

Better Regulation and Medicines

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NZSMI Conference, Auckland,
28 October 2010



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Government policy

Stem the flow of new regulation

- Regulation as last resort (behavioural economics etc. self regulation)
- One In One Out

Cull existing regulations:

- ***Your Freedom*** website enables the public to suggest regulations to remove or change
- Departments review regulation e.g. medical research
- Remove regulation after 7 years unless a case can be made



Regulating the Regulator

How regulation is enforced is critical to reducing the burden

Government is asking regulators to explore alternatives to enforcement and recognise industry's own efforts:

- Reduce scale of inspection and monitoring where good independent certification and audit exist
- Give industry responsibility for elements of enforcement in statutory framework (co-production)
- Seek opportunities to replace inspection with industry alternatives

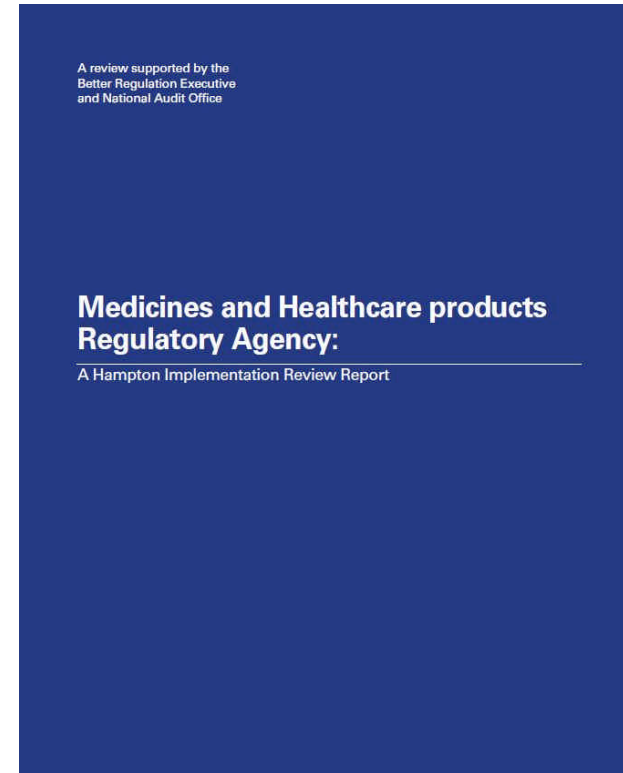


Regulating the regulators (2)

Review the need for a regulator

‘Hampton’ Reviews - Inspecting the Inspectors

- Are regulations easily understood, implemented and enforced?
- Is authoritative and accessible advice on compliance available?
- 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

Roles

- **Department of Health**
 - **Better Regulation Minister**
 - **Board Level Champion** - champion the new approach within DH
 - **Better Regulation Unit (BRU)** – assurance, constructive challenge, cultural change, support Minister
- **Government wide**
 - Business department / Better Regulation Executive /Cabinet Office
 - External validation of costs to business
 - Cabinet Committee challenge



Access to medicines

- **Prescription only**
 - Access to pre licensed medicines – very few
 - Doctor/pharmacist
- **Non-prescription**
 - Pharmacist only
 - Over the counter medicines pharmacy, supermarkets, chain stores -unlike rest of Europe



Medicines policy

- Self care, self medication, 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
 - Switches: Orlistat 1999-2009 UK/EU catching up



Origins of recent medicines regulation

- Thalidomide – 1960's
- Crisis led to change in regulation - grown incrementally over 4 decades
- Now mix of national (Medicines Act, 1968) and increasingly European regulation



A regulatory mountain...

- Cost of compliance with regulation more than £413m (890m NZD) p.a.
- £211m (454m NZD) p.a. for marketing authorisations/ variations regulations
- 25,000 updates to licences
- 2,500 new licences
- 60,000 side effect reports



Impetus for BROMI



2005 *Better Regulation of Over the Counter Medicines Initiative*

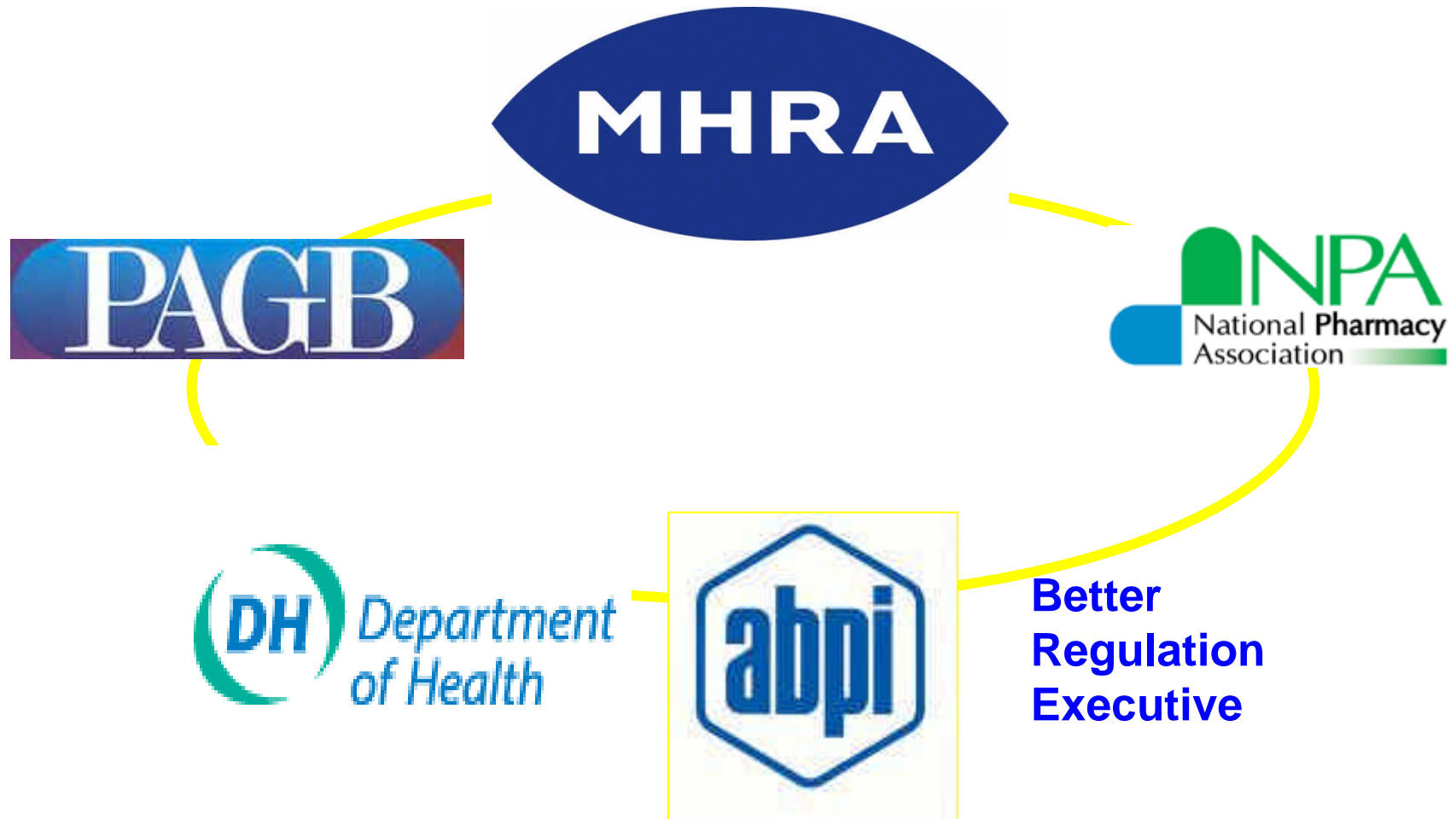
Needed better way to address low risk processes not altering intrinsic nature of the medicine as current regime for non-prescription sector disproportionate

Limited (6000 +) active ingredients well known

Regulator receptive and wanting to change.

Trusted single trade body for the sector – already managing code of practice of advertising practice

BROMI Stakeholders

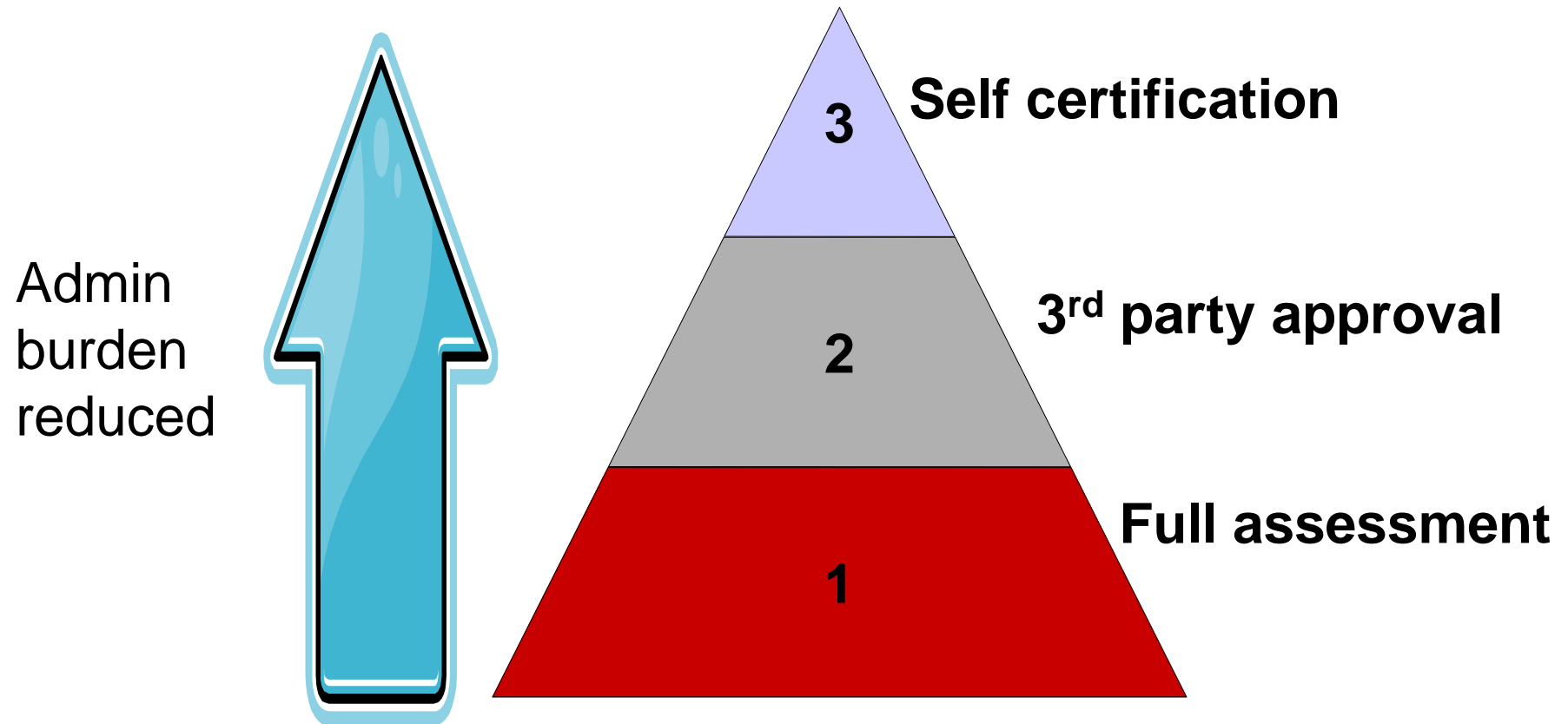


BROMI approach



- Deregulation? Too slow and too expensive
- Able to work in partnership with non-prescription industry to identify where simpler approach would benefit all - not compromise public safety
- Business still needed to follow regulators guidance on BROMI requirements
- BROMI extended to research sector 2008: *Better Regulation of Medicines Initiative*

3 tier approach



BROMI work streams (1)



- **Patient information work stream**
 - Now running for 4 years
 - Extended in 2007/8 product information self certification to prescription only sector
 - New, electronic code of practice on pack design
 - Self certification model for non-statutory package info
 - Review of statutory warnings – make them comprehensible

Some practical examples: Variations



- Now incorporated in the European Variations Directive
- Examples of BROMI type change:
 - Increase in shelf life
 - Adding a measuring device
 - removal / change of ink on capsule shell