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

Part 1. Product Information

a)	Title:	IMB Suspension of Marketing of Nimesulide containing medicines
b)	Product Name/Type:	Aulin/Mesulid/Mesine
c)	Reference:	MIMS Publication - July 2007

Part 2. Problem/Issue

a)	Problem/Issue:	Nimesulide is a non-steroidal anti-inflammatory drug (NSAID) which was authorised in Ireland in 1995 for the treatment of acute pain, the symptomatic treatment of painful osteoarthritis and for primary dysmenorrhoea. The potential for hepatotoxicity associated with use of nimesulide has been an ongoing concern for the IMB and guidance was issued to healthcare professionals relating to its use in a number of Drug Safety Newsletters (July 1999, July 2002, July 2003 and July 2004). A formal European-wide re-evaluation of the benefit/risk profile of nimesulide-containing medicinal products for systemic and topical use was conducted between 2002 and 2004. This review concluded that the benefit/risk profile remained positive, subject to revision of the product information to further highlight the risk of hepatotoxicity and a restriction of the maximum oral dose to 100mg twice daily. In May 2007, the IMB received new information from the National Liver Transplant Unit (NLTU), regarding six cases of hepatic failure that required transplantation following treatment with oral nimesulide, two of which resulted in a fatal outcome. These cases were identified as part of a retrospective audit of all cases of fulminant hepatic failure (FHF) of unknown origin (non-A, non-B, non-paracetamol overdose) transplanted at the NLTU from January 1994 until February 2007. Four of these cases were not previously known to the IMB and three occurred since 2006. As the risk of serious hepatotoxicity may be idiosyncratic in nature, introduction of further warnings or restrictions to the product information were not considered an adequate measure to prevent the occurrence of such reactions and it was the IMB's view that oral nimesulide could no longer be considered safe under normal conditions of use. Consequently, the IMB suspended the marketing and sale of nimesulide for oral use in Ireland and this action, together with a recall of the product to patient level was initiated on the 15th May 2007. Healthcare professionals and patients were informed of this urgent regulatory action though a media release and Q&A document, as well as direct contact with a range of professional organisations. A freephone helpline dealt with some 1,500 enquiries, within the first few days of the suspension. In accordance with its obligations arising from this urgent regulatory action, the IMB informed the relevant parties at national and international level and has initiated a further EU review of the safety of systemic nimesulide-containing products. The outcome of this evaluation is expected in July 2007 and will be communicated to healthcare professionals when available. Healthcare professionals are requested to continue to report any suspected cases of nimesulide induced hepatotoxicity that may have occurred, to ensure availability of all relevant data in the context of the review currently underway.