

BROMI Variations – Training Presentation

BROMI Variations Training Meeting,
8th May 2008,
The Cumberland Hotel, London



BROMI Variations Training
Meeting 8 May 2008

BROMI Variations Launch – What is it all about?

- Working within EU framework
- Expedited processing of certain categories
- Self-certification of certain Type IA changes
- Initiative available for portal submissions only
- Bulk applications can be made however only allowed for the same change over licences with the same marketing authorisation holder



BROMI Variations Launch – Key Benefits

- Freeing up assessors' and industry's time
- Responsibility of MAHs – risk based approach.
- Quicker and more predictable approval times for industry
 - Implementation requirements are the same as normal variation activities



BROMI Variations Launch – Available guidance

- MHRA guidance available

(<http://www.mhra.gov.uk/home/groups/pl/documents/websiteresources/con2033962.pdf>)

- Based on EU guidance on dossier requirements for Type IA and Type IB Notifications
- Colour coded
 - to distinguish from EU guideline
 - to help applicants identify if change they are applying for fits into scheme
- Additional criteria for applications that are not assessed or validated

- company certifying acceptability of change



BROMI Variations Launch – Available guidance

7	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product	Conditions to be fulfilled	Documentation to be supplied	Procedure type
<input type="checkbox"/>	a) Secondary packaging for all types of pharmaceutical forms	1, 2, 8	1, 2, 5, 10	Self Certification
<input type="checkbox"/>	b) Primary packaging site			
<input type="checkbox"/>	1. Solid pharmaceutical forms, e.g. tablets and capsules	Not a BROMI change. Submit by usual route		
<input type="checkbox"/>	2. Semi-solid or liquid pharmaceutical forms	”		
<input type="checkbox"/>	3. Liquid pharmaceutical forms (suspensions, emulsions)	”		
<input type="checkbox"/>	c) All other manufacturing operations except batch release	”		
<input type="checkbox"/>	d) Additional Distributor or Own Label Supplier	1, 5, 6, 7	1, 2, 10	IA
<input type="checkbox"/>	e) Replacement or addition of a manufacturing site for part or all of the manufacturing process of a sterile finished product.	1, 2, 3, 4,	1, 2, 3, 4, 5, 6, 7, 8, 9, 10	IB

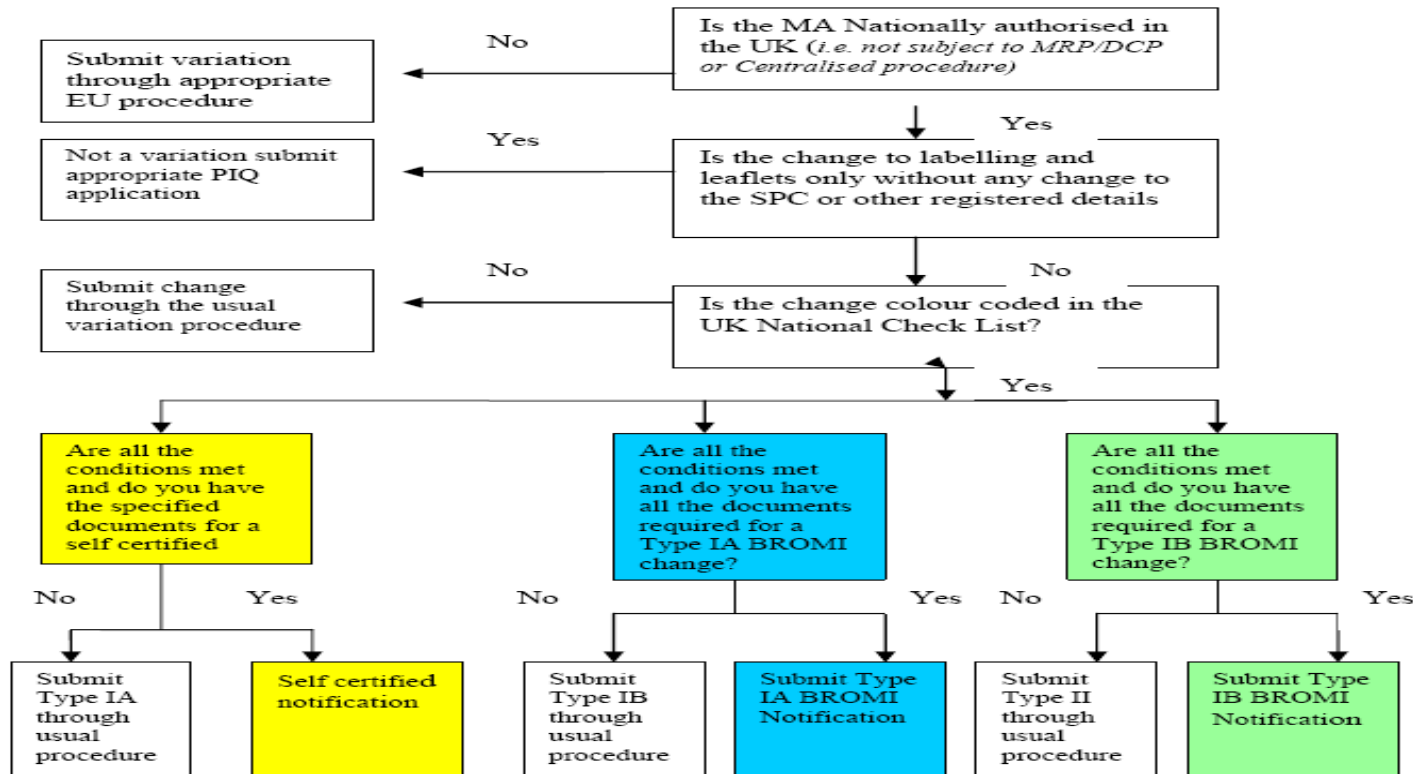


BROMI Variations Launch – Hints & Tips

- Strategy
 - Changes should only relate to national marketing authorisations (No MRP, DCP or Centralised)
 - Know what change is required before you start; use the BROMI flow chart
 - Use flow charts decision making and deciding what category a particular change fits into. Also, use the variations guideline to help categorise the change
 - Think carefully about the categorisation/classification of simultaneous changes
 - Follow the BROMI variations checklist. If a condition / document is not applicable to the change being applied then it is not a BROMI. Don't try to make it a BROMI when it isn't!



BROMI Variations Launch – Hints & Tips



BROMI Variations Launch – Hints & Tips

- Document requirements
 - Define the changes clearly, and remain consistent throughout the documentation
 - Send the complete documentation package required by the guideline including the checklist but do not send anything unnecessary
 - Ensure any relevant additional documents (packaging components / label text / SmPC / dossier pages) are included with the application. Remember: If other additional component are impacted by the change but not explicitly referenced in the documentation requirements in the BROMI checklist, include them
 - Be clear & concise in your application - don't presume the agency know what you mean, put yourself in their shoes!



BROMI Variations Launch – Hints & Tips

- Portal submission
 - The BROMI variations process uses portal applications only.
 - Add a sufficient description of the change in the scope box on the application form.
 - Choose the correct option on the application form
 - including BROMI fees category
 - Use the comments section to add a description of the change, if the category doesn't fit into the portal form.



BROMI Variations Launch – Hints & Tips

- Internal Company Processes
 - Create/develop your own internal procedures for submission **AND FOLLOW THEM.**
 - BROMI puts the onus on the Company to get it right
 - Example process guidance is in delegate packs
 - If there is time and resources available, have a brief internal quality check before submission.



BROMI Variations Launch – Pitfalls

- Pitfalls identified via pilot/audit activities
- Audit activity will still continue however there are consequences of not complying with the BROMI variation requirements.
 - Approval of application withdrawn
 - Enforcement action.



BROMI Variations Launch – Pitfalls

- Common reasons for invalid applications
 - Application not suitable for BROMI scheme
 - Wrong category chosen
 - Omission of key documents
 - Suitability of documentation and/or declarations
 - Omission of SPC, labels and leaflets
 - Multiple changes in one application



BROMI Variations Launch – Pitfalls

- Pitfalls are easily avoided
- Seek advice if unsure

MHRA contact details:

variationqueries@mhra.gsi.gov.uk

or Regulatory Information Service Desk:

0207 084 3400



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