IRISH MEDICINES BOARD

news MEDICINAL PRODUCTS LETTER

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GENERAL

STAFF CHANGES

ÁINE MARIE O'HANLON, and CATHAL BRENNAN were appointed as Scientific Officers in the Medical Devices Department.

BRIAN AYLWARD and ELEANOR CAREY were appointed as Medical Officers in the Medical Assessment Section of the Human Medicines Department.

HUMAN MEDICINES

FEE CHANGES FOR 2009

As in previous years, the IMB consulted 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 Health and Children. Sanction for the proposal was given in December 2008. The net result is that a fee increase of 4.9% overall is to be implemented from 1st January 2009. Full details of current fees are available from the IMB website in the *Guide to Fees* and the new fee application form should be used for all applications from 1 January 2009.

UPDATE ON REGULATORY REQUIREMENTS FOR ELECTRONIC SUBMISSION OF ADVERSE REACTION REPORTS

The Medicinal Products (Control of Placing on the Market) Regulations, 2007 (S.I. 540 of 2007), which transposes the EU legislation nationally, specifies the requirement for electronic reporting by marketing authorisation holders and holders of certificates of traditional-use registration

The IMB is continuing to monitor company compliance with electronic reporting requirements and has been in contact with companies that have not yet initiated electronic reporting regarding their plans for implementation. Companies that have not yet initiated electronic submission of ICSRs to the IMB are again reminded to contact the IMB by sending an e-mail to **eudravigilanceimb-test@imb.ie** for more information. An outline of the registration process can also be found in section 4 of the IMB Guide to the Electronic Submission of ICSRs and SUSARs, which is available on the IMB website **www.imb.ie**.

In addition, the IMB is continuing to closely monitor the quality and consistency of parallel reports submitted and as previously indicated, companies are advised of the need for appropriate validation and quality control measures to ensure provision of accurate and complete reports. The IMB has contacted companies individually when the quality of electronic reports submitted is considered appropriate to allow companies to discontinue parallel reporting and to date, a number of companies have discontinued parallel reporting. It is important for companies to continue

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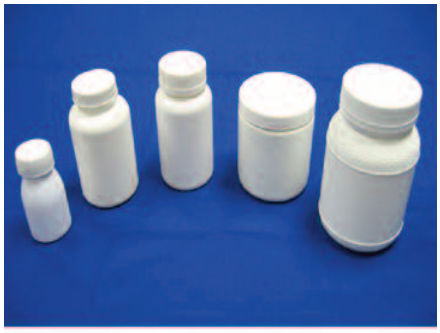


to ensure that all available information is included in electronic reports, particularly all available patient identifiers, to assist in the detection of duplicate reports.

In some cases, an insufficient quantity of reports has been received from companies to allow a meaningful evaluation of the quality and consistency of reports. Companies are requested to maintain the practice of parallel reporting until such time as the IMB contacts them to advise that parallel reporting may be discontinued. The IMB continues to provide feedback in the case of reports that have been associated with important discrepancies.

PROVISION OF DATA ON THE DETAILED DESCRIPTION OF THE PHARMACOVIGILANCE SYSTEM (DDPS)

Marketing Authorisation holders are reminded that full details of the proposed pharmacovigilance system should be provided in Module 1.8 of the application dossier, in line with the requirements as laid down in section 2.2 of Volume 9A of *The Rules Governing Medicinal Products in the European Union – Guidelines on Pharmacovigilance for Medicinal Products for Human Use*.

The cover letter for the application should confirm registration of the Qualified Person for Pharmacovigilance (QPPV) with the EudraVigilance system, which is an essential requirement to facilitate validation and allow assessment to proceed. Applicants should only apply for a mutual-recognition procedure timeslot when this registration step is complete.

A copy of the registration of the QPPV with the EudraVigilance system and identification of the process used for electronic reporting to the Competent Authorities should be provided in Module 1.8.

CLARIFICATION REGARDING MEDICINAL STATUS OF CERTAIN PRODUCTS CONTAINING VITAMINS UNDER THE MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) REGULATIONS 2003 – 2008.

In general, any substance which is restricted by the prescription regulations is considered automatically to be a prescription-only medicine.

Products in oral form containing the following vitamin substances which do not make medicinal claims, and subject to the maximum daily doses stated below, may be presented as food supplements and marketed in accordance with the European Communities (Food Supplements) Regulations, S.I. 506 of 2007:

Vitamins	*Maximum Daily Dose without prescription*
Folic acid	*500 microgram*
Vitamin A	*7,500 IU (2.25 mg)*
Vitamin D (ergocalciferol; cholecalciferol)	*3000, IU (75µg)*
Vitamin B6	*50 mg*
Vitamin B12	*25 microgram*
Phytomenadione (Vitamin K1)	*Any dose*

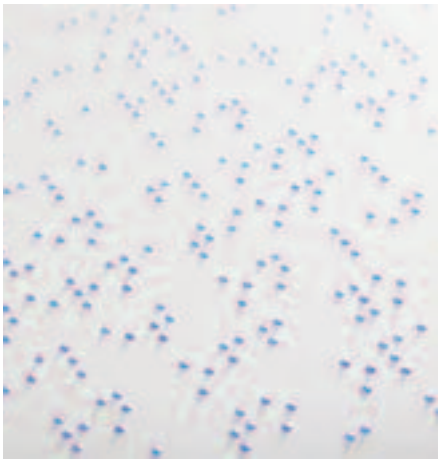
However, following advice received from the Department of Health and Children, the IMB understands that products containing vitamins exceeding the dosage levels above may also be marketed as food supplements, when no medicinal claim is made.

All other products containing substances listed in the prescription regulations continue to be regulated as prescription medicines.

The IMB reserves the right to review the status of any product and determine the appropriate prescription status. Those proposing to market a product may seek advice from the IMB prior to launch to ensure that the appropriate classification has been made.

BRAILLE AND PATIENT ACCESSIBLE LEAFLETS – REQUIREMENT TO COMPLY BY 30 OCTOBER 2010

Applicants are reminded that they must comply with the requirements of Directive 2001/83/EC as amended, as implemented by S.I. 540 of 2007, Medicinal Products (Control of Placing on the Market) Regulations, 2007, to include Braille on the packaging of medicinal products and to provide the leaflet in patient-accessible format, by 30 October 2010. The IMB is assessing compliance with this requirement through the submission by marketing authorisation holders of a 'Braille declaration' (also known as *Marketing authorisation holder's declaration of compliance with Article 56a of Directive 2001/83/EC as amended*) – see IMB website *Guide to labels and leaflets* for full details: http://www.imb.ie/images/uploaded/documents/AUT-G0034_Guide_to_labels_and_leaflets_of_human_medicines_v2.pdf. Further details of these requirements are also available at:http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2005/04_05/braille_text20050411.pdf.



Please note that the applicant should include additional information in Braille e.g. pharmaceutical form, should a potential risk of confusion of identification with other products exist. It should be noted that even in cases where Braille is not required as the product is for administration by healthcare profes-

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sionals only, a 'Braille declaration' must be submitted in which Section 1b is completed to this effect, and Section 2 must be completed as the MAH must provide the leaflet in patient-accessible format. The declarations provided should include the PA numbers. Where a declaration has previously been submitted and annotated to indicate deferral of one or other requirement of Article 56a, a revised declaration must be submitted to the IMB and the deferred requirements implemented by 30 October 2010. Declarations may be submitted at renewal, by means of variation to update in line with the requirements of Directive 2001/83/EC as amended, or by Article 61.3 notification procedure, and applicants are requested therefore to address this requirement promptly.

REQUIREMENT FOR SUBMISSION OF ARTICLE 61(3) NOTIFICATIONS FOLLOWING A CHANGE IN THE NAME OF A MEDICINAL PRODUCT

The IMB would like to clarify its requirements for submission of labelling and package leaflet mock-ups following the change in the name of a medicinal product (Type IB no. 2 notification). In accordance with the Notice to Applicants, Volume 2A, Chapter 5, Variations (February 2004), only consequential changes to the summary of product characteristics, labelling or package leaflet can be processed as part of a variation or notification. In the case of a change to the name of a medicinal product, this consequential change to the product information is considered to only include the change to the product name, wherever it appears. If any other changes are proposed to labelling or package leaflet, they must be registered by way of an Article 61(3) notification. This requirement for submission of an Article 61(3) notification also applies to the submission of mock-ups for a product that has not previously been marketed and is proposed to be marketed following a name change.

NATIONAL AUTHORISATION RENEWAL APPLICATIONS

Following a review of queries that commonly arise, and with a view to reducing the amount of correspondence between the manufacturing authorisation holders and the IMB during the procedure, we would like to advise applicants of the following issues that may help in the preparation of national renewal applications.

Manufacturers

Manufacturing sites and activities listed in the application form should correspond to those in the currently approved schedule. Replacement, addition or deletion of any site or any manufacturing activity or any change to name and/or address of a manufacturer, can only be made by way of appropriate variation.

GMP of Active Substance Manufacturer

A declaration of GMP compliance for the active substance(s) is required from the QP at each site of batch release, and at **each site using the active substance as starting material** (ICH Q7A). A single declaration may be made by the QP at one site on behalf of all QPs involved provided that this is clearly stated and that this is underpinned by a technical agreement (GMP Guide Chapter 7).

Quality Overview

The specifications of the active substances and the release and shelf-life specifications of the finished product, together with a reference to test methods, must be included. Changes to specifications are not permitted at renewal. Compliance with Ph Eur monographs for active substances and excipients is required, as well as compliance with specific BP monographs for formulated preparations where they exist. A declaration should be included, signed by the expert, confirming that the product complies with Article 23 of Directive 2001/83/EC, that all changes related to the quality of the product have been made by way of appropriate variation, and that the product is manufactured in accordance with all current CHMP quality guidelines.

Summary of Product Characteristics

Applicants are asked to review the EC Notice to Applicants *Guideline on the Summary of Product Characteristics* (October 2005) as well as the *EMEA QRD template* and to update their SPC accordingly. In particular applicants are asked to review the *Note for Guidance on Excipients in the Label and Package Leaflet of Medicinal Products for Human Use* [CPMP/463/00]. Those excipients which are listed in the Annex to this guideline must be stated quantitatively in Section 2 of the SPC. In addition they must be declared on the label, followed by a direction to refer to the leaflet for further information. The relevant warning from the annex must be added to the leaflet text. In addition, applicants should consult the *Note for Guidance on Maximum Shelf-life for Sterile Products for Human use after First Opening or Following Reconstitution [CPMP/QWP/159/96]* and provide the relevant data where appropriate.

Further information on these or any other issues relating to renewals can be found in the *IMB Guide to Renewal of Product Authorisations* which is available from the IMB website; **www.imb.ie.**

VETERINARY MEDICINES

FEE CHANGES FOR 2009

As in previous years, the IMB consulted 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 2008. The net result is that a fee increase of 4.9% overall is to be implemented from 1 January 2009. Full details of current fees are available from the IMB website in the *Guide to Fees (Veterinary)* and the new fee application form should be used for all applications from 1 January 2009.

IDEAS FOR IMPROVEMENT IN COMMUNICATIONS

The Veterinary Medicines Department is committed to improving service levels on an ongoing basis. Ideas as to how communications on veterinary medicines could be improved or how the use of the website as it relates to veterinary medicines could be enhanced or made more efficient would be gratefully received. Please send your ideas before 27 February 2009 to Ms. Michelle Sinnott (michelle.sinnott@imb.ie).

IMB VETERINARY PHARMACOVIGILANCE INFORMATION DAY 2008

The Veterinary Medicines Department held a very successful Vet Pharmacovigilance Info Day on 9 October 2008. A large section of the veterinary pharmaceutical industry was in attendance. The meeting was updated by IMB and EMEA speakers in respect of recent developments on pharmacovigilance and EudraVigilance. The meeting also heard the experience of industry and other national authority speakers in relation to pharmacovigilance inspections undertaken in recent times. In addition, the IMB outlined its approach to veterinary pharmacovigilance inspections for 2009.

RESIGNATION FROM THE ADVISORY COMMITTEE FOR VETERINARY MEDICINES

Mr. Joseph Britton, MPSI, Pharmacist, resigned from the ACVM with effect from 7 October, 2008. The IMB wishes to thank Mr. Britton for his contribution to its work over the last 2½ years.

STAFF CHANGES IN THE VETERINARY MEDICINES DEPARTMENT

There have been a number of staff changes within the department in recent times. An up-to-date organisational chart is maintained by following the hyperlink on the personnel page of the IMB website (http://www.imb.ie/EN/About-Us/Organisational-Structure/Personnel.aspx).

SUSPECTED ADVERSE REACTION REPORTING REQUIREMENTS

The IMB would like to remind marketing authorisation holders that from 1 January 2009 it is expected that all suspected adverse reaction reports relating to nationally authorised veterinary medicinal products will be submitted to the IMB electronically, using EudraVigilance.

Information on how to report through EudraVigilance is available on the EudraVigilance website http://eudravigilance.emea.europa.eu/veterinary/

VETERINARY MEDICINES INFO DAY 2009

The Veterinary Medicines Department is planning to hold a Veterinary Medicines Info Day in September 2009. A keynote feature of the day will be the effect of the changes in the Variations Regulations on applications and on IMB processes. Ideas for other topics should be submitted as soon as possible to Ms. Michelle Sinnott (michelle.sinnott@imb.ie). Further information on the date, venue and programme outline will be available on the IMB website shortly.

COMPLIANCE

EXPORT CERTIFICATION SCHEME UPDATE

Applicants for Certificates of Pharmaceutical Product (CPP) are no longer required to attach a Summary of Product Characteristics (SPC) with their application. The latest current version of the SPC will be included if required with the issued CPP documentation.

Please contact Patrick Keating, Senior Controlled Drugs and Export Certificate Administrator, Compliance Department.

MATERIALS MANAGEMENT & ENSURING THE SUPPLY CHAIN

Over the past 12-18 months, there has been increased focus on the supply chain activities relating to the manufacture and distribution of medicinal products to the market place. This area is of paramount importance especially where there is an increased and perceived risk of counterfeit materials. This was addressed as part of the IMB GMP Information Day 2008 (see website for details of presentation and references therein). The following article on this area will focus on the IMB expectations of manufacturers of medicinal products. It is proposed to include a second article in the next newsletter (edition number 32) which will focus on wholesalers / distributors of medicinal products.

Part A: Manufacturers of medicinal products

When considering the supply chain of medicinal products and the risks affecting manufacturers, one of the greatest risks arises when materials of questionable source and quality are sourced and used. Such was the case with products manufactured using contaminated glycerol and heparin which resulted in multiple adverse events and multiple deaths on a global scale. In anticipation of any proposed changes to EU and national legislation and/or GMP guidelines, manufacturers should take proactive measures to ensure that effective measures are in place to minimise the risks of such incidents occurring.

The following guidance can be considered to apply to active substances, in light of the requirement for manufacturers to use as starting materials, active substances which have been manufactured in accordance with GMP. A similar risk based approach should be applied to excipient manufacturers, especially where excipients impart critical quality attributes (see accompanying article on reduced testing).

Areas for consideration, which are by no means exhaustive, are as follows:

1. Supply chain mapping

The supply chain for all active substances should be mapped, outlining the roles and activities performed by each party in the supply chain. The complete address of each party should be documented to enable accurate and complete checking, where appropriate, of such addresses on receipt of goods. This includes checks performed on incoming labelling and supporting documentation such as certificates of analyses. The term 'supplier' can be misinterpreted and thus more appropriate descriptive wording should be considered e.g. manufacturer (including sites involved in packaging, labelling and importation of active substances), distributor, broker etc.

2. Audit program

A risk-based audit program should be in place to enable the manufacturer to satisfy itself of the level of compliance with GMP of the manufacturers of active substances. In establishing the risk-based program, various factors should be considered such as (a) the nature of the material, (b) nature of the finished product, (c) potential TSE risk, (d) dedicated versus multi material producing facility, (e) compliance history of the site etc. A schedule should be established to ensure that active substance manufacturers are subject to initial and ongoing audits to ensure continual compliance with GMP.

3. Audits and audit reports

Audits should be performed by personnel appropriately trained to carry out the function, and audit reports should be made available to the appropriate Qualified Person(s). Such audit reports should be readily available and may be subject to review by an inspector during routine GMP inspections. Where audits are performed by third party personnel, steps should be taken to ensure that (a) such personnel are qualified to perform the audit and (b) that no conflict of interest exists. Third party audit reports should be subject to formal review and acceptance (or rejection) and measures should be taken to ensure that corrective actions identified within such reports are resolved.

Audit reports should outline the scope of the audit and should identify areas which were not assessed by the auditor in addition to identifying those areas which were covered in the audit. Reports should critically describe and assess the manufacturing process, facilities, and measures taken to ensure the quality of material purchased. Critical quality attributes which could affect the manufacturing process for, or the quality, safety and efficacy of the finished product should be adequately described e.g. residual solvents, particle size, polymorphism etc.

4. Checks performed at goods receipt – supporting documentation

Checks performed at goods receipt should be of sufficient detail to enable the discrimination of similar materials such as different grades of the same materials and different manufacturers of the same materials. Procedures should be in place to describe the checks to be performed on containers e.g. integrity checks, checks for security seals and the presence and accuracy of approved labelling. Where several labels are present on containers, procedures should describe what labelling is permitted.

Certificates of analyses (CoA) received should be checked to ensure their authenticity and accuracy. The results of analytical testing performed by the manufacturer should be compared against the CoA received to ensure ongoing compliance. Where significant differences in test results occur (whether within specification or out-of-specification), an appropriate investigation should be launched to identify the root cause and to implement appropriate corrective actions. Where reduced testing is considered, please refer to the appropriate article in this newsletter.

5. Quality Control testing at the manufacturing site

Materials received should be subjected to quality control testing

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using validated test methods, as described in the appropriate marketing authorisations. Where analytical test results are taken from the raw material manufacturer's CoA, appropriate justification and continuous monitoring should be in place to support this practice (see article on reduced testing of raw materials). Any out-of-specification results obtained should be appropriately investigated and a system should be in place to communicate such issues to the manufacturer of the active substance.

6. Changes to approved suppliers

Changes to approved suppliers should be managed through a formal change control process. A regulatory impact assessment should be conducted to assess whether changes to the appropriate marketing authorisation(s) are required. Records should be maintained of current suppliers and suppliers which are no longer employed.

Finally, it is implicit that procedures are in place to describe all of the aforementioned measures and that training is provided to all relevant personnel.

REDUCED TESTING OF RAW MATERIALS

The practice whereby manufacturers of finished medicinal products do not perform all quality control specification tests on incoming raw materials (i.e. active substances and excipients) is commonly referred to as reduced testing. The results of analytical tests which are not performed are commonly obtained from the raw material manufacturer's certificate of analysis. This practice of performing reduced testing can present a risk to the quality of the incoming raw materials and ultimately, the finished product and thus should only be considered when complete knowledge of the supply chain is available, fully understood, maintained, well documented and accepted (see related article on supply chain management).

Any decision to reduce the degree of testing should equally be justified and should be appropriately documented. The degree of reduced testing, or the frequency at which full testing is performed should also be justified and documented and should based on the statistical evaluation of appropriate analytical data obtained from the raw material manufacturer.

At the extreme of performing reduced testing is the practise of solely performing identity testing. While this test may ensure the identity of the raw material, in many cases it cannot provide any information regarding the quality of the material. In considering reduced testing, a risk based approach should be adopted whereby the full specification is reviewed and the risk of not performing a test is addressed. Of particular importance are tests which provide information regarding the critical quality attributes of the raw material. These are attributes which can impact on the manufacturability of the medicinal product and importantly can impact on the quality, safety and efficacy of the finished product. Examples include particle size (especially for suspension products), polymorphism, chirality etc.

In the event that a material fails a specification test when full testing is performed, such full testing should be immediately re-instated for subsequent batches of material received until such time that the issue has been fully investigated, a root cause identified, corrective actions put in place and continuous monitoring is in place for a defined period of time / appropriate number of batches received and fully tested.

Any consideration to perform reduced testing on raw materials should include a regulatory impact assessment to assess whether any variation is required to the appropriate marketing authorisation(s), prior to the implementation of reduced testing.

EU GMP GUIDE ANNEXES – SUPPLEMENTARY REQUIREMENTS – ANNEX 19 REFERENCE AND RETENTION SAMPLES

The EMEA has recently published supplementary requirements in relation to Annex 19, in order to clarify if it is necessary to retain a sufficient number of samples of each batch of a sterile medicinal product in order to carry out a sterility test on two separate occasions.

The supplementary requirement states that, for retention purposes, it is not necessary to keep the full number of samples required in table 2.6.1.3 of the European Pharmacopoeia sterility test monograph to repeat the sterility test performed for release purposes, but only a sufficient quantity to allow the carrying out, on two occasions, of a confirmative test using the minimum quantities described in table 2.6.1.2 of the monograph.

Manufacturers (including importers) are therefore advised to review, and amend where necessary, their procedures in relation to reference and retention samples in order to ensure that they comply with the supplementary requirements.

EMEA PUBLISHES A CONCEPT PAPER ON THE REVISION OF THE GUIDELINE ON PARAMETRIC RELEASE

On 26 November 2008, the EMEA published a concept paper on the revision of the Guideline on Parametric Release. The deadline for comments on this paper is 28 February 2009.

This concept paper addresses the need to update the CPMP Note for Guidance on Parametric Release. This guidance was originally adopted in February 2001. At the time the guidance was developed, the main application area foreseen was the replacement of sterility testing, and this is clearly reflected in the current text. The possibility to apply the same concepts to areas other than sterility was acknowledged and briefly discussed.

With the development of the

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new ICH Q8, Q9 and Q10 guidelines, the general ideas in the current parametric release guidance have been further elaborated. It was therefore reasonable to review the current guidance as it does not reflect the recent regulatory developments in Process Analytical Technology, Quality by Design and Real Time Release, and to extend it to aspects other than sterilisation.

The concept paper can be found on the EMEA website at:

http://www.emea.europa.eu/pdfs/human/qwp/56995908en.pdf

QP DECLARATIONS IN RELATION TO 'ATYPICAL' ACTIVE SUBSTANCES

The term 'atypical' active substance has been employed to describe an active substance, the primary industrial use of which is not as a pharmaceutical active substance. It has been acknowledged that companies have found it difficult to provide declarations of GMP compliance for such substances. In addressing this issue, the EMEA has published a Q&A document on this topic which is designed to provide guidance to manufacturers which include atypical active substance in medicinal products. In such situations, manufacturers should endeavour to obtain the substance from a manufacturer that complies with GMP for active substances. In situations where this is not possible, the manufacturing authorisation holder should assess and document the extent of GMP compliance and provide a risk-based justification for the acceptance of any derogation. The basis for accepting atypical active substances and providing QP declarations of GMP compliance will be subject to review during inspections of manufacturing authorisation holders.

The full Q&A text can be found on the EMEA website at http://www.emea.europa.eu/Inspections/GMPfaq.html

EUROPEAN LEGAL PROPOSAL AMENDING DIRECTIVE 2001/83/EC TO COMBAT COUNTERFEIT MEDICINAL PRODUCTS IN THE EU

The European Parliament has raised concerns in recent years over the increasing threat of counterfeit medicinal products and committed itself internationally to addressing theses risks to public health. Concerns were also raised regarding the source and quality of active substances. The distribution chain was identified as a potentially high risk area, where counterfeit medicinal products could enter into the legitimate supply chain.

The European Commission undertook a study to assess the various policy options available to prevent the counterfeiting of medicinal products. The Directorate-General for Enterprise and Industry initiated a public consultation in March 2008 in preparation of a legal proposal which would amend the regulatory framework for medicinal products (in particular Directive 2001/83/EC) to combat counterfeit medicinal products.

On 10 December 2008 the Commission adopted a legal proposal to combat counterfeit medicinal products. This proposal is entitled Commission Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source.

This text has yet to be discussed with the European Parliament and the European Council. The first of these discussions is expected to occur in January 2009. It is anticipated that it will be at least two years before it will be adopted as a legal text.

Various points of specific interest and impact to both GMP and GDP are included within the proposed text. Please see the link below for the Commission Proposal and other documentation of interest.

http://ec.europa.eu/enterprise/pharmaceuticals/counterf_par_trade/counterfeit_key.htm

The main points of interest for wholesale distributors and others involved in supply chain include the following:

- A definition of trading of medicinal products and the distinction between products imported into the Community to be placed on the market and those imported only for the purpose of export, i.e. transhipment of products (import for export). Implementing legislation will be established to further define the requirements for all possible transhipment scenarios.
- The issue of safety features for the identification and traceability of medicinal products is also addressed. Again further legislation is required for implementation of these features as it has not yet been decided what the extent of these features should be and to which products they should apply.
- The use of a Community database for the centralised recording of wholesale authorisations is introduced. It is intended that this database will be of a similar format to the EudraGMP database currently in use and maintained by the EMEA for manufacturer's authorisations and certificates of compliance with GMP.
- A number of amendments are made to Article 80 of Directive 2001/83/EC: traders of medicinal products will be expected to maintain the same standard of record-keeping as currently required to be kept by wholesale distributors; further requirements include a quality system setting out responsibilities, processes and risk management and the requirement to notify the competent authority (and MAH) when it is suspected that products are infringing certain listed requirements.
- Persons involved in trading must ensure the medicinal products are authorised and must adhere to the requirements of Article 80(d) to (h) (i.e. have an emergency plan in place, maintain records which are made available to the

competent authority for inspection purposes, comply with the principles of GDP, maintain a quality system and notify suspected infringements). They must also notify their activity to the competent authority.

- Holders of wholesale authorisations must audit their supplying wholesale distributors to verify their compliance with GDP. This audit may be conducted by the wholesale distributor or by a body accredited for that purpose by the competent authority of a Member State. Where the product is obtained from a manufacturer or importer, the distributor must verify that the manufacturer/importer holds a manufacturer's authorisation.

- Wholesale distribution to third countries is addressed and relevant Articles of Directive 2001/83/EC which do not apply in these situations are listed.

- The proposal also introduces the need for the competent authorities to report after an inspection on whether the wholesale distributor complies with the principles of GDP. Within 90 days of the inspection a certificate of good distribution practice must be issued. These certificates must be entered into the Community database. Information relating to non conformance with GDP must also be entered in the database. The Commission will adopt guidelines laying down the principles for inspections.

New requirements impacting on the holders of manufacturer's authorisations (including the use of active substances used as starting materials) are also included.

REVISION OF ANNEX 1

The revision to Annex 1 has an implementation date of March 2010 for the requirements for capping of vials. The revised sections cover both freeze-dried and conventional liquid / powder dosage forms in vials. These changes do not relate to terminally-sterilised dosage forms in vials.

The new text associated with the requirements for capping is as follows:

- The container closure system for aseptically filled vials is not fully integral until the aluminium cap has been crimped into place on the stoppered vial. Crimping of the cap should therefore be performed as soon as possibly after stopper insertion.

- As the equipment used to crimp vial caps can generate large quantities of non-viable particulates, the equipment should be located at a separate station equipped with adequate air extraction.

- Vial capping can be undertaken as an aseptic process using sterilised caps or as a clean process outside the aseptic core. Where this latter approach is adopted, vials should be protected by Grade A conditions up to the point of leaving the aseptic processing area, and thereafter stoppered vials should be protected with a Grade A air supply until the cap has been crimped.

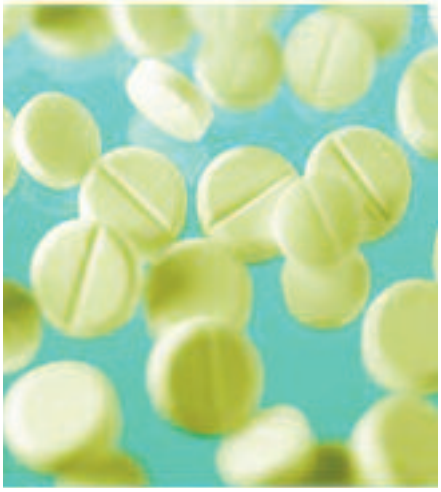
- Vials with missing or displaced stoppers should be rejected prior to capping. Where human intervention is required at the capping station, appropriate technology should be used to prevent direct contact with the vials and to minimise microbial contamination.

- Restricted access barriers and isolators may be beneficial in assuring the required conditions and minimising direct human interventions into the capping operation.

In response to a number of queries received by inspectors during inspections, the following clarifications can be made.

- If the capping operation is undertaken as an aseptic operation then capping operations should be performed in grade A/B conditions. The seals / caps are required to be sterilised. All controls applicable to an aseptic operation are applicable here with the exception of continuous non-viable monitoring. The extent and frequency of non-viable monitoring in operation should be appropriately justified.

- If the capping operation takes place as a clean process outside the aseptic core:
  - Vials should be protected by grade A air supply. In order to minimise direct contact with vials and the risk of microbial contamination, use of separation technologies, such as isolators and/or restricted access barrier systems, should be considered.
  - In-process control should be performed to reject vials with missing or displaced stoppers before capping. The system should be appropriately qualified with appropriate, documented justification for minimum acceptance criteria assigned. For example microbial ingress studies, or other appropriate studies, should be considered as part of the qualification assessment of the minimum acceptable stopper displacement.
  - It is not essential to sterilise the caps.
  - Viable monitoring should take place throughout the capping process. Appropriate alert and action limits should be set.
  - The air supply should be qualified to meet Grade A standard, incorporating both viable and non-viable monitoring.



GOOD MANUFACTURING PRACTICE (GMP) AND MARKET COMPLIANCE INFORMATION DAY

The IMB hosted an Information Day focussed on GMP and market compliance activities on 23 October last. The event was targeted primarily at the relevant sectors of the pharmaceutical industry and other stakeholders engaged in or supporting medicinal product and active pharmaceutical ingredient manufacture.

The event attracted an unprecedented level of interest from the relevant sectors of the pharmaceutical industry, being attended by over 240 delegates.

The programme for the day was structured to cover a number of important topics impacting on GMP and market compliance activities. Key areas of interest and themes discussed during the day included measures to improve material supply chain management, the impact of regulatory updates on manufacturing, the promotion of compliance via improved self-inspection activities and feedback from various aspects of the IMB's inspection and quality surveillance programmes.

The programme also included a number of parallel sessions covering more specific topics relevant to both GMP and market compliance, which allowed for in-depth discussion and focus on particular issues. These included sterile product manufacture; process analytical technology initiatives; the investigation of quality defects, and findings from recent market surveillance work performed by the Compliance Department on active substances received by Irish manufacturers from third countries. The inclusion of the parallel sessions also allowed delegates flexibility with respect to their selection of areas of interest and participation within the event.

Feedback received from stakeholders on the event has been very positive. In particular, delegates commended the range of issues covered, and the useful discussion and feedback on issues facilitated through the parallel sessions.

Human New Product Authorisations (Issued) (September 2008 – December 2008)

PA Number	Product Name
PA0043/006/014	NUROFEN FOR CHILDREN
PA0043/006/017	NUROFEN FOR CHILDREN ORANGE SUSPENSION
PA0043/006/017	NUROFEN FOR CHILDREN ORANGE SUSPENSION
PA0281/135/001	Osteole
PA0281/136/001	Efaxil XL
PA0281/136/002	Efaxil XL
PA0583/001/002	Dysport
PA0688/009/001	Amlodipine
PA0688/009/002	Amlodipine
PA0688/010/001	Sumatriptan
PA0688/010/002	Sumatriptan
PA0688/011/001	Sumagran
PA0688/011/002	Sumagran
PA0823/049/021	Nicorette Invisi
PA0823/049/022	Nicorette Invisi
PA0823/049/023	Nicorette Invisi
PA0915/015/001	Bicalinn
PA0915/015/001	Bicalinn
PA0915/016/001	Fintex
PA1334/002/001	Glibenclamide
PA1334/002/002	Glibenclamide
PPA0465/212/001	Famvir
PPA0465/213/001	Dovobet
PPA1151/050/002	AUGMENTIN DUO 400mg/57mg per 5ml powder for oral suspension
PPA1151/064/001	Eltroxin
PPA1151/067/001	Diovan
PPA1151/067/002	Diovan
PPA1151/072/001	Innovace
PPA1151/074/002	Salamol Easi-Breathe
PPA1151/075/001	XALATAN
PPA1151/075/001	XALATAN
PPA1151/076/001	EFEXOR
PPA1151/076/002	EFEXOR
PPA1151/078/001	Elantan LA
PPA1151/079/001	Serc 16
PPA1151/080/001	Telfast
PPA1151/080/002	Telfast
PPA1151/081/001	Traxam
PPA1151/083/001	Nebilet
PPA1151/084/001	CORDARONE X
PPA1151/084/002	CORDARONE X
PPA1151/085/001	COVERSYL ARGININE PLUS
PPA1151/090/001	Zispin SolTab
PPA1151/090/002	Zispin SolTab
PPA1151/090/003	Zispin SolTab
PPA1447/004/001	ACTONEL Once a Week
PPA1447/005/001	PARIET
PPA1447/005/002	PARIET
PPA1447/008/001	ZISPIN SOLTABS
PPA1447/008/002	ZISPIN SOLTABS
PPA1447/008/003	ZISPIN SOLTABS
PPA1447/009/001	Zomig Rapimelt
PPA1447/009/002	ZOMIG

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Human New Product Authorisations (Issued) cont. (September 2008 – December 2008)

PA Number	Product Name
PPA1447/012/001	Teveten
PPA1447/013/001	Seroquel
PPA1447/013/002	Seroquel
PPA1447/013/003	Seroquel
PPA1447/014/001	Tenormin
PPA1447/015/001	TOPAMAX
PPA1447/015/002	TOPAMAX
PPA1447/015/003	TOPAMAX
PPA1447/015/004	TOPAMAX
PPA1447/018/001	LOSEC MUPS
PPA1447/018/001	LOSEC MUPS
PPA1447/018/002	LOSEC MUPS
PPA1447/018/002	LOSEC MUPS
PPA1447/018/003	LOSEC MUPS
PPA1447/018/003	LOSEC MUPS
PPA1447/019/001	ACULAR
PPA1447/023/001	PULMICORT Turbohaler
PPA1447/023/002	PULMICORT Turbohaler
PPA1447/026/001	ZANAFLEX
PPA1447/026/002	ZANAFLEX
PPA1447/027/001	Zanidip
PPA1447/029/001	Protium
PPA1447/029/002	Protium
PPA1447/030/001	Xatral
PPA1463/008/001	PROTIUM
PPA1463/008/002	PROTIUM
PPA1463/009/001	SEROXAT

Human New Product Authorisations Withdrawn (September 2008 – December 2008)

PA Number	Product Name
PA0013/107/001	Salagen 5mg Film-coated Tablets
PA0021/061/001	Bayer Multivitamin & Mineral Effervescent Tablets
PA0021/076/001	Rennie Duo
PA0022/069/009	PREMIQUE CYCLE 10
PA0030/020/003	Proflex
PA0035/046/002	COGENTIN
PA0037/063/002	Lederfolin 350 mg/35ml Solution for Injection or Infusion
PA0043/004/002	Karvol Decongestant
PA0043/006/004	Nurofen
PA0043/027/001	CURATODERM
PA0043/027/002	Curatoderm
PA0043/042/001	STREPSILS CHESTY COUGH
PA0043/043/001	Galoxiway
PA0043/043/002	Galoxiway
PA0048/044/004A	Paraplatin
PA0057/068/001	HFA-134A Beclometasone Dipropionate
PA0057/068/002	HFA-134a Beclometasone Dipropionate
PA0057/068/003	HFA-134a Beclometasone Dipropionate Autohaler
PA0057/068/004	HFA-134a Beclometasone Dipropionate Autohaler
PA0073/033/001	Prednisolone
PA0073/033/002	Prednisolone
PA0095/008/001	Rubex Lemon
PA0095/008/004	Rubex 100 mg Tablets
PA0095/008/005	Rubex 200 mg Tablets
PA0095/020/001	Liquid Paraffin BP
PA0095/021/001	Calamine B.P.
PA0102/015/001	Pyralvex Oromucosal Solution
PA0108/021/002	FEMOSTON 2/20
PA0108/023/002	TEVETEN
PA0115/001/002	Depixol
PA0115/005/006	CLOPIXOL
PA0115/005/010	Clopixol Acuphase 100 mg/2ml Solution for Injection
PA0144/003/001	LactiCare
PA0167/004/003A	Potassium Chloride Sodium Chloride and Glucose
PA0167/010/009A	Chlorhexidine Acetate BP 0.02% w/v Irrigation solution
PA0167/025/001A	Gentran 40 (Dextran 40 Intravenous Infusion BP 10%
PA0167/026/001A	Dextran 40
PA0167/027/001A	Gentran 70 (Dextran 70 Intravenous Infusion BP 6.0
PA0167/028/001A	Dextran 70
PA0167/037/005	Mannitol
PA0167/050/013A	Sodium Chloride/Glucose
PA0167/052/005A	Potassium Chloride and Sodium Chloride
PA0167/055/005A	HALF STRENGTH COMPOUND SODIUM LACTATE IV INFUSION
PA0172/011/001	PREPARATION H
PA0240/014/001	Gallium Citrate
PA0240/025/001	Thallous Chloride
PA0282/075/001	Zynor
PA0282/075/002	Zynor Allergy
PA0285/003/001	Serophene
PA0285/005/005	Saizen Use with Syringe & Bacteriostatic Solvent

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Human New Product Authorisations Withdrawn (cont.) (September 2008 – December 2008)

PA Number	Product Name
PA0320/006/001	Peroxyl 1.5% Mouthwash
PA0320/008/001	DURAPHAT 2800 PPM FLUORIDE
PA0361/009/001	OMNOPON
PA0372/008/001	Formoterol
PA0408/020/001	RIMOXYN NAPROXEN
PA0408/020/002	RIMOXYN NAPROXEN
PA0408/060/001	CLINDAMYCIN
PA0417/013/001	ACTAL
PA0437/002/001	Sodium Nitroprusside
PA0437/016/008	GENTAMICIN INJECTION BP
PA0437/055/001	Vinorelbine
PA0455/005/001	Scholl Antiseptic Foot Balm
PA0521/011/001	RHESONATIV
PA0540/135/001	NORITATE
PA0549/009/001	ETHYPHARM KETOPROFEN SR
PA0549/009/002	ETHYPHARM KETOPROFEN SR
PA0566/012/001	Vamin 9 Glucose, Solution for Infusion 100mls
PA0577/033/001	Gercor
PA0577/033/002	Gercor
PA0577/033/003	Gercor
PA0577/033/004	Gercor
PA0577/033/005	Gercor
PA0577/033/006	Gercor
PA0585/024/001	Carboplatin
PA0592/003/001	Varitect
PA0592/003/003	VARITECT
PA0618/007/001	Codella
PA0618/010/002	Suleo-C
PA0618/013/001	Derbac C
PA0618/013/002	Derbac C Shampoo
PA0618/017/001	CARYLDERM LOTION
PA0618/017/002	Carylderm
PA0618/027/002	MEROCET
PA0656/001/001	Ostram
PA0678/012/008	AUGMENTIN 1000/62.5 mg Prolonged Release Film-Coat
PA0696/009/002	OROVITE
PA0711/009/004	Diclac 150 mg Prolonged-release Tablets
PA0711/016/001	Verap
PA0711/016/002	Verap
PA0711/044/002	Cedine
PA0711/047/001	Lispril
PA0711/050/004	Sivatin
PA0711/052/002	PAROXETINE
PA0711/057/002	FLUCOL
PA0711/057/005	Flucol
PA0711/057/007	Flucol

PA Number	Product Name
PA0711/070/001	Fentanyl 25 micrograms/hour Transdermal Patch
PA0711/070/002	Fentanyl 50 micrograms/hour Transdermal Patch
PA0711/070/003	Fentanyl 75 micrograms/hour Transdermal Patch
PA0711/070/004	Fentanyl 100 micrograms/hour Transdermal Patch
PA0711/071/001	Ternaf
PA0711/083/001	Alfu
PA0711/091/001	Risperidone
PA0711/091/002	Risperidone
PA0711/091/003	Risperidone
PA0711/091/004	Risperidone
PA0711/099/001	Valproat
PA0711/099/002	Valproat
PA0711/135/001	Felodipine
PA0749/003/002	Methotrexate Teva
PA0749/003/003	Methotrexate Teva
PA0815/003/001	Orfiril
PA0823/016/002	BENADRYL SKIN ALLERGY RELIEF LOTION
PA0858/001/001	QUELLADA-M
PA0858/001/002	QUELLADA-M CREAM
PA0876/001/001	Aciclovir
PA0892/001/001	Mitomycin-C Kyowa 2 mg, Powder for Solution for Injection
PA0892/001/003	Mitomycin-C Kyowa 20 mg, Powder for Solution for Injection
PA0899/013/003	Furadantin
PA0969/007/001	Terbinafine
PA0979/009/003	FYBOGEL LEMON
PA0979/015/006	Gaviscon Peppermint Tablets 500
PA0979/015/007	Gaviscon Lemon Tablets 500
PA1014/001/001	Copaxone
PA1077/035/001	POLIOMYELITIS LIVE ATTENUATED (ORAL) MONODOSE
PA1077/047/002	SEREVENT Rotadisks
PA1161/001/003	Ponstan Paediatric
PA1189/004/001	Contramal retard
PA1230/002/001	Fungster
PA1238/002/001	Tumelin
PA1238/002/002	Tumelin
PA1238/002/003	Tumelin
PA1288/003/001	Colofibre
PA1332/024/001	Novantrone
PA1332/025/001	NORMISON
PA1332/025/002	NORMISON
PA1332/026/001	Loramet

Human New Product Authorisations (Mutual Recognition Procedure) (September 2008 – December 2008)

PA Number	Product Name
PA0126/182/001	Venex XL
PA0126/182/002	Venex XL
PA0126/182/003	Venex XL
PA0167/130/001	Ciprofloxacin Redibag
PA0167/133/001	Plasma Volume Redibag 6 % Solution for Infusion
PA0281/114/001	Fluoxetine
PA0281/114/001	Fluoxetine
PA0408/065/001	Rangabax
PA0408/065/002	Rangabax
PA0408/065/003	Rangabax
PA0408/065/004	Rangabax
PA0408/070/001	Alfirum XL
PA0408/071/001	Lamotrigine
PA0408/071/002	Lamotrigine
PA0408/071/003	Lamotrigine
PA0408/071/004	Lamotrigine
PA0408/071/005	Lamotrigine
PA0677/018/001	Stamicis 1mg kit for radiopharmaceutical preparation
PA0711/150/001	Pravastatin Sodium
PA0711/150/002	Pravastatin Sodium
PA0711/150/003	Pravastatin Sodium
PA0711/159/001	Bisop
PA0711/159/002	Bisop
PA0711/159/003	Bisop
PA0711/159/004	Bisop
PA0711/159/005	Bisop
PA0711/159/006	Bisop
PA0711/160/001	Venlafaxine
PA0711/160/002	Venlafaxine
PA0749/077/001	Venlafaxine Teva
PA0749/077/002	Venlafaxine Teva
PA0749/081/001	Levofloxacin Teva
PA0749/081/002	Levofloxacin Teva
PA0789/016/001	Oxaliplatin Ebewe 5 mg/ml powder for solution for infusion

PA Number	Product Name
PA0899/030/001	Ondansetron 2 mg/ml Solution for injection
PA1009/008/003	Zomacton
PA1058/010/001	Novolizer Formoterol
PA1058/010/002	Novolizer Formoterol
PA1122/003/001	Potassium Chloride Sterile BP
PA1130/020/001	Alendromax
PA1130/020/002	Alendromax
PA1142/004/001	Detrunorm
PA1142/004/001	Detrunorm
PA1287/002/001	Domperidone
PA1311/014/001	Simvastatin Aurobindo
PA1311/014/002	Simvastatin Aurobindo
PA1311/014/003	Simvastatin Aurobindo
PA1311/014/004	Simvastatin Aurobindo
PA1353/003/001	Nexodal
PA1380/014/001	Amlodipine
PA1380/014/002	Amlodipine
PA1380/019/001	Glemide
PA1380/019/002	Glemide
PA1380/019/003	Glemide
PA1380/019/004	Glemide
PA1380/045/001	Percarnil
PA1380/045/002	Percarnil
PA1380/045/003	Percarnil
PA1390/018/001	Glimepiride
PA1390/018/002	Glimepiride
PA1390/018/003	Glimepiride
PA1390/018/004	Glimepiride
PA1410/056/001	Yaz
PA1436/003/001	Simvastatin Bluefish
PA1436/003/002	Simvastatin Bluefish
PA1436/003/003	Simvastatin Bluefish
PA1438/001/001	Denzapine
PA1438/001/002	Denzapine
PA1462/002/001	Prindex
PA1462/002/002	Prindex
PA1462/002/003	Prindex

Human New Product Authorisations (Decentralised Procedure) (September 2008 – December 2008)

PA Number	Product Name
PA0102/023/005	Movicol Chocolate
PA0126/171/001	Fluvistad
PA0126/175/001	Pantium
PA0126/175/002	Pantium
PA0170/020/004	Actonel
PA0566/042/001	Rocuronium
PA0566/044/001	Piperacillin/Tazobactam
PA0566/044/002	Piperacillin/Tazobactam
PA0568/017/001	Perindopril tert-butylamine
PA0568/017/002	Perindopril tert-butylamine

PA Number	Product Name
PA0568/021/001	Glydium
PA0577/098/001	Statease
PA0577/098/001	Statease
PA0577/099/001	Aripil
PA0577/099/002	Aripil
PA0577/100/001	Venlofex
PA0577/100/002	Venlofex
PA0577/101/001	Myzaar Comp
PA0577/101/002	Myzaar Comp
PA0577/102/001	Myval

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Human New Product Authorisations (Decentralised Procedure) – cont. (September 2008 – December 2008)

PA Number	Product Name
PA0577/102/001	Myval
PA0577/105/001	Protizole
PA0577/105/002	Protizole
PA0585/031/001	Olanzapine Pliva
PA0585/031/002	Olanzapine Pliva
PA0585/031/003	Olanzapine Pliva
PA0585/031/004	Olanzapine Pliva
PA0585/031/009	Olanzapine Pliva
PA0585/031/010	Olanzapine Pliva
PA0585/032/001	Eironil
PA0585/032/002	Eironil
PA0585/032/003	Eironil
PA0585/032/004	Eironil
PA0585/032/005	Eironil
PA0585/033/001	Bicalutamide
PA0585/033/002	Bicalutamide
PA0585/034/001	Gabapentin
PA0585/034/002	Gabapentin
PA0690/020/001	Technescan MIBI
PA0711/113/001	Piperin
PA0711/113/002	Piperin
PA0711/121/001	Granisetron
PA0711/129/002	Mycolat
PA0711/129/002	Mycolat
PA0711/137/001	Fetanex
PA0711/137/002	Fetanex
PA0711/137/003	Fetanex
PA0711/137/004	Fetanex
PA0711/137/005	Fetanex
PA0711/137/006	Fetanex
PA0711/140/001	Alprol
PA0711/140/002	Alprol
PA0711/140/003	Alprol
PA0711/141/001	Dozept
PA0711/141/002	Dozept
PA0711/147/001	Metophage
PA0711/147/002	Metophage
PA0736/029/001	Rocuronium
PA0736/030/001	Fluconazole
PA0749/046/001	Levocetirizine Teva
PA0749/055/001	Gabapentin Teva
PA0749/055/002	Gabapentin Teva
PA0749/055/003	Gabapentin Teva
PA0749/055/004	Gabapentin Teva
PA0749/055/005	Gabapentin Teva
PA0749/064/001	Risonate Once Weekly 35mg Film-Coated Tablets

PA Number	Product Name
PA0789/015/001	Fludarabine phosphate "Ebewe"
PA0840/009/001	Letrozole Synthon
PA0967/009/003	Venlift XL
PA0967/009/004	Venlift XL
PA0967/009/005	Venlift XL
PA0967/017/001	Ranolift
PA0967/017/002	Ranolift
PA0967/017/003	Ranolift
PA1025/001/002	Dovobet Scalp
PA1025/003/001	Xamiol
PA1130/013/001	Famlov
PA1130/013/002	Famlov
PA1130/013/003	Famlov
PA1130/013/004	Famlov
PA1135/005/001	Sevikar
PA1135/005/002	Sevikar
PA1135/005/003	Sevikar
PA1189/005/002	Ixprim
PA1311/004/001	Ondansetron Aurobindo
PA1311/004/002	Ondansetron Aurobindo
PA1311/005/001	Terbinafine Aurobindo
PA1311/005/002	Terbinafine Aurobindo
PA1312/001/001	Ranitidine
PA1327/009/001	Methotrexate
PA1327/009/002	Methotrexate
PA1335/001/001	Piperacillin/Tazobactam
PA1335/001/002	Piperacillin/Tazobactam
PA1348/004/001	Granisetron Martindale Pharma
PA1348/004/002	Granisetron Martindale Pharma
PA1352/004/001	Clonidine Hydrochloride
PA1364/001/001	Fluoxetine
PA1364/001/001	Fluoxetine
PA1380/001/001	Granisetron
PA1380/001/001	Granisetron
PA1380/001/002	Granisetron
PA1380/001/002	Granisetron
PA1380/004/001	Ropinirole
PA1380/004/002	Ropinirole
PA1380/004/003	Ropinirole
PA1380/004/004	Ropinirole
PA1380/004/005	Ropinirole
PA1380/004/006	Ropinirole
PA1380/004/007	Ropinirole
PA1380/015/001	Gemcitabine
PA1380/015/002	Gemcitabine
PA1380/060/001	Donecept
PA1380/060/002	Donecept

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Human New Product Authorisations (Decentralised Procedure) – cont. (September 2008 – December 2008)

PA Number	Product Name	PA Number	Product Name
PA1390/001/001	Mycophenolate Mofetil	PA1390/005/001	Irinotecan Hydrochloride
PA1390/002/001	Pravastatin sodium	PA1390/009/001	Bicalutamide
PA1390/002/002	Pravastatin sodium	PA1390/013/002	Finasteride
PA1390/002/003	Pravastatin sodium	PA1423/002/001	Pyridostigmine

Veterinary Product Authorisations Issued (September 2008 – December 2008)

VPA Number	Product Name	VPA Number	Product Name
V/C/0137/000	Duvaxyn WNV Emulsion for Injection	10988/073/001	Shotaflor
10861/100/001	Suvaxyn MH ONE	10277/106/001	Tribovax 10 for cattle and sheep
10786/002/001	Kariflox 10% Oral Solution	10816/005/002	Benazepril hydrochloride Le Vet for dogs
10782/003/001	Tilmovet 25% Oral Solution	10816/005/003	Benazepril hydrochloride Le Vet for dogs
10977/009/001	AviPro Thymovac	V/C/132/00/0/0	MAVACOXIB
10825/003/002	Fasinex 100 for sheep	V/C/132/00/0/1	MAVACOXIB
10825/004/002	Fasinex 240 24% w/v Oral Suspension for Cattle	V/C/132/00/0/2	MAVACOXIB
V/C/057/X/027	Zubrin	V/C/132/00/0/3	MAVACOXIB
10665/001/001	Pluset Powder and solvent	V/C/132/00/0/4	MAVACOXIB
10996/207/001	Nuflor Minidose 450 mg/ml solution for injection for cattle	10778/002/001	Cephacare flavour 50 mg tablets for cats and dogs
10277/104/001	Procyon Dog Lepto	10778/002/002	Cephacare flavour 250 mg tablets for dogs
10953/003/001	Busol for cattle, horses, rabbits	10778/002/003	Cephacare flavour 500 mg tablets for dogs
10660/001/001	Release	10988/070/001	Equimax Tabs, 150 mg / 20 mg for Horses
10809/003/001	Fenflor	10996/208/001	Diluvac Forte
10774/002/001	Enroxil Max 100 mg/ml solution for injection for cattle	10826/005/001	Animedazon Spray for cattle, sheep and pigs
10556/001/001	Calicivac	10782/001/001	Pharmasin for pigs, broilers, pullets, turkeys and calves
10989/057/001	SEDATOR 1.0 mg/ml		
10809/002/001	Fenflor For pigs		
EU/2/04/042/001-002	Novem		
EU/2/04/042/003-004	Novem		

Veterinary Product Authorisations Withdrawn (September 2008 – December 2008)

VPA Number	Product Name	VPA Number	Product Name
10966/017/001	Atussin Syrup	10484/020/001	Forazole
10983/028/001	Marbocyl 5mg Tablets	10799/009/001	Millophylline V
10990/014/001A	Ascaraject 7.5% Solution for Injection	10007/045/001	Four C Dry Cow Intramammary Suspension
10996/085/001	Porcilis Aujeszky	10861/062/001	Poulvac MD Vac CA
10545/017/001	Ripercol Pour-on Solution	10545/017/001	Ripercol Pour-on Solution
10861/062/001	Poulvac MD Vac CA	10996/085/001	Porcilis Aujeszky
10007/044/001	Benestermycin Dry Cow Intramammary Suspension	10990/014/001A	Ascaraject 7.5% Solution for Injection
10007/045/001	Four C Dry Cow Intramammary Suspension	10983/028/001	Marbocyl 5mg Tablets
		10966/017/001	Atussin Syrup

IRISH MEDICINES BOARD

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