IRISH MEDICINES BOARD

news MEDICINAL PRODUCTS LETTER

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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

STAFF CHANGES

CATHAL GALLAGHER, LISA MOORE and LORRAINE M. NOLAN were appointed as Pharmaceutical Assessors in the Human Medicines Department.

MARIA O'MAHONY was appointed as Medical Officer in the Human Medicines Department.

MAJELLA QUINN was appointed as Pharmacovigilance Assessor in the Human Medicines Department.

EIMEAR LYNCH was appointed as Scientific Officer in the Quality Management section.

ELIZABETH STUART was appointed as HR Executive in the Human Resources section.

JAMES O'CALLAGHAN was appointed as Product Manager, JULIET DORAN was appointed as Pre-Market Evaluation Assessor and PAULINE BOWE was appointed as Medical Officer in the Medical Devices Department.

PAUL McNEILL was appointed as Veterinary Assessor and RHONA DUANE was appointed as Quality Assessor in the Veterinary Medicines Department.

HUMAN MEDICINES

PERIODIC SAFETY UPDATE REPORTS (PSURS) – WORK-SHARING INITIATIVE

The IMB has started to receive and assess PSURs under the worksharing initiative approved by the Heads of Medicines Agencies (HMA).

To ensure appropriate management and processing of relevant PSURs, companies are requested to ensure that they adhere to the agreed guidance regarding submission, in particular clearly indicating the following information in the cover letter with all submissions:

- A statement that the PSUR is being submitted under the PSUR work-sharing project on assessment of PSURs and
- Confirmation that the PSUR will be submitted in all Member States where products containing the active ingredient are authorised.

In addition, to facilitate processing MAHs are asked to include the following information in the cover letter to the IMB:

- A statement indicating the IMB status in the procedure (i.e. P-RMS/P-CMS) and
- For generic medicinal products, a statement clearly indicating whether or not that product is authorised in the P-RMS.

A table in Word format should be annexed to the cover letter which contains the following information:

- Member States in which the relevant product is authorised,
- Product name, pharmaceutical form and strength,
- Marketing authorisation number, along with MRP/DCP procedure numbers, where applicable and

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CONTENTS

- A single contact point (including an email address) for communications regarding submissions under the scheme.

If the relevant product is not authorised in the P-RMS, a copy of this table should also be sent to the P-RMS. (An Excel spreadsheet outlining the EU harmonised birth dates (EU HBDs), related data lock points (DLPs) and allocated PSUR Reference Member States (P-RMSs) is available on the HMA website.)

Further guidance and information is available from the HMA website **http://www.hma.eu/index.html**

UPDATE ON ELECTRONIC REPORTING OF ADVERSE REACTIONS

Further to previous updates regarding electronic submission of adverse reaction reports, the IMB has closely monitored experience to date with the currently operational parallel paper reporting of individual case safety reports (ICSRs). A significant number of issues/discrepancies have been identified when comparing electronic ICSRs with the paper copies submitted (>50 in a two-month period). These include information missing from the electronic versions primarily related to demographic data, medical history and adverse reactions for which case information could not have been completed without a paper copy of the report. The IMB will continue to monitor this issue and will advise individual companies in relation to issues arising with their reports and of the need to maintain/discontinue parallel reporting, as appropriate. Therfore, in order to facilitate cessation of parallel paper reporting companies are requested to ensure that the electronic versions of the individual cases are complete and accurate before submission.

The IMB would like to take this opportunity to also highlight that the 'Sender' information as provided in the E2B electronic format of ICSRs submitted to the IMB is automatically used as the contact information for follow-up/acknowledgement of each case by the IMB. It is considered a matter for individual companies to ensure that if this is not the person responsible for case follow-up that the correspondence is passed to the appropriate person in the company.

CLINICAL TRIAL APPLICATIONS

We would like to remind applicants for clinical trials that due to the tight timelines involved and limited opportunity for correspondence, all quality information as required by CPMP/QWP/185401/2004 final 'Guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials', must be provided in the IMPD. A declaration to the effect that all required documentation has been submitted has now been included in the revised IMB national requirements application form. If the IMB establishes during assessment that a major piece of quality information has not been submitted, the clinical trial application should be withdrawn and could be re-submitted later (along with appropriate fees). It must also be noted however, that the IMPD should be tailored for the specific Irish clinical trial application and therefore redundant information should not be submitted.

ACTIVE SUBSTANCES IN THE FORM OF MESILATES, (DI)ISETIONATES, TOSILATES OR BESILATES

Following recent discussions at QWP and CMD(h), marketing authorisation holders of medicinal products containing active substances in the form of mesilates, (di)isetionates, tosilates or besilates are requested to undertake a risk assessment on the occurrence of mesilate esters and related compounds as impurities in their medicinal products.

Preclinical studies with certain mesilate esters have revealed that their DNA alkylation action can induce mutagenic, carcinogenic and teratogenic effects. This has been reported for methyl and ethyl mesilate and it is not unreasonable to suspect that similar toxic effects may exist in alkyl esters of other low molecular weight sulfonic acids, e.g. tosilates. Although there are no data showing the toxic effect of such esters in humans, there is nevertheless a potential risk that genotoxic substances as described above may be present as impurities in medicinal products containing active substances in the form of sulfonic acid esters.

For this reason the IMB requests all marketing authorisation holders concerned to undertake a risk assessment on the occurrence of these impurities in their preparations. A letter including additional guidance on how to perform this risk assessment has been published in the 'News' section of the IMB website.

If the outcome of the risk assessment is that the risk is not satisfactorily controlled taking into account the requirements of the 'Guideline on the limits of genotoxicity impurities (EMEA/CHMP/QWP/251334/2006)' the market compliance section of the IMB should be immediately informed using the following email address: **kevin.odonnell@imb.ie**. If consequential amendments to the registered manufacturing process or control of the active substance and/or finished product are required, a variation to the marketing authorisation should be submitted within 3 months.

All concerned marketing authorisation holders are requested to carry out this risk assessment as soon as possible but not later than 30 June 2008. Following this date confirmation that this risk assessment has been carried out may be requested during inspections of related manufacturing sites.

INVENTED NAMES FOR DIFFERENT SALT FORMS OF EXISTING ACTIVE SUBSTANCES

The IMB has recently introduced new naming policy due to potential safety issues as stated below.

If two (or more) products contain the same active substance but in different salt forms, and the strength as expressed in the product name refers to the quantity of the salt, then the products should not have the same or similar invented names.

For example, if a company wished to market tablets and an active substance is present as sodium salt in product 1 and the active substance is present as potassium salt in product 2, then two **distinct** invented names would be required.

Similarly, any invented name of a generic product of one salt form should not be similar or liable for confusion with any invented names of products containing the alternative salt form(s).

If the MA holder wishes to use the INN as product name rather than an invented name, then the product name must include the name of the salt form, e.g. 'active substance *sodium* XXmg tablets' rather than 'active substance XXmg tablets'.

IMPLEMENTATION OF THE TRADITIONAL HERBAL MEDICINES PRODUCTS DIRECTIVE [2004/24/EC]

SUBMISSION OF APPLICATIONS (JAN 2010)

Background: The IMB wishes to provide an update on the national implementation of the European Directive on Traditional Herbal Medicinal Products (2004/24/EC). This Directive was transposed into Irish legislation by the Medicinal Products (Control of Placing on the Market) Regulations of 2007 which came into effect on **23 July 2007**. Following on from this the IMB established the Traditional Herbal Medicinal Products Registration Scheme for applicants to apply for certificates of traditional-use for relevant herbal medicinal products.

Timeframe for implementation:

According to the Medicinal Products (Control of Placing on the Market) Regulations 2007 no medicinal product can be placed on the market without a prior marketing authorisation or certificate of traditional-use registration. However, the regulations provide an exemption from this requirement until **30 April 2011** for traditional herbal medicinal products that were on the market in the State on the coming into force of the regulations.

Submission of applications:

In order to ensure that relevant products hold either a marketing authorisation or a certificate of traditional-use registration by the 30th April 2011, the new regulations also included a provision for the IMB to establish dates by which applications for traditional-use registration must be submitted. The IMB have now set the date by which an application must be submitted for products on the market to **31 Jan 2010**.

Information and guidance on making an application to the scheme is published on the IMB website [www.imb.ie]. Applications should be addressed to: Receipts and Validation Section,

Irish Medicines Board, Earlsfort Centre, Earlsfort Terrace, Dublin 2. Any further queries on the above can be put in writing to the below address or sent via e-mail to **customerser vice@imb.ie**

VETERINARY MEDICINES

NEW GUIDELINES ADOPTED BY CVMP

The following guidelines have been adopted by the Committee for Medicinal Products for Veterinary Use and are due to come into effect on the 1 October 2008. They are available from the EMEA website:

- Guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with Bovine Viral Diarrhoea (BVD) virus **(EMEA/CVMP/IWP/205351/200)**.
- Guideline on the Quality of Combination Herbal Medicinal Products / Traditional Herbal Medicinal Products **(EMEA/HMPC/CHMP/CVMP/214869/2006**.

NEW FREQUENTLY ASKED QUESTIONS ON IMB WEBSITE

The Veterinary Medicines Department has recently updated the frequently asked questions (FAQs) on our website. For answers to questions such as 'How will I know if a product has been exempted by the IMB from the requirements for a marketing authorisation and how are these products monitored?' and 'What is the difference between an 'animal remedy' and a 'veterinary medicinal product?' view the FAQ site.

Suggestions for new questions or for the further development of the site are requested. Please send any such questions or comments to **vetinfo@imb.ie** .

PROPOSAL FROM THE IMB AND UK'S VETERINARY MEDICINES DIRECTORATE (VMD)

Work Sharing between VMD and IMB for National Applications

The EU Commission is consulting on a change to the Variation Regulations, one component of which is work sharing for the assessment of national variations. This will have significant implications for the future operation of individual agencies. It is anticipated that this major change to the system of variations will not be implemented before March 2010. In the interim the opportunity exists to develop some national work sharing initiatives.

MAHs often submit the same national variation applications to a number of countries. Where the supporting data are identical and the underlying data for the MA are very similar, it should be possible to conduct a single assessment rather than each national authority assessing the data individually. MAHs would benefit from receiving basically the same questions from the involved countries and doing so in a similar timeframe.

Agencies have resource constraints, and at times these can be particularly severe in one or two areas of specialism. By being aware of these it should be possible to provide/receive assistance at certain times.

The IMB and UK's VMD are embarking on a work-sharing initiative for certain national type II variations. The scope of the procedure will initially be limited to pharmaceutical products but following a trial 12 month period it may be extended to include immunological products and/or additional countries. Participation by an MAH in the procedure is entirely optional but the scheme offers a number of advantages to industry, in particular they will receive a single set of questions and decision according to the same timescale. The proposed implementation date is in June 2008 and further details of the proposal are available under the publications section of the Veterinary-Medicines/Licensing/Variation section on the IMB website.

STAFF CHANGES IN THE VETERINARY MEDICINES DEPARTMENT

The following recent staff appointments are announced:
Ms. Susann Bradley, Quality Assessor
Ms. Julia Ivanova, PA to the Director of Veterinary Medicines
Ms. Lisa Woods, Pharmacovigilance Officer.

An up-to-date list of staff in the Veterinary Medicines Department and the current organizational chart is available on the IMB website (**www.imb.ie**)

COMPLIANCE

GMP UPDATES

There have been a number of revisions to the EU GMP Guide which are published on the European Commission Website. These include:

- Revised Introduction to Part I of the GMP Guide to introduce the concept of Quality Risk Management.
- Revised Part I - Chapter 1 on Quality Management to include the concept of Quality Risk Management as an integral part of the quality system – effective 1 July 2008
- New Annex 20 on Quality Risk Management implements ICH Q9 and becomes effective on 1 March 2008. It should be noted that the new Annex is not intended, however, to create any new regulatory expectations but rather provides an inventory of

internationally acknowledged risk management methods and tools together with a list of potential applications at the discretion of manufacturers.

- Revised Annex 1 'Manufacture of Sterile Medicinal Products'

The revision of Annex 1 was necessary in particular to align the classification table for environmental cleanliness of clean rooms with ISO standards. Two public consultations took place in preparation of this new revision. The revised Annex 1 provides supplementary guidance on the application of the principles and guidelines of GMP to sterile medicinal products. The guidance has been updated in four main areas:

- Classification table for environmental cleanliness of clean rooms, and associated text
- Guidance on media simulations
- Guidance on bioburden monitoring
- Guidance on capping of freeze-dried vials

The new annex 1 should be implemented by 1 March 2009 except for the provisions on capping of vials, which should be implemented by 1 March 2010.

There are also a number of revisions to the GMP Guide which have been made available on the European Commission website for public consultation. These include the following:

Public Consultation on revisions of GMP Part II

An amendment is proposed to Part II of the GMP Guide to incorporate principles of Quality Risk Management as laid down in the ICH guideline Q9, which also correspond to similar changes made to Part I Chapter 1 of the Guide and published in February 2008.

Comments should be sent to **entr-gmp@ec.europa.eu** and **GMP@emea.europa.eu** by 31 October 2008. It should be noted that changes besides the implementation of ICH Q9 are currently not foreseen and would need proper discussion at the ICH level.

Public Consultation on revisions of GMP Annex 13

Based on practical experiences a revision of Annex 13 was deemed necessary to clarify certain points related to reference and retention samples, the two-step release procedure for investigational medicinal products and the principle of independence between production and quality control functions.

Comments should be sent to **entr-gmp@ec.europa.eu** and **GMP@emea.europa.eu** by 31 October 2008.

Public consultation on revisions of GMP Annex 11 on Computerised Systems and related changes in GMP Part I/ Chapter 4 on Documentation

Annex 11 has been updated in response to the increased use of computerised systems and the increased complexity of these systems. Consequential amendments are also proposed for Chapter 4 of the GMP Guide (Documentation).

Comments should be sent to **entr-gmp@ec.europa.eu** and **GMP@emea.europa.eu** by 31 October 2008.

GMP & MARKET COMPLIANCE INFORMATION DAY 2008

The Compliance Department will hold an Information Day for Manufacturers and Marketing Authorisation Holders on 23 October at the Crown Plaza Hotel in Santry. A number of presentations on current topics of interest to manufacturers and marketing authorisation holders will be given. Full details of the programme, including details on how to register, will be announced on the IMB website. Anyone interested in attending this information day should reserve places at an early stage as there is usually a significant number of attendees and places are limited.

EUDRAGMP & MANUFACTURER'S / IMPORTER'S AUTHORISATION (MIA)

In April 2007 the EMEA launched a database called EudraGMP, which contains information on manufacturing and importation authorisations issued by EEA competent authorities. It also contains information on GMP certificates which Member State competent authorities issue following each satisfactory GMP inspection.

As noted on the EMEA's website (**http://www.emea.europa.eu/Inspections/EudraGMP.html**), it is planned to provide access to the general public to manufacturing and importation authorisations and certain GMP certificates, with the exception of any information of commercially and/or personally confidential nature. It is anticipated that the component of EudraGMP which can be accessed by the public will go live later this year.

The IMB will be modifying the format of the current manufacturer's authorisation so that the information presented with be compatible with the EudraGMP database and EU format for a manufacturer's/importer's authorisation. The Compliance Department will contact each authorised manufacturer in the coming months to verify the accuracy of the information before issuing the revised authorisation document and entering the authorisation details onto the EudraGMP database.

NEW PROCESS FOR INSPECTION REPORTING

The system for reporting deficiencies after inspections has been modified. Within 15 calendar days of completion of the inspection, either a deficiency summary report or the full inspection report will be sent to the facility that was inspected. A response from the company will be requested within 28 days. Where a summary report has been sent at this stage, the full inspection report will be sent within 28 days of completion of the inspection and will refer to the same due date for the company's response as stated in the letter accompanying the summary report. The purpose of this process is to ensure that the companies which have been inspected receive the official list of deficiencies within a short timeframe following the inspection and to facilitate close-out within 90 days of the inspection.

INSPECTION NOTIFICATIONS & ELECTRONIC COPIES OF REPORTS

The IMB sends inspection notifications by email to manufacturers and wholesalers. In the case of authorised manufacturing sites, this email is usually sent to the primary Qualified Person named on the manufacturing authorisation, the head of quality for active substance manufacturers and, in the case of authorised wholesalers, the notification is sent to the Responsible Person. Manufacturers and wholesalers are requested to respond to this notification as set out in the text of the notification. As all manufacturers and wholesalers are subject to inspection by the IMB this notification process is not considered to be confidential information.

At the request of a company who has been inspected, the IMB can provide an electronic version of the inspection report and the preferred method for doing this is using a Eudralink mailbox (see below). In making the request the company must specify in writing the intended recipient(s) of the electronic version of the report. If the company does not have a Eudralink mailbox, the report can be forwarded by email, but only when the IMB has received written confirmation that the company is satisfied to receive the inspection report using an unsecured connection. The procedure for requesting electronic copies of inspection reports will be described in the inspection notification email.

An application form for a Eudralink mailbox may be requested from the following address; **eudralink@emea.europa.eu**

PLANNING OF INSPECTIONS OF ACTIVE SUBSTANCE MANUFACTURERS

At present, the IMB schedules routine inspections of manufacturers of medicinal products every 2 years. GMP certificates issued following these inspections are valid for three years unless the outcome of the next inspection determines that the GMP certificate should be withdrawn.

The IMB conducts inspections of active substance manufacturing sites, currently at intervals of approximately 3 years, in relation to requests from the manufacturers for GMP certification of these sites. Most API manufacturers wish to maintain continuity of the GMP certification at these sites. If the outcome of the inspection process is that the site complies with the principles and guidelines of GMP as defined in Part II of the Guide then a GMP certificate is issued which is valid for up to three years from the date of inspection.

In order to schedule inspections effectively and provide an opportunity for sites to maintain GMP certification, the IMB needs adequate notice to perform these inspections and complete any correspondence following the inspection so that a decision on the compliance of the site can be made. Manufacturers of active substances whose intention is to maintain continuous GMP certification are asked to volunteer for an automatically scheduled two-year inspection frequency. This would facilitate the planning of inspections of active substance sites and any manufacturers volunteering for such a programme of ongoing inspection would receive priority in the planning of inspections.

Any active substance manufacturing site wishing to volunteer for an ongoing inspection programme at two-yearly intervals should contact the Planning Manager (Ms Yvonne Maloney) in the Compliance Department.

REVISED IMB GUIDANCE NOTE ON PARALLEL IMPORTATION

The IMB wishes to advise wholesalers, manufacturers, marketing authorisation holders and other interested parties that it has published a new guide on parallel importation of medicinal products.

This guide, entitled *Guide to Parallel Imports*, is an amalgamation of two former guides on parallel product authorisations and on 'dual pack registrations'. It is numbered AUT-G0006, and is dated February 5th, 2008. It is available on the IMB website at **www.imb.ie**

The guide applies to nationally-authorised products which are parallel-imported from another Member State of the EU or an EEA country and distributed on the Irish market. The IMB operates two schemes for these products. Where the product to be imported differs in any respect from that on the Irish market, a parallel import licence must be obtained before the product may be distributed in Ireland. Where the product to be imported is identical in all respects (including identical packaging, labels and leaflets) to the product on the Irish market, a dual pack import registration (DPR) is required before the product can be legally distributed in Ireland.

Products which are authorised by the European Commission are not covered by this guide; importers wishing to distribute these products must notify the EMEA and the IMB of their intentions.

The application forms mentioned in the guide are also available from the IMB's website, **www.imb.ie**

Holders or potential holders of either parallel import licences or dual pack import registrations are strongly advised to review this new IMB guide carefully, as there are specific provisions that should be met by holders of such licences or registrations and by manufacturers or wholesalers of such products. Significant non-compliance issues have been identified to date with the supply of such products, and this has resulted in market action, including several product recalls from the Irish market.

RISK ASSESSMENTS AND QUALITY RISK MANAGEMENT ANNEX 20 (ICHQ9)

In the lead-up to the introduction of Annex 20 (ICHQ9) to the EC Guide to GMP many companies have already established systems and procedures for the application of risk assessment and quality risk management (QRM) approaches and tools to a number of aspects of their quality systems.

These have included risk assessments associated with facility design and new product introductions. In particular, risk assessment techniques have been effectively used for the assessment of the introduction of high potency dosage forms especially

with respect to containment and cleaning strategies.

In routine manufacturing applications, risk assessments and QRM approaches have been employed in the management of change controls and in the handling of deviations. One of the most commonly used techniques is that of failure mode and effects analysis (FMEA) in which the probability, severity and likelihood of detection of the failure are estimated, and risks are prioritised on the basis of a risk priority number (RPN), which is the product of these factors.

It has been noted during some recent inspections that companies have performed detailed evaluations of the probability of failure and severity but then assessed the likelihood of detection of the failure as low, despite the fact that scientifically sound methods of analysis were available for the parameter at hand. Where available, such detection controls should be taken into account and used where practical. These controls can be useful when verifying the accuracy of the cause(s) identified in the risk assessment exercise for the failure mode at hand or the adequacy of the proposed risk-reduction controls. In circumstances where adequate methods of verification are available, the expectation is that these should be used.

If the controls are detection-related, having increased detection capability would have the effect of reducing the final estimated magnitude of the RPN compared to cases where increased detection capability was not implemented.

Note that it is not expected that verification would have to be used in all circumstances, particularly in repeat situations where the causes of potential failure modes or the adequacy of the proposed risk-reduction controls identified during risk assessment exercises have already been verified, and the knowledge and experience gained from the previous occasion can be used to support the current risk assessment.

Examples of situations where verification has not been employed are where scientifically sound analytical methods have been developed to detect contaminants such as lubricating oil in tabletting. It has been observed during inspection that the

risk assessment exercises performed rated the likelihood of detection of the failure as low because the companies had decided not to perform the testing.

Another example concerns deviations where the risk of microbial contamination has been identified but the product had not been subjected to microbiological testing even though valid microbial limits tests were available for use.

The IMB Compliance Department strongly supports the application of risk assessment tools and the application of QRM principles and approaches. However, where there is a method of supporting or verifying the hypothesis put forward in a risk management exercise with real analytical data, this should be considered.

SAMPLING AND ANALYSIS – THE IMB'S REQUEST FOR SAMPLING & ANALYSIS SUPPORTING ITEMS FORM

The Market Compliance Section operates a wide-ranging sampling and analysis programme as part of the IMB's pre- marketing and post-marketing product surveillance activities. A risk-based approach is taken when carrying out sampling and analysis activities which extend to authorised human and veterinary medicinal products, active substances, products intended for export, enforcement-related samples, and borderline products. Products which are sampled are analytically tested and/or have their packaging and labelling examined for compliance with the authorisation. The extent of analysis or examination carried out on each sample is dependent on the reason for sampling.

In 2007, a total of 464 medicinal and other product types were analysed or had their packaging and labelling examined. This represented an increase in market surveillance and compliance work of approximately 46% over 2006 figures. Of these 464 samples, 183 were sent for laboratory analysis and 281 were examined for compliance with packaging and labelling requirements.

A key component in facilitating the smooth running of this programme is the IMB's Request for Sampling & Analysis Supporting Items form that is sent to a pharmaceutical company when one of its products is selected for analytical testing. A copy of this form is shown below.

The provision of the requested information and supporting items by authorisation holders and manufacturers contributes to the smooth running of the programme. It is timely for the IMB to remind companies to ensure that all of the items requested on the Sampling and Analysis Supporting Items form are in fact provided when requested. These include items such as copies of analytical test methods (shelf life analytical test method), quantities of reference standards, copies of certificates of analysis, copies of sample chromatograms, etc.

A declaration is required to be made on the form that the items provided do comply with the list of items requested, and that the analytical methods provided are those currently in use at the quality control laboratory, and that they reflect those currently registered in the relevant Marketing Authorisation. All items (parcels) provided must also be identified with the IMB reference number assigned by Market Compliance to the request form. If any assistance or clarification is needed before the items requested are despatched, please contact the Market Compliance Section.

Any reference standards provided should have a minimum of 6 months left to their expiry dates, and they must be shipped in accordance with their labelled instructions unless otherwise justified. Such justification must be provided to the Market Compliance Section in writing. Reference standards requiring any special storage conditions (i.e. storage at 2 - 8°C, etc.) should be sent directly to Dr. Michelle Cuffe, Executive Analytical Chemist, Drugs & Toxicology Section, Public Analyst's Laboratory, Seamus Quirke Road, Galway. Pharmaceutical companies must ensure that any items shipped to the IMB or to the Public Analyst's Laboratory reach these actual destinations and not a transit warehouse.

Irish Medicines Board, Market Compliance Section, Sampling & Analysis Programme
REQUEST FOR SAMPLING & ANALYSIS SUPPORTING ITEMS

IMB reference number: _____

From: _____ (Compliance, Irish Medicines Board)

To: _____ at _____

Re. ***Product / Material:*** _____

As part of the Irish Medicines Board's Sampling & Analysis Programme we request that you send the following checked items to IMB within **28 days** of the date of receipt of this fax/letter.

☐ 1 copy of the **registered release and shelf life specifications** for the above product / material.

☐ 1 copy of the currently used **analytical test method(s)** for the tests specified below. If no individual tests are specified, please forward the complete set of currently used **analytical test method(s)** for this product / material.

Note: *If more than one method is used for performing a particular test, please forward a copy of all of the methods, indicating clearly for which market each method is used.*

☐ A quantity of **reference materials (unopened, if possible) specified in the methods** for performing the tests outlined, **with a minimum of 6 months expiry on the reference materials**. (If you are providing reference materials other than those specified, please clearly justify your reasons for this).
☐ Copies of the **current, in-date, certificate of analysis for each reference material** provided.
☐ A quantity of any **placebo samples** required for performing the tests outlined above (e.g. for the related substances test).
☐ Any additional specific items (e.g. SOPs, MSDSs, internal standards, reference spectra and chromatograms) required for performing the tests specified above.

Please forward the items above, together with this checklist, to **Sampling & Analysis Programme, Market Compliance Section, Compliance Department, Irish Medicines Board, Earlsfort Centre, Earlsfort Terrace, Dublin 2.**

Important Information:

1. You are requested to ensure that the items provided are correct and as requested.
2. You are requested to ensure that the materials provided are transported in accordance with their labelling instructions, unless otherwise justified. (Please clearly justify your reasons for this.)
3. If any of the materials require special transport and storage conditions (e.g. refrigeration), you are requested to forward those materials under the requisite conditions directly to Dr. Michelle Cuffe, Executive Analytical Chemist, Public Analyst's Laboratory, Seamus Quirke Road, Galway, Ireland.
4. You are requested to ensure that all items sent to either the IMB or the Public Analyst's Laboratory are identified using the IMB reference number given above.
5. The test methods you are supplying should be the method used for determining compliance to the shelf life specifications, where the release and shelf life methods are different.

You are requested to sign this declaration and return this signed document with the requested items:

I, _____, declare that the items being provided with this request comply with the list of items requested above. I further declare that the analytical methods being provided are those currently in use at the laboratory and that they reflect those currently registered in the relevant marketing authorisation.

Signed: _____ Date: _____

Yours sincerely,

_____ _____

Kevin O'Donnell, IMB
Senior Inspector

Date

Human New Product Authorisations Issued (January 2008 – April 2008)

PA Number	Product Name
PA0148/060/002	Botox
PA0148/060/003	Botox
PA0167/004/007	Potassium Chloride and Sodium Chloride in Glucose
PA0167/004/008	Potassium Chloride and Sodium Chloride in Glucose
PA0688/014/001	Bisoprolol Fumarate
PA0688/014/002	Bisoprolol Fumarate
PA0688/014/003	Bisoprolol Fumarate
PA0688/014/004	Bisoprolol Fumarate
PA0688/014/005	Bisoprolol Fumarate
PA0823/051/001	Motilium Fastmelts 10 mg Tablets
PA0844/001/001	IMMUCYST BCG IMMUNOTHERAPEUTIC
PA0970/050/008	Pulmicort
PA0970/050/009	Pulmicort
PA1080/020/001	Topamat Film Coated Tablets
PA1080/020/002	Topamat Film Coated Tablets
PA1080/020/003	Topamat Film Coated Tablets
PA1080/020/004	Topamat Film Coated Tablets
PA1217/002/002	Ciprofloxacin Hikma 2 mg/ml solution for infusion
PA1286/001/001	Cozaar Comp
PA1326/001/001	Halls Mentholyptus Original
PA1326/001/002	Halls Mentholyptus Extra Strong
PA1326/001/003	Halls Mentholyptus Blackcurrant
PA1326/001/004	Halls Mentholyptus Honey and Lemon
PPA0465/106/002	Cozaar
PPA0465/109/002	Cozaar Comp
PPA0465/193/002	Zanidip
PPA0465/203/001	Sabril
PPA0465/204/001	Cardicor
PPA0465/204/002	Cardicor
PPA0465/204/003	Cardicor
PPA0465/204/004	Cardicor
PPA0465/208/001	REDUCTIL
PPA0465/208/002	REDUCTIL
PPA0465/209/001	Bettamousse
PPA0465/210/001	BETAGAN
PPA1151/005/002	Cozaar
PPA1151/009/002	Zantac
PPA1151/026/001	DIAMICRON
PPA1151/036/002	SEROQUEL
PPA1151/037/001	ARICEPT
PPA1151/040/001	PHARMATON
PPA1151/042/001	Xatral
PPA1151/047/001	ADALAT RETARD
PPA1151/049/001	CIPRAMIL
PPA1151/050/001	AUGMENTIN
PPA1151/051/001	TRITACE
PPA1151/051/002	TRITACE
PPA1151/051/003	TRITACE
PPA1151/051/004	TRITACE
PPA1151/053/001	Dovobet
PPA1151/054/001	PRAVITIN
PPA1151/055/001	ATECOR
PPA1151/055/002	ATECOR
PPA1151/055/003	ATECOR
PPA1151/057/001	ZANIDIP
PPA1151/058/001	Sporanox
PPA1151/060/001	Imodium
PPA1151/061/001	ZOCOR
PPA1151/062/001	Nasonex
PPA1151/063/001	Amaryl
PPA1151/063/002	Amaryl
PPA1151/063/003	Amaryl
PPA1151/064/002	ELTROXIN
PPA1151/064/003	ELTROXIN
PPA1151/065/001	CREON
PPA1151/068/001	Mycostatin
PPA1328/012/001	Flixonase
PPA1328/077/001	Becotide Evohaler
PPA1463/001/001	Zoton Fastab
PPA1463/001/002	Zoton Fastab
PPA1463/002/001	NEXIUM
PPA1463/002/002	NEXIUM

Human New Product Authorisations (Mutual Recognition Procedure) (January 2008 – April 2008)

PA Number	Product Name
PA0013/091/004	Co-Diovan
PA0013/091/005	Co-Diovan
PA0013/118/004	Co-Tareg
PA0013/118/005	Co-Tareg
PA0019/053/003	Campto 20 mg/ml concentrate for solution for infusion
PA0019/054/001	Sayana
PA0038/090/002	Zemplar

continued on next page ▶

Human New Product Authorisations (Mutual Recognition Procedure) – continued (January 2008 – April 2008)

PA Number	Product Name
PA0038/090/003	Zemplar
PA0038/090/004	Zemplar
PA0148/065/001	Vistabel
PA0167/132/001	Immunine 200 IU powder and solvent for solution for infusion
PA0167/132/002	Immunine 600 IU powder and solvent for solution for infusion
PA0167/132/003	Immunine 1200 IU powder and solvent for solution for infusion
PA0299/016/001	Citrafleet
PA0436/044/001	Eflavex 1 mg Tablets
PA0436/044/002	Eflavex 2 mg Tablets
PA0436/044/003	Eflavex 4 mg Tablets
PA0436/045/001	Dalzior 0.5 mg Tablets
PA0454/002/003	APO-go PFS
PA0566/041/001	Furosemide 20mg/2ml solution for injection
PA0585/030/001	Oxaliplatin 5 mg/ml Powder for Solution for Infusion
PA0749/023/001	Seretral 50mg Film-coated Tablets
PA0749/023/002	Seretral 100mg Film-coated Tablets
PA0749/024/001	Lansoprazole TEVA
PA0749/024/002	Lansoprazole TEVA
PA0749/035/001	Finasteride TEVA
PA0749/054/001	Tizanidine Teva
PA0749/054/002	Tizanidine Teva
PA0969/010/001	Terbinafine Medimpex
PA0970/018/008	Seroquel XR
PA0970/018/009	Seroquel XR
PA0970/018/010	Seroquel XR
PA0970/018/011	Seroquel XR
PA1063/027/001	Mirzaten
PA1063/027/002	Mirzaten
PA1063/027/003	Mirzaten
PA1077/037/006	Requip-Modutab
PA1077/037/007	Requip-Modutab
PA1077/037/008	Requip-Modutab
PA1077/037/009	Requip-Modutab
PA1077/116/001	Menitorix
PA1122/001/001	Water for Injections Ph. Eur.
PA1122/002/001	Sodium Chloride BP
PA1130/002/001	Pravastatin sodium
PA1130/002/002	Pravastatin sodium
PA1130/002/003	Pravastatin sodium
PA1130/012/001	Salipraneb 0.5mg/2.5mg per 2.5ml Nebuliser Solution
PA1140/002/001	Furosemide
PA1140/003/003	Midazolam BP
PA1140/003/004	Midazolam BP
PA1189/005/001	Ixprim 37.5 mg/325 mg film-coated tablets
PA1239/001/001	Formoterol
PA1284/002/001	Omeprazole Bentley
PA1284/002/002	Omeprazole Bentley
PA1284/002/003	Omeprazole Bentley
PA1284/003/001	Mylcer
PA1284/003/002	Mylcer
PA1284/003/003	Mylcer
PA1284/004/001	Losapol
PA1284/004/002	Losapol
PA1284/004/003	Losapol
PA1284/005/001	Soothome
PA1284/005/002	Soothome
PA1284/005/003	Soothome
PA1284/006/001	Lemowan
PA1284/006/002	Lemowan
PA1284/006/003	Lemowan
PA1284/007/001	Kalgriff
PA1284/007/002	Kalgriff
PA1284/007/003	Kalgriff
PA1284/008/001	Hentom
PA1284/008/002	Hentom
PA1284/008/003	Hentom
PA1284/009/001	Tumelin
PA1284/009/002	Tumelin
PA1284/009/003	Tumelin
PA1284/010/001	Bentome
PA1284/010/002	Bentome
PA1284/010/003	Bentome
PA1284/011/001	Tulzol
PA1284/011/002	Tulzol
PA1284/011/003	Tulzol
PA1284/012/001	Davliet
PA1284/012/002	Davliet
PA1284/012/003	Davliet
PA1284/013/001	Vomlez
PA1284/013/002	Vomlez
PA1284/013/003	Vomlez
PA1284/014/001	Pugritex
PA1284/014/002	Pugritex
PA1311/001/001	Sertraline
PA1311/001/002	Sertraline
PA1311/012/001	Mirtazapine Aurobindo
PA1311/012/002	Mirtazapine Aurobindo

continued on next page ▶

Human New Product Authorisations (Mutual Recognition Procedure) –continued (January 2008 – April 2008)

PA Number	Product Name
PA1311/012/003	Mirtazapine Aurobindo
PA1346/001/001	Vantas
PA1350/003/001	Everose
PA1353/001/001	Esmolol
PA1353/001/002	Esmolol
PA1368/001/001	Ciprofloxacin Pharmathen
PA1368/003/001	Fluconazole Pharmathen
PA1416/001/001	Rapydan
PA1419/002/001	Medronate DRAXIMAGE
PA1424/001/001	SITAMIC
PA1436/001/001	Mirtazapine Bluefish
PA1436/001/002	Mirtazapine Bluefish
PA1436/001/003	Mirtazapine Bluefish

Human New Product Authorisations (Decentralised Procedure) (January 2008 – April 2008)

PA Number	Product Name
PA0437/056/002	Oxaliplatin Mayne
PA0577/059/002	Zismirt orotab
PA0577/059/003	Zismirt orotab
PA0577/059/004	Zismirt orotab
PA0577/087/001	Myzaar
PA0577/087/002	Myzaar
PA0577/087/003	Myzaar
PA0623/010/001	Levofolinic acid medac
PA0711/114/001	Galtam
PA0711/114/002	Galtam
PA0711/114/003	Galtam
PA0711/116/001	Roni
PA0711/116/002	Roni
PA0711/116/003	Roni
PA0711/116/004	Roni
PA0711/116/005	Roni
PA0711/117/001	Fluvat
PA0711/117/002	Fluvat
PA0711/118/001	Pendrex
PA0711/118/002	Pendrex
PA0711/120/001	Nebol
PA0711/126/001	Omeprazole
PA0711/126/002	Omeprazole
PA0711/126/003	Omeprazole
PA0711/127/001	Leonore
PA0749/025/001	Famciclovir
PA0749/025/002	Famciclovir
PA0749/026/001	Losartan/Hydrochlorothiazide Teva 50mg/12.5mg Film
PA0749/026/002	Losartan/Hydrochlorothiazide Teva 100mg/25mg Film-
PA0749/034/001	Aripez
PA0749/034/002	Aripez
PA0749/044/001	Irinotecan Teva
PA0949/004/001	Ferinject
PA1038/002/001	Tardcaps XL 75 mg
PA1038/002/002	Tardcaps XL 150 mg
PA1049/009/001	Xomolix
PA1063/025/001	Ramipril Niche
PA1063/025/002	Ramipril Niche
PA1063/025/003	Ramipril Niche
PA1063/025/004	Ramipril Niche
PA1128/003/001	Tramadol
PA1130/009/001	Topirama
PA1130/009/002	Topirama
PA1130/009/003	Topirama
PA1130/009/004	Topirama
PA1130/009/007	Topirama Capsules
PA1130/010/001	Caberex 1 Milligram Tablets
PA1130/010/002	Caberex 2 Milligram Tablets
PA1130/010/003	Caberex 4 Milligram Tablets
PA1130/014/001	Cabergoline 0.5 Milligram Tablets
PA1294/003/001	Paclitaxel
PA1324/001/001	Magnegita
PA1338/001/001	Ranitidine
PA1350/001/001	FerroLogic 20 mg/ml solution for injection/concent
PA1366/003/001	Epirubicin
PA1384/001/001	Oxaliplatin

Human New Product Authorisations Withdrawn (January 2008 – April 2008)

PA Number	Product Name
PA0002/024/001	Ecostatin
PA0002/024/002	Ecostatin
PA0002/077/001	PRAVASTATIN SODIUM
PA0002/077/002	PRAVASTATIN SODIUM

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Human New Product Authorisations Withdrawn (cont) (January 2008 – April 2008)

PA Number	Product Name
PA0002/077/003	PRAVASTATIN SODIUM
PA0004/056/001	ANTISEPTIC THROAT DROPS MENTHOL AND EUCALYPTUS
PA0006/010/002	SOFRADEX EYE/EAR
PA0021/004/003	Canesten
PA0021/004/006	CANESTEN DERMATOLOGICAL
PA0021/074/004	Redoxon
PA0022/069/007	PREMIQUE CYCLE
PA0035/016/001	DECADRON 500 microgram Tablets
PA0035/021/002	Hydrocortone
PA0038/071/001	CHIROCAINE
PA0038/071/002	CHIROCAINE
PA0038/071/003	CHIROCAINE
PA0043/025/002	STREPSILS INTENSIVE SUGAR FREE ORANGE
PA0043/037/001	Crookes Ibuprofen Liquid
PA0046/033/001	PROTAMINE SULPHATE LEO
PA0050/017/001	Valium
PA0050/067/002	Mobiflex Tablets 20 mg
PA0050/067/005	Mobiflex Vials 20mg Powder and Solvent for Solution
PA0050/071/001	Fansidar
PA0050/086/002	Rocephin 1M
PA0073/018/001	Pholcolin
PA0073/019/001	Palfium
PA0073/025/001	Aspirin
PA0073/031/001	Papaveretum B.P.
PA0073/034/001	Isoniazid
PA0073/034/002	Isoniazid
PA0073/039/001	Boestrol
PA0073/039/002	Boestrol
PA0073/051/001	Dopagen
PA0073/051/002	Dopagen
PA0073/051/003	Dopagen
PA0073/053/001	Promethazine Hydrochloride
PA0073/053/002	Promethazine Hydrochloride
PA0073/056/001	Digoxin
PA0073/060/002	Antimet
PA0073/063/001	Bufigen
PA0073/063/002	Bufigen
PA0073/063/003	BUFIGEN
PA0073/073/001	ANTAROL
PA0073/073/002	ANTAROL
PA0073/073/003	ANTAROL
PA0073/083/001	Hexogen
PA0073/091/011	Bupivacaine Hydrochloride BP 0.375%
PA0073/091/013	Bupivacaine Hydrochloride B.P. 0.75% w/v
PA0073/092/001	Mucogen
PA0073/093/001	Nolgen Tablets 10 mg (Tamoxifen Tablets BP 10 mg)
PA0073/093/002	Nolgen
PA0073/098/001	Metoprolol Tartrate
PA0073/098/002	Metoprolol Tartrate
PA0073/100/001	Ergometrine
PA0073/104/001A	Chlorpromazine 1 ml
PA0073/104/003	Chlorpromazine BP
PA0073/104/004	Chlorpromazine BP
PA0073/104/005	Chlorpromazine BP
PA0073/123/001	Isosorbide Dinitrate
PA0073/130/001	Pancuronium
PA0073/133/001	Vologen
PA0073/133/002	Vologen
PA0073/133/004	VOLOGEN RETARD
PA0073/142/001	Hyperbaric Bupivacaine Hydrochloride
PA0073/150/001	Tramex
PA0073/152/001	Atenolol
PA0073/152/002	Atenolol
PA0118/018/001	Minims Rose Bengal
PA0126/051/002	Tetracycline
PA0126/129/001	Tazamel
PA0126/129/002	Tazamel 30mg Film-coated tablets
PA0126/129/003	Tazamel
PA0126/155/001	Sulpromel
PA0126/155/002	Sulpromel
PA0126/155/003	Sulpromel
PA0126/155/004	Sulpromel
PA0167/008/001	Sodium Chloride Intravenous Infusion BP 0.9% w/v.
PA0167/009/001A	Glucose Intravenous Infusion BP 5% w/v. (Viaflex c
PA0167/037/001	Mannitol
PA0167/050/001A	Sodium Chloride 0.18% w/v and 4.0% w/v Glucose Int
PA0167/050/015A	Sodium Chloride/Glucose
PA0167/054/001A	Ringers Intravenous Infusion
PA0172/023/001	Denorex
PA0172/033/001	Robitussin Junior
PA0172/033/003	ROBITUSSIN SOFT PASTILLES FOR DRY COUGH
PA0257/034/001	Lanepa
PA0277/053/003	Clarityn Rapide
PA0281/099/002	Caprill
PA0281/099/003	Caprill
PA0281/099/004	Caprill
PA0298/010/005	AMOXYCILLIN Sachet Sugar Free

continued on next page ▶

Human New Product Authorisations Withdrawn (cont) (January 2008 – April 2008)

PA Number	Product Name
PA0299/010/001	Clinicide Lotion
PA0299/011/001	CLINIMAL LOTION
PA0308/012/001	Gelcotar
PA0320/009/001	ELYZOL
PA0345/003/001	Moxydar
PA0408/009/001	Rimapen Penicillin VK
PA0408/029/003	Rimatidine
PA0416/009/001	Femin-9
PA0436/009/001	Diclofenac Sodium
PA0436/009/002	Diclofenac Sodium
PA0437/011/004A	FLOUROURACIL GLASS VIAL
PA0469/017/001	MICANOL
PA0469/017/002	MICANOL
PA0535/005/002	CALCORT
PA0540/037/001	Claforan
PA0540/080/002	Trental
PA0566/004/001	COMPLEVEN
PA0577/066/001	Azromax
PA0577/066/002	Azromax
PA0585/012/001	PRESINEX
PA0590/006/001	DIFFERIN Cutaneous Solution 0.1% w/w
PA0590/012/001	Tetralysal
PA0590/013/001	Sterax Cream 0.05% w/w
PA0590/013/002	Sterax Cutaneous Emulsion 0.05% w/w
PA0590/013/003	Sterax
PA0593/007/001	Cimetidine 200
PA0593/007/002	Cimetidine 400
PA0593/007/003	Cimetidine 800
PA0593/018/001	ZOPICALM
PA0654/003/001	Estradiol TTS
PA0654/008/001	Emcoretic
PA0654/009/001	NEUROBION
PA0675/002/001	DEXEMEL 4%
PA0678/048/001	Andrews Antacid (orange)
PA0678/048/002	Andrews Antacid Fruit Flavours
PA0678/096/001	Semprex
PA0710/002/001	Cuplex
PA0711/058/003	PRAVITIN
PA0711/078/001	Amlodipine
PA0711/078/003	Amlodipine
PA0711/080/001	Glepid
PA0711/080/002	Glepid
PA0711/080/003	Glepid
PA0711/080/004	Glepid
PA0711/080/005	Glepid
PA0735/008/001	Omniscan
PA0735/008/004	Omniscan
PA0735/008/005	Omniscan
PA0748/035/001	Ortho-Creme Contraceptive
PA0809/001/002	Fluoro-Uracil Roche
PA0863/001/001	Q.V.SKIN
PA0863/002/001	Q.V. SKIN
PA0863/003/001	Egoderm
PA0863/003/002	Egoderm
PA0863/005/001	Q.V.
PA0888/001/001	Flutamide
PA0899/018/001	Fortipine LA
PA0970/053/002	Xylocaine 1% With Adrenaline (Epinephrine)
PA0979/011/002	GAVISCON
PA0979/011/003	GAVISCON LEMON FLAVOUR
PA0979/018/001	DETTOL ANTISEPTIC PAIN RELIEF SPRAY
PA0985/002/001	Ubit
PA1037/001/001	Baricol
PA1046/003/001	Amiodarone
PA1046/003/002	Amiodarone
PA1046/004/001	ACICLOVIR
PA1046/004/003	ACICLOVIR DISPERSIBLE BP
PA1046/006/001	TRAMADOL HYDROCHLORIDE
PA1046/007/001	Diclofenac Sodium
PA1046/007/002	Diclofenac Sodium
PA1046/008/001	Sodium Valproate
PA1046/008/002	Sodium Valproate
PA1046/008/003	Sodium Valproate
PA1046/009/001	Cimetidine
PA1046/009/002	Cimetidine
PA1046/009/003	Cimetidine
PA1046/011/001	Paracetamol
PA1046/012/001	RANITIDINE
PA1046/012/002	RANITIDINE
PA1046/013/001	Amisulpride
PA1046/013/002	Amisulpride
PA1046/013/003	Amisulpride
PA1046/013/004	Amisulpride
PA1046/015/001	Glimepiride
PA1046/015/002	Glimepiride
PA1046/015/003	Glimepiride
PA1046/015/004	Glimepiride
PA1046/015/005	Glimepiride
PA1077/018/001	Andropatch
PA1077/060/002	Kemadrin

continued on next page ▶

Human New Product Authorisations Withdrawn (cont) (January 2008 – April 2008)

PA Number	Product Name
PA1077/107/001	Vunexin
PA1077/107/002	Vunexin
PA1077/107/003	Vunexin
PA1077/107/004	Vunexin
PA1077/109/001	Ondansetron
PA1077/109/002	Ondansetron
PA1077/110/001	Lamotrigine
PA1077/110/002	Lamotrigine
PA1077/110/003	Lamotrigine
PA1077/110/004	Lamotrigine
PA1077/110/005	Lamotrigine
PA1077/110/006	Lamotrigine
PA1155/005/001	HIOXYL
PA1217/001/001	Dobutamin Hikma 250 mg/ 50 ml ampoule
PA1217/001/002	Dobutamin Hikma 250 mg/ 50 ml vial
PA1217/001/003	Dobutamin Hikma 250/20 ml ampoule
PA1217/001/004	Dobutamin Hikma 250 mg/ 5 ml ampoule
PA1300/001/001	Gabapentin 600 mg Film Coated Tablets
PA1300/001/002	Gabapentin 800 mg Film Coated Tablets
PA1332/012/001	Ascal
PPA0465/015/002	Vibramycin
PPA0465/029/001A	Calpol Infant
PPA0465/039/001A	Losec 20 mg Gastro-resistant Hard Capsules
PPA0465/039/001B	Losec
PPA0465/039/001C	Losec
PPA0465/039/001D	Losec
PPA0465/041/004A	Becotide 250 Inhaler
PPA0465/044/001B	Estraderm TTS
PPA0465/044/001C	Estraderm TTS
PPA0465/044/003B	Estraderm TTS
PPA0465/044/003C	Estraderm TTS
PPA0465/058/002A	Zoton
PPA0465/058/002B	Zoton
PPA0465/058/002C	Zoton
PPA0465/070/001A	Imigran
PPA0465/070/001B	Imigran
PPA0465/070/001C	Imigran
PPA0465/070/001D	Imigran
PPA0465/070/002A	Imigran
PPA0465/070/002B	Imigran
PPA0465/070/002C	Imigran
PPA0465/105/001A	Combivent Metered
PPA0465/127/001A	Serevent Inhaler
PPA0465/150/001	Rogaine Regular Strength
PPA0465/166/001	Reminyl
PPA0465/170/001	Surmontil

Veterinary New Product Authorisations Issued (January 2008 – April 2008)

VPA Number	Product Name
10960/069/001	Ceemast DC Intramammary Suspension
10545/034/001	Flubenol 5% Oral Powder
10019/106/001	CIDR 1380 Cattle Device
10999/120/001	Closiver Injection
10989/056/001	Rapidexon 2mg/mlSolution for Injection
10955/018/001	Vetivex 1
10996/209/001	Cephaguard
10019/110/001	Spirovac Liquid for Injection
10861/096/001	Duramune DAPPi+Lepto
10778/003/001	Benazecare 5mg Film Coated Tablets for Dogs
10778/003/002	Benazecare 20mg Film Coated Tablets for Dogs
10810/004/001	Revertor 5mg/ml solution for Injection for Dogs
10955/017/001	Ovuplant
10790/002/001	Floxamax 10% Oral Solution
10787/001/001	Lanflox 100mg/ml Oral Solution
10846/008/001	Selectan

continued on next page ▶

Veterinary Product Authorisations Withdrawn (January 2008 – April 2008)

VPA Number	Product Name	VPA Number	Product Name
10861/085/001	Suvaxyn ERY	10996/078/001	Bovilis IBR
10996/140/001	Colisorb	10996/082/001	Bovilis IBR+PI3 Live
10996/141/001	Porcovac Plus	10545/018/001	Flubenol 44mg/ml Easy Paste
10966/022/001	Peroxyderm	10545/026/001	Flubenol Easy 220mg Chewable Tablets
10960/044/001	Duo Tablets	10019/100/001	Uniprim Oral Powder for Horses
10960/041/001	Osmonds Calf Shield	10861/033/001	Triangle BVD
10987/061/001	Chanamast LC Intramammary Suspension	10861/047/001	Suvaxyn I-Aujeszky O/W
10019/066/001	Imuresp RP	10861/048/001	Suvaxyn Aujeszky
10019/070/001	Spirovac	10861/055/001	Poulvac IB H120
10019/052/001	Dermisol	10861/056/001	Poulvac Marek CVI
10545/002/001	Ovitelmin Drench 5% w/v Oral Suspension	10996/137/001	Nobilis Marek THV Iyo
10545/003/001	Ovitelmin S&C	10996/090/001	Nobilis ND Hitchner live
10545/016/001	Ripercol 3.2% Oral Solution	10545/024/001	Flubenol 50% Premix
10987/003/001	Chanamast DC Intramammary Suspension		