

4<sup>th</sup> July 2014

## **Update regarding changes to the classification of Nicotine Replacement Therapy**

Dear Healthcare Professional,

The Health Products Regulatory Authority (HPRA; formerly the Irish Medicines Board) wishes to inform you that a number of Nicotine Replacement Therapy (NRT) medicines have recently been reclassified and have been authorised for sale in general retail and grocery outlets.

NRT medicines were previously available in pharmacies only and the HPRA's decision to reclassify NRT to permit general sale will result in these medicines being more readily accessible to people wishing to avail of assistance to reduce or quit smoking. It is anticipated that NRT medicines will become available in general retail outlets in Ireland later this year. The first products to be authorised will be from the Nicorette™ range.

### **Active substances affected:**

Certain NRT medicines containing the active substance Nicotine are affected by the reclassification. A range of NRT medicines in various forms including transdermal patches, lozenges, gums, oral inhalers and oromucosal sprays have been reclassified and will be on sale in general retail outlets in the coming months.

Consumers must be aged 18 years to purchase NRT in general retail and grocery outlets. NRT medicines will continue to be available in pharmacies. The important role of pharmacists, GPs and other healthcare professionals in promoting smoking cessation, and providing specific smoking cessation advice is recognised and encouraged.

### **Rationale and background to the changes:**

The HPRA's decision regarding the reclassification of NRT to permit general sale aligns with HPRA policy to make healthcare products available at the most convenient point of access for consumers, where it is safe to do so.

It is recognised that 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 this in preventing smoking-related diseases. It is also in line with the Department of Health's Tobacco Free Ireland initiative and is an important measure in further progressing national tobacco control policy.

As part of its assessment of this change to the legal classification of NRT medicines, the HPRA has reviewed the evidence to support the safe and effective use of NRT medicines purchased without the direct input of a healthcare professional. The evidence draws from experience from other countries where NRT medicines have been available through general sale for many years, such as UK, Norway, Sweden, Finland, Denmark and the U.S. Although the HPRA is aware of some evidence to the contrary, there is a body of evidence, including a recent Cochrane review, which suggests that NRT medicines can demonstrate a worthwhile efficacy with or without the input of a healthcare professional.

It is difficult to reach a definitive consensus on the 'real life' effectiveness of NRT medicines in the general sale setting. Nonetheless, cigarettes are available in convenient and accessible locations nationwide and after pharmacy hours. It is intended that by widening the availability of NRT medicines beyond pharmacies, there will be an increased awareness and use of NRT, with the aim that this will translate into lower smoking levels. Increased accessibility may also help with compliance and help smokers not to relapse. The HPRA considers that the potential risks associated with NRT medicines are far outweighed by the health benefits associated with smoking cessation.

The labelling and package leaflet which accompanies the relevant products allow for safe self-selection and use of NRT by consumers. Detailed advice on how to use NRT medicines safely and effectively is included on the labelling and package leaflet supplied with each medicine. Each pack will state that the chances of a successful quit are increased where additional support is sought from healthcare professionals or a support programme. The pack also encourages consumers to call the HSE national quitline (1 800 201 203) or to access its website ([www.quit.ie](http://www.quit.ie)). Patients are encouraged to read the accompanying package leaflet for these medicines 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 and with the restrictions applied to tobacco products sold in general retail and grocery outlets. Consumers must be aged 18 to purchase NRT medicines from general sale outlets and could be asked for proof of age at the time of purchase.

The product information for NRT will continue to recommend that pregnant or breastfeeding women and those with gastric or cardiac diseases should seek the advice of a healthcare professional before using NRT medicines.

#### **Implementation of the reclassification of NRT:**

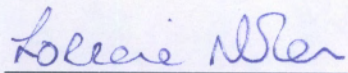
The HPRA is working with Marketing Authorisation Holders to implement this change and NRT medicines with the amended classification status will begin to appear in retail and grocery outlets over the coming months.

The product information for the NRT medicines involved has been updated to reflect this change and is available on [www.hpra.ie](http://www.hpra.ie).

It would be appreciated if the contents of this letter could be highlighted to relevant staff, where appropriate.

If you have any queries in relation to this letter please contact the HPRA by email: [customerservice@hpra.ie](mailto:customerservice@hpra.ie) or by telephone: 01-6764971.

Yours sincerely,



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Director of Human Products Authorisation & Registration