IRISH MEDICINES BOARD

Information Day - New Variations Regulations

Submission of Variations

Crowne Plaza Hotel, Santry, 22nd January 2010

Kevin Horan,
IT Manager

Topics

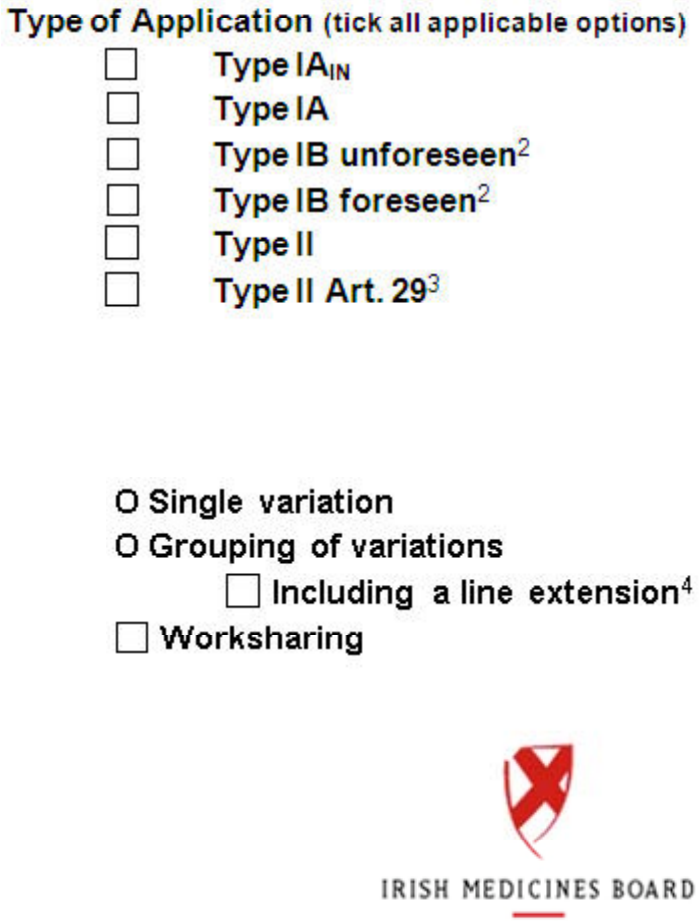
- Key changes in form structure
- Supporting documentation
- eCTD / NeeS / VneeS submissions
- RIO Submissions

IRISH MEDICINES BOARD

Application types

- New options available to indicate the application types included in the submission – user should select all that are applicable

- For submission type the valid options are:-
  - Single
  - Single + Worksharing
  - Grouping
  - Grouping + line extension
  - Grouping + line extension + work sharing
  - Grouping + work sharing



IRISH MEDICINES BOARD

Products Concerned

- Each product included in the submissions must be entered into the products concerned grid

(Invented)Name(s):	Active substance(s)	Pharmaceutical form	Strength	MA holder name(s):	MA number(s): [8]
Newcastle	Active X	Tablet	15mg	Test Pharma Co	PA11836/001/001
Sunderland	Active Y	Tablet	20mg	Test Pharma Co	PA11836/001/002
Leeds	Active P	Solution for injection	100IU	Test Pharma Co	PA11836/009/001
Bristol	Active P	Solution for injection	200IU	Test Pharma Co	PA11836/009/003

IRISH MEDICINES BOARD

Type of Change

- Each change applied for in the submission must be listed.
- All changes apply to all products in the submission.
- For each change the relevant conditions and documentation must be provided where applicable as detailed in the classification guideline.

IRISH MEDICINES BOARD

Type of Change

		Procedure type		
☒	**D.2 Change in the name and/or address of the PMF certificate holder**	☐ IA_{IN}	☒ IB^9	**Implement. Date:**

A.5 Change in the name and/or address of a manufacturer of the finished product, including quality control sites		**Procedure type**		
☒	a) Manufacturer responsible for batch release	☒ IA_{IN}	☐ IB^9	**Implement. Date:** 01/01/2010
☐	b) All other	☐ IA	☐ IB^9	**Implement. Date:**

- For 1A and 1Ain changes an implementation date must be provided.
- For 1A and 1A in where a condition is not met as per the classification guide this change will default to a type 1B .
- For variations not listed in the guideline the “other variation” option should be selected.

IRISH MEDICINES BOARD

Justification for grouping / Work Sharing

- When grouping or work sharing is applied for a justification must be provided

PRECISE SCOPE AND BACKGROUND FOR CHANGE, AND JUSTIFICATION FOR GROUPING, WORKSHARING AND CLASSIFICATION OF UNFORESEEN CHANGES (if applicable) (*Include a description and background of all the proposed changes. In case of grouping and worksharing a justification should be provided in a separate paragraph. If a variation concerns an unforeseen change, include a justification for its proposed classification).* Test background for change

IRISH MEDICINES BOARD

Present / Proposed

PRESENT[10,11]	PROPOSED[10,11]
All changes outlined here apply to all of the products listed	All changes outlined here apply to all of the products listed
PA11836/001/001 Current text for this product	Proposed text for this product

- In the present and proposed section where data is applicable to all products a single entry for the present and proposed is suitable.
- For slight differences in text between each product it is recommended that the applicant provide a present and proposed section for each product in the submission.

IRISH MEDICINES BOARD

Supporting information

- Where a submission contains more than one product the supporting documentation to be provided e.g. summary of product characteristics ,labelling ,package Leaflet etc..

- Each document should clearly indicate the licence number that it refers too.

IRISH MEDICINES BOARD

Electronic Submissions

- IMB strongly recommends the use of electonic submissions for both human and veterinary submissions in the following formats:

  - Electronic Common Technical Document (eCTD).
  - Non eCTD Electonic Submission (NeeS).
  - Veterinary Non eCTD Electronic Submission(VNeeS) .
  - RIO Online Submission and Tracking Portal.

IRISH MEDICINES BOARD

eCTD / NeeS / VNeeS

- For a grouped variations with a mix of variation types the “highest” variation type should be used.

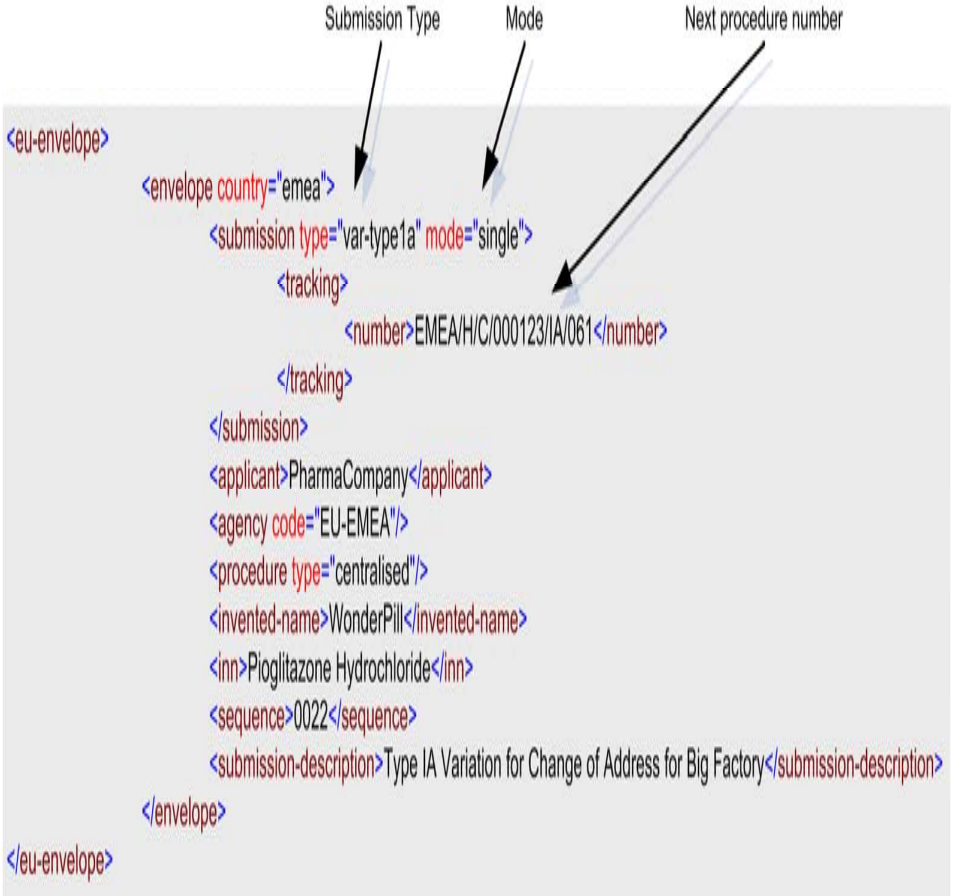
- Current eCTD specification does not provide the capability to use grouped or work sharing across multiple MA’s , the applicant should create separate eCTD sequences for each MA in the submission.

- For eCTD / NeeS / VNeeS , grouped submissions can be provided on a single CD / DVD with each of the MA’s in a separate folder on the disk.

IRISH MEDICINES BOARD

eCTD

- Changes to the envelope element of the eCTD eu-regional.xml file
  - Submission type
    - Var-type1b
    - Var-type2
    - Extension
  - Mode
    - Single
    - Grouping
    - Extension
  - For work sharing a “tracking” number is provided and referenced in the envelope in the tracking section.



IRISH MEDICINES BOARD

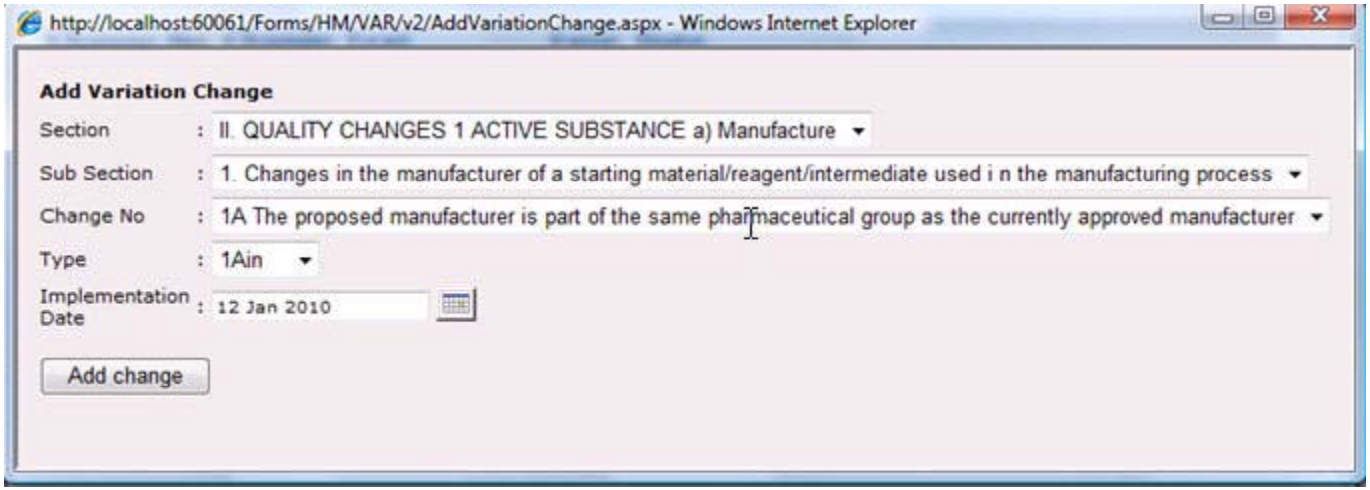
RIO

- No major changes to the current process.
- System provides the applicant with the ability to submit grouped variations.
- System will generate a single standard application form and guideline document containing all products.
- System will provide multi-document upload.
- Available by mid February

IRISH MEDICINES BOARD

RIO

- Drop down filtering system on the change types linked to the conditions and documentation.



IRISH MEDICINES BOARD

RIO

- Once a change is selected you will be able to add conditions and documentation to the change.

IRISH MEDICINES BOARD

References

- Application for variation to a marketing authorisation December 2009
- Classification guideline for variations
- EMA/ CMD(h) explanatory notes on variation form for human medicinal products only
- eCTD Variations Q&A document
- Guide to electronic submissions - Human Medicines 2009
- Guide to electronic submissions - Veterinary Medicines 2009
- The IMB website www.imb.ie will be updated regularly to reflect any changes or guidance

IRISH MEDICINES BOARD

Thank You

For further information or comments
please Email: kevin.horan@imb.ie

IRISH MEDICINES BOARD