



## **Ensuring medicines safety**

Modern medicines have improved the way in which diseases are managed and controlled. Despite all their benefits, evidence continues to mount that adverse reactions to medicines are a common, yet often preventable, cause of illness, disability and even death.

The WHO defines pharmacovigilance as the science and activity relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem<sup>1</sup>.

Mechanisms for evaluating and monitoring the safety of medicines in clinical use are vital. In practice, this means having a well-organised pharmacovigilance reporting system in place. Ongoing safety surveillance is critical to the safe use of medicines in real world settings where issues such as individual medical history, diet and concomitant medication may impact on individual patient responses.

While all innovative medicines are tested under clinical trial conditions, the nature of a clinical trial means that a limited number of selected individuals are involved.<sup>2</sup> Some adverse effects only come to light after the controlled study has ended and the product is used in larger populations, where interactions with diet and other medication, may lead to possible adverse effects.

Health professionals are in the best position to report suspected ADRs observed in their every day patient care. Therefore, all healthcare providers such as medical practitioners, pharmacists, nurses and dentists should report ADRs as part of their professional responsibility, even if they may be doubtful about the precise relationship with the given medication.

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<sup>1</sup> World Health Organisation, *The importance of Pharmacovigilance: Safety monitoring of medicine products*. Accessed on 14 September 2009. Available at: <http://apps.who.int/medicinedocs/collect/edmweb/pdf/s4893e/s4893e.pdf>

<sup>2</sup> World Health Organisation, *Pharmacovigilance: Ensuring the safe use of medicines*. Accessed 14 September 2009. Available at: <http://apps.who.int/medicinedocs/collect/edmweb/pdf/s6164e/s6164e.pdf>

Pharmacovigilance programmes aim to:

- improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions;
- improve public health and safety in relation to the use of medicines;
- contribute to the assessment of benefit, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use;
- promote understanding, education and clinical training in pharmacovigilance and its effective communication to health professionals and the public.

Pharmaceutical companies play an active and important role in the reporting of ADRs. Any adverse drug reaction should immediately be reported to the pharmaceutical company responsible for the marketing of the product in question, which in turn has a responsibility to report this to the NADEMC and to their corporate headquarters for review. Quality-related issues should also be reported as they may lead to adverse events. PIASA member companies take their responsibility to build a body of knowledge for the products they research and develop very seriously.

Pharmacovigilance reporting remains important at three levels: Corporate responsibility to maintain a company's reputation, ethical responsibility to ensure patient safety and legal responsibility to the South African Department of Health in terms of international codes and standards".

Pharmaceutical companies and healthcare providers need to continually contribute to this body of knowledge in order to ensure safe medicine use. "PIASA's pharmacovigilance working group, with representation from member pharmaceutical companies, carries the responsibility of staying abreast of pharmacovigilance reporting and promoting the use of international pharmacovigilance reporting standards in Africa."