

EN

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Answer given by Ms Kyriakides
on behalf of the European Commission
(10.9.2024)

1. EU actions in the field of medicines serve numerous objectives, recognising the crucial role of medicines for public and patient health. The Pharmaceutical Strategy for Europe¹ and the reform of the EU pharmaceutical legislation² aim at balancing several main objectives, including access to medicines, competitiveness of the EU pharmaceutical sector, as well as affordability of medicines for both patients and healthcare systems. The Commission's reform proposal aims at facilitating earlier entry of generic and biosimilar medicines to improve affordability of medicines, at increasing the availability of comparative clinical data to support more evidence-based decisions on pricing, and at increasing the transparency of public funding for research and development of medicines. The proposal also contains measures aimed at enhancing the security of supply and preventing shortages of medicines. The European Parliament and the Council are currently discussing the reform, and the importance of those objectives is acknowledged by all three EU institutions.

It remains that pricing and reimbursement decisions regarding medicines fall under the competence of the Member States and are based on national considerations on the allocation of national health budgets. To enhance affordability of medicines, the Commission promotes cooperation between national authorities, through exchange of information and best practices on national pricing, reimbursement and procurement policies.

2. Notwithstanding the actions enhancing affordability of medicines described in point 1, as already mentioned, pricing and reimbursement of medicines are a national competence, and the way Member States regulate in this area is outside the remit of EU law.

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761>

² https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en