IRISH MEDICINES BOARD

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GENERAL

NEW VARIATIONS REGULATION

The new 'Variations Regulation' (Commission Regulation EC No 1234/2008) came into force on 1 January 2010 and applies immediately to human and veterinary medicinal products authorised through the centralised and MRP/DCP routes. The regulation will become legally applicable to 'purely national' marketing authorisations at a later date. However, in line with many other European regulatory agencies, the IMB has taken the decision to implement the general principles of the new Regulation to all marketing authorisations from 1 January 2010. It is felt that having a single set of rules and procedures will simplify operation of the new regulation for both MA holders and the IMB.

The IMB would like to highlight that the timelines set out in the Regulation and the 'automatic' approval of Type IB notifications after 30 days do not currently apply to variations for purely nationally authorised products; when further experience of the operation of the new regulation has been gained, this aspect of the regulation will be implemented. In the meantime, applicants must continue to wait for notification of approval of their IB variation from the IMB. Our aim is to apply the timelines as soon as possible.

For more information on the new variations regulation and how the IMB will implement it, please refer to the IMB's website.

HUMAN MEDICINES

GUIDANCE FOR MARKETING AUTHORISATION HOLDERS ON DIRECT HEALTHCARE PROFESSIONAL COMMUNICATIONS – PUBLICATION OF NATIONAL GUIDANCE

The IMB has recently published national 'Guidance for Marketing Authorisation Holders on Direct Healthcare Professional Communications (DHPC)', which is consistent with relevant EU guidance.[1] These guidance documents highlight the importance of accurate and timely communication of emerging safety concerns as an essential part of regulatory pharmacovigilance as well as an important step in risk management and in particular as a risk minimisation tool. The guidance aims to ensure timely availability of objective and evidence-based information on the appropriate and safe use of a medicinal product or on the most appropriate management of risk. The recently published guidance document is intended to provide advice to MAHs on how to best communicate in the context of a risk management process. Such communication is warranted when an emergent drug safety issue that could modify the benefit/risk balance requires risk minimisation measures.

Among the key principles for communication of safety information are the following:

- Healthcare professionals should be notified of significant, new, or emerging information before the general public;
- A DHPC should not usually be distributed before the corresponding regulatory procedure (national approval →

1. *Further information is available from the IMB's website and Eudralex: Volume 9A of the Rules Governing Medicinal Products in the EU.*

CONTENTS

or CHMP Opinion) has been completed;
- Agreement is needed between the marketing authorisation holder and competent authorities (and other partners as appropriate) on the content and format of the information with consideration of the supportive evidence, recipients, and distribution timetable.
- The DHPC template should be followed and is provided in *Annex 5.4 of the Volume 9A guidance of the Rules Governing Medicinal Products in the EU*.

When preparing a DHPC, the following key points should be considered:

- Safety information should be clear and concise;
- The reason for dissemination should be explained (e.g., availability of new data);
- Recommendations to healthcare professionals should be given on how to minimise risk, if known;
- The safety concern should be placed in the context of the overall benefit of treatment;
- Safety information must be objective and not misleading;
- The DHPC should include the content of any information communicated directly to the general public;
- Estimated timescales for follow-up action should be stated;
- Contact details for further information should be provided, including the website address, telephone number, and postal address of the marketing authorisation holder;
- A call for reporting of adverse reactions should be included with reference to the national spontaneous reporting system;
- Relevant references should be cited as an annex.

The same principles should also apply to educational materials required by EU-RMPs (Risk Management Plans). Such materials will have been agreed in the context of the assessment of the RMP as formal risk minimisation measures essential for the safe and effective use of the medicine.

Submission Procedures

DHPCs: The marketing authorisation holder should submit a draft communication plan to the IMB contact that includes: objective, timetable, recipients, dissemination method, related communications and post-communication strategy.

Educational materials agreed as formal risk minimisation measures during the assessment of an EU-RMP: Educational materials should be submitted to the IMB for national assessment prior to distribution. The proposed educational materials along with details of the risk management plan and all specified risk minimisation measures should be submitted via the Receipts and Validation unit of the IMB. Electronic submissions are preferable to paper documents.

TRANSFERS OF PRODUCT AUTHORISATIONS AND PARALLEL PRODUCT AUTHORISATIONS FOR HUMAN MEDICINES

A marketing authorisation or parallel import licence may be transferred from the existing authorisation/licence holder to another holder using a transfer procedure. A transfer may occur before a product is authorised or after authorisation, to a company related to the existing holder or to an unrelated company. The transfer procedure must be used where the legal entity of an authorisation/licence holder is changed as the marketing authorisations or parallel import licences are transferred to a new company number.

Guidance in relation to transfers may be found in the 'Guide to transfers of marketing authorisations and parallel import licences for human medicines' which can be located on the IMB's website.

In order to transfer an authorisation/licence, the proposed holder or another person acting on his behalf must submit an application to the Receipts and Validation unit of the IMB. Details of the application requirements are outlined in the above mentioned guide. The IMB Receipts and Validation unit (imbreceiptsandvalidation@imb.ie) can provide the new (P)PA numbers in advance in order to facilitate the preparation of the application. Please note that there are two different transfer application forms, application form A for *Transfer after Authorisation* and application form B for *Transfer before Authorisation of a marketing authorisation or parallel import licence*.

We would like to specifically highlight issues surrounding the national requirements for transfer of the marketing authorisation holder *during* a national or decentralised/mutual recognition procedure. If an authorisation/licence holder is proposing to transfer an application before a product is authorised it is not sufficient to inform the IMB during responses to assessment queries. The applicant is required to submit the following information in an electronic application for transfer before authorisation:

- Cover letter
- Application Form B for Transfer *before* Authorisation of a Marketing Authorisation or Parallel Import Licence for Human Medicines
- Updated Module 1
- Payment

HERBAL MEDICINAL PRODUCTS – MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET) REGULATIONS 2007 (S.I. NO. 540 OF 2007) AND (AMENDMENT) REGULATIONS 2009 (S.I. NO. 3 OF 2009)

Medicinal products are governed by the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) and (Amendment) Regulations 2009 (S.I. No. 3 of 2009). The Regulations transposed into Irish law the provisions of Council Directive 2004/24/EC regarding traditional herbal medicinal products. The Regulations state that no medicinal product can be placed on the market without a prior marketing authorisation or certificate of registration. 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 (20 July 2007). After this date no herbal medicinal product may be sold in Ireland that has not been authorised or registered by the IMB. To facilitate this process, following discussions with the Food Safety Authority of Ireland →

(FSAI), the IMB is implementing the following policy.

Those marketing herbal products must determine if their products are medicinal products as defined by Council Directive 2001/83/EC as amended (for further information see the 'Guide to the Definition of a Medicinal Product' on the IMB's website).

a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

If a herbal product falls within the definition of a medicinal product then an application must be made to the IMB for authorisation or registration using the following routes:

a) A marketing authorisation (MA) (as per Article 8(3) of Directive 2001/83/EC as amended, for a full authorisation or Article 10a for well-established use authorisation). Products in this case must be able to demonstrate appropriate standards of quality, safety and efficacy and be accompanied by the necessary information for safe use.
b) 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'.

The IMB will take appropriate action against herbal medicinal products which are not authorised or registered after the 30 April 2011.

It should be noted that any herbal substances that are listed in the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (SI No. 540 of 2003 and amendments) are considered to be medicinal products by the IMB. Please see the IMB's website. If a herbal product does not fall within the definition of a medicinal product and is considered to be a food supplement, then it must be notified to the FSAI (for further information see the FSAI's website). Council Directive 2002/46/EC defines food supplements as 'foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities'.

The IMB wishes to emphasise that it is the responsibility of the individual or company marketing the herbal product to correctly classify it. In cases of doubt, the IMB Classification Committee may be consulted (for further information please see the IMB's website).

RECOMMENDATIONS FOR LABELLING OF PEEL-OFF BLISTERS

The IMB would like to provide the following advice in relation to product information for products which are packaged in peel-off blisters. Such packaging is often required for oro-dispersible tablets due to their method of manufacture and inherently fragile nature. Where a product is supplied in a peel-off blister presentation, damage can be caused to the tablet if pushed through the foil in the blister pack. In order to ensure correct use of these product types, the IMB recommends that clear information on how to remove the tablets from the blisters should be included in the SPC, package leaflet and labels for these products. The following approaches are suggested:

- SPC: instructions on how to correctly remove the tablets from the peel-off blisters should be included in the SPC.
- Package leaflet: detailed instructions on how to remove the tablets from the peel-off blister should be provided in the package leaflet. The instructions should preferably be accompanied by pictograms where these are unambiguous/clearly interpretable.
- Outer carton label: if space permits, a statement referring the user to the package leaflet for instructions on how to remove the tablets should be included. For example 'See package leaflet for details on how to open the blister'.
- Blister labels: it is recommended that a pictogram indicating that the tablets should not be pushed through the blister is included on one side of the blister. On the other side, it is recommended that a distinctive arrow, indicating the point where the blister is to be peeled from, should be included.

Where such additional information is included in the product information it should not affect the legibility of the other information as required by Articles 54-69 of Directive 2001/83/EC.

NATIONAL RULES SCHEME FOR HOMEOPATHIC MEDICINES

As provided for by national legislation S.I. 540 of 2007, the national rules scheme for homeopathic medicines has been implemented. A guideline to the scheme, along with application forms, is available on the IMB's website. Intending applicants are advised that applications for products already on the market, must be submitted to the IMB by 30 September 2010.

VETERINARY MEDICINES

COLLECTION OF INFORMATION ON THE USE OF VETERINARY ANTIMICROBIAL AGENTS

Further to the provision of a template by the European Medicines Agency (EMA) to be used by Member State authorities to collect data on the use of veterinary antimicrobials, the IMB is preparing plans to collect the information for the year 2009 in respect of all such products marketed in Ireland. The IMB will shortly be writing to marketing authorisation holders requesting them to provide the information set out in the template on the EMA's website.

It is expected that this survey will be repeated annually from now on.

GUIDE TO THE DECENTRALISED AND MUTUAL RECOGNITION PROCEDURES FOR VETERINARY MEDICINAL PRODUCTS USING IRELAND AS RMS

The Veterinary Medicines Department takes this opportunity to advise interested parties that updated and revised guidance on the decentralised procedure (DCP) and the mutual recognition procedure (MRP) is now available on the IMB's website.

The guidance document, which was published on 30 April 2010, provides a detailed overview of the stages of the application procedures along with information on the fees charged by the IMB for these procedures.

Companies considering choosing the IMB to act as reference member state (RMS) will find information about the services provided by the Veterinary Medicines Department when acting as RMS in addition to an overview of department personnel and the assessment teams. Useful information has also been included for interested parties visiting the offices of the IMB.

The guidance document can be accessed on the IMB's website.

FONT SIZE ON PRODUCT LITERATURE

The Veterinary Medicines Department wishes to advise all applicants submitting label mock-ups for approval that the recommended minimum font size is font size 8. The IMB recommends that applicants ensure that all text is clearly legible prior to submission of mock ups. Cases will be considered on an individual basis and applicants are advised that this may necessitate the submission of a hard copy of the mock-ups representing the actual size and quality of the product literature for further assessment. For further information please contact Deirdre O'Keeffe (deirdre.okeeffe@imb.ie).

SUBMISSION OF MOCK UPS FOLLOWING THE COMPLETION OF PROCEDURES

Applicants are reminded that following completion of all new applications for product authorisation mock-ups must be provided to the IMB within 30 days of Day 90/210 of the procedure. If the applicant fails to provide mock ups within 90 days the authorisation will be issued in the absence of mock-ups and a condition will be inserted into the authorisation stating that mock-ups must be provided for approval prior to marketing the product in Ireland. If the product is not to be marketed, applicants are requested to notify the IMB of this upon receipt of the request for mock-ups. In this instance, the same condition will be inserted into the authorisation and the authorisation will be issued. Subsequent submission of the mock-ups for review and approval should be via a Type IB variation C.II.6. For further information please contact Deirdre O'Keeffe (deirdre.okeeffe@imb.ie).

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

Interested parties should note that the Directorate General for Health and Consumers (DG Health and Consumers) has commissioned a public consultation of stakeholders and interested parties on their views on the strengths and weaknesses of the current legal framework for veterinary medicinal products and how it might be improved. The public consultation entitled 'Better regulation of veterinary pharmaceuticals: how to put in place a simpler framework, safeguarding public and animal health while increasing the competitiveness of companies' was launched on 13 April 2010.

Based upon the results of the public consultation, DG Health and Consumers, among others, intends to prepare a report on the impact assessment of a revision of the veterinary legal framework.

The Heads of Medicines Agencies has established a working group on legislation to input into the process. Animal health companies and other stakeholders should consider what amendments to the current veterinary legislation (Directive 2001/82/EC, as amended; Regulation (EC) No 726/2004 and other legislation relating to veterinary medicinal products) they consider necessary and avail of this opportunity to make submissions to the European Commission.

Full details (including an online submission form) are available on the European Commission's Enterprise and Industry (Pharmaceuticals) website.

The deadline for submission of observations/comments via the online submission form is 15 July 2010.

TYPE IA AND FORESEEN TYPE IB VARIATION APPLICATIONS

Submission of Type IA and foreseen Type IB variation applications in the correct format will greatly facilitate their processing by the IMB and reduce the possibility of invalidation or rejection. Applicants are requested to take note of the following issues which will improve the quality of their submissions:

- The present and proposed sections of the application form should always be completed.
- The page from the variation guideline should have the relevant conditions and documents 'checked' or 'ticked'.
- Where listed conditions or documents are not relevant, this should be clearly identified on the page from the variation guideline (e.g. marked as N/A).
- Supporting documents should be clearly indexed and presented in the order listed in the variation guideline.
- The implementation date for the variation should be included in the relevant section of the variation form.
- For Type IB foreseen variation applications which are included in the guideline and all the required supporting documents are not provided, a justification for the absence of specific documents should be provided, as appropriate.

COMPLIANCE

GMP & MARKET COMPLIANCE INFORMATION DAY 2010

The Compliance Department will hold an Information Day for manufacturers and marketing authorisation holders on 14 October 2010 at the Crowne 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's website over the coming months. Check the 'Events' section of the website for updates. Anyone interested in attending this Information Day should reserve a place at an early stage as there is usually a significant number of attendees and places are limited.

It is planned to have a similar format to the corresponding Information Day held in 2008 with topics of general interest in the morning, followed in the afternoon by parallel sessions on more specific topics. Some routine topics will be covered, such as GMP Guide updates, updates on legislative changes etc but the IMB is also inviting suggestions for topics which the industry would like to have covered during the day. The suggested topics may be either of general interest or of a more specific nature suitable for a parallel session. Suggested topics may be communicated to the IMB either directly via the e-mail address **complance@imb.ie** or via industry representative organisations. Please provide any suggested topics by 30 June 2010.

CERTIFICATION OF MA COMPLIANCE

The Qualified Person (QP) has the responsibility to certify, and release for sale, only batches which have been manufactured in accordance with GMP and the relevant marketing authorisation (MA). This legal responsibility is defined in European and national legislation.

Due the size and complexity of many pharmaceutical operations, maintenance of the MA often lies with MA holder (MAH) offices or a central regulatory office which is separate from the site of manufacture where the final QP certification of each batch of the product takes place. The QP often relies on documentation prepared by such 'third parties' as the basis for certification of MA compliance for the batches being released. The IMB has previously stated that technical agreements defining the responsibilities of each party should be in place with offices which undertake these duties. In addition, QPs performing certification should ensure that their reliance on these 'third party' offices described in technical agreements is well-founded.

Personal audit of all such offices by the QPs could be one mechanism but is not necessarily expected. If issues were identified it might certainly be a measure which the QP making a personal declaration may want to do in order to provide the necessary level of assurance required.

The QP should know that such offices operate a quality system and should ensure that he/she has evidence that this is the case. The QP should know that there is appropriate oversight of the quality system in place at these offices (MAH or other regulatory office).

The QP should be made aware if regulatory issues are identified at these offices, either by a regulatory authority which has carried out an MAH inspection or through the company's own audit programme. This aspect should be covered in the technical agreement.

In conclusion, having a technical agreement in place with third parties who are responsible for maintaining information in marketing authorisations is not, in itself, adequate assurance on which to base certification of compliance with the marketing authorisation. QPs should satisfy themselves that reliable systems are in operation at these offices so that their reliance, when certifying batches, is well founded.

NEW IMB CONTACT INFORMATION FOR REPORTING QUALITY DEFECTS, PRODUCT RECALLS AND EMERGENCY SITUATIONS REGARDING MEDICINAL PRODUCTS TO THE IMB

Following a recent restructuring of the Market Compliance Section within the Compliance Department, Ms. Aoife Farrell has been appointed as Quality Defects and Recall Manager. In light of this, the IMB's contact details for reporting quality defects, product recalls and other emergency situations in relation to medicinal products and active substances have changed.

The new contact details are as below.

On foot of this notice, medicinal product manufacturers, wholesalers and marketing authorisation/registration holders are requested to update their recall procedures and other related documentation to reflect the above. Manufacturers of active substances are also requested to do so.

Contact Name & Title	***Office Telephone***	***Mobile Telephone Number & Fax Numbers*** *(manned during office hours only)*	***E-mail Address*** *(for out of hours contact)*
Ms. Aoife Farrell Quality Defects & Recall Manager*	*Tel: +353 1 676 4971 Fax: +353 1 676 4061*	*+353 86 024 9808*	*aoife.farrell@imb.ie*
*Dr. Kevin O'Donnell** Market Compliance Manager*	*Tel: +353 1 676 4971 Fax: +353 1 676 4061*	*+353 87 956 2818*	*kevin.odonnell@imb.ie*
*Ms. Breda Gleeson** Market Compliance Inspector*	*Tel: +353 1 676 4971 Fax: +353 1 676 4061*	*+353 87 970 3559*	*breda.gleeson@imb.ie*
Mr. Rob Smyth Market Compliance Technical Officer	*Tel: +353 1 676 4971 Fax: +353 1 676 4061*	*Not provided*	*rob.smyth@imb.ie*
*Mr. John Lynch** Director of Compliance*	*Tel: +353 1 676 4971 Fax: +353 1 676 4061*	*+353 87 234 7294*	*john.lynch@imb.ie*
Please note that the following email address is also in use and can be accessed out-of-hours by IMB staff: recallsandqualitydefects@imb.ie			

** Aoife Farrell is now the primary IMB contact person for such reports.*
*** Kevin O'Donnell, Breda Gleeson and John Lynch are also available out-of-hours.*

IMPORTANT NOTE CONCERNING THE IMB'S SAMPLING AND ANALYSIS PROGRAMME

The Market Compliance Section operates a wide-ranging sampling and analysis programme as part of the IMB's pre- and post-marketing product surveillance activities. This involves the sampling and analytical testing and/or examination of the packaging and labelling of authorised human and veterinary medicinal products, active substances, products intended for export, enforcement-related samples, and borderline products.

A key element of the programme involves evaluation of the suitability of company analytical methods and therefore much of the testing that is performed employs the analytical methods (and, in some cases, reference materials) used by the product manufacturer. An important component of this programme is the timely provision of analytical methods, reference standards and other supporting items to the IMB by the pharmaceutical company concerned.

To facilitate this aspect of the process, the IMB's sampling and analysis group sends a form entitled 'Request for Sampling & Analysis Supporting Items' to the concerned company when one of

its medicinal products has been selected for analytical testing. These include items such as copies of finished product specifications (release and shelf-life specifications), analytical test methods (mainly shelf-life analytical test methods), quantities of reference standards, and copies of certificates of analysis for the concerned batch and/or reference standards. Copies of sample chromatograms may also be requested: these can include HPLC chromatograms from a related substances test method in order to assist with peak identification.

The provision of the *complete* information and *necessary* supporting items by authorisation holders and manufacturers is critical to ensuring that the IMB's market surveillance testing can be progressed. The purpose of this article is to bring this point to your attention, as the IMB has encountered a number of recurrent problems in this area. These include:

- Where the IMB requests that a company provide the dissolution test method for a product and, where the product in question is a gastro-resistant capsule that requires a gastro-resistance test to be carried out as part of the dissolution test, the company should also provide a copy of the gastro-resistance test method.
- Likewise, if an assay is required to be performed as part of a dissolution test, a copy of the assay method should also be sent to the IMB along with the reference standards needed.
- If the analytical method in question requires two reference standard solutions to be prepared (e.g. →

for a comparison of standards test) and this requires that 2 x 100mg of reference standard are used, the company should send at least 2 x 100mg of that reference standard to the IMB.

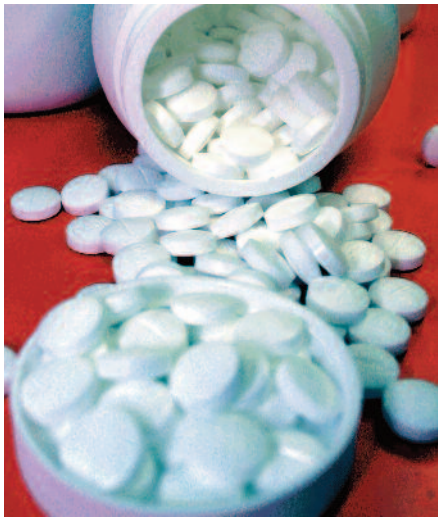
- Where an assay requires preservative materials to be included in the reference solution, the company should provide the IMB with both the requisite amount of the active substance reference standard as well as the requisite amount of the preservative reference standards, unless it can be scientifically justified as to why the preservative materials are not needed, and likewise for resolution and system suitability tests.

- Any reference standards that are provided should have a minimum of six months remaining to their expiry date. In addition, reference standards requiring controlled temperature shipment should be sent under the requisite conditions to the address specified in the 'Request for Sampling & Analysis Supporting Items' form – see also point immediately below

- If the item in question is labelled as requiring cold storage but is known to be stable outside of refrigerated conditions and is shipped to the IMB outside of its labelled conditions, the company must communicate this to the IMB and specify the period for which the item may be held outside those conditions. Shipment of such materials in this way should be exceptional.

All of the items requested by the IMB should be sent to the address specified on the 'Request for Sampling & Analysis Supporting Items' form and not to a transit warehouse or other location.

In addition, the IMB requires a copy of the analytical method that the company's quality control (QC) laboratory uses when carrying out its own testing. This is because such methods are often more complete with respect to the detail involved in sample preparation, injection sequences and calculation parameters etc., than the methods that are registered in the marketing authorisation for the



product. It should be noted, however, that the company's analytical method used by its QC laboratory is required to be consistent with the method currently registered in the relevant marketing authorisation for the product.

When a company receives an IMB 'Request for Sampling & Analysis Supporting Items' form it would be useful, if they sent an exact copy of this form to their QC laboratory (when requesting the analytical method).

A declaration is required to be made on the IMB's form. This confirms that the items provided by the company comply with the list as requested, that the analytical methods provided are those currently in use at the QC laboratory, and that they reflect those currently registered in the relevant marketing authorisation. This declaration must be signed and dated in the appropriate area on the form.

Failure to comply with these requests in a timely manner may be followed up by the IMB via a regulatory compliance inspection at the marketing authorisation holder.

If clarification is required with respect to any of the above, please contact the IMB's sampling and analysis group within the Market Compliance Section at + 353 1 676 4971.

UPDATE ON THE IMB COSMETICS PROJECT

In 2007, the IMB initiated a project in conjunction with the Department of Health and Children to assess the feasibility of the former undertaking the role of Competent Authority for cosmetics.

This project has involved close interaction with the current Competent Authority, the Department of Health and Children and other stakeholders, as well as information gathering through participation in a number of European meetings relating to cosmetics. These include: the Standing Committee on Cosmetic Products; the Working Group on Cosmetic Products; and Platform of European Market Surveillance Authorities in Cosmetics (PEMSAC).

The project has now progressed to a stage of formal agreement between the Department of Health and Children and the IMB to transfer the Competent Authority role for cosmetics to the IMB. The legislation required for this transfer to occur is being prepared by the Department of Health and Children and it is envisaged that this will be finalised during 2010.

When the legislation comes into force, the IMB will be responsible for the regulation of cosmetics in Ireland and will carry out the functions of the Competent Authority for cosmetics including:

- the maintenance of a notification database of cosmetic product manufacturers, importers and Responsible Persons;
- establishment of a market surveillance system involving inspection, market sampling and analysis and

review of product information files;
- enforcement of the legislation where necessary;
- generation of Certificates of Free Sale; and
- participation in international activities including relevant EU working groups.

Following on from the formal agreement with the Department of Health and Children, the IMB has begun the process of integrating the competent authority role for cosmetics into the new Healthcare Products Distribution Section within the Compliance Department. The Section also incorporates the areas of Controlled Drugs, Good Distribution Practice and the distribution of medical devices. Nicola Hickie, the Cosmetics Project Officer since the initiation of the project, is the lead in terms of co-ordinating the transfer of the competent authority role from the Department of Health and Children and the implementation of systems and processes within the IMB to ensure an efficient transfer.

Later this year, the IMB, in conjunction with other bodies and agencies, will hold an Information Day for industry outlining the revised regulatory framework for cosmetics and the role of the IMB in this area. Further details will be published on the IMB's website, nearer to the event which is anticipated for quarter three.

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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