IRISH MEDICINES BOARD

Notice Information: Human Medicines - 3rd Party Publications 01 October 2007

Part 1. Product Information

a) Title: Adverse Reaction Reporting for 2005 - Update

b) Product Name/Type: Adverse Reaction Reporting for 2005 - Update

Part 2. Enquiries

a) All enquiries should be made to:

The IMB monitors the safety 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. The IMB acknowledges the significant contribution of healthcare professionals to the continued surveillance of the safety of medicines through the voluntary reporting system and while the burdensome nature of form filling is recognised and acknowledged, the collection of adverse reaction reports is essential to ensure the continued surveillance of the safety of authorised medicines. In 2006, the IMB received a total 1,907 suspected adverse reaction reports that occurred in Ireland from healthcare professionals and pharmaceutical companies. Breakdown of Reports by Source Marketing Authorisation Holders 1119 General Practitioners 212 Hospital Doctors 148 Nurses 125 Community Care Doctors 105 Hospital Pharmacists 72 Clinical Trials 62 Community Pharmacists 61 Dentists 2 Health Care Professionals (other) 1 _____ Total 1907 Individual case reports were followed up by the IMB, where necessary, to ensure availability of comprehensive case information for review and evaluation. Such data is essential in the context of consideration of both individual case reports, as well as cumulative safety information. In keeping with its legal obligations, the IMB continued to exchange anonymised details of relevant adverse reaction reports with pharmaceutical companies and to submit case information to the European Medicines Agency (EMEA) within the agreed timeframes and formats. The IMB also continued to provide details of reports received to the WHO for inclusion on their international database. During 2006, the IMB continued to encourage adverse reaction reporting and, in addition to the regular IMB column in this publication, three issues of the IMB's Drug Safety Newsletter [DSN] on relevant safety issues were circulated to doctors, dentists and pharmacists; one issue was specific to the safe use of Clexane (enoxaparin) and Plavix (clopidogrel), while the remaining two issues covered a variety of safety topics. A copy of the DSNs, general updates on safety issues considered to be of public health interest and copies of the IMB's regular article in this publication are available from the 'Publications' section of the IMB website (www.imb.ie). In addition to written publications, a number of presentations on pharmacovigilance and adverse reaction reporting were made to healthcare professionals as part of under-graduate and post-graduate training courses or continuing education programmes. Finally, the IMB is pleased to announce that in addition to 'freepost' reporting of adverse reactions to the Pharmacovigilance Section at Irish Medicines Board, The Earlsfort Centre, Earlsfort Terrace, Dublin 2, on-line reporting of adverse reactions will be available through the IMB website in the coming months. The IMB is always keen to help, encourage and establish adverse reaction 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).