IRISH MEDICINES BOARD

Notice Information: Human Medicines - 3rd Party Publications 31 October 2005

Part 1. Product Information

a)	Title:	ADVERSE DRUG REACTION REPORTING
b)	Product Name/Type:	Adverse Drug Reaction Reporting - MIMS
c)	Reference:	MIMS Publication October 2005
d)	Prescription Required:	No

Part 2. Problem/Issue

a) Problem/Issue:

The IMB monitors the safety of all authorised medicinal products available on the Irish market on an on-going basis. Part of this monitoring is carried out through review and evaluation of suspected adverse drug reactions (ADRs) and the IMB encourages all healthcare professionals to notify suspected ADRs observed during their practice. The IMB greatly appreciates the interest in reporting and acknowledges the enormous contribution of busy healthcare professionals to the continued surveillance of the safety of medicines through the voluntary reporting system. While the burdensome nature of form filling is recognised and acknowledged, the collection of ADR reports is essential to ensure continued, effective surveillance of the safety of licensed medicines. During 2004, the IMB received a total of 1,727 suspected adverse drug reaction (ADR) reports, occurring in Ireland in association with use of medicinal products. The following table provides a breakdown of reports by source: Breakdown of ADR Reports Received During 2004 (by Source) Marketing Authorisation Holders 46 % General Practitioners 16 % Hospital Doctors 7.76 % Clinical Trials 11 % Community Pharmacists 4.05 % Community Care Doctors 8.3 % Nurses 4.86 % Hospital Pharmacists 1.85 % Dentists 0.18 % Total 100 % During 2004, in addition to our regular column in this publication, one issue of the IMB's Drug Safety Newsletter (DSN) was published. Topics covered included rosuvastatin (Crestor), nimesulide (Aulin/Mesulid), TNF-alpha inhibitors, atypical antipsychotics, codeine-containing analgesics, methotrexate – recommendations for safe prescribing, dispensing & monitoring, and an update on adverse drug reaction reporting. Copies of the DSN are available on request or from the website at www.imb.ie. The IMB's national ADR database now includes anonymised case details of over 34,000 suspected ADR reports provided by healthcare professionals and pharmaceutical companies since the programme started in 1968. This information is helpful not only to the IMB in its evaluation of the safety profile of medicinal products, but is also used for the provision of anonymised summaries of information in response to enquiries. Spontaneous reporting of suspected ADRs is an inexpensive and effective method for the lifetime surveillance of medicines following their introduction to the marketplace. While an individual's experience may be limited to one or two cases, when collated with additional reports from other sources may contribute considerably to the assessment of a potential safety hazard. Healthcare professionals are reminded that it is not necessary to determine a causal relationship between a drug and subsequent event prior to reporting a suspected ADR. You are particularly reminded to report: • All suspected adverse reactions to new medicinal products (i.e. those available on the market for less than two years). • Serious suspected reactions to established medicines. A serious reaction is defined as one which is fatal, life threatening, results in persistent or significant disability/incapacity, results in or prolongs hospitalisation. This definition also includes cong

congenital abnormalities or birth defects and serious adverse clinical consequences. • Any suspected increase in the frequency of minor reactions. • Any suspected teratogenic effects. • Any suspected reactions associated with the use of vaccines. The IMB is always keen to help, encourage and establish ADR monitoring and reporting practices. Any centres or practices wishing to develop their reporting systems should contact the IMB (telephone 01-6764971, fax 01- 6762517, e-mail imbpharmacovigilance@imb.ie). ADR report forms are available on request from the Pharmacovigilance Unit at the above contact details. Additional ADR report forms are available to download from the 'Publications' area of our website www.imb.ie. These may be completed and forwarded in an envelope marked 'Freepost' to our usual address.

Part 3. Keywords

a) Keywords:	ADVERSE DRUG REACTION