IRISH MEDICINES BOARD

news LETTER

MEDICINAL PRODUCTS

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HUMAN MEDICINES

ELECTRONIC SUBMISSION OF RESPONSES

Applicants are reminded that the IMB now accepts and strongly recommends electronic only submissions, either in eCTD format, non-eCTD (NeeS) format or through the IMB's online portal RIO. Where an application has been submitted electronically all subsequent correspondence relating to that application e.g. responses to requests for supplementary information, mock-ups etc, should also be submitted electronically unless otherwise requested. For non-eCTD submissions, applicants are also requested to ensure that the submitted responses are easily navigable and that folder- and file- naming conventions for a CTD submission in NeeS format are used. Further information on electronic submissions can be found in the IMB Guide to Electronic Submissions- Human Medicines, November 2009, on the IMB website (www.imb.ie).

HERBAL MEDICINAL PRODUCTS

The IMB would like to inform applicants that the deadline for the submission of applications for herbal medicinal products has been extended from 1 January 2010 to 1 April 2010 at the request of stakeholders. All herbal medicinal products must be approved by the IMB if they are intended to remain in the Irish marketplace after 30 April 2011, as per Directive 2001/83/EC as amended.

Herbal medicinal products may be licensed via two routes in Ireland:

- A Marketing authorisation (MA) (as per Article 8(3) for a full authorisation or article 10a for well-established use authorisation, of Directive 2001/83/EC as amended). Applications in this case must demonstrate appropriate standards of quality, safety and efficacy and be accompanied by the necessary information for safe use. For more detail on products in this category please see the Human Medicines Licensing section of the IMB website;
- A certificate of traditional-use registration (as per Article 16a of Directive 2001/83/EC as amended). Products in this category are registered under the Traditional Herbal Medicinal Products Registration Scheme and are known as traditional herbal medicines.

For more information please see the IMB website at http://www.imb.ie/EN/Medicines/Human-Medicines/Herbal-Medicines.aspx.

METHOD OF SALE, SUPPLY AND PROMOTION

The IMB wishes to advise stakeholders that in accordance with Regulation 12 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (SI No 540 of 2007) we are required to publish the method of sale, supply and promotion of all products with a marketing authorisation, certificate of registration or certificate of traditional-use registration granted or renewed following the entry into force of the Regulations (20 July 2007). An internal project to check the current details of the MoSS&P (method of sale, supply and promotion) for each MA as published on our website (www.imb.ie) has commenced. The classification of each MA will be in accordance with the schedules of the Medicinal Products (Prescription and Control of Supply Regulations 2003 as amended) or approved requests for reclassification. The wording published will be as specified in SI no 540 of 2007. All MA holders shall be contacted as details of their MA ranges are →

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checked to advise them that the website details have been checked and amended where necessary. Applicants are advised to check published details for each of their marketing authorisations to ensure that details are correct. Sections 6 and 7 of the SPC may be harmonised with the website text at the time of the next regulatory activity; a separate variation application will not be required.

Any queries regarding this project should be submitted (by email) to **customerservice@imb.ie** clearly marked as 'Method of sale, supply & promotion project'.

USE OF COLOUR ON LABELLING

When submitting label mock-ups for approval, applicants are reminded of the recommendations of the *Guideline on the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use*, Revision 1, 12 January 2009 which is available on **http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol2/c/2009_01_12_readability_guideline_final.pdf**. This guideline highlights the need for judicious use of colour in preparing such mock-ups, and recommends that:

> *'Colours should be chosen to ensure a good contrast between the text and the background to assure maximum legibility and accessibility of the information. Highly glossy, metallic or reflective packaging should be avoided, as this affects the legibility of the information. Different colours in the name of the product are discouraged since they may negatively impact on the correct identification of the product name. The use of different colours to distinguish different strengths is strongly recommended.*
>
> *Similarity in packaging which contributes to medication error can be reduced by the judicious use of colour on the pack. The number of colours used on packs will need careful consideration as too many colours could confuse. Where colour is used on the outer pack it is recommended that it is carried onto primary packaging to aid identification of the medicine.'*

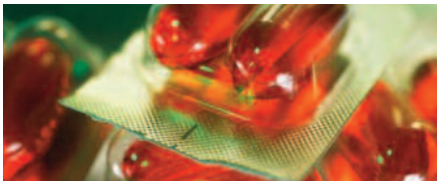
Thus it can be seen that the use of further colour to highlight non-critical areas of product information, such as number of tablets in a pack, could potentially be confusing, and may detract from critical information such as strength at the point of dispensing of the medicine. The IMB recommends that colour should only be used for such purposes after a critical evaluation of its effect within and across product ranges. Any such proposal will be considered by the IMB on a case-by-case basis and will be rejected if it appears to compromise the legibility of essential information.

NEW EUDRAVIGILANCE BUSINESS RULES

The European Medicines Agency (EMA) has published new EudraVigilance business rules for exchanging safety/acknowledgement messages and individual cases safety reports (ICSRs) in the EEA. These rules are detailed in a guidance entitled *Note for Guidance EudraVigilance Human – Processing of Safety Messages and Individual Case Safety Reports (ICSRs)* (Doc. Ref. EMEA/H/20665/04/ Final – Revision 1), which is available on the EMA and EudraVigilance websites (see links below). The new business rules apply to all stakeholders involved in exchanging safety messages and ICSRs electronically at Community level in line with Regulation (EC) No 726/2004, Directive 2001/83/EC as amended, Directive 2001/20/EC, Volume 9A and Volume 10 of the Rules Governing Medicinal Products in the European Union.

The guidance has been drawn up based on the experience gained with use of EudraVigilance, and describes new validation rules, including mandatory ICH E2B(R2) data elements, which are applicable to all ICSRs which qualify for expedited and periodic reporting originating within or outside the EEA. The aim of the new rules is to improve the quality and consistency of ICSRs submitted to EudraVigilance, thus supporting EU pharmacovigilance and risk management activities.

Since a large number of stakeholders in the Community transmit safety data electronically, any changes in the validation procedures require a common approach to avoid disruptions in the data exchange process. With this in mind, a detailed implementation plan has also been prepared to ensure a coordinated implementation approach of the revised EudraVigilance business rules within the Community. The implementation plan is addressed in the document *Implementation Plan for The Note for Guidance EudraVigilance Human – Processing of Safety Messages and Individual Case Safety Reports (ICSRs)* (Doc. Ref. EMEA/H/20665/04/Final, Revision 1), which is also available on the EMA and EudraVigilance websites. All stakeholders need to follow this common approach, and have until 1 June 2010 to implement these new business rules. Please note that technical changes based on the revised business rules are scheduled to take place at a later date.



From 1 June 2010, the EMA will perform routine data quality control checks based on the updated business rules and validation process. Senders will receive on a monthly basis listings of ICSRs which do not comply with the new mandatory data elements and validation rules as described in the revised Note for Guidance. A corrected version of affected ICSRs, classified as 'error reports' according to the revised guidance, should be retransmitted electronically by the sender to the appropriate EudraVigilance module immediately and no later than 15 days following the receipt of the listings. For ICSRs classified as 'error reports' originating in the EEA and reported initially by MAHs/sponsors to the IMB, EMA will send listings directly to the MAHs/sponsors. The MAH/sponsor should send a corrected version of affected ICSRs to the IMB, who will forward the corrected reports to the appropriate EudraVigilance module. This procedure aims to provide regular feedback to senders to allow correction of non-compliance.

The new business rules and the implementation plan are available on
The EMA website: **http://www.emea.europa.eu/htms/human/phv/phvwp.htm** and
The EudraVigilance website: **http://eudravigilance.emea.europa.eu/human/index.asp**

If you have any questions concerning these new business rules, please contact the EudraVigilance helpdesk (Tel. +44 (0)20 7523 7523; email: **eudravigilance@emea.europa.eu**).

HOMEOPATHIC MEDICINES NATIONAL RULES SCHEME

The national rules scheme (NRS) for homeopathic medicinal products is due to be launched by the IMB in 2010. The NRS was devised to provide a legal framework to license homeopathic medicinal products that do not qualify for registration under the simplified registration scheme (SRS). The NRS will therefore allow for homeopathic medicinal products such as those with therapeutic indications or those outside the potency range (i.e. below D4) of the SRS to be licensed.

Provision for a NRS was made by article 16.2 of the EU Directive 2001/83/EC, as amended. Specifically, Article 16.2 permits Member States to introduce national rules for the pre-clinical tests and clinical trials of homeopathic medicinal products other than those provided for under the SRS according to Article 14 (1).

Accordingly, SI No. 540 of 2007 both transposes the above provision and sets down the criteria for how the NRS will operate in Ireland.

In general, in order to qualify for the scheme, therapeutic claims made must be for mild, self-limiting conditions, the homeopathic dilution must guarantee the safety of the product and the product must be administered orally or externally.

In particular, the Regulations state that in order to obtain an authorisation for a homeopathic medicinal product under the NRS it must be demonstrated:

- That the product is a homeopathic product that conforms with the principles and characteristics of homeopathy as practised in the State;
- That the indication sought is appropriate;
- That any such indication is suitable for use without the intervention of a registered medical practitioner for diagnosis, treatment or monitoring;
- That the efficacy of the product is based on evidence that the particular class of product has been in use in the state as a homeopathic treatment for the indication sought and
- That the safety of the product has been established as set down in the relevant regulations.

A public consultation on the scheme was posted in December 2009 on the IMB website and interested parties were invited to submit comments on the scheme. A response document to the consultation will be published providing a general overview of the comments received and the changes made to the proposals as a result.

Applications to the scheme are to be submitted in Common Technical Document (CTD) format and will progress through IMB systems similar to other national applications.

There will be no requirement to submit clinical trial data in support of efficacy, however, alternative support data will be required. Details of the type of data required in place of the clinical trial data and in support of the proposed indication will be set down in the guideline to the scheme, which will be available on the website.

It is anticipated that the introduction of NRS will, in addition to the SRS already established, facilitate licensing of all homeopathic medicinal products on the Irish market.

It is planned to launch the NRS in 2010 in order to comply with the Regulations, which states that: 'The provisions of these Regulations shall not apply until 30 April 2011 to homeopathic medicinal products to which Regulation 11 applies and which were on the market in the State on the coming into force of these Regulations.'

The new Regulations include a provision for the IMB to establish dates by which applications must be submitted with a view to ensuring that the market authorisations are held by 30 April 2011. In this regard, the date for submission of applications to the scheme will be posted on the IMB web site in early 2010.

VETERINARY MEDICINES

ADVANCE NOTICE OF REQUIREMENT TO PROVIDE INFORMATION ON USAGE OF ANTIMICROBIAL MEDICINES

In accordance with a request from the EU Commission and following various requests from international scientific bodies (the World Organisation for Animal Health and the World Health Organization) and the European Parliament, the IMB wishes to inform marketing authorisation holders (MAHs) that early in 2010 it expects to collect data on the usage of antimicrobial veterinary medicines in Ireland for the year 2009. It is currently estimated that a template for the provision of the necessary data will be developed by the European Medicines Agency by March 2010. Assuming this is the case, the IMB expects that it will be requesting all MAHs with antibacterial medicines marketed in Ireland to file returns for the year 2009. It is expected that this will become an annual exercise thereafter. The requested information will be submitted to the European Medicines Agency and is expected to inform decisions in respect of possible future risk management plans. The scope of the exercise will include all usage of authorised antimicrobial medicines, including antimicrobial premixes, intramammaries and other dose forms and including use in all veterinary species. The scope excludes coccidiostats, biocides and anti-fungal medicines.

CHANGES TO JOINT IE/UK PROCEDURES

The Veterinary Medicines Department of the Irish Medicines Board (IMB) and the Veterinary Medicines Directorate (VMD) in the UK have a number of initiatives in place to encourage pharmaceutical companies to maintain product availability in both markets and thus increase availability of medicines. There are three procedures included in this category – worksharing, harmonisation and joint labelling. The IMB and VMD have recently agreed to a number of changes to these procedures. A brief description of these procedures and the changes that will take place is outlined on page 4.

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Worksharing (Partnership Initiative)

Worksharing involves a single assessment between the UK and Ireland of type II variations for nationally authorised products. Following receipt of a valid application in both agencies a lead country is assigned and a timetable is created to facilitate the assessment of the variation.

The name of this procedure will now be amended to **Partnership Initiative** in order to avoid confusion with the EU worksharing procedure for variation applications which is effective from 1 January 2010. In addition, the lead country will now issue the timetable to both the applicant and the other country. The scope of this procedure will be restricted to variations which are classified as Type II under the current variation regulations (1084/2003 and 1085/2003) and the new variation regulation (1234/2008) until the new variation regulations are effective in both countries for nationally-authorised products.

Harmonisation

The harmonisation procedure is relevant for nationally-authorised products and involves harmonisation of the SPC and product literature in Ireland and the UK. The harmonisation process is dealt with as a variation by both agencies. A common renewal date will shortly be agreed for any harmonised products for which one has not already been assigned.

Joint Labelling

The joint labelling procedure is relevant for products authorised via a European procedure (MRP or DCP) in which Ireland and the UK were both involved and involves co-ordination of approval of final colour mock-ups. A lead country is assigned and a timetable is created in order to facilitate the joint assessment of the mock ups. The lead country will now issue the timetable to both the applicant and the other country. In addition, it will be assumed that the joint labelling procedure is the default position for any procedures involving Ireland and the UK.

Further information on these procedures is available on the IMB website at: **http://www.imb.ie/EN/Publications/Publications.aspx?q=clarification%20paper**

IMB VETERINARY INFORMATION DAY

A very successful Veterinary Information Day was held on the 8th September 2009. The numbers of attendees was higher than in recent years. The meeting venue, being outside Dublin and some distance from the airport, suited some delegates but unfortunately may have discommoded others. The meeting focused particularly on the new variations regulations and their associated changes. Speakers from the Department of Agriculture, Fisheries and Food and from the political arena gave useful insights into the elaboration of EU and national legislation and on the operation of the 'cascade' and exceptional authorisation procedures in Ireland. The IMB is grateful for the participation of invited speakers in the meeting and for the opportunity to meet with delegates to discuss matters of mutual interest. The meeting papers may be requested from Michelle Sinnott (**michelle.sinnott@imb.ie**).

WITHDRAWAL PERIOD FOR INJECTABLE PRODUCTS CONTAINING IVERMECTIN IN CATTLE

The EU Commission adopted a binding decision [C(2009)7652 of 1/10/2009] on 1 October 2009 for withdrawal periods for **injectable formulations** of ivermectin in **cattle** (this decision does not apply to other presentations of ivermectin in cattle nor to injectable formulations of ivermectin for species other than cattle). This follows on from the opinion of the Committee for Medicinal Products for Veterinary Use (CVMP) that withdrawal periods of:

- 49 days should be established for all injectable products authorised for use in cattle containing ivermectin as a single active ingredient when administered at a dosage of 200 micrograms of ivermectin/kg bodyweight
- 49 days should be established for all injectable products authorised for use in cattle containing ivermectin in combination with closantel as a second active ingredient
- 66 days should be established for all injectable products authorised for use in cattle containing ivermectin in combination with clorsulon as a second active ingredient.

The IMB has already informed marketing authorisation holders (MAHs) that they should submit Type 1B variation applications to the IMB to amend the authorisations for any products concerned by these changes as soon as possible. In accordance with its *Guide to the Implementation of Packaging Changes to Authorised Veterinary Medicinal Products,* the IMB does not regard these specific changes as falling within the category of those which present an urgent safety risk to human health. Accordingly, the IMB expects that the MAHs concerned will coordinate the supply/importation/distribution of amended product livery within three months of the approval of the amendment. MAHs should ensure that products in old livery will not be released from the manufacturer or wholesaler after three months from the date of that approval.

The IMB expects that all concerned products on the market will comply with the revised withdrawal periods on or before 30 June 2010. The IMB will be working with the relevant MAHs to ensure that accurate advice is disseminated to users, retailers and stockists of the relevant products in a timely manner. The IMB will also be working with the Department of Agriculture, Fisheries and Food who have responsibility for monitoring compliance of products in the marketplace.

For more information on packaging changes see: **http://www.imb.ie/EN/Publications/Publications/Guide-to-the-Implementation-of-Packaging-Changes-to-Authorised-Veterinary-Medicinal-Products.aspx?page=1&year=0&categoryid=46&letter=&q=**

AVAILABILITY OF VETERINARY MEDICINAL FOR MINOR PRODUCTS USE IN IRELAND

The IMB is sensitive to animal health and welfare needs in Ireland and wishes to remind potential applicants that it operates a service item fee in respect of applications for veterinary medicines of limited commercial potential where there is no authorised alternative available here. The IMB requests companies to consider including Ireland as a Concerned Member State in respect of such products which are to be submitted to other Member States under a Mutual Recognition or Decentralised Procedure. Further details on the conditions and fees for service items may be obtained from Michelle Sinnott (michelle.sinnott@imb.ie). The IMB is committed to working with stakeholders to help improve the situation concerning product availability for minor species within the confines of national legislation.

POSSIBLE REVISION TO THE EU DIRECTIVES GOVERNING THE AUTHORISATION OF VETERINARY MEDICINAL PRODUCTS

Interested parties should note that the EU Commission has initiated a study on the impact of the existing legislation on the availability of veterinary medicines and the proper functioning of the internal market. Such a study is a prerequisite to any decision to propose a revision of the EU legislation governing the authorisation, use and monitoring of veterinary medicines in the Community. Assuming the incoming EU Commission agrees to take on board this task, it is expected that work on the possible shape of the new regulatory regime will commence late in 2010. Experience with the previous revision shows that the elaboration of legislation is a complex and time-consuming task, involving detailed discussions both by the European Parliament and Council Working Group, with various amendments being put forward along the way. Unless there is general agreement on the changes needed and provided that any proposal does not get aligned to reforms of other legislation, e.g., that for human medicines, this process could take up to five years. The Heads of Medicines Agencies has established a working group on legislation to input the process as soon as the EU Commission decides its approach. Animal health companies and other stakeholders should consider what amendments they consider necessary and be prepared to make submissions to the Commission in due course.

COMPLIANCE

GUIDANCE DOCUMENT FOR VARIATIONS TO MANUFACTURER'S / WHOLESALER'S AUTHORISATIONS

A guidance document will shortly be made available on the IMB website relating to submission of variation applications for manufacturer's / importer's authorisations (MIA) and wholesaler authorisations. The guidance outlines the minimum supporting documentation that should accompany applications to vary MIAs and wholesaler authorisations. The provision of the required supporting documentation will facilitate the expedited approval of variation applications.

REVISED FORMAT FOR MANUFACTURER'S / IMPORTER'S AUTHORISATION (MIA)

The IMB has begun reformatting the information on the current authorisations for manufacturers of human and veterinary medicines and capturing this information on a standard electronic 'Application Form'. This information will be stored on a database and can then be transferred to the EudraGMP database at the European Medicines Agency (EMA) from which GMP Certificates and a MIA, in EU format, can be issued.

Part of this project involves verification of the accuracy of the information which has been entered on the application form. A verification of accuracy will first be done internally at the IMB. A printed version of the completed application form for each manufacturer will also be sent to the primary Qualified Person (QP) at the manufacturing site and manufacturers will be asked to verify if the information in the application form reflects the activities covered under the current version of the manufacturer's authorisation held by the site. For contract manufacturers and contract laboratories located in third countries and named on an MIA, the manufacturer concerned will be requested to provide the date of the last inspection of each third country site by an EEA Authority and the name of the EEA Authority which performed the inspection.

Further details on this project will be provided in due course to the QPs at the manufacturing sites.

ELECTRONIC APPLICATIONS FOR AUTHORISATIONS / CERTIFICATE OF PHARMACEUTICAL PRODUCT (CPP) / GMP CERTIFICATES

In order to reduce storage costs and to address current environmental concerns, the IMB accepts submissions, via electronic mail, of all documentation relating to applications, variations, export certificates etc. This is optional and as for any standard electronic mail, the security of the transmission is not guaranteed. The electronic documentation may also be provided on CD or DVD.

In order for a system of electronic submissions to work effectively, you are requested to facilitate the process as follows.

Emailed submissions should include a scanned signed copy of the relevant application form and this →

should be included along with any relevant accompanying electronic documents. Where electronic mail is used the email should be sent to **compliance@imb.ie** and the subject line on the email should clearly indicate the type of application being submitted. The IMB has a limit of 10MB for attachments and does not allow Zip or compressed file attachments to be processed through its email system.

Submissions larger than 10MB should be submitted either on CD or DVD and should be labelled with the applicant's name, authorisation / licence number, and submission type (e.g. variation)

The current versions of application forms/publications, which will be the only forms accepted, are available from: **http://www.imb.ie/EN/Publications/Publications.aspx**

Payment of Fees relating to Authorisations, Export Certificates etc

It should be noted that there is an option to pay fees through Electronic Fund Transfer (EFT) rather than by cheque. A document explaining how to pay by EFT may be downloaded from the following section of the IMB website: **http://www.imb.ie/images/uploaded/documents/8485923_PaymentFeesInstructions.pdf**

CHARGES RELATING TO THIRD COUNTRY INSPECTIONS

From 1 January 2010, the IMB will be requesting advance payment of certain costs relating to inspections of manufacturing sites in third (non-EEA) countries. Such costs would include flights and the inspection fees charged in accordance with the IMB Schedule of Fees. The company will be notified of these charges at the time of planning of the inspection and payment should be received before commencement of the inspection.

GDP INFORMATION DAY

The IMB will host a one-day seminar focusing on wholesale distribution of medicinal products for human use on 25 February 2010. The event will cover various topics on Good Distribution Practice (GDP) and the implications for the medicinal product supply chain, with particular emphasis on the evolving regulatory requirements in this area.

The programme will be structured to include presentations on topics of general interest in the morning. The afternoon programme will consist of sessions run in parallel which will cover more specialised topics relating to GDP and market compliance activities.

This information day will be of interest to those working in the following sectors of the pharma-related industry: distribution and wholesale; logistics and storage, including cold chain distribution; transportation; quality assurance; regulatory affairs and compliance; legal services; training.

The seminar will take place at the the Crowne Plaza Hotel, Northwood Park, Santry Demesne, Dublin 9. More information and applications for attendance are available in the events section of the IMB website or alternatively e-mail **compliance.infoday@imb.ie**.

ROBBERIES AT MANUFACTURING SITES

The IMB has become aware of a number of robberies which have recently occurred at manufacturing and distribution sites. It is important to highlight that the IMB Compliance Department should be notified in the event of a robbery occurring on-site, including details of any theft or damage to medicinal products. In the event of theft or damage to controlled drugs or scheduled substances, the matter should also be immediately notified to the Gardaí.

DRUG PRECURSORS

On 22 December 2009, the European Communities (Control of Drug Precursors) Regulations 2009 (S.I. No. 558 of 2009) were signed by the Minister for Health and Children. These Regulations give full effect to Regulations (EC) No. 273/2004 (European Parliament and Council), No. 111/2005 (Council) and No. 1277/2005 (Commission).

The IMB will be responsible for the issuing of licences and registrations for precursor chemicals. In addition, the legislation also provides the IMB with authority to conduct inspections of sites where precursors are used. It is anticipated that the inspection role will be undertaken during 2010. Further updates on this will be issued shortly.

GMP UPDATES

Revision of Chapters 1 and 2 of the EU GMP Guide

The European Commission has published draft revisions of Chapters 1 and 2 of the GMP Guide. These chapters are being revised to align the content with concepts described in ICH Q10. The draft chapters can be found on the Commission's website and comments should be sent to **entr-gmp@ec.europa.eu** and **ADM-GMDP@ema.europa.eu** by 31 May 2010 using the required form available on the EMA website.

Revision of Chapter 7 of the EU GMP Guide

A concept paper for revision of Chapter 7 (Contract Manufacture and Analysis) has been published on the EMA website. It is intended to revise this chapter so that it will reflect more accurately the scope of contracted activities in the current manufacturing environment and also take into account the implementation of ICH Q10. Any comments on this concept paper should be forwarded to **gmp@europa.eu** by 31 January 2010.

Part III of the EU GMP Guide – Explanatory Notes for preparation of a Site Master File

It has been proposed to introduce an informational section of the GMP Guide. Part III of the EU GMP Guide will contain documents which are not GMP guidelines and have no →

statutory force but complement the GMP guidelines and other regulatory procedures. The first document proposed for inclusion in Part III of the Guide is entitled *Explanatory notes for pharmaceutical manufacturers on the preparation of a Site Master File and content of a Site Master File*. The content of this document is identical to that published by the Pharmaceutical Inspection Co-operation Scheme (PIC/S). This document is available on the Commission's website and is open for public consultation until 31 March 2010. Comments should be sent to **entr-gmp@ec.europa.eu** and **ADM-GMDP@ema.europa.eu** by 31 May 2010.

Pharmaceutical Inspection Co-operation Scheme (PIC/S) Technical Interpretation of Revised Annex 1

The PIC/S has published a new Technical Interpretation Document for the revised Annex 1 to the PIC/S GMP Guide. The document summarises the key changes to Annex 1 and also describes the interpretation which an inspector from a national regulatory authority should adopt when performing inspections at manufacturers of sterile medicinal products. The document, which came into use on 1 December 2009, can be downloaded from the PIC/S website (**http://www.picscheme.org/news.php**).

The IMB no longer publishes product statistics in this newsletter. The status of authorisations are updated regularly on our website, please use the below link for the most up to date details.
http://www.imb.ie/EN/Medicines/HumanMedicines/HumanMedicinesListing.aspx
http://www.imb.ie/EN/Medicines/VeterinaryMedicines/VeterinaryMedicinesListing.aspx

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