

British Biosimilars Association (BBA) launches in UK

• Sector group of the British Generic Manufacturers Association (BGMA) launched to promote vital medicines which increase patient access and will drive further value to the NHS

(London – Monday, April 18th) A new industry body, the British Biosimilars Association (BBA), has been formally launched today with the sole focus of increasing the understanding and use of biosimilar medicines in the UK.

The BBA is the expert sector group of the British Generic Manufacturers Association (BGMA) exclusively focused on biosimilar medicines. BBA members' core focus will be ensuring patients can benefit from these lifesaving and life changing medicines to the same extent as those elsewhere in Europe. Currently, the UK lags behind some European countries in the take-up of biosimilar medicines. Restricting patient access to these medicines costs the NHS money that could be used for other treatments.

Biological medicines are protein based and made or derived from living organisms. They can be tailor made so they bind to specific targets in the body, something that is not possible with conventional medicines. A biosimilar medicine is manufactured to be similar to an existing licensed "reference" biological medicine after expiry of its patent, with no meaningful differences in terms of quality, safety or efficacy.

Currently, there are seven biosimilar molecules on the market in the UK (somatropin, follitropin alfa, filgrastim, infliximab, epotein alfa, insulin glargine and etanercept). However, this is set to increase due to a number of factors including patent expiries, increasing clinical awareness and knowledge as well as supportive guidance from organisations such as the National Institute for Health and Care Excellence (NICE) to generate confidence in using these products.

Keith Ridge, NHS England's Chief Pharmaceutical Officer, said: "We very much welcome the creation of the British Biosimilars Association with its clear focus on providing information about these vitally important medicines. Biosimilar medicines have enormous potential to deliver increased patient access as well as savings to the NHS which can be reinvested elsewhere. It is important that clinicians are aware of their potential and that wherever appropriate biosimilar competition is encouraged. We look forward to continuing to work with the BBA and its members to that end."

Tim de Gavre, Chair of the BBA, said: "Biological medicines are playing a significant role on a global scale in providing effective treatments for patients and contributing to improved survival rates for patients as well as providing better quality of life. These medicines are much larger in size



and complex than traditional small molecule equivalents and are considerably more expensive to develop and manufacture. Therefore biosimilar medicines - equivalents which have no meaningful differences from the reference product in terms of quality, safety or efficacy - have a significant role to play in providing better access for patients, choice for clinicians, driving down cost to the NHS and ultimately improving health outcomes for patients. Biosimilars also have a role in creating budget headroom so that the NHS can afford new and innovative therapies.

"Our role through the BBA is to promote the benefits of these medicines to patients' representatives, healthcare professionals, regulators and payers, to increase understanding and to drive a sustainable environment for the development, production and continuing optimised use of biosimilar medicines across the UK."

Andrew Roberts, vice-Chair of the BBA, added: "Biosimilar medicines are an example of where we can see the future developing already. However, in order for them fully to realise their potential from a patient benefit and savings perspective, policy makers and clinicians need to understand and reflect these developments in their decision making. Without this, the UK risks falling behind the rest of Europe in gaining access to these vital medicines."

Warwick Smith, Director General of the BBA and the BGMA, said: "Biosimilar medicines provide competition by offering choice as well as clinical benefits and cost savings. Benefits may include enhanced delivery mechanisms, and a different value proposition which increases patient access by constraining the costs to the NHS.

"At present, six of the top 10 medicine expenditures by the NHS are on biological drugs. With many more due to come off patent in the next few years, biosimilar medicines offer a real opportunity to increase patient choice and access to this vital class of medicines as well as delivering value to NHS.

"It is vital that the UK maximises the potential offered by the increased use of biosimilar medicines. The cost savings that can be achieved through the use of biosimilar medicines in place of their equivalent less cost-effective originator drugs will release much needed funds to the NHS when budgets are under significant pressure. The BBA's mission is to explain the benefits of biosimilar medicines and thus to promote their use."

Towards, the end of last year, NHS England, in collaboration with industry and regulatory partners, launched a 'What is a biosimilar' briefing. The document provides key clinical and non-clinical stakeholders with accessible information on how to support the appropriate use of all biological medicines, including biosimilar medicines for the benefit of NHS patients. Drawing on NHS, regulatory, professional and industry expertise, the document provides an authoritative source of reference on this complex topic. Elsewhere, national and regional meetings have been held to increase awareness of biosimilars among key audiences. Additionally, NICE has published information on implementing specific biosimilars in the NHS such as infliximab.



The NHS England document "What is a biosimilar medicine?" is available at: http://www.england.nhs.uk/wp-content/uploads/2015/09/biosimilar-guide.pdf

The new association is open to all manufacturers of biosimilar medicines - not just BGMA members - who wish to promote their use in the interests of British patients. The Association's founder members are Accord, Allergan, Boehringer Ingelheim, Napp, Sandoz, and Teva. For further information please visit www.britishbiosimilars.co.uk

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About the BBA

The British Biosimilars Association (BBA) is the expert sector group of the British Generic Manufacturers Association (BGMA) exclusively focused on biosimilars. The members of the BBA ensure access to high quality, safe and effective biosimilar medicines for UK patients. As industry experts, we partner with patients' representatives, healthcare professionals, regulators and payers to increase understanding and to drive a sustainable environment for the development, production and continuing optimised use of biosimilar medicines across the UK.

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