OUR WAY FORWARD

The Uppsala Monitoring Centre (WHO Collaborating Centre for International Drug Monitoring) has, within the framework of the Monitoring Medicines project, developed a **unique web-based reporting tool** for patients. The patient reporting tool will be offered to 4–5 national pharmacovigilance centres for piloting during 2012. Thereafter it will be available to any country wishing to use it.

The patient reporting tool is built in a way that any country accepting adverse reaction reports in the international standard format (E2b) can use it. Language, style sheets and logos can be adapted to meet local needs. The reporting facility will always be connected to a national pharmacovigilance centre and reports will be transmitted to the database of the WHO Programme (VigiBase) according to the same reporting routines as for all other case reports.

In countries adopting the new reporting tool, patients will be in a better position to express their experiences with medicine therapy directly to the health authorities. Patients will be more confident that their views count, and that national health authorities are doing everything to ensure the safety, quality and effectiveness of medicines if they are involved more fully in pharmacovigilance.

MONITORING MEDICINES

The Monitoring Medicines project is funded through the 7th Framework Programme (FP7) of the European Commission.

The overall aim of 'Monitoring Medicines' is to learn more about why ADRs occur so that we can act to reduce patient deaths and negative health impacts arising from undetected medicines safety problems.

http://www.monitoringmedicines.org

REPORTING TOOL

http://www.who-umc.org

For more information on the web-based reporting tool please contact the Uppsala Monitoring Centre: info@who-umc.org

REFERENCE LITERATURE

1. Experiences with adverse drug reaction reporting by patients: an 11-country survey. van Hunsel F, Härmark L, Pal S, Olsson S, van Grootheest K. Drug Saf. 2012 Jan 1;35(1):45–60.
2. Safety monitoring of medicinal products: reporting system for the general public. WHO Library Cataloguing-in-Publication Data ISBN 978 92 4 150319 8

MONITORING MEDICINES

http://www.monitoringmedicines.org

EMPOWERING PATIENTS IN PHARMACOVIGILANCE

If we don't count on patients, patient-care will not count

MONITORING MEDICINES

the UPPSALA MONITORING CENTRE

World Health Organization

EUROPEAN COMMISSION

PROBLEM

Healthcare professionals are currently the only people that are requested to report adverse drug reactions (ADRs) and other medicine-related problems to pharmacovigilance centres.

In many countries self-medication is common, and sometimes patients buy medicines via the internet or from unauthorized medicine outlets. Information on ADRs following such unsupervised treatment with medicines will normally not reach health professionals and will not be reported unless the patient is admitted to a health facility for treatment of the reaction.

DIRECT PATIENT REPORTING – PART OF THE SOLUTION?

Studies from pioneer countries *(ref 1)* that have invited reports also directly from patients, show that reports of ADRs submitted to pharmacovigilance centres directly from patients may contribute to

- faster identification of new safety problems associated with drug therapy
- a better understanding of how medicine use may adversely affect the quality of patients' lives
- more detailed information about adverse events, contributing to a better characterization of the nature of the risks involved in medical treatment
- problems being described in layman's language, which can be used by authorities when giving advice on how to prevent such problems.
- a better understanding of the burden of medicine-related problems in society.

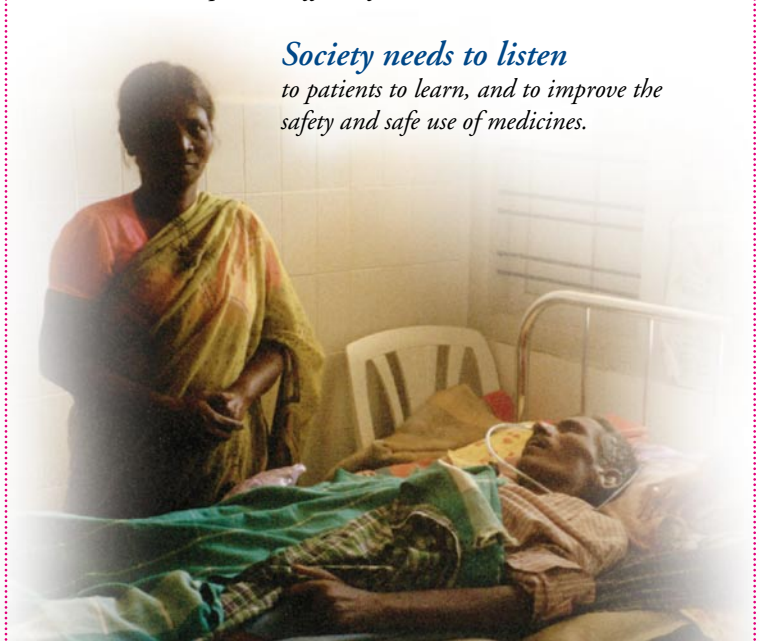
OTHER BENEFITS OF DIRECT PATIENT REPORTING

- patients will feel included and engaged in their own treatment decisions.
- patients will be encouraged to better understand the functions of their body, their ailments and the benefits and harms of treatment options. They are then more likely to adhere to rational treatment advice.
- a health system that engages patients as equal stakeholders will enjoy the trust and confidence of its patients.

It is important to acknowledge that direct patient reporting complements reporting by health professionals. The competence and experience of health professionals in understanding how various underlying factors may influence clinical signs, symptoms and treatment outcomes is invaluable.

Patients want to share
their experiences when they have suffered from unpleasant effects of medicines.

Society needs to listen
to patients to learn, and to improve the safety and safe use of medicines.



CURRENT DEVELOPMENT

In 2008, the countries participating in the WHO Programme for International Drug Monitoring (the global pharmacovigilance programme), requested WHO to develop a document providing advice on how to set up pharmacovigilance activities for direct patient reporting. Development of this publication was incorporated into the aims of the European Commission-funded FP7 project Monitoring Medicines. As part of this project, a thorough review of the approaches used in those countries that had already accepted direct patient reporting was conducted. This study (*ref 1*) was published in January 2012.

In March 2012, based on this review and the work of its experts and consultants, WHO published the document 'Safety Monitoring of Medicinal Products – Reporting system for the general public' (*ref 2*). EU legislation on pharmacovigilance requires EU countries to have direct patient reporting systems in place by July 2012.