IRISH MEDICINES BOARD

news LETTER

MEDICINAL PRODUCTS

JULY – SEPTEMBER 2005 Issue No. 21

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

GENERAL

IMB signs Confidentiality Agreement with FDA

Shown above is Mr Pat O'Mahony, Chief Executive of the IMB and Dr Murray Lumpkin of the FDA at the recent signing of a confidentiality agreement between the IMB and the FDA. The agreement provides for a formal system of sharing information between the two organisations in a timely manner to further enable the common goal of protecting public health. The FDA has similar agreements in place with the European Commission/EMEA and competent authorities in a number of other countries.

STAFF CHANGES

MAURA O'DONOVAN and JAYNE CROWE were appointed Medical Officers in the Human Medicines Department.

LORCAN ALLEN was appointed Toxicologist in the Human Medicines Department.

CONOR O'DONOVAN was appointed Pharmaceutical Assessor in the Human Medicines Department.

CLAIRE McCARTHY was appointed Pharmaceutical Assessor in the Human Medicines Department.

CONTENTS

HUMAN MEDICINES

Legislation and Guidelines

The following EU guidelines have been adopted.

CPMP/EWP/021/97 Revision 1 Guideline on Clinical Investigation of Medicinal Products for Hormone Replacement Therapy of Oestrogen Deficiency Symptoms in Postmenopausal Women (Adopted by CHMP October 2005)

CPMP/EWP/329339/05 Overview of Comments received on Draft Guideline on Clinical Investigation of Medicinal Products for Hormone Replacement Therapy of Oestrogen Deficiency Symptoms in Postmenopausal Women CPMP/EWP/021/97 rev 1

CPMP/EWP/139391/04 Reflection Paper on the regulatory guidance for the use of Health-Related Quality of Life (HRQL) measures in the evaluation of medicinal products (Adopted by Committee July 2005)

CPMP/EWP/2158/99 Guideline on the Choice of the Non-Inferiority Margin (Adopted by Committee July 2005)

CHMP/EWP/5872/03 corr Guideline on Data Monitoring Committees (Adopted by Committee July 2005)

CPMP/EWP/519/98 Revision 1 Guide line on Clinical Investigation of Steroid Contraceptives in Women (Adopted by Committee July 2005)

Topic S8, Step 4 Note for Guidance on Immunotoxicity studies for Human Pharmaceuticals

(EMEA/CHMP/167235/05 - adopted October 2005)

CPMP/QWP/2819/00 (EMEA/CVMP/814/00) *Rev. 1* Guideline on Quality of Herbal Medicinal Products / Traditional Herbal Medicinal Products (CHMP/CVMP adopted July 05)

CPMP/SWP/799/95 Guideline on the Non-Clinical Documentation for Mixed Marketing Authorisation Applications (CPMP adopted 12 October 2005)

Update of the 'Guideline on the Summary of Product Characteristics' (October 2005)

Module 1 - Administrative information (Part 1: Summary of the dossier - Part 1A Application form - Administrative data) (October 2005)

The following EU Commission guidelines have been drafted.

Draft update of the 'Guideline on changing the classification for the supply of medicinal products'.

Draft 'Guidance concerning the patients' consultation requirements for the package leaflet (Article 59(3) and 61(1) of Directive 2001/83/EC amended by Directive 2001/27/EC'

NEW MEDICINES LEGISLATION

Transitional arrangements

Directives 2004/27/EC and 2004/24/EC are due to be transposed into Irish law by means of regulations to be made under the Irish Medicines Board Act. As the making of the regulations has been delayed, transitional arrangements have been agreed between the Department of Health and Children and the IMB in relation to the new requirements in the directives for medicinal products for human use. The following guidance is provided to PA holders and applicants in order to assist them in making applications to the IMB. It does not include an exhaustive list of the provisions of the directives: those which place obligations on the competent authority will apply, as appropriate, from 30 October 2005, while many others are provided for by current practice or by the Irish Medicines Board Act.

1 Directive 2004/27/EC provisions which apply from 30 October 2005

1.1 Article 10(1) provisions for data exclusivity and market exclusivity

The new periods of exclusivity therefore apply to applications submitted from 30 October 2005.

1.2 Article 8 and 9 which describes the content and handling of the dossier

Applicants must also use updated application forms for new and renewal applications and structure the dossier in the updated CTD format as soon as they are provided by the European Commission.

1.3 Articles 8.1 and 10 which provide for the legal bases of applications, including the provision relating to the European reference product

1.4 Articles 24(2) and 24(3) relating to the renewal of marketing authorisations

1.5 Chapter 4 relating to the new decentralised procedure and the revised mutual-recognition procedure.

1.6 Articles 46F and 46a which require manufacturing authorisation holders to use only active substances which have been manufactured in accordance with GMP.

2 Directive 2004/24/EC provisions which will take effect on the date of making of the regulations

2.1 Articles 23a, paragraphs 1 and 2 which require notification of the date of marketing and of a cessation in marketing

2.2 Articles 24(4) – (6) relating to the 'sunset clause'.

2.3 Article 24(4), second paragraph, which provides for public assessment reports.

3 Provisions relating to labels and leaflets

The Medicinal Products (Control of Placing on the Market) Regulations, as currently drafted, provide for specific transitional arrangements for

the label and leaflet requirements in Title V of the directive. These draft regulations state that the requirements do not apply to any product authorisation in force on 30 October 2005 or any application for a product authorisation made before that date until 30 October 2010, i.e., a transitional period of five years. It is assumed that at least the former date will be changed to the date of making of the regulations.

Title V of the directive will therefore apply to national applications submitted from the date of making of the regulations, although applicants are encouraged to submit labels and leaflets in line with the new requirements as soon as possible.

As the requirements of Title V will apply to mutual-recognition and decentralised applications from 30 October 2005, these applications will have to include labels and leaflets in line with the revised Title V requirements when submitted to the IMB from 30 October 2005.

4 Periodic Safety Update Reports (PSURs)

PSURs and Renewals

To aid submission of PSURs on an EU-wide basis, the new PSUR submission schedule applies from 30 October, therefore renewal applications submitted after October 2005 may include a three-year PSUR, together with bridging data sufficient to meet the timeline for submission of the renewal application.

For products that are due for renewal during the next five years, the existing submission cycle applies (i.e., six monthly, yearly for the following two years and in support of the first renewal application. Thereafter, the three-year submission schedule will apply.

The provision for a further renewal on pharmacovigilance grounds may apply to products with an existing authorisation, for which a PSUR submission schedule will be determined on a case by case basis.

Submission of PSURs unrelated to renewal applications

The schedule for submission of PSURs outside the circumstances of renewal applications remains unchanged, (as outlined above), and unless otherwise specified, thereafter at three yearly intervals. This submission will be based on the data lock points (DLP), which should be set according to the EU birth date (EBD) or the International Birth Date (IBD). Each PSUR should cover the period of time since the last PSUR and should be submitted within 60 days of the DLP.

Mutual recognition and decentralised procedures

From 30 October, several new aspects are introduced to the 'mutual recognition' procedure (MRP). The main changes are:

- The setting up of a statutorily based Co-ordination Group which will formally replace the Mutual Recognition Facilitation Group (MRFG).
- The introduction of a new 'decentralised procedure' (DCP) for products which do not already have a marketing authorisation within the EU.
- The introduction of the concept of 'potential serious risk', which will be the only basis for disagreement between Member States regarding the recognition of an existing authorisation or a recommendation to authorise.
- The need for harmonisation of labels and package leaflets during the procedure.
- The introduction of a new referral stage (to the Co-ordination Group) prior to arbitration by the CHMP.
- The requirement for an assessment report to be made publicly available.
- The inclusion of homeopathic medicinal products in MRP and DCP procedures, except in arbitration procedures involving referral to CHMP.

Co-ordination Groups

Over the past few months much work has been carried out to prepare for these changes. The MRFG and VMRFG have worked with each other, and with the Heads of Medicines Agencies, to prepare for their transformation into the co-ordination groups. These groups will be called CMD(h) and CMD(v) – Co-ordination Group for Mutual Recognition and Decentralised Procedures (human or veterinary). Work on new and updated Best Practice Guides and other documents for the CMDs is well advanced, and some documents are already available for consultation. When the CMDs meet for the first time in November many of these documents will be ready for adoption.

Decentralised Procedure

A basic timeframe for the decentralised procedure is given in Directive 2001/83/EC. Within this, a more detailed timetable common to human and veterinary procedures has been agreed; the flow chart is available on the MRFG website and on the IMB website under New Medicines Legislation. Within this timetable, the precise standard operating procedures (SOPs) will be finalised by the co-ordination groups. The draft SOP for the decentralised procedure for human medicines has been published by the MRFG and is available on their website and on the IMB website under New Medicines Legislation.

Potential Serious Risk Guideline

The concept of 'potential serious risk' is underpinned by a Commission Guideline, as specified in the Directive. A draft of the Guideline is now under consideration by the Commission.

Assessment of labelling

The harmonisation of labelling and leaflets during the MRP and DCP will require a considerable amount of additional work during the procedures for all concerned, but it is to be hoped that the provision will enable authorisations to be issued more rapidly after agreement is reached. The use of the QRD templates as recently published (http://www.emea.eu.int/htms/human/qrd/qrdplt/24530905en.pdf) should assist the assessment. A version of the QRD template, annotated specifically for MRP and DCP will shortly be available.

Referral to CMD

The new 60-day referral procedure will occur where there is disagreement between Member States involved in a procedure. It will give the whole CMD the opportunity to

discuss the issue, and so help to avoid the need for referral to CHMP.

The management of the CMD referral procedure has been the subject of discussion by MRFG and VMRFG, with a view to adopting a virtually identical procedure for the human and veterinary groups. A Standard Operating Procedure is available on the MRFG website.

Publicly available assessment report

A draft Best Practice Guide has been published on the MRFG website. For every product, consultation with the applicant is envisaged before an assessment report is made publicly available. It is expected that this provision will apply for all procedures reaching Day 90 after 30 October.

Data protection and market exclusivity

Directive 2004/83/EC provides for a common eight-year data protection period in the EU. After eight years, generic applications may be submitted and authorised by the competent authority, although the generic product cannot be marketed until the expiry of a further two-years' of market exclusivity for the reference product. This period of market exclusivity can be extended by a further year if, during the first eight years, the marketing authorisation holder obtains approval for one or more new therapeutic indications of significant clinical benefit.

A separate one-year of data protection may be obtained for a new therapeutic indication for a well-established substance and a separate one-year may also be obtained for a change in the classification of supply of a medicinal product. These periods of exclusivity relate only to the data submitted for the new indication or change in classification, not to the entire data package for the medicinal product.

Guidance on the issues relating to data protection and market exclusivity is included in Chapter 1 of the Notice to Applicants which is due to be published in November.

Legal basis of applications

The legal basis of applications in Article 10 of Directive 2001/83/EC has been amended by Directive 2004/27/EC. The new requirements are explained in Chapter 1 of the Notice to Applicants which is due to be published in November. A revised version of the Module 1.2 application form, incorporating the changes in the legal basis for applications, has been published on the website of the EU Commission and must be used for all new applications from 30 October.

European reference product

Article 10.1, third paragraph, of Directive 2001/83/EC, as amended by Directive 2004/27/EC, allows a generic application to be made when the reference product is not authorised in the Member State where the application is made but is authorised in another Member State. The conditions under which this provision may be used is explained in Chapter 1 of the Notice to Applicants which is to be published in November.

One aspect of the provision which has been clarified by the EU Commission is that it is only applicable in situations where the reference product is not authorised in the Member State where the application is made. It cannot be used in situations where the reference product is authorised in the Member State but the applicant wishes to refer to a reference product with a different SPC in another Member State.

Labels and leaflets

A number of guidance documents have recently been published in the area of patient information as a result of the changes arising from the new legislation, Directive 2004/27/EC.

The new label and leaflet requirement are detailed in Articles 54 to 69 of Directive.

Guides which should be consulted for further information include:

- *Draft guidance concerning consultations with target patient groups for the package leaflet* which has been published by the European Commission (August 05), and which discusses user testing. This is available from their website, at http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/08_05/USERTESTING_ 20050817.pdf.

- The European requirements for Braille *Guidance concerning the Braille requirements for labelling and the package leaflet* have been published (April 05) and are available also from the website of the European Commission, at http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/04_05/Braille_text20050411.pdf

  Please note separate guidance is available in this newsletter on the implementation of this requirement by the IMB.

- The revised *QRD human product information template with explanatory notes* Version 7 (published 07/2005) for centralised products is a useful guide to aspects of the layout and detail to be included in product information, and is available from http://www.emea.eu.int/htms/human/qrd/qrdplt/AnnotatedTemplate-H.pdf

- A guidance document *Draft operational procedure on handling of Consultation with target patient groups on the package leaflets (PL) for centrally authorised products for human use* looks at procedural impacts of the new legislation on centralised applications and is available on the EMEA website http://www.emea.eu.int/pdfs/human/euleg/27737805en.pdf

- An MRFG/CMD(h) concept paper on *Achieving Harmonised Patient Information* for European MR/DCP procedures is available on the Heads of Agencies website, and discusses the aim of harmonising patient information during the MR/DCP procedures http://heads.medagencies.org/mrfg/docs/pi/harmon_PI_concept.pdf

- MRFG have also published a useful paper *Questions and answers on the implementation of the new legislation* applicable to products authorised through MRP http://heads.medagencies.org/mrfg/new_legislation/docs/QA_new_legislation.pdf

Further information

Applicants are advised to watch for new information appearing on the MRFG websites (http://heads.medagencies.org) as well as the IMB website (www.imb.ie).

Further information on the implementation of these provisions is available in our newsletters available on **www.imb.ie** on the EMEA's website www.emea.eu.int and EU Commission's website. http://pharmacos.eudra.org, These sites should be consulted regularly for further updates.

Transitional arrangements for medicinal products will follow the guidance issued by the EMEA for centralised products, and by MRFG for mutual recognition products. National transitional arrangements are indicated elsewhere in this newsletter.

Requirements for Braille on labels and for package leaflet formats suitable for people with visual impairment

In order to ensure improved access to information on their medicines for people with visual impairment, Article 56a of Directive 2001/83/EC as amended by Directive 2004/27/EC has been introduced. It requires that the name of the medicinal product must be expressed in Braille format on the packaging, allowing improved differentiation of medicines. It also requires that the marketing authorisation holder ensures that the package information leaflet is available on request in formats which are suitable for people with visual impairment. The 'leaflet' provided should not be abridged in any way.

Further details on these requirements are available in the following EU guidance: *Guidance concerning the Braille requirements for labelling and the package leaflet (Article 56a of Directive 2001/83/EC as amended)*, available on the website of the European Commission at http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/04_05/Braille_text20050411.pdf

IMB Requirements

The following approach is being taken by the IMB to ensure compliance with this requirement:

A 'declaration of compliance' (see below for format) must be provided by the applicant for all new applications, at renewal and for variations to update patient information in line with the provisions of Article 56a of the new legislation. The relevant sections 1a or 1b, and 2 must be completed and the declaration must be signed and dated by the applicant's authorised representative. The Declaration will remain applicable to the product unless substituted with a revised declaration.

The Market Compliance Section of the IMB Compliance Department will check compliance of the labelling and the other provisions of Article 56a. As part of this work, the Market Compliance Section will obtain samples of medicinal products from the marketplace for checking, and will also perform inspections, as necessary, in order to monitor compliance with the provisions of Article 56a and with the declaration provided over the shelf life of the product.

The Braille requirement applies to all products authorised after the date of making of the relevant Irish regulation. It does not apply immediately to products authorised before that date, however companies are encouraged to apply the provisions to all medicinal products as soon as possible, and at the latest by 30 October 2010, at renewal or by way of variation.

Format of Braille declaration

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

Marketing authorisation holder's declaration of compliance with Article 56a of Directive 2001/83/EC as amended

Section 1a or 1b, and Section 2 must be completed- tick box if applicable

Section 1a

☐ I <*insert name*>, being the person responsible for communication on behalf of <*insert applicant company name*>, hereby declare that <*insert product name and PA number*> is in compliance with Article 56a of Directive 2001/83/EC as amended by Directive 2004/27/ EC, as interpreted by in the European Commission guidance 'Guidance concerning the Braille requirements for labelling and the package leaflet (Article 56a of Directive 2001/83/EC as amended)'.

The following text appears in Braille on the labelling <*add here in non-Braille text, the text which appears in Braille*>:

I furthermore declare:

- that the text which appears in Braille is easily readable, clearly comprehensible and does not adversely affect the legibility of the non-Braille labelling text, and
- that the Braille used is in a format suitable for Irish patients.

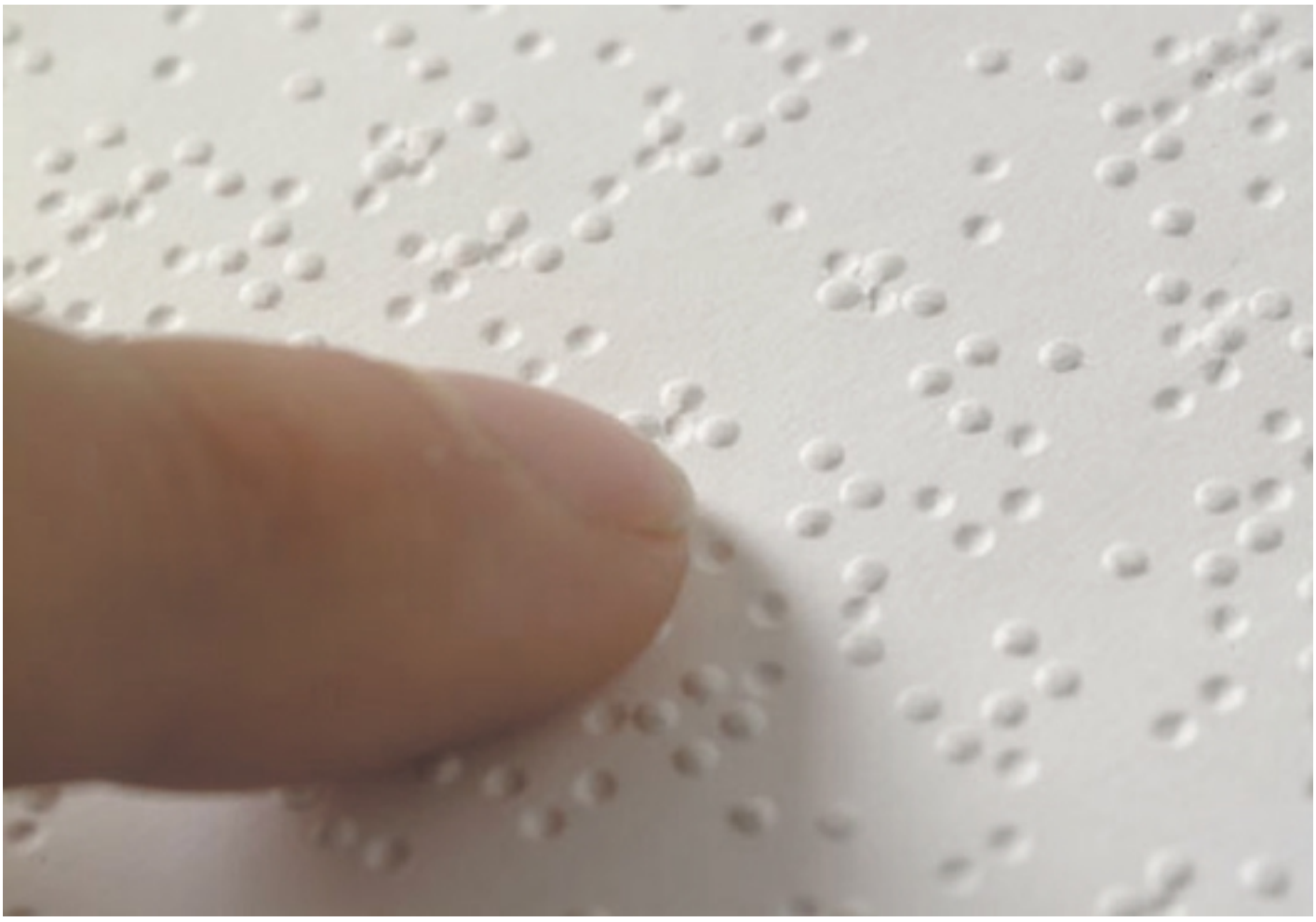
Section 1b

☐ I hereby declare that no Braille is required on the labelling as per European Commission guidance 'Guidance concerning the Braille requirements for labelling and the package leaflet (Article 56a of Directive 2001/83/EC as amended)' because the product is intended for administration by healthcare professionals only.

Section 2

☐ I hereby declare that the package information leaflet is available in formats suitable for the blind and partially-sighted in accordance with Article 56a of Directive 2001/83/EC as amended by Directive 2004/27/EC.

<*Signature, date and position*>



Marketing of medicinal products and withdrawals

The IMB has recently published a draft *Guide to Marketing Status Notifications and the Sunset Clause for Medicinal Products for Human Use* and a draft form, *Notifications of Marketing Status for Medicinal Products for Human Use*. The form must be used to notify the IMB when a medicinal product is marketed and/or when marketing ceases. This applies to medicinal products with product authorisations and to homeopathic products with certificates of registration but it does not apply to parallel import products. It will be applicable to herbal medicinal products with a certificate of traditional use registration. The guide and form are issued as drafts until the Medicinal Products (Control of Placing on the Market) Regulations are made by the Department of Health and Children.

As a result of this new notification process, the IMB document *Guidance on Withdrawals of Medicinal Products for Human Use* has been revised and is now issued as *Guide to Withdrawal of Authorisations or Certificates for Medicinal Products for Human Use*, with a revised form, *Notification of Withdrawal of Authorisations or Certificates for Medicinal Products for Human Use*. This process applies to medicinal products with a product authorisation, parallel import products, homeopathic products with a certificate of registration and will also be applicable to herbal medicinal products with a certificate of traditional use registration.

VARIATIONS

Type IB notifications

From January 2006, in addition to Type IA notifications, Type IB notifications submitted under an incorrect category will also be refused by the IMB. The marketing authorisation holder will no longer be given a 30-day period to correct the error by providing a revised application form and supporting documentation for the correct notification category. A new application must be submitted and a new fee will apply.

Type II variation applications

Any typographical errors identified in the marketing authorisation dossier can be corrected only by a Type II variation with details clearly stated in the 'present' and 'proposal' section of the variation form. However, such errors may be corrected in conjunction with another Type II variation for the same product.

Article 61(3) Notifications of Directive 2001/83/EC

Companies are reminded of their responsibility to include all the required documentation when submitting Article 61(3) notifications. Two copies of the currently approved colour mock-ups with changes highlighted are required, along with two copies of the proposed colour mock-ups signed and dated on each page. Also the applicant should ensure that all sections of the application form are completed appropriately. Applications cannot be assessed until the required documentation is submitted.

Labels and Package Leaflets

Applicants are reminded that information of a promotional nature is not permitted on product labelling or package leaflets. Contact details permitted include the telephone or fax number, and the e-mail address of the marketing authorisation holder. References to websites or e-mails linking to websites, coupons, product-specific phone lines, mail clubs etc are considered to be promotional in nature and are not permitted.

PHARMACOVIGILANCE

Provision of Usage Data

In accordance with Article 13 of Regulation (EC) No 726/2004, Article 23 of Directive 2004/27/EC, and the Notice to Marketing Authorisation Holders *(Volume 9 of the Rules Governing Medical Products in the EU – Pharmacovigilance-Medicinal Products for Human and Veterinary Use)*, companies are reminded of the obligation to provide usage data for products for which they hold marketing authorisations, in a timely manner on request from the IMB.

For practical purposes, these data should be presented on an annual basis for the period specified as an estimate of the number of patients treated, or prescriptions dispensed. Where relevant, the data should be broken down by presentation (e.g., oral, parenteral, topical etc.).

Electronic Adverse Reaction Reporting

Further to previous guidance on this topic, the IMB is pleased to inform companies that detailed information regarding electronic reporting of adverse reactions, originating from both clinical trial and post-marketing environments, is now available in the *Guide to the Electronic Submission of ICSRs and SUSARs Associated with Use of Human Medicines*. This document can be found in the Pharmacovigilance section of the website **www.imb.ie**, under 'Electronic Reporting'.

The guide provides additional information and clarification on many aspects of electronic reporting of ICSRs and SUSARs, including technical requirements and standards, use of the Eudravigilance Gateway and EVWeb interface, testing and production phases, as well as links to a number of useful documents and websites.

Companies are reminded of their obligation to submit ADR reports electronically from 20 November 2005, in accordance with the consolidated Directive 2001/83/EC as amended (Directive 2004/27/EC) and Regulation (EC) 726/2004.

Further information on electronic reporting is available in Part III – EU Electronic Exchange of Pharmacovigilance Information - *Volume 9 of the Rules Governing Medical Products in the EU – Pharmacovigilance-Medicinal Products for Human and Veterinary Use*. Volume 9 has been revised in the context of the amended legislation and it is expected to be released for consultation by the European Commission shortly.

Electronic Adverse Reaction Reporting - Compliance with E2B regulations - Reminder

In order to allow the IMB to meet compliance requirements for elec-

tronic reporting, companies who have not yet completed the testing phase and continue to submit paper copies of adverse reaction reports as of December 2005 are reminded to provide details of the primary source reporter, until paper copies of reports are no longer required. At a minimum the reporter's profession/occupation must be included in the adverse reaction report, eg nurse, GP, dentist etc.

HOMEOPATHIC MEDICINES

Complex products with and without indications

The final phase of the Simplified Registration Scheme (SRS) for homeopathic medicinal products was launched on 1 October 2005. Applications for the SRS for complex products without indications are being accepted as of 1 November 2005. A notice to this effect appeared in *The Irish Times* of 30 September.

One change was made to this notice from that which appeared in the last issue of the Newsletter, namely, that those products with indications will be dealt with under a separate scheme, to be announced. This change follows on from the proposed addition of Article 9 of the Medicinal Products (Control of Placing on the Market) Regulations. This Article makes provision for the authorisation of homeopathic medicinal products (HMP) with mild indications for self-limiting conditions; see websites (**www.imb.ie**) and (www.dohc.ie).

Guidelines and application forms for the scheme to facilitate these HMP will be available in due course. Applications to authorise these products will be accepted in the latter part of 2006 following the expiration of the final deadline for receipt of applications under the SRS for products currently on the Irish market. New products which qualify for the SRS can, however, continue to be submitted for registration.

VETERINARY MEDICINES

Legislation and Guidelines

The following European guidelines have been adopted.

CVMP/743/00 rev 1 Revised Guideline on Requirements and Controls applied to Bovine Serum used in the production of Immunological Veterinary Medicinal Products (CVMP adopted July 05)

EMEA/CVMP/814/00 (CPMP/QWP/2819/00) *Rev. 1* Guideline on Quality of Herbal Medicinal Products / Traditional Herbal Medicinal Products CPMP/CVMP Adopted July 05)

Legislation changes

The Veterinary Department is continuing preparations in advance of the implementation of the Animal Remedies Regulations 2005. Amongst the considerable number of changes which will affect the authorisation of veterinary medicinal products and veterinary homeopathic medicinal products are those which affect transparency and maintenance of the supply of medicines on the national market. The IMB has already prepared a draft template for publication of assessment reports and has published the draft on the IMB website for comments from interested parties. The IMB has also published draft guidelines and forms on the notification of marketing and of ceasing to market the products and the application of the so-called 'sunset' clause. For VPAs issued after 30 October 2005, the form must be used to notify the IMB when the veterinary medicinal product is marketed or when marketing ceases. This process applies to both pharmaceuticals and immunologicals as well as registered veterinary homeopathic remedies. Similarly, the IMB has also prepared a guideline and form for notification of the withdrawal of an authorised veterinary medicinal product or, in the case of a homeopathic veterinary medicinal product, a certificate of registration. The form specifies the reason for withdrawal,

which may be commercial or may relate to concerns regarding the quality (including GMP status), safety or efficacy of the product. For more details of these procedures contact Ms. Sinead Barron (sinead.barron@imb.ie).

Mutual recognition and decentralised procedures

With the introduction of the new legislation on 30 October, several new aspects are introduced to the 'mutual recognition' procedure (MRP). The main changes are:

- The setting up of statutorily based co-ordination groups which will formally replace the mutual recognition facilitation groups (VMRFG).
- The introduction of a new 'decentralised procedure' (DCP) for products which do not already have a marketing authorisation within the EU.
- The introduction of the concept of 'potential serious risk', which will be the only basis for disagreement between member states regarding the recognition of an existing authorisation or a recommendation to authorise.

- The need for harmonisation of labels and package leaflets during the procedure.
- The introduction of a new referral stage (to the relevant co-ordination group) prior to arbitration by the CVMP.
- The requirement for an assessment report to be made publicly available.
- The inclusion of homeopathic medicinal products in MRP and DCP procedures, except in arbitration procedures involving referral to CVMP.

Coordination Groups

Over the past few months much work has been carried out to prepare for these changes. The VMRFG and MRFG have worked with each other, and with the Heads of Medicines Agencies, to prepare for their transformation into the co-ordination groups. These groups will be called CMD(h) and CMD(v) – Co-ordination Group for Mutual Recognition and Decentralised Procedures (human or veterinary). Work on new and updated Best Practice Guides and other documents for the CMDs is well advanced, and some documents are already available for consultation. When the CMDs meet for the first time in November many of these documents will be ready for adoption.

Decentralised Procedure

A basic timeframe for the decentralised procedure is given in the Directives (2001/82/EC). Within this, a more detailed timetable common to human and veterinary procedures has been agreed; the flow chart is available on the MRFG website and on the IMB website under New Medicines Legislation. Within this timetable, the precise standard operating procedures (SOPs) will be finalised by the Co-ordination Group. The SOP for veterinary medicines is almost complete at the time of writing and will be made available on the IMB website as soon as possible.

Potential Serious Risk Guideline

The concept of 'potential serious risk' is underpinned by a Commission Guideline, as specified in the Directive. A draft of the Guideline is now under consideration by the Commission.

Assessment of labelling

The harmonisation of labelling/leaflet during the MRP and DCP will require a considerable amount of additional work during the procedures, for all concerned but it is to be hoped that the provision will enable authorisations to be issued more rapidly after agreement is reached. The use of the QRD templates as recently published (http://www.emea.eu.int/htms/vet/qrd/qrdplt/26556805en.pdf) should assist the assessment. A version of the QRD template, annotated specifically for MRP and DCP will shortly be available. A Best Practice Guide is almost complete.

Referral to CMDs

The new 60 day referral procedure will occur where there is disagreement between member states involved in a procedure. It will give the whole CMD the opportunity to discuss the issue/s, and so help to avoid the need for referral to CVMP. The management of the CMD referral procedure has been the subject of discussion by VMRFG and MRFG, with a view to adopting a virtually identical procedure for the human and veterinary groups. A draft Standard Operating Procedure is available for consultation and will be finalised by the CMD.

Publicly available assessment report

Work on Best Practice Guides and templates is well advanced. For every product, consultation with the applicant is envisaged before an assessment report is made publicly available. It is expected that this provision will apply for all procedures reaching Day 90 after 30 October.

Further information

Applicants are advised to watch for new information appearing on the VMRFG and (www.hevra.org) as well as the IMB website (www.imb.ie).

Product literature issues

With the introduction of the new legislation on 30 October, several changes are introduced to the requirements for product literature for veterinary medicinal products.

All new applications submitted to the IMB after 30 October 2005 for a national authorisation or through the mutual-recognition or decentralised procedures must comply with the new requirements. Applicants should ensure that they submit the required information in line with updates given on the EU Commission, EMEA and VMRFG websites.

For applications currently in-house, applicants will be asked to revise the product literature in line with the new requirements before authorisation.

Products which are currently authorised should comply with the new requirements by 30 October 2010 at the latest. The update may be done at the time of renewal of the product authorisation, during the next variation affecting the product literature (in both these cases the changes must be clearly outlined in the application) or by the submission of a variation or notification application, as applicable.

The new legislation includes changes to:

- format and content of the SPC
- content of labels
- content and format of package leaflets
- package leaflets written in terms comprehensible for the general public

New SPC format

The IMB has updated the national SPC template in line with Directive 2001/82/EC, as amended by Directive 2004/28/EC. We are implementing the same template as outlined by the EMEA and Quality Review of Documents Group. The new SPC template and SPC conventions are on the IMB website www.imb.ie for immediate use, under Veterinary Medicines/Publications/applications forms/SPC template/Veterinary template. This SPC template is for pharmaceuticals and immunologicals products. For queries please contact sinead.barron@imb.ie.

Format and Content of the SPC

Authorisations issued after 30 October 2005 will be issued in accordance with the new SPC format. To facilitate this applicants are requested, where relevant, to submit the SPC in the new format by e-mail to

vetspcs@imb.ie as detailed in IMB Newsletter No 20. The revised SPC guideline has been released for consultation and is available on the EMEA website at http://www.emea.eu.int/pdfs/vet/ewp/006505.en.pdf

Products with SPCs and packaging harmonised between UK and Ireland

The new legislation requires that changes be made to the SPC format and labelling of authorised products. A number of Marketing Authorisation Holders have taken advantage of the 'harmonisation' initiative set up between the IMB and the Veterinary Medicines Directorate (VMD) in the UK, to achieve a common SPC and packaging in UK and Ireland. For products which are harmonised in this way, the IMB and VMD have agreed that MAHs will be requested to submit a simultaneous variation to both authorities, in order to update the SPC and labelling in accordance with the new requirements. In Ireland this will be by way of a standard national type II variation, fee code 597.

It is hoped that the necessary changes will be implemented in the market place within 3 years (i.e. by 30 October 2008). MAHs of harmonised products are asked to plan for the submission of the variations as necessary to achieve this.

Content of labels

Changes to the content of labels include the requirement to provide space for the prescribed dose to be indicated. The manufacturer need no longer be declared on the immediate label but remains a requirement for the package leaflet. QRD templates are available at http://www.emea.eu.int/htms/vet/qrd/qrdplt/26556805en.pdf. These templates are applicable to centralised authorised products and annotated versions specifically for MRP and DCP will shortly be available. As far as possible these templates will 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 will remain applicable for MRP, DCP and national applications. These requirements are in line with national requirements currently applicable and will be detailed on the IMB website once finalised.

Content and format of package leaflets

One significant change to the package leaflet is that the order in which information must be provided is specified in the legislation. For details of changes to the content and layout, applicants are again referred to the QRD templates referenced above.

Package leaflets written in terms comprehensible for the general public

The new legislation requires that the package leaflet be written in terms that are comprehensible to the general public A draft European guideline on readability has been agreed by CVMP and will be released for consultation shortly. The guideline will be applicable for new applications only; a policy will be developed for existing products in the future.

Changes to the method of sale and supply

Changes relating to the prescribing of veterinary medicines proposed in the draft revision of the Animal Remedies Regulations in Ireland are not directly linked to the implementation of the EU Directive. Any resultant change to the sale and supply declarations on product literature will be dealt with independently of those changes arising directly from the EU Directive requirements.

Disposal of Veterinary Medicinal Products

VPA holders should be aware that the draft Animal Remedies Regulations introduce an obligation on the supplier to take back unused or out-of-date veterinary medicinal products. Once the Animal Remedies legislation is finalised and published, the IMB will review the adequacy of the standard disposal statements currently used and included on the labeling of veterinary medicinal products. Any change to the current standard disposal statements will be communicated to VPA holders.

Financial forecast for Veterinary Department for 2006

In accordance with practice over recent years, the IMB has been in discussion with stakeholders about the budget for the provision of its veterinary services for 2006. In common with applicant companies, the IMB faces a particular challenge in 2006 with the full impact of the new medicines legislation. The Veterinary Department will also implement the IMB's new IT system for the management of applications (NIMBUS), as well as new transparency measures regarding its authorisation procedures and the continued roll-out of its quality management procedures. Against a commitment to continue to improve service levels to customers, the IMB will also have to provide additional resources for improved pharmacovigilance measures as required by the new legislation.

In order to address the projected resource needs for 2006, the IMB estimates that overall costs will increase by at least 6%. However, efficiencies gained from new IT and business practices mean that the IMB is seeking sanction for an overall fee increase of 4.5% for next year. If you would like to receive information on the proposed fee increases for 2006 please contact the IMB's Director of Finance and Corporate Affairs, Ms. Rita Purcell, by phone or by e-mail at the following address: foi@imb.ie.

Meetings between clients and IMB's Veterinary Department

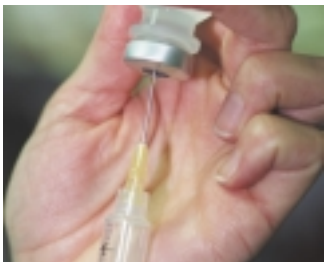
The IMB has a long tradition of meeting with stakeholders and on matters of mutual interest. This facility has been deemed to be very useful to applicant companies in particular. The protocol for such meetings includes sending a written request some weeks in advance to the relevant persons in the Veterinary Department, agreeing the agenda and notifying (for security reasons) the personnel planning to attend the meeting. Following the meetings, the IMB and the relevant parties agree the record of the meeting. Over recent years, the Veterinary Department has taken responsibility for taking the minutes of such meetings. Following standard procedure, the draft minutes are forwarded to and agreed between those involved in the meeting. The procedure has proved valuable to all parties and the IMB wishes to continue to ensure that records of all meetings are documented. However, in order to improve our

service to stakeholders and to share the burden involved, the IMB is pleased to offer visitors the opportunity of preparing the minutes for agreement. By this means, it is expected that stakeholders can more clearly ensure their objectives are captured in the record of the meeting. It is also expected that by sharing the workload, the IMB personnel involved can attend to other services, thereby improving the efficiency of the Veterinary Department.

The IMB is also pleased to inform stakeholders that it is possible to hold 'virtual' meetings with personnel from the IMB's Veterinary Department using a video link. To avail of this facility, it will be necessary to ensure that the systems operated by stakeholders are functional and compatible with those of the IMB. Therefore, applicants wishing to use the facility will first need to test it with the IMB's Information Technology and Change Management Department (contact: **neasa.ryan@imb.ie**). Stakeholders requesting this facility should clearly state so when arranging the meeting as the IMB will need to organise the meeting room and necessary hardware in advance. This initiative serves to underscore the IMB's commitment to customer service.

Diary date

The Veterinary Department is committed to continue to improve communications with stakeholders. The department plans to hold an IMB Vet InfoDay, tentatively scheduled for a central Dublin location, on 9 May 2006. Final details of the IMB Vet InfoDay will be posted on the news section of the IMB website over the coming weeks.



COMPLIANCE

WHOLESALE WORKSHOP FOR SUPPLIERS OF MEDICINAL PRODUCTS TO THE GROCERY TRADE 25TH NOVEMBER 2005

The Irish Medicines Board is hosting a workshop for wholesalers involved in the supply of medicinal products to the grocery trade on 25th November, 2005. The workshop takes place at the Crowne Plaza Hotel, Dublin Airport, Santry Demesne, Dublin 9.

The workshop will focus on the principles of Good Distribution Practice (GDP) for medicinal products. This will include presentations from a number of IMB staff members, and there will be discussion on specific issues of interest, including the Responsible Person, product recalls and requirements for a quality system.

While the workshop is being hosted primarily for the grocery wholesale sector, participants from the wider distribution/wholesale sector and from other stakeholder groups are also welcome.

Registration for the event commences at the Crowne Plaza Hotel on November 25th at 12.30pm. The workshop takes place from 1.15pm to 5.15pm approximately.

UPDATE ON THE TRANSFER OF CONTROLLED DRUGS LICENSING FUNCTIONS FROM THE DEPARTMENT OF HEALTH AND CHILDREN TO THE IMB

The arrangements to enable the transfer are now at an advanced stage of development, and it is anticipated that legislation to enable the IMB to undertake functions will be in place by the end of 2005 or early 2006.

A formal information meeting on the transfer of the controlled drug functions to the IMB will be hosted for the relevant sectors to coincide with the implementation of the legislation. Notification of the information meeting will be provided in due course. As part of the process of finalising arrangements for the transfer, the Controlled Drugs staff have relocated from the Department of Health and Children to the Compliance Department of the IMB.

GMP REQUIREMENTS FOR ACTIVE SUBSTANCES

With the impending changes in EU and national legislation, all manufacturers of medicinal products have a responsibility to use, in all batches that they manufacture, only active substances that are manufactured according to Good Manufacturing Practice (GMP).

It is expected that manufacturing authorisation holders gain assurance that the active substances used are manufactured in accordance with GMP, by way of auditing active substance suppliers.

As a minimum, finished product manufacturers will be required to demonstrate:

- A good history of active substance quality;
- Knowledge of GMP compliance, preferably via audit, of the active substance manufacturer and any broker who is involved in repackaging;
- Only as an interim measure will paper based audits (e.g. through questionnaires) be considered acceptable, when quality risk management indicates that audit resource should be prioritised to other active substance suppliers.

UPDATED GOOD MANUFACTURING PRACTICE (GMP) GUIDE

The European Commission has now published the restructured Volume IV of the Rules Governing

Medicinal Products in the European Union (Good Manufacturing Practices).

Principal changes are as follows:

GMP for Active Substances

With effect from 30th October 2005, Proposed Annex 18 is withdrawn and is replaced by Part II of the GMP Guide. Part II is identical to Proposed Annex 18, except for a modified introduction extending its scope.

Product Quality Reviews and On-going Stability

Amendments to Chapter 1 - Product Quality Reviews (PQRs) and Chapter 6 - On-going Stability Monitoring have been finalised and will come into effect from 1st January 2006.

A new introduction to the Guide, reflecting the restructuring activity has also been published. More information can be found at: http://pharmacos.eudra.org/F2/pharmacos/new.htm

ANNEX 1 – MANUFACTURE OF STERILE MEDICINAL PRODUCTS

A proposed revision to Annex 1 has been published on the Commission website for a period of consultation which ends on the 30th April 2006. Details can also be found at:

http://pharmacos.eudra.org/F2/pharmacos/new.htm:

APPOINTMENTS AND NEW INSPECTORS

Recent appointments within the Inspection section include: Mr. Paul Sexton, appointed to the post of GMP Manager; Dr. Patrick Costello, appointed to the post of Blood / Tissues Manager; Dr. Lorraine Nolan, appointed to the post of Controlled Drugs/GDP Manager; Ms. Celine Creighton, appointed to the post of GCP / Pharmacovigilance Inspection Manager.

Ms. Lisa Anne Byrne and Ms. Deirdre O'Regan have joined the GCP / Pharmacovigilance Inspections section, and Mr. Gerard Sheridan has taken up a position in the GMP Inspection section.

Mr. Stan O'Neill, Senior Inspector, will lead on issues relating to Sterile GMP and will represent the IMB at the ad hoc Working Party of GMP Inspection Services at the EMEA.

Human New Product Authorisations Issued (July–September 2005)

PA Number	Product Name	PA Number	Product Name
PA0074/054/001	ONDANSETRON	PA0540/138/007	Loavel
PA0074/054/002	ONDANSETRON	PA0540/138/008	Loavel
PA0074/058/005	Lamot Dispersible	PA0711/029/005	TRADOL SR
PA0074/058/006	Lamot Dispersible	PA0711/029/006	TRADOL SR
PA0074/058/007	Lamot Dispersible	PA0711/029/007	TRADOL SR
PA0074/058/008	Lamot Dispersible	PA0736/001/003	Hemohes 6%
PA0074/058/009	Lamot Dispersible	PA0736/001/004	Hemohes 10%
PA0077/124/002	Fraxiparine	PA0743/014/001	CLENIL MODULITE
PA0077/124/003	Fraxiparine	PA0743/014/002	CLENIL MODULITE
PA0077/124/004	Fraxiparine	PA0743/014/003	CLENIL MODULITE
PA0077/124/005	Fraxiparine	PA0743/014/004	CLENIL MODULITE
PA0077/124/006	Fraxiparine	PA0812/001/002	Zanidip
PA0126/134/001	Co-Amoxiclav	PA0868/005/001	Viartril-S Sachets
PA0126/149/001	Arthrimel	PA0966/009/001	Hyraz
PA0361/017/001	HYOSCINE	PA0966/009/002	Hyraz
PA0361/017/002	HYOSCINE	PA0966/009/003	Hyraz
PA0476/015/002	AMOCLAV	PA0966/009/004	Hyraz
PA0476/026/001	GLIMEPIRIDE	PA0966/009/005	Hyraz Titration Pack
PA0476/026/002	GLIMEPIRIDE	PA1009/007/002	Desmotabs Melt
PA0476/026/003	GLIMEPIRIDE	PA1009/007/003	Desmotabs Melt
PA0476/026/004	GLIMEPIRIDE	PA1009/007/004	Desmotabs Melt
PA0540/138/001	Loavel	PA1009/017/003	Nordurine Melt
PA0540/138/002	Loavel	PA1009/017/004	Nordurine Melt
PA0540/138/003	Loavel	PA1009/017/005	Nordurine Melt
PA0540/138/004	Loavel	PA1017/005/001	ROCKSPRING RAMIPRIL
PA0540/138/005	Loavel	PA1017/005/002	ROCKSPRING RAMIPRIL
PA0540/138/006	Loavel	PA1017/005/003	ROCKSPRING RAMIPRIL

continued on next page ▼

Human New Product Authorisations Issued (July–September 2005) cont.

PA Number	Product Name
PA1017/005/004	ROCKSPRING RAMIPRIL
PA1044/004/001	XYMEL
PA1044/004/002	XYMEL
PA1044/004/003	XYMEL
PA1044/007/001	DOXATAN
PA1077/109/001	Ondansetron
PA1077/109/002	Ondansetron
PA1094/001/001	LORAT
PA1121/001/001	IBUCAPS IBUPROFEN
PA1140/002/001	Furosemide
PA1140/003/001	Midazolam Injection BP
PA1140/003/002	Midazolam Injection BP
PA1184/001/001	Pravastatin Sodium
PA1184/001/002	Pravastatin Sodium
PA1184/001/003	Pravastatin Sodium
PPA0465/005/002	Serc
PPA0465/075/004A	LIPITOR
PPA0465/097/003	Neurontin
PPA0465/099/002	Zomig Rapimelt
PPA0465/104/004	Amaryl

PA Number	Product Name
PPA0465/107/001A	PARIET
PPA0465/107/002A	PARIET
PPA0465/146/001	Nasonex
PPA0465/147/001	Teveten
PPA0465/147/002	Teveten
PPA0465/154/001	Mercilon
PPA0465/160/001	Salazopyrine EN
PPA0465/161/001	Hytrin
PPA0465/161/002	Hytrin
PPA0465/161/003	Hytrin
PPA0465/162/001	Minocin SA
PPA0465/163/001	Tritace
PPA0465/163/002	Tritace
PPA0465/163/003	Tritace
PPA0465/163/004	Tritace
PPA0465/164/001	Dilzem SR
PPA0465/164/002	Dilzem SR
PPA0465/164/003	Dilzem XL
PPA0465/164/004	Dilzem XL
PPA0465/166/001	Reminyl

Human New Product Authorisations Withdrawn (July–September 2005)

PA Number	Product Name
PA0024/005/001	BECOTIDE INHALER
PA0024/005/004	Becotide 250
PA0024/005/005	Becotide 100
PA0016/004/001	COLESTID
PA0823/028/001	Sinutab
PA0823/027/001	Veganin
PA0735/009/001	Visipaque
PA0735/009/011	Visipaque
PA0823/015/001	Benadryl
PA0823/025/002	Mucolex
PA0894/001/001	Cremalgin Balm
PA0437/034/001	Phenytoin
PA0540/029/001	Anzemet Injection
PA0540/029/002	Anzemet
PA0540/029/003	Anzemet
PA0437/020/001	Fentanyl Citrate
PA0437/020/002	Fentanyl Citrate
PA0590/001/001	Alcoderm
PA0590/001/002	Alcoderm Lotion
PA0590/002/001	Ionax Scrub
PA0590/003/001	Ionil T

PA Number	Product Name
PA0590/005/001	Psorigel
PA1110/007/001	Gelcotar
PA0970/054/002	Xylocaine Accordion
PA0016/013/001	Neo-Medrone Acne
PA0544/004/002	Adsorbed Diphtheria and Tetanus Vaccine BP Syringe
PA0187/051/005	Salazopyrin
PA0022/087/001	HibTITER
PA0282/052/001	Nifedipine
PA0282/052/002	Nifedipine
PA0516/016/001	Dilzem Once Daily
PA1046/004/002	ACICLOVIR
PA0437/032/001	AMIKACIN
PA0437/047/001	Etoposide
PA0437/035/001	Morcap SR
PA0437/035/002	Morcap SR
PA0437/035/003	Morcap SR
PA0743/009/002	Urimin
PA0298/011/001	Co-Trimoxazole
PA0298/011/002	Co-Trimoxazole Paediatric
PA0585/006/001	Sodium Cromoglycate

Human New Product Authorisations (Mutual Recognition) (July–September 2005)

PA Number	Product Name	PA Number	Product Name
PA0013/079/005	Diovan	PA0577/067/001	Depreger
PA0038/089/002	Tarka	PA0577/067/002	Depreger
PA0062/041/001	Eligard	PA0577/070/001	Nagerine
PA0062/041/002	Eligard	PA0585/018/001	Citalopram
PA0062/042/001	Tamsulosin Hydrochloride	PA0585/018/002	Citalopram
PA0062/043/001	Hystream	PA0585/018/003	Citalopram
PA0111/003/003	RIMACTAZID 150/75	PA0711/050/005	Sivatin
PA0111/006/001	RIMCURE	PA0805/002/005	Lexapro
PA0111/007/001	RIMSTAR	PA0805/003/005	Entact
PA0126/135/001	Serimel	PA0810/001/007	Lipantil Supra
PA0126/135/002	Serimel	PA0923/001/007	Blopress
PA0126/141/001	Fungasil	PA0970/030/005	Atacand
PA0126/145/001	Citalopram	PA0970/057/004	Crestor
PA0126/145/002	Citalopram	PA1045/004/001	Oraqix
PA0126/145/003	Citalopram	PA1046/014/001	Pravastatin
PA0126/147/001	Zomel	PA1046/014/002	Pravastatin
PA0126/147/002	Zomel	PA1046/014/003	Pravastatin
PA0126/148/001	Osteomel	PA1063/019/001	SertraNiche
PA0126/148/002	Osteomel Once Weekly	PA1063/019/002	SertraNiche
PA0144/047/001	Duac Once Daily Gel	PA1077/108/001	IPV-Infanrix
PA0281/122/001	Amlid	PA1166/002/001	Plan B (Norlevo)
PA0281/122/002	Amlid	PA1185/004/001	OsteoEze
PA0281/123/001	Zotrole	PA1189/002/001	Clarosip
PA0281/123/002	Zotrole	PA1189/002/002	Clarosip
PA0409/025/001	Disodium Pamidronate	PA1189/002/003	Clarosip
PA0409/025/002	Disodium Pamidronate	PA1189/003/001	Clarithromycin Grunenthal
PA0409/025/003	Disodium Pamidronate	PA1189/003/002	Clarithromycin Grunenthal
PA0409/025/004	Disodium Pamidronate	PA1189/003/003	Clarithromycin Grunenthal
PA0540/032/005	Batrafen 10mg/g		

Veterinary New Product Authorisations Issued (July–September 2005)

VPA Number	Product Name	VPA Number	Product Name
10809/001/001	ENROX ORAL SOLUTION 100 MG/ML	10999/104/001	NOROCARP LARGE ANIMAL 5% SOLUTION FOR INJECTION
10999/098/001	NOROCARP 5% SMALL ANIMAL SOLUTION FOR INJECTION	10999/105/001	MACROMECTIN 0.08 % DRENCH
10999/102/001	NOROCARP 5 %W/V SOLUTION FOR INJ FOR CATTLE		

Veterinary New Authorisation Issued (Mutual Recognition) (July–September 2005)

VPA Number	Product Name	VPA Number	Product Name
10850/007/001	VIRBAMEC SUPER SOLUTION FOR INJECTION	10996/188/001	PANACUR PET PASTE

Veterinary Product Authorisations Withdrawn (July–September 2005)

VPA Number	Product Name	VPA Number	Product Name
10016/043/001	ADSPEC STERILE	10965/005/001	HARTZ CONTROL FLEA COLLAR FOR CATS
10823/012/001	PHARMAMIN SC	10965/006/001	HARTZ CONTROL LONG LIFE FLEA COLLAR FOR DOGS
10824/001/001	SWITCH		
10917/002/001	OTODEX SHAMPOO FOR DOGS		
10960/040/001	MASTEX CONCENTRATED		

Veterinary Product Authorisations Withdrawn (July–September 2005) cont.

VPA Number	Product Name	VPA Number	Product Name
10965/007/001	HARTZ CONTROL LONG-LIFE FLEA COLLAR FOR DOGS	COLLAR FOR CATS	
10965/008/001	HARTZ CONTROL LONG LIFE FLEA	10996/057/001	AMFIPEN LA
		10996/112/001	PANACUR PELLETS 1.5%

Veterinary Immunological New Authorisations Issued (Mutual Recognition) (July–September 2005)

VPA Number	Product Name	VPA Number	Product Name
10861/086/001	BRONCHI-SHIELD	10007/041/001	ENTERISOL IIEITIS
10861/087/001	ARTERVAC		

Veterinary Immunological New Authorisations Issued (July–September 2005)

VPA Number	Product Name	VPA Number	Product Name
10019/075/001	VANGUARD 7		