An Roinn Sláinte agus Leanaí
DEPARTMENT OF HEALTH AND CHILDREN

Oifig an Aire
Office of the Minister

16 August 2010

Ms Mary Maguire
Meetings Administrator
Corporate Services Department
South Dublin County Council
County Hall, Tallaght
Dublin 24

Dear Ms Maguire

The Minister for Health and Children, Mary Harney, T.D., has asked me to thank you for your letter concerning the Low Dose Naltrexone.

Naltrexone 50 mg is licensed in Ireland for use as an additional therapy within a comprehensive treatment program including psychological guidance for alcohol dependence to support abstinence. Naltrexone 4.5 mg 'low dose naltrexone', is not licensed for use in Ireland. In order for a licence to be granted, there needs to be an application from a company which proposes to market the product in Ireland.

Under EU Directive 2001/83/EC, which governs medicinal products for human use, and the national legislation that transposes this, a registered medical practitioner is permitted to prescribe an unauthorised medicinal product to meet the special needs of one of his / her patients. The use by the patient of the product is under the direct personal responsibility of the prescriber.

In Ireland, such prescribing can happen where there is no product authorised for the particular medical condition or where a product is authorised but the authorization holder has chosen not to market the product here. The prescribing of low dose naltrexone fits into the first category.

An unauthorised product prescribed in Ireland will not have been assessed for safety, quality or efficacy by the Irish Medicines Board (IMB) or the European Medicines Agency. It may, however, have undergone a similar assessment, and have been authorised, in another country. The IMB operates a scheme whereby wholesalers and manufacturers are required to notify it of the importation of an unauthorised ('exempt') medicinal product.

I trust that this clarifies the matter for you.

Yours sincerely

Darragh Scully
Private Secretary