Through a collaboration with the MHRA, medicines information pharmacists are tackling the under-reporting of adverse drug reactions

Give adverse drug reactions the yellow card

By Kate Towers, BPharm

You have discovered that one of your patients has an unusual drug reaction. You do plenty of research and engage the help of medicines information pharmacists so that your patient has a good clinical outcome. But, do you go one step further and submit a yellow card for the reaction? For various reasons, the answer to this question is often “no”.

At several sites across the UK, MI pharmacists are addressing this problem by submitting yellow cards for all adverse drug reaction (ADR) queries they receive, as part of a pilot project run by UK Medicines Information in conjunction with the Medicines and Healthcare products Regulatory Agency.

There has long been an issue with under-reporting of ADRs. Through its yellow card scheme, the MHRA receives around 26,000 ADR reports a year. Compare that to over 900 million prescriptions dispensed in the UK annually — not to mention the over-the-counter and herbal medicines that are taken — this number is a drop in the ocean. Moreover, how many of those ADR reports had been reported immediately?

The MHRA has done a lot of research into barriers to reporting, and lack of time is a recurring theme. For a busy practitioner, it is easy to see how the process gets delayed — you need to find a yellow card, complete the clinical details and put it in the post, or find the time to submit it online, and then the information might need clarification once it reaches the MHRA and the data are entered.

Simon Wills, head of Wessex Drug and Medicines Information Service at Southampton University Hospitals NHS Trust, has been leading the pilot. He believes ADR reporting is a huge opportunity for pharmacists to contribute to medicines safety. Indeed, that was the buzz at the recent UKMi practice development seminar, held in Coventry (23–24 September).

UKMi receives about 800,000 queries per year — 15–20% of those relate to adverse drug reactions. Imagine if a yellow card was submitted for every ADR-related query received by MI services in the UK. In Dr Wills’s own words: “The potential for an increase in ADR reporting is huge!”

However, according to Dr Wills the challenges to get the pilot off the ground were substantial. Who would fund such a programme? Where would he find the time to do it? How could this be done without adding to the already large workload of UKMi pharmacists?

Onside

There began a collaboration between UKMi, the MHRA and CoAoS (the software provider for the UKMi database, MiDatabank). At the end of 2009, Dr Wills obtained a grant from the MHRA’s “targeted research programme” to get the initiative started. The money funded a pharmacist to work part time as a project manager for the pilot.

A new MiDatabank module was developed by CoAoS so that ADR reporting could take place within the existing database, thereby enabling MI pharmacists to report easily as part of their current practice.

In addition to tracking the number of reports submitted by the pilot sites, the calibre of the reports is being monitored: “We hope that these reports will be at least as good as, if not better than, those submitted manually,” says Dr Wills. Mick Foy, head of pharmacovigilance at the MHRA, is optimistic about the quality of UKMi reports: “It’s early days yet, but it seems that they compare very well.”

The type of reports submitted will also be tracked. “People are good at submitting yellow cards for black triangle drugs,” Dr Wills explains, “but are generally poorer at filling in yellow cards for other medicines, herbal products and for reactions in..."
paediatric patients.” He hopes that, though UKMi, more reports of this nature will be submitted.

Extra time
Finally, the pilot will also assess the feasibility of the initiative in terms of MI pharmacist time. Victoria Mott, lead MI pharmacist at Oxford Radcliffe Hospitals NHS Trust (one of the pilot sites), says that initially some pharmacists were wary of how much extra work completing the yellow cards would involve. However, in practice it only takes an extra four to eight minutes on top of what the pharmacist does already. “As we get more familiar with the system it is getting quicker and easier,” she comments. And it is not just MI pharmacists who will be able to do this. As more pharmacists rotate through MI centres, and therefore receive MiDatabank training, she hopes that in five to 10 years’ time this will be something that pharmacists can do routinely as part of their clinical practice.

During the pilot, pharmacists have been inputting the necessary information, which is then sent via email to the MHRA where the data are entered. According to Mr Foy, the big score will come when MI pharmacists will be able to enter reports directly into the MHRA database. Not only will it save MHRA staff time, it will mean the data are available for analysis, in both the UK and Europe, far quicker.

This development is not far away — it is expected to be ready when the project rolls out nationally next year. “No other country is operating a system where this happens,” says Mr Foy of the ability for UKMi staff to make additions to the MHRA database in real time. If this part of the project is successful, not only will the UK be the first country to do it, pharmacists will be the first professional group to make it happen. “This is a great way to raise the profile of pharmacy but, more importantly, it is a real win for patient safety,” Dr Wills enthuses.

Playing for Europe
These developments are timely. The EU has recently adopted new legislation that aims to build on the existing pharmacovigilance processes to make them more efficient and transparent. The legislation mandates that the European Medicines Agency’s existing Pharmacovigilance Working Party be upgraded to a Pharmacovigilance Risk Assessment Committee. The PRAC will have representatives from all member states and will include healthcare professionals, pharmacovigilance experts and patients. Most importantly, the PRAC will have clout — its decisions will have a clear legal footing, unlike those of the existing working party. Crucially, it will be able to demand that companies conduct post-marketing safety and efficacy studies if required.

To streamline the pharmacovigilance process, pharmaceutical companies will no longer have to report an ADR to the regulatory body in each member state — they will report once to the Europe-wide ADR database (Eudravigilance). Once the legislation is fully enacted in 2012, this database will also become more accessible to healthcare professionals and the public.

Searching the database will be easier and, for the first time, all patients in the EU will be allowed to report ADRs directly to their country’s regulator (something that has been going on in the UK since 2005). ADR data collected by the MHRA and other European regulators have long been incorporated into Eudravigilance. It is hoped that the new pharmacovigilance arrangements will boost ADR reporting throughout the continent and ensure that any decisions made regarding pharmacovigilance are transparent and enforced.

So, the next time you enlist the help of MI pharmacists to investigate an ADR, bear in mind that their additional effort behind the scenes is contributing to the bigger picture of medicines safety.