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European Parliament

Parliament adopts its position on EU pharmaceutical reform

- Ensuring safe, efficient and quality medicinal products
- Fostering innovation and development of medicines to address unmet medical needs
- Boosting research in novel antimicrobials to fight antimicrobial resistance (AMR)

MEPs support comprehensive reform of EU pharmaceutical legislation © Viewfinder / Adobe Stock

MEPs adopted their proposals to revamp EU pharmaceutical legislation, to foster innovation and enhance the security of supply, accessibility and affordability of medicines.

The legislative package, covering medicinal products for human use, consists of a new directive (adopted with 495 votes in favour, 57 against and 45 abstentions) and regulation (adopted with 488 votes in favour, 67 against and 34 abstentions).

Incentives for innovation

MEPs want to introduce a minimum regulatory data protection period (during which other companies cannot access product data) of seven and a half years, in addition to two years of market protection (during which generic, hybrid or biosimilar products cannot be sold), following a marketing authorisation.

Pharmaceutical companies would be eligible for additional periods of *data protection* if their particular product addresses an unmet medical need (+12 months), if comparative clinical trials are being conducted on the product (+6 months), and if a significant share of the product's research and development takes place in the EU and at least partly in collaboration with EU research entities (+6 months). MEPs also want a cap on the combined data protection period of eight and half years.

A one-time extension (+12 months) of the two-year *market protection* period could be granted if the company obtains marketing authorisation for an additional therapeutic indication which provides significant clinical benefits in comparison with existing therapies.

Orphan drugs (medicines developed to treat rare diseases) would benefit from up to 11 years of market exclusivity if they address a "high unmet medical need".

Combatting antimicrobial resistance (AMR)

To boost research and the development of *novel antimicrobials*, MEPs want to introduce market entry rewards and milestone payment reward schemes (e.g. early-stage financial support when certain R&D objectives are achieved prior to market approval). These would be complemented by a subscription model scheme through voluntary joint procurement agreements, to encourage investment in antimicrobials.

They support the introduction of a "transferable data exclusivity voucher" for priority antimicrobials, providing for a maximum of 12 additional months of data protection for an authorised product. The voucher could not be used for a product that has already benefited from maximum regulatory data protection and would be transferable only once to another marketing authorisation holder.

More details on MEPs' specific proposals are available here.

Quotes

Rapporteur for the directive Pernille Weiss (EPP, DK) said: "The revision of the EU pharmaceutical legislation is vital for patients, industry and society. Today's vote is a step towards delivering the tools to tackle present and future healthcare challenges, particularly for our market attractiveness and access to medicine across EU countries. We hope Council takes note of our ambition and commitment to create a robust legislative framework, setting the scene for effective negotiations."

Rapporteur for the regulation Tiemo Wölken (S&D, DE) said: "This revision paves the way to addressing critical challenges such as medicines shortages and antimicrobial resistance. We are strengthening our healthcare infrastructure and boosting our collective resilience ahead of future health crises - a significant milestone in our pursuit of fairer, more accessible healthcare for all Europeans. Measures improving access to medicines, whilst incentivising areas of unmet medical needs, are crucial parts of this reform."

Next steps

The file will be followed up by the new Parliament after the 6 - 9 June European elections.

Background

On 26 April 2023, the Commission put forward a "pharmaceutical package" to revise the EU's

pharmaceutical legislation. It includes proposals for a new directive and a new regulation, which aim to make medicines more available, accessible and affordable, while supporting the competitiveness and attractiveness of the EU pharmaceutical industry, with higher environmental standards.

In adopting this report, Parliament is responding to citizens' expectations to ensure the EU's strategic autonomy for medicines and access to quality and affordable treatments across the EU, to address security of supply issues, invest in strategic sectors and reduce bureaucracy, as expressed in proposals 8(3), 10(2), 12(4), 12(6), 12(12), 12(17), 17(3) and 17(7) of the conclusions of the Conference on the Future of Europe.

Further information

Adopted texts will be available here (10.04.2024)
Recording of the plenary debate (10.04.2024)
Procedure file (directive)
Procedure file (regulation)
Legislative train - Revision of the EU pharmaceutical legislation
EP Research: Revision of the EU pharmaceutical legislation (April 2024)
Free photos, videos and audio material

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