NEWS

For immediate release

22 May 2012

Capturing patients' experience of the harms of medicines

An important side-event at the 65th World Health Assembly (Geneva, 21-26 May 2012) will report on progress in a project encouraging direct reporting from patients about problems they have with their medicines.

All medicines carry some measure of risk, of adverse reactions in particular. In the past, information about such events has come largely from health professionals who reported them to their national medicines safety (pharmacovigilance) centres.

The EU-funded Monitoring Medicines project, in collaboration with countries around the world, has developed guidelines for setting up patient reporting systems, based partly on the experience of the handful of countries that already have such systems in place (Netherlands, Sweden, UK, US, for example). This follows European Union legislation that will be in place from July 1st 2012, requiring patient reporting to be included in national medicines safety systems.

The side-event, entitled, 'Empowering patients in pharmacovigilance: first results from an interregional consortium,' will take place on 24 May, in Room IV, Palais du Nations, Geneva, from 12.30-14.00. A number of experts will make short presentations about the challenges and opportunities of reporting by patients. Representatives from two European and one African patient organization have been invited. There will be the opportunity for the exchange of views and discussion of best practice and how to capitalise on this great source of significant information.

Why is patient reporting important?

There are two principal reasons: first, it is almost certain that many patients experience adverse effects from their prescribed or over-the-counter medicines which never come to the notice of their physicians or pharmacists. Such events may affect their health or adherence to their therapy in damaging ways. Such events provide critical intelligence about the safety and quality of medicines which needs to be in the public domain (this includes, amongst much else, the identification of counterfeit or sub-standard medicines).

Second, the real-life experience of patients is often not captured accurately or fully in consultation with health professionals. Patients, when describing their own experience in their own words shed light on issues, large and small, which might not otherwise be revealed.

Guidance

The project team has produced guidance notes for countries setting up patient reporting systems: Safety Monitoring of medicinal products: Reporting system for the general public.

This publication is available at:
http://www.monitoringmedicines.org/DynPage.aspx?id=90889&mn1=6701

An explanatory leaflet has been produced for the side-event, and is attached to this release.

The meeting is being hosted by the WHO and its collaborating centre, Uppsala Monitoring Centre, who are responsible for the receipt and analysis of global safety data, collected from the 107 members of the WHO Programme. UMC has developed a web-based patient reporting tool which countries can integrate into their existing systems and use for the management and transmission of patient-reported data. This tool also allows patients to report electronically.

Although the WHO database contains more than seven million individual reports of adverse drug reactions and associated problems, it still represents only a small percentage of all incidents of medicinal harm experienced across the world - covering the entire range from death to mild headache or temporary constipation (for example). Including direct reporting from patients should help compensate for the shortfall, enrich our knowledge, and contribute to the safer use of medicines worldwide.

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For more information about the meeting or about medicines safety in general, or a report of the outcome of the meeting, please contact:

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More information is available on the WHO website www.who.int/gb, in World Health Assembly Journal, Preliminary Number, 3 May 2012, on the UMC website and on the Monitoring Medicines web site http://www.monitoringmedicines.org/

Notes for editors

Pharmacovigilance is the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. More than half the countries in the world have pharmacovigilance centres whose primary responsibility is the collection of adverse drug reaction data from health professionals. This global enterprise started in the 1960s after thalidomide, an approved and widely used drug, was found to cause radical birth defects in the children of women who took it while pregnant.

While all drugs are subjected to rigorous testing and trial before approval, the numbers of people exposed to the trial drugs are inevitably very small in comparison with the numbers of patients who may eventually use them, and patients who eventually use them may be very different (in age or genetic characteristics, for example) from the trial population. Only when a drug is in widespread use does its complete safety profile begin to emerge. Hence, the vital importance of monitoring medicines after they are approved and marketed, and of exploiting as many sources of information as possible.