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Web Exclusive: Drug Safety in Europe

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In the United States, the Food and Drug Administration monitors post-marketing safety for all approved drug and therapeutic biologic products through its Adverse Event Reporting System. Health care professionals and consumers voluntarily report adverse drug reactions, or ADRs, to MedWatch, and those reports become part of the AERS database.

Across the Atlantic, the European Union (as well as individual countries around the world) has developed a similar program for monitoring drug safety and reporting ADRs. The United Kingdom's Prescription Event Monitoring system functions under the Drug Safety Research Unit, a non-government system that monitors newly marketed drugs intended for widespread use in the UK. PEM prompts general practitioners to report all adverse events from prescriptions, which the DSRU tracks in a database in order for early detection of serious ADRs. The UK's green form return rate is 60 percent, with only half of those containing clinically relevant data.

A 2004 study by British researchers at the University of Liverpool over a six-month period showed that of 1,225 patients admitted to two hospitals because of ADRs, 28 died as a direct result of the ADR. Researchers estimate ADRs that result in hospital admission are responsible for 5,700 deaths per year in the UK. Take into account ADRs occurring during a patient's hospital stay, and ADR deaths jump to more than 10,000 per year.

The European Medicines Agency (www.emea.europa.eu) coordinates pharmacovigilance with the network of regulators in the 27 European Union member states that analyze and carry out ADR reports. The EMEA defines pharmacovigilance as the process of monitoring, evaluating, and improving the safety of medicines in use. Pharmaceutical companies, government agencies, and health care professionals all play a part in monitoring drug safety and reporting ADRs. The EMEA keeps track of the reports and trends in statistics with the EudraVigilance system (www.eudravigilance.org), a central computer database created by the EMEA in 2001 that contains ADR reports on all medicines licensed in the EU.

In July 2007, the EMEA and Heads of Medicines Agencies met to review the status and achievements of the European Risk Management Strategy. Achievements to date include revised EU pharmaceutical legislation providing the legal tools to monitor drug safety through the systematic implementation of risk management plans, and improved electronic reporting of ADRs to EudraVigilance. Following a scheduled November 2007 meeting, EMEA and HMA will publish priority areas for the program.

For more, visit the Medicines and Healthcare Products Regulatory Agency at www.mhra.gov.uk