IRISH MEDICINES BOARD

Press Release

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IRISH MEDICINES BOARD ANNOUNCES 2013 PERFORMANCE OUTTURN

The Irish Medicines Board (IMB) today released details of its key activities and performance highlights for 2013, a year in which the national regulatory authority played an active part in the introduction of interchangeable medicines in Ireland. In 2013, some 11 active substances were published by the IMB (representing over 580 medicines) and it is currently working through a further 29 priority substances.

The IMB's review of 2013 also highlights a 20% increase in the numbers of counterfeit and illegal medicines detained by the IMB in co-operation with the Revenue's Customs Service and An Garda Síochána. The IMB continues to emphasise the health dangers for those who purchase prescription medicines over the internet, as there are no guarantees as to the safety, quality or effectiveness of these products.

According to Pat O'Mahony, Chief Executive, 2013 was a significant year of work outputs with all departments of the IMB delivering on their work programmes whilst also taking on new additional projects and responsibilities. "Protecting public and animal health is our organisation's core focus and the sizeable programme of work achieved during 2013 across each of the health products we regulate was evidence of our commitment to this goal."

During 2013, key highlights of the IMB's work included:

- 102 clinical trials were approved to commence in Ireland, an increase of over 30% in clinical trial applications compared to 2012. This growth positively reflects increasing research and innovation conducted in Ireland. The key areas of interest continue to include oncology and haematology. While the IMB received 10 applications for clinical investigations of medical devices, the number of clinical investigations ongoing in Ireland remains lower than expected.

- The total number of new human medicines authorised in 2013 was 752. In overall terms, the number of products authorised has decreased relative to previous years and this is reflective of a trend throughout the EU during 2013 which has been attributed to product patent lifecycles. 17,749 variations to human medicines were also issued;

- There were 188 new veterinary medicine applications assessed, accounting for a 24% increase on 2012;

- 334 new medical devices were registered with the IMB for Class I general, custom-made and in-vitro diagnostic devices;

- The assessment and evaluation of 2,835 (2,757 in 2012; 2,784 in 2011) suspected individual adverse reactions reports in relation to human medicines and 272 (244 in 2012) reports in respect of veterinary medicines. In addition, there were 2,268 (2,225 in 2012) vigilance reports for medical devices, broadly in line with the previous 12 months;

- During 2013, IMB personnel undertook 313 inspections and audits to ensure industry compliance with relevant standards and legislation;

- During 2013, 774 quality defects were reported to, or identified by, the IMB, representing a slight annual increase in the number of quality defects recorded;

- A total of 3,932 (3,911 in 2012) enforcement investigations involving breaches of medicinal product legislation were initiated. This figure includes the detention of prescription medicines being imported into Ireland via mail order;

- 919,965 dosage units of counterfeit and illegal medicines had been detained by its enforcement section by year end (758,276 units in 2012); resulting in a 20% increase in detentions year on year.

In conclusion, Mr O'Mahony noted that the legislative to change the IMB's name to the Health Products Regulatory Authority (HPRA) would take effect on the 1st July next. "Our work programme for 2013 included the start of the processes required to effect a name change which highlights the fact that our organisation is now responsible for a wide range of health products and related health functions. Our new name, more clearly reflects the wider scope of our work, functions and responsibilities across the health products sector. At the same time, it is intended to build on the IMB's established reputation as a professional, progressive and science driven public sector organisation."

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ABOUT THE IRISH MEDICINES BOARD
The Irish Medicines Board (IMB) is the competent authority for human and veterinary medicines, medical devices, blood, tissues & cells, organs for transplantation and cosmetics in Ireland. Its role is to protect and enhance public and animal health through the regulation of medicines, medical devices and other health products.