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European Commission Publishes Proposals to Revise Current EU Pharmaceutical Legislative Framework

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Yesterday, the European Commission published two legislative proposals concerning the regulation of medicinal products in the European Union. The proposals seek to consolidate existing legislation into two instruments, a revised and amplified version of Directive 2001/83, the Community code on medicinal products, and a revised and amplified version of Regulation 726/2004, the European Medicines Agency (EMA) Regulation. The proposals include a draft regulation laying down EU procedures for the authorisation and supervision of medicinal products for human use and creation of rules governing the EMA and a draft directive relating to medicinal products for human use. The European Commission also proposed a Council Recommendation on antimicrobial resistance.

The proposals would introduce several changes to existing concepts regarding the regulation of medicinal products. The intention of the European Commission is to achieve a balance between patient access to affordable medicinal products and the need to stimulate innovation. In particular – and as anticipated – data and market exclusivity available to innovative medicinal products would change. In addition, Regulation (EC) No 141/2000 (the Orphan Regulation) and Regulation (EC) No 1901/2006 (the Paediatric Regulation) would be repealed, and their provisions would be incorporated within the draft regulation.

Regulatory protection periods for innovative medicinal products

As anticipated, the standard data and market exclusivity periods for which the current Community code provides will – if the proposals are adopted in their current form – be reduced. The standard period for regulatory protection would be reduced from 10 years, including eight years of data protection and an additional two years of market exclusivity, to a total maximum period of eight years. “Basic” data exclusivity would be reduced from eight to six years, with an additional two years of market exclusivity.

However, to encourage innovation, the proposals would render the data exclusivity period modulable. Accordingly, marketing authorization holders would have the possibility to extend the basic data exclusivity in accordance with the following provisions:

- + 24 months of data exclusivity if the medicinal product is launched in all 27 EU member states covered by the marketing authorization. There are, however, conditions related to this additional exclusivity, including the requirement that the product be launched within two years from the marketing authorization or within three years for small- and medium-sized enterprises, not-for-profit entities or “companies with limited experience in the EU system”.
- + 6 months of data exclusivity for products that address an unmet medical need.
- + 6 months of data exclusivity if comparative clinical trials are conducted.
- + 12 months of data exclusivity for an additional therapeutic indication.

In theory, the modulation of regulatory protection periods may permit marketing authorization holders to achieve a total of up to 12 years of regulatory protection in relation to their medicinal products. As regards exclusivity related to launch of a product in all 27 EU member states: Given the role of pricing and reimbursement in any decision by marketing authorization holders concerning launch, and the fact that it is the competent authorities of the individual EU member states who have sole power to determine pricing and reimbursement of medicinal products within their territory, the possibility to not only achieve agreement with the competent authorities of all 27 EU member states concerning pricing and reimbursement status of a medicinal product, but also then launch the products on all 27 markets may be a challenge even for large and experienced marketing authorization holders.

Orphan medicinal products

If adopted in their current form, the proposals would merge the regulation of orphan medicinal products into the general framework applicable to all medicinal products in the EU and introduce the following main changes:

- **Flexible criteria for defining orphan conditions**: The proposals would largely maintain the existing criteria for orphan designation based on the prevalence of a life-threatening or chronically debilitating condition for which no satisfactory method of diagnosis, prevention or treatment of the condition exists within the EU in no more than five persons per 10,000. However, the proposals recognize that the prevalence criterion may not necessarily be appropriate to the identification of rare diseases in all cases. Consequently, the proposals envisage the possibility for the European Commission to supplement the criteria on which orphan designation is determined if this is scientifically justified and is based on a recommendation from the EMA.
- **EMA empowerment**: The proposals suggest transferring responsibility for the adoption of decisions on orphan designation from the European Commission to the EMA for purposes of expediting and facilitating the procedure. However, this would mean that the EMA would be provided with decision-making powers in relation to orphan designation. Orphan designations would have an initial validity period of seven years, which may be extended by the EMA in certain circumstances.
- **Amended regulatory protection periods***:* The proposals provide that the "basic" market exclusivity period for orphan medicinal products would be nine years. Market exclusivity would be extended to 10 years if the orphan medicinal product were to address a high unmet medical need. Additional market exclusivity extensions could be granted, in certain circumstances, in accordance with the following provisions:
    - + 12 months of market exclusivity if the medicinal product is launched in all EU member states.
    - + 12 months of market exclusivity for each of the first two indications of orphan medicinal products, i.e., up to an additional two years total.

Market exclusivity would, however, be reduced to five years if the use of the active substance in the medicinal product is well established and the related application for market authorization were based on bibliographic data.

Orphan medicinal products would benefit from the same data protection periods as those established for innovative medicinal products. This would include the potential extensions available in relation to innovative products, with the exception of the extension for additional therapeutic indications from which an orphan product would benefit only in relation to the extended market exclusivity period, if applicable.

Similarly to issues relating to the modulable data exclusivity periods detailed above, in theory, the modulable market exclusivity periods could permit orphan medicinal products to be subject to a total market exclusivity period of up to 13 years. However, in practice, the chances of having an orphan medicinal product fulfill all the conditions above and benefiting from the maximum market exclusivity period are slim. We would anticipate that most orphan medicinal products may face a reduced market exclusivity period of nine years compared to the 10 years available today. However, the possibility to review the eligibility criteria for market exclusivity after six years would be removed.

Reduced marketing authorization assessment periods

It is also proposed that the period for assessment of applications for marketing authorisation be shortened. The EMA would have 180 days to complete its assessment regarding a positive or negative opinion instead of the current 210 days. The European Commission would then have 46 days instead of the current 67 to decide whether to grant a marketing authorization.

Moreover, medicinal products of major interest from the point of view of public health and therapeutic innovation may be eligible for an accelerated assessment which would be conducted within 150 days.

The European Commission anticipates that the "clock-stops" that can currently result in an increase in the review period will be reduced as a result of the proposed strengthening of EMA scientific support to developers of medicinal products. As this is expected to improve the quality of initial applications, a reduction in delays caused by clock-stops and expedited evaluations for marketing authorisation are anticipated.

Antimicrobial resistance measures

Among the innovative provisions in the proposals are a series of measures to combat antimicrobial resistance and to encourage development of innovative antimicrobials. This includes introduction of a transferable data exclusivity voucher available to those antimicrobial products that bring a significant clinical benefit with respect to antimicrobial resistance. A developer of an antimicrobial that is provided a voucher can either use the voucher for one of its own products or sell it to another marketing authorisation holder. A maximum of 10 vouchers will be granted over a period of 15 years.

Other topics

The proposals also address several other matters, including:

- Restructuring of the EMA committees.
- Increased transparency on the contribution of public funding to research and development costs.
- Incentives for research and innovation, including for orphan and paediatric medicinal products.
- New concepts of unmet medical need and high unmet medical need.
- Enhancing scientific and regulatory support by strengthening the EMA Priority Medicines (PRIME) scheme.
- Changes to the regulatory regime for generics and biosimilars.
- New obligations in relation to continuity of supply and prevention of shortages.
- Rules on repurposing of medicinal products.
- The possibility for EU member states to permit electronic product information instead of paper product information.

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