Pharmacovigilance

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Having recently passed our GMP (Good Manufacturing Practice), GDP (Good Distribution Practice) and PVP (Pharmacovigilance Practice) inspections by the MHRA (Medicines Healthcare Regulatory Authority) in the last month, I have been reflecting on the importance of pharmacovigilance across the whole of the supply chain.

Pharmacovigilance is a series of systems put in place relating to the detection, assessment, understanding and prevention of adverse reactions and other events, particularly long and short term side effects of medicines and other unwanted reactions.

We have moved away from simply looking for ADRs (Adverse Drug Reactions), i.e. ADRs are usually specific symptoms brought on in a patient that are unwanted, and moved on to looking at AERs (Adverse Event Reporting) i.e. ADRs plus looking also at overdosage, accidental or inappropriate ingestion, use in pregnancy etc.

Until the early 1970s there was no legislation in Europe, and in the UK, the Medicines Act gave the responsibility for the efficacy and side effects of the medicines to the manufacturer but gave no regard to the detection or attribution of problems to particular medicines or groups of medicines.

The standards of communication record keeping and trending of reported incidents was, therefore, patchy to say the least. There were, of course, some very good examples of manufacturers noticing a trend and taking preventative action but there were also some horror stories where connections (now obvious) were missed for an extended period of time.

Even so, it was not until the mid 1990s that European legislators started to tackle the problem of communication between manufacturers, suppliers, doctors and patients regarding possible problems or reactions that may have been caused by the medication.

In early 2000, an agreement was reached among the European Relevant Authorities and a framework was published in 2004 as Volume 9A of the Rules Governing Medicinal Products in the European Union. These guidelines define the responsibility of all sectors of the pharmaceutical supply chain to be aware of and report ADRs and AERs to the relevant manufacturer or local medical authority.

Durbin PLC's pharmacovigilance system covers all distribution activities across all areas of my business to ensure that we are doing our part in communicating all incidents and reports to the manufacturer. Naturally, all my staff are fully and regularly trained in the company's pharmacovigilance procedures and practices and know that they are doing their bit.

If we all play our part as healthcare professionals, we can ensure that no patients' problems with their medicines go unreported or un-investigated and we can all look forward to safer and more reliable medicines in the future. MEH

Durbin PLC is a British company based in South Harrow, London. Established in 1963, the company specialises in supplying quality assured pharmaceuticals, medical equipment and consumable supplies to healthcare professionals and aid agencies in over 180 countries. As well as reacting rapidly to emergency situations, Durbin PLC responds to healthcare supply needs from local project level to national scale programmes.
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