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

IMB EU Presidency

It was our great privilege to host a series of meetings during the Irish Presidency of the European Union.

Readers will be aware that the revised medicines legislation package was agreed towards the end of the Italian Presidency. With this agreement in place, debate during the Irish Presidency concentrated on the practical aspects of implementation of the new legislation. Our Presidency also coincided with the Accession of the 10 new member states and it was a particular honour to host the presidency during this historic period. We had the privilege of welcoming over 320 delegates from the European Commission, EMEA and competent authorities in the existing 15 and 10 new Member States, along with EEA countries, to a total of 15 meetings.

Our schedule began on 12 January with a meeting of the Competent Authorities for Medical Devices. The heads of the various medicines regulatory agencies attended meetings in January and in May; and informal meetings of CPMP, COMP, MRFG, CVMP, VMRFG and Emacolex were hosted at various venues in April and May. The EU Telematics (IT) Steering Committee was hosted in May, along with an IMB-led IT conference.

In hosting these various meetings, and delivering progress on a range of topics, we have enhanced the standing of Ireland and of the IMB in the network of European competent authorities. One particular achievement at the level of the heads of medicines regulatory agencies is the establishment of a permanent secretariat to facilitate and coordinate the work of the network of agencies in the 25 EU Member States and EEA countries. This initiative should result in a significant improvement in the speed and consistency of decision making within the network.

We acknowledge the generous support of the Department of Health and Children, who provided financial support for the running of the various meetings.

INSPECTORATE INFORMATION DAY
15 OCTOBER 2004, CITYWEST HOTEL, SAGGART, CO. DUBLIN

As announced in the last IMB Newsletter, the Inspectorate Department will hold an Information Day for manufacturers and other interested parties on 15 October 2004, at the CityWest Hotel, Saggart, Co. Dublin.

A variety of Inspectorate staff will present on a number of Good Manufacturing Practice and Inspectorate-related topics of current interest. Many of the topics chosen for the day are based on suggestions made to the Inspectorate Department by a number of industry groups, and we are grateful to those groups for their helpful comments.

The topics and speakers planned for the day are listed on the following page. Please note that the order in which the presentations will be given has yet to be arranged, and will be decided prior to the event.

Applications may be submitted by post, by fax to 01 676 4061 or by e-mail to applics.infoday@imb.ie and should contain the following information for each delegate:

- Company Name
- Manufacturer's Licence Number (if applicable)
- Delegate Name
- Contact telephone number and e-mail address for delegate

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OPENING TIMES

The IMB reception will now open from 9.00 –18.00 including during lunch.

- Details relating to payment, i.e. cheque or bank transfer

The cost per delegate is €250.

All applications will be acknowledged shortly after receipt of the application and fee.

For any queries please contact Ms. Jennifer Henry at the Inspectorate Department on 01 6764971. Details are also available on the IMB website **www.imb.ie**.

DRAFT PROGRAMME – INSPECTORATE INFORMATION DAY 15 OCTOBER 2004

Topic / Provisional Title of Talk	*Speaker*
Welcome & Opening Address	Mr. Pat O'Mahony *CEO*
General Talk on the activities of the ad hoc Working Party of GMP Inspection Services at the EMEA	Mr. John Lynch *Director of Inspection*
Recall Issues & Discussion on IMB's New Recall Guidance Document	Ms. Breda Gleeson *Technical Officer*
GMP Issues relating to API Inspections	Dr. Victor Garvin *Inspector*
IMB's Market Surveillance Programme – Current Sampling and Analysis Issues	Mr. Patrick Walsh *Sampling and Analysis Officer*
Inspectorate Related Issues for Manufacturers of Investigational Medicinal Products	Dr. Chris Cullen *Senior Inspector*
QP Issues and Topics of current Interest	Mr. Greg McGurk *Inspector*
Validation of Computerised Systems	Dr. Patrick Costello *Inspector*
Technical Agreements and third Country Importation Issues	Mr. Paul Sexton *Senior Inspector*
TSE Issues for Inspections	Ms. Zoe Nelson *Inspector*
Risk Assessment – GMP Requirements for Risk Assessment in Qualification, Validation & Change Control	Mr. Kevin O'Donnell *Inspector*
Question & Answer Session	

INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE ANNUAL MEETING (ISOP)

Pharmacovigilance - Current and Future Challenges

DUBLIN, 6 – 8 OCTOBER 2004

This year the IMB has the pleasure of acting as the local organisers for the annual ISoP meeting, which will take place from 6 - 8 October 2004, at the Conrad Hotel in Dublin.

ISoP (formerly known as ESOP) is an organisation established to bring together experience and expertise in pharmacovigilance from academia and the pharmaceutical industry, as well as regulatory agencies. This year, the latest developments in the field of drug safety will be discussed.

A significant aspect of the ISoP meeting is presentation of posters on results of research activities, with publication of abstracts and poster submissions.

The ISoP annual meeting provides an opportunity for all those involved in pharmacovigilance around the world to meet. Further information regarding the conference is available from the IMB website under 'ISOP, Dublin, October 2004'. It is also possible to register for the conference from this webpage.

Meeting Venue and Arrangements

The venue for ISoP 2004 is the Conrad Hotel in Dublin. Accommodation has been block-booked at the conference venue and at a number of hotels in the area, with special rates for meeting participants agreed. Hotel reservations must be made directly with hotels by participants.

Scientific Agenda

The WHO Annual National Centres Meeting of countries participating in the WHO Programme for International Drug Monitoring will take place in Dublin immediately prior to ISoP 2004 and an overlapping session of both groups is scheduled for Wednesday afternoon, 6 October 2004.

Topics on the scientific agenda include:

- Medication errors
- Patient-related risk determinants
- Surrogate markers in pharmacovigilance
- Pharmacovigilance planning
- Benefit/risk of OTC analgesics
- Depression and suicide as an ADR
- Knowledge, opinion and awareness in Pharmacovigilance.
- Vaccine vigilance
- Systems for ADR detection
- Future challenges in pharmacovigilance

Social Programme

A welcome reception will take place on the opening day of the meeting at the historic Chester Beatty Library in Dublin Castle, at 19.00, Wednesday 6 October 2004.

The conference dinner will take place at the Jameson Distillery, close to the centre of the city, on Thursday 7 October 2004 at 19.30.

Contact Details

For further information, contact Ms. Deirdre McCarthy, of the Pharmacovigilance Unit on 01 6764971 or email **isopmeeting@imb.ie**.

Please also visit the ISoP website **www.isoponline.org.**

IMB BANK DETAILS

It has recently come to the attention of the IMB that the IBAN number (international bank account number) appearing at the bottom of our invoices is incorrect. Companies will recently have received annual maintenance fee invoices from the IMB, which show an incorrect IBAN number. The correct number, which will be needed for all payments made by electronic funds transfer, is IE 54 AIBK 931012 33712185.

NEW STAFF APPOINTMENTS SINCE OUR LAST NEWSLETTER

Gillian Gormley – *Medical Officer*
Laurence O'Dwyer – *Pharmaceutical Assessor*
Fergal Seeballuck – *Pharmaceutical Assessor*
Oliver Cahill – *Assistant Accountant*

OTHER CHANGES

Following our commitment to implementing an IMB wide Quality Management System, Caitríona Fisher, **Quality Manager** will have responsibility for this area and regulatory affairs queries on procedures for authorising medicines for human use should now be sent directly to the Human Medicines Department.

HUMAN MEDICINES

NEW LEGISLATION AND GUIDELINES

- Draft Commission Directive laying down principles and detailed guidelines for good clinical practice as regards investigational medical products for human use, as well as the requirements for authorisation of manufacturing or importation of such products.
- Notice to Applicants:
  Volume 2A: Updated Chapter 7 'General Information'
  Volume 2B: eCTD specifications (new); revised CTD; revised questions and answers.
- CPMP/QWP/20054/03 Annex II to Note for Guidance on Process Validation Non-Standard Processes (Adopted by CHMP July 2004)
- CPMP/QWP/450/03 Annexes to Specifications for class 1 and class 2 residual solvents in active substances (Adopted by CHMP July 2004)
- CHMP/QWP/297/97 *Rev. 1 corr* Guideline on Summary of Requirements for Active Substances in the Quality Part of the Dossier.
- CPMP/EWP/2986/03 Note for Guidance on Clinical Investigation of Medicinal Products for the Treatment of Cardiac Failure – *Addendum* on Acute Cardiac Failure (CHMP adopted July 2004)
- CPMP/EWP/3020/03 Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Lipid Disorders (CHMP adopted July 2004)
- CPMP/EWP/2998/03 Note for Guidance on the Inclusion of Appendices to Clinical Study Reports in Marketing Authorisation Applications (CHMP adopted June 2004)
- CPMP/EWP/225/02 Note for Guidance on the Evaluation of the Pharmacokinetics of Medicinal Products in Patients with impaired Renal Function (CHMP adopted June 2004)

RENEWALS

Companies are reminded that signed and dated final colour mock-ups of labels and leaflets submitted with comments on the draft schedule must be identical to those submitted with the original renewal application, incorporating only changes to text or livery agreed with the assessor during the renewal process. All other changes to text or livery must be submitted to the IMB as a separate variation application or an Article 61.3 notification.

IMPLEMENTATION OF VARIATION CHANGES TO PILS AND LABELS

Marketing authorisation holders are reminded that when submitting a variation application, they must declare the proposed date of implementation of the change. The standard variation application form includes tick boxes and space to enter the date. Where it is intended that the change will be implemented at the 'next production run/next printing', the date should be provided. Failure to provide this information may result in a delay in the validation of the variation application. The maximum period of time permitted between approval of a variation and implementation is six months.

READABILITY OF THE LABEL AND PACKAGE LEAFLETS

The European Commission Guideline on the *Readability of the Label and Package Leaflet of Medicinal Products for Human Use* came into operation in January 1999. The objective of the guideline is that the label and leaflet are 'readable' and there are defined criteria including those relating to print size and type, syntax and paper. Specifically, the particulars appearing in the leaflet should be printed in characters of at least 8 points, leaving a space between lines of at least 3mm. The IMB is concerned that marketing authorisation holders are using fonts smaller than 8 points and that this interferes with patients' ability to read the leaflet.

The IMB requires that marketing authorisation holders ensure that their labels and leaflets are compliant with the minimum point size outlined in this guideline by no later than 31 October 2005, unless otherwise agreed with the IMB. IMB inspectorate staff will perform a random review of medicinal products on the market after this deadline to test for compliance. Amendments to the font size of labels and leaflets can be submitted at the time of renewal or by formal variation. New applications should be compliant at the time of submission.

ADOPTION OF THE USE OF RECOMMENDED INTERNATIONAL NON-PROPRIETARY NAMES (rINNS) ONLY AND DISCONTINUATION OF THE CONTINUED USE OF BRITISH APPROVED NAMES (BANS) FOR MEDICINAL SUBSTANCES WITH THE EXCEPTIONS OF ADRENALINE AND NOR-ADRENALINE

European law requires the use of recommended international non-proprietary names (rINNs) for substances used in medicinal products. This requirement is also reflected in Irish Legislation (S.I. No71 of 1993: The Medical Preparations (Labelling and Package Leaflets) Regulations, 1993 as amended).

Until now, the UK has had a well-established national naming system, the British Approved Name (BAN). In order to facilitate product authorisation holders and in particular those who were marketing products in both the UK and Ireland, the IMB has facilitated the use of BANs.

However in Mail 138 the UK competent authority, the Medicines and Healthcare Products Regulatory Agency (MHRA) announced the changeover from BANs to rINNs from 1 December 2003, the effective date of the British Pharmacopoeia 2003. The MHRA are implementing this change as they recognise that the use of the BAN is not sustainable in the longer term. Other EU Mem-

ber States routinely use the rINN and consequently products accepted onto the UK/Irish market from other member states use this naming system, as do medicines which have a pan-European licence.

In light of the MHRA decision to implement the changeover to rINNs for virtually all medicinal substances where BANs are currently used, with the exceptions of adrenaline and noradrenaline (see below), the IMB has decided to implement the same changes in Ireland for product authorisation holders.

Therefore for all products for which BANs have been used for the declared active substance, with the exceptions of adrenaline and noradrenaline, product authorisation (PA) holders are requested to apply for a variation to change the name to the rINN only.

Variations must be submitted to IMB no later than 31 March 2005.

In situations where the affected substance is not the declared active ingredient, but is named in the product particulars e.g. in the interactions section of the SmPC, the name should be updated no later than December 2005 and this can be done with another regulatory activity such as a variation (even if not in a directly related section of the SmPC) or renewal.

The name changes have been published in the July 2003 edition of the British Pharmacopoeia and a list is available from the IMB website **www.imb.ie.**

Existing Product Authorisations (with the exceptions of adrenaline and noradrenaline)

Where existing PAs already use only the rINN for all affected substances in their product particulars (SmPC, labels and package leaflets), no further action will be necessary.

In all other cases product authorisation holders should follow the guidance detailed below.

a) Where the affected substance is the declared active ingredient in the product, variations should be submitted to IMB no later than **31 March 2005**. The new Type 1A variation Category 3 should be used to update the authorisation.

For Type 1A Category 3 variations to update BANs to rINNs, the following supporting documentation is required:

- A copy of the rINN list
- Revised SmPC, labels and leaflets

The revised package leaflet should, for a period of 12 months, contain the following boxed statement on the section where the active ingredient is described – e.g. "*What is in your medicine?*"

> The active ingredient in this medicine is (new name). This is the new name for (old name). The ingredient itself has not changed.

Product Authorisation holders will also be requested to notify the professions of the change once the variation is approved.

b) Where the affected substance is not the declared active ingredient but is named in the product particulars (e.g. in the interactions section of the SmPC), then the name should be updated in conjunction with other regulatory activity such as a variation (even if not in a directly-related section of the SmPC) or renewal. Any such changes should be made at the first available opportunity and should be highlighted in a covering letter. If no other regulatory activity is to be undertaken before 31 December 2005, these changes must be made by variation.

In addition, it should be noted that some salts and esters are affected by these changes and this may affect substance other than the active ingredient in the product literature. Furthermore the names of some excipients are also different and consequently Section 6.1 of the SmPC should be updated where relevant.

Pending and new applications for Product Authorisations (with the exceptions of adrenaline and noradrenaline)

All new product authorisations granted must use only the rINNs for the substances they contain or which are mentioned in their SmPC's.

This also applies to the substance named on the label and in the patient leaflet and to the product name where this includes the active ingredient name.

Product Authorisations for Parallel Imports

Arrangement for parallel import product authorisations (PPAs) will mirror those for product authorisations.

Holders of PPAs should update their authorisations to use only the rINN and variations must be submitted to IMB by **31 March 2005**.

Please note that the PPA holder does not need to wait for the PA holder of the reference product to make the change.

Special cases: Products containing Adrenaline and Noradrenaline (Epinephrine and Norepinephrine)

Adrenaline and noradrenaline have been identified as the only two substances for which the BANs will be retained and will be used in conjunction with the rINNs.

For products containing adrenaline and noradrenaline the INN in parentheses should follow the BAN in the name of the product and Product Authorisation holders will be required to follow a standardised approach for product particulars. Full details are available from the IMB website **www.imb.ie**.

For further information regarding the above please contact Muireann Lydon or Cathy Hempenstall on 01 6764971 or e-mail **cathy.hempenstall@imb.ie**.

RESTRICTION OF THE USE OF THE TERM 'MAXIMUM' AND ITS ABBREVIATION 'MAX' IN RELATION TO PARACETAMOL-CONTAINING PRODUCTS.

The IMB wishes to advise applicants that a policy has been adopted to restrict the use of the term Maximum and its abbreviation Max in relation to paracetamol-containing products to products containing the maximum permitted strength of 1000mg per dosage unit.

This policy has been adopted due to concerns regarding the potential safety implications when the Maximum or Max is used for products containing different quantities of the active substance 'paracetamol', particularly as these products may be used interchangeably by the patient.

PHARMACOVIGILANCE

Submission of PSURs

As a follow up to previous articles on PSUR submission in the IMB Newsletter, we would like to inform companies that PSURs (both paper and CD-Rom versions, should be submitted to the Receipts and Validation section of the IMB, from 1 October 2004. It is already standard procedure that PSURs forming part of a renewal application are submitted to this section.

Companies are reminded that the following information should be included in the covering letter accompanying the PSUR:

- Brand name of the product
- PA Number
- Authorisation procedure i.e. Centralised, MR or National
- Number of PSUR
- Period covered

Alternatively, the template for PSUR submission (Annex 3 - Notice to Marketing Authorisation Holders) should be completed and submitted with PSURs.

Submission of Adverse Drug Reaction/Adverse Event Reports

Further to previous guidance (IMB Quarterly Newsletter Nos. 11, 12 and 15) on submission of suspected adverse drug reaction (ADR) reports to the IMB, companies are reminded of the following requirements when submitting ADR/ADE reports:

- 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.
- Cases of Irish origin must be submitted under separate cover and not included in batches of 'Rest of World' reports. They must also be identified according to type (initial/follow-up).
- Correspondence regarding Clinical Trial reports should include reference to the IMB Clinical Trial number and the relevant protocol number.

HOMEOPATHIC MEDICINES – LAUNCH OF THE THIRD PHASE OF THE SIMPLIFIED REGISTRATION SCHEME FOR HMP.

The IMB is continuing the registration of homeopathic medicinal products as outlined in previous issues of the Newsletter (14, 15 and 16).

The third phase of the registration process will be launched in October for the registration of single animal products. The following notice appeared in the Irish Times on 1 September 2004 and gives particulars of the scheme.

MEDICINAL PRODUCTS (LICENSING AND SALE) REGULATIONS, STATUTORY INSTRUMENT NUMBER 142 OF 1998:

Simplified Registration Scheme for Homeopathic Medicinal Products for Human use.

Companies who wish to market Homeopathic Medicinal Products of animal origin, 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, 2001/83/EC and 2004/27/EC; are hereby notified that applications for such registration can be submitted to the Irish Medicines Board with effect from 1 October 2004.

All applications for products containing single animal substances, in homeopathic dilution, must be submitted to IMB between 1 October 2004 and 31 January 2005, in order that such products may lawfully remain on the market.

Any product in the single animal category for which an application has not been submitted by the date above must be removed from the market by 31 April 2005.

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

It should be noted that the deadline (31 March 2004) for submission of applications to register single mineral homeopathic products has now passed. Single mineral products, for which a registration application has not been received by the IMB, can no longer remain lawfully on the market.

HERBAL MEDICINES UPDATE – APPOINTMENT TO THE NEW EMEA COMMITTEE ON HERBAL MEDICINAL PRODUCTS

Following agreement on the EU Council Directive on Traditional Herbal Medicinal Products in March 2004, a new Committee on Herbal Medicinal Products (HMPC) has been established at the European Medicines Agency. This committee will be responsible for issues relating to traditional herbal medicinal products registered in accordance with this Directive.

The IMB is pleased to announce that Dr. Dairine Dempsey has been appointed as the Irish representative to the HMPC, with Dr. Elaine Breslin as her alternate.

VETERINARY MEDICINES

LEGISLATION AND GUIDELINES

The following guidelines have been adopted:

Quality

- EMEA/CVMP/541/03 CVMP Guideline on the Chemistry of New Active Substances. Adopted by CVMP May 2004. Implementation in December 2004.
- EMEA/CVMP/1069/02 Joint CVMP/CHMP Guideline on Summary of Requirements for Active Substances in the Quality Part of the Dossier. This Guideline is intended to provide guidance regarding the requirements to be included for chemical and herbal active substances in the quality part of the dossier, depending on the described classification. Adopted by CVMP June 2004. Implementation in February 2005.
- EMEA/CVMP/540/03 Guideline on Quality Aspects of Pharmaceutical Veterinary Medicines for Administration via Drinking Water. Adopted by CVMP July 2004. Implementation date in January 2005.

SAFETY

- CVMP/VICH/467/03-FINAL. Final VICH GL 36 (Safety): Studies to evaluate the safety of residues of veterinary drugs in human food: General approach to establish a microbiological ADI. Adopted by CVMP June 2004. Implementation in May 2005.
- CVMP/VICH/468/03-FINAL VICH GL 37 (Safety): Studies to evaluate the safety of residues of veterinary drugs in human food: Repeat-dose Chronic Toxicity Testing. Adopted by CVMP June 2004. Implementation in May 2005.
- EMEA/CVMP/865/03-FINAL Position Paper on Data requirements for removing the target animal batch safety test for immunological veterinary medicinal products in the EU. Adopted by CVMP July 2004. Implementation January 2005.

Efficacy

- EMEA/CVMP/625/03-FINAL 'Guideline on specific efficacy requirements for ectoparasiticides in cattle'. Adopted by CVMP July 2004. Implemented in January 2005.

VETERINARY INFORMATION DAY

The Veterinary Department held a very successful Information Day Meeting with stakeholders on 1 July 2004 in Dublin. The meeting reviewed progress in key IMB activities in recent years and provided updates on operational and technical issues. Invited speakers from the Department of Agriculture and Food also provided updates on regulatory developments. Copies of the meeting documentation are available priced €50 (contact **emily.hassett @imb.ie**).

PUBLICATION OF SUMMARIES OF PRODUCT CHARACTERISTICS (SPCS)

The Veterinary Department has begun the process of publishing the SPCs of authorised veterinary medicinal products on the IMB web site **www.imb.ie**. The process has commenced with new and amended authorisations but will be extended to include all authorisations in due course. It is expected that this service will meet the demand of stakeholders for increased information on licensed medicines.

GUIDE TO TRANSFERS

A veterinary product authorisation (VPA) may be transferred from the existing VPA holder to another VPA holder using a transfer procedure. A transfer may occur before a product is authorised or after authorisation, to a company related to the existing VPA holder or to an unrelated company.

The transfer procedure must be used where the legal entity of a VPA holder is changed as product authorisations are transferred to a new VPA company number.

Transfer before Authorisation

Where a VPA is transferred before authorisation, the new VPA holder must notify the IMB using the transfer application form, which should be accompanied by a revised Part IA, SPC, and label and package leaflet mock-ups. For Immunologicals a copy should also be submitted to Department of Agriculture and Food for notification.

Transfer after Authorisation

In order to avail of this procedure, the following conditions must be met:

1. For transfer to a related company, the new authorisation holder must be an individual or company which is either:
   (a) a subsidiary of an existing VPA holder or
   (b) formed due to the merger of previous VPA holders.

2. The existing authorisation must have a remaining period of validity of more than three months. If the period is less than three months, the existing VPA must be renewed first before the transfer application can be processed.

3. No change may be made, as part of the transfer application, to the authorisation schedule or approved SPC. No change may be made to the technical data in Parts II, III and IV.

4. No change may be made to the texts of the labels and leaflet, other than the VPA number and the VPA holder's name and address. Any change to the layout and design must not adversely affect the readability of their contents.

5. Once the new product authorisation has been granted no further

stocks bearing the old VPA number may be manufactured or released for sale by the qualified person. Batches of the original product may be sold for a period of six months after issue of the transferred authorisation. At the end of this period, any remaining stocks of the original product must be recalled from wholesale level.

The transferred VPA is authorised with the same schedule (authorisation document) as the existing VPA, except for the name and address of the VPA holder and the VPA number. It is issued for the remaining period of validity of the existing authorisation.

Any change to the transferred VPA, e.g., revised label/leaflet text or the introduction of a new manufacturer, must be applied for using the variations procedure.

On expiry, the transferred VPA is renewed in the usual way by the new VPA holder.

Transfer using New Application Procedure

Where the application does not meet the conditions laid down for this administrative transfer procedure or the applicant wishes to obtain a VPA under conditions other than those specified, the VPA may be transferred by applying for a new VPA under the usual national procedure

Making an Application

In order to transfer a VPA, the proposed VPA holder or another person acting on his behalf must submit an application consisting of the following:

- Transfer application form and signed statements from existing VPA holder/applicant and proposed new VPA holder (one copy)
  Form A - for applications to transfer an authorised product
  Form B - for application to transfer an application, i.e., before authorisation of the product
- Veterinary Medicines Fee Application Form (one copy) - only for transfers of authorised products
- Revised Part IA, SPC, labels and leaflet (three copies) - only for transfers before authorisation
- Covering letter (one copy)

Additional requirements apply to companies or individuals not already holding a VPA in Ireland:

- Evidence of establishment in the European Union, e.g. certificate of incorporation or equivalent.
- Confirmation that the VPA holder has established within his undertaking a scientific service in charge of information about the medicinal product within the meaning of Article 13 of Council Directive 92/28/EEC.
- Confirmation that the VPA holder has adequate procedures in place to recall the medicinal product from the Irish market.
- Confirmation that the VPA holder has adequate procedures in place for pharmacovigilance in accordance with current Directives and Regulations in force in the European Union.

Fees

Fees for transfer of an existing VPA to a related company, to an unrelated company or to a company which does not already hold a VPA are detailed in the IMB's Guide to Fees.

Fees are payable to the Irish Medicines Board.

Account no.: 33712185;
sort code 93-10-12
Allied Irish Bank,
1-3 Baggot Street Lower,
Dublin 2

Payment is to be made with the VPA transfer application.

Fees for transfer application before authorisation are subject to an administrative fee of €120. In the fee application form, the fee code 733 (pharmaceutical) and 953 (immunological) should be used, specifying a two-hour charge.

Address for submitting applications:

Receipt and Validation,
Irish Medicines Board,
Block A, Earlsfort Centre,
Earlsfort Terrace,
Dublin 2.

For Immunologicals a copy should also be submitted to Department of Agriculture and Food for notification.

INSPECTORATE

NEW IMB GUIDANCE NOTE ON PRODUCT RECALLS

The Inspectorate Department would like to thank all those who commented on the above draft document. We extended the comment period to mid August 2004 and many useful and helpful suggestions were received. Much positive comment was also received on its content.

The deadline for comment has now passed. We will take all comments and suggestions on board when finalising the draft document, and it is hoped that the finalised version will be published on the IMB Website by, or before, December of this year.

Human New Product Authorisations Issued (May–August 2004)

PA Number	Product Name
PA0007/002/010	ATROVENT INHALER CFC-FREE
PA0043/006/009	NUROFEN 200 mg MELTLETS
PA0043/006/010	NUROFEN FOR CHILDREN MELTLETS
PA0298/014/001	Trimethoprim BP
PA0298/014/002	Trimethoprim BP
PA0417/016/004	HALIBORANGE EFFERVESCENT VITAMIN C
PA0476/017/001	CIPROFLOXACIN OLINKA
PA0476/017/002	CIPROFLOXACIN OLINKA
PA0476/017/003	CIPROFLOXACIN OLINKA
PA0476/017/004	CIPROFLOXACIN OLINKA
PA0568/002/003	COVERSYL
PA0711/009/005	DICLAC RELIEF
PA0899/020/001	ELTROXIN
PA1017/002/001	CETRINE
PA1017/002/002	CETRINE ALLERGY
PA1146/001/001	GABAPENTIN MASTERFARM
PA1146/001/002	GABAPENTIN MASTERFARM
PA1146/001/003	GABAPENTIN MASTERFARM
PPA0465/051/003A	KLACID LA
PPA0465/115/001A	FOSAMAX ONCE WEEKLY
PPA0465/124/001A	KLIOGEST
PPA0465/125/001A	CREON 10000
PPA0465/125/002A	CREON 25000
PPA0465/126/001A	DYAZIDE
PPA0465/128/001A	IDEOS
PPA0465/132/001A	DOVONEX
PPA0465/132/002A	DOVONEX
PPA0465/132/003A	DOVONEX SCALP
PPA0465/133/001A	NOLVADEX D
PPA0465/144/001A	CASODEX
PPA1151/001/002A	SINEMET
PPA1151/001/003A	SINEMET PLUS
PPA1151/003/001A	ZOTON
PPA1151/003/002A	ZOTON
PPA1151/005/001A	COZAAR
PPA1151/006/001A	SERETIDE 500

Human New Product Authorisations Withdrawn (May–August 2004)

PA Number	Product Name
PA0007/001/005	Mexitil PL Perlongets
PA0016/004/002	Colestid Orange
PA0016/004/003	Colestid
PA0016/025/001	Cytosar
PA0016/025/003	Cytosar
PA0016/055/001	Alprazolam
PA0016/055/002	Alprazolam
PA0016/055/003	Alprazolam
PA0017/051/001	Migril
PA0017/101/001	Exosurf Neonatal
PA0019/021/001	Terracortril Nystatin
PA0019/043/003	CARDURA
PA0019/043/004	CARDURA
PA0019/047/003	ZITHROMAX
PA0019/047/004	ZITHROMAX
PA0019/047/005	ZITHROMAX
PA0019/047/006	ZITHROMAX
PA0019/047/007	ZITHROMAX
PA0022/044/001	LORAZEPAM
PA0022/044/002	LORAZEPAM
PA0024/001/012	Ventolin Inhaler
PA0024/005/002	Becotide Rotacaps
PA0024/005/003	Becotide Rotacaps
PA0035/065/003	Utinor
PA0038/058/001	Calcijex
PA0038/058/002	Calcijex
PA0040/001/002	Sectral
PA0040/001/003	Sectral
PA0040/017/001	Intraval Sodium
PA0040/017/004	Intraval Sodium
PA0040/026/008	Stemetil E.F.F.
PA0040/070/006	Oruvail 150
PA0040/074/001	Water
PA0040/074/002	Water
PA0040/074/003	Water
PA0050/125/001	Cymevene
PA0050/137/001	CAL-D-VITA EFFERVESCENT
PA0050/137/002	CAL-D-VITA CHEWABLE
PA0057/062/001	Minitran 5
PA0057/062/002	Minitran 10
PA0057/062/003	Minitran 15
PA0060/023/002	POLIOMYELITIS VACCINE LIVE (ORAL)
PA0086/013/001	Dimotane
PA0086/013/002	Dimotane
PA0100/016/002	Saventrine I.V.
PA0126/103/004	CLAVAMEL PAEDIATRIC SACHETS
PA0148/015/001	Prefrin
PA0148/040/003	Betagan Ophthalmic
PA0167/032/016	Travasept 15
PA0167/032/017	Travasept 30

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Human New Product Authorisations Withdrawn (January–April2004)

PA Number	Product Name	PA Number	Product Name
PA0167/032/018	Travasept 100	PA0540/117/003	Orudis
PA0167/067/005	Heparin Sodium BP 2500	PA0610/005/001	Orovite
PA0167/067/009	Heparin Sodium BP 20000	PA0711/011/007	Nifed Retard
PA0167/067/011	Heparin Sodium BP 25000	PA0748/012/005	TOPAMAX
PA0167/067/013	Heparin Sodium BP 75000	PA0748/012/006	TOPAMAX
PA0187/014/002	Cetiprin Novum	PA0748/033/003	Retin-A Lotion
PA0218/025/003	ACTRAPID NOVOLET	PA0748/033/005	RETIN-A
PA0218/036/001	MIXTARD 50	PA0771/006/001	Tamofen
PA0236/010/001	Cyclophosphamide	PA0771/006/002	Tamofen
PA0236/020/002	Olbetam	PA0771/006/003	Tamofen
PA0277/001/001	Optimine	PA0771/006/004	TAMOFEN
PA0281/015/001	IBUPROFEN	PA0778/004/003	Cytotec
PA0281/015/002	IBUPROFEN	PA0778/014/001	Synphase
PA0281/112/001	Acidopine	PA0823/010/001	Calpol Six Plus
PA0282/015/001	Oxytetracycline	PA0823/010/007	Calpol
PA0282/027/001	Amilco	PA0855/018/001	Lasoride
PA0285/001/001	PERGONAL	PA0934/001/001	NALTREXIN
PA0295/002/001	Sodium Chloride 0.9%	PA0936/009/001	Caverject Dual Chamber
PA0295/002/005	Sodium Chloride 0.45%	PA0936/009/002	Caverject Dual Chamber
PA0295/003/001	Glucose 5%	PA0936/009/006	Caverject
PA0295/003/005	Glucose 10%	PA0936/014/001	Epogam
PA0295/004/001	Sterile Water	PA0936/014/003	Epogam
PA0295/005/001A	Sodium Lactate	PA0936/024/001	FEMULEN
PA0295/006/001	COMPOUND SODIUM LACTATE	PA0936/034/001	DOXORUBICIN
PA0295/007/001	Sodium Chloride 0.18%/Dextrose 4.0%	PA0936/034/002	DOXORUBICIN
		PA0936/034/003	DOXORUBICIN
PA0295/007/003	Sodium Chloride 0.9%/Dextrose 5.0%	PA0936/034/004	DOXORUBICIN
PA0408/032/001	Rimafen	PA0936/034/005	DOXORUBICIN RAPID DISSOLUTION
PA0408/032/002	Rimafen	PA0936/034/006	DOXORUBICIN RAPID DISSOLUTION
PA0408/037/001	Rimaflox	PA0936/034/007	DOXORUBICIN
PA0408/037/002	Rimaflox	PA0936/034/008	DOXORUBICIN
PA0423/001/001A	Sterile Water for Irrigation	PA0936/056/001	MINODIAB
PA0423/002/001A	Sodium Chloride	PA0936/058/003	Zavedos
PA0437/046/001	Midazolam Injection	PA0936/062/004	Prostin E2
PA0437/046/002	Midazolam Injection	PA0936/071/005	Solu-Medrone
PA0437/046/003	Midazolam Injection	PA0936/072/005	Provera
PA0468/004/003	Frumil Double Strength	PA0936/072/006	Provera
PA0468/016/001	Maalox	PA0936/076/001	LONITEN
PA0468/021/003	Acthar Gel	PA0936/076/003	LONITEN
PA0484/001/001	Bonfields Hydrocortisone	PA1077/016/007	Zofran
PA0484/022/001	Epsom Salts	PA1077/021/003	CO-AMOXICLAV PAEDIATRIC SACHET
PA0540/007/002	Zolerim	PA1077/022/001	CO-AMOXICLAV DUO SACHETS
PA0540/065/001	Relefact LH-RH	PA1077/091/002	Tagamet
PA0540/095/001	Calsynar	PA1077/096/003	Penbritin
PA0540/095/002	Calsynar		

Human New Product Authorisations (Mutual Recognition) (May–August 2004)

PA Number	Product Name
PA0002/076/001	PACLITAXEL INJECTION CONCENTRATE
PA0013/110/005	ESTRADOT
PA0013/115/001	MYFORTIC
PA0013/115/002	MYFORTIC
PA0062/039/001	Vesitirim
PA0062/039/002	Vesitirim
PA0062/040/001	Vesikur
PA0062/040/002	Vesikur
PA0126/119/002	FELODIPINE 5mg
PA0126/119/003	FELODIPINE 10mg
PA0126/129/001	Tazamel
PA0126/129/002	Tazamel
PA0126/129/003	Tazamel
PA0167/050/022	SODIUM CHLORIDE 0.3% AND GLUCOSE 3.3%
PA0281/117/001	CIPRAPINE
PA0281/117/002	CIPRAPINE
PA0281/117/003	CIPRAPINE
PA0521/012/001	OCTANATE 250 IU
PA0521/012/002	OCTANATE 500 IU
PA0521/012/003	Octanate 1000 IU
PA0521/013/001	OCTAPLEX
PA0577/047/003	Ciprager
PA0577/053/001	CARVEDILOL FILM-COATED
PA0577/053/002	CARVEDILOL FILM-COATED
PA0577/053/003	CARVEDILOL FILM-COATED
PA0577/053/004	CARVEDILOL FILM-COATED
PA0585/016/001	Ondansetron
PA0593/036/001	SIMVASTAD
PA0593/036/002	SIMVASTAD
PA0593/036/003	SIMVASTAD
PA0593/036/004	SIMVASTAD
PA0711/057/001	FLUCOL
PA0711/057/002	FLUCOL
PA0711/057/003	FLUCOL
PA0711/057/004	FLUCOL
PA0711/058/001	PRAVITIN
PA0711/058/002	PRAVITIN
PA0711/058/003	PRAVITIN
PA0711/058/004	PRAVITIN
PA0711/062/001	MIRAP
PA0711/062/002	MIRAP
PA0711/062/003	MIRAP
PA0748/052/001	LYRINEL XL
PA0748/052/002	LYRINEL XL
PA0748/052/003	LYRINEL XL
PA0819/029/001	OMEPRAZOLE-RATIOPHARM
PA0819/029/002	OMEPRAZOLE-RATIOPHARM
PA0822/020/001	Inspra
PA0822/020/002	Inspra
PA0891/006/001	MUNTEL
PA0891/007/001	SITOR
PA0935/001/002	FSME-IMMUN 0.25ML JUNIOR
PA0935/001/003	FSME-IMMUN 0.5ML
PA1058/006/001	NOVOPULMON NOVOLIZER
PA1070/001/001	Folicid
PA1106/001/001	Elastoplast Back Pain Medical Plaster
PA1112/002/001	ALBUREX
PA1112/002/002	ALBUREX
PA1136/001/001	INFUKOLL N
PA1136/001/002	INFUKOLL N

Veterinary New Product Authorisations Issued (May–August 2004)

VPA Number	Product Name
10948/001/003	LANODIP CONCENTRATE TEAT DIP 4:1
10948/001/004	LANODIP READY TO USE TEAT DIP
10948/001/002	LANODIP CONCENTRATE TEAT DIP 3:1
10960/053/001	BOVIMAST DC
10835/052/001	FASINEX SUPER 19.5% ORAL SUSPENSION
10021/030/002	DRONTAL CAT XLTABLETS
10835/046/001	SENTINEL SPECTRUM TABLETS FOR VERY SMALL DOGS
10835/046/002	SENTINEL SPECTRUM TABLETS FOR SMALL DOGS
10835/046/003	SENTINEL SPECTRUM TABLETS FOR MEDIUM DOGS
10835/046/004	SENTINEL SPECTRUM TABLETS FOR LARGE DOGS

Veterinary New Authorisations Issued (Mutual Recognition) (May–August 2004)

VPA Number	Product Name	VPA Number	Product Name
10988/066/001	ALIZIN	10857/063/004	FRONTLINE COMBO SPOT-ON DOG XL
10857/062/001	FRONTLINE COMBO SPOT-ON CAT	10999/101/001	NOROCLAV 50 MG TABLETS
10857/063/001	FRONTLINE COMBO SPOT-ON DOG S	10999/101/002	NOROCLAV 250 MG TABLETS
10857/063/002	FRONTLINE COMBO SPOT-ON DOG M	10835/025/003	FORTEKOR 2.5MG TABLETS FOR CATS
10857/063/003	FRONTLINE COMBO SPOT-ON DOG L	10995/026/001	ENZAPROST
		10810/001/001	EQUIMUCIN 2G ORAL POWDER

Veterinary Product Authorisations Withdrawn (May–August 2004)

VPA Number	Product Name	VPA Number	Product Name
10021/014/003	DRONTAL PLUS FLAVOUR	10987/009/001	CHANAZOLE
10206/005/001	OSCOFAS FLUKE & WORM DRENCH	10988/063/001	OXYTETRACYCLINE 20%
10861/032/001	PEP	10996/038/001	CRESTAR IMPLANT AND

Veterinary Immunological New Authorisations Issued (May–August 2004)

VPA Number	Product Name	VPA Number	Product Name
10861/084/001	Duramune DAPPi + LC	10996/180/001	Nobilis TRT inac
10861/085/001	Suvaxyn ERY		

Veterinary Immunological Review Authorisations Issued (May–August 2004)

VPA Number	Product Name	VPA Number	Product Name
10019/071/001	Felocell CVR	10996/090/001	Nobilis ND Hitchner Live
10019/072/001	Vanguard CPV	10996/091/001	Nobilis ND Clone 30 Live
10019/074/001	Vanguard Lepto ci	10996/151/001	Tetanus Toxoid Concentrated
10861/074/001	Felovax IV	10996/170/001	Nobivac Rabies
10857/054/001	Rabisin		

Veterinary Immunological Review Authorisations Withdrawn (May–August 2004)

VPA Number	Product Name	VPA Number	Product Name
10857/031/001	Mucobovin		