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Answer given by Mr Várhelyi
on behalf of the European Commission
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The Commission's pharmaceutical reform proposal¹ aims to enhance patient safety through accurate information on medicines and introduces electronic alternatives to paper package leaflets. These electronic formats are intended to improve medicine access and distribution within the Union, offering at least equal, if not superior, quality of information compared to paper leaflets.

The shift to electronic leaflets addresses issues like medicine shortages, multilingual packaging, timely updates in patients' languages, small market needs, hospital requirements, health emergency availability, and reduced administrative burdens, all while being environmentally friendly.

Recognising varying digital literacy and internet access across Member States, the proposal permits discretionary measures for electronic information provision, ensuring no patient is left behind. It considers different age groups and digital literacy levels, ensuring accessibility for all patients. If Member States choose electronic-only leaflets, paper versions must remain available on demand, free of charge.

The proposal retains the requirement for medicine labelling and package leaflets to be available in the official language(s) of each Member State, ensuring clarity and comprehensibility for all users.

The Commission also believes that electronic product information is not directly linked to parallel trade, which is driven by price differences in the EU rather than regulatory requirements.

The proposal is under discussion by the co-legislature, with both the European Parliament and the Council proposing amendments while recognising the benefits of electronic product information.

¹ COM/2023/192 final.