IRISH MEDICINES BOARD

news MEDICINAL PRODUCTS LETTER

JANUARY - APRIL 2009 Issue No. 32

IRISH MEDICINES BOARD, KEVIN O'MALLEY HOUSE, EARLSFORT CENTRE, EARLSFORT TERRACE, DUBLIN 2 TEL: 01 676 4971 FAX: 01 6767836 EMAIL: FOI@IMB.IE

GENERAL

STAFF CHANGES

Benita Cullen and Agnieszka Przybyszewska were appointed as Medical Officers.
The following have recently resigned from their positions with the IMB;
Pauline Bowe – Medical Officer, Medical Devices
James O'Callaghan – Product Manager, Medical Devices Post Market Evaluation
Stan O'Neill, Senior Inspector, Compliance Department
Claire McCarthy, Executive Pharmaceutical Assessor

NEW IMB STRUCTURE

On 23 March 2009 the Irish Medicines Board launched its new structure for safety, licensing and registration of human medicines and medical devices. The introduction of a new dedicated safety department reflects the Boards commitment to safety management across the organisation.

The new structure has been in development for approximately 12 months and is the result of a comprehensive consultation process involving a wide range of external stakeholders, including both the pharmaceutical and medical device industries.

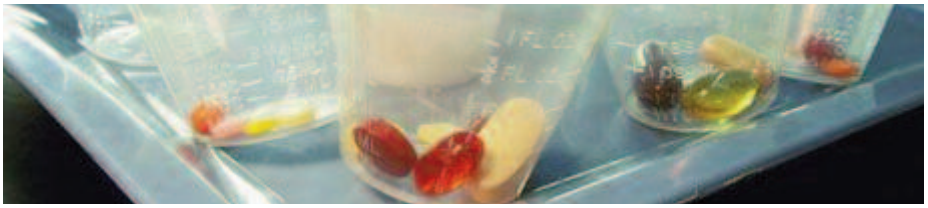
New arrangements see the introduction of a Human Products Safety Monitoring Department and a Human Products Authorisation & Registration Department. These two new departments replace the Human Medicines and Medical Devices departments.

We are pleased to announce that Ms. Ann O'Connor is the new Director of Human Products Authorisation & Registration and Dr. Joan Gilvarry is the new Director of Human Products Safety Monitoring. For the remainder of 2009 Ms. Ann O'Connor will continue to lead on medical device issues.

Ms. Maria Carleton has taken on the role of Planning & Regulatory Affairs Manager within the new Human Products Authorisation & Registration Department, while her colleague Ms. Mairead Finucane (Medical Device Auditor) has joined the Compliance Department. Dr. Niall MacAleenan and his pre-marketing team have moved into the Human Products Authorisation & Registration Department while Ms. Anne Tobin and her Vigilance & Compliance team are now part of the new Human Products Safety Monitoring Department.

Ms. Rachel Mahon is managing the Business Process Co-ordination Unit with responsibility for the management of all processes for both pre-licensing and post-licensing activities.

A new role of 'Information & Education Officer' will reside within the Safety Monitoring Department. The responsibilities of this role include the development of education programmes for healthcare professionals, industry stakeholders



CONTENTS

Figure 1: Human Products – Authorisation & Registration Departmental Structure

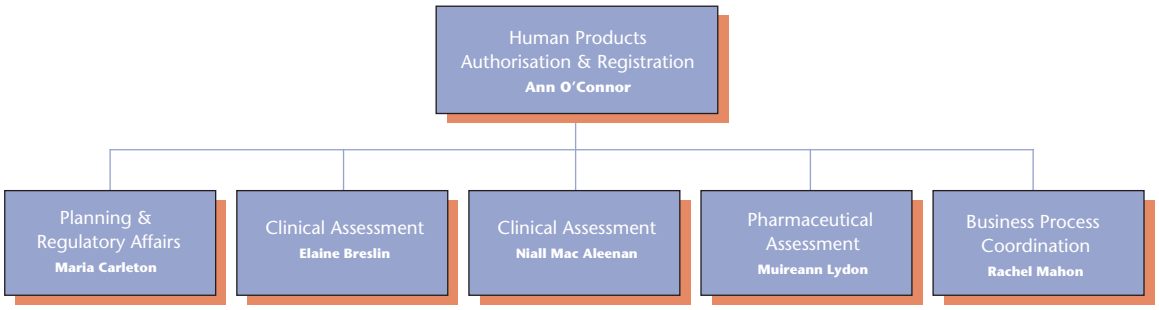
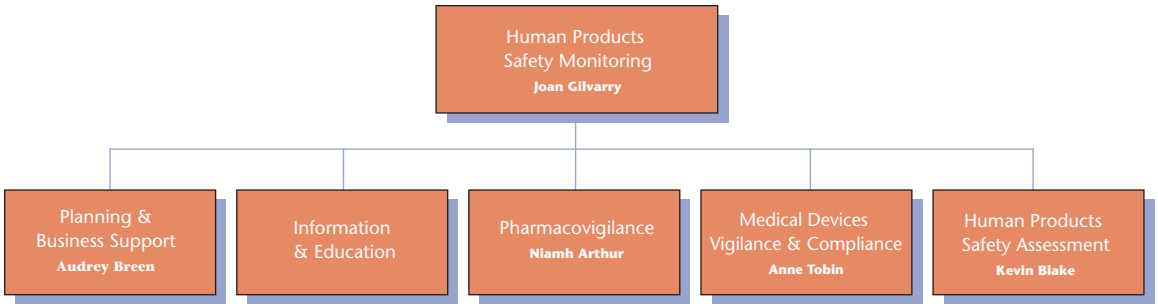


Figure 2: Human Products - Safety Monitoring Departmental Structure



and the public on product safety and related issues. It will also aim to provide an authoritative safety information resource to the public and healthcare professionals.

The registration of medical device manufacturers; clinical investigation of non CE marked devices; classification of medical devices and the monitoring of notified bodies for medical devices will be handled via the Clinical Assessment team managed by Dr. Niall MacAleenan, within the new Human Products Authorisation & Registration Department.

A number of other changes will be introduced over the coming months, notably in the customer service and case management teams. A further update will be provided as these changes are implemented.

Stakeholders should continue to use their existing email contacts with the IMB and to check the IMB website regularly for updates at www.imb.ie

HUMAN MEDICINES

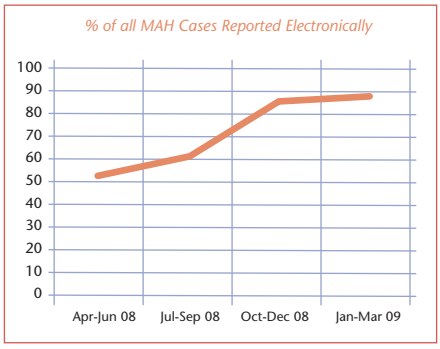
DEAR HEALTHCARE PROFESSIONAL COMMUNICATIONS

Safety information should be provided to healthcare professionals in the format of a Dear Healthcare Professional Communication (DHPC), as defined in Volume 9A of the Rules Governing Medicinal Products in the EU. Volume 9A clearly establishes the principles for the content and format of DHPCs, as well as describing situations where dissemination of DHPCs should be considered. Such DHPCs should not include any material or statement which might constitute advertising within the scope of Title VIII of Directive 2001/83/EC, or which is considered to be promotional or commercial by the Competent Authority. Draft DHPCs intended for distribution in Ireland should be submitted for assessment, local amendment and formal approval by the IMB and in certain circumstances in consultation with the EMEA. It is also a requirement that the IMB approves the distribution list and the timeframe for distribution of the communication.

The IMB has initiated a project to make (DHPCs) accessible via our website. The IMB considers that these are important safety communications which allow the marketing authorisation holder to highlight new or emerging safety information to healthcare professionals following approval of their content by the IMB. In order to facilitate this initiative, marketing authorisation holders are requested to ensure that a pdf. copy of the final agreed DHPC is provided on approval.

UPDATE ON REGULATORY REQUIREMENTS FOR ELECTRONIC SUBMISSION OF ADVERSE REACTION REPORTS

A review has been undertaken of the proportion of company reports received during the past year which have been submitted electronically to the IMB. The IMB has noted that a total of 73% of company reports were submitted electronically during the period April 2008 – March 2009. This represents a significant increase in the proportion of reports (60%) received electronically by the IMB over the same period a year previously (April 2007- March 2008). The IMB hopes to increase this proportion further over 2009 and has been in contact with companies that have not yet initiated electronic reporting regarding their plans for implementation. Companies that have not yet contacted the IMB in this regard are reminded to do so, by contacting the IMB by email at **eudravigilanceimb-test@imb.ie**. Details of the registration process can be found in section 4 of the *IMB Guide to the Electronic Submission of ICSRs and SUSARs*, which is available on the IMB website **www.imb.ie**. Companies should note that the Medicinal Products (Control of Placing on the Market) Regulations, 2007 (S.I. 540 of 2007), which transposes the EU legislation nationally, specifies the requirement for electronic reporting by marketing authorisation holders and holders of certificates of traditional-use registration.



The IMB continues to closely monitor the quality and consistency of parallel reports submitted and companies are advised of the need for appropriate quality control and validation measures to ensure provision of accurate and complete reports. In particular all available patient identifiers should be submitted, to aid in the detection of duplicate reports. The IMB is continuing to contact individual companies when the quality of electronic reports submitted is considered appropriate to allow companies to discontinue parallel reporting and to date a number of companies have done so.

Companies are requested to maintain the practice of parallel reporting until such time as the IMB contacts them to advise that parallel reporting may be discontinued. In some cases, an insufficient number of reports have been received from companies to allow a meaningful evaluation of the quality and consistency of reports. The IMB continues to provide feedback in the case of reports that have been associated with important discrepancies.

ASSESSMENT OF VARIATIONS THAT AFFECT PRODUCT INFORMATION BY MEDICAL OR PHARMACEUTICAL ASSESSORS

All national variations should be submitted to the Receipts and Validation Unit in the IMB. After validation the application will be assigned to either a pharmaceutical or medical assessor or both, depending on the nature of the change.

Applicants must consider the effect a variation to the marketing authorisation will have on the SPC and product livery. Such changes should be clearly outlined in the present and proposed section of the application form and referenced in the covering letter. This will facilitate the correct assessor(s) being assigned in a timely manner and help streamline the assessment process.

Changes to the SPC

If a change to the SPC is proposed that solely affects sections 1 to 3 or section 6, a pharmaceutical assessor will be assigned. Similarly if a change is proposed that affects sections 4 or 5 only, a medical assessor will be assigned. When a change impacts on both the clinical and pharmaceutical sections of the SPC this should be clearly indicated so that both a medical and pharmaceutical assessor is assigned. For example, if a change in formulation results in the inclusion of an excipient listed in the annex of the note for guidelines on *Excipients in the label and package leaflet of medicinal products for human use* (CPMP/463/00), this will require amendment to both the pharmaceutical (section 2 and section 6.1) and clinical (section 4.4) sections of the SPC and dual assessment will be required. Therefore, all changes proposed to the SPC should be clearly highlighted in the application.

Changes to Product Labels and Leaflets

Changes to product labels and package leaflets are to be clearly marked. Text versions or mock-ups with tracked changes are helpful in assessments. Signed and dated colour mock-ups of the final revised labels and leaflets should also be provided (text versions are acceptable if the product is not currently marketed). Any change which affects the name of the medicinal product, composition, pharmaceutical form and pharmaceutical particulars (e.g. storage, in-use shelf life etc) will be assessed by a pharmaceutical assessor. If a package leaflet appears in QRD format, changes to the product name or section 5 and 6 are generally subject to pharmaceutical assessment only. Changes which affect clinical particulars (including excipient warnings) and pharmacological properties are subject to medical assessment.

DEADLINE FOR BRAILLE REQUIREMENTS

Applicants are reminded of the deadline for implementation of the Title V (label and leaflet requirements) of Directive 2001/83EC as amended, including Article 56a Braille and patient accessible leaflets, as implemented by S.I. 540 of 2007 Medicinal Products (Control of Placing on the Market) Regulations 2007. This legislation gives an exemption from compliance with the labelling and leaflet requirements in the regulations until 30 October 2010, for those products either

▶

already on the market or for which an application has been received on the date the regulations came into force (23 July 2007). Thereafter the exemption no longer applies and all authorisations must be in compliance with labelling and leaflet requirements under Title V of the Directive. With this deadline fast approaching, applicants are encouraged to submit 'Braille declarations' and associated labelling for any remaining products as soon as possible or by April 2010, to ensure the deadline can be met after the usual six month implementation time. Further details are outlined below.

Applicants must include in Braille the invented name, strength (where the product is available in more than one), and the pharmaceutical form (where a risk of confusion occurs), on the outer carton of medicinal products. Products which are for administration by healthcare professionals only are excluded. Furthermore applicants must meet the requirement to provide the leaflet in a format suitable for people who are blind or partially-sighted ('patient accessible' leaflet), by that date. As all medicinal products are required to have a patient information leaflet (or display this information on the outer carton), this requirement for patient accessible leaflets applies to all medicinal products, and products which are intended for administration by healthcare professionals only are not excluded.

The IMB is implementing this requirement through the submission and assessment of Braille declarations, which cover Braille requirements in Section 1, and patient accessible leaflets in Section 2. The text of this Braille declaration can be found in the IMB *Guide to labels and leaflets of human medicines* on www.imb.ie, along with further detailed guidance and clarification on issues applicants have encountered to date. These declarations may be submitted for a particular product at time of renewal, by means of variation to update in line with the requirements of Directive 2001/83EC as amended, or by Article 61.3 notification. The versions of the labels on which the Braille will be applied should also be submitted at this time. Further guidance has previously been published in IMB Newsletters issue number 31 Sept – Dec 08 (re

previous deferrals of requirements), Newsletter issue number 27 May-August 2007 (re submission of Braille declaration to cover patient accessible leaflets), Newsletter issue number 26 January-April 2007 (re Braille alphabets, market compliance activities, pharmaceutical form, dot heights), Newsletter issue number 22 Sept-Dec 2005 (re findings from market compliance), and Newsletter issue number 21 July to Sept 2005 (re new legislation). Further details of the EU requirements for Braille are now incorporated in the European Commission *Guideline on the readability of the labelling and package leaflet of medicinal products for human use* Rev 1, 12 Jan 2009 available in Notice to Applicants Volume 2. http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol2/c/2009_01_12_readability_guideline_final.pdf. Further guidance will be published in future IMB newsletters as required; therefore applicants may find these a useful source of information in case of future queries.

USE OF INVENTED NAMES FOR MODIFIED RELEASE OR PROLONGED RELEASE PRODUCTS

The IMB would like to clarify the position with regard to invented names for modified-release or prolonged-release products. As stated in IMB newsletter issue number 24 (April – July 2006) an invented name should be proposed for new applications for product authorisations for modified-release or prolonged-release products. This is to ensure adequate distinction between products which may not have comparable bioavailability and may not be interchangeable. In certain cases the IMB may request that invented names are used for non-modified / prolonged-release products. Should a marketing authorisation holder not wish to market the product, a 'registration' name using the INN may be acceptable subject to the following conditions: a) The MAH commits not to market the product using the 'registration' name, b) The MAH commits to changing the name to an invented name by way of variation prior to marketing in Ireland. Each request will be assessed on a case-by-case basis and the conditions as detailed above will be stated in section 9 of the schedule.

PROCEDURE FOR CHANGES TO LABELS AND/OR PACKAGE LEAFLET FOLLOWING MR TYPE I NOTIFICATIONS

The IMB would like to inform MAHs of its position regarding the submission of updated national mock-ups of the labels and package leaflet, following the approval of MR Type I notifications, where the labels and/or package leaflet are affected. It is no longer intended to review Irish artwork during the national phase of these procedures, apart from notifications to change the name of the medicinal product (category no. 2) or to change the pack size of the finished product fill-weight of non-parenteral multi-dose products (category no. 41b), where artwork will still be assessed.

Further to RMS approval of such notifications (apart from categories 2 and 41b), an approval letter will be issued by the IMB, stipulating the following:

a) The label and/or package leaflet have not been reviewed and it is assumed that there has been no change to the currently approved artwork, with the exception of the change outlined in the application as it pertains to the Irish market.
b) Additional changes to the artwork or submission of mock-ups for the first time must be registered by way of an article 61(3) notification.

It is the responsibility of the applicant to ensure that the correct change is incorporated into the labelling and/or package leaflet and it is assumed that any such change will not adversely affect the legibility of

the artwork. Any additional changes, including changes to artwork design, must be registered separately, by way of an Article 61 (3) notification. The IMB reserve the right to request and assess artwork, in the event that the change is considered to have a potentially significant impact on the labels and/or package leaflet.

This change in procedure will apply from 29 May 2009.

IMPLEMENTATION OF THE PROVISIONS FOR LABELS AND PACKAGE LEAFLETS (TITLE V OF DIRECTIVE 2001/83/EC AS AMENDED) FOR PRODUCTS EITHER ON THE MARKET OR FOR WHICH AN APPLICATION HAD BEEN RECEIVED PRIOR TO 23 JULY 2007

Applicants are reminded of the deadline for implementation of the requirements for labelling and package leaflets required by Title V of Directive 2001/83/EC as amended and S.I. 540 of 2007 Medicinal Products (Control of Placing on the Market) Regulations 2007. This legislation gives an exemption from compliance with the labelling and leaflet requirements in the regulations until 30 October 2010, for those products either on the market or for which an application has been received prior to the date on which the regulations came into force (23 July 2007). After 30 October 2010 the exemption no longer applies and all authorisations must be in compliance with labelling and leaflet requirements under Title V of the Directive.

In order to comply with this legal requirement, MAHs are requested to update their labels and package leaflets by way of appropriate variation, as soon as possible. Alternatively updates may be accepted as part of renewal applications provided that these proposals are clearly made by the MAH in the renewal application and that the updated package leaflet has been subject to a user test, the results of which should be provided with the renewal application (unless otherwise justified e.g. if the product is not currently marketed in Ireland). If, following the review of the renewal application, the user test submitted or justification for absence of same is deemed to be unacceptable by the IMB, the package leaflet will not be updated and the MAH will be required to submit a separate variation to update the package leaflet including the results of a new user test.

If it is proposed to bridge the readability testing of a package leaflet to the results of an already approved user test carried out on another package leaflet, then the two package leaflets must be identical. If there are any differences in the two package leaflets, these differences should be tested by way of focused testing.

Applicants are reminded that some of the changes to the labels and leaflet (e.g. inclusion of strength and pharmaceutical form in the product name) also have implications for the SPC and this should be considered when submitting the applications.

In all cases the application should be submitted to the IMB as soon as possible and not later than 30 April 2010 in order to ensure that the deadline for the implementation of the updated labels and package leaflet can be met.

Further guidance on this topic including more detailed guidance on some of the individual topics (e.g. user testing) has been published in the IMB *Guide to Labels and Leaflets of Human Medicines,* which is available on the IMB website (www.imb.ie).

VETERINARY MEDICINES

IMB VETERINARY INFO DAY ON TUESDAY 8 SEPTEMBER 2009

An IMB Veterinary Info Day will be held in the Green Isle Hotel, Clondalkin, Co. Dublin on Tuesday, 8 September 2009. The location, beside the N7 and adjacent to the M50, has been chosen to facilitate delegates from around the country as well as visitors travelling via Dublin Airport. Location details are hyperlinked: http://www.greenislehotel.com/map.html. The date for the meeting has been chosen to facilitate those wishing to attend the APHA annual conference on 9 September, which will take place at the same venue.

The IMB meeting is intended primarily for companies marketing veterinary medicinal products in Ireland. Particular attention will be given to the impact of changes in the variations to marketing authorisations as a result of recent changes in European legislation. Updates on other IMB veterinary medicines activities and performance will also be given. Ample time will be set aside for discussions and questions. Keynote presentations will also be delivered by invited experts. A preliminary programme will be available over the coming weeks on the IMB website. The price of attending has been maintained at the same level as in 2007, being €300 per delegate (including lunch and refreshments). A special offer enabling four delegates to attend for the price of three is available until 31 July 2009. Delegates from non-profit making organisations may attend at a price of €100 per delegate. Further details of registration may be obtained from Ms. Michelle Sinnott (michelle.sinnott@imb.ie).

JOINT LABELLING FOR USE IN IRELAND AND UK

The Veterinary Medicines Department of the IMB and the Veterinary Medicines Directorate in the UK have a number of initiatives in place to encourage pharmaceutical companies to main-tain product authorisations in both markets and thus increase availability of veterinary medicines for the benefit of animal

health and welfare. The IMB understands that due to economies of scale, it is not always viable to have special packaging for the Irish market. These initiatives are therefore focused on enabling companies to achieve and maintain common packaging for authorised products which are identical in terms of formulation, packaging and manufacture.

The harmonisation procedure is relevant for nationally authorised products and involves harmonisation of the SPC and product literature in Ireland and the UK. The harmonisation process is dealt with as a variation in both Ireland and the UK. Assessment of the variations is coordinated between the two countries. No technical assessment is carried out as part of the procedure.

The joint labelling procedure is relevant for products authorised via a European procedure (MRP or DCP) in which Ireland and the UK were both involved and involves coordination of the approval of final colour mock-ups. The joint labelling procedure is dealt with during the national phase of the European procedure with no additional fees. Assessment of the mock-ups is coordinated between the two countries. No technical assessment is carried out as part of the procedure as the SPC and label text will have been agreed during the European procedure.

The alignment procedure is relevant for specific nationally-authorised immunological products and involves harmonisation of the SPC and product literature in Ireland and the UK. The alignment procedure is dealt with as a variation in both Ireland and the UK. Assessment of the variations is coordinated between the two countries. Technical assessment is carried out as part of the procedure.

Clarification papers outlining these procedures are available in the veterinary publications section of the IMB website (www.imb.ie). It is the applicant's responsibility to ensure that products which have achieved a joint label are maintained in the future by ensuring that any changes requested or submitted to one authority are also submitted to the other.

If an applicant wishes to use a joint label in Ireland and the UK but does not wish to avail of any of these procedures, it may be possible for them to do so by making applications to vary the authorisations in one or other country. In this situation there will be no official coordination between Ireland and the UK and it will the applicant's responsibility to coordinate the procedure.

KEY PERFORMANCE HIGHLIGHTS OF 2008 AND PLANS FOR 2009

The Veterinary Medicines Department achieved a record output of 1,371 units processed in 2008; this figure was comfortably ahead of the management target of 1,260 set in February 2008. A stretching target has been set for 2009 and we look forward to reporting on our performance in due course. The department also produced an excellent performance as Reference Member State for outgoing mutual recognition and decentralised procedures in 2008. IMB achieved second place in the league of top performing member states with 22 outgoing procedures. The department is committed to improving its services still further and has made a number of investments to improve its business processes and in developing its personnel over recent times. Plans for the roll-out of the on-line applications system, RIO, are advanced and it is hoped that the department will be in a position to offer this service to applicants before the end of the year. The department is also committed to being ready to accept electronic submissions from applicants by the deadline of 1 January 2010. The department is also open to enquiries to act as RMS – contact vetinfo@imb.ie to register your interest. The department is currently updating its information pack for applicants using IMB as RMS to provide applicants with improved advice. Finally, the department is continuing to work on implementing ideas that have been received from stakeholders for improvements in communications and overall service.

NEW COVER LETTER TEMPLATE AVAILABLE FOR MUTUAL RECOGNITION OR DECENTRALISED PROCEDURES

The Veterinary Medicines Department wishes to advise applicants intending to submit new applications for mutual recognition or decentralised procedures that an optional cover letter template is now available on the Heads of Medicines Agency website at www.hma.eu under CMDv / CMDv Guidance / Applications / Template for submission of application dossier. Applicants should note that this is a cover letter only and has been designed to standardise the information provided to Member States at the time of submission of a new application and may be used in addition to the EU application form available in Eudralex Volume 6B of the Notice to Applicants (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol6_en.htm).

STAFF CHANGES IN THE VETERINARY MEDICINES DEPARTMENT

There have been a number of staff changes in the department in recent times. As usual, an up-to-date organisational chart is maintained by following the hyperlink on the personnel page of the IMB website (http://www.imb.ie/EN/About-Us/Organisational-Structure/Personnel.aspx).

RESIGNATION FROM THE ADVISORY COMMITTEE FOR VETERINARY MEDICINES

Mr. Matt Browne MPSI, resigned from the ACVM with effect from 30 April 2009. The IMB wishes to thank Mr. Browne for his contribution to its work over the last 3½ years.

COMPLIANCE

PACKAGE LEAFLETS AND PATIENT INFORMATION ON THE PACKAGING OF MEDICINAL PRODUCTS

The IMB routinely undertakes surveillance activities in the Irish marketplace in relation to the package leaflets and patient information that are required to be supplied with medicinal products.

It has come to our attention that certain human medicinal products have been marketed in Ireland without a package leaflet, and the particulars of the approved package leaflets were not provided on the primary labelling of the products concerned. This represents a breach of Regulation 16(1)(b) of the Medicinal Products (Control of Placing on the Market) Regulations, 2007.

Manufacturers and marketing authorisation holders are advised to ensure that all packs of authorised medicinal products for human use that are released for marketing in Ireland either contain the approved package leaflet for the product, or carry the particulars of the approved package leaflet on the approved primary labelling of the product. The availability of such information is important from a patient safety perspective, as it is intended to ensure the correct use of the product.

Unless the terms of the marketing authorisation state otherwise, the above requirement applies equally to 'bulk' dispensing packs of medicinal products that are supplied to pharmacies (such as 100 count tubs of antibiotic capsules) as well as to packs of products that are intended to be supplied directly to the patient by a person authorised to do so.

Any marketing authorisation holder that is marketing a medicinal product in Ireland which does not carry the required package leaflet information on the packaging of the product is advised to contact the IMB Market Compliance Section to discuss this matter and to plan a course of action to bring the product into compliance at an early date.

NON-COMPLIANCE WITH GMP FOR CEP HOLDERS (ACTIVE SUBSTANCE MANUFACTURERS)

A number of medicinal products (human and veterinary) are manufactured using active substances which have a certificate of suitability (CEP) granted by the European Directorate for Quality of Medicines (EDQM). The EDQM operates a programme for inspecting manufacturers for which it has granted CEPs or which have applied for CEPs. Where significant GMP deficiencies have been found, it has withdrawn or suspended the CEPs or refused the applications. Details of withdrawals, suspensions and refusals are published on the website of the EDQM (www.edqm.eu). The IMB wishes to highlight this development to marketing authorisation holders and to emphasise that, where the CEP is no longer valid, the legal requirements for the Qualified Person to certify batches of product manufactured from this source for release onto the market cannot be met. The IMB is working with the industry to raise awareness of this matter. Manufacturers of medicinal products have a duty to satisfy themselves that active substances are manufactured in accordance with EU GMP and should take all necessary steps to ensure that they discharge their legal obligations in this regard.

NEW SYSTEM FOR CONTROLLED DRUG LICENCES

A new website has been developed to facilitate online submissions for import/export licences for controlled drugs. This website is named PharmaTrust and will be used by all licence holders who hold a controlled drugs licence or registration issued under the Misuse of Drugs Acts 1977 and 1984. Initial testing of the website will be undertaken over the following weeks by three nominated licence holders and pending a successful outcome it will be rolled out to all licence holders over the next 3-4 months.

ISSUE OF FREE SALE CERTIFICATES FOR MEDICAL DEVICES BY IMB COMPLIANCE DEPARTMENT

The issuing of free sale certificates (FSC) for medical devices will be transferred from the former Medical Devices Department to the Licensing Section of the Compliance Department shortly. The present electronic submission system and format of the FSC will remain the same and a formal notification of the transfer date will be placed on the IMB website and in the IMB newsletter.

GMP INSPECTIONS AT IRISH MANUFACTURING SITES BY OTHER REGULATORY AUTHORITIES

Manufacturers are requested to inform the IMB of inspections planned at their facilities by other regulatory authorities. It is acknowledged that many manufacturers do already notify the IMB with regard to these inspections. Notifications can be sent by email to **compliance@imb.ie** and should state the planned dates of the inspection, the name of the inspecting authority and the type of product being covered in the inspection. In the event that the IMB wishes to observe part or all of the inspection it will contact the manufacturer in advance.

WHOLESALE – ESTABLISHING ENTITLEMENT TO RECEIVE MEDICINAL PRODUCTS

A wholesaler can only supply product to a person who is entitled to receive it. When supplying to another wholesaler, if the wholesaler's authorisation held by the intended recipient has expired then the supplying wholesaler should clarify with the intended recipient if an application for renewal of the wholesaler's authorisation has been submitted to the Irish Medicines Board (IMB). The

supplier should request documentary evidence from the intended recipient that the IMB has received the renewal application and that the IMB does not object to continuation of the wholesaling activities whilst the renewal application is being processed. In relation to an application for a renewal of a Wholesaler's Licence issued under "Medical Preparations (Wholesale Licences) Regulations 1993-1996, the transitional of provisions described under Article 15 of the current legislation, Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (SI 538 of 2007) will apply.

It should also be noted that the list of authorised wholesalers which appears on the IMB website will be revised to reflect the withdrawal of a wholesaler's authorisation by the authorisation holder or the revocation of an authorisation by the IMB.

UPDATE TO IMB WHOLESALE GUIDANCE DOCUMENT

The IMB is currently updating the guide on the wholesaling of medicinal products for human use in Ireland. This guide will include changes in the IMB's expectations of wholesalers arising from the revised legislation (Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (SI No 538 of 2007)). The document will be issued on the IMB website for public consultation at the end of May. It is important to emphasize points relating to the key aspects of supply chain management for wholesalers and these are set out in the article below.

Following on from the article in IMB newsletter issue number 31 on supply chain management relating to manufacturing activities, there follows several points on the IMB's expectations of wholesalers / distributors on the same issue.

Goods-In

An important stage in the management of the supply chain are the checks carried out at the goods-in stage. These checks should be carried out by a trained person and should be documented. Amongst other items the presence of a marketing authorisation number (e.g. PA or EU number) should be verified. Additional requirements for exempt medicinal products, controlled drugs and medicinal products requiring controlled temperature storage should be established as necessary. Records of these checks must be maintained and available for review by an inspector.

Suppliers

All medicinal products should be received from approved wholesalers or manufacturers. It is the responsibility of the receiving wholesaler to verify the authority of their suppliers to supply that category of medicinal products. Wholesalers should have methods of controlling their approved suppliers and also the categories of products that may be supplied. A list of authorised wholesalers is available on the IMB website (www.imb.ie) and can be used to verify the authorisation date of wholesaler's authorisations.

Where the wholesaler acts as the primary distributor, contracts should be in place between the parties and should cover responsibilities for recalls, returns and any other quality-related items.

Deliveries

Deliveries of products should be carried out in a controlled manner in order that products are not exposed to adverse conditions. Delivery drivers should be trained in GDP principles. Delivery requirements for cold chain products are covered in the IMB guidance document *Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medicinal Products and Active Substances*. Evidence that products are transported under appropriate conditions may be reviewed during an IMB inspection. Products should only be supplied to those persons who are authorised to receive them.

Counterfeits

Wholesalers and distributors should be aware of the possibility of counterfeit medicinal products entering the supply chain. The IMB should immediately be contacted in the event of a product being suspected as being counterfeit. This should be done prior to other action being carried out. A written procedure should be in place outlining the steps to be taken and training provided to staff on this procedure. Wholesalers should be wary of any suspect offers from suppliers and contact the IMB with this information.

Storage

Each member of the supply chain is responsible for the storage conditions of products under their control. The product should be stored under the conditions as recommended by the manufacturer and evidence of this must be available to an IMB inspector. For relevant products temperature conditions must be monitored at all times including occasions when temperature monitoring devices are off-site for calibration. All excursions from recommended storage conditions should be investigated immediately and may involve contacting the manufacturer to determine if the excursion would have an effect on the product quality.

Disposal

A full audit trail should be available for any medicinal products sent for disposal. This may include an inventory of waste and certificates of destruction from a contract disposal company.

Self Inspections

As part of wholesalers' self inspections all aspects of the supply chain should be examined including suppliers and customers, goods-in, storage, dispatch and all relevant procedures, forms and completed records.

Human New Product Authorisations (Issued) (January 2009 – April 2009)

PA Number	Product Name
PA0035/082/004	Cozaar
PA0540/103/002	Intal 5 Inhaler CFC-Free
PA0540/103/002	Intal 5 Inhaler CFC-Free
PA0639/001/004	Granocyte 34
PA0639/001/005	Granocyte 13
PA0678/011/004	Panadol Max Strength Cold & Flu Hot Berry Fruits
PA0748/031/002	Sibelium
PA1130/026/001	Rispeva
PA1286/004/004	Cozaar
PPA0465/070/003	Imigran Ftab
PPA1151/030/002	STILNOCT
PPA1151/033/002	Pariet
PPA1151/049/002	CIPRAMIL
PPA1151/061/002	ZOCOR
PPA1151/061/003	ZOCOR
PPA1151/072/002	Innovace
PPA1151/073/001	DIFENE Dual Release
PPA1151/078/002	Elantan LA 25
PPA1151/086/001	Fucidin
PPA1151/087/001	Colpermin
PPA1151/091/001	RISPERDAL
PPA1151/091/002	RISPERDAL
PPA1151/091/003	RISPERDAL
PPA1151/093/001	NIZORAL
PPA1151/095/001	Cozaar Comp
PPA1151/104/001	CASODEX
PPA1328/049/001	Arythmol
PPA1328/050/001	AUGMENTIN DUO
PPA1328/079/001	Cardura XL
PPA1328/079/002	Cardura XL
PPA1328/080/001	Coversyl Arginine
PPA1328/080/002	Coversyl Arginine
PPA1328/082/001	Istin
PPA1328/083/001	Lipitor
PPA1328/083/002	Lipitor
PPA1328/085/001	Lustral
PPA1328/085/002	Lustral
PPA1328/086/001	Fosamax Once Weekly
PPA1328/087/001	Aricept
PPA1328/087/002	Aricept
PPA1328/088/001	Capozide
PPA1328/090/001	Actonel Plus
PPA1328/095/001	Hytrin
PPA1328/095/002	Hytrin
PPA1328/095/003	Hytrin
PPA1328/096/001	Omnexel
PPA1328/097/001	Naprosyn EC
PPA1328/097/002	Naprosyn EC
PPA1447/007/001	VASCACE
PPA1447/007/002	VASCACE
PPA1447/007/003	VASCACE
PPA1447/025/001	OXIS Turbohaler
PPA1447/025/002	OXIS Turbohaler
PPA1447/031/001	FLIXOTIDE Evohaler
PPA1463/006/001	SERETIDE Diskus
PPA1463/011/001	ZIMOVANE
PPA1463/012/001	LEXAPRO
PPA1463/012/002	LEXAPRO
PPA1463/013/001	PROSCAR
PPA1463/014/001	Imuran
PPA1463/015/001	Augmentin
PPA1463/016/001	Zanidip
PPA1463/017/001	Xatral
PPA1473/001/001	NEXIUM
PPA1473/001/002	NEXIUM
PPA1473/002/001	LIPITOR
PPA1473/002/002	LIPITOR
PPA1473/002/003	LIPITOR
PPA1473/002/004	LIPITOR
PPA1473/003/001	PROTIUM
PPA1473/003/002	PROTIUM
PPA1473/004/001	ZOTON FasTabs
PPA1473/004/002	ZOTON FasTabs
PPA1473/005/001	Adalat LA
PPA1473/005/002	Adalat LA
PPA1473/006/001	Cardura XL
PPA1473/006/002	Cardura XL
PPA1473/007/001	Imuran
PPA1473/007/002	Imuran
PPA1473/008/001	Proscar
PPA1473/009/001	Zantac
PPA1473/010/001	NIZORAL
PPA1473/011/001	ACTONEL Once a Week
PPA1473/012/001	Ikorel
PPA1473/012/002	Ikorel
PPA1473/016/001	Beconase Aqueous Nasal Spray
PPA1473/025/001	Zispin Soltabs
PPA1473/025/002	Zispin Soltabs
PPA1473/025/003	Zispin Soltabs
PPA1488/001/001	ZOTON FasTab
PPA1488/001/002	ZOTON FasTab
PPA1488/002/001	ISTIN
PPA1488/002/002	ISTIN
PPA1500/004/001	Zanidip
PPA1500/005/001	Zoton FasTab

continued on next page ▶

Human New Product Authorisations (Issued) cont. (January 2009 – April 2009)

PA Number	Product Name	PA Number	Product Name
PPA1500/005/002	Zoton FasTab	PPA1562/001/001	Zoton
PPA1500/009/001	Seretide 500 Diskus	PPA1562/001/002	Zoton

Human New Product Authorisations Withdrawn (January 2009 – April 2009)

PA Number	Product Name	PA Number	Product Name
PA0002/007/010	MYCOSTATIN PASTILLES	PA0282/073/003	Norace
PA0002/015/001	MOTIVAL	PA0282/073/004	Norace
PA0007/001/001	MEXITIL	PA0289/005/001	NITRONAL
PA0007/001/003	MEXITIL	PA0289/005/002	NITRONAL
PA0007/001/004	MEXITIL	PA0289/005/003	Nitronal
PA0007/015/002	Alupent Expectorant	PA0290/012/001	ISOPTO PLAIN
PA0013/083/002	Lopresor 100 mg Film-coated Tablets	PA0290/013/001	ISOPTO ALKALINE
		PA0299/014/001	Fleet Micro Enema
PA0013/089/002	Foradil Certihaler	PA0372/007/001	Cefuroxime Sodium
PA0013/102/001	TEOPTIC	PA0372/007/002	Cefuroxime Sodium
PA0013/102/002	TEOPTIC	PA0372/007/003	Cefuroxime Sodium
PA0013/113/001	Bentifen	PA0408/012/001	Rimoxallin (Amoxicillin Oral Suspension BP)
PA0013/113/002	BENTIFEN SINGLE DOSE UNIT		
PA0013/118/001	Co-Tareg	PA0408/012/002	Rimoxallin (Amoxicillin Oral Suspension BP)
PA0013/118/002	Co-Tareg		
PA0013/118/003	Co-Tareg	PA0436/044/003	Eflavex 4 mg Tablets
PA0013/118/004	Co-Tareg	PA0486/001/001	CLICKHALER SALBUTAMOL
PA0013/118/005	Co-Tareg	PA0486/002/001	CLICKHALER BECLOMETASONE
PA0021/004/005	Canesten	PA0486/002/002	CLICKHALER BECLOMETASONE
PA0021/061/002	Bayer Multivitamin & Mineral Film Coated Tablets	PA0486/002/003	CLICKHALER BECLOMETASONE
		PA0540/013/001	ANTHISAN PLUS STING RELIEF (SPRAY)
PA0030/021/004	NCH FRUIT G		
PA0030/021/005	NCH FRUIT G	PA0540/084/001	Tritace 1.25mg Capsules
PA0030/021/006	NCH MINT G	PA0540/084/002	Tritace 2.5mg Capsules
PA0030/021/007	NCH MINT G	PA0540/084/003	Tritace 5mg Capsules
PA0038/091/001	Ziaxel	PA0540/084/004	Tritace 10mg Capsules
PA0043/006/007	Nurofen Caplets	PA0540/123/002	RYNACROM
PA0048/016/001	BiCNU 100 mg Powder and Solvent for Solution for I	PA0540/127/003	STEMETIL
		PA0540/127/004	STEMETIL
PA0061/006/001	NOVIAL	PA0540/138/001	Loavel
PA0061/006/002	NOVIAL 28	PA0540/138/002	Loavel
PA0126/148/001	Osteomel	PA0540/138/003	Loavel
PA0172/029/004	ADVIL JUNIOR	PA0540/138/004	Loavel
PA0261/003/001	Deca Durabolin 100mg/ml, Solution for Injection (a	PA0540/145/001	Diltiazem Hydrochloride 60mg Prolonged - Release T
PA0261/003/002	Deca Durabolin 25 mg / ml Solution for Injection (	PA0540/151/001	Mizollen
		PA0540/152/001	Negram
PA0261/003/005	Deca Durabolin 50 mg/ml Solution for Injection (am	PA0540/156/003	Priadel
		PA0540/158/005	Solian 100mg/ml Oral Solution
PA0261/009/001	Sustanon 100 Ampoules	PA0540/159/002	SOLPADOL
PA0261/009/003	SUSTANON 250 AMPOULES	PA0544/002/001	Rubavax
PA0281/085/002	Diclo (Enteric-Coated)	PA0544/002/004	Rubavax Vaccine Live
PA0282/073/001	Norace	PA0544/003/001	Measavax
PA0282/073/002	Norace	PA0577/031/001	Geramil

continued on next page ▶

Human New Product Authorisations Withdrawn (cont.) (January 2009 – April 2009)

PA Number	Product Name
PA0585/019/001	Cholstat 10mg tablets
PA0585/028/001	Venlafaxine
PA0585/028/002	Venlafaxine
PA0585/028/003	Venlafaxine
PA0585/031/001	Olanzapine Pliva
PA0585/031/002	Olanzapine Pliva
PA0585/031/003	Olanzapine Pliva
PA0585/031/004	Olanzapine Pliva
PA0585/031/009	Olanzapine Pliva
PA0585/031/010	Olanzapine Pliva
PA0585/033/001	Bicalutamide
PA0585/033/002	Bicalutamide
PA0711/002/004	CAPTOR
PA0711/085/001	Larig 5 mg Dispersible Tablets
PA0748/003/008	Risperdal
PA0748/040/002	RAPIFEN TM
PA0751/001/001	Sodium Chloride
PA0809/003/001	NEOSTIGMINE BROMIDE
PA0818/001/001	TENSOPRIL
PA0818/001/002	TENSOPRIL
PA0818/001/003	TENSOPRIL
PA0868/002/001	Dermestril
PA0868/002/002	Dermestril
PA0868/002/003	Dermestril
PA0876/003/001	Norflocux
PA0876/005/001	Flutamide
PA0876/006/001	Simvacux
PA0876/006/002	Simvacux
PA0876/006/003	Simvacux
PA0876/006/004	Simvacux
PA0899/026/001	Lederfen 300 mg Tablets
PA0899/026/002	Lederfen 450 mg Tablets
PA0929/001/001	Metformin Germania
PA0967/011/001	Lamidus
PA0967/011/002	Lamidus
PA0967/011/003	Lamidus
PA0967/011/004	Lamidus
PA0967/012/001	Lamotrigine Ranbaxy
PA0967/012/002	Lamotrigine Ranbaxy
PA0967/012/003	Lamotrigine Ranbaxy
PA0967/012/004	Lamotrigine Ranbaxy
PA0968/003/001	Airtal 100mg Film-coated Tablets.
PA0968/003/001	Airtal 100mg Film-coated Tablets.
PA0970/033/001	Betaloc 200mg Prolonged Release Tablets
PA0970/040/002	Heminevrin 192 mg Capsules
PA0970/040/003	HEMINEVRIN
PA0970/050/001	PULMICORT INHALER
PA0970/050/002	PULMICORT LS
PA0970/056/001	XYLOPROCT
PA0971/002/001	Dobutamine-hameln 250 mg/50 ml ampoule
PA0971/002/002	Dobutamine-hameln 250 mg/ 50 ml vial
PA0971/002/003	Dobutamine-hameln 250 mg/20 ml ampoule
PA0971/002/004	Dobutamine-hameln 250 mg/ 5 ml ampoule
PA0979/013/002	Lemsip Pharmacy with Phenylephrine
PA0980/003/001	ANABACT
PA1001/005/001	FLUVIRIN (INACTIVATED INFLUENZA VACCINE)
PA1022/003/002	Iomeron 250
PA1027/002/001	WinRho SDF
PA1044/002/003	Profloxin 750 mg film-coated Tablets
PA1044/004/002	XYMEL
PA1044/004/003	XYMEL
PA1044/005/001	FLUCOMEL
PA1044/005/002	FLUCOMEL
PA1044/005/003	FLUCOMEL
PA1052/001/001	Cardiolite
PA1052/002/001	NEUROLITE
PA1077/047/001	SEREVENT Inhaler
PA1077/093/009	Augmentin ES
PA1077/104/001	Avodart
PA1130/010/003	Caberex 4 Milligram Tablets
PA1142/012/001	Topicycline
PA1161/003/001	Mebeverine 50mg/5ml Sugar Free Oral Suspension
PA1178/001/001	Vastatifix
PA1178/001/002	Vastatifix
PA1178/001/003	Vastatifix
PA1189/001/002	ZYDOL
PA1189/002/001	Clarosip
PA1189/002/002	Clarosip
PA1189/002/003	Clarosip
PA1228/001/001	Striant SR Mucoadhesive
PA1244/001/001	Tamsulosin Hydrochloride
PA1244/002/001	Hystream
PA1255/001/001	Alutard Avanz
PA1255/001/002	Alutard Avanz
PA1255/001/003	Alutard Avanz
PA1285/016/001	Glimepiride 1 mg Tablets
PA1285/016/002	Glimepiride 2 mg Tablets
PA1285/016/003	Glimepiride 3 mg Tablets
PA1285/016/004	Glimepiride 4 mg Tablets

continued on next page ▶

Human New Product Authorisations Withdrawn (cont.) (January 2009 – April 2009)

PA Number	Product Name
PA1380/028/001	Ciclosporin Dumex
PA1380/028/002	Ciclosporin Dumex
PA1380/028/003	Ciclosporin Dumex
PA1380/029/001	Ciclosporin Pharmachemie
PA1380/029/002	Ciclosporin Pharmachemie
PA1380/029/003	Ciclosporin Pharmachemie
PA1410/028/001	Ciproxin
PA1410/028/008	Ciproxin Oral Suspension 250mg/5ml
PA1410/028/009	Ciproxin Oral Suspension Forte 500 mg/5ml
PA1410/033/001	Alka Antacid
PA1443/001/001	Balmosa Cream
PA1471/001/001	Vomlez
PA1471/001/002	Vomlez
PA1471/001/003	Vomlez
PPA0465/008/002C	Amoxil
PPA0465/031/003A	Naprosyn EC 250 mg Tablets
PPA0465/040/002	PROZAC
PPA0465/044/002B	Estraderm TTS 50 Micrograms/ 24hours transdermal pa
PPA0465/067/001A	Coversyl
PPA0465/067/002	Coversyl
PPA0465/067/003	Coversyl Plus
PPA0465/078/005A	Risperdal
PPA0465/102/001A	SOTACOR
PPA0465/102/002A	SOTACOR
PPA0465/124/001A	KLIOGEST
PPA0465/126/001A	DYAZIDE
PPA0465/138/001A	Xatral 2.5mg Tablets
PPA0465/148/001	Sinemet
PPA0465/148/002	Sinemet
PPA0465/152/001	Lexotan
PPA0465/152/002	Lexotan
PPA0465/173/001	Atrovent UDV's
PPA0465/173/002	Atrovent UDV's
PPA0465/174/004	Requip
PPA0465/187/001	Nicorette
PPA0465/187/002	Nicorette
PPA0465/187/003	Nicorette Mint
PPA0465/187/004	Nicorette Mint
PPA0465/200/001	Betaloc
PPA1328/036/001	Serevent Inhaler

Human New Product Authorisations (Decentralised Procedure) (January 2009 – April 2009)

PA Number	Product Name
PA1390/006/001	Carboplatin
PA1130/018/001	Prindavam
PA1410/058/001	Qlaira
PA1390/008/001	Risperidone
PA1390/008/002	Risperidone
PA1390/008/003	Risperidone
PA1390/008/004	Risperidone
PA1390/008/005	Risperidone
PA1390/008/006	Risperidone
PA0937/010/001	Epirubicine HCL
PA0711/115/004	Oxydon
PA0711/115/005	Oxydon
PA0126/184/001	Vilbinitan
PA0126/184/002	Vilbinitan
PA0995/005/001	Leticia
PA0995/006/001	Vivides
PA1380/007/001	Lisinopril Actavis
PA1380/007/002	Lisinopril Actavis
PA1380/007/003	Lisinopril Actavis
PA1380/007/004	Lisinopril Actavis
PA1380/006/001	Luvinsta XL
PA0590/025/001	Oracea
PA1380/009/001	Paroxetine
PA1380/009/002	Paroxetine
PA1451/001/001	Cisplatin Teva
PA1451/001/002	Cisplatin Teva
PA0970/018/012	Seroquel XR
PA0749/068/001	Zolmitriptan Teva
PA0408/067/001	Irbesartan Ranbaxy
PA0408/067/002	Irbesartan Ranbaxy
PA0408/067/003	Irbesartan Ranbaxy
Pa0126/180/001	Piperacillin/Tazobactam Stragen
Pa0126/180/002	Piperacillin/Tazobactam Stragen
PA0749/074/001	Ropinirole Teva
PA0749/074/002	Ropinirole Teva
PA0749/074/003	Ropinirole Teva
PA1120/001/002	Paracetamol, Guaifenesin, Phenylephrine Hydrochloride Wrafton 500 mg / 100 mg / 6.1 mg Capsules, hard
PA0749/060/001	Tevaquel
PA0749/060/002	Tevaquel
PA0749/060/003	Tevaquel
PA0749/060/004	Tevaquel
PA0749/060/005	Tevaquel
PA1327/011/001	Donepezil hydrochoride

continued on next page ▶

Human New Product Authorisations (Decentralised Procedure) – cont. (January 2009 – April 2009)

PA Number	Product Name
PA1327/011/002	Donepezil hydrochoride
PA1390/010/001	Midazolam
PA1390/010/002	Midazolam
PA1130/015/001	AnastArrow
PA0865/016/001	Hypoloc Plus
PA0865/016/002	Hypoloc Plus
PA1489/001/001	Escitalopram-Vera
PA1489/001/002	Escitalopram-Vera
PA1489/001/003	Escitalopram-Vera
PA1489/001/004	Escitalopram-Vera
PA1438/001/005	Denzapine
PA0736/031/001	Gentamicin
PA0736/031/001	Gentamicin
PA0736/031/002	Gentamicin
PA0736/031/002	Gentamicin
PA0126/178/001	Ceftazidime
PA0126/178/002	Ceftazidime
PA0126/178/003	Ceftazidime
PA0126/178/004	Ceftazidime
PA0577/104/001	Tavager
PA0577/104/002	Tavager
PA0711/153/001	Esciprex
PA0711/153/002	Esciprex
PA0711/153/003	Esciprex
PA0711/153/004	Esciprex
PA0126/173/001	Emwepel
PA0126/173/002	Emwepel
PA0126/173/003	Emwepel
PA0967/014/001	Pantoprazole Ranbaxy
PA0967/014/002	Pantoprazole Ranbaxy
PA1390/004/001	Epirubicin Hydrochloride
PA0865/015/001	Nebilet Plus
PA0865/015/002	Nebilet Plus
PA0749/069/001	Flumazenil Teva
PA0967/013/001	Pantoprazole
PA0967/013/002	Pantoprazole
PA0711/139/001	Losat Comp
PA0711/139/002	Losat Comp
PA1490/001/001	Letrozole
PA0566/049/001	Paclitaxel
PA1438/001/003	Denzapine
PA1438/001/004	Denzapine
PA1380/041/001	Cefalexin
PA1380/041/002	Cefalexin
PA0711/154/001	Alopur
PA0711/154/002	Alopur
PA0585/035/001	Epirubicin
PA1338/003/001	Citalopram
PA0711/149/001	Calcil 50 micrograms/ml Cutaneous Solution
PA0711/158/001	Emazole
PA0711/158/002	Emazole
PA1390/003/001	Losartan Potassium
PA1390/003/002	Losartan Potassium
PA1390/003/003	Losartan Potassium
PA1389/005/001	Furosemide
PA1389/005/001	Furosemide
PA0785/007/001	Phoxilium
PA1470/001/001	Donepezil hydrochloride
PA1470/001/002	Donepezil hydrochloride
PA1390/012/001	Terazosin
PA1390/012/002	Terazosin
PA1390/012/003	Terazosin
PA1462/001/001	Glepark
PA1462/001/002	Glepark
PA1462/001/003	Glepark
PA1462/001/004	Glepark
PA0749/072/001	Carsem XL
PA0749/075/001	Amisulpride Teva
PA0749/075/002	Amisulpride Teva
PA0749/075/003	Amisulpride Teva
PA0749/075/004	Amisulpride Teva
PA1436/004/001	Alendronic Acid Bluefish Once weekly

Human New Product Authorisations (Mutual Recognition Procedure) (January 2009 – April 2009)

PA Number	Product Name
PA0749/086/001	Vinorelbine Teva
PA0573/004/005	Salofalk
PA1380/052/001	Hyplafin
PA1380/044/001	Fostolin Once Weekly
PA0736/027/001	Ondansetron B.Braun
PA0736/027/001	Ondansetron B.Braun
PA1380/022/001	Valsotens
PA1380/022/002	Valsotens
PA1380/022/003	Valsotens
PA1410/052/003	Rennie Dual Action Chewable Tablets
PA0566/051/001	SmofKabiven Peripheral
PA0749/089/001	Pantoprazole Teva
PA0749/089/002	Pantoprazole Teva
PA0913/025/003	Targin
PA0913/025/004	Targin
PA1347/006/001	Nolpaza
PA1347/006/002	Nolpaza

continued on next page ▶

Human New Product Authorisations (Mutual Recognition Procedure) – cont. (January 2009 – April 2009)

PA Number	Product Name	PA Number	Product Name
PA1063/038/001	Pantoprazole Niche	PA1311/015/001	Metformin Aurobindo
PA1063/038/002	Pantoprazole Niche	PA1311/015/002	Metformin Aurobindo
PA0102/023/006	Movicol Plain Sachet	PA1311/015/003	Metformin Aurobindo
PA1130/022/001	Sumatriptan Arrow	PA0126/181/001	Losamel
PA1130/022/002	Sumatriptan Arrow	PA0126/181/002	Losamel
PA1516/001/001	Dolenio	PA0126/181/003	Losamel
PA1436/009/001	Metformin Bluefish	PA1410/018/004	Gadovist
PA1436/009/002	Metformin Bluefish	PA1422/002/001	Epirubicin Hydrochloride
PA1436/009/003	Metformin Bluefish	PA1513/004/001	Alendronic Acid Apotex
PA0789/019/001	Gemcitabine Ebewe	PA0711/173/001	Valaciclovir
PA0789/019/002	Gemcitabine Ebewe	PA0172/038/001	Caltrate

Veterinary New Product Authorisations Issued (January 2009 – April 2009)

VPA Number	Product Name	VPA Number	Product Name
10861/097/001	Cydectin 2% LA Injection for Sheep	10782/005/002	Vetmulin 100g/kg Premix for medicated Feeding stuff
10277/103/001	Orbax Oral Suspension 30mg/ml	10987/076/001	Prazitel Plus Tablets
10996/210/001	Vectin 22.75mg Chewable Tablets for Horses	10782/005/001	Vetmulin 20g/kg Premix for Medicated Feed
10799/011/001	Buprenodale	10664/001/001	Domosedan Gel
10277/105/001	Procyon Dog Parvo	10987/077/001	Cazitel Plus Tablets
10996/211/001	Plerion 5 chewable tablets for dogs	10987/078/001	Exitel Plus Tablets
10996/211/002	Plerion 10 chewable tablets for dogs	10782/002/001	Vetmulin 450 mg/g granules f or use in drinking water for pigs
10861/094/001	Duvaxyn R Suspension for Injection	10021/054/001	Bayer Cat Wormer Film-Coated Tablets
10782/004/001	Tilmovet 200g/kg Premix for medicated feeding stuff for Pigs	10021/055/001	Bayer Big Dog Wormer Tablets
10782/004/002	Tilmovet 100g/kg Premix for medicated feeding stuff for Pigs	10021/056/001	Bayer Big Cat Wormer Film-Coated Tablets
10782/004/003	Tilmovet 4% Premix for Medicated Feed	10277/107/001	Porcilis Coli 6C Suspension for Injection
10021/057/001	ByeMite		

Veterinary Product Authorisations Withdrawn (September 2008 – December 2008)

VPA Number	Product Name	VPA Number	Product Name
10983/036/001	Tecvax Pasteurella 1/6 Suspension for Injection	10988/048/001	Colamox Injection 50ml
10983/028/002	Marbocyl 20mg Tablets	10988/048/002	Colamox Injection 100ml
10983/028/003	Marbocyl 80mg Tablets	10814/002/001	Amoxival 100mg Tablets
10996/119/001	Panacur Granules	10814/002/002	Amoxival 200mg Tablets
10835/035/001	PLT Tablets	10545/032/001	Janamax 0.08%w/v Abamectin Sheep Drench
10987/011/001	C.N.F Scour Diet Oral Powder	10545/029/001	Jancare 15% w/v Oral Suspension
10545/030/001	Furexel Combi	10545/033/001	Janamax Pour-On for Cattle 1% w/v
10974/014/001	Torvac Suspension for Injection	10545/009/001	Telmin Granules 100mg/g
10007/039/001	Insol Dermatophyton Suspension for Injection	10021/039/001	Bayer Dog Wormer Tablets

IRISH MEDICINES BOARD

This Bulletin is designed by Ashfield Press Publishing Services for

IRISH MEDICINES BOARD, KEVIN O'MALLEY HOUSE, EARLSFORT CENTRE, EARLSFORT TERRACE, DUBLIN 2
tel: +353 1 6764971 fax: +353 1 6767836 email: foi@imb.ie: http://www.imb.ie