IRISH MEDICINES BOARD

# news MEDICINAL PRODUCTS LETTER

SEPTEMBER – DECEMBER 2007 Issue No. 28

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## GENERAL

### STAFF CHANGES

*Almath Spooner, Anna Marie Coleman, Breda Kiely* and *Niamh Curran* were appointed Pharmaceutical Assessors in the Human Medicines Department.

*Gavin Ryan* was appointed Pre-Clinical Assessor in the Veterinary Department.

### IMB'S NEW WEBSITE

The new IMB website (**www.imb.ie**) was formally launched on the 19 October 2007. The site is structured around the core organisational activities and has a range of new functionalities. It has a comprehensive list of human and veterinary medicines authorised by the IMB and associated information available to users. Human and veterinary medicines authorised by the European Medicines Agency (EMEA) are no longer included within the IMB's listing but are available directly from the EMEA's website (**www.emea.europa.eu**).

A useful new feature of the IMB site is the ability to search the database of authorised human and veterinary medicines using key fields e.g. by active substance etc. The listing of authorised products on the website can also be searched by authorisation date range for products which have been authorised or withdrawn during the period in question. The site is expected to be further improved over the coming months and will be updated more frequently with useful information on human and veterinary medicines and updates in the IMB. It is expected that a hyperlink will be added to the site during 2008 to provide for the on-line reporting of suspected adverse reactions to human and veterinary medicines by marketing authorisation holders and, separately, by healthcare professionals and veterinary practitioners and other users.

The response from users to the new site has been very positive and a large increase in the number of registered users has been recorded. Registered users will receive automatic updates each time the site is updated. Registration is simple with details given on-site.

### ANNUAL MEETING OF NATIONAL PHARMACOPOEIA SECRETARIES

The Member State signatories of the European Pharmacopoeia Convention send delegations to the European Pharmacopoeia Commission which is the governing body of the European Pharmacopoeia. Each year the secretaries of the National Pharmacopoeia Authorities (NPA) meet to be briefed by staff of The European Directorate of the Quality of Medicines on the latest developments and activities in the European Pharmacopoeia. Tradition has been established that the meeting takes place at the invitation of one of the Member States.

In 2007, the meeting was hosted by Croatia in Rjeka on the Dalmatian Coast. Following that meeting, an invitation was issued by the IMB to host the meeting in Ireland in 2008. The IMB will therefore organise the 2008 NPA Secretaries meeting in Dublin on the 28 and 29 April.

The IMB looks forward to welcoming its Member State partners from the European Pharmacopoeia and is confident that the 2008 NPA meeting will be equally informative and successful as was the meeting in 2007 in Croatia.

## CONTENTS

## HEADS OF MEDICINES AGENCIES WORKING GROUP OF ENFORCEMENT OFFICERS

The IMB will host a meeting of the Heads of Medicines Agencies Working Group of Enforcement Officers (HMA WGEO) in Dublin on 28 and 29 April 2008 in Dublin. This meeting is held once during each Presidency of the EU. Delegates from all EU member states, and Norway, Liechtenstein, Iceland and Switzerland, are invited to attend. Also attending are the EU Commission and the European Medicines Agency (EMEA). Invited speakers from industry and the Pharmaceutical Security Institute also attend. The meeting brings together enforcement officers from both human and veterinary medicines agencies and police where they perform the medicines enforcement function. The aim of the group is to promote co-operation and assist in the enforcement of the medicinal products and medical devices legislation in the EEA.

In Ireland the IMB carries out the enforcement functions for both medicinal products and medical devices for human use, while the Department of Agriculture, Food and Fisheries carries out the enforcement functions in relation to animal remedies. The IMB currently holds the Chair of HMA WGEO.

# HUMAN MEDICINES

## ARTICLE 61(3) NOTIFICATIONS FOR PRODUCTS AUTHORISED VIA THE MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

Following the implementation of the new pharmaceutical legislation in October 2005, the text of labels and package leaflets is now harmonised as part of the European phase of the Mutual Recognition (MR) and Decentralised (DC) procedures.

In order to allow changes to be made to the harmonised label and leaflet text, CMD(h) has recently agreed an Article 61(3) procedure for products authorised through the MR or DC procedures. It should be noted that, in line with Article 61(3) of Directive 2001/83/EC (as amended), this procedure only applies to changes to the label and package leaflet text which do not affect the SPC.

The new Article 61(3) procedure for products authorised through the MR or DC procedures is available on the IMB website at the following address: **http://www.imb.ie/images/uploaded/documents/sop_Art61_3.pdf**

A copy of the EU Article 61(3) notification form which is to be used for such applications is available on the 'Publications' page of the IMB website at **http://www.imb.ie/images/uploaded/documents/notification_form_Art61_3.doc**

At the end of the European phase of the new Article 61(3) procedure, the RMS will notify the involved CMSs and the marketing authorisation holder (MAH) that the procedure has been concluded. The national phase of the procedure will then begin and MAHs will be required to submit signed and dated label and package leaflet mock-ups incorporating the revised harmon-ised text to the IMB. The IMB will then review these mock-ups in order to ensure that they are acceptable.

Once the IMB is satisfied with the revised mock-ups, the MAH will receive an automatic email listing the details of the case and stating that the case has been issued. Once the MAH has received this email, the MAH should implement the approved label and leaflet changes within the agreed timeframe. MAHs are requested to note that the IMB will not issue approval letters for these European Article 61(3) notifications and that the automatic email will serve as evidence of approval of the proposed labels and leaflet.

In cases where the proposed change to the label or package leaflet does not affect the harmonised label and leaflet text approved via the MR or DC procedures (e.g. changes to product livery), a national Article 61(3) application should be submitted directly to the IMB. The IMB application form should be used for such applications – this form is also available on the 'Publications' page of the IMB website at **http://www.imb.ie/images/uploaded/documents/8727273_Form%20art61(3).doc** This form should also continue to be used for Article 61(3) applications relating to products that have been authorised on a purely national basis. The IMB will continue to issue approval letters for these national Article 61(3) procedures.

MAHs are also reminded that for all Article 61(3) applications, only those changes that are clearly highlighted in the application form or specifically requested by the regulatory authorities during the procedure can be considered to have been approved at the end of the procedure.

## VARIATIONS TO CHANGE THE NAME AND/OR ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Variations to change the name and/or address of the MA holder where the legal entity of the holder remains the same are classified as Type 1A (no.1) variations.

When submitting these variations the following points should be noted:

As the name and/or address change affects the entire range of products, for products licensed via the national procedure, the variation application should cover all PAs held by the marketing authorisation holder.

Variation applications relating to products licensed via the mutual recognition/decentralised procedure

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(MR/DCP) should be submitted via the MR system, within three months of submission of the national variations. Where possible variation applications for all MR/DCP products should be submitted together.

Please note that once an authorisation to change the name and/or address has been issued (even for one authorisation), the IMB database is updated with the changes and all subsequent documents will be issued to the new address. Only one name/address per MA holder can be maintained on the IMB system.

## REMINDER TO SUBMIT MARKETING STATUS NOTIFICATIONS FOR ALL AUTHORISATIONS AND CERTIFICATES

Authorisation and certificate holders are reminded of their obligation under Regulation 15 of the Medicinal Products (Control of Placing on the Market) Regulations, 2007, which came into effect on 23 July 2007. This regulation requires the holder to notify the IMB of the date that the product was placed on the market and to notify the IMB no less than two months in advance of a cessation in marketing, either temporary or permanent, unless there are exceptional circumstances.

Holders are required to submit notification of the current marketing status for products authorised on or before 23 July 2007 also.

Notifications should be made using the form **Notification of Marketing Status of Human Medicines** which is available on the IMB website and which should be submitted electronically to **hm_marketing@imb.ie** .

Further information is available in the Guide to Notification of Marketing Status of Human Medicines available on the IMB website.

## UPDATE ON ELECTRONIC REPORTING OF ADVERSE REACTIONS OCCURRING OUTSIDE THE EUROPEAN ECONOMIC AREA

The IMB would like to take this opportunity to highlight an update in the accepted mechanism for reporting of adverse reactions occurring outside the European Economic area (EEA).

Companies and sponsors are advised that, with immediate effect, there will no longer be a requirement to submit adverse reaction case reports occurring outside the EEA directly to the IMB provided the companies/sponsors are meeting their legal obligations for adverse reaction reporting of non-EEA cases through direct submission of such cases to EudraVigilance. However, where required, companies/sponsors must continue to be in a position to provide these data immediately on request to the IMB.

For detailed information and guidance please see the updated IMB 'Guide to Electronic Submission of ICSRs and SUSARs Associated with Use of Human Medicines' which can be found in the Pharmacovigilance section of the IMB website at **www.imb.ie**, under 'Electronic Reporting'.

## AGREEMENT OF PRODUCT NAMES IN THE NATIONAL PHASE OF MR/DC PROCEDURES

The IMB would like to clarify the procedure for agreement of invented names for products in the national phase of Mutual Recognition (MR) and Decentralised (DC) procedures. Proposals for the introduction of invented names or the amendment of agreed invented names will be accepted during the MR/DC procedures and in the national phase up to issue of the draft schedule. No further requests for name changes will be facilitated once the draft schedule has been sent out for comment. A post-authorisation variation will be required for any name changes that are requested after issue of the draft schedule. Applicants are encouraged to agree the product name as early as possible and preferably during the MR/DC procedure itself in order to facilitate timely issue of authorisations. Applicants are also reminded that, when a name change is proposed during the procedure, it should be clearly identified as such and an updated Module 1 Annex 6.19 should be provided. It should not be assumed that lack of comments on a name implies acceptance of the name, if the name change was not clearly identified.

# VETERINARY MEDICINES

## RECEIPT OF NOTICE THAT APPLICATION HAS BEEN VALIDATED

As promised to stakeholders at the IMB Veterinary Medicines Information Day on 13 November 2007, the IMB is pleased to report that it has begun a test phase of automated email notification of the validation and progression of applications to applicant companies. These emails will provide summary information on the status of the application as it progresses through various milestones of the procedure. Once the test phase has been completed early in January 2008, the system will be applied to all future applications.

## SUBMISSION OF APPLICATIONS TO THE IMB

All applications for submission to the IMB should be marked for the attention of the Receipts & Validation Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Terrace, Dublin 2 and not addressed to a particular individual in the Veterinary Medicines Department. This is to ensure that documentation

does not by-pass the procedure for check-in and is not subject to unnecessary handling and delay. Your co-operation in this matter is requested. Applications addressed to individual personnel in the Veterinary Medicines Department will have to be forwarded to the Receipts & Validation Section for validation and data entry onto the IMB workflow system. The Veterinary Medicines Department is working closely with the Receipts & Validation Section to optimise document handling and improve customer service levels in the future. Documentation supplied in response to a list of questions from an assessor should continue to be sent to the relevant person identified in the letter of request.

## IMB VETERINARY MEDICINES INFORMATION DAY 2007

The Veterinary Medicines Department held its 2007 Information Day on 13 November at the Crowne Plaza Hotel, Santry. Fifty-one delegates from the animal health industry and related organisations, including the Department of Agriculture, Fisheries and Food, joined 20 staff from the IMB for a successful day of interaction. In his welcoming address, Dr. J.G. Beechinor, Director of Veterinary Medicines, described the theme for the day as 'evolution' and identified objectives which, he said, included not only the delivery of information from the IMB to the industry but also the exchange of views and opinions on matters of mutual interest.

In the morning sessions, staff members from the IMB's Veterinary Medicines Department delivered updates on a variety of topics. These included the evolution and impact of recent changes within the IMB (and, specifically, the Veterinary Medicines Department), experiences with the European decentralised procedure for mutual recognition of products, and the issues associated with generics. Changes to pharmacovigilance measures and new obligations of marketing authorisation holders were covered in detail, with input from the IMB Compliance Department. The IT and Change Management Departments also participated, giving delegates an insight into the ongoing development of IT systems within the IMB, including a preview of the proposed on-line application system, 'RIO'.

After a buffet lunch and 'networking time', invited speakers from the animal health industry joined an IMB team for a lively session devoted to common Irish-UK packaging. A representative from the UK's Veterinary Medicines Directorate was present, enabling the identification of a number of recommendations which will be considered by both agencies. The IMB then presented a review of proposed changes to the route of sale and supply of vaccines, which have resulted from the deliberations of a working group set up by the IMB. To end the day, an invited speaker from the Department of Agriculture, Fisheries and Food provided an update of recent European and national legislation relating to maximum residue limits and the sale and supply of veterinary medicines.

Delegates gave a positive reaction to the day, with 88% of those who submitted an evaluation rating all criteria as 'good' or 'excellent'.

## IMB PACKAGING HARMONISATION INITIATIVES

As announced at the IMB Veterinary Medicines Information Day, the IMB is committed to work with stakeholders to provide for common Irish-UK packaging where this can be achieved. Three specific initiatives to facilitate this have been set up in co-operation with the Veterinary Medicines Directorate (VMD), and the IMB is pleased with progress on these.

The following table summarises these three procedures:

During a meeting with representatives of the Animal and Plant Health Association (APHA) and subsequent discussions during the Info Day, a number of improvements to these procedures were suggested and are being put in place. The IMB will continue to work with APHA and with the UK's VMD to achieve and maintain common labelling or packaging where this is requested by applicants. By means of these initiatives, the IMB hopes to maintain as many authorised veterinary medicinal products as possible on the market in Ireland. Further details of the three procedures are available on the Veterinary pages of the IMB website in the 'Availability' section.

| *Procedure title* | *Type of veterinary medicinal product (VMP) concerned* | *Scientific assessment involved* | *IMB Contact* |
|---|---|---|---|
| *Harmonisation* | *Any VMP nationally authorised in IE and UK* | | *mary.ogrady@imb.ie* |
| *Alignment* | *Any immunological VMP nationally authorised in IE and UK* | *No*<br>*Yes* | *michele.johnson@imb.ie* |
| *Joint packaging post MRP/DCP* | *Any VMP in the final stages of MRP or DCP in IE and UK* | *No* | *sarah.walsh@imb.ie* |

## IMB INITIATIVE ON UNIQUE, LOW-VOLUME, NEEDED VETERINARY MEDICINES

The IMB requests marketing authorisation holders with low-turnover medicines carrying unique indications to consider including Ireland as a concerned member state in any future mutual recognition or decentralised procedures. The IMB will consider, on request and provided appropriate justification is provided, applying a service-item fee for such applications. Further information or queries should be sent to vetinfo@imb.ie

## IMB POLICY IN RELATION TO THE CLASSIFICATION OF METHODS OF SUPPLY FOR VETERINARY VACCINES

The Board of the IMB adopted a report on the above subject at their meeting on 28 November 2007. The report is available from the IMB website (www.imb.ie). Prior to the allocation of a vaccine to a supply category a benefit/risk analysis, based on the criteria outlined below, is required:

### VPO

Vaccines which fulfil any of the criteria listed below should be allocated to the VPO category:

- Have a very high safety risk.
- Have a novel method of administration that requires special administration skills.
- Have known, or are suspected of having, serious side effects when administered with other commonly-used vaccines.

### POM

Vaccines which fulfil any of the criteria listed below, and where none of the points relating to the VPO category apply, should be allocated to this POM category:

- Require the professional advice of a veterinary practitioner on the special skills for correct administration.
- Require advice and/or diagnosis of a specific disease by a veterinary practitioner for effective use of a product.
- Contain a live zoonotic agent.
- Present a defined risk to the target and/or non-target species, to the person administering the product, to the consumer of the treated animal or to the environment.
- Where the strain of the infectious agent contained within the vaccine is not representative of the strains of the infectious agents present in Ireland.
- May cause effects which impede or interfere with disease control policies.
- Where, in the case of certain intensive farming systems, there is a need for the monitoring of laboratory results by a veterinary practitioner to ensure an ongoing effective vaccination programme.
- Contain a new active substance.

### POM(E)

Vaccines which fulfil any of the criteria listed below, and where none of the points relating to either the VPO or POM categories apply, should be allocated to this POM(E) category:

- Require professional point-of-sale advice regarding effective use of the vaccine.
- Require professional point-of-sale advice regarding safety risks associated with the vaccine.
- Require professional point-of-sale advice regarding disposal of unused vaccine or vaccine containers.

### PS

Vaccines which fulfil any of the criteria listed below, and where none of the points relating to the VPO, POM or POM(E) categories apply, should be allocated to this PS category:

- Require professional point-of-sale advice.

### LM

Vaccines which fulfil any of the criteria listed below, and where none of the points relating to the VPO, POM, POM(E) or PS categories apply, should be allocated to this LM category:

- Where the storage requirements, point-of-sale information and advice are easily understood.

Vaccines falling into this category should have a package leaflet specifying (a) what the vaccine induces protection against, (b) the necessity for consideration of herd history and (c) the desirability of seeking advice from a veterinary practitioner when first purchased by the end-user.

**New authorisations issued henceforth will reflect the policy now in force.**

As a consequence of this policy decision, marketing authorisation holders of vaccines are requested to make application to amend authorisations (as necessary) by 30 June 2008. Companies are reminded that applications for variation submitted in bulk benefit from a reduced fee compared to that for applications submitted separately. The IMB will evaluate and approve all applications before December 2008. Recognising that some products have a seasonal cycle, and in deference to the wish of the industry, the Board has decided that all packaging and literature for vaccines which require amendment should comply with the IMB policy now agreed before 30 June 2009. The IMB will work with the Department of Agriculture, Food and Fisheries to ensure compliance with this decision and the timelines.

## PERSONNEL CHANGES IN THE VETERINARY MEDICINES DEPARTMENT

There have been several changes to the personnel in the Veterinary Medicines Department in recent times as the IMB strengthens its team in line with the re-organisational plan adopted in late 2006. For an up-to-date organisational chart and the names of individual personnel please refer to the IMB website (www.imb.ie). The Veterinary Management Team will update this document monthly as necessary.

## FEE CHANGES FOR 2008

As in previous years, the IMB began its consultations with stakeholders in relation to the annual adjustment of fees in late summer. This consultation was also posted on the IMB website to allow interested parties to make their views known. Following this consultation, a consolidated fee proposal was made to the Department of Agriculture, Fisheries and Food. Sanction for the proposal was given in December 2007. The net

result is that a fee increase of 4.5% overall is to be implemented from 1st January 2008. Full details of current fees are available from the IMB website (**http://www.imb.ie/EN/Publications/Medicines/Veterinary-Medicines/Veterinary-Medicines-Fee-Application-Form-2007.aspx?categorypageid=1737&categorytypeid=-1**). Note that a separate categorisation of fees for immunological veterinary medicines is no longer operating; fees for such applications are the same as those for other veterinary medicines.

## APPROVED EU GUIDELINES

The following guideline was adopted by CVMP in September 2007 (EMEA/CVMP/VICH/1052/2004). It will come into effect on 1 July 2008: Guidance on Target Animal Safety: Examination of live veterinary vaccines in target animals for absence of reversion to virulence at step 7.

## PROVISION OF EXEMPTIONS FROM THE REQUIREMENT FOR A MARKETING AUTHORISATION FOR CERTAIN CATEGORIES OF VETERINARY MEDICINES

New legislation – European Communities (Animal Remedies) (no 2) Regulations, 2007, SI no 786 of 2007 – now provides for the IMB to grant certain exemptions from the requirement for a product authorisation for 'an animal remedy, intended solely for an aquarium fish, a caged bird, a homing pigeon, a terrarium animal, a small rodent, a ferret and a rabbit (kept exclusively as a pet)'. In order to benefit from this provision, applicants are requested to make a formal application under the 'classification enquiry' system described on the IMB website (**http://www.imb.ie/EN/Medicines/Veterinary-Medicines/Classification-Enquiries~.aspx**). Details of the applicable fees are also given in the publications section of this site. For further information on the procedure, contact Mr. James McKenna, Veterinary Assessor (**James.mckenna@imb.ie**). The IMB welcomes this provision in the interests of animal welfare and hopes that applicants will respond positively to this development.

# COMPLIANCE

## NOTIFICATION SYSTEM FOR EXEMPT MEDICINAL PRODUCTS

The IMB has set up a notification system for exempt medicinal products, in accordance with the requirements of the Medicinal Products Regulations 2007 (SI 538/2007, 539/2007, 540/2007). The guidance notes for the notification system will be available on the IMB website on January 30th 2008. The requirement for wholesalers and manufacturers to notify the IMB of this activity will commence on 1 February 2008. Please see the guidance notes for definition of exempt medicinal product and further information.

*Human New Product Authorisations Issued (September 2007 – December 2007)*

| PA Number | Product Name | PA Number | Product Name |
|---|---|---|---|
| PA0172/004/007 | Aniall | PA1140/006/002 | Warfarin |
| PA0281/133/001 | Coval | PA1140/006/003 | Warfarin |
| PA0281/133/002 | Coval | PA1140/006/004 | Warfarin |
| PA0401/003/001 | MACROTEC | PA1140/006/005 | Warfarin |
| PA0540/130/002 | TILADE CFC-FREE | PA1140/006/007 | Warfarin |
| PA0755/008/001 | Motilium | PA1140/006/008 | Warfarin |
| PA0979/021/003 | Lemsip Max Hot Lemon | PA1140/006/009 | Warfarin |
| PA0979/027/001 | Lemsip Sinus 500mg/6.1mg/25mg Capsules | PA1140/006/010 | Warfarin |
| PA1035/001/001 | Duraglan | PPA0465/041/006 | Becotide Evohaler |
| PA1140/006/001 | Warfarin | PPA0465/156/002 | Calcichew-D3 Forte |
| | | PPA0465/199/001 | Activelle |

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## Human New Product Authorisations Issued – continued (September 2007 – December 2007)

| PA Number | Product Name | PA Number | Product Name |
|---|---|---|---|
| PPA0465/202/001 | MAXOLON | PPA1151/034/001 | SEROXAT |
| PPA0465/205/001 | Dalacin C | PPA1151/037/002 | ARICEPT |
| PPA0465/206/001 | ZINERYT | PPA1151/038/001 | CERIS |
| PPA0465/207/001 | Zispin SolTab | PPA1151/043/001 | PROSCAR |
| PPA1151/006/002 | Seretide 250 Diskus | PPA1151/044/001 | CRESTOR |
| PPA1151/007/002 | Losec MUPS | PPA1151/045/001 | DULCOLAX |
| PPA1151/014/003 | Coversyl Arginine | PPA1151/046/001 | Klacid LA |
| PPA1151/014/004 | Coversyl Arginine | PPA1151/046/002 | Klacid Forte |
| PPA1151/020/001 | OMNEXEL | PPA1151/052/001 | Xyzal |
| PPA1151/026/002 | DIAMICRON | PPA1151/056/001 | Dona |

## Human New Product Authorisations (Mutual Recognition Procedure) (September 2007 – December 2007)

| PA Number | Product Name | PA Number | Product Name |
|---|---|---|---|
| PA0126/169/001 | Perdamel | PA0736/026/001 | Naloxone 400 micrograms/ml solution for injection |
| PA0126/169/002 | Perdamel | PA0749/037/001 | Sumatriptan Teva |
| PA0126/169/003 | Perdamel | PA0749/037/002 | Sumatriptan Teva 100 mg Film-coated Tablets |
| PA0126/169/004 | Perdamel | PA0749/039/001 | Azithromycin Teva |
| PA0126/169/005 | Perdamel | PA0749/049/007 | Rispeva |
| PA0126/169/006 | Perdamel | PA0749/049/008 | Rispeva |
| PA0126/169/007 | Perdamel | PA0749/049/009 | Rispeva |
| PA0126/169/008 | Perdamel | PA0749/049/010 | Rispeva |
| PA0167/037/015 | Mannitol | PA0749/052/001 | Simvastatin Teva |
| PA0167/037/016 | Mannitol | PA0749/052/002 | Simvastatin Teva |
| PA0167/052/012 | Potassium & Sodium Chloride | PA0749/052/003 | Simvastatin Teva |
| PA0167/127/001 | Fluconazole Redibag | PA0749/052/004 | Simvastatin Teva |
| PA0170/022/001 | Actonel Plus Ca & D 35mg film-coated tablets + 100 | PA0749/052/005 | Simvastatin Teva |
| PA0290/078/001 | Anatera 100mg/ml solution for injection | PA0785/006/003 | Prismasol |
| PA0372/006/002 | Omeprazole | PA0785/006/004 | Prismasol |
| PA0372/006/003 | Omeprazole | PA0805/002/006 | Lexapro |
| PA0372/006/004 | Omeprazol | PA0967/007/001 | BellPrav |
| PA0372/010/001 | Meloxicam | PA0967/007/002 | BellPrav |
| PA0372/010/002 | Meloxicam | PA0967/007/003 | BellPrav |
| PA0585/027/001 | Finocar | PA0967/008/001 | Pravator |
| PA0585/029/001 | Paclitaxel | PA0967/008/002 | Pravator |
| PA0688/017/001 | Fexofenadine Hydrochloride | PA0967/008/003 | Pravator |
| PA0688/017/002 | Fexofenadine Hydrochloride | PA0967/011/001 | Lamidus |
| PA0711/106/006 | Rispone | PA0967/011/002 | Lamidus |
| PA0711/106/007 | Rispone | PA0967/011/003 | Lamidus |
| PA0711/106/008 | Rispone | PA0967/011/004 | Lamidus |
| PA0711/106/009 | Rispone | PA0967/012/001 | Lamotrigine Ranbaxy |
| PA0711/125/001 | Clozapine | PA0967/012/002 | Lamotrigine Ranbaxy |
| PA0711/125/002 | Clozapine | PA0967/012/003 | Lamotrigine Ranbaxy |
| PA0711/125/003 | Clozapine | PA0967/012/004 | Lamotrigine Ranbaxy |
| PA0736/025/001 | Flumazenil | PA0967/015/001 | Finasteride Ranbaxy |

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## *Human New Product Authorisations (Mutual Recognition Procedure) –continued (September 2007 – December 2007)*

| PA Number | Product Name | PA Number | Product Name |
|---|---|---|---|
| PA1009/006/006 | Pentasa Sachet | PA1241/003/003 | Eligard |
| PA1063/026/001 | Resdal | PA1270/001/001 | Flexove |
| PA1063/026/002 | Resdal | PA1330/002/001 | Alendronic Acid 70mg "once weekly" film-coated tab |
| PA1063/026/003 | Resdal | | |
| PA1104/002/001 | Fostimon | PA1350/002/001 | Sorbisterit |
| PA1104/002/002 | Fostimon | PA1350/004/001 | OsvaRen |
| PA1142/004/002 | Detrunorm XL | PA1382/001/001 | Osmohale |
| PA1142/009/001 | Propinorm XL | | |

## *Human New Product Authorisations (Decentralised Procedure) (September 2007 – December 2007)*

| PA Number | Product Name | PA Number | Product Name |
|---|---|---|---|
| PA0022/078/002 | Meningitec | PA0749/027/001 | Granisetron Teva |
| PA0126/165/001 | Nebimel | PA0749/027/002 | Granisetron Teva |
| PA0126/167/001 | Cozatan | PA0749/028/001 | Anastrozole Teva |
| PA0126/167/002 | Cozatan | PA0775/002/002 | Spiriva Respimat |
| PA0126/170/001 | Estelle | PA0840/004/001 | Anastrozole Synthon |
| PA0126/170/002 | Estelle | PA0967/009/001 | Venlift |
| PA0312/011/001 | Metformin Hydrochloride | PA0967/009/002 | Venlift |
| PA0437/058/001 | Gemcitamine | PA0967/010/001 | Venlafaxine |
| PA0437/058/002 | Gemcitamine | PA0967/010/002 | Venlafaxine |
| PA0437/058/003 | Gemcitamine | PA1128/004/001 | Azathioprine |
| PA0577/088/001 | Agerdex | PA1130/007/001 | Trandopril 0.5 mg Capsules |
| PA0577/090/001 | Geroquel 25 mg Film-coated Tablets | PA1130/007/002 | Trandopril 1 mg Capsules |
| PA0577/090/002 | Geroquel 100 mg Film-coated Tablets | PA1130/007/003 | Trandopril 2 mg Capsules |
| PA0577/090/003 | Geroquel 200 mg Film-coated Tablets | PA1130/007/004 | Trandopril 4 mg Capsules |
| PA0577/090/004 | Geroquel 300 mg Film-coated Tablets | PA1239/002/001 | Losartan Potassium Liconsa |
| PA0711/106/005 | Rispone | PA1239/002/002 | Losartan Potassium Liconsa |
| PA0711/112/001 | Gemabin | PA1239/002/003 | Losartan Potassium Liconsa |
| PA0711/112/002 | Gemabin | PA1239/003/001 | Venlafaxine Liconsa |
| PA0711/115/001 | Oxydon | PA1239/003/002 | Venlafaxine Liconsa |
| PA0711/115/002 | Oxydon | PA1239/003/003 | Venlafaxine Liconsa |
| PA0711/115/003 | Oxydon | PA1286/007/001 | Arcoxia |
| PA0711/119/001 | Brimon 2mg/ml eye drops solution | PA1347/001/001 | Pantoprazole KRKA |
| PA0749/022/001 | Galantamine Teva | PA1347/001/002 | Pantoprazole KRKA |
| PA0749/022/002 | Galantamine Teva | PA1426/001/001 | Amiodarone Stragen |
| PA0749/022/003 | Galantamine Teva | | |

## *Human New Product Authorisations Withdrawn (September 2007 – December 2007)*

| PA Number | Product Name | PA Number | Product Name |
|---|---|---|---|
| PA0004/026/001 | Day Cold Comfort | PA0021/038/001 | Baythrom |
| PA0004/027/001 | Night Cold Comfort | PA0021/058/001 | Aspro |
| PA0004/058/001 | Paracetamol Caplets | PA0021/059/001 | Becosym Forte |
| PA0006/011/001 | Soframycin | PA0021/060/001 | Benerva |
| PA0006/011/002 | Soframycin Eye | PA0021/060/002 | Benerva |
| PA0019/024/005 | FELDENE | PA0021/068/001 | Ephynal |
| PA0021/006/001 | Bayer Aspirin | PA0021/068/002 | Ephynal |
| PA0021/016/001 | Lasonil | PA0021/071/001 | Paracodol |

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## *Human New Product Authorisations Withdrawn (cont) (September 2007 – December 2007)*

| PA Number | Product Name |
|---|---|
| PA0021/071/002 | Paracodol |
| PA0021/072/001 | Redoxon C |
| PA0021/072/002 | Redoxon C |
| PA0021/074/001 | Redoxon Plain Effervescent |
| PA0022/058/001 | PREMARIN VAGINAL |
| PA0022/058/005 | Premarin |
| PA0022/068/002 | Cathate |
| PA0022/090/003 | TAZOCIN |
| PA0040/063/001 | Piportil Depot |
| PA0040/063/002 | PIPORTIL DEPOT |
| PA0040/068/003 | MYOCRISIN |
| PA0040/068/004 | MYOCRISIN |
| PA0040/068/005 | Myocrisin |
| PA0043/006/003 | NUROFEN MICRO-GRANULES |
| PA0046/029/001 | SELEXIDIN INJECTION |
| PA0047/038/001 | Kefadol |
| PA0047/038/003 | Kefadol |
| PA0047/038/004 | Kefadol |
| PA0061/010/001 | DEXAMETHASONE |
| PA0074/007/001 | Migranat |
| PA0126/082/001 | Diclomel 25 |
| PA0126/082/002 | DICLOMEL 50 |
| PA0126/169/001 | Perdamel |
| PA0143/011/001 | Noxyflex S |
| PA0148/002/001 | PROPINE STERILE OPHTHALMIC |
| PA0167/096/011 | Glucose |
| PA0172/032/001 | DIMOTANE CO |
| PA0172/032/002 | DIMOTANE CO PAEDIATRIC |
| PA0185/035/002 | Tramake Insts/Tramadol Hydrochloride |
| PA0185/035/003 | Tramake Insts/Tramadol Hydrochloride |
| PA0255/003/003 | Isoprenaline Hydrochloride |
| PA0277/062/001 | Tinaderm Plus |
| PA0277/062/002 | Tinaderm Plus |
| PA0408/004/002 | Rimadol Paracetamol |
| PA0437/008/006 | Vincristine Sulphate Injection |
| PA0437/016/001A | Gentamicin |
| PA0506/014/001 | Valderma |
| PA0535/005/001 | CALCORT |
| PA0535/005/003 | Calcort |
| PA0540/019/002 | MERBENTYL |
| PA0577/046/003 | Histaclar Syrup |
| PA0677/017/001 | Flucis |
| PA0711/017/003 | Acic Lyophilisate |
| PA0711/069/001 | Onton 2mg/ml Solution for Injection or infusion |
| PA0743/010/002 | BREXIDOL TABLETS |
| PA0743/010/003 | BREXIDOL |
| PA0812/002/002 | Lomexin |
| PA0812/002/003 | Lomexin |
| PA0904/001/001 | Primedol Paracetamol |
| PA0913/017/001 | MXL |
| PA0913/017/002 | MXL |
| PA0913/017/003 | MXL |
| PA0913/017/004 | MXL |
| PA0913/017/005 | MXL |
| PA0913/017/006 | MXL |
| PA0913/021/005 | Zytram-SR |
| PA0913/021/006 | Zytram-SR |
| PA0913/021/007 | Zytram-SR |
| PA0913/021/008 | Zytram-SR |
| PA0913/023/001 | Zeropan |
| PA0913/023/002 | Zeropan |
| PA0913/023/003 | Zeropan |
| PA0913/023/004 | Zeropan |
| PA0946/001/001 | Kolanticon Gel |
| PA0970/034/001 | Betazok 100 mg Prolonged-release Film-coated Table |
| PA0970/043/001 | KINIDIN DURULES |
| PA0979/005/001 | DETTOL FRESH |
| PA1091/002/001 | EZETIMIBE 10mg Tablets |
| PA1091/003/001 | Vytorin |
| PA1091/003/002 | Vytorin |
| PA1091/003/003 | Vytorin |
| PA1091/003/004 | Vytorin |
| PA1332/021/001 | Zamadol SR 50mg Prolonged-Release Capsules |
| PA1332/021/002 | Zamadol SR 100 mg Prolonged-Release Capsules |
| PA1332/021/003 | Zamadol SR 150 mg Prolonged-Release Capsules |
| PA1332/021/004 | Zamadol SR 200mg Prolonged-Release Capsules |
| PA1332/021/005 | Zamadol |
| PPA0465/041/001A | Becotide Inhaler |
| PPA0465/041/002A | Becotide Inhaler |
| PPA0465/110/001A | AULIN |

*continued on next page* ▶

## *Veterinary New Product Authorisations Issued (September 2007 – December 2007)*

| VPA Number | Product Name |
|---|---|
| 10007/042/001 | Ubrolexin Intramammary suspension |
| 10999/100/001 | Reproval Tablets |
| 10788/001/001 | Enroxil 50mg/ml Solution for Injection |
| 10788/001/002 | Enroxil 100mg/ml solution for Injection |
| 10277/098/001 | Procyon Dog Pi/CvL |
| 10277/100/001 | Procyon Dog Pi/L Powder & Solvent for Suspension for Inejction |
| 10277/101/001 | Procyon Dog DA2PPi/L Powder & Solvent for Suspension for Injection |

| VPA Number | Product Name |
|---|---|
| 10815/004/001 | Ovarelin 50ug/ml, solution for injection |
| 10861/095/001 | Poulvac Pabac IV |
| 10277/102/001 | Resflor Injection Solution |
| 10999/114/001 | Carprogesic 20mg Tablets |
| 10999/114/002 | Carprogesic 50mg Tablets |
| 10999/118/001 | Noroclav Palatable Tablets 500mg |
| 10815/005/001 | CEVAC Transmune |
| 10815/006/001 | Coliscour 2MIU/ml Oral solution |
| 10846/009/001 | Hipracox Broilers |
| 10999/119/001 | Closamectin Solution for Injection |
| 10999/100/002 | Reproval Tablets |

## *Veterinary Product Authorisations Withdrawn (September 2007 – December 2007)*

| VPA Number | Product Name |
|---|---|
| 10019/042/001 | Clamoxyl Palatable Tablets |
| 10019/030/001 | Orbenin LA |
| 10019/028/001 | Orbenin Ophthalmic Ointment |
| 10019/043/001 | Clamoxyl LA suspension for Injection |
| 10835/042/001 | CAPSTAR 11.4mg tablets for cats and small dogs |
| 10835/042/002 | CAPSTAR 57mg tablets for large dogs |
| 10835/026/001 | Program 40 Injectable Suspension for cats |

| VPA Number | Product Name |
|---|---|
| 10835/026/002 | Program 80 Injectable suspension for cats |
| 10989/047/001 | Equi P Horse Wormer |
| 10990/011/001 | Duocycline 5% solution for injection |
| 10857/008/001 | Water for Injections 100%v/v Solvent for Parentera |
| 10857/009/010 | Intraval Sodium 2.5g Powder for solution for injection |
| 10857/009/002 | Intravel Sodium 5g Powder for solution for Injection |

## *Veterinary Immunological Review Authorisations Issued (September 2007 – December 2007)*

| VPA Number | Product Name |
|---|---|
| 10277/075/001 | Paracox |
| 10988/040/001 | Leucogen |

| VPA Number | Product Name |
|---|---|
| 10861/070/001 | Duvaxyn EHV1,4 |

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