

May, 2013

## BGMA to Stage a Workshop on API Importation Requirements - supported by the MHRA

The British Generic Manufacturers Association (BGMA), with support from the MHRA, will be holding a workshop on Monday, June 10th, to look at the practicalities of the new API importation requirements coming through implementation of the Falsified Medicines Directive from 2 July this year.

The purpose of the event, which will take place at the BGMA's offices near Tower Hill, London between 10am and 4pm, is to provide the latest guidance to regulatory and quality professionals in pharmaceutical companies, particularly QPs.

The session will be designed to help participants understand the new legislative requirements and what is required to be in compliance in their daily decision-making.

The agenda will include:

- Presentations by the MHRA inspectorate
- A Q&A session with the MHRA
- Generic medicines industry worked examples and scenarios from Mark King, a Director of Quality, and member of the QP assessment panel and Mary Browne, Chair of the BGMA Regulatory working group and a manufacturing site Director

To book a space please contact Debbie Fowler at the BGMA by email at <a href="mailto:debbie.fowler@britishgenerics.co.uk">debbie.fowler@britishgenerics.co.uk</a>.

Tickets cost £250 + VAT for BGMA members, £300 + VAT for non -members. The event will include a buffet lunch and refreshments.

Spaces are limited and tickets will only be confirmed on receipt of payment. No refunds will be given for cancellations.

**ENDS** 

For further information contact:

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## Notes for Editors:

The British Generic Manufacturers Association represents the interests of UK-based manufacturers and suppliers of generic medicines and promotes the development and understanding of the generic medicines industry in the United Kingdom.

Generic medicines contain the same active ingredient and are as effective as the equivalent brand and cost much less, making the NHS drugs bill affordable. More than two thirds (68.9%) of all medicines dispensed by the NHS are generics yet they cost only 29% of the NHS drugs bill, a saving of more than £10billion\* in England & Wales alone. Without generics, the NHS drugs bill would be approximately twice its current level. The average cost to the NHS of a generic medicine is £3.79, whilst the average cost of a branded medicine is £19.73. Competition from generics also stimulates the research based pharmaceutical industry to develop new medicines.

Our 25 members account for around 90% of the UK generics market by volume. Their work keeps medicines affordable for the NHS which allows further investment in other healthcare priorities, and promotes innovation in the development of new medicines.

We represent the views and interests of our members and industry to the UK government, the devolved administrations, regulators, other relevant third parties, including where appropriate the Institutions of the European Union.

\* The saving of £10bn per year due to generic competition is based on a calculation of what the NHS drugs bill would be if all prescription medicines cost the NHS the average price of branded drugs, i.e. without the impact of lower priced generic medicines.