# Capsulas

## The processing of the pharmaceutical legislation reform is moving at full speed in the European Parliament

*The Committee on Industry, Research and Energy of the European Parliament (ITRE) voted on the amendments to the European Union's (EU) pharmaceutical legislation package*

On Thursday 22 February, the Committee on Industry, Research and Energy of the European Parliament (ITRE) voted on the amendments to the European Union's (EU) pharmaceutical legislation package. Although the lead committee for processing this reform in the Parliament is the Committee on the Environment, Public Health and Food Safety (ENVI), other committees can draft opinions on matters that also fall within their scope. ITRE exercised this option to issue its report.

This vote marked the first official confirmation of a clear division on some of the key aspects of the reform. The opinion on the directive was adopted with 34 votes in favour, 26 against and two abstentions. For the regulation, the result was 35 votes in favour, 27 against and one abstention.

In this capsulas, we will review the fundamental aspects of this position and highlight the key upcoming dates in the parliamentary decision-making process.

### Amendments to the proposal for a directive

Regulatory protection of innovative medicines is undoubtedly the main issue.

The Commission proposed to lower data protection from eight to six years, and to grant additional periods of protection if certain conditions are met (e.g. supply in all Member States where the marketing authorisation is valid). On the other hand, the current 2+1 regime for the protection of marketing protection was maintained.

ITRE proposes to amend Article 81 of the proposed directive as follows:

- The basic period of data protection is increased to nine years and the maximum total data protection - i.e. the basic nine plus the variable extension as appropriate - will be thirteen years;
- Further extensions of twelve months are proposed where any of the following conditions are met: (i) if the marketing authorisation holder demonstrates that a significant part of the pre-clinical development of the medicinal product has been carried out in the EU; (ii) if an application has been made to conduct a clinical trial for a new medicinal product on EU territory; (iii) if the company supports the establishment of public-private partnerships, hospital institutes, centres of excellence or bioclusters to accelerate the development of new medicinal products; or (iv) if the medicinal product includes a majority - a concept to be defined by the European Medicines Agency - of critical active substances produced in the EU;
- It is also proposed to increase some incentives already foreseen by the Commission: if at least one of the indications of the medicinal product addresses an unmet medical need, it is proposed that the protection be increased by 12 months instead of the six months initially foreseen;

- The same increase from 6 to 12 months is proposed where the initial marketing authorisation application is supported by clinical trials with an appropriate comparator;
- Regarding the incentive to supply all Member States and its relation to national pricing and reimbursement procedures, the ITRE report instructs the Commission to ensure that no holder will be unduly deprived of receiving such an extension "for actions beyond its control".

As can be seen, this is an interesting proposal that is very much aimed at stimulating new medicines development activities to take place on EU territory. On the other hand, the proposal also requires companies to keep the market adequately supplied in order to meet patients' needs.

In addition, ITRE is clearly in favour of EU strategic and production autonomy, an idea widely supported both by companies focused on innovative medicines and by generic and biosimilar manufacturers. In this regard, the proposal to add a new recital 49a to the directive with implications for public procurement is noteworthy. ITRE notes that using the lowest price as the main selection criterion in a call for tender may reduce incentives for industry and lead to shortages in the EU. On the other hand, awarding contracts to a single company is another cause of weakness. In situations where access to critical medicines is difficult, it might be more efficient to explore joint tendering campaigns between Member States. This approach can strengthen the administration's negotiating position and allow for incentives for production activities and diversification of sources of supply.

Overall, these are interesting ideas that will stimulate the debate. On the other hand, the proposal includes many indeterminate notions. In the interests of greater legal certainty, terms such as "support" for public-private partnerships would need to be defined more precisely.

Amendments to the proposal for a regulation

In relation to the amendments to the regulation, the most notable relate to the transferable extension of exclusivity for the development of new priority antimicrobials, the so-called voucher. ITRE considers this to be a positive measure, although "its strict conditions (...) may reduce its effectiveness".

What does the voucher requested by ITRE look like? The amendments seek to restrict the definition of priority antimicrobial as a counterbalance to a more generous regulation for the voucher in terms of the timeframe for its use.

In the Commission's proposal, the extension could only apply to a medicinal product that was in its first four years of data protection. ITRE considers that the voucher should apply to any medicinal product with at least two years of protection remaining. In practical terms, according to ITRE's proposal, if a product can have up to thirteen years of regulatory data protection, the voucher could be applicable up to year eleven.

In addition, it is proposed to combine this initiative with an additional incentive scheme to be developed by the Commission, so that it can provide adequate financial support to those developing priority antimicrobials.

In the field of orphan medicinal products, the focus has been on the definitions of unmet medical need and high unmet medical need. The Commission considers that a medicinal product meets a high unmet medical need when at least one of its indications is linked to an orphan disease for which (i) there is no satisfactory method of diagnosis, prevention or treatment; or (ii) even where such a method exists, the

applicant has demonstrated that the product represents an exceptional therapeutic advance.

The ITRE report considers that it is dangerous to differentiate between unmet medical needs and proposes to remove the specific regulation for highly unmet medical needs.

As in the directive, it is proposed to extend the terms of protection from nine to ten years in general cases, and from ten to twelve years in cases where no satisfactory treatment has been approved in the EU for the indication concerned. Finally, the five-year protection applicable when the application for authorisation is based on bibliographic data is extended to six years. It is proposed that the maximum total protection, considering the additional periods, should be 15 years.

In relation to the so-called regulatory sandbox, ITRE is committed to maintaining it and broadening its scope so that it can, for example, contribute to generating evidence to inform future adaptations of the legislative framework.

Finally, in relation to notifications of cessations, interruptions or suspensions of the marketing of medicinal products, ITRE proposes that the temporary interruption of supply of a medicinal product for which the same medicinal product is available in a different pack size should not have to be notified.

## Next steps

The ITRE report is addressed to the lead committee of the reform process, ENVI, which will have to adopt its own position. In the absence of an official agenda, everything seems to indicate that this could be on 11 March. We are probably now witnessing a prologue to what will happen in ENVI. In fact, the rapporteur for the ENVI directive, Pernille Weiss, is also a member of ITRE.

Once ENVI takes a position, the next step is a plenary vote. At least in theory, this could happen in one of the two sessions of the European Parliament in April, before the next European elections. More haste less speed. In our opinion, the scale of this reform would justify not speeding up the debates in these last few weeks.

In the meantime, little has come out of the Council process. The current Belgian rotating presidency is focused on the trilogues of the European Health Data Space and the text of the reform of the pharmaceutical legislation has not yet been dealt with in depth.