

Better Regulation, DH Simplification Plan and BROMI

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8 May 2008



Aims

- Government agenda
- DH Simplification Plan
- BROMI
- Benefits to date
- Challenges for 2008/9

Sea Change 2005 (Ideas)



- **PM wanted to improve competitiveness of UK PLC**
- **Budget announced:**
 - Better Regulation Task Force – *Less is More*
 - Hampton Review of Inspection and Enforcement
- **Risk based approach to regulation and inspection**

Principles of good regulation:

- proportionate, transparent, accountable, consistent, targeted

Better Regulation (Action)

- **Tackling the burden at the centre**
 - Admin Burden measurement and targets; Legislative and Regulatory Reform Act; New Impact Assessment; Davidson
- **Departments held to account**
 - Simplification Plans; Performance assessment for departments
- **A voice for business**
 - Better Regulation Executive (May 2005)
 - Revised code on consultation; New Simplification Portal
- **Changing the way regulation is done**
 - Macrory and Rogers; Local Better Regulation Office
 - Regulatory Enforcement and Sanctions Bill
- **Risk based inspection (Hampton)**

Challenge for MHRA/DH



- **Tradition of trying to reduce burden of 'red tape' for NHS frontline staff**
- **Focus shifted to private sector**
- **Balancing Act**
 - Re-assurance for the citizen
 - Protection, improved standards and dignity for cared for
 - Removal of unnecessary bureaucracy for business
 - Staff want paperwork kept to a minimum, to devote more time to care.
- **Not diminishing, improving accountability for public safety**

Health and Social Care 'Burden'



- £1.2 billion from 90 regulations
- 7 = 85%
- 3 Medicines regulations over 1/4 of total
- DH net 25% reduction target by 2010, includes reducing EU regulation (£300m)
- EU component: 5% non-discretionary, 20% in total

MOST BURDENSOME REGULATIONS



	DH Regulation Title	Total After BAU Reduction £m
1	NMS - Care Homes for Adults 18-65	237
2	Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994	211
3	NMS - Care Homes for Older People	179
4	Medicines Act 1968	150
5	NMS Domiciliary Care	125
6	Medicines (applications for Grant of Product Licences - products for Human Use) Regulations 1993	52
7	Private and Voluntary Health Care (England) Regulations 2001	66
	Other	180
	Total	1,200

BROMI Ticks the Boxes



- “Rules” haven't changed - what has changed is the way in which the regulations are being applied in practice.
- A risk based approach e.g. where change is associated with small or no risk to public health companies have more freedom.
- Assessment can be focussed on those changes which have the potential to impact adversely on patient safety.
- Collaborative partnership – MHRA listening to business - sensible proportionate approach
- Administrative burden savings

BROMI Benefits



- Action proportionate to the problem - benefits all parties:
 - Efficiency gains for MHRA.– refocus resources on critical activities
 - Savings in time, money and hassle - enabling business to be more efficient and competitive at home and abroad
 - Recognise not admin burdens but time to market greatest gain - products reaching the market in quicker time, Savings to the over the counter (OTC) medicines sector estimated at **£100m.**
- Extended to innovative and generic sectors
- Extendible to other areas of MHRA work?
- EU adopting the approach

Simplification Plan



- **Brings together all the better regulation activity aware of, across the DH family, work closely with MHRA and industry**

“The Department is committed to ensuring delivery of its key priorities through better regulation and reducing unnecessary burdens on business, charitable and voluntary sectors and on frontline public sector staff, enabling them to do what they do best, delivering better services and developing world class products.”

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

Delivery of the Plan



- **Channel for policy suggestions from industry and monitor delivery on better regulation agenda**
- **MHRA doing more than share**
- **2006 Plan**
 - Majority from medicines sector (**104m**)
 - BROMI simplification
 - Harmonisation of EU directives:
 - Variations
 - Clinical Trails
 - IT
 - Risk based inspection
- **2007 Plan**
 - Extension of BROMI to ABPI (**12m**)
 - Fundamental Reform of health and adult social care regulation
 - Projected to deliver ABR by 2010
- **2008 Plan**
 - Already collecting ideas and examples for December 2008 Plan

Challenges



- EU context for much of medicines regulation and increasingly health
- MHRA leading on Clinical Trials Directive, Variations—potentially v. large gains (Davidson)
- MHRA working towards culture of Hampton compliance and access to McCrory Powers
- Taking a lead role in moves towards transatlantic simplification

Conclusions

- **Key messages**
 - Success is achieving delivery which people feel on the ground
 - Partnership between government and industry is central to success
 - Risk based approach brings results and tribute to maturity of the sector