HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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Health Products Regulatory Authority Publishes 2014 Annual Report

More than 730,000 falsified medicines detained over 12-month period

The Health Products Regulatory Authority (HPRA) today published its annual report of key activities and performance highlights for 2014. The report, which is the first to feature the organisation's new name and brand identity, highlights a year of significant activity for the national regulator of health products. There was a continued focus on tackling the issue of falsified and illegal prescription medicines as well as on drawing attention to the associated dangers. The list of interchangeable medicines, which facilitates generic substitution by pharmacists and is linked to the HSE's reference pricing system, was significantly expanded during the year.

During 2014, key highlights of the HPRA's work included:

- The HPRA's enforcement activity led to the detention of 730,056 dosage units. Sedatives accounted for 56% of all products found while erectile dysfunction and weight loss products accounted for 13% and 7% of detentions respectively. There were 3,703 enforcement cases opened while 10 District Court prosecutions were initiated. Offences prosecuted included procurement and importation without legal authorisation, supply of prescription only medicines without prescription and wholesale of medicines without a wholesaler's authorisation.
- Continued operation of national pharmacovigilance systems for reporting adverse reactions (side effects) relating to the use of both human and veterinary medicines. A total of 2,884 suspected adverse reaction reports associated with the use of human medicines were received representing a slight increase when compared with 2013. There were 300 reports of suspected adverse reactions and events associated with the use of veterinary medicines.
- The HPRA ranked 10th in terms of reporting rates for adverse reactions among 121 country members who participate in the World Health Organization's International Drug Monitoring programme for human medicines.
- A total of 102 medicine recalls were initiated in 2014. Of these, 16% were recalls to patient / user level, 37% to pharmacy / retail level and 47% to wholesale level.
- The HPRA also introduced measures to reclassify the sale of nicotine replacement therapy (NRT) products to general sale status at retail outlets. Prior to this amendment, these products were restricted to pharmacy sale only.
- The ongoing operation of the national medical devices vigilance system, which aims to minimise risks to the safety of patients, users and others, resulted in the receipt of 2,113 medical device vigilance reports. This represented a slight annual decrease.
- There were a total of 260 national and foreign inspections and audits carried out to ensure industry compliance with relevant standards and legislation. This compared to 313 inspections and audits in 2013. The majority of these inspections are carried out at manufacturing and distribution sites.

- 80 clinical trials were approved to commence in Ireland for human use, down from 102 in the previous year. The key areas of interest continue to include oncology and haematology. There were 10 applications for clinical investigations of a medical device, a level of activity broadly similar to the previous 12-month period.
- A total of 13,205 variations to marketing authorisations issued for human medicines were authorised through the national or mutual recognition procedures. The number of variations reduced compared to 2013 due to the implementation of a new European work-sharing procedure. The HPRA approved 1,502 variations to veterinary authorisations granted through the national, mutual recognition or centralised procedures which continued the upward trend in numbers during recent years.
- New human medicine product authorisations reduced from 752 in 2013 to 615. This reflects a trend being seen throughout Europe which has been attributed to product patent lifecycles. There were 75 new medicines for veterinary use authorised which was a reduction on the peak of 85 authorisations in 2013.

According to Pat O'Mahony, Chief Executive, all areas and departments contributed to the delivery of a sizeable programme of work during a year which saw the HPRA change its name from the Irish Medicines Board (IMB). "The key activities and outcomes for 2014 across both our pre market and post market functions highlight the expanding and ever-changing nature of our work. Our new name is a reflection of this expanded role and marks the beginning of an exciting new chapter in the history of our organisation."

Mr. O'Mahony further outlined the HPRA's efforts during 2014 to stem the flow of falsified medicines into Ireland and the concerns for the health of those who may use these products. "During the year, working with our partners in An Garda Síochána and Revenue's Customs Service, we detected more than 730,000 dosage units coming into Ireland. Once again, we urge members of the public not to take risks with their health and to remember that the consumption of even very small quantities of these illegal medicines can have very serious consequences".

While maintaining its core focus of protecting public and animal health through the regulation of health products, the HPRA continues to evolve and expand as an organisation due to changes in its operating environment and in response to the addition of further competencies. In 2014, this involved the regulator becoming the national competent authority for the authorisation of clinical field trials on veterinary medicines. The HPRA continued to provide support to the Department of Health in respect of the revision of European medical devices legislation and, in addition, contributed significantly to the consultation proposals on the development of the new clinical trials EU Regulation.

View the full HPRA annual report for 2014 (pdf).

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NOTE TO EDITOR

Please note that Mr Pat O'Mahony has been Chief Executive of the Health Products Regulatory Authority since 2002. He will shortly take up a new role with the Department of Health. He has been appointed Deputy Secretary, Head of Governance and Performance, Department of Health, to enhance the focus on performance within the Department and the wider health service.

Current Deputy Chief Executive, Ms Rita Purcell, will assume the role of Acting Chief Executive of the HPRA during the recruitment process.

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.