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Managing Medicines Risks in Europe: PATIENT SAFETY COMES FIRST

On Wednesday, January 27, Michèle Rivasi MEP (France, *Greens*) and Linda McAvan MEP (United Kingdom, *S&D*) chaired an expert meeting on the European Commission's legislative proposals on pharmacovigilance, at the European Parliament in Brussels¹.

The experts highlighted the need to improve patients' safety in Europe by genuinely strengthening pharmacovigilance², which is the process of evaluating and improving the safety of medicines.

The experts questioned a number of the Commission's proposals that could weaken the current pharmacovigilance system, such as the possibility that premature marketing authorisations become the rule rather than an exception justified on public health grounds or the risk that Member States' pharmacovigilance authorities could be increasingly bypassed in favour of pharmaceutical companies.

The legal provisions to allow direct reporting of adverse drug reactions by patients to health authorities were strongly welcomed and experts shared recent evidence on the added value of spontaneous patient reports that provided crucial complementary information to health professional reports.

MEP Michèle Rivasi (France, *Greens*) said:

"The influenza A/H1N1 "false pandemic" is just another example of the influence of commercial interests over the health sector. Evidence shows that it is irresponsible to outsource the collection and interpretation of pharmacovigilance data to pharmaceutical companies because of their conflicts of interest. Public funding of pharmacovigilance activities should be maintained to preserve the independence of health authorities."

MEP Linda McAvan (United Kingdom, *S&D*) said:

"A robust pharmacovigilance system has the potential to quietly save many lives in Europe. To work well, side-effects need to be reported quickly, and Member States need to cooperate to detect signals and then follow these up with action. I want to encourage the "informed patient", and welcome the proposals to enable patients to directly report their own side-effects."

Recommendations put forward to strengthen the Commission's proposals included to proactively prevent adverse drug reactions, to clarify roles and responsibilities to ensure independent expertise and to avoid of conflicts of interest in the collection and analysis of pharmacovigilance data.

Other propositions were aimed at restoring citizens' trust, including granting public access to pharmacovigilance data, increasing transparency in decision-making, and improving information in patient leaflets and on packages (i.e. black triangle for medicines 'under intensive monitoring' in order to encourage patients to report adverse drug reaction).

The European Parliament is currently discussing the pharmacovigilance proposal and is expected to vote on it later this year in the May plenary sessions.

¹ - Detailed program and presentations available here: www.aim-mutual.org/?page=17&id=201.

Speakers' quotes:

Prof. Joan-Ramon Laporte, Director of the Catalan Institute of Pharmacology (ICF) (Spain), said:

"Lessons should be learnt from recent safety issues. Proactive pharmacovigilance (drug utilisation data follow-up, observational studies, meta-analyses of clinical trials) is a complementary strategy to spontaneous reporting, which is particularly valuable when adverse drug reactions are common."

Dr. Thomas Stammschulte, Responsible for the documentation and assessment of adverse drug reactions of the German Medical Association (Germany) added:

"Spontaneous reporting of ADRs by patients and health care professionals is a cornerstone of pharmacovigilance. The reliable collection and subsequent analysis of the clinical data require the independent expertise of pharmacovigilance centres with knowledge of local prescribing patterns. Detection of signals of drug safety problems on a case-by-case basis and by statistical methods in big databases (i.e. Eudravigilance) is a complementary approach that requires good quality data."

Florence Vandeveld, Representative of the Medicines in Europe Forum, said:

"There is a risk that the European Commission's proposals open the door to 'easy' marketing authorisations to become the rule. The shift of 'responsibilities' to the pharmaceutical industry means that companies will have greater control over pharmacovigilance information, with the risk of data being withheld. Independence and transparency are key principles in drug safety data and they should be strongly upheld."

Andrew Herxheimer, Co-convenor of the Cochrane Adverse Effects Methods Group, said:

"Patients' reports add value: they are more direct and give more and better context than indirect reports from professionals (for example, they describe the impact on people's lives). Indirect and direct reports complement each other, generating multicultural knowledge."

Martine Van Hecke, Coordinator of the health team of the Belgian Consumer Organisation Test-Achats, added:

"Our experience shows that consumers report correctly and in a detailed manner. Direct reporting is an essential tool to empower and engage consumers to be further involved in the management of their own health. The European Commission proposals should strongly encourage and facilitate patient reporting initiatives"

Ilaria Passarani, Head of Health Department at European Consumers' Organisation (BEUC) said:

"Consumers have the right to know more about the side effects of medicines. Pharmacovigilance information concerns consumers' health and safety and it belongs to them. It should be made public in a user-friendly and timely manner"



Presentations available here: www.aim-mutual.org/?page=17&id=201

For more detailed information on this event, please contact:

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² - Pharmacovigilance can be defined in more detail as the process of evaluating and improving the safety of medicines, which takes place in stages from drug development to post-marketing surveillance, and including risk management and preventing of drug errors; communicating drug information; promoting rational drug use; and crisis preparedness.