The power of safety: pharmacovigilance in an era of globalisation

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The past few decades have been pivotal in the field of pharmacovigilance – the science and activities of detecting, assessing, understanding and preventing adverse events or any other drug-related problems. Starting as a discipline in response to the thalidomide tragedy of the early 1960s and relying then only on countries sharing information on spontaneously reported adverse events, pharmacovigilance is now more proactive and extensive thanks to its own successes of identifying several drug associated problems in several countries. The high profile withdrawals of cerivastatin, rofecoxib, rosiglitazone among others highlight the importance that patients and policy makers place on safety and indicate the need for prompt and appropriate actions in the interest of patients. Whilst the processes by which some withdrawals have been made are still being debated by experts, the need to ensure that medicines are safe and that they are safely used is agreed by all. So after nearly 45 years of formal pharmacovigilance across the world, is the world any safer, better and well protected? Do we now have systems able to protect all including the poor and vulnerable? In an era of globalisation where diseases as well as medicines and vaccines of varying standards and quality cross national borders freely, can non-pharmacovigilantes feel confident and comfortable that the best science is being utilised to ensure that the best practice is in place to guarantee not just the safety of products but more importantly the safety of patients?

A growing field

When the Sixteenth World Health Assembly adopted resolution WHA 16.36 of 1963 to reaffirm "the need for early action in regard to rapid dissemination of information on adverse reactions due to medicines" only ten countries responded leading to the subsequent creation of the WHO Pilot Research Project for International Drug Monitoring in 1968. This programme later became the WHO Programme for International Drug Monitoring (www.who-umc.org) which has since grown from 10 countries to 106 countries with another 34 officially indicating their willingness to join once they attain the required technical competencies of sharing information with other members of what is essentially a global network of countries who have accepted that early identification of unknown drug related problems is the rapid sharing of information among countries. The fastest growth in pharmacovigilance over the past decade has been in Africa fuelled probably by the staggering increase in financial resources from global health agencies to increase access to life saving medicines for priority conditions like malaria, tuberculosis and HIV/AIDS.

A changing field

The face of pharmacovigilance in changing across the globe driven by changing regulations in Europe, USA and Japan – the so called ICH (International Conference on Harmonisation of

Technical Requirements for Registration of Pharmaceuticals for Human Use) countries and the expansion of access to medicines in developing countries[1]. The factors underpinning some of these changes are the need for more information and transparency in the decision making process and the need to utilise all available data and data sources to ensure and assure patient safety. Thus whereas in the 1960s pharmacovigilance consisted largely of the collection of individual case safety reports (ICSRs) and their analysis, pharmacovigilance in 2011 involves spontaneous reporting, active data collection methods and use of patient information as well as cohort studies where feasible and appropriate. Pharmaceutical manufacturers now submit periodic safety update reports on their products and may be required to undertake post-authorisation safety studies. Risk management plans and risk minimization strategies as well as crisis management and communication strategies all form part of daily fodder of pharmacovigilance. Newer methods are being explored and older methodologies are being reconsidered. The distinction between "vigilance" and "epidemiology" is becoming blurred and the focus is now on the patient and the need to use all available data to keep the patient safe and to ensure that all medicines are associated with significantly much less risk in relation to the benefits that they afford.

A dynamic field

Traditionally pharmacovigilance centres and systems have focused on capturing events related to the intrinsic nature of the drug. Currently, most pharmacovigilance systems are literally structured to capture all "drug related events" including unexpected lack of efficacy; quality defects; drug abuse; medication errors; interactions with traditional and herbal medicines; and poisoning events that are not necessarily related to the intrinsic nature of the medicines. There is now an acknowledged acceptance of the importance of genetic differences in drug safety making pharmacogenetics and pharmacogenomics essential areas in pharmacovigilance. The players in pharmacovigilance are also changing. International organisations like the International Society of Pharmacovigilance (ISoP), the International Society of Pharmacoepidemiology (ISPE) and the International Union of Basic and Clinical Pharmacology (IUPHAR) now play leading roles in pharmacovigilance alongside national authorities, the pharmaceutical industry, academia, consumer groups and the media.

An enduring field?

Safety and the need for to ensure that all patients are protected is extremely high on the global agenda both for individuals as well as for institutions and nations. The force of safety is thus acting as the force of good and pharmacovigilance experts can feel justifiably pleased that after more than 40 years of being so successful that they are not noticed, the world is waking up to one major fact: the force of safety is powerful, undeniable and enduring.

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[1] See Pal, S et al. World Medicines Situation 2011: Pharmacovigilance and safety of medicines. WHO/EMP/MIE/2011.2.7. Available online at http://www.who.int/medicines/areas/policy/world_medicines_situation/en/ (accessed 28th September 2011)