



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

MEDICINES AND HEALTHCARE  
PRODUCTS REGULATORY AGENCY



BRITISH GENERIC MANUFACTURERS ASSOCIATION

## MHRA-BGMA-EGA Info Day

20 January 2010

Radisson SAS Hotel  
22 Portman Square, London W1H 7BG, UK

Wednesday 20 January 2010

12:00 Registration and Welcome Buffet Lunch

13:00

### Opening Speeches:

■ **Welcome Speech** | Warwick Smith, Director, BGMA and Beata Stepniewska, Regulatory Affairs Director, EGA

### Session 1 - MHRA as the RMS in the European Procedures

**Chairs** | Paul Fleming, Dr. Reddys for BGMA and Sue Roach, Arrow Generics for EGA

#### ■ **MHRA as the RMS in the European Procedures** | David Hook, MHRA

- MHRA capacity as an RMS
- MHRA actions to ensure capacities fully used
  - Advertisement and allocation of cancelled slots
  - How can the industry ensure that any late availability of slots is used
  - Advice from the MHRA
- MHRA policy on “slot” booking and possible future developments
  - Is the current system effective?
  - How can the industry help the MHRA to make the system even more efficient?
- Completion of the national phase of the procedures
  - Has the new system resulted in better compliance from the industry with the 5 day submission time for final texts?
  - Has there been an increase in PIQ submissions as a result?
  - What are the average times now for MA grant?
- Areas for improvement - dossier completeness, clock stops and common deficiencies
  - Advice for industry on how to make the DCP more efficient for MS?
  - Communication with the MHRA as a RMS during the procedure - what is the MHRA’s advice to the industry?
  - Duplicates, how does the MHRA recommend these are handled?

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- **Electronic working with the MHRA** | *David Wheeler, MHRA*
  - Sentinel upgrade - benefits and impact on ways of working
  - e-CTD - future direction
    - National issues as a non-mandatory part of the e-CTD- possible way of exclusion?
  - Integration with IT systems of other member states

Q&A Session with session speakers

15:15 Coffee Break

15:45 **Session 2 - MHRA view on BROMI and inspections**  
**Chairs** | Paul Fleming, Dr Reddys (for BGMA) and Michel Mikhail, Fresenius-Kabi (for EGA)

- **BROMI - making the most of the work saving opportunities available** | *Mick Foy, MHRA*
  - Brief introduction
  - Pharmacovigilance - literature, PSURS
  - Patient information
- **MHRA Risk Based Inspections** | *Andy Cochrane, MHRA*
  - How companies are scored for different GxPs?
  - Experience since implementation in April 2009
    - Results of the review
  - Specific issues for generic medicines companies:
    - GMP for APIs
    - Pharmacovigilance
    - GCP for bioequivalence studies

Q&A Session with session speakers

18:00 End of Info Day and Networking Cocktail

For further information please visit [www.egagenerics.com](http://www.egagenerics.com)

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