IRISH MEDICINES BOARD

news MEDICINAL PRODUCTS LETTER

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GENERAL

IMB Celebrates 10 years

The IMB was established under the Irish Medicines Board Act 1995, which came into operation in early 1996. The IMB celebrated its first 10 years' establishment when the IMB staff and the newly appointed Board members joined in a celebration, with the focus on a great out-turn for the IMB in 2005.

Mr. Wilf Higgins, Dr. Joan Gilvarry, Mr. Pat O'Mahony, Chairman, Mr. John Lynch, Mr. Pat O'Mahony, CEO, Ms. Ann O'Connor, Dr. Brendan Buckley and Ms. Rita Purcell

Pat O'Mahony, CEO, and Mr Pat O'Mahony, Chairman of the Board.

WORKSHOP FOR WHOLESALERS WHO SUPPLY TO GROCERY RETAIL SECTOR

A workshop for wholesalers involved in the supply of medicinal products to the grocery trade was held at the Crowne Plaza Hotel, Dublin on Friday 25th November 2005. The event attracted a wide attendance, involving representatives who supply medicinal products to the grocery trade, representatives from the wider distribution/wholesale sector and other stakeholder groups.

Talks and presentations by IMB staff were given on the following themes:

- The standard Good Distribution Practice (GDP) inspection agenda
- GDP deficiencies
- The responsible person
- Batch traceability and product recalls
- Quality systems

These presentations provided an overview of the principles and requirements of GDP for medicinal products, and also requirements for compliance with the terms and conditions of the wholesale licence issued by the IMB.

The presentations were followed by an active discussion session on GDP-related issues including recalls, counterfeit products and temperature-mapping. The discussion involved a high level of participation from the audience, reflecting the level of interest in the presentations and discussion topics.

IMB MEDICAL DEVICES INFORMATION DAY - 'SAFE MANAGEMENT OF INFUSION DEVICES'

The IMB will be holding an information day on Wednesday 14th June 2006 in the Education Theatre,

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Adelaide & Meath Hospital incorporating the National Children's Hospital, Tallaght, Dublin 24 to discuss safe management of infusion devices. Presentations will be made by speakers from the IMB, the Medicines and Healthcare products Regulatory Agency in the UK and also by a number of speakers from hospitals in Ireland and the UK.

The information day is targeted at healthcare professionals who use or manage medical devices for patients in the healthcare setting including:

- Risk managers
- Clinical engineers
- Pharmacists
- Practice nurses
- Nursing staff

Other healthcare professionals may also be interested in attending.

A copy of the agenda can be downloaded from the website (www.imb.ie). It is envisaged that the day will be split into three sessions. The first session will provide some general information on infusion pumps and information relating to adverse incidents relating to infusion devices. The second session will give details on points that need to be considered in the management of infusion devices, including purchase, storage and risk management. The afternoon session will focus on training and how training systems can be implemented. A question and answer session will take place after each session.

Two registration forms for this event can be downloaded from the website (www.imb.ie), one for healthcare professionals and one for industry representatives. A copy of this registration form should be filled in for each attendee and returned by the Friday 2nd June 2005 to Sinead Carty in the Medical Devices Department. A booking fee is being charged for this conference; it includes all refreshments, lunch and conference documentation. Registration applications should be made as soon as possible as there is a limit on the number of places available.

If you have any queries relating to this conference, please contact Sinead Carty at 01-6764971 or e-mail **medicaldevices@imb.ie**

STAFF CHANGES

Angella Mulhall was appointed Technical Officer within the Medical Devices Department.

Donal Parsons was appointed IT Support Technican within the IT and Change Management Department.

Donna Harkin was appointed Scientific Officer Haemovigilance within the Human Medicines Department.

Kevin Blake and *Sinead Harrington* were appointed Medical Officers within the Human Medicines Department.

Clodagh Brennock was appointed Scientific Officer Pharmacovigilance within the Human Medicines Department.

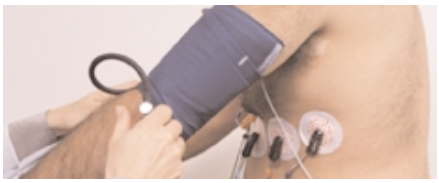
Patrick Buckley was appointed Technical Officer within the Medical Devices Department.

Brendan Quinn was appointed Enforcement Officer within the Compliance Department.

Sarah Beesley and *Elizabeth O'Connor* were appointed Scientific Officers within the Human Medicines Department and the Veterinary Medicines Department respectively.

Cora Nestor, Robert Byrne and *Catherine McHugh* were appointed Pharmaceutical Assessors within the Human Medicines Department.

Lydnsey Glennon was appointed Human Resources Officer within the Human Resources Section.



HUMAN MEDICINES

LEGISLATION AND GUIDELINES

CPMP/EWP/6172/03 Guideline on the Clinical Evaluation of Medicinal Products Intended for Treatment of Hepatitis B (Adopted by CHMP February 2006)
EMEA/75401/06 *Rev. 1* Time allowed for Applicants to respond to Questions and Issues raised during the assessment of new Marketing Authorisation Applications in the Centralised Procedure (Adopted by CHMP February 2006)
CPMP/QWP/2819/00 *Rev. 1* (EMEA/CVMP/814/002) Guideline on Quality of Herbal Medicinal Products / Traditional Herbal Medicinal Products (CHMP/CVMP Adopted March 2006)
CPMP/QWP/2820/00 *Rev. 1* (EMEA/CVMP/815/00) Note for Guidance on specifications: Test procedures and Acceptance Criteria for Herbal Substances, Herbal Preparations and Herbal Medicinal Products / Traditional Herbal Medicinal Products (CHMP/CVMP Adopted March 2006)
CHMP/SWP/94227/04 Guideline on the Non-Clinical Investigation of the Dependence Potential of Medicinal Products (CHMP adopted March 2006)

PHARMACOVIGILANCE SAFETY VARIATIONS

Electronic submission of safety variations requested by the IMB's Pharmacovigilance section

The IMB is pleased to announce the establishment of a designated e-mail address to which safety variations requested by the IMB's Pharmacovigilance section should be submitted – **safetyvariations@imb.ie**.

Applicants are advised that this e-mail box should only be used for those safety variations specifically

requested by the IMB's Pharmacovigilance Section. Other variation applications, including those related to pharmacovigilance/safety issues that are initiated by companies and which have not been specifically requested by the IMB's Pharmacovigilance Section, should not be submitted through this e-mail address as they cannot be processed through this system.

Each electronic submission should include the following:

- Cover letter
- Copy of the IMB pharmacovigilance request letter
- Application form in PDF or Word
- Copy of the SPC in Word or PDF with changes highlighted via track change version
- Clean copy of the updated SPC in Word or PDF
- Fee application form

Applicants wishing to pay by cheque should note that the cheque must be sent simultaneously to IMB Receipts & Validation along with a copy of the cover letter.

APPLICATIONS TO REFORMAT THE DOSSIERS OF EXISTING PRODUCTS TO CTD FORMAT

Companies are reminded that applications to reformat the dossiers of existing products to CTD format must be accompanied by a signed declaration from the PA holder stating that the content/data of the Quality Module (Module 3) is identical to the currently approved Quality Part and that there have been no changes to the dossier as a result of the reformatting.

TYPE 1A/1B NOTIFICATIONS

On a number of occasions, the IMB has requested applicants to improve the quality of Type IA/IB notification applications (ref: *IMB Newsletter Issue 16, 19 and 21*). However, the IMB is still receiving a large number of deficient applications. The following procedures will apply to all Type IA/IB notifications received from the 1st September 2006.

Incorrect Classification

All type IA/IB notifications which are incorrectly classified will be deemed unacceptable and will not be further processed. Applicants will be required to resubmit the application correctly classified, with the correct supporting documentation.

Incorrect Conditions / Documentation*

All type IA/IB notifications which do not meet the required conditions will be deemed unacceptable. Applicants will be required to resubmit such applications as Type II variation applications.

Type IA notifications which are not supported by all of the required documentation will be deemed unacceptable and will not be further processed.

For type IB notifications not supported by all of the required documentation, applicants will be requested to supplement the application with the complete documentation within 30 days. The application will be deemed unacceptable if the requested documentation is not provided within that timeframe.

Applicants will be required to (a) resubmit the application as a Type IA/IB notification when the required documentation becomes available or (b) resubmit the application as a Type II variation, in the absence of the required documentation.

In all cases, resubmission of applications must be accompanied by full fees.

* *Note – documentation refers to the data requirements that are explicitly stated in the Guideline on dossier requirements for Type IA and Type IB Notifications, including final label/leaflet mock-ups (signed and dated) incorporating the proposed change(s), where applicable. Applicants are required to provide a justification if documentation is not provided and deemed to be not applicable to the notification.*

PRODUCT INFORMATION REQUIREMENTS UNDER DIRECTIVE 2001/83EC AS AMENDED BY DIRECTIVE 2004/27/EC- FURTHER GUIDANCE.

The requirement for Braille to appear on the outer cartons of medicinal products as per Directive 2001/83/EC as amended, is being applied to MR products authorised since 30th October 2005. It will also be applicable to all new applications for product authorisations submitted nationally after the date of implementation of the Irish regulations, and with a five year transition period for those products authorised before the date of the regulations. The IMB website guidance on Braille should be consulted for the IMB approach to this requirement.

To date, several issues have arisen which have necessitated clarification and these are highlighted here:

- Addition of Braille can be done at time of renewal or by means of variation to update in line with the new legislation.
- The 'Braille declaration' submitted should show exactly what information appears on the carton including units, backslashes etc.
- There is no requirement for flat dot mockups to be provided at this time, however normal mockups should be provided along with the Braille declaration to indicate from which label version onwards the Braille declaration applies.
- One Braille declaration suffices per product strength and will be kept on file. The declaration should therefore be updated if there is a change in product name.

- If there is a change in packaging layout e.g. Article 61.3 notification, the company must satisfy themselves that this does not affect the legibility of any text now underlying the Braille, to maintain compliance with the Braille declaration on file.
- IMB market surveillance will determine that the information provided in Braille on the carton is that which was stated in the Braille declaration on file and correctly interpretable.
- Where a product is for administration by the patient themselves, Braille must appear as per EU Braille guideline.
- The format of Braille to be used should be in line with the requirements of the European Braille guideline 'Guidance concerning the Braille requirements for labeling and the package leaflet' (Article 56a of Directive 2001/83/EC as amended) April 2005. The timelines for implementation of these variations follow the current implementation timelines.
- The quality of the embossing mechanism and medium used must be carefully evaluated to ensure that the carton will still be readable at the end of shelf life.

The requirement for 'accessible' leaflets, i.e. leaflets to be available in formats suitable for the blind or partially sighted applies for all PA's.

USER TESTING OF PACKAGE LEAFLETS

For all MR, Decentralised and Centralised marketing authorisations granted after 30th October 2005, requirements as set out in Directive 2001/83/EC as amended by Directive 2004/27/EC apply.

The requirements will apply to all new applications for products submitted nationally after the date of implementation of the Irish regulations (Medicinal Products (Control of Placing on the Market) Regulations) or for products which undergo significant changes to the SPC and in other situations such as change in legal status, or in situations where safety issues arise.

A 'User test Outcome Report' is required to be submitted in Module 1.3.4 of the application dossier unless adequate justification is given for not submitting such a report.

To date, the following issue has arisen on a few occasions, namely: 'Is there a need for user testing of patients leaflets for products administered by healthcare professionals only?' User testing of patient leaflets is required for products administered by healthcare professionals. The results of consultation with target patient groups will need to be taken into account for all leaflets regardless of the classification, unless adequate justification is given for not submitting such results.

In approving package leaflets, the competent authority will look for evidence that people who are likely to rely on the package leaflet can identify, understand and apply the key information.

Any user test submitted in support of a package leaflet must address for example the following:

- safety issues
- significant side effects
- warnings
- indication(s)
- how to take/use the product
- dosage
- what to do if a dose is missed?
- what to do in the event of an overdose
- views and observations of patients

Further information on current IMB findings in relation to Braille has been published in IMB Newsletter 21 and further guidance will be added to the website periodically.

VETERINARY MEDICINES

LEGISLATION AND GUIDELINES

EMEA/CVMP/814/00 (CPMP/QWP /2819/00) *Rev. 1* Note for Guidance on Quality of Herbal Medicinal Products / Traditional Herbal Medicinal Products (CHMP/CVMP Adopted March 2006)

EMEA/CVMP/815/00 (CPMP/QWP/ 2820/00) *Rev. 1* Note for Guidance on specifications: Test procedures and Acceptance Criteria for Herbal Substances, Herbal Preparations and Herbal Medicinal Products / Traditional Herbal Medicinal Products (CHMP/CVMP Adopted March 2006)

VETERINARY LICENSING APPLICATIONS

The Receipts & Validation Section is now responsible for the receipt and validation of all veterinary licensing applications. Please forward all new applications, variations, transfers and renewal applications with relevant fees to the Receipts & Validations Section at the address below.

On submission of **new marketing authorisation applications** the Veterinary Medicines Department requests that the applicant provide an electronic copy of the SPC on CD-ROM or portable hard disk or by e-mail to vetspcs@imb.ie

Irish Medicines Board
Receipts & Validation Section
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

NEW REQUIREMENTS REGARDING ENVIRONMENTAL RISK ASSESSMENT

Directive 2001/82/EC, as amended by Directive 2004/28/EC, includes new provisions regarding the consideration of effects on the environment in the risk/benefit assessment of veterinary medicinal products and new data requirements regarding such effects. An environmental risk assessment (ERA) is mandatory therefore in respect of all veterinary medicinal products, whether it is a pharmaceutical or a biological product and independent of the type of application (including 'full' and 'bibliographical' etc.) or procedure for a marketing authorisation.

This provision is, in principle, also applicable to Type II variations and extension applications. However, the EU Commission has been requested to clarify whether the provision of an ERA would be restricted to those Type II variations falling under Annex II of Regulation (EC) No 1085/2003.

The CVMP is currently reflecting on how to carry out an ERA for renewals of existing marketing authorisations in circumstances where no data had been submitted with the original application. It is expected that during the course of 2006, an EMEA guidance note will be developed which might assist in this task. Nevertheless, applicants are reminded that ERAs must be submitted for all applications, including bibliographical applications and renewal applications where they have not been provided previously.

Applications which do not contain an ERA or where the assessment of the application, including the ERA, shows that there is a negative risk/benefit balance shall, in accordance with Article 30 of Directive 2001/82/EC as amended, be refused.

IMB LABELLING REQUIREMENTS

QRD templates are available at http://www.emea.eu.int/htms/vet/qrd/qrdplt/26556805en.pdf. These templates are applicable to centrally authorised products and annotated versions specifically for MRP and DCP are published on the HEVRA website. As far as possible these templates should also be used for national procedures as they are a useful guide to the layout and level of detail that should be included in the product literature. Some additional national requirements remain applicable for MRP, DCP and national applications. These requirements are detailed on the IMB website (www.imb.ie) and in the tables below.

Table 1 *Additional national requirements for pharmaceutical products*

PHARMACEUTICAL PRODUCTS

Immediate packaging	*Outer packaging*	*Leaflet*
Abbreviation for route of sale and supply – to be placed in a box	*Abbreviation for route of sale and supply – to be placed in a box*	*Abbreviation for route of sale and supply – to be placed in a box and explanatory phrase*
-	-	*For multidose parenteral only: The statement 'Should any apparent growth or discolouration occur, the product should be discarded'*
For multidose parenteral products only – An in- use shelf life	*For multidose parenteral products only - An in use shelf life*	*For multidose parenteral only products - An in use shelf life*
For multidose parenteral products only – The name and concentration of antimicrobial preservative, or an indication that the product does not contain a preservative, as applicable	*For multidose parenteral products only – The name and concentration of antimicrobial preservative, or an indication that the product does not contain a preservative, as applicable*	*For multidose parenteral products only – The name and concentration of antimicrobial preservative, or an indication that the product does not contain a preservative, as applicable*
-	-	*Veterinary Product Authorisation (VPA) number*
The words 'Keep out of reach and sight of children'	*The words 'Keep out of reach and sight of children'*	*The words 'Keep out of reach and sight of children'*
National waste disposal instructions, as appropriate	*National waste disposal instructions, as appropriate*	*National waste disposal instructions, as appropriate*

Table 2 *Additional national requirements for immunological products*

IMMUNOLOGICAL PRODUCTS

Immediate packaging	*Outer packaging*	*Leaflet*
Abbreviation for route of sale and supply – to be placed in a box	*Abbreviation for route of sale and supply – to be placed in a box*	*Abbreviation for route of sale and supply – to be placed in a box and explanatory phrase*
In-use shelf life	*In-use shelf life*	*In-use shelf life*
Keep out of the reach and sight of children	*Keep out of the reach and sight of children*	*Keep out of the reach and sight of children*
-	-	*Veterinary Product Authorisation (VPA) number*
-	*Reference to the antimicrobial preservative, if present.*	*Name and concentration of antimicrobial preservative*
-	-	*Use only sterile needles and syringes for administration (if applicable)*
-	-	*If a product is classified as LM the following warning is required 'Prior to first time use on a farm, it is strongly recommended that the advice of a veterinary surgeon is sought'.*
National waste disposal instructions, as appropriate	*National waste disposal instructions, as appropriate*	*National waste disposal instructions, as appropriate*

HARMONISED PRODUCT LITERATURE

In relation to dual-labelled products (i.e. packaging labelled for sale in both Ireland and UK), issues have arisen relating to the new UK requirement to include the statement 'UK authorised veterinary medicinal product' on the product literature. Following consultation between the IMB and the UK's Veterinary Medicines Directorate, it has been agreed that the following statement should be included on harmonised immediate and outer packaging and package leaflets:

'Veterinary Medicinal Product authorised for use in UK and IE'.

On the immediate packaging of small containers, due to space constraints, this can be shortened to:

'Authorised for use in UK and IE'.

APPOINTMENTS TO ADVISORY COMMITTEE FOR VETERINARY MEDICINES (ACVM)

The following persons were appointed by the Minister for Health & Children to the ACVM on 21 February 2006:

Mr. Patrick Brangan (Chairman)
Dr. Tom Barragry
Mr. Rory Breathnach
Mr. Joseph Britton
Mr. Matt Browne
Ms. Gene Canavan
Mr Michael F. Clancy
Mr. Tom McGuinn
Dr. Hamish D. Rodger
Dr. Donal Sammin
Mr. John McManus
Dr. Ann Cullinane

COMPLIANCE

GMP CERTIFICATES

The revised European Legislation has introduced a new requirement that a Good Manufacturing Practice (GMP) certificate is issued by the competent authority within 90 days of carrying out an inspection if the manufacturer is found to comply with the principles and guidelines of GMP. Information from the certificate will be input into a EudraGMP database that is currently being developed by the EMEA.

This post-inspection GMP certificate is used for the purpose of confirming to a manufacturer (whether of active substances or medicinal products) the overall conclusion of an inspection with respect to compliance with GMP.

A common style and format has been adopted and, since 30th October, 2005, all GMP certificates have been in the new format.

The IMB would like to bring to your attention the following changes that result from the introduction of this new requirement.

- For manufactures of active substances

Manufacturers of active substances who wish to apply for a new or renewed Good Manufacturing Practice (GMP) certificate are requested to apply 20 weeks in advance of the desired date of issue of the certificate.

This time frame is necessary to allow for the scheduling and the close-out of the inspection.

The IMB will issue a GMP certificate to active substance manufacturing sites which are found to comply with the principles and guidelines of GMP. This GMP Certificate is part of the overall inspection process and will be issued free of charge to the manufacturer. Duplicates of valid GMP Certificates may be ordered through the Export Certification Scheme and a fee will be charged in accordance with the IMB Schedule of Fees.

- For manufacturers of medicinal products

The IMB will issue a GMP certificate to manufacturing sites, where partially manufactured or finished medicinal products are produced, that are inspected after 30th October 2005 if the manufacturer is found to comply with the principles and guidelines of GMP. This GMP Certificate is part of the overall inspection process and will be issued free of charge to the manufacturer.

Duplicates of valid GMP Certificates can be requested from the IMB through the Export Certification Scheme. A fee for additional GMP certificates will be charged in accordance with the IMB Schedule of Fees.

Manufacturing sites that were last inspected prior to the 30th October 2005 can still apply for GMP certificates through the Export Certification Scheme.

QP DISCRETION / COMPLIANCE WITH THE MARKETING AUTHORISATION

A reflection paper has been published on the EMEA website at http://www.emea.eu.int/Inspections/docs/QPdiscretion.pdf

The European Commission has signalled its possible future support for a corresponding amendment to Annex 16 of the GMP Guide (Certification by a Qualified Person and Batch Release). This will partly depend on feedback from the industry on the practical implementation of the details in this reflection paper. The EMEA is presently considering, together with the Commission, how this feedback should be collected and further information on this will be provided in the coming months.

INFORMATION DAY

The IMB Information Day for GMP and Market Compliance will be held on Thursday November 9th, 2006. Further details on the venue, agenda and application form will be available on the IMB website.

Human New Product Authorisations Issued (January – March 2006)

PA Number	Product Name
PA0290/069/003	CILOXAN
PA0329/009/001	PECTODRILL FOR CHESTY COUGHS
PA0329/009/002	PECTODRILL SUGAR FREE CHESTY COUGHS
PA0329/009/003	Tussidrill sugar-free for dry coughs
PA0436/028/002	Nasobec Allergy
PA0476/018/001	PRAVASTATIN
PA0476/018/002	PRAVASTATIN
PA0476/018/004	PRAVASTATIN
PA0544/002/004	Rubavax Vaccine, Live
PA0566/020/002	Voluven (Polyolefine/Freeflex Bag)
PA0566/020/003	Voluven (PVC Bag)
PA0577/078/001	Migrastat
PA0577/078/002	Migrastat
PA0585/011/001	CLARITHROMYCIN
PA0585/011/002	CLARITHROMYCIN
PA0711/084/001	Sertraline
PA0711/084/002	Sertraline
PA0711/087/001	Tamsulosin
PA0711/089/001	Lansoprazole
PA0711/089/002	Lansoprazole
PA0711/091/001	Risperidone
PA0711/091/002	Risperidone
PA0711/091/003	Risperidone
PA0711/091/004	Risperidone
PA0754/007/001	Vinorelbine "Ebewe"
PA0754/008/001	Epirubicin "Ebewe"
PA0968/002/003	KESTINE FLASH
PA0968/002/004	KESTINE FLASH
PA1063/021/001	Prolosin
PA1063/023/001	Kamiren
PA1069/001/001	FLUZAC
PA1103/001/001	MELOXICAM FAL
PA1103/001/002	MELOXICAM FAL

PA Number	Product Name
PA1140/004/001	Pethidine Injection BP
PA1285/002/001	Mirtazapine
PA1285/002/002	Mirtazapine
PA1285/002/003	Mirtazapine
PA1285/003/001	Mirtazapine Olinka
PA1285/003/002	Mirtazapine Olinka
PA1285/003/003	Mirtazapine Olinka
PA1285/004/001	Clarithromycin
PA1285/004/002	Clarithromycin
PA1285/005/001	Citalopram
PA1285/005/002	Citalopram
PA1285/005/003	Citalopram
PA1300/001/001	Gabapentin
PA1300/001/002	Gabapentin
PPA0465/015/002	Vibramycin
PPA0465/048/002	Canesten
PPA0465/078/007	Risperdal Quicklet
PPA0465/078/008	Risperdal Quicklet
PPA0465/080/004	Detrusitol SR
PPA0465/110/001A	AULIN
PPA0465/123/002	Zinnat
PPA0465/129/003	Lexapro
PPA0465/149/001	Daonil
PPA0465/152/001	Lexotan
PPA0465/152/002	Lexotan
PPA0465/168/001	Zanaflex
PPA0465/168/002	Zanaflex
PPA0465/173/001	Atrovent UDV's
PPA0465/173/002	Atrovent UDV's
PPA0465/174/001	Requip
PPA0465/174/002	Requip
PPA0465/174/003	Requip
PPA0465/174/004	Requip

Human New Product Authorisations Withdrawn (January – March 2006)

PA Number	Product Name
PA0007/004/001	TRANXENE
PA0007/059/001	PHARMATON VIT-AL PLUS
PA0012/073/001	NUVELLE
PA0016/001/001	PROSTIN E2 ORAL
PA0021/079/001	Rennie Relieve
PA0021/081/001	Valderma Care Antiseptic Skin
PA0022/001/004	ATIVAN
PA0022/001/005	ATIVAN
PA0022/076/001	ISOVORIN

PA Number	Product Name
PA0047/005/001	Nebcin
PA0047/005/002	Nebcin
PA0047/005/003	Nebcin
PA0050/089/001	HIVID
PA0050/089/002	HIVID
PA0050/148/002	Loron 520
PA0054/064/001	NUTRIZYM
PA0057/054/006	Aerolin Autohaler
PA0057/061/001	Acupan

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Human New Product Authorisations Withdrawn (cont.) (January – March 2006)

PA Number	Product Name
PA0062/029/001	Lipobase
PA0062/037/001	Cardene
PA0062/037/002	Cardene
PA0062/037/003	Cardene SR
PA0062/037/004	Cardene SR
PA0073/020/002	Morphine Sulphate
PA0073/020/005	Morphine Sulphate
PA0073/020/006	Morphine Sulphate
PA0073/105/004	Sodium Chloride
PA0073/107/005	Water for Injections
PA0073/114/001	Ferrotab
PA0073/118/001	Dextrose
PA0073/128/001	Cimagen
PA0073/128/002	Cimagen
PA0073/128/003	Cimagen
PA0118/047/001	Timolol Chauvin
PA0118/047/002	Timolol Chauvin
PA0126/082/004	Diclomel 50
PA0126/082/005	Diclomel 100
PA0126/107/001	Innomel
PA0126/107/002	Innomel
PA0126/107/003	Innomel
PA0126/107/004	Innomel
PA0126/109/001	VIAZEM XL
PA0126/109/002	VIAZEM XL
PA0126/109/003	VIAZEM XL
PA0126/109/004	VIAZEM XL
PA0126/109/005	VIAZEM XL
PA0126/145/001	Citalopram
PA0126/145/002	Citalopram
PA0126/145/003	Citalopram
PA0167/080/001	HEMOFIL M ANTIHAEMOPHILIC
PA0167/080/002	HEMOFIL M ANTIHAEMOPHILIC
PA0167/080/003	HEMOFIL M ANTIHAEMOPHILIC
PA0167/095/001	Ivelip
PA0167/095/002	IVELIP
PA0167/116/001	GAMMABULIN
PA0185/002/001	Parake
PA0185/028/001	Galenamox
PA0185/028/002	Galenamox
PA0185/028/003	Galenamox
PA0185/028/004	Galenamox
PA0185/034/001	Nitedri
PA0218/024/001	MONOTARD INSULIN
PA0218/025/001	ACTRAPID
PA0218/025/004	ACTRAPID PENFILL
PA0218/025/005	ACTRAPID NOVOLET
PA0218/026/001	INSULATARD 100IU
PA0218/026/004	INSULATARD PENFILL 100IU
PA0218/026/005	INSULATARD NOVOLET 3 ML
PA0218/027/001	ULTRATARD 100IU/ML
PA0218/029/004	MIXTARD 30 PENFILL 3ML
PA0218/029/005	MIXTARD 30 NOVOLET 100IU/ML
PA0218/033/005	MIXTARD 10 NOVOLET 3ML
PA0218/034/004	MIXTARD 20 PENFILL 3ML
PA0218/034/005	MIXTARD 20 NOVOLET 100IU/ML
PA0218/035/004	MIXTARD 40 PENFILL 3ML
PA0218/035/005	MIXTARD 40 NOVOLET 3ML
PA0218/036/005	MIXTARD 50 NOVOLET 3ML
PA0261/012/001	PREGNYL 500
PA0277/001/002	OPTIMINE
PA0277/003/001	Tinaderm-M
PA0277/007/001	NETILLIN AMPOULE
PA0277/007/003	NETILLIN AMPOULE
PA0277/007/004	NETILLIN
PA0277/007/006	NETILLIN
PA0277/007/008	NETILLIN VIAL
PA0277/018/005	Pilocarpine
PA0277/065/001	WATER FOR INJECTION
PA0277/069/001	Uni-Dur Sustained Release
PA0277/069/002	Uni-Dur Sustained Release
PA0278/007/002	Anhydrol
PA0278/018/001	Dithrogel
PA0278/018/002	Dithrogel
PA0278/018/003	Dithrogel
PA0278/018/004	Dithrogel
PA0278/018/005	Dithrogel
PA0278/018/006	Dithrogel
PA0281/011/001	Thiozine
PA0282/010/001	IBUPROFEN
PA0282/010/002	IBUPROFEN
PA0282/010/003	IBUPROFEN
PA0282/049/001	Diltiazem Hydrochloride
PA0388/006/001	Epsom Salts Ph. Eur
PA0405/003/001	Gerivent
PA0405/025/001	Cimetidine
PA0405/025/002	Cimetidine
PA0405/025/003	Cimetidine
PA0405/026/001	Geroxicam
PA0405/026/002	Geroxicam
PA0405/032/001	Cyproterone Acetate
PA0408/001/003	Rimacilin Ampicillin Mixture BP
PA0408/021/001	Rimazine Chlorpromazine
PA0408/021/002	Rimazine Chlorpromazine

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Human New Product Authorisations Withdrawn (cont.) (January – March 2006)

PA Number	Product Name
PA0408/021/003	Rimazine Chlorpromazine
PA0408/024/001	Rimaprin Aspirin BP
PA0409/004/001	Chendol
PA0409/004/002	Chendol
PA0422/006/001	Lowasa
PA0437/021/001	Bacteriostatic Water
PA0437/021/002	Bacteriostatic Water
PA0437/021/003	Bacteriostatic Water
PA0473/003/004	Zepholin S.R.
PA0522/007/001	Super Vitamin C
PA0566/001/001	HAES STERIL
PA0566/001/002	HAES STERIL
PA0577/009/001	Inamide
PA0577/012/001	Geroxicam Dispersible
PA0577/012/002	Geroxicam Dispersible
PA0577/015/001	Glibenclamide
PA0577/019/001	Diclofenac
PA0577/019/002	Diclofenac
PA0675/001/001	ICODIAL 7.5%
PA0675/001/003	Icodial
PA0678/079/001	Otomize
PA0696/003/001	Quinaband
PA0705/005/003	Mitoxana Lyophilisate
PA0705/005/004	Mitoxana Lyophilisate
PA0705/005/005	Mitoxana Lyophilisate
PA0705/005/006	Mitoxana Lyophilisate

PA Number	Product Name
PA0711/042/001	Luvased Mono
PA0743/004/001	Slomon SR
PA0819/021/001	Ulcid
PA0819/029/001	OMEPRAZOLE-RATIOPHARM
PA0819/029/002	OMEPRAZOLE-RATIOPHARM
PA0822/008/001	Accuretic
PA0833/004/001	ZOLGEN
PA0833/004/002	ZOLGEN
PA0849/005/001	Albutein 5%
PA0849/005/002	Albutein 20%
PA0849/005/003	Albutein 25%
PA0891/004/001	Butenafine Hydrochloride 10 mg/g
PA0913/007/001	Gastrobid Continus
PA0913/020/001	Distalgesic
PA0936/036/001	Estracyt
PA0936/088/001	CORVERT
PA0970/036/003	BRICANYL
PA1112/002/001	ALBUREX
PPA0465/130/001A	ZISPIN
PPA1071/006/001A	Protium
PPA1071/006/002A	Protium
PPA1071/008/001A	Prothiaden
PPA1071/010/001A	Becotide 50 Inhaler
PPA1071/010/002A	Becotide 100 Inhaler
PPA1071/012/001A	Tagamet
PPA1071/013/001A	Brufen Retard

Human New Product Authorisations (Mutual Recognition) (January – March 2006)

PA Number	Product Name
PA0038/079/004	Arythmol SR
PA0038/079/005	Arythmol SR
PA0038/079/006	Arythmol SR
PA0047/095/001	Strattera
PA0047/095/002	Strattera
PA0047/095/003	Strattera
PA0047/095/004	Strattera
PA0047/095/005	Strattera
PA0047/095/006	Strattera
PA0102/023/004	Movicol Paediatric Plain
PA0108/029/001	Coepratenz Plus
PA0312/009/001	Dexsol
PA0408/060/001	CLINDAMYCIN
PA0549/015/001	Ethirfin
PA0549/015/002	Ethirfin
PA0549/015/003	Ethirfin
PA0549/015/004	Ethirfin

PA Number	Product Name
PA0549/015/005	Ethirfin
PA0577/071/001	Gerozac
PA0577/073/001	Tamsulosin
PA0592/007/001	Intratect
PA0623/007/001	Metoject
PA0711/080/001	Glepid
PA0711/080/002	Glepid
PA0711/080/003	Glepid
PA0711/080/004	Glepid
PA0711/080/005	Glepid
PA0711/081/001	Sumatran
PA0711/081/002	Sumatran
PA0818/004/002	Levonelle
PA0862/001/001	SMART DOSE
PA0865/014/001	Omesar Plus
PA0865/014/002	Omesar Plus
PA0969/006/001	Rigevidon

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Human New Product Authorisations (Mutual Recognition) (cont.) (January – March 2006)

PA Number	Product Name	PA Number	Product Name
PA0979/011/008	Gaviscon Advance	PA1077/103/004	Ropinirole Saint-Germain
PA0985/002/001	Ubit	PA1077/103/005	Ropinirole Saint-Germain
PA1009/019/001	Bravelle	PA1130/005/001	Ipratropium Bromide
PA1077/102/001	Ropinirole Paucourt	PA1130/005/002	Ipratropium Bromide
PA1077/102/002	Ropinirole Paucourt	PA1135/002/001	Benetor Plus
PA1077/102/003	Ropinirole Paucourt	PA1135/002/002	Benetor Plus
PA1077/102/004	Ropinirole Paucourt	PA1148/003/001	Klariger
PA1077/102/005	Ropinirole Paucourt	PA1148/003/002	Klariger
PA1077/103/001	Ropinirole Saint-Germain	PA1252/001/001	Tamsulosin Hydrochloride
PA1077/103/002	Ropinirole Saint-Germain	PA1252/002/001	Tacap
PA1077/103/003	Ropinirole Saint-Germain		

Veterinary New Product Authorisations Issued (January – March 2006)

VPA Number	Product Name	VPA Number	Product Name
10806/001/001	Genestran	10987/064/001	Canidryl
10960/061/001	Tetroxy 10%	10987/064/002	Canidryl
10960/062/001	Dipen	10987/064/003	Canidryl

Veterinary New Authorisation Issued (Mutual Recognition) (January – March 2006)

VPA Number	Product Name	VPA Number	Product Name
10545/030/001	Furexel Combi	10996/193/001	Cyclix
10989/051/001	Octacillin		

Veterinary Product Authorisations Withdrawn (January – March 2006)

VPA Number	Product Name	VPA Number	Product Name
10966/025/001	Sedalin	10988/051/001	Tectonik Pour-On
10966/025/002	Sedalin		

Veterinary Immunological New Authorisations Issued (Mutual Recognition) (January – March 2006)

VPA Number	Product Name	VPA Number	Product Name
10277/089/001	AquaVac ERM	10996/192/001	Nobilis IBmuli+ND+EDS
10277/090/001	Procyon Dog DA2PPi/CvL	10996/195/001	Nobivac Forcat
10996/191/001	Nobilis Paramyxo P201	10996/196/001	Porcilis M.hyo

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