BRITISH GENERIC MANUFACTURERS ASSOCIATION

December 9th, 2015

BGMA Coordinates Patient Safety Update with MHRA

- **2,600 hospital pharmacies targeted with single set of clear information for patients**

In the largest ever coordinated communication of its type, the British Generic Manufacturers Association (BGMA) has distributed patient information aimed at removing unnecessary duplication and improving impact when contacting pharmacists, GPs and other healthcare professionals about important safety information.

The BGMA - which is the trade association for generic medicines manufacturers – oversaw in liaison with the UK medicines regulator, the MHRA, the distribution of patient reminder cards for zoledronic acid specifically detailing the risks associated with osteonecrosis of the jaw (ONJ).

The updates were on two zoledronic acid products – one with indications for osteoporosis and one for cancer related conditions. Instead of 11 generic manufacturers - who each hold marketing authorisations for the products - sending out individual updates, the BGMA coordinated a single communication which was distributed to 2,600 hospital pharmacies across the UK.

Currently when important new safety information becomes known about a medicine all individual drug manufacturers are required by law to communicate to healthcare professionals. This results in multiple copies of the same information being sent to busy healthcare professionals. The BGMA initiative replaces that with a single high quality communication for generic products.

Paul Fleming, Technical Director of the BGMA, said: "The project saw safety information centrally co-ordinated by the BGMA on behalf of the 11 generic companies which was then approved by the MHRA and sent to healthcare professionals. This meant the regulator was not required to review separate applications and those receiving the mailings received one set of consistent, clear information.

"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."

Sarah Branch, Deputy Director MHRA said: "Removing regulatory duplication and improving the quality of communications to healthcare professionals and patients is an important priority. MHRA hopes that this will pave the way for other similar opportunities."

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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 £13.5billion 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.