



Department of

**Health, Social Services
and Public Safety**

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AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÄNNYSTRIE O

**Poustie, Resydènter Heisin
an Fowk Siccar**

From The Chief Pharmaceutical Officer
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For Action: Directors of Pharmaceutical Services of the Boards & CSA
Directors of Pharmaceutical Services of HSC Trusts
Regional Quality Improvement Authority

Our reference: PHC/12/08

Date: 18 August 2008

D R U G P R O C U R E M E N T A D V I C E

ADVICE TO CLINICIANS, PHARMACISTS AND PROCUREMENT STAFF

Dear Healthcare Professional

Restrictions on the import of unlicensed Melatonin products following the grant of a marketing authorisation for Circadin ® 2mg tablets

At the beginning of June 2008, a licensed modified release melatonin product, Circadin ® (Lundbeck), became available in the UK.

Before June 2008, melatonin was only available in the UK in unlicensed medicinal products, many of which were non-pharmaceutical grade products imported from the United States of America, where melatonin products are classed as supplements, not medicines. These products are not required to be manufactured to the standards of Good Manufacturing Practice normal for pharmaceuticals. **It is therefore important to ensure that the licensed product available in the UK is used wherever possible. This includes off-label use of the licensed product, if deemed suitable by the clinician.**

It is recognised, however, that there may be individual patients for whom the UK product cannot meet their clinical needs. In particular, there may be some need for alternative dosage forms, or strengths, or for an immediate release product.

Importation of unlicensed melatonin products remains possible under the MHRA scheme for the import of unlicensed medicines. Details of the scheme are available at:-

<http://www.mhra.gov.uk/Howweregulate/Medicines/Importingandexportingmedicines/Importingunlicensedmedicines/index.htm>

Prescribers will need to provide written details of the special clinical need to the importer for submission to the MHRA. Details have to be provided with every order and not just the first occasion.

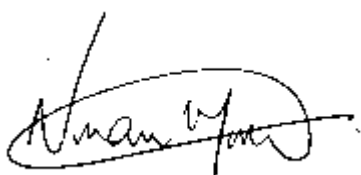
Patient identification is not required in letters from clinicians in order to maintain patient confidentiality.

The MHRA does not provide template letters for clinicians. Importers are familiar with the MHRA requirements for letters concerning special clinical need. For questions on this area we would ask any newly affected parties to contact their proposed importer in the first instance. For all other enquiries on this notice, please contact Ms Raia Stoyanova on 0207 084 2625.

Area Boards/RQIA should bring this information to the attention of private hospitals/clinics registered with them, Out of Hours Centres and any other relevant care facilities.

The Central Services Agency is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Norman Morrow', written over a horizontal line.

DR NORMAN MORROW
Chief Pharmaceutical Officer

For information:
CMO
CNO
CDO
CISSI
SMO
Director, Health Estates
Public Health Branch
DHSSPS, Library
Extended nurse prescribers

Regional Medicines and Poisons Information Service
Regional Director of Supplies
RPLS
Pharmaceutical Society of NI
Senior Prison Pharmacist
Prison Service, Dundonald House
Nursing Officer, Health Estates
Medical Officer, Castle Buildings
Regional Procurement Pharmacist
NICPPET