this way to reduce the risk of shortages of certain medicines, as occurred during the pandemic.

Concerning the Bolar exemption, the EC proposes harmonizing national provisions by broadening it. For example, studies, trials and other activities designed to generate data for:

- a marketing authorization for generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations;
- a health technology assessment;
- pricing and reimbursement applications;
- any activity for these purposes, including the offer, manufacture, sale, storage, import, use and purchase of patented products or processes, including by third-party suppliers and service providers;

would not be considered an infringement of patent rights or of supplementary protection certificates (SPCs).

For so-called orphan medicines, the EC would like to ensure that generics and biosimilars enter the market as soon as the period of market exclusivity comes to an end. If this proposal were to be adopted, current French case law, according to which the establishment of a price and a reimbursement rate justifies bringing requests for a preliminary injunction, would become obsolete.

By encouraging the early entry of generics and biosimilars into the world's second-largest market for pharmaceutical products, the EC is seeking to increase competition between originator and generic companies. In effect, if originator manufacturers wish to maintain the status quo of 8+2+1 protection, they will no longer be able to make supply conditional on advantageous pricing, and will have to comply with the new rules set by the European Union.

A consultation of the key stakeholders is planned. For the time being, these are obviously only proposals that need to be discussed and then adopted by the Council and the European Parliament. However, there is no doubt that by publishing such proposals, the EC is sending out a strong signal to the pharmaceutical industry.

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[1] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: reform of the pharmaceutical legislation and measures addressing antimicrobial resistance:

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023DC0190
