IRISH MEDICINES BOARD

Notice Information: Human Medicines - 3rd Party Publications 01 January 2008

Part 1. Product Information

a)	Title:	Moxifloxacin (Avelox) & Hepatic failure and serious skin reactions
b)	Product Name/Type:	Moxifloxacin (Avelox)
c)	Reference:	MIMS Publication - January 2008

Part 2. Problem/Issue

a)	Problem/Issue:	Moxifloxacin (Avelox) is an antibacterial medicine authorised in Ireland for the treatment of the following bacterial infections: - Acute exacerbation of chronic bronchitis - Community acquired pneumonia, except severe cases - Acute bacterial sinusitis (adequately diagnosed) Moxifloxacin should only be use in the treatment of infections caused by bacteria susceptible to moxifloxacin and consideration should always be given to official guidance on the appropriate use of antibacterial agents. Following a recent European review of new safety information regarding risk of serious side effects associated with the use of moxifloxacin, the IMB would like to highlight to healthcare professionals that while skin reactions and liver impairment are known to occur with moxifloxacin, the product information has now been updated to include severe liver failure and serious skin reactions such as toxic epidermal necrolysis as known side effects of this medicine. Although these reactions appear to occur very rarely, they can be life threatening. Healthcare professionals are reminded to be vigilant of the early signs and symptoms of liver or skin reactions with moxifloxacin and patients should be advised to stop treatment if such symptoms occur and to seek medical advice before continuing treatment. Healthcare professionals are reminded that suspected adverse reactions, including those associated with use of any of moxifloxacin-containing products should be reported to the IMB, either on-line on the IMB website at http://www.imb.ie/ or using a downloadable version of the adverse reaction report form also available from the IMB's website. Downloaded forms should be completed and sent by freepost to the IMB at "Freepost", Pharmacovigilance Section, Irish Medicines Board, The Earlsfort Centre, Earlsfort Terrace, Dublin 2. Alternatively, completed forms may be submitted by fax to (01) 6762517. Finally, post-paid report cards can be obtained directly from the Pharmacovigilance Section of the IMB at (01) 6764971.