

WHAT DO BOOTS PHARMACISTS KNOW ABOUT YELLOW CARD REPORTING OF ADVERSE DRUG REACTIONS?

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This article describes a Boots The Chemists in-house questionnaire designed to inform the company's in-house training and improve pharmacists' awareness of adverse drug reaction reporting, both within the company and through the yellow card scheme. The authors hope that their findings will be of interest to other community pharmacists



CHRISTOPHER ICGA

The recent leading article in *The Pharmaceutical Journal*, "Don't forget about yellow cards",¹ echoes the sentiment that stimulated Boots to undertake a survey of its pharmacists a year after the inclusion of community pharmacists in the yellow card scheme. We wanted to establish what Boots pharmacists knew about drug safety terminology, to what extent they were aware of the yellow card scheme and what use, if any, they had made of it. We believe our findings will be of interest to other community pharmacists and in the light of recent comment in *The Pharmaceutical Journal*,^{2,3} we set out a selection below. We recognise that our findings have limitations in terms of sample size and selection but we have no reason to believe that Boots pharmacists are unrepresentative of community pharmacists as a whole. Should anyone wish to repeat our survey with other groups of pharmacists, a more detailed account of our methods and results is available on request.

The Boots organisation is in the unusual position of being both the holder of marketing authorisations and a retail pharmacy company. Pharmacists employed by Boots The Chemists therefore have a dual role in the reporting of suspected adverse drug reactions (ADRs). As health care professionals involved in the UK yellow card scheme, they have a professional role in identifying and reporting suspected ADRs to all

licensed drugs. As employees of a company which holds over 300 product licences, they also have a responsibility to report suspected ADRs associated with these products to the pharmacovigilance department in Boots.

In November 2000, a questionnaire was sent out to a random selection of 200 Boots pharmacists throughout the UK. The questionnaire covered five areas:

1. General information on the pharmacist's job title, store size and location
2. Knowledge of the meaning of some important terms involved in drug safety
3. Awareness and knowledge of the yellow card scheme and how it operates
4. Reporting experience with the yellow card scheme
5. Knowledge of the requirements and procedures for reporting reactions on Boots licensed products, and experience in reporting these reactions

Pharmacists were asked to complete the questionnaire from their own knowledge, without reference to other sources of information, and to return the questionnaires via the internal mail system to the pharmacovigilance department. Of the 200 questionnaires sent out, 98 were returned — a return rate of 49 per cent. Responses to questions covering areas 1 and 5 are not reported here.

OUR FINDINGS

Some of the barriers to reporting arise simply from uncertainty about the definitions of terms used by regulatory authorities. Although most (79 per cent) knew the correct definition of an adverse drug event, a small majority (54 per cent) believed wrongly that a definite causal relationship had to exist before a reaction could be considered an ADR. Confusion exists over the regulatory definition of "serious", which, for example, is not deemed necessarily to include reactions that affect the quality of life or entail time off work.

All Boots pharmacists said they were aware of the yellow card scheme although one was unaware of its extension to community pharmacists. Quite a number (38 per cent) believed incorrectly that nurses were included in the scheme whereas most (87 per

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Key messages for reporting ADRs

1. Report, even if:

- 1 The ADR is already well recognised, but serious
- 1 You are not certain that the drug caused the adverse reaction

2. Report **all** ADRs, serious or not, if they involve:

- 1 A black triangle drug
- 1 An over-the-counter medicine
- 1 An unlicensed herbal medicine

3. **Serious** means an ADR that:

- 1 is lethal or life-threatening
- 1 results in admission to hospital or prolongs a hospital stay
- 1 causes disability or a congenital abnormality

4. Consider consulting the patient's general practitioner before reporting but remember that the **GP's approval is not necessary** for you to act

cent) correctly identified that preregistration trainees were not included. There was significant misunderstanding in the range of products on which yellow card reporting was encouraged. Twenty per cent of Boots pharmacists were not aware that over-the-counter medicines were included; a majority (68 per cent) were not aware that unlicensed herbal medicines were also included.

Over half (53 per cent) believed incorrectly that reactions involving established drugs should only be reported if these were not covered in the product information. Such confusion means that, once included in the product information, recurring ADRs may not be reported, leading to false assumptions about their prevalence. There was also confusion over the degree of certainty needed to report ADRs. Forty-seven per cent of pharmacists believed that a definite or probable causal relationship was required (in fact, a suspicion is enough).

Other significant gaps in knowledge included awareness of the information necessary to report an ADR. Forty-seven per cent believed that the patient's name was needed before an ADR could be reported (in fact, initials or any other identifier is enough). An overwhelming 92 per cent believed incorrectly that information on other drugs being taken by the patient would be necessary when reporting an ADR. Conversely, all correctly identified that the name of the drug is necessary, and most (98 per cent) that information on the ADR, on the identity of the reporter is indeed necessary (85 per cent) and that neither the patient's or GP's permission is needed before reporting an ADR (75 per cent).

Our survey showed that experience of actually using the yellow card scheme was low. Although the majority of pharmacists had been aware of one or more ADRs over

REFERENCES

1. Don't forget about yellow cards (edit). *Pharm J* 2002;269:2.
2. Cox A. Embracing ADR reporting could improve pharmacists' standing. *Pharm J* 2002;269:13.
3. Major E. The yellow card scheme and the role of pharmacists as reporters. *Pharm J* 2002;269:25-26.

the preceding year, only 7 per cent had actually reported an ADR and none had reported more than three ADRs. The most frequent reason for not reporting was that the reaction was already a well-recognised effect of the drug. Only 6 per cent said they had been too busy to send in a yellow card. Significantly, although 99 per cent of pharmacists welcomed their involvement in the scheme, 68 per cent said that they did not feel confident reporting ADRs on yellow cards.

Our conclusions from the above findings are that familiarity with the scheme is likely to wane in the face of more pressing and immediate issues for community pharmacists and when opportunities to report arise infrequently. To achieve significant improvement in the use of the yellow card scheme by community pharmacists, dedicated and protected opportunities for deeper learning in this area is needed. Since we undertook the surveys, we have worked hard to raise awareness of the need to report ADRs.

In our view, there is a continuing and repeated need for reminders about the precise parameters and processes for ADR reporting. In the accompanying table we set out the key messages which our survey suggested were not getting through as successfully as might be hoped. These need to be fully absorbed by community pharmacists to help them play a wider role in this important area of pharmacovigilance.