Question for written answer E-000456/2024
to the Commission
Rule 138
Roman Haider (ID)

Subject: Pharmaceutical legislation

The Commission has drawn up a regulation (COM(2023)0193) and directive (COM(2023)0192)[1] to reform the pharmaceutical legislation.[2]In a detailed analysis of the legislative proposals, the Centre for European Policy (cep) says that many of the delegations of power to the Commission go too far.[3]

1. How does the Commission justify delegating the decision to introduce purely electronic package leaflets to itself, when this health policy decision falls within the remit of the Member States?

2. The cep considers the proposed reduction in the period of IP protection for innovative companies to be too drastic. Although it would boost competition by enabling earlier market entry of generics and biosimilars, it would reduce the incentive to bring new medicines to the EU market at all. How does this align with the Commission's objective of supporting innovation in the European pharmaceutical industry?

3. What is the Commission's response to the criticism that having to refuse the authorisation of new medicines because of 'inadequate' environmental risk assessments will prevent patients from being able to access new, safe and effective medicines?

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[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0193
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0192
[3] https://www.cep.eu/fileadmin/user_upload/cep.eu/Analysen/COM_2023_192_193_Reform_des_Arzneimittelrechts/cepPolicyBrief_Pharmaceutical_Legislation_Reform_COM_2023__192_193_Long_Version.pdf