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# *Editorial*

# Adverse drug reaction of the month – a new series

This issue of the *Postgraduate Medical Journal* sees the launch of a new series of articles, *Adverse drug reaction of the month*. The series has two objectives. First, it is intended to inform practising clinicians about significant adverse reactions (ADRs), as well as their diagnosis, management and prevention. Second, we unashamedly wish to use it to promote the Committee on Safety of Medicines/Medicine Control Agency (CSM/MCA) 'yellow card' scheme.

The series will be based on individual case reports, or case-series, derived from the CSM/MCA's ADR data-base. The case reports will generally be provided by the staff of the CSM/MCA's Regional Monitoring Centre (in Wales, West Midlands, Merseyside and the Northern Region). The case-series will usually be assembled by staff of the MCA's Postlicensing Division and will examine ADR profiles for individual, or classes of, products. The CSM and MCA have always regarded the confidentiality of the 'yellow card' scheme as inviolate and neither the names of patients or reporting doctors are divulged to third parties. Case-reports will therefore be anonymised and only published with the consent of the reporting doctor. Further some minor changes (eg, patient's age, gender) may be made to the details provided, if this appears necessary to protect confidentiality.

**Table** Important early warnings of new adverse reactions identified through spontaneous ADR reporting schemes since 1993 and the resultant UK action in respect of marketing authorisations/product information

| *Year* | *Product* | *Adverse reaction and resultant action* |
|---|---|---|
| 1993 | thymoxamine (Opilon) | hepatotoxicity led to improved warnings |
| 1993 | clozapine (Clozaril) | myocarditis led to warnings |
| 1993 | paroxetine (Seroxat ▼) | withdrawal symptoms, dystonic reactions led to improved warnings |
| 1993 | remoxipride (Roxiam ▼) | aplastic anaemia led to drug withdrawal worldwide |
| 1993 | high-lipase pancreatins (Creon 25000 ▼, Nutrizym 22 ▼, Pancrease HL ▼, Panzytrat 25000 ▼) | colonic strictures in children with cystic fibrosis led to advice to use lower strength pancreatins in this group |
| 1994 | rifabutin (Myobutin ▼) | uveitis and drug interactions led to warnings and dose reduction |
| 1994 | halofantrine (Halfan ▼) | cardiac arrhythmias led to additional warnings and contraindications |
| 1994 | tiaprofenic acid (Surgam) | severe cystitis led to additional warnings and contraindications |
| 1995 | tramadol (Zydol ▼) | psychiatric reactions led to warnings |
| 1995 | cyproterone acetate (Cyprostat Androcur) | dose-related hepatoxicity led to restricted indications and the requirement for hepatic function monitoring |
| 1995 | quinolone antibiotics | tendonitis and tendon rupture led to improved warnings |
| 1995 | tacrolimus (Prograf ▼) | hypertrophic cardiomyopathy led to warnings, dose reduction and monitoring requirement |
| 1996 | alendronate (Fosamax ▼) | oesophageal reaction led to improved advice on taking the product |

▼ Indicates drug was under intensive monitoring at the time

**'Yellow card' reporting critera**

New products (marked ▼ in adverts and presenting literature): all suspected reactions
Established product: only serious suspected reactions

We also hope that the *Adverse drug reaction of the month* series will prompt doctors to send us 'yellow card' reports. Although most developed countries now have comparable ADR reporting schemes, the UK's yellow card scheme has been unquestionably the most significant and influential from a world-wide perspective. Some of the recent early warnings, produced by the scheme, are shown in the table. Success is a tribute to the medical profession but it could be improved. The types of report we seek are as shown in the box, but we should emphasise that:

- we ask for reports of suspected - not proven - ADRs. Unlike a diagnosis of hepatitis due to hepatitis B virus infection, or meningitis due to haemophilus influenza B, certainty in the diagnosis of an ADR in an individual patient is unusual. Suspicions, based on good clinical judgement, are what we seek.
- we ask for reports of all suspected reactions to new products (marked ▼ in prescribing literature and promotional material) to expand on the inevitably limited experience from premarketing clinical trials.
- we ask for reports of serious suspected ADRs even if a causal association, in general, is already well recognised. Case-series of established ADRs often enable us to identify new predisposing factors (eg, age, co-medication) or a changing incidence.
- we need more sustained reporting from hospital doctors. Around two-thirds of our total reports come from general practitioners and, whilst they provide invaluable data, we wish to receive many more reports from hospitals, where patients with the most serious ADRs are likely to be managed.
- we need more reports from specialists (eg, oncologists, haematologists) using 'niche' products. They tend to be the predominant prescribers of many novel agents, such as products derived from biotechnological sources, and could provide us with a wealth of valuable information.

Please support the 'yellow card' system.

MICHAEL D RAWLINS
ALASDAIR M BRECKENRIDGE
*Committee on Safety of Medicines*

SUSAN M WOOD
PATRICK C WALLER
ROSALIND COULSON
*Postlicensing Division, Medicines Control Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ, UK*

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