Better Regulation and Medicines

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Policy context

• Self care, prevention and better management of long term conditions are critical to improved quality at a reduced cost in the NHS.

• Encouraging manufacturers to make more medicines available OTC in pharmacies and other outlets, ensuring that this can be done safely.

• **Building on strengths – delivering the future:**
  – increasing drugs over the counter
  – Reliance on pharmacist advice
  – Prescribing for minor ailments
  – Orlistat 1999-2009 UK/EU catching up
Better regulation and the regulators

- Aim to improve competitiveness of UK PLC (World Bank ranking 5th)

- Minimising the burden:
  - Better Regulation Executive
  - Administrative burdens 25% reduction by 2010
  - Hampton compliance reviews
  - Macrory powers
  - Regulators compliance code
Assessment of regulators

- Regulations easily understood, implemented and enforced
- Authoritative and accessible advice on compliance
- No inspection without a reason
- Penalties proportionate to the offence
- Provide information once, not for the sake of it
- Measure outcomes not outputs
- Accountable for efficiency and effectiveness of operation
- Stakeholder perceptions important
Legacy of medicines regulation

Thalidomide – 1960’s

Regulation has grown incrementally over 4 decades

Control of medicines in UK governed by mix of national (Medicines Act 1968) and European regulation
A regulatory mountain...

- Cost of compliance with regulation more than £413m (743m AUD) p.a.

- £211m (381m AUD) p.a. for marketing authorisations/ variations regulations

- 25,000 updates to licences
- 2,500 new licences
- 60,000 side effect reports
BROMI – the beginning

– 2005 Health Minister announced setting up of *Better Regulation of over the counter Medicines Initiative (BROMI)* – later *Better Regulation of Medicines Initiative*

– BROMI established to look at how unnecessary regulatory burdens in relation to medicines could be eased
Stakeholders
BROMI Aims

1. Identify, working with stakeholders, where simplified approach would benefit all and not compromise public safety

2. Improve efficiency of managing minor changes: time taken to approve minor changes costing business money and resources

3. Follow MHRA guidance on BROMI requirements
Prerequisites for BROMI

- Alignment with new, proportionate approach to risk
- OTC market intrinsically lower risk with long-term evidence of any side-effects of ingredients
- PAGB trusted and respected - history of self-regulation
- Already operating code of advertising practice
3 tier approach

1. Full assessment
2. 3rd party approval
3. Self certification

Admin burden reduced
BROMI work streams (1)

- **Patient information work stream**
  - Extending product information self certification to POM sector
  - Developing code of practice on pack design
  - Self certification model for non-statutory package info
  - Review of statutory warnings – comprehensible
  - Variations, copy licences and change of ownership
BROMI work streams (2)

• Authorisation work stream
  – MHRA guidance to market authorisation holders;
  – Industry code of practice on MAH responsibilities regarding quality systems and processes
  – New MHRA audit and complaints procedure - no serious risk found from first batch of notifications
  – Enforcement role on breaches – remove privileges
Change of name
Change of name

Pre BROMI:

- Submit application day 0
- Validated day 5
- Assessed & approved 65% by day 35
- Assessed & questions sent 35% by day 35
- Response received by day 65
- Response assessed & approved 30% by day 95
- Response assessed & refused 5% by day 95

BROMI:

- Submit application day 0
- Validated & valid 80% by day 14
- Validated & invalid 20% by day 14
- Min = 35
- Max = 95 days
- Max = 14 days
Feeling the difference: leaflets

- Self-certification of certain changes to labels and leaflets piloted May 2006, Rolled out to all in Nov. 2006

- Over 1800 notifications

- Fee charged to reflect level of work reduced by 60%
Feeling the difference:
Third party approval

3rd party pre-approval of pack design in compliance with Code of Practice

Approvals issued in 30 days instead of 90 days
BROMI work streams (3)

- **Pharmacovigilance**
  - **ASPRs** – 10,000 less
    Published, literature screening by designated lead; database of ADRs minimise duplication
  - **PSURs** - self cert for substances with established safety profile
  - **DDPs**- no re-submission for simple changes
Industry views (1)

• “We utilised BROMI to take around 10 weeks out of the artwork approval process for some new pack sizes of a Hay fever product. This allowed us to launch these new packs in June during the hay fever season.

• We made a significant profit in those 10 weeks on these new pack sizes which otherwise we would not have made…”
Industry views (2)

“The timings are clear and predictable which allows the factories and the business to plan to implement changes as efficiently as possible so component write off costs can be avoided or reduced…”
Communicating BROMI

- BROMI progress reports
- PAGB newsletter
- DH Simplification Plan
- Seminars and training days
- National business award
BROMI: a success story?

- Proportionate, risk based (application of) regulation brings benefits for all:
  - Regulator can better target internal resources
  - Industry greater predictability and quicker time to market = £100 million; administration costs reduced by 1/3 (£8m); increased ability for stock planning
  - Consumers have updated medicines faster, more timely, safer and cheaper
  - Innovation encouraged and allows companies to be responsive to market needs
Extending BROMI

• Shorthand for risk based assessment of processes

• Next steps:
  – fee processes and costs
  – risk based inspection regime
  – consolidation and review of medicines legislation
  – OTC medicines licenses

• Simplification models also explored in US/EU co-operation discussions

• BROMI: job done? New EU regulation
Challenges (1)

• National focus to date but huge benefits working across EU on common approaches

• Developing sound switch models for P supply – new therapeutic areas and demonstrating the public health benefits

• Implementing the new EU market authorisations regulation
Challenges (2)

• Potentially huge gains but change takes commitment, time, money and resources

• Industry needed to embrace the increased responsibility and changes needed in governance and processes to gain best value

• Stakeholders must work together for all to reap the benefits of the changing self care landscape for the benefit of all