Press Release
Thursday 17th July

HPRA PUBLISHES LIST OF POTENTIAL MEDICINES TO BE SOLD WITHOUT PRESCRIPTION

List of Twelve Active Substances Suitable for Reclassification Announced

Thursday 17 July 2014, The Health Products Regulatory Authority (The HPRA), formerly the Irish Medicines Board (IMB), today published a list of 12 active substances***** contained in medicines currently classified as prescription-only medicines (POM) which could be safely reclassified and switched to over the counter (OTC) sale. This could result in a total of 34 medicines being sold through pharmacies without prescription. The list includes medicines for the treatment of migraine, acid-reflux symptoms, hay fever, cold sores, muscle pain and inflammation, fungal skin and nail infections and other inflammatory skin conditions. The HPRA is now requesting expressions of interest from pharmaceutical companies who are the Marketing Authorisation Holders (MAH) for these medicines to apply to reclassify their medicines.

According to Lorraine Nolan, Director of Human Authorisation, the HPRA, the medicines on the list are currently only available under prescription; however, in line with certain conditions, these could be reclassified to be made available for sale through pharmacies without prescription.

"This is an important development which sees the HPRA proactively inviting submissions for reclassification. It represents the outcome of measures which have been undertaken by the HPRA to explore unmet needs in the availability of non-prescription medicines in Ireland and follows recommendations made by an independent consultative panel established by the Authority to specifically assist its review of this area.

"The Authority is pleased to bring this reclassification initiative forward with this initial list of products. This will see an increase in the range of medicines that can be made available to Irish patients through pharmacies without prescription. Dependent on the nature, quality of applications and the relevant engagement process with Marketing Authorisation Holders, further lists of appropriate substances may be considered in the future".

"Our proactive stance with regard to these medicines is consistent with Irish health policy which aims, where appropriate, to provide patients with increased access to healthcare at the lowest point of complexity and cost. We look forward to commencing this engagement process with Marketing Authorisation Holders in the coming weeks", she concluded.

Further information on the publication of this list and the process for classifying the Method of Sale and Supply (MoSS) of medicines, is available at www.hpra.ie

The determination of how a medicine is supplied is based on a range of factors including the overall safety profile of the product, the proposed condition for treatment, the expected duration of use, the suitability of a condition for self-diagnosis and self-treatment, the interaction potential as well as the possibility of misuse. To have a medicine reclassified the MAH for each medicine containing a substance included on the list, must apply to the Authority and demonstrate that all criteria are met. The HPRA considers that medicines containing substances on the list either meet these criteria currently or could meet these criteria following amendment of their marketing authorisation.

ENDS

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***** The list of initial 12 active substances is available **here**.

Notes to Editor:

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.

CONSULTATIVE PANEL REVIEW
In 2011 the HPRA, then Irish Medicines Board (IMB), established the Consultative Panel on the Legal Classification of Medicines. The Panel was independently chaired and consisted of external representatives drawn from a wide range of interested stakeholders including patients, healthcare professionals, the Department of Health and relevant government agencies. The focus of the Panel was to review current unmet needs in the availability of non-prescription medicines and to suggest recommendations to address this.

Further information is available Consultative Panel regarding the Classification of Medicines.