IRISH MEDICINES BOARD

Notice Information: - 3rd Party Publications 10 July 2008

Part 1. Product Information

a)	Title:	Champix (varenicline) - MIMS Publication
b)	Product Name/Type:	Champix (varenicline)
c)	Reference:	MIMS July 2008

Part 2. Problem/Issue

a)	Problem/Issue:	Champix (varenicline) is a medicinal product authorised for use throughout the European Union through the European licensing process for the treatment of smoking cessation in adults. It is a non-nicotine aid which can help relieve the cravings and withdrawal symptoms associated with stopping smoking. The recommended dose of varenicline is 1mg twice daily following a 1-week titration (i.e. 0.5mg daily for the first three days [days 1-3], then 0.5mg twice daily for the next three days [days 4-7], increasing to 1mg twice daily thereafter [day 8 onwards]). However, for patients who cannot tolerate the adverse effects of varenicline, the dose may be lowered temporarily or for the duration of treatment, to 0.5mg twice daily. The patient should set a date to stop smoking and varenicline dosing should start 1-2 weeks before this date. Patients should be treated with varenicline for 12 weeks. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment with varenicline at 1 mg twice daily may be considered. Varenicline has been marketed in Ireland since December 2006 and since that time the IMB, in conjunction with the European Medicines Agency (EMEA), has closely monitored its safety. The most frequently reported adverse reactions notified in association with varenicline include gastrointestinal disorders such as increased appetite, nausea, vomiting and taste disturbance, general effects such as fatigue, and CNS effects, including headache, somnolence, dizziness and sleep disorders. It is important to note that these suspected reactions may not necessarily have been caused by varenicline and may relate to other factors including nicotine withdrawal. Following concerns about reports of depression, suicidal ideation and suicidal behaviour associated with use of varenicline, the available data were reviewed at EU level. This review concluded that smoking cessation, with or without treatment, may be associated with symptoms of anxiety and depression, including exacerbation of underlying psychiatric illnesses. As a result, the product information for varenicline was updated to include additional warnings about the risk of depression associated with its use and as a symptom of nicotine withdrawal. It was also recommended that patients should be advised accordingly. Further review of data is underway to facilitate assessment of a causal

	association between varenicline and depression/suicide related effects and the outcome of this review and further updates to the product information will be communicated, when available. Healthcare professionals are reminded to adhere to the approved recommendations for use of varenicline and to closely monitor patients during use, advising them to report any symptoms associated with their treatment to their doctor. All suspected adverse reactions associated with use of varenicline should be notified to the IMB in the usual way.

Part 3. Keywords

a) Keywords:	Champix (varenicline)