

Wednesday, April 16th, 2014

BGMA partners with MHRA to Launch Quality Forum

The British Generic Manufacturers Association (BGMA) has launched a new forum in conjunction with the MHRA to focus on ensuring the manufacturing quality of generic medicines in the UK.

The new group will meet three times a year to share and discuss the latest issues which impact on the quality of generic medicines. The forum will bring together generic medicines companies, those who provide manufacturing and quality control services, as well as the MHRA. Topics to be covered will include current MHRA approaches to inspection, trends and the auditing that companies perform themselves.

Paul Fleming, the BGMA's Technical Director, said: "As regulatory requirements and supply chains become ever more complex, supporting high quality standards is vitally important for the pharmaceutical industry, patients and the value we deliver to the NHS. From a generic medicines perspective, we wanted to launch something that was closely aligned with the regulator in order to increase mutual understanding as well as share the latest information quickly and easily.

"Quality is a key component in ensuring that patients get their medicines in a timely and affordable manner. Our forum will provide a vital conduit between industry and the regulator on a topic which is critically important to the successful operation of the generic medicines marketplace in the UK, Europe and internationally."

Mark Birse, Group Manager GMDP Inspections at the MHRA said: "We are pleased to support this initiative by the generic medicines industry. We are always keen to share knowledge and expertise so that companies can fully understand the regulatory environment in which they operate. This is key to ensuring that safe and high quality generic medicines are being made and distributed, and provides the trust needed by patients and healthcare professionals to use them. We are also keen to maintain dialogue directly with industry experts who can also provide important feedback and intelligence from their perspective."

Thomas Broeer, Chair of the BGMA, added: "As an industry, we rank quality issues extremely highly and are therefore pleased to be proactively engaging on the topics and challenges which impact them. As an industry association, we have a productive relationship with the regulator and this is another example of how we can work together for the benefit of patients."

The forum will be open to members and associate members of the BGMA and for further information please contact email <u>jeremy.durrant@britishgenerics.co.uk</u>. Full information will also be available on the website <u>www.britishgenerics.co.uk</u>. The first meeting takes place on June 4th, with the second on November 12th.

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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 of all medicines dispensed by the NHS are generics yet they cost only around 29% of the NHS drugs bill, a saving of more than £11billion* in England & Wales alone. Without generics, the NHS drugs bill would be approximately twice its current level.

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.