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PGEU GPUE

Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

PGEU Response to the European Commission's update of the guideline on "*Excipients in the labelling and package leaflet of medicinal products for human use*"

The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 32 European countries. In Europe over 400.000 community pharmacists provide services throughout a network of more than 160.000 pharmacies, to an estimated 46 million European citizens daily.

PGEU's objective is to promote the role of pharmacists as key players in healthcare systems throughout Europe and to ensure that the views of the pharmacy profession are taken into account in the EU decision-making process.

The Pharmaceutical Group of the European Union (PGEU) welcomes the European Commission's update of the guideline on excipients in the labelling and package leaflet of medicinal products for human use and welcomes the opportunity to respond to this consultation.

As healthcare professionals, patient safety is the primary concern for community pharmacists. Therefore, clear and guidelines on the provision of information concerning excipients contained in medicinal products is welcomed.

Pharmacists, acknowledged as the experts in medicines provide personalised information, advice, treatment and support for patients in their local communities. When dispensing prescribed or over-the-counter medicines, pharmacists provide counselling and information on the safe, effective and rational use of medicines. This includes information on avoiding and reporting adverse drug reactions (ADRs), allergies or hypersensitivities, interactions and the safe use of the medicine.

Pharmacists are also able to provide information and advice on the use of particular medicinal products based upon their excipients and potential affects. The community pharmacy network in Europe is 100% computerised and utilises electronic patient medication records that are able to store information on previous known allergies, hypersensitivities and ADRs. Shared medication records are also in operation in several Member States where vital safety information can be securely shared between healthcare professionals in order to prevent or record allergies, sensitivities or ADRs.

As such, having clear information on excipients known to cause an effect to the patient present on the package and labelling of the medicinal product is vital for improving patient safety and adherence to treatment.

When comparing the 2003 guidelines to the draft 2017 guidelines, we note the new proposed wording on the section "*EXCIPIENTS IN THE LABELLING*", no longer includes advice to '*see leaflet for further information*'. Whilst we appreciate that additional wording relating the 'E-number' is included in the new guideline, we suggest that the wording should be as transparent as possible and direct readers to sources of more detailed information concerning excipients and their potential effects. As such, we recommend to retain the wording '*see leaflet for further information*' in the next guideline text.

In conclusion, the PGEU supports the Commission's revised guidelines on excipients in the labelling and package leaflet of medicinal products for human use.

END