

BEUC-X-2025-011

Brussels, 11 February 2025

Subject: The Council must ensure consumers' immediate access to package leaflets

Dear Health Attaché,

I am writing to you on behalf of the European Consumer Organisation (BEUC) regarding package leaflets. As the Council's negotiations on the pharmaceutical legislation unfold, we want to stress the importance of keeping this essential source of information on medicines.

Package leaflets provide easy access information on the safe use of medicines. When consumers open the medicine package, they find the leaflet inside, which invites to read it. Accessing information through QR codes or any other digital means, on the other hand, is more burdensome as it requires extra steps and tools - such as having a functioning mobile phone at hand. This risks undermining patients' safety.

We do acknowledge nonetheless that electronic product information (ePI) can come with advantages and meet some specific needs, such as those of people with impaired sight. For this reason, we support introducing ePI as a complementary tool to package leaflets. To ensure their safe use by consumers, it is important that means to access the information electronically do not allow the identification or tracking of users in line with the EU's General Data Protection Regulation and ePrivacy Directive. Moreover, they must not be used for commercial purposes such as advertising or marketing activities.

Member States must ensure that consumers continue having easy access to information as essential as medicines' contraindications, warnings, instructions of use, and potential side effects. For this reason, **we call on keeping the package leaflets**, and for allowing exceptions only on specific cases and grounds. For example, when there are problems in respect of the availability of a medicine.¹

We are extremely concerned about plans to allow Member States to remove package leaflets without considering the real impact on consumers, including the most vulnerable. Decisions on access to information on medicines cannot sideline the stakeholders most affected.

I take the opportunity to share with you a [joint statement](#) from a broad coalition of European umbrella organisations, which calls for keeping the package leaflets.

Yours sincerely,

Ancel-la Santos
Deputy Head of Food, Health and Safety

¹ Please see [BEUC's position on the European Commission's proposal for a revised pharmaceutical legislation](#), section 2 on 'Package leaflets', December 2023. In these specific cases, for example importing a medicine package from another country due to a shortage, a printed copy of the leaflet should be made available at the pharmacy free of charge.