IRISH MEDICINES BOARD

Notice Information: - 3rd Party Publications 28 August 2008

Part 1. Product Information

a)	Title:	Adverse Reaction & Quality Defect Reporting - MIMS Publication
b)	Product Name/Type:	MIMS
c)	Active Substance:	
d)	Reference:	MIMS August 2008

Part 2. Problem/Issue

a) Problem/Issue:

The Irish Medicines Board (IMB) monitors the safety and quality of all authorised medicines available on the Irish market on an on-going basis and part of this monitoring is carried out through review and evaluation of suspected adverse reactions and quality defects. The IMB's website now includes a facility for on-line reporting of quality defects and suspected adverse reactions associated with the use of medicinal products. It is hoped that this facility will further enhance the existing reporting systems through the provision of a convenient electronic mechanism for reporting.

To avail of the new on-line facility, reporters can log on to www.imb.ie and follow the link to 'On-line Reporting' under the Safety & Quality Section of the website where further instructions on how to complete the individual case report forms are available. Certain mandatory fields are required to successfully submit a report on-line and these include reporter details and a contact email address. The latter will facilitate return of a unique adverse reaction report identifier number as confirmation of a successfully submitted report. In addition, for adverse reaction reports, in line with the legislative requirements, the minimum criteria for a valid adverse reaction report must be provided for a report to be accepted.

The IMB 'freepost' systems for reporting quality defects and adverse reactions to medicinal products remain in place and reporters can continue to use the various downloadable or hard-copy forms for reporting purposes.

The IMB is always keen to help, encourage and establish safety and monitoring reporting practices. Any centres or practices wishing to develop their reporting systems should contact the relevant sections of the IMB for further information. In this regard, for suspected adverse reaction reporting, the IMB Pharmacovigilance Section may be contacted on telephone (01) 6764971, or by fax on (01) 6762517. With respect to quality defect reporting, the IMB Market Compliance Section may be contacted via telephone (01) 676 4971 and by fax on (01) 6764061.

Email addresses for the relevant groups are as follows:

Pharmacovigilance -

imbpharmacovigilance@imb.ie

Market Compliance - recallsandqualitydefects@imb.ie Registering with the IMB fo

recallsandqualitydefects@imb.ie

Registering with the IMB for safety alerts and updates.

Users of the IMB website have the option of registering their contact information with the IMB to enable them to receive direct and immediate notification of alerts/updates by email or text message. To facilitate prompt access to these updates, users are encouraged to avail of this option by registering on the website at www.imb.ie .

Part 3. Keywords

a) Keywords: Adverse Reaction Quality Defect Reporting