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Risk Minimisation and Educational Materials

IMB Submission Requirements

IMB Information Day, 2nd December 2011

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Risk Minimisation

Risk Minimisation

- A set of activities used to reduce the probability of an adverse reaction occurring or its severity should it occur

Routine Risk Minimisation Activities

- The warnings and information contained within the Summary of Product Characteristics and Patient Leaflet and the careful use of labeling and packaging, which aim to reduce the probability of an adverse reaction occurring or its severity should it occur

Additional Risk Minimisation Activities

- A risk minimisation activity put in place to reduce the probability of an adverse reaction occurring or its severity should it occur which is not a routine risk minimisation activity e.g. educational material or patient register.



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Legislation

- CHMP or National Competent Authority may make recommendations on conditions or restrictions with regard to the safe and effective use of the medicinal product. These conditions usually affect only the decision addressed to the Marketing Authorisation Holder. However in certain conditions the Commission may also adopt a decision addressed to the Member States.
- Directive 2001/83/EC (Annex IIB) Conditions of the Marketing Authorisation (Regulation EC 726/2004)
- *“Authorisation must be subject to certain essential conditions and it is the responsibility of the Member State concerned to ensure that such conditions are met”*
- Annex IIB
- *Conditions or restrictions regarding supply and use imposed on the marketing authorisation holder*
- *Conditions or restrictions with regard to the safe and effective use of the medicinal product*

Annex II

ANNEX II

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION

B. CONDITIONS OF THE MARKETING AUTHORISATION

• CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER

Medicinal product subject to special and restricted medical prescription (See Annex I: Summary of Product Characteristics, section 4.2).

• CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

Prior to launch in each member State the MAH shall agree the final educational material with the National Competent Authority.

The MAH shall ensure that, at launch, all physicians, pharmacists and patients expected to prescribe/use XXXX are provided with educational material informing about the correct and safe use of the product.

Educational material for patients should highlight the following:

Educational material for physicians should highlight the following:

Educational material for pharmacists should highlight the following:



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Risk Minimisation and Educational Materials

- The **requirement** to produce educational material will only be included as a condition of authorisation, when it is deemed necessary for the safe and effective use of a product. The need for additional educational material will depend on the risk and is considered on a case by case basis
- Marketing Authorisation Holders may produce material to inform and educate healthcare professionals and patients
- Only educational materials which are included in an EU-Risk Management Plan, or which are a condition of the marketing authorisation require IMB approval



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When may educational materials be considered?

- Often proposed, may not be most effective risk management tool
- Device administered
- Specific adverse drug reactions e.g. ADRs that require monitoring or early detection
- Drug Titration
- Medication Errors



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Additional Educational Material

- Clear objectives with key principles and key messages of Annex IIB
 - Enhance understanding of the specific risk(s) and methods to reduce either the frequency or severity
 - Enhance patient information, awareness and provide information on the need for additional precautions
- Must be in line with the Summary of Product Characteristics and Patient Information Leaflet



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Additional Educational Material

- Form of educational material will depend on the specific safety concern:
 - Guide to prescribing or dispensing
 - Checklist for actions for prescribing or dispensing
 - Patient information brochures
 - Patient Alert Card/ Patient Monitoring Card
- Advised to consult patient groups/ healthcare professionals and risk communication experts to ensure good comprehension and acceptance of the educational material



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IMB Guideline for Educational Materials

- Irish Medicines Board - Guide to Submission of Risk Minimisation Plans (June 2011)
- Volume 9A - Guidelines on Pharmacovigilance for Medicinal Products for Human Use
- CHMP - Guideline on Risk Management Systems for Medicinal Products for Human Use (EMEA/CHMP/96268/2005)



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IMB Submission

- Risk Minimisation Plan and Educational Materials should be sent in electronic format to IMB Vigilance Assessment

1. Application letter

2. Draft educational material documents

- Non-promotional
- pdf and word format.
- CD, DVD submissions should include typed text and images



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3. Reference Documents

- Annexes I to III of the Marketing Authorisation, including Product Information – Summary of Product Characteristics, Patient Information Leaflet
- Approved Risk Management Plan and Annexes describing the risk minimisation tools
- Literature References

4. Communication Plan and Distribution List



IMB Assessment

- Assessment – Case Reference Number (CRN 1234567)
- The agreed final version should be provided
- Timeline for IMB assessment – 2 months
- Updates are handled in the same way and should be submitted with tracked changes



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Effectiveness of Educational Material

- Assessment of the effectiveness of the intervention is part of the risk management process and will be outlined in the Risk Management Plan
- Methods of evaluation are appropriate to the specific risk and the risk minimisation activity and may include drug utilisation studies, other database studies etc.



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IMB Human Products Monitoring Department

Queries may be addressed to the Vigilance Assessment Team
at the IMB

Email: *vigilance_assessment@imb.ie*

Thank You



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