

Applying Better Regulation Principles to Non-Prescription Medicines:

A UK Regulatory Perspective

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Applying Better Regulation Principles

- Better Regulation – UK Perspective
- Better Regulation of Medicines Initiative (BRMI)
 - Background
 - Work streams
 - Variations
- Next Steps

Applying Better Regulation Principles



- UK Government agenda
- Dept of Health Simplification Plan
- BROMI

Health and Social Care 'Burden'

- 2005-6
 - DH identified 90 regulations affecting private sector, estimated cost £1.2 billion
 - 7 regulations accounted for 85% total, including 3 medicines regs (>25%)
 - DH has net 25% reduction target by 2010 (£300m)
 - EU has its own 25% reduction target by 2012



Source: Dept of Health, UK

Simplification Plan

- All UK Government departments committed to produce simplification plans
 - Assessed twice annually
 - DH simplification plan brings together all DH better regulation activity
 - Includes BROMI



“The Department is committed to ensuring delivery of its key priorities through better regulation and reducing unnecessary burdens on business..., enabling them to..., deliver better services and develop world class products.”

Rt Hon Alan Johnson, MP
Secretary of State for Health, December 2007

Principles of Better Regulation

- Proportionate
- Accountable
- Transparent
- Consistent
- Targeted

BRONI-Better Regulation of Medicines Initiative

Background

- October 2005 – UK OTC trade association (PAGB) strategy workshop focussed on new ways of working
- November 2005 – AESGP conference
UK Health Minister announced setting up of Better Regulation of OTC Medicines Initiative (BRONI)
- BRONI established to look at how unnecessary regulatory burdens primarily in relation to OTC medicines could be eased.

BROMI Stakeholders



Cabinet office

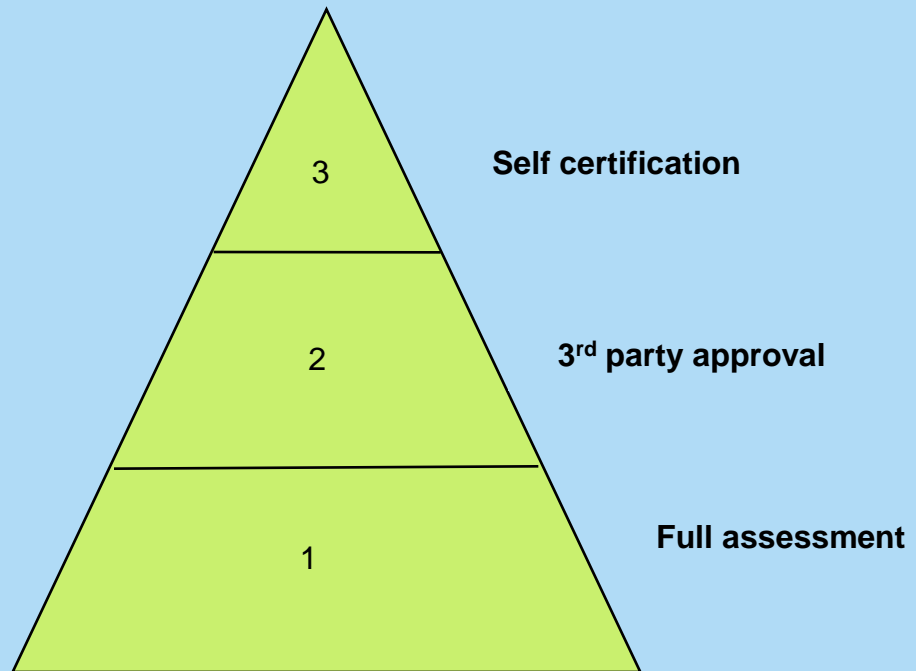
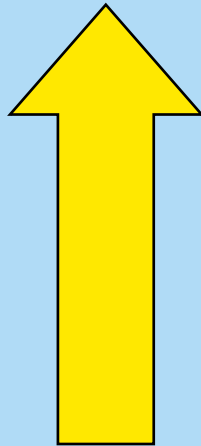
BROMI Terms of Reference

- Consider current administrative burden on (OTC) medicines regulation.
- Identify where a 'lighter touch' approach to the operation and delivery of (OTC) medicines regulation would benefit all stakeholders.
- Determine measures for a proportionate approach to regulation while maintaining safeguards to protect public health.
- Make proposals to facilitate change and tackle barriers.
- Agree criteria for a successful outcome.

Models of regulation, 3 tier approach

Risk based assessment

Admin
burden
reduced



BROMI - 3 Main Workstreams

- Patient Information
 - Self certification of minor changes to labels and leaflets, with MHRA audit
 - Third party approval with rapid assessment by MHRA for pack re-design, with industry Code of Practice
- Licensing processes
 - Variations; 'Change of Ownership' applications; Copy licences (Article 10(c)), Renewals
- Vigilance
 - Literature screening: ADR reporting; PSURs; good PhV practice

Patient Information – Work Stream

- Self- Certification of certain minor changes – since May 2006
 - Changes to UK distributor details
 - Removal of text specific to non-UK markets
 - Amendment of statutory warnings in line with guidance
 - ‘Keep out of reach of children’ amended to:
‘Keep out of reach and sight of children’
- Third Party Pre-Approval
 - Pilot started in January 2007 with PAGB – extended to non-PAGB members

Licensing Process - Variations

- Variations – High Volume work stream
- Approx 22,000 variation applications received annually in UK.
 - 50% Type IA
 - 80% National
- Risk based approach to assessment
- Reduction in administrative burden
- Predictable approval times
- Delivery of new ways of working

Current Regulatory Framework

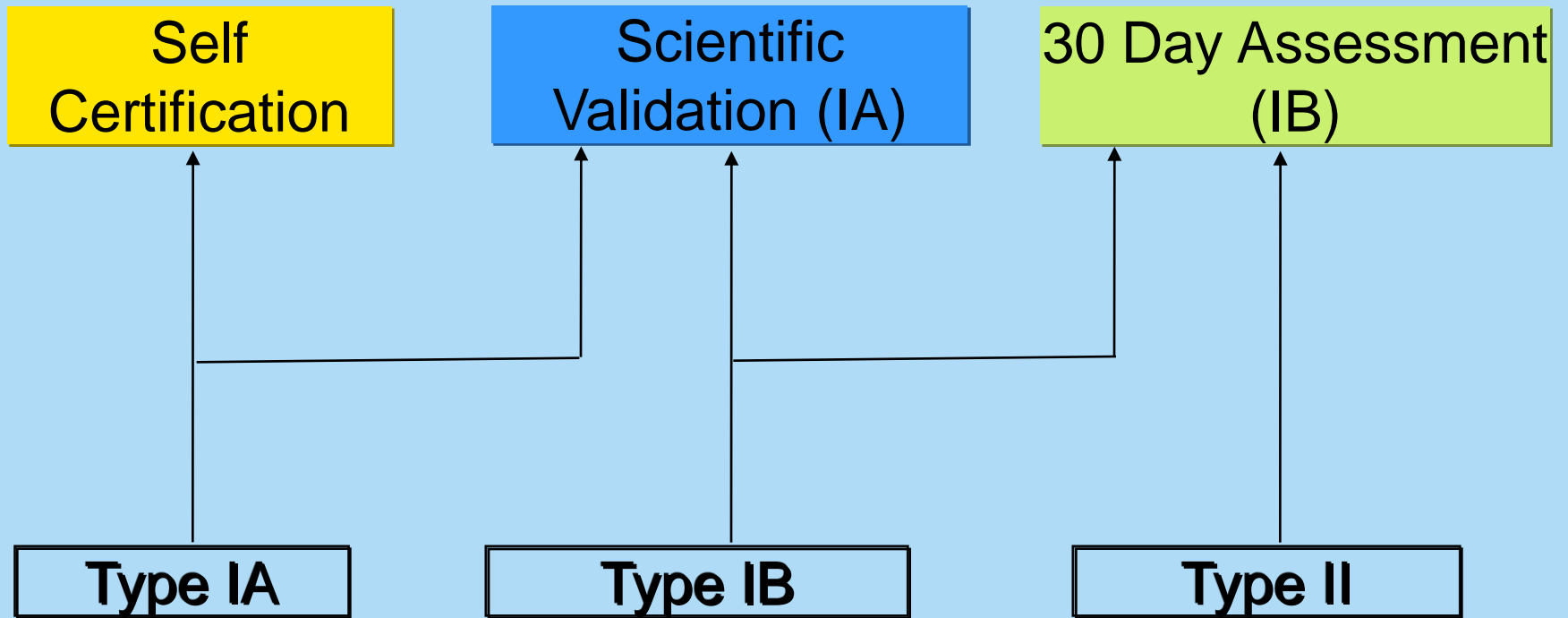


Regulation EC 1084/2003 – Mutual Recognition

Regulation EC 1085/2003 – Centralised Procedure

UK – Follows principles of Regulations EC 1084/2003 and EU Best Practice Guidance

Variations – Proposal for 3-tier model for certain categories of change – Based on MR procedures



Variations – 3 tier model

Self Certification BROMI – ‘Tell and do’

- Approx 80% of current Type IA;
- Approx 7000 per annum in UK

Type IA BROMI – 14 day scientific validation

Type IB BROMI – 30 day assessment procedure

BROMI – Variations

Pilot - 2007

Mainstream Process Rolled-out to MAHs – 1st April 2008.

- National Applications
- Portal Applications

- Launch Conference- May 2008
 - Training
 - Workshops
 - Advice on amendments to company internal procedures

BROMI -Variations

How would the 3-tier model help my company?
Some examples

Change in name and address of MA Holder (same legal entity)

Current – Type IA with 14 Day validation procedure

BROMI – Self Certified change that can be implemented immediately

Minor Change in the Manufacture of the Active Ingredient

Current – Type IB 30-Day assessment procedure

BROMI – Under certain conditions Type IA 14-Day validation

Replacement or addition of a manufacturer for a sterile product

Current – Type II 90-Day assessment procedure

BROMI – Type IB 30-Day assessment procedure

Revision of the EU Variations Regulation



Examples of BROMI principles

- BROMI self-certification changes reflected in new 'Do and tell' procedure
- BROMI principles of 'down-grading' variation type seen within work sharing proposals.
- Practical experience from BROMI Variations experience assisting detail in the new Classification Guidelines

BROMI – a successful beginning

- Removing burdens whilst maintaining an effective safety net
- Engaging industry and regulators – changing attitudes
- Measuring the benefit to industry and regulators – real cost savings included within reduction target.
- Providing practical information to influence legislative changes
- Award winning initiative



BROMI – Next Steps

Product Information – Develop existing procedures

Variations – Can further streamlining be introduced?

Renewals – Pilot ongoing- Reduced documentation requirements

Vigilance – Streamline documents for submission with PSURs

BROMI – Further Information



<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/BetterRegulationofMedicine>