Capsulas

The Council of the EU adopts its position on the pharmaceutical package, kicking off the crucial stage of its legislative process

The Council's negotiating position in the review of European pharmaceutical legislation

Two years after the European Commission presented its proposal to reform the pharmaceutical legislation framework - the most ambitious overhaul in two decades - and more than a year after the European Parliament adopted its negotiating mandate, the Council of the European Union finally unveiled its position on the European pharmaceutical package.

The importance of this revision is significant, as the resulting regulation and directive will replace Directive 2001/83/EC (on medicinal products for human use) and Regulations 141/2000 (on orphan medicinal products), 726/2004 (on Community procedures for the authorisation and supervision of medicinal products for human and veterinary use) and 1901/2006 (on paediatric medicinal products).

With the prospect of the Polish Presidency of the Council finally reaching an agreement, the European Parliament decided to renew its negotiating mandate, thereby reaffirming that the position adopted last year remained fully valid and that it was ready to begin inter-institutional negotiations. Finally, after overcoming the deadlock caused by some member states in mid-May, it was officially announced on 4 June that the Council had adopted its negotiating position.

Below, we analyse some of the main elements included in this position.

Regulatory data protection periods

One of the main points of disagreement within the Council has been the length of regulatory data protection periods.

The Council proposes to maintain the current eight years of regulatory data protection. This period can only be extended for an additional 12 months in the case of medicinal products benefiting from a transferable exclusivity voucher (TEV). The modulation through incentives is applied to the marketing protection period, which is reduced from two years to one year, with the possibility of extending it through incentives such as conducting comparative studies or demonstrating that the medicine addresses unmet medical needs. Taking into account the overall calculations, the Council's proposal means that, at best, medicinal products will enjoy a period of protection equivalent to the current one, except for medicinal products benefiting from a VTE.

This approach differs from that of the Commission and Parliament, which proposed modulating regulatory data protection rather than marketing protection. Because, under the Commission and Parliament's model, it was possible to extend the period of data exclusivity; but the baseline protection was lower—6 years and 7.5 years, respectively—than that proposed by the Council.

Transferable exclusivity vouchers

Closely linked to the exclusivity periods is the incentive of creating TEVs, designed as a tool to combat antimicrobial resistance. The Council adopts the Commission's original proposal that TEVs extend regulatory data protection by one year. This differs from the European Parliament's position, which proposed that the additional protection period vary—12, 9, or 6 months—depending on the pathogen.

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The Council's position on TEV is a key point in the reform, as the proposal raised concerns among several member states, who questioned its effectiveness and warned about the budgetary impact of transferring this exclusivity to medicinal products with a high financial burden. In this context, the Council proposes adding a new paragraph to Article 41 of the regulation: if a voucher is transferred to another medicinal product, the marketing authorisation holder (MAH) must demonstrate that the annual gross sales of the recipient product in the EU have not exceeded €490 million in any of the previous four financial years.

Supply obligations and shortage prevention measures

Another point of discussion has been the supply obligations of Member States. The Council introduced a new article in the regulation, Article 5a, which allows a Member State to request the marketing authorisation holder (MAH) of a centrally authorised medicinal product to place the product on the market within its territory. If the MAH cannot comply with this request, the Member State may inform the Commission, which will then initiate a procedure requiring both parties to provide explanations for the failure to place the medicinal product on the market.

The Council's proposal aligns with the Parliament's approach by making effective marketing a condition for benefiting from the incentive scheme to extend regulatory protection, as originally proposed by the Commission. However, the Parliament introduced a new Article 58a in the Directive, which imposes a general obligation on the marketing authorisation holder (MAH) to request price and reimbursement in good faith when required by a Member State. The Council now takes a stricter stance by imposing an obligation to market centrally authorised medicinal products.

This effective placing on the market requires completion of the prior price and reimbursement procedure. It will be important to closely monitor the development of this article, as Member States may increasingly request marketing of these products. Additionally, it will be necessary to consider how to handle situations where the price and reimbursement procedure cannot be successfully completed. A key issue may be the role of the European Commission if called upon to mediate disagreements.

Beyond marketing, in cases of shortages, MAHs are obliged to establish a shortage prevention plan, which must be made available to competent authorities upon request. In such cases, the MAH must submit the plan within a maximum of two days from the request.

Furthermore, the Council proposes tightening the requirements for critical medicinal products subject to a shortage prevention plan, or priority antimicrobials, before they can be withdrawn from the market. Specifically, when the withdrawal of one of these products is proposed, the MAH must publish its intention on its website in advance and offer to transfer the authorisation, negotiating the transfer on reasonable terms.

Hospital exemption

The impact assessment accompanying the Commission's proposal highlighted the uneven application of the hospital exemption, which permits the preparation of advanced therapy medicinal products under certain conditions. This exemption constitutes an exception to the general rule in the European Union that requires medicinal products to have marketing authorisation before use.

During the formation of the Council's position, questions arose about whether Spain, one of the

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Member States where the hospital exemption is most widely used, could promote a model based on its national experience. However, the Council's position remains largely aligned with the Commission's initial proposal. Certain elements are further specified, such as the data to be reported - specifically the number of patients and administrations of the product - and it is established that both the preparation and use of the medicinal product will require national authorisation.

The Council, like the Commission and the Parliament, does not address some still unresolved issues related to the hospital exemption, such as the precise definition of what constitutes "occasional" preparation, nor the applicable advertising or sanctioning regime. Article 2 of the Directive, which is the only one applicable to these products, does not regulate these matters.

Next steps

Inter-institutional negotiations between the European Parliament, the Council and the Commission are scheduled to begin on 17 June, under the Polish presidency. The bulk of the negotiations will take place under the Danish presidency, which begins on 1 July, and from whom a position close to the measures aimed at favouring innovation in the EU is expected.

A decisive phase is now underway in which the European institutions will have to reconcile positions on a key regulatory framework for the future of the pharmaceutical sector in Europe. The inter-institutional negotiation will not only test the capacity for political consensus, but also the balance between innovation, access and sustainability.

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