IRISH MEDICINES BOARD

news LETTER

MEDICINAL PRODUCTS

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IRISH MEDICINES BOARD, EARLSFORT CENTRE, EARLSFORT TERRACE, DUBLIN 2 TEL: 01 676 4971 FAX: 01 676 7836 EMAIL: FOI@IMB.IE

GENERAL

2003 IMB Information Days

An information day on Human Medicines is scheduled to take place Monday 29th September 2003 in the Great Southern Airport Hotel.

Proposed topics for discussion are:

- implementation of CT Directive
- IMB IT Strategy
- ADR Reporting

Registration forms for this day can be downloaded from our Website at www.imb.ie or are available from Ms Margaret Miley. The cost is €250 per person.

Recent Appointments at IMB

Mr. Paul Sexton was appointed as Senior Inspector with the Irish Medicines Board in June 2003. Paul has been a member of the Inspectorate team since March 2002. Dr. Audrey Kinahan was also appointed recently as Senior Pharmaceutical Assessor (half-time) and Dr. Fiona Quaife joined the staff as Pharmaceutical Assessor in August.

Recruitment advertisement for current vacancy appended to this publication will appear in *The Irish Times*, 3 October 2003 – Closing date 24 October 2003

Proposed Fees increase for 2004

The IMB is in discussion with the Department of Health and Children, the Department of Agriculture and Food and the various trade associations on a proposed fee increase for 2004. At the time of writing, the discussions have not concluded, but it is expected that final agreement will be reached with the departments to allow the proposed increase to come into effect in January 2004. Under the IMB Act, 1995, the IMB is required to ensure that the cost of the services it provides is fully funded. Once government approval for a fee increase has been given, the IMB will update stakeholders accordingly.

HUMAN MEDICINES

LEGISLATION AND GUIDELINES

Legislation

- Commission Regulation (EC) No. 1085/2003, concerning variations for medicinal products falling within the scope of Council Regulation (EEC) No. 2309/93.
- Commission Regulation (EC) No. 1084/2003, concerning variations to medicinal products granted by a competent authority of a Member State.
- Updated Annex I to 2001/83 on the Community code relating to medicinal products for human use.

Application forms/formats

- Part 1A - Administrative information:
- User Guide for the Part IA application Form.
- Revised EU variation application form.
- Notice to Applicants, Updated CTD, July 2003.

CONTENTS

Guidelines

- Guideline on the dossier requirements for type IA and IB notifications for minor variations to the terms of marketing authorisations in the mutual recognition and the centralised procedure.
- Updated Guideline on the processing of renewals in the mutual recognition procedure for veterinary medicinal products.
- Topic E2B(M), Step 5 Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (Release for information July 2003).
- CPMP/SWP/4447/00 Note for guidance on Environmental Risk Assessment on Medicinal Products for Human Use (Released for consultation July 2003).
- CPMP/QWP/609/96 Rev. 1 Note for guidance on Declaration of Storage Conditions for Medicinal Products Particulars and Active Substances (Annex to note for Guidance on Stability Testing of New Active Substances and Medicinal Products, Annex to Note for Guidance on Stability of Existing Active Substances and Related Finished Products)(Adoption by CPMP April 2003).
- CPMP/EWP/205/95 Revision 2 Note for Guidance on Evaluation of Anticancer Medicinal Products in man (CPMP adopted July 2003).
- CPMP/EWP/569/02 Addendum on Paediatric Oncology (CPMP released for consultation July 2003).
- CPMP/EWP/967/01 Note for guidance on the Evaluation of Medicinal Products indicated for Thrombolysis in Acute Myocardial Infarction (STEMI) (CPMP adopted June 2003).

NEW VARIATION REGULATIONS

The Commission has recently published the revised variations regulations (EC) No. 1084/2003 and 1085/2003, which come into effect from 1 October 2003. The new regulations define variations as Type 1A and 1B minor variations and Type II major variations. The Commission guideline on dossier requirements has also been updated to include details on all Type IA and IB variations, the conditions which apply and the documentation which must be submitted with applications. A new variation form has been drafted and the MRFG has revised its Best Practice Guides for mutual-recognition variations. Relevant documents have now been uploaded onto the Publications section of the IMB website.

The IMB is implementing the new categories of Type IA and IB from 1 October, 2003 for national applications. From 1 October, applicants should use the new application form and submit variations in line with the regulations and with the dossier requirements set out in the Commission's guideline. From 1 January 2004, no variation application will be accepted unless it is accompanied by the new form and the appropriate documentation. The current variation fees will apply to new variations submitted from 1 October. The fees specified in SI No. 252 of 2002 are under review at present with the Department of Health and Children.

CHANGE IN PROCEDURE FOR RENEWAL APPLICATIONS

IMB procedures for processing renewal applications are being revised. Starting in October 2003, applicants will be sent a single request for comments on the draft schedule and for signed and dated colour mock ups of the labels and leaflet, along with any queries which have arisen from the assessment. The response from applicants should include:

- any corrections to the draft schedule annotated on the copy which is sent to them,
- responses to any queries which have been raised,
- signed and dated colour mock ups which have been amended in line with comments from the assessors.

This change is taking place so that the proposed renewal schedule can be agreed during the assessment, rather than at the end of the procedure.

Failure to respond to the query letter and request for comments on the draft schedule within 30 days, or to send a complete response, will result in the PA being considered withdrawn and the files closed.

In relation to specific IMB requirements the request for a quality defect report will be replaced by a signed statement that any significant quality defect which impacts on the safe and appropriate use of the medicinal product has been satisfactorily addressed by the PA holder, and notified to the inspectorate department of the IMB where appropriate.

PIGGYBACK PAs

IMB policy on piggyback PAs where the original product is withdrawn has been changed. Where the original is withdrawn, the holder of a piggyback PA can either obtain a letter of access to another PA or submit Part II data on his own behalf. The original Part II data (including all variations) may be submitted as a Type II complex variation, however a different Part II or a letter of access to another PA must be submitted as a new application, for which a new PA number will be assigned.

Whichever option is chosen, it must be applied for sufficiently in advance of the next renewal application in order for the application to be approved before the authorisation expires. If none of the options are available, the piggyback PA holder should advise the IMB that the PA is not being renewed.

This policy will apply from 1 November.

INCLUSION OF SAFE5TY DATA IN THE SPC

PA holders are reminded that, while it is possible to include new safety information (as reported in the Periodic Safety Update Report) in the SPC at the time of renewal, it is not possible to perform routine updates to the SPC at renewal. New safety information refers to safety information which comes to light at the time of renewal only. Otherwise, all safety information should be incorporated into the SPC by way of a variation application, as it arises.

SUBMISSION OF ADVERSE DRUG REACTION/ADVERSE EVENT REPORTS

Further to previous guidance (see IMB Quarterly Newsletter Nos. 11 and 12) on submission of suspected adverse drug reaction (ADR) reports to the IMB, it is necessary to again request companies to adhere to the following points:

- All cases of Irish origin should be submitted *under separate cover* to foreign cases and should also be identified according to type (initial/follow-up).
- Spontaneous and clinical trial reports should be segregated and submitted *under separate cover*.
- All correspondence regarding spontaneous reports should include reference to the product authorisation (PA) number and in the case of follow-up reports for Irish cases, *the IMB case reference number*.
- All correspondence regarding clinical trial reports should include reference to the Irish Medicines Board clinical trial number and the relevant protocol number. As of 01 May 2002, the Irish Medicines Board is issuing reference numbers for ADR reports originating in Ireland only. In addition to the IMB's clinical trial number, these numbers should also be quoted on any relevant follow-up correspondence.
- Post marketing surveillance study reports should be sent to the Clinical Trials Unit only.

PERIODIC SAFETY UPDATE REPORTS

When preparing PSURs for submission, companies are reminded of the need to relate the "Company Core Data Sheet" (CCDS) – "Company Core Safety Information" (CCSI) and the safety information to the Irish SPC, as outlined in Volume 9 - Notice to Marketing Authorisation Holders (1.4.3.4):

"When meaningful differences exist between the CCSI and the safety information in the EU SPC (or the official data sheets/product information documents approved in a country), a brief comment should be prepared by the marketing authorisation holder, describing the local differences and their consequences on the overall safety evaluation and on the actions proposed or initiated. This commentary may be provided in the cover letter or other addendum accompanying the local submission of the PSUR".

GUIDELINE ON EXCIPIENTS IN THE LABEL AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE

This Notice to Applicants guideline has now been revised and a new version issued in July 2003. The legal basis for the guideline comes from Directive 2001/83/EC which requires the European Commission to publish guidelines (article 65) on the excipients which must be included on labelling, because they have a 'recognised action or effect' (article 54); information on them must be given in the package leaflet for the 'safe and effective use of the medicinal product' (Article 59).

The revised version of the guideline provides new definitions and examples of excipients, details how excipients are to be named and clarifies the requirements for inclusion of excipients in the label and package leaflet. The annex to the guideline provides an amended list of specific excipients which must be declared on the label and for which information must appear in the package leaflet. The information for the leaflet is written in clear and understandable terms for the patient. The specified wording should be used, where relevant, in all package leaflets.

The IMB will implement the requirements of the guideline to all leaflets. PA holders should ensure their leaflets comply with the requirements by 1 January 2005. Any leaflet submitted with an application for renewal up to the end of December 2004 should include the required label and leaflet statements; for other authorised products, a variation application should be submitted by the end of December 2004.

PROMOTION TO THE PUBLIC

We would like to draw PA holder's attention to the following restrictions on the sale, supply and promotion of certain medicinal products.

Sample packs

Under Article 14.3 of the Medical Preparations (Advertising) Regulations 1993, a controlled drug under Section 2 of the Misuse of Drugs Act 1997 (SI No 12 of 1977) may not be supplied as a sample to doctors or dentists, nor any product which is an antidepressant, hypnotic or tranquilliser. Section 2 of the Misuse of Drugs Act includes such substances as codeine, dextropropoxyphene, pholcodine and selegilene.

Window displays

Recently we have become aware of inappropriate promotion of certain analgesics by window displays in pharmacies. The products contained codeine, which along with other analgesics such as dextropropoxyphene, may not be promoted to the public. PA holders should note that window displays are, effectively, promoting products to the public. This matter has also been brought to the attention of the Pharmaceutical Society of Ireland.

CLINICAL TRIALS – SUBMISSION OF A REVISED INVESTIGATOR BROCHURE

Permission holders are reminded that any revisions to investigator's brochures should be submitted as clinical trial variations with the following information clearly indicated:

1 The sections which have been updated and the justification for the update
2) Any change in the 'expectedness' of an Adverse Drug Reaction, including any increase in the specificity or severity of a previously expected effect.

The permission holder is requested to comment on the impact of these updates on the study and submit variations to the protocol and/or patient information leaflet, where necessary.

IMPLEMENTATION OF THE CLINICAL TRIALS DIRECTIVE

The IMB is currently working on a project to implement the requirements of the Clinical Trials directive (2001/20/EC) in relation to the application for clinical trial authorisation and the procedures for meeting the 60-day timeline for completing the assessment. A draft procedure will be presented at the Human Medicines Information Day on 29 September and will also be available shortly afterwards from the IMB website.

We are also working on a number of forms and guidelines to support the application process. These include:

- Application form for additional IMB requirements for clinical trials.
- Guide to making an application for clinical trial authorisation
- User Guide to the EU application forms
- Guidance on the investigational medicinal product dossier
- Protocol template

Draft documents will be posted on the IMB website by the end of 2003.

Comments on the proposed procedure and the draft documents should be sent to Dr Caitríona Fisher, caitriona.fisher@imb.ie. Please check the website for the comments due date.

HERBAL MEDICINES PROJECT

Comment on the IMB Herbal Medicines Project report and on the report on the IMB Herbal Medicines Seminar held in May 2002 is still awaited from the Minister for Health and Children.

EU DIRECTIVE ON TRADITIONAL HERBAL MEDICINAL PRODUCTS

The Italian Presidency held two Council Working Group meetings on the proposed Directive on Traditional Medicinal Products, on 7 and 8 July 2003 and 22 July 2003 respectively. The Commission proposal following the first reading at the European Parliament and including the outcome of the last Council Working Group in October 2002 formed the basis for the discussion.

Overall the modified Directive received the support of the majority of Member States.

The next Council Working Group meeting is scheduled for 2 September 2003 with a view to forwarding the proposal to COREPER on 12 September 2003 and then on to the second Reading at the European Parliament.

The aim of the Italian Presidency is to ensure that the Directive will undergo its second reading at Parliament before the appointment of the new Parliament next year.

HOMEOPATHIC MEDICINES PROJECT

Homeopathic Medicinal Products for Human use:

Simplified Registration Scheme. Medicinal Products (Licensing and Sale) Regulations, S. I. No. 142 of 1998.

Companies who wish to market homeopathic medicinal products which qualify for the Simplified Registration Scheme, as provided for in the above regulations and in accordance with EU Directives for Human Medicines, 92/73/EEC and 2001/83/EC are notified that applications for such registration can be submitted to the IMB with effect from the 1st of October 2003.

Applications will be considered sequentially by the IMB, in the following order:

1. Mineral, single substance products.
2. Plant, single plant products.
3. Animal, single animal products.
4. Complex, products that contain more that one homeopathic stock.
5. Other, any homeopathic medicinal product not included in categories 1 – 4.

All applications for products containing single mineral substances, in homeopathic dilution, must be submitted to the IMB by 31 January 2004, in order that they may lawfully remain on the market.

The remaining categories should be submitted during 2004/2005 and companies will be notified in due course of the appropriate dates.

Any product in the single mineral category for which an application has not been submitted by the date above must be removed from the market by 31 March 2004.

Guidance Notes and Application Forms are available directly from the IMB or on the web site at **www.imb.ie**.

VETERINARY MEDICINES

LEGISLATION AND GUIDELINES

The following guidelines have been adopted by the CVMP from June and July 2003:

- Note for Guidance on Declaration of Storage Conditions for Veterinary Medicinal Products and Active Substances (EMEA/CVMP/422/99-Rev.2-FINAL) Implementation date. October 2003
- Note for Guidance on Quality of Modified Release Dosage Forms for Veterinary Use (EMEA/CVMP/680/02-FINAL). Implementation date February 2004.
- Warning regarding inadvertent self-injection of mineral-oil containing products – confirmation of scope of warning (EMEA/CVMP/692/03) – warning applies to both immunological and pharmaceutical products.

These documents are available on the EMEA web site: **http://www.emea.eu.int**

CHANGES TO EU VETERINARY MEDICINES LEGISLATION

The IMB notes that political agreement on a revised text for the EU Directive and Regulation on veterinary medicinal products has been reached under the Greek presidency and that the modified proposals will

now be referred to the Council of Ministers for adoption ahead of a Second Reading in the European Parliament, possibly in October. The outcome of these discussions will be closely monitored by the IMB as they are likely to impact in a significant way on the regulation and availability of medicines in Member States. The IMB is not directly represented in these discussions; rather the representation is made by officers of the relevant government departments who inform the IMB of the progress achieved.

The IMB is also in discussion with the Department of Agriculture and Food on the definition of biocidal products and their overlap with animal remedies regulated within the scope of the veterinary medicinal products legislation. As and when those discussions are concluded, it is expected that a revised IMB 'Guide to the Definition of an Animal Remedy' will be issued.

NEW VARIATION REGULATIONS

The Commission has recently published the revised variations regulations (EC) No. 1084/2003 and 1085/2003, which come into effect from 1 October 2003 for mutual recognition and centralised authorisations. The new regulations define variations as Type IA and IB minor variations and Type II major variations. The Commission guideline on dossier requirements has also been updated to include details of all Type IA and IB variations, the conditions, which apply, and the documentation, which must be submitted with applications. For veterinary medicines, the VMRFG has prepared draft revisions of its Best Practice Guides for mutual-recognition variations. These are currently available for consultation and will be finalised prior to the implementation date on 1st October (they can be viewed on the HEVRA website http://www.hevra-com). Relevant documents have now been uploaded onto the Publications section of the IMB website.

The IMB is implementing the new categories of Type IA and IB from 1 October, 2003 for national applications. From 1 October, applicants should use the new application form and submit variations in line with the regulations and with the dossier requirements set out in the Commission's guideline. From 1 January 2004, no variation application will be accepted unless the new form and the appropriate documentation accompany it. The current variation fees will apply to new variations submitted from 1 October.

STAFF CHANGES IN VETERINARY DEPARTMENT

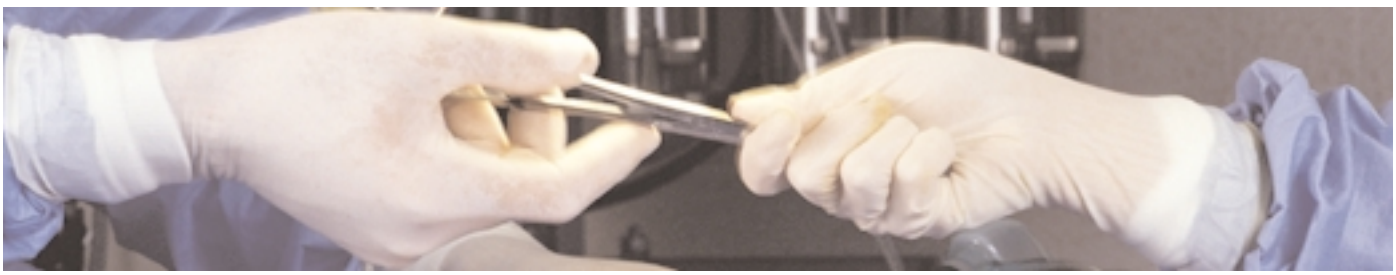
MS. PEARL HEALY, who has recently joined the Veterinary Department from the Human Medicines Department, has taken over responsibility for licence renewals and variations from *MS. CELINE DOUDELLE*. Celine has replaced *MS. SIMONA BORDEAN* who herself was recently promoted and has joined the Human Medicines Licensing Team. Celine will be taking leave of absence for some months, commencing in October, having volunteered to work in Africa in a project to support the poor and children suffering from HIV/Aids. *MS. EMILY HASSETT* has recently joined the Veterinary Department and has responsibility for the management of borderline applications for classification status and clinical trials as well as to provide support for her colleagues in the administration of the department. *MS. SINEAD MURPHY* continues to devote significant time to the ongoing scanning of application files and to support her colleagues in the day-to-day administration activities. Finally, *DR. TRACY KEANE* has taken up a position with the Human Medicines Department and will cease involvement in the licensing of veterinary vaccines once her current files are closed out.

THE USE OF BENZATHINE PENICILLIN IN FOOD-PRODUCING ANIMALS

Following the unanimous opinion of the Committee for Veterinary Medicinal Products, EMEA, in January 2003 that the marketing authorisations for veterinary medicinal products containing benzathine penicillin intended for intramuscular and / or subcutaneous administration to food-producing species be suspended, the EU Commission endorsed the decision on the 22 May, 2003. The rationale for the decision was that it was not possible to establish withdrawal periods on the basis of the available data due to the persistence of residues at the site of injection.

CHANGES TO TELEPHONE NUMBERS OF VETERINARY DEPARTMENT

The IMB has responded to concerns of difficulty in contacting its offices and has changed its internal telephone system. This should facilitate quicker access to IMB personnel. While the IMB's telephone number has remained unchanged (+ 353 (0) 1 676 4971) the extension numbers previously in existence have been changed. All queries on the licensing of veterinary medicines should be routed through the Veterinary Administration Team and communicated to Ms. Sinead Barron on extension 3316, Ms. Pearl Healy on 3318, or Ms. Sinead Murphy on 3319. Alternatively, you may send an email to **vetinfo@imb.ie** or a fax to +353 1 676 7836.



INSPECTORATE

RESPONSES TO INSPECTION REPORTS

Each inspection report includes instructions regarding the format of the response that the company should follow.

In relation to the supporting information which should accompany the response, this should be kept to a minimum. In particular, it is generally not necessary to include copies of SOPs. Typically, a statement that the relevant SOP will be / has been amended, or will be introduced by a specific date will suffice.

There will be occasions where companies will be requested to provide SOP's, but this will be indicated to the company, for example, in the cover letter with the inspection report, or in follow-up correspondence.

RETURNS OF MEDICINAL PRODUCTS REQUIRING REFRIGERATED TEMPERATURE

Distributors of medicinal products, particularly wholesalers, are aware that validation is required for the distribution of 'cold chain' products (products requiring storage between 2ºC and 8ºC). This is to demonstrate that the required temperature conditions are maintained throughout the distribution period.

In relation to returns, it was previously communicated to wholesalers that cold chain returns could only be accepted if returned on the same day (i.e. on the day on which the packs were distributed). This position has been revisited and modified.

The revised IMB position is that cold chain products may only be returned to saleable stock where there is no reasonable possibility that the cold chain has been compromised. For example, under the following circumstances, the return of product could be considered:

1. the batch number of the distributed product is known, and:
2. the entire process is validated (i.e. delivery to customer, opening of the packaging, examination of the product, returning of the product to the packaging and sealing of the packaging, collection by the courier/transporter, and return to the distribution site refrigerator).

However, the IMB is not aware of any cold chain system that would have the ability to perform to the above criteria.

Alternatively, return of cold chain products could be considered where there is a unique monitoring system attached to the product which would demonstrate whether the product has been stored outside refrigerated conditions.

MANUFACTURERS OF INVESTIGATIONAL MEDICINAL PRODUCTS (CLINICAL TRIAL PRODUCTS)

The Clinical Trials Directive 2001/20/EC is due for implementation by 1 May, 2004. The procedures relating to manufacturers of investigational medicinal products (IMPs) have not yet been fully developed, (i.e. requirements for licensing, format of licence, requirements or nature of inspections, etc).

However, manufacturers of IMPs are invited to inform the Inspectorate of their activities in this area. Manufacturing may be considered as compounding, filling, packing, labelling or other related activities. The following details should be provided to the Inspectorate Department when informing IMB of activities in this area: company name, company address, contact name, contact number, contact email address and description of activities performed. The IMB will meet with any manufacturer which intends to apply for a licence to manufacture IMPs. The provision of this information will enable a smooth transition when the Directive is implemented.

The above information should be submitted to Ms. Fiona McEvoy, IMB's Inspectorate Department, in writing or by email to fiona.mcevoy@imb.ie

WHEN IS A BATCH OR PRODUCT WITHDRAWAL CLASSIFIED AS A RECALL?

A product recall may be defined as the retrieval from the marketplace of a batch or batches of any medical preparation, whether for human or veterinary use. A product recall will normally arise because the product/batch has been found not to conform with acceptable standards of safety, quality and/or efficacy.

Once a batch of a medicinal product has been QP-released and has left the manufacturing facility which released it, the batch is considered to have been placed onto the market. Any retrieval of such a batch is considered to be a batch/product recall. Thus, all withdrawals of product from a primary distributor are considered by IMB to be recalls, even if the product is still under the ownership of the manufacturer or PA/VPA Holder when in the posession of the primary distributor.

All recalls of medicinal product from the Republic of Ireland marketplace are required to be notified to the Inspectorate Department of IMB in advance of the recall ocurring, so that the terms of the recall can be agreed, and the implications for other products, for the supply chain and for patients/users can be considered and evaluated.

In cases where a batch or product was manufactured and/or QP-released in the Republic of Ireland, and is being recalled in another marketplace (i.e. not in the Republic of Ireland), the Inspectorate Department must be promptly informed of such actions by the PA/VPA holder or by the manufacturer.

NEW INSPECTORATE CONTACT DETAILS FOR QUALITY DEFECTS, PRODUCT RECALLS AND EMERGENCY SITUATIONS

In light of IMB's recent restructuring as part of the NIMBUS project, IMB's office-hours contact details and out-of-hours contact details for quality defects, product recalls and other

emergency situations have changed. The new contact details are as follows:

Name	*Position*	*Office contact details*	*Out-of-hours Contact Details*
Mr. John Lynch	Director of Inspection, Inspectorate Department	01-676 4971 john.lynch@imb.ie	01-8305697 087-2347294
Mr. Kevin O'Donnell	GMP Inspector, Inspectorate Department	01-676 4971 kevin.odonnell@imb.ie	087-9562818

Please update your recall procedures and other related documentation to reflect the above.

PROVISION OF PRODUCT RECALL INFORMATION ON IMB'S WEBSITE

From January 2004 onwards, the Inspectorate Department will post on the IMB website (www.imb.ie) details concerning all recalls of medicinal products from the Republic of Ireland marketplace from January 2004 on. The format of such notifications, and the extent of information provided in the notifications, is currently being determined. Interested parties who wish to discuss the planned notification of product recalls on IMB's website are invited to contact Kevin O'Donnell at kevin.odonnell@imb.ie

Information which is the subject of Caution-in-Use notifications to healthcare professionals, or information which is the subject of a Dear Doctor letter issued at the request of IMB, will also be made available on IMB's website when considered necessary.

LINK BETWEEN NEWSLETTER INSPECTORATE GUIDANCE ARTICLES AND IMB WEBSITE

Please be advised that the Inspectorate Department plans to place all guidance articles published in this and in future editions of the IMB Newsletter on the Inspectorate pages of the IMB website.

BATCH SPECIFIC REQUESTS

PA/VPA Holders and Manufacturers are advised that all batch specific request applications are to be sent to the Receipts and Validation Unit in IMB, and not to the Inspectorate Department. The Inspectorate Department does not review or approve such applications, but we are available to provide advice on GMP and GDP matters relating to the application. This is particularly relevant for cases where repackaging and/or overlabelling activities are being proposed, and also for proposals arising out of a quality defect issue.

In this regard, GMP and GDP-related queries relating to batch specific request applications may be forwarded to Kevin O'Donnell, but the application and associated documentation should be addressed to the Receipts & Validation Unit in IMB.

MUTUAL RECOGNITION AGREEMENTS

The latest updates on all of the MRAs are available from the website of the European commission at: http://www.emea.eu.int/htms/technical/mra/mra.ht

Human New Product Authorisations Issued (May – August 2003)

PA Number	Product Name	PA Number	Product Name
PA0004/058/001	PARACETAMOL CAPLETS	PA0711/024/004	RANITIC
PA0013/066/002	RITALIN LA	PA0823/033/001	SUDAFED NON-DROWSY DECONGESTANT
PA0013/066/003	RITALIN LA		
PA0013/066/004	RITALIN LA	PA0913/023/001	ZEROPAN
PA0077/158/001	AMISULPRIDE	PA0913/023/002	ZEROPAN
PA0077/158/002	AMISULPRIDE	PA0913/023/003	ZEROPAN
PA0077/158/003	AMISULPRIDE	PA0913/023/004	ZEROPAN
PA0077/158/004	AMISULPRIDE	PA1009/017/001	NORDURINE
PA0126/110/001	PROZAMEL	PA1009/017/002	NORDURINE
PA0144/045/001	PRURICALM	PA1063/003/001	BIOCARD
PA0290/063/002	ALOMIDE ALLERGY	PA1063/003/002	BIOCARD
PA0476/014/001	HISTEK ALLERGY	PA1063/003/003	BIOCARD
PA0476/014/002	HISTEK	PA1063/003/004	BIOCARD
PA0711/017/001	ACIC	PPA0465/080/003A	DETRUSITOL SR
PA0711/017/003	ACIC LYOPHILISATE	PPA0465/085/003A	EFEXOR XL

Human New Product Authorisations Issued (continued) (May – August 2003)

PA Number	Product Name
PPA0465/085/004A	EFEXOR XL
PPA0465/092/005A	LAMICTAL DISPERSIBLE
PPA0465/092/006A	LAMICTAL DISPERSIBLE
PPA0465/092/007A	LAMICTAL DISPERSIBLE
PPA0465/099/001A	ZOMIG
PPA0465/104/001A	AMARYL
PPA0465/104/002A	AMARYL
PPA0465/104/003A	AMARYL
PPA1071/007/001A	VENTOLIN EVOHALER
PPA1071/008/001A	PROTHIADEN
PPA1071/009/001A	ZANTAC TABLETS 150 MG
PPA1071/009/002A	ZANTAC
PPA1071/010/001A	BECOTIDE 50 INHALER
PPA1071/010/002A	BECOTIDE 100 INHALER
PPA1071/011/001A	BECONASE AQUEOUS
PPA1071/012/001A	TAGAMET
PPA1071/012/002A	TAGAMET
PPA1071/013/001A	BRUFEN RETARD

Human Product Authorisations Withdrawn (May – August 2003)

PA Number	Product Name
PA0009/007/002	XYLOPROCT
PA0009/016/006	XYLOCAINE
PA0009/016/009	XYLOCAINE PLAIN
PA0009/016/013	XYLOCAINE PLAIN
PA0009/016/022	XYLOCAINE
PA0009/035/002	EMLA PATCH
PA0013/021/001	TAVEGIL
PA0013/047/001	WATER FOR INJECTION PH.EUR.
PA0013/049/001	CLIMAVAL
PA0013/049/002	CLIMAVAL
PA0013/055/001	CLIMESSE
PA0013/071/002	ESTRAPAK
PA0016/002/001	DALACIN C PAEDIATRIC
PA0016/010/002	MYCIFRADIN SULPHATE
PA0016/031/001	PROSTIN F2 ALPHA STERILE
PA0016/043/001	PREPIDIL
PA0016/050/001	LOMEXIN
PA0016/050/002	LOMEXIN PESSARY
PA0016/050/003	LOMEXIN VAGINAL CREAM
PA0017/097/001	DUACT
PA0017/097/002	DUACT LA
PA0019/003/001	ATARAX
PA0019/003/002	ATARAX
PA0019/007/001	TERRACORTRIL
PA0019/008/001	TERRACORTRIL
PA0019/009/001	TERRAMYCIN
PA0019/009/007	TERRAMYCIN
PA0019/023/003	HYPOVASE
PA0019/025/001	DIABINESE
PA0019/025/002	DIABINESE
PA0019/033/001	GYNO-TROSYL
PA0019/033/002	GYNO-TROSYL
PA0019/033/003	GYNO-TROSYL
PA0019/036/001	ALEXAN
PA0019/036/002	ALEXAN
PA0019/036/003	ALEXAN
PA0019/036/004	ALEXAN
PA0019/037/001	FASIGYN
PA0022/043/002	OXAZEPAM
PA0022/043/003	OXAZEPAM
PA0022/053/001	ANTEPSIN
PA0022/053/002	ANTEPSIN
PA0022/053/003	ANTEPSIN
PA0024/001/009	VENTOLIN INHALER
PA0030/031/001	BRADOSOL
PA0037/004/001	LOXAPAC
PA0037/004/002	LOXAPAC
PA0037/004/003	LOXAPAC
PA0037/004/006	LOXAPAC
PA0037/004/007	LOXAPAC
PA0037/004/008	LOXAPAC
PA0046/016/007	BURINEX
PA0046/024/008	ONE-ALPHA
PA0046/062/003	BOCATRIOL
PA0050/135/001	ETHYL CHLORIDE BP
PA0054/009/001	OPTIMAX
PA0054/041/001	SEPTOPAL
PA0054/041/002	SEPTOPAL
PA0057/012/001	NORGESIC
PA0062/024/001	STAFOXIL
PA0062/024/002	STAFOXIL
PA0073/096/001	DANAZANT
PA0073/096/002	DANAZANT
PA0077/003/001	HEXOPAL
PA0077/008/002	BENORAL
PA0077/045/001	STROMBA

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Human Product Authorisations Withdrawn (continud) (May – August 2003)

PA Number	Product Name
PA0077/051/001	MICTRAL
PA0077/116/001	TRIFYBA
PA0148/043/002	PRED G LIQUIFILM STERILE OPHTHALMIC
PA0167/068/003	ISOTONIC GENTAMICIN
PA0167/068/006	ISOTONIC GENTAMICIN
PA0167/068/011	ISOTONIC GENTAMICIN
PA0167/068/014	ISOTONIC GENTAMICIN
PA0261/030/001	GYNOXIN
PA0277/010/001	ATROPINE SULPHATE
PA0277/011/001	CHLORAMPHENICOL
PA0277/012/001	HOMATROPINE
PA0277/012/002	HOMATROPINE
PA0277/014/001	HYPROMELLOSE
PA0277/018/001	PILOCARPINE
PA0277/018/002	PILOCARPINE
PA0277/018/003	PILOCARPINE
PA0277/018/004	PILOCARPINE
PA0281/024/001	PURINOL - ALLOPURINOL
PA0281/024/002	PURINOL - ALLOPURINOL
PA0289/008/002	PRAXILENE
PA0365/080/001	ZAROXOLYN
PA0365/080/002	ZAROXOLYN
PA0372/001/003	METROLYL
PA0372/001/004	METROLYL
PA0437/017/001	CARBOPLATIN
PA0439/001/001	GOLYTELY
PA0447/005/006	PROZAC DISPERSIBLE
PA0469/004/001	METAZEM
PA0473/003/009	ZEPHOLIN AMPOULE
PA0473/009/001	PENTOXIFYLLINE AMPOULES
PA0473/009/002	PENTOXIFYLLINE S.R.
PA0473/009/003	PENTOXIFYLLINE 600 MG SR
PA0484/002/001	BENZYL BENZOATE
PA0544/023/003	HB-VAX II
PA0549/002/001	ETHYPHARM IBUPROFEN SPARKLETS
PA0549/002/002	ETHYPHARM IBUPROFEN SPARKLETS
PA0585/004/001	TIMOLOL EYE DROPS
PA0585/004/002	TIMOLOL EYE DROPS
PA0610/003/001	MENTHOL AND WINTERGREEN HEAT RUB
PA0748/006/001	DELFEN CONTRACEPTIVE
PA0748/039/001	RETINOVA
PA0778/008/001	MAXAQUIN
PA0778/013/001	NORIMIN
PA0778/015/001	NORINYL - 1
PA0778/016/001	MENOPHASE
PA0838/003/001	NYCOPREN
PA0838/003/002	NYCOPREN
PA0872/005/003	FEMATRIX 7 DAY 80
PA0964/003/001	PAVULON
PA0970/002/001	ZAFIRLUKAST ZENECA
PA0970/002/002	ZAFIRLUKAST ZENECA
PA0980/001/001	CLINITAR
PA0980/001/002	CLINITAR
PA1058/003/001	DIUREXAN
PA1063/004/001	ISOTRATE
PA1063/004/002	ISOTRATE
PA1063/004/003	ISOTRATE
PA1063/005/001	SELEGILINE
PA1063/005/002	SELEGILINE
PA1063/007/001	TRAMADOL HYDROCHLORIDE
PA1063/008/001	ZACTOLINE
PA1063/008/002	ZACTOLINE
PA1077/093/003	AUGMENTIN JUNIOR
PA1077/093/005	AUGMENTIN PAEDIATRIC
PA1110/008/001	QUINOCORT
PPA0465/049/001A	CLARITYN
PPA0465/049/001C	CLARITYN
PPA0465/049/001E	CLARITYN
PPA0465/051/001C	KLACID
PPA0465/051/001F	KLACID

Human New Product Authorisations (Mutual Recognition) (May – August 2003)

PA Number	Product Name
PA0012/072/002	SKINOREN
PA0030/021/009	NICOTINELL MINT
PA0030/040/003	BOOTS NICOTINE
PA0043/039/001	E45 ITCH RELIEF CREAM
PA0050/151/001	BEROCCA PLUS
PA0050/151/002	BEROCCA PLUS
PA0118/047/001	TIMOLOL CHAUVIN
PA0118/047/002	TIMOLOL CHAUVIN
PA0126/125/001	SIMVATAN
PA0126/125/002	SIMVATAN
PA0126/125/003	SIMVATAN
PA0126/125/004	SIMVATAN

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Human New Product Authorisations (Mutual Recognition) (continued) (May – August 2003)

PA Number	Product Name
PA0148/062/001	RELESTAT
PA0148/063/001	LIQUIVISC
PA0167/009/030	GLUCOSE 5%
PA0167/054/005	RINGERS
PA0167/112/001	BUPIVACAINE HYDROCHLORIDE
PA0167/112/002	BUPIVACAINE HYDROCHLORIDE
PA0172/019/003	SECLODIN
PA0240/007/002	MYOVIEW
PA0282/086/001	HAY-RITE 10MG TABLETS
PA0282/087/001	FLUCAZOL
PA0282/087/002	FLUCAZOL
PA0282/087/003	FLUCAZOL
PA0320/008/002	DURAPHAT 5000 PPM FLUORIDE
PA0408/057/001	LISINOPRIL
PA0408/057/002	LISINOPRIL
PA0408/057/003	LISINOPRIL
PA0408/057/004	LISINOPRIL
PA0544/037/001	VIATIM
PA0566/027/001	HYPERHAES
PA0566/032/001	SODIUM CHLORIDE 0.9%
PA0566/032/002	SODIUM CHLORIDE 0.9%
PA0566/032/003	SODIUM CHLORIDE 0.9%
PA0566/032/004	SODIUM CHLORIDE 0.9%
PA0573/003/001	SALOFALK GRANU-STIX
PA0573/003/002	SALOFALK GRANU-STIX
PA0573/003/003	SALOFALK GRANU-BOX
PA0577/041/004	ZESGER
PA0577/047/001	CIPRAGER
PA0577/047/002	CIPRAGER
PA0577/048/001	ZOLPIGER
PA0669/004/002	OCTEGRA
PA0669/004/003	OCTEGRA
PA0689/002/001	SOLARAZE
PA0711/047/001	LISPRIL
PA0711/047/002	LISPRIL
PA0711/047/003	LISPRIL
PA0711/047/004	LISPRIL
PA0711/048/001	CITROL
PA0748/009/004	SPORANOX I.V.
PA0818/004/001	LEVONELLE
PA0819/019/002	FELODIPINE XL
PA0819/019/003	FELODIPINE XL
PA0959/002/001	MOMENDOL
PA1054/001/001	ANDROGEL
PA1054/001/002	ANDROGEL
PA1054/002/001	TESTOGEL
PA1054/002/002	TESTOGEL
PA1063/015/001	RITECHOL
PA1063/015/002	RITECHOL
PA1063/015/003	RITECHOL
PA1077/099/001	HEPATYRIX
PA1090/001/001	DICLOFENAC SODIUM 4% SPRAY GEL
PA1091/001/001	EZETROL
PA1091/002/001	EZETIMIBE
PA1099/001/001	OMACOR

Veterinary New Product Authorisations Issued (May – August 2003)

VPA Number	Product Name
10915/010/001	LEVITAPE
10960/047/001	KEELOGANE SC
10960/049/001	BOVISEAL NON ANTIBIOTIC
10999/099/001	PARAFEND PLUS ORAL SUSPENSION

Veterinary Mutual Recognition Authorisations Issued (May – August 2003)

VPA Number	Product Name
10817/001/001	BIOAMOXI
10835/047/001	MILBEMAX FOR SMALL DOGS AND PUPPIES
10835/047/002	MILBEMAX FOR DOGS
10835/048/001	MILBEMAX FOR SMALL CATS AND KITTENS
10835/048/002	MILBEMAX FOR CATS
10989/050/001	SEDAXYLAN, 20 MG/ML SOLUTION FOR INJECTION

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Veterinary Product Authorisations Withdrawn (May – August 2003)

VPA Number	Product Name	VPA Number	Product Name
10007/030/001	EQUITRIM	10913/002/001	FENAZOLE
10019/002/001	TERRAMYCIN Q50	10913/002/002	FENAZOLE
10019/009/001	TERRAMYCIN Q100	10954/008/001	CIDIROL
10019/024/001	VALBAZAN CATTLE WORMER	10987/047/001	CHANAMAST
10484/019/001	FORANS WOUND POWDER		

Veterinary Immunological Review Authorisations Issued (May – August 2003)

VPA Number	Product Name	VPA Number	Product Name
10019/066/001	IMURESP RP	10996/078/001	BOVILIS IBR
10019/067/001	RISPOVAL RS	10996/080/001	TOXOVAX
10846/003/001	HIPRABOVIS-4	10996/082/001	BOVILIS IBR+PI3 LIVE
10857/032/001	TRIVACTON 6	10996/086/001	NOBILIS RISMAVAC + CA126
10857/033/001	IMOCOLIBOV	10996/145/001	HEPTAVAC
10857/034/001	MILOXAN	10857/044/001	GESKYPUR

Veterinary Immunological New Product Authorisations Issued (May – August 2003)

VPA Number	Product Name	VPA Number	Product Name
10857/051/001	GALLIVAC IB88	10996/175/001	NORVAX COMPACT 4

Veterinary Immunological Mutual Recognition Authorisations Issued (May – August 2003)

VPA Number	Product Name	VPA Number	Product Name
10007/037/001	INGELVAC PRRS KV	10996/128/001	PORCILIS PRRS-IM
10846/004/001	MYPRAVAC SUIS SUSPENSION FOR INJECTION	10996/128/002	PORCILIS PRRS-IDAL
		10996/176/001	NOBIVAC PI
10857/048/001	PROGRESSIS	10977/007/001	TAD SALMONELLA VAC E

Appendix 1 – Recruitment Advertisement

IRISH MEDICINES BOARD

BÓRD LEIGHEASRA NA hÉIREANN
EARLSFORT CENTRE, EARLSFORT TERRACE, DUBLIN 2.
TEL: +353 1 676 4971 FAX: +353 1 676 7836

The Irish Medicines Board is the regulatory agency for human and veterinary medicines in Ireland as well as Competent Authority for Medical Devices. A vacancy now exists for:

GMP INSPECTOR

Reporting to the Director of Inspection, an Inspector is responsible for auditing of manufacturers and wholesalers of medicinal products for compliance with Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP), respectively.

Candidates must hold degree in Pharmacy, Pharmaceutical Chemistry, Chemistry, Microbiology, Biochemistry or other Biological Sciences, and have a minimum of five years experience in a facility licensed to manufacture medicinal products for human or veterinary use in at least one of the following areas: Quality Assurance, Compliance, Quality Control, Production. At least some of the experience should have been gained at a managerial level. A thorough knowledge of computer validation and/or auditing would be an advantage. Eligibility to act as a Qualified Person would also be an advantage. There is a requirement for travel within Ireland and, possibly, abroad. A full clean driving licence and use of a car are required.

Salary scale: €46,109 – €54,443 (*under review*).

The Board is an equal opportunities employer.
Shortlisting of applicants will be undertaken.

Applications in writing with a current curriculum vitae should be submitted to the Human Resources Manager at the above address from whom details of the post may be obtained

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Closing date for receipt of applications is Friday 24th October 2003.