'Industry trade associations join forces to support ground-breaking collaboration with NHS England and other key stakeholders on biosimilar medicines'

The Association of the British Pharmaceutical Industry (ABPI), the UK BioIndustry Association (BIA) and the British Generic Manufacturers Association (BGMA) have joined forces to welcome NHS England's new publication "What is a biosimilar medicine?".

The publication is a result of collaborative working between the Medicines and Healthcare product Regulatory Agency (MHRA), NHS England, National Institute of Health & Care Excellence (NICE), the Royal Pharmaceutical Society (RPS) and the pharmaceutical industry trade associations.

The document is the first collaborative publication on biosimilar medicines at a country level, following the 2013 launch of the European Commission's consensus document, "What you need to know about biosimilar medicinal products".

Biological medicines have revolutionised patient treatment by offering new and effective medicines for acute and chronic conditions including a wide range of inflammatory and autoimmune diseases, neutropenia, cancers, and enzyme or hormone deficiencies.

As originator biological medicines come off patent and more biosimilar medicines become available, it is important that all staff in the NHS with responsibility for commissioning, prescribing, administering, supplying and monitoring all biological medicines, including biosimilar medicines, are given authoritative information to support their successful introduction.

This 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.

Keith Ridge, Chief Pharmaceutical Officer, NHS England, said:

> "As the range of biosimilar medicines increases, it is important that the NHS plans for their timely, appropriate and cost effective introduction. Therefore all staff in the NHS, from senior managers to commissioners, through to front line health professionals need to understand more about biosimilars. I hope the information contained in this document will serve that purpose, and will help ensure the NHS makes the most of these important medicines."

Virginia Acha, Executive Director, Research, Medical and Innovation at the ABPI said:

> "Europe has been leading the global development and regulation of biosimilars for over 10 years. Patients and healthcare systems benefit from additional choices and increased competition which biosimilars in a range of treatment areas can provide. ABPI and its members believe that what we

need now is a process for translating the successful experience of biosimilar development and regulation into the clinical pathway. This NHS publication is a critical step in developing the understanding and awareness to do this - we thank NHS England and all of the contributing organisations for a robust and successful collaboration. We hope that this publication sparks conversation and improves understanding amongst healthcare professionals, patients and all those with an interest in biosimilar medicines."

Steve Bates, CEO of the UK BioIndustry Association, said:

"Over the past decade, the BIA has been engaged with regulators contributing to the development of guidelines to set regulatory standards for the approval of biosimilar medicines, including pharmacovigilance considerations. The BIA and its members have been happy to work in partnership with NHS England and stakeholder organisations on this new document, which we hope will be a useful guide to healthcare professionals and ensure that patient safety remains the primary driver when considering the introduction of biosimilar medicines to the NHS."

Warwick Smith, Director General of the BGMA, said:

"In our view 2015 represents a breakthrough year for biosimilars which have the potential to offer the NHS considerable cost savings, especially as they are often used to treat long-term conditions. This will enable the NHS to treat more patients with these life-changing products.

We strongly support NHS England's efforts to ensure that balanced information and guidance is made available across the NHS to support the appropriate use of the growing number of biosimilar medicines in the best interests of patients."

ENDS

Notes to the editors

A biosimilar medicine is a biological medicine which is highly similar to another biological medicine already licensed for use. It is a biological medicine which has been shown not to have any clinically meaningful differences from the originator biological medicine in terms of quality, safety and efficacy.

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

About the partners

- **The ABPI** represents innovative research-based biopharmaceutical companies, large, medium and small, leading an exciting new era of biosciences in the UK. Our industry, a major contributor to the economy of the UK, brings life-saving and life-enhancing medicines to patients. Our members supply 90 per cent of all medicines used by the NHS, and are

researching and developing over two-thirds of the current medicines pipeline, ensuring that the UK remains at the forefront of helping patients prevent and overcome diseases. The ABPI is recognised by government as the industry body negotiating on behalf of the branded pharmaceutical industry, for statutory consultation requirements including the pricing scheme for medicines in the UK.

- Established over 25 years ago at the infancy of biotechnology, **the BIA** is the trade association for innovative enterprises involved in UK bioscience. Members include emerging and more established bioscience companies; pharmaceutical companies; academic, research and philanthropic organisations; and service providers to the bioscience sector. The BIA represents the interests of its members to a broad section of stakeholders, from government and regulators to patient groups and the media. Our goal is to secure the UK's position as a global hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives.

- The BGMA's Biosimilars expert Sector Group is exclusively focused on biosimilar medicines. Its members 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.

About the programme

The ABPI, BIA and BGMA will continue to work with and alongside NHS England as it pursues its work programme of disseminating further information and understanding around the topic of biosimilar medicines. Most immediately, building on this document, the industry trade associations have joined together to host a press briefing at the Science Media Centre today, 24th September 2015. The aim of the event is to raise awareness among journalists about biosimilar medicines to facilitate better understanding of the topic.