BRITISH GENERIC MANUFACTURERS ASSOCIATION

Press Information

March 14th, 2012

BGMA Partners With MHRA to Improve Patient Safety Information

The British Generic Manufacturers Association (BGMA) has completed a ground-breaking partnership project with the MHRA – the UK's medicines regulator - aimed at reducing cost and improving efficiency around communicating important drug safety information to healthcare professionals.

Currently when important new safety information becomes known about a medicine all individual drug manufacturers are required by law to send printed literature to all healthcare professionals - including GPs, nurses and pharmacists.

However, the BGMA, - the representative trade body of the UK generics industry - has successfully completed a breakthrough project involving 12 separate generic companies which were required to communicate information for the diabetic drug Pioglitazone.

The project saw safety information centrally co-ordinated by the BGMA on behalf of the 12 companies which was then approved by the MHRA and sent to healthcare professionals. This meant the regulator was not required to approve 12 separate applications and those receiving the mailings received one set of consistent, clear information.

Michael Cann, BGMA Chairman, said: "Reducing cost, removing unnecessary duplication and improving efficiency is very important in the healthcare industry particularly for those operating within the NHS. This project is a great example of how partnerships between the regulator and provider companies can be very effective in driving through a more streamlined, clearer process which ultimately is good news for patients.

"We see this as the common sense first step towards a more improved system which reduces the workload for the regulator and provides healthcare professionals with greater clarity and consistency over important drug safety information. In the future we would like to improve the system further through greater use of electronic communication."

Director of Vigilance and Risk Management of Medicines at the MHRA, Dr. June Raine said: "This project was part of BROMI programme which introduces new, proportionate approaches to regulation of medicines while ensuring safeguards to protect public health are maintained.

"We are publishing our fifth BROMI report which demonstrates how we can deliver real change in the way we regulate in the UK with benefits to the industry, regulator and healthcare professionals."

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Notes for Editors:

The saving of £9.5bn 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.

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 (67.4%) of all medicines dispensed by the NHS are generics yet they cost only 29.6% of the NHS drugs bill, a saving of around £9.5bn 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 £4.01, 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 22 members account for around 85% of the UK generics market by volume. Their work keeps medicines affordable for the Department of Health 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.