

Better Regulation and Medicines

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Contents

- **Policy and regulatory context**
- **Legacy of medicines regulation**
- **BROMI history and aims**
- **Outcomes**
- **Benefits**
- **Extending BROMI**
- **Challenges**



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



Reports: www.berr.gov.uk/whatwedo/bre/inspection-enforcement/implementing-principles/reviewing-regulators)

Simplification portal: www.betterregulation.gov.uk

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

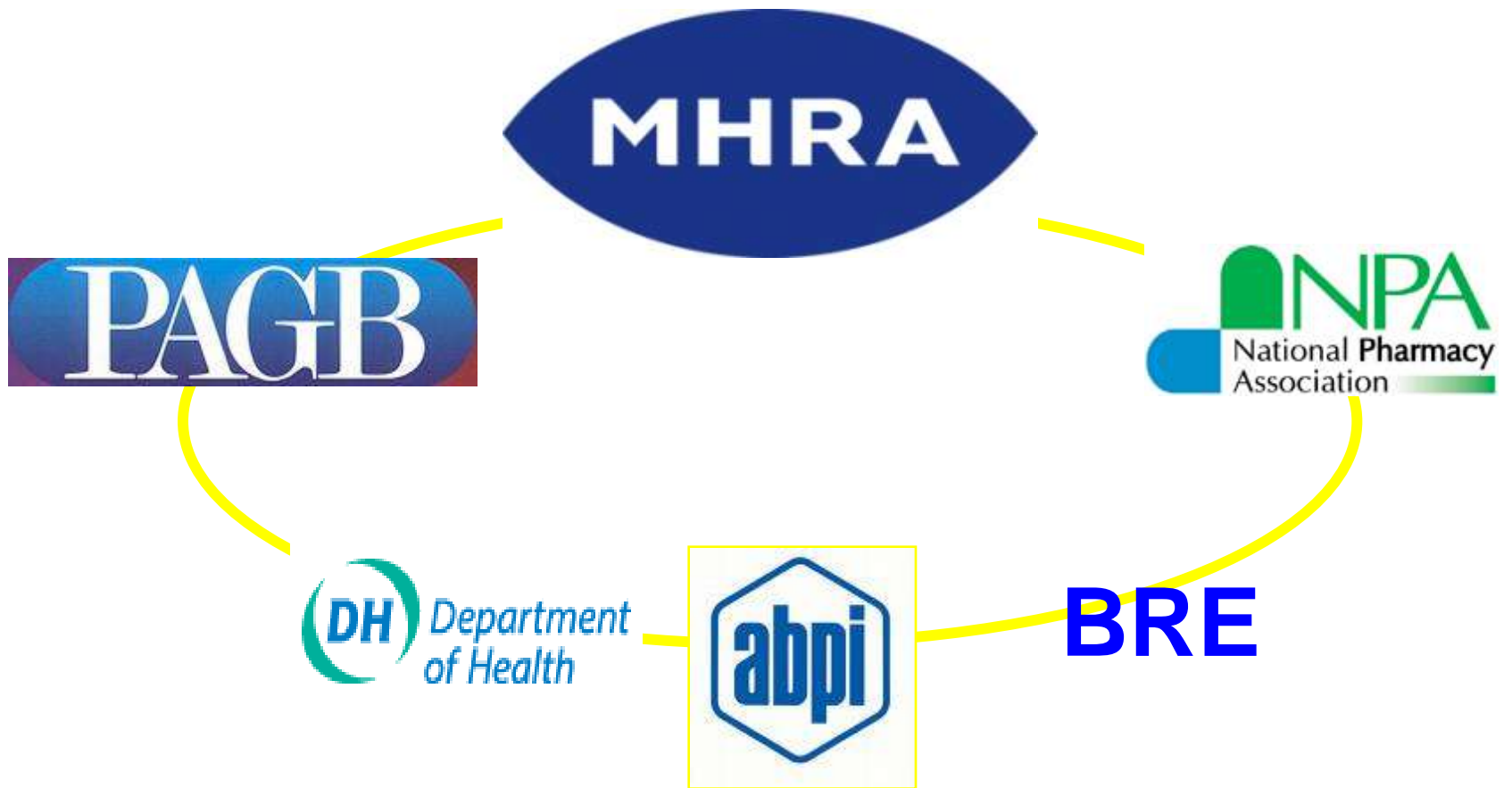


BROMI – the beginning

- 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



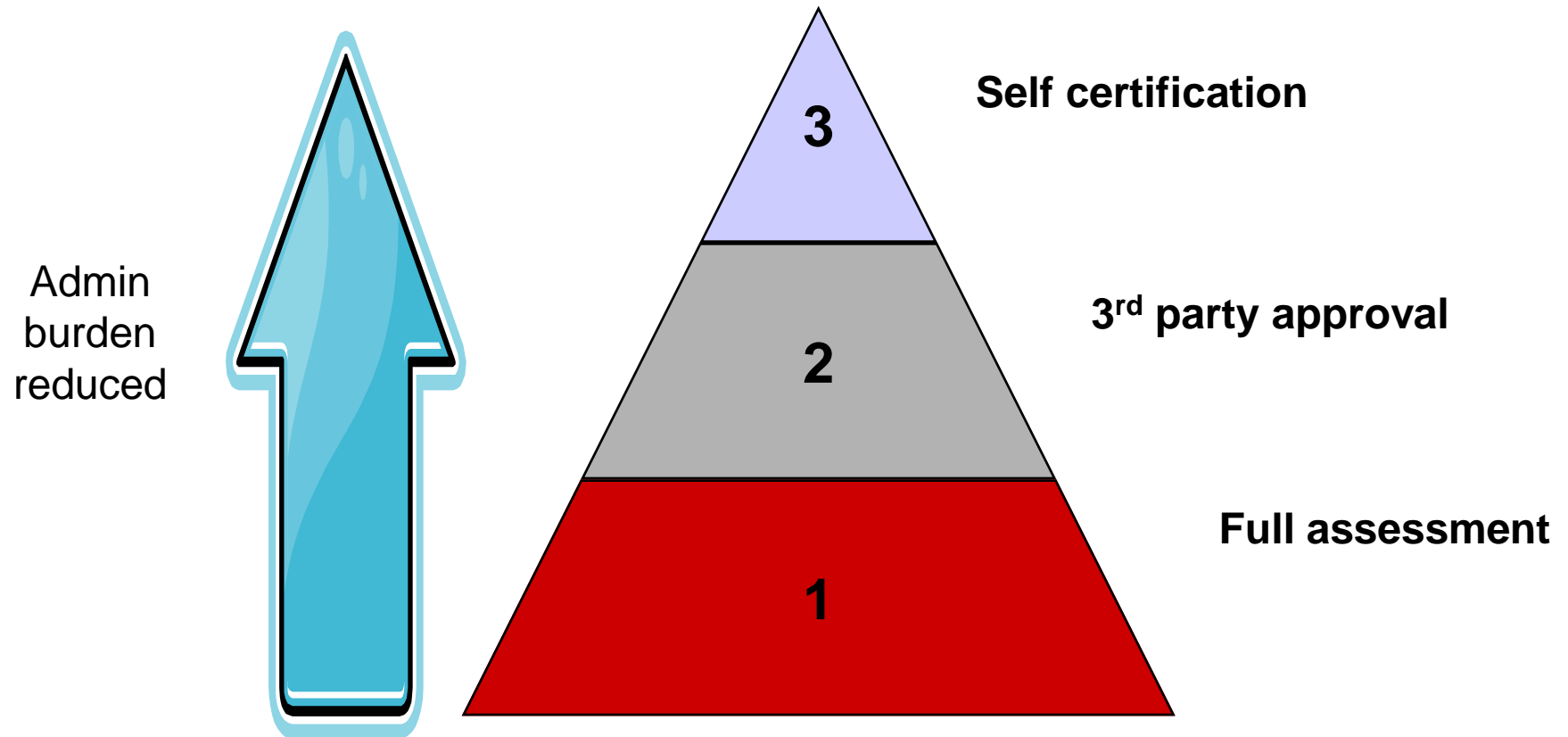
BROMI Aims

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



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

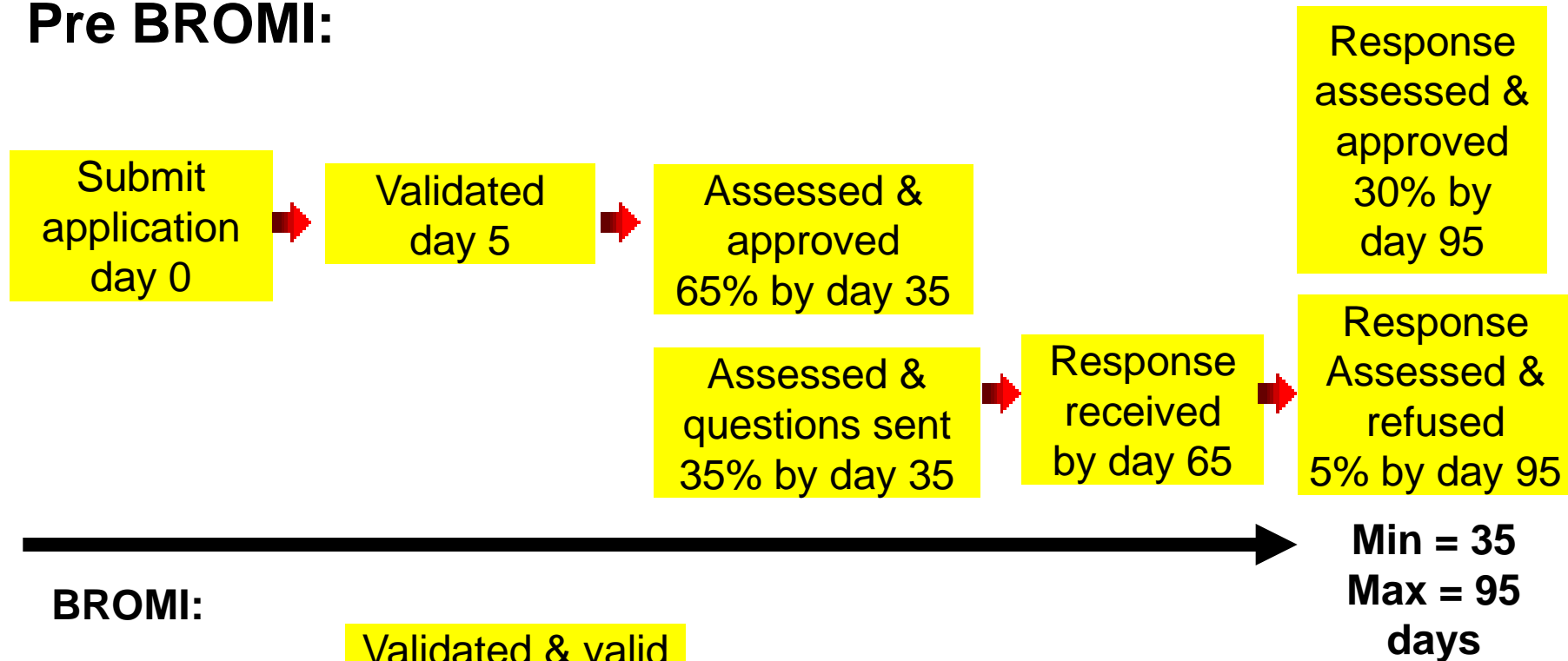


Johnson & Johnson

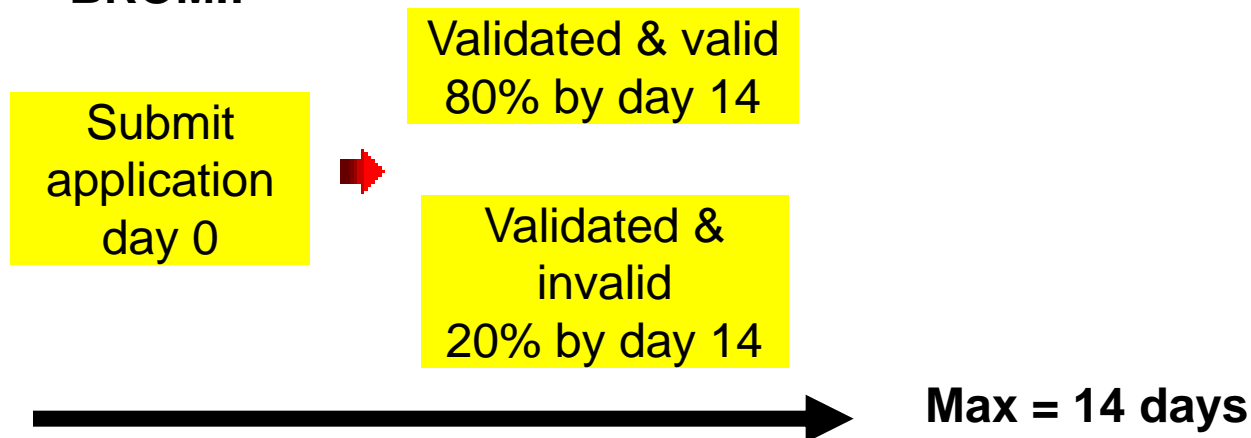


Change of name

Pre BROMI:



BROMI:



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



Focus On...

For a number of years now, our 'Focus On' section is where we have, literally, focused on different members of the Committee and tried to explain what we all do and provide for the membership. We have radically change this, although retaining the title, looking at new regulations, legislation and research deemed important to our everyday work.

BROMI Pharmacovigilance

Article By: Medicines and Healthcare Products Regulatory Agency

Summary

The Better Regulation Of Medicines Initiative (BROMI) is a ground-breaking initiative which is changing medicines regulation from within to deliver new and updated medicines to patients faster. BROMI is a collaborative group comprising industry, government, and health professionals led by the Medicines and Healthcare products Regulatory Agency (MHRA).



Update Report (PSUR) synchronisation scheme has already reduced the burden on MA holders in the production of PSURs. The

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