IRISH MEDICINES BOARD

news LETTER

MEDICINAL PRODUCTS

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NEW NAME FOR THE IMB

IRISH MEDICINES BOARD (IMB) TO BECOME THE HEALTH PRODUCTS REGULATORY AUTHORITY (HPRA) ON 1 JULY

On 1 July 2014, the IMB will change its name to the Health Products Regulatory Authority (HPRA).

Established in 1996, the IMB name has served us well. However, over the last 18 years our regulatory remit has expanded to include other health products as well as a number of health related functions. In addition to medicines, we now have a role in regulating a range of areas including:

- Medical devices
- Controlled drugs
- Clinical trials
- Blood products and components
- Tissues and cells
- Cosmetic products
- The protection of animals used for scientific purposes
- Organs intended for transplantation

Our new name now 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.

While our name is changing, the mission of the HPRA will remain the same: To protect and enhance public and animal health through the regulation of medicines, medical devices and other health products.

We wish to give all our stakeholders advance notice so that you are aware of this change when you visit our website from 1 July and start to see documents and other materials displaying our new name and logo from that date forward. It may also be necessary to update your internal systems and records.

GENERAL

VET INFORMATION DAY 2014

An IMB Veterinary Medicines Information Day has been scheduled for Friday, 26 September 2014 at the Crowne Plaza Hotel, Northwood Park, Santry, Dublin 9. The primary objective of this event is to provide information to stakeholders on how the new veterinary medicines legislation is likely to affect the authorisation, monitoring and use of veterinary medicinal products over the coming years. The meeting venue and arrangements has been made to facilitate participation by stakeholders and to provide networking time for discussions with IMB personnel. The event will also consider recent developments in relation to the authorisation of veterinary medicinal products and the performance of the IMB. Further details of the event are available on the IMB website (www.imb.ie).

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GMP INFORMATION DAY 2014

The IMB will hold an Information Day, primarily for manufacturers of active substances and medicinal products, on Wednesday 12th November 2014 at the Crowne Plaza Hotel in Santry. Full details of the programme, including how to register, will be announced at a future date on the IMB website. Accordingly, those interested in attending this information day should 'Subscribe to IMB Website Updates' or periodically check the 'Events Section' of the IMB website for updates (www.imb.ie).

As soon as details are announced, those interested in attending this information day should register their places as a large number of attendees is expected and places will be limited.

The general topics covered on the day will include a regulatory update encompassing:-

- GMP Updates
- Safety features

The IMB is inviting suggestions for topics which the industry would like to see covered during the day. When submitting your suggested topic(s) please categorise it/them under one of the following:

- Manufacture of active substance
- Manufacture of biological active substance
- Manufacture of non sterile medicinal products
- Manufacture of sterile medicinal products
- Investigational Medicinal Products
- Process Validation
- Cleaning Validation
- Quality System
- Quality Control Laboratories
- Contract Manufacture
- Supply Chain
- Market Compliance Issues (Quality Defects, Recalls, Sampling and Analysis, MAH Inspections, Exempt Medicinal Products)
- Other

Questions may also be submitted in advance of the information day to compliance.infoday@imb.ie and these may be addressed through the presentations or separately in a Questions and Answers session. In order to be able to facilitate the possible inclusion of topics and questions, the IMB requests that suggestions are submitted no later than 1 October 2014 with the subject of the email "suggestions for GMP information day".

WHOLESALE DISTRIBUTION INFORMATION DAY 11 NOVEMBER 2014

The Compliance Department will hold an Information Day for wholesale distributors of medicinal products on Tuesday 11 November 2014 at the Crowne Plaza hotel in Santry. Full details of the programme, including details on how to register, will be announced at a future date on the IMB website. Accordingly, those interested in attending this information day should 'Subscribe to IMB Website Updates' or periodically check the 'Events Section' of the IMB website for updates (www.imb.ie).

As soon as details are announced, those interested in attending this information day should book their places as a large number of attendees is expected and places will be limited. It is planned to have topics which should be of general interest, potentially followed by an 'Inspectors Clinic'.

The general topics covered on the day will include a regulatory update encompassing:-

- GDP Updates (Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use)
- Legislation (Falsified Medicines Directive)

The IMB is requesting suggestions for topics which the industry would like to see covered during the day (e.g. transport of medicinal products, controlled drugs, precursor chemicals, cold chain medicinal products, exempt medicinal products etc.).

Questions may also be submitted in advance of the information day to compliance.infoday@imb.ie and these may be addressed through the presentations or separately in a Questions and Answers session. In order to be able to facilitate the possible inclusion of topics and questions, the IMB requests that suggestions are submitted no later than 1 October 2014 with the subject of the email "suggestions for GDP information day".

IMB PHARMACOVIGILANCE INFORMATION DAY 21 NOVEMBER 2014

As previously highlighted the IMB will hold a Human Medicines Pharmacovigilance Information Day on Friday 21 November 2014 in Dublin. The meeting will particularly focus on the European Pharmacovigilance legislations, two years following its introduction. The aim of the seminar is to provide updates on implementation of the revised legislative provisions and to discuss their impact on stakeholders.

The seminar should be of interest to those dealing with pharmacovigilance of human medicinal products, in particular Marketing Authorisation Holders (MAHs) and Healthcare Professionals (HCPs). A copy of the agenda is available on the IMB website (www.imb.ie) together with registration information and relevant contact details.

The event will be held from 9am to 5pm at the Crowne Plaza Hotel, Santry, Dublin. Further information about the venue can be found on their website www.crowneplaza.com.

HUMAN MEDICINES

ELECTRONIC REPORTING OF ICSRS TO MARKETING AUTHORISATION HOLDERS

On receipt of serious ICSRs from healthcare professionals, members of the public, and other sources, the IMB has a responsibility to forward cases to the relevant marketing authorisation holder (MAH) of the suspect product(s) on an expedited basis in accordance with EU legislation and guidance. This transfer has traditionally been achieved by secure fax, however the IMB is now in a position to forward such cases electronically and in accordance with E2B standards, via the EudraVigilance gateway. Any MAH can opt to receive their cases electronically.

If you wish to receive ICSRs via E2B, please email **eudravigilanceimb-test@imb.ie** with the following information:

- Contact details for the company representative who will manage the testing phase
- The interchange ID for receipt of ICSRs
- Information on which MAHs with licences in Ireland use this Interchange ID (This will allow the IMB to identify which cases to send to the Interchange ID)
- Contact details for the MAH's Pharmacovigilance department (for general pharmacovigilance queries including case-related queries)

Testing will typically involve

submission of a single test case by the IMB. Once the IMB has received an electronic acknowledgement the company may go into production for receipt of electronic cases from the IMB. For further information please refer to the Guide to Electronic Transmission of ICSRs and SUSARs associated with the use of Human Medicines, available on the IMB website www.imb.ie.

VETERINARY MEDICINES

REPORT ON VETERINARY ANTIMICROBIAL CONSUMPTION IN 2012 AND UPDATE ON COLLECTION OF THE 2013 DATA

A report on the consumption of veterinary antimicrobials in Ireland during 2012 is available on the IMB website (**www.imb.ie**). The data follow a similar pattern to previous years, although it appears that there has been a 14% increase in overall consumption over the 2011 position.

In accordance with the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) http://www.bigwavemediatraining.ie/courses-adobe-id-ess.php requirements, the IMB has commenced collecting data on the supply of antimicrobials to the Irish market for the year 2013. The reporting form is similar to that of previous years, but has been modified yet again to facilitate completion of the information and subsequent analysis. The Excel form being released to marketing authorisation holders by the IMB contains in-built formulas, which might not work if the document is copied for completion elsewhere.

It is expected that the data will be collected before **30 May 2014**. Any queries on the use of the form should be sent to the IMB (**gavin.ryan@imb.ie**). For those applicants who do not have access to the data collection form, it is available on request from the IMB (**michelle.sinnott@imb.ie**).

AUTHORISATION OF PRODUCTS IN ACCORDANCE WITH ARTICLE 6(3) OF DIRECTIVE 2001/82/EC, AS AMENDED

In accordance with Article 6 of Directive 2001/82/EC, as amended, "*a veterinary medicinal product (VMP) containing pharmacologically active substances not included in Annexes I, II or III to Regulation (EEC) No 2377/90 may be authorised for particular animals of the equidae family that have been declared, ... as not being intended for slaughter for human consumption. Such VMPs shall neither include active substances that appear in Annex IV to Regulation (EEC) No 2377/90 nor be intended for use in the treatment of conditions, as detailed in the authorised Summary of Product Characteristics, for which a veterinary medicinal product is authorised for animals of the equidae family.*"

Based on various clarifications from the European Commission, including one provided very recently, the IMB understands that:

- Article 6(3) of the Directive is intended to be used in exceptional circumstances, where an alternative VMP is not authorised;
- It is not possible to grant a marketing authorisation (MA) in accordance with that Article where a similar product has already been authorised, for the same indication, in horses declared as not being intended for human consumption;

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- It is not possible to accept a generic application referring to products authorised in accordance with Article 6(3) of Directive 2001/82/EC; and,
- It is not possible to grant a MA in accordance with that Article via the mutual recognition or decentralised procedure where a national authorisation has already been granted in accordance with that Article.

SWITCHING APPLICATIONS – A NEW FEE CODE FOR CHANGES TO THE LEGAL SUPPLY CLASSIFICATION

Marketing authorisation holders (MAHs) are advised that the IMB Guide to fees for veterinary products 2014 includes a new fee code (code 578) that applies to applications for changes to the legal supply classification.

Within the relatively recent past, the IMB has approved a change in prescription status, from 'Prescription Only Medicine' to 'Licensed Merchant', for:

- Fipronil-containing spot on products for dogs and cats (which did not include an indication for flea allergic dermatitis);
- Imidacloprid-containing spot on products for cats (which did not include an indication for flea allergic dermatitis); and,
- A toltrazuril-containing oral suspension for cattle.

In support of a variation to change from prescription to non-prescription

status, applicants are required to provide information on the changed risks associated with use of the products, and in particular how the change to the authorization of the product in question to a non-prescription medicine with the consequential likely absence of veterinary involvement in the decision to use this treatment would impact on target animal safety, user safety, environmental safety or (where relevant) consumer safety. Further, in order to facilitate use as a non-prescription product, some changes to the summary of product characteristics/labelling text may be necessary to include use of more user-friendly /lay person terminology.

For information/guidance on the IMB approach to the assessment of changes in prescription status, MAHs are referred to the "Report of the working group on the methods of supply of companion animal antiparasitic medicines" which is available at www.imb.ie.

COMPLIANCE

DELEGATED ACT ON SAFETY FEATURES FOR MEDICINAL PRODUCTS FOR HUMAN USE

Directive 2011/62/EU ('Falsified Medicines Directive'), amending Directive 2001/83/EC (Human Medicines Directive), as regards the prevention of the entry into the legal supply chain of falsified medicinal products, was published in July 2011. This Directive introduces obligatory 'safety features' to allow verification of the authenticity of medicinal products ('unique identifier'). It places the European Commission under an obligation to adopt delegated act(s) setting out the details relating to the unique identifier.

The delegated act(s) shall set out:

- The characteristics and technical specifications of the unique identifier.
- The modalities for verification of the safety features.
- The provision on the establishment, management and accessibility of the repositories system in which information on the safety features is to be contained.
- The lists containing the medicinal products or product categories which, in the case of prescription medicines, shall not bear the safety features (referred to as the 'white list'), and, in the case of non-prescription medicines, shall bear the safety features (referred to as the 'black list').
- The procedures for the notification of medicinal products by the national competent authorities to the Commission, as regards medicinal products (not) at risk of falsification.

A public consultation on a Commission concept paper on the safety features was concluded in 2012. In addition, on four occasions, the Commission consulted an expert group (which includes representatives from the national competent authorities) on the delegated act(s) on the safety features. Before adopting the delegated act(s), the Directive requires the Commission to perform a study assessing benefits, costs and cost effectiveness. This study was conducted in the form of an impact assessment and was finalised at the end of 2013. The outcomes of the impact assessment were as follows:

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- The unique identifier will be carried by a 2D barcode (data matrix) and shall contain the manufacturer product code, a serial number, a national reimbursement number (if present), the batch number and the expiry date.
- Medicine authenticity shall be guaranteed by systematic verification of the safety features at the dispensing point and risk-based verification by wholesale distributors. Medicines will be systematically checked-out at the dispensing point. Wholesale distributors will verify the safety features when the product is not obtained from the holder of the manufacturing authorisation or the holder of the marketing authorisation and also when the product is returned by another wholesale distributor or a pharmacy.
- The repository system shall be established and managed by stakeholders with supervision by the relevant competent authorities.

The Commission held a stakeholder workshop in Brussels on the 28 April 2014. Details of the presentation of the delegated act(s) is scheduled for the end of 2014. Thereafter, the requirements must be implemented within three years in Member States which don't already have verification systems. The implementation period is not more than six years for Member States that have existing systems.

COSMETICS CERTIFICATES OF FREE SALE – UPDATE

We would like to inform manufacturers and Responsible Persons (RPs) for cosmetic products of a change to the application process for a Certificate of Free Sale (CFS) relating to a cosmetic product.

From 1 June 2014, it will no longer be necessary to state the CPNP number in the application. Accordingly, the CPNP number will no longer be listed on the CFS issued by the IMB. In order to facilitate this change the following is required from applicants:-

1. All RPs must submit a once-off statement of compliance ('Organisation Declaration') to ISO 22716:2007 (Cosmetics: Good Manufacturing Practices), or an equivalent GMP standard, and to Regulation (EC) No 1223/2009 on cosmetic products. The statement of compliance is required in order to reflect the additional legislative provisions of the Cosmetics Regulation (Regulation (EC) No 1223/2009 as amended). This declaration should be notarised by a 'Notary Public' and the original sent to the IMB. A draft template for the Organisation Declaration will be provided. The Notary Public must be Irish based.
2. From 1 June 2014, in accordance with the 'Guide to Applications for Certificates of Free Sale for Cosmetics: AUT-G0051', each application must continue to include the product code number and product description.
3. It is the duty of the applicant to ensure that the product code number and product description that accompany the application are correct as the IMB cannot re-issue certificates if errors and omissions are subsequently discovered.

Issuing of the revised Certificate of Free Sale will commence immediately after the applicant submits the notarised Organisation Declaration. As a result, the IMB will no longer issue CFSs with CPNP numbers after 31 May 2014.

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