Press Release

Friday, 4 July 2014

NICOTINE REPLACEMENT THERAPY (NRT) MEDICINE
APPROVED FOR SALE IN RETAIL OUTLETS

The HPRA Reclassifies NRT to General Sale from Pharmacy Only Status

The Health Products Regulatory Authority (HPRA), formerly the Irish Medicines Board, today announced it is authorising a Nicotine Replacement Therapy (NRT) product to be sold in general retail and grocery outlets. NRT products are currently only available in pharmacies and the HPRA's decision to switch Nicorette™ NRT from 'Pharmacy Only Status' to 'General Sale Status', follows an application from the authorisation holder. This will be the first NRT product range available for general sale in Ireland, and will result in these products being more widely accessible by people wishing to seek assistance to reduce or quit smoking. It is anticipated that the products within this range will become available on general sale in retailers in Ireland from later this year (late August or early September).

The HPRA's decision follows a detailed assessment of the safety and efficacy of several NRT products which have been available in non-pharmacy outlets in other EU countries for some time.

Mr Pat O'Mahony, Chief Executive, the HPRA outlines that; "The switching of NRT products to general sale status is aligned with our policy to make healthcare products available at the most convenient point of access for people, where it is safe to do so. NRT products have been in use since the late '70s and are a well-established treatment for smoking cessation. We have reviewed supporting evidence and experience of NRT use; this includes experience of other EU countries and we are satisfied that it is appropriate to classify them for general sale in Ireland."

"This change in the availability of NRT medicines reflects an increased public health awareness of the need to reduce smoking and the positive benefits of NRT use in helping prevent smoking-related diseases. It is also in line with the Department of Health's Tobacco Free Ireland initiative and an important measure in further progressing national tobacco control policy," Mr O'Mahony continues.

The HPRA states that NRT medicines in various forms including gums, oral lozenges, inhalers and patches will be on sale in retail outlets such as grocery shops in the near future. NRT medicines will also continue to be available in pharmacies.

Mr O'Mahony concludes: "The labelling and package leaflet which accompanies each of these medicines is designed in a manner which allows for safe self-selection and use of NRT and includes detailed advice on how to use NRT medicines safely and effectively. The HPRA always encourages patients to read the accompanying leaflet for all healthcare products and to seek further advice from a healthcare professional, where necessary".

NRT medicines will continue to be governed by medicines legislation and retailers will be subject to certain restrictions of sale, consistent with the authorised indications. Consumers must be aged 18 to purchase NRT medicines from retail and grocery outlets and could be asked for proof of age at the time of purchase. The HPRA advises that the product information for NRT

medicines will continue to recommend that pregnant or breastfeeding women and those with heart, circulatory or stomach problems should seek the advice of a healthcare professional before taking NRT medicines.

ENDS

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NOTES TO EDITORS:
Pharmacy-only status applies to medicines that can be sold in a pharmacy under the supervision of a pharmacist. General sale means that the medicines may be sold in pharmacies and non-pharmacy retail outlets e.g. supermarkets.

Over time, if the benefit-risk balance of a given pharmacy-only medicine is considered positive, application for general sale status may be considered. Sufficient evidence must be provided to ensure that such a medicine can be safely supplied without the intervention of a pharmacist. Switching from pharmacy-only to general sale status is not a natural continuum and products will be considered on a case by case basis.

The HPRA's Guide to Reclassification can provide further information and is available at:
Guide to Reclassification

ABOUT THE HEALTH PRODUCTS REGULATORY AUTHORITY:
The Health Products Regulatory Authority (HPRA) protects and enhances public health and animal health by regulating medicines, medical devices and other health products. The products under its remit include human and veterinary medicines, medical devices, blood and blood components, tissues and cells, organs for transplantation and cosmetics. Formerly known as the Irish Medicines Board (IMB), it became the Health Products Regulatory Authority on 1 July 2014.