From: KEPKA - Consumers Protection Center
Subject: PCIM/11/01 - Public Consultation on implementing measures for pharmacovigilance

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Profile of interest representative:
ΚΕΝΤΡΟ ΠΡΟΣΤΑΣΙΑΣ ΚΑΤΑΝΑΛΩΤΩΝ

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Dear Madam/Sir,

We welcome the adoption of the new pharmacovigilance legislation as an important step to strengthen the EU pharmacovigilance system and to increase consumers' trust in the safety of medicines.

For a proper implementation of the legislation it is necessary to guarantee that the European Medicines Agency and the national competent authorities have adequate resources to perform their tasks and are in the position to have a complete oversight on the safety profile of all medicines on the market.

In implementing the legislation it is important to bear in mind the new definition of adverse reaction that now includes also misuse, abuse and medication errors.

The technical requirements for the pharmacovigilance master file, the quality systems, the collection, processing and assessment of data, the formats and protocols should be designed as to ensure an efficient detection of signals and a proper management of risks.

Kindly note that we fully agree with BEUC's position on this issue.

Being always at your disposal.

Yours sincerely,
Nikolaos Tsemperlidis, President KEPKA, Member of Economic and Social Council of Greece,

Evangelia Kekeleki, General Secretary KEPKA, Vice President Single Market Observatory, Member EESC and Member ECCG

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