BGMA Associate Membership

Making medicines affordable
Promoting Innovation
November 2011

GENERICS -THE FACTS

- Generic medicines meet the same standards of quality, safety and efficacy as originator brands.
- Generics have to demonstrate that they are bioequivalent to the original product.
- The average cost to the NHS of a branded medicine is £19.73. The average cost of a generic medicine to the NHS is £4.01.
- On one product, based on current usage the generics industry has saved the taxpayer £1.1bn alone.
- According to NHS figures, in 2010 approximately 927 million items were prescribed in England alone. Of the total number of items more than two thirds (67.4 per cent) were dispensed generically which saves the NHS £9.5billion annually, a figure higher than the total drugs bill of £8.2billion.
- In the UK, a free market approach with competition between manufacturers and incentives for GPs to prescribe and pharmacists to dispense generics has led to a high market share for generic products.
- Generic prices in the UK are the lowest in the developed world and are constrained by free market competition.
- The market share that generics reach and the savings they generate are impacted by national legislation and regulation.
- Further growth and NHS savings are constrained by regulatory delays and costs, and the actions of some originator companies in trying to avoid or delay generic competition.
- Competition from generics also stimulates the research based pharmaceutical industry to develop new medicines.

About the BGMA

The British Generic Manufacturers Association (BGMA) represents the interests of United Kingdom based manufacturers and suppliers of generic medicines and promotes the development of the generic medicines industry in the United Kingdom.

We represent the views and interests of our members and industry generally to the UK government, the devolved administrations, regulators, other relevant third parties, including where appropriate the Institutions of the European Union. The BGMA is made up of 21 members of the generic manufacturing industry, who between them account for more than 85% of the total UK market by volume.

The BGMA operates through a series of expert working groups that cover Regulatory Affairs, Economic & Commercial (Pricing, Reimbursement, Market Access, etc), Secondary Care, Sustainability and Biosimilars.

Full members of the BGMA are normally UK based generic manufacturers or suppliers and are companies primarily or solely active as generic medicine manufacturers or suppliers at the manufacturer level of the supply chain.

A key feature of the strong generics industry in the UK is that it introduces competition to the supply of prescription medicines making drugs more affordable to the NHS and enhancing their availability to patients.

About Associate Membership

A new tier of associate membership is available to companies or organisations involved with the wider supply chain of the generics industry. These could include non-generic pharmaceutical companies involved in wholesale, market data, logistics, packaging, professional and financial services as well as management consultancies.

The key benefit of the associate member scheme will be to create regular opportunities for relevant individuals and organisations connected to the generic medicines industry to interact directly with generic manufacturers and the BGMA, and to build relationships. Additionally, associate members will benefit from shared knowledge and understanding which will help further business interests as well as inputting into the future shape and direction of the sector.

The aim of the associate membership scheme is to increase engagement and understanding between relevant industry companies and allow generic manufacturers to share, where appropriate, industry data and expertise, contacts and opportunities for networking.

Key associate benefits

- Weekly political update with an annual value of £7,000.
- Associate Member Forum to drive your interests.
- Web portal with industry information that could aid your business decisions.
- Networking opportunities including a parliamentary reception.
- Annual Business Day.
- Company's details on our website.
- Access to an email list of BGMA members.

Associate members benefits:

a) Copies of the Association's regular Political Update, providing details of parliamentary and public policy activity of interest to the generic industry. These are distributed on a weekly basis and contain the latest industry information from a UK government, regulatory, and EU perspective providing recipients with access to issues which will have a commercial impact on the generics industry. The commercial value of this service is approximately £7,000 per year. An example of the weekly political and regulatory update has been included in the appendix of this document.

b) A quarterly associate membership e-newsletter with updates from the BGMA working groups including regulatory news updates.

c) Membership of the Associate Member Forum, which acts as the interface between full member and associate member activities. This committee represents associate membership interests and drives forward topics of interest to be addressed by the full membership as well as help shape event content.

d) There will also be a web portal on the BGMA website where associate members can seek information on current association policy and responses to Government activity. Additionally, all public BGMA Government and regulatory consultation response documentation will be available to view.

e) A Parliamentary networking reception. Previous attendees at similar BGMA events have included health ministers, health select committee members, shadow ministers and relevant MPs such as those active in the medicines supply chain. This is an opportunity for high-level networking and to discuss relevant topics and industry issues.

f) Two Annual Business Days. These will be conference style events with presentations and seminars around topics impacting the generics industry. This is an unparalleled opportunity to network with key figures across the generic medicines industry and as well as attend, associate members will have the opportunity to have exhibition stands and distribute marketing materials. The event will include a lunch with a relevant industry speaker. A small charge may be applied to attend to cover costs.

g) Your company's details on our website including links to your web pages.

h) Access to an email list of BGMA members.

Fees and Contact Details

Associate members will be charged an annual fee of £5,000 plus VAT to join the BGMA.

To discuss any details of the associate membership scheme further please contact Jeremy Durrant, Communications Director of the BGMA on +44 (0)20 7866 7883 or by email on jeremy.durrant@britishgenerics.co.uk

Indicative Event Calendar

- Annual Business Day – May, 2012
- Parliamentary Reception – October, 2012
- Annual Business Day – November, 2012

Current Full BGMA members

Appendix
Political & Regulatory Bulletin

Pharmaceuticals

Westminster

Lords Debate on Health: Non-communicable Diseases

Lord Crisp (Crossbencher) stated that the WTO agreed in 2001 that in public emergencies, countries could apply for exemption to international patents relating to essential medicines so they could be produced generically.

He said that the EU, US and pharma companies had argued that these rules should also apply to non-communicable diseases (NCDs) and asked the Government for their position on this.

Health Minister, Earl Howe said that access to essential medicines was a priority for the Government.

He said the Government was supporting countries to develop domestic health financing mechanisms to ensure sustainable and long-term funding for cost-effective interventions to tackle NCDs, not just drugs but diagnostics and vaccines as well.

Please click here to view the full debate online

Regulatory

NHS continuing to perform strongly - DH

The Department of Health has published the Quarter 1 report setting out NHS quality and financial performance between April and June 2011. It found that the NHS continues to achieve good results against the majority of key quality standards. Highlights of the report include:

- Primary Care Trusts (PCTs) are estimating they can achieve £5.9 billion savings this financial year. Every penny saved will be reinvested in patient care. This means the NHS is broadly on track to deliver the efficiency savings it needs by 2014/15.
- The NHS made important progress in preparing to modernise, with 257 pathfinder clinical commissioning groups (CCGs) now established, covering 97% of the population and increasingly taking on delegated responsibility from PCT clusters.

Better access to drugs for rare disease patients - DH

Health Secretary, Andrew Lansley MP has announced plans under which the Department of Health will commission expert assessment of the evidence on the use of off-label medicines, including in rare conditions, to inform patients' and doctors' decision-making.

Access to medication is currently limited for patients with rare diseases as drug manufacturers are unable to recruit enough people into clinical trials and generate enough sales to license the drug for use in rare conditions. Similarly, NICE cannot normally appraise drugs outside their licensed indication, which means they cannot be recommended for use on the NHS. Nevertheless, many rare conditions can be treated with drugs outside their licensed indication.

The ABPI commented on the announcement, stating:

> *"Whilst we are supportive of the initiative in principle, it will always be preferable for a medicine to be licensed for the purposes for which it is used and has been subject to the rigorous scrutiny of the regulatory authorities.*
>
> *"The regulatory and licensing system in the UK exists to protect the public, so the circumstances when an unlicensed or off-label medicine is prescribed should continue to be strictly limited to occasions where there is no suitable licensed alternative available and use is in the best interests of the patient concerned."*

Community pharmacists can improve patient care - RPSGB

Giving evidence to the National Assembly for Wales Health and Social Care Committee inquiry into the contribution of community pharmacy, the Royal Pharmaceutical Society in Wales has emphasised that the community pharmacy contractual framework should be better utilised to improve health by allowing community pharmacists to take more responsibility for the pharmaceutical care of patients.

The RPS response to the inquiry acknowledged that the overall policy intent of the Welsh Government was supportive of community pharmacy but noted an emerging gap between intent and action.

The RPS written report recommended that:

- The contractual framework for community pharmacy should be used to ensure greater involvement of community pharmacists in medicines management aspects of patient care.
- Enhanced service developments that incorporate the skills of pharmacist prescribers should be developed to meet the needs of patients and address capacity issues in the NHS.
- Pharmacy services should be developed that aim to improve medicines safety and help people to understand more about their medicines.
- Clinical networks of pharmaceutical care should be developed which facilitate a shift of services from hospital to community settings.

Sam Lister appointed Director of Communication at Department of Health

Sam Lister, Health Editor at The Times, has been appointed as the new Director of Communications at the Department of Health following an open competition under the provisions of the Civil Service Commission's Recruitment Principles.

He is expected to join the Department towards the end of the year.

New online patent inspection service launched - BIS

The Intellectual Property Office (IPO) has launched Ipsum, a free online patent system that will remove the cost to business of requesting patent documents and is expected to save UK business nearly £100,000 a year.

The launch of Ipsum is seen as a step towards implementing the recommendations in the 'Hargreaves Review of Intellectual Property and Growth" which highlighted that patent backlogs could have a negative effect on innovation and growth.

The new service is open to anyone, benefiting businesses researching patents, patent attorneys working for clients protecting their IP rights and potential inventors looking for the best way to find information on patent applications.

European Medicines Agency's Management Board officially appoints Guido Rasi as new Executive Director

The European Medicines Agency's (EMA) Management Board has formally appointed Guido Rasi as the new Executive Director of the Agency. He will take up office on 16 November 2011.

The Management Board also endorsed the Agency's implementation plan for its 'Road map to 2015' that aims to optimise performance in three strategic areas: addressing public-health needs, facilitating access to medicines and optimising the safe and rational use of medicines.

In addition, the Board congratulated the Agency to the increased involvement of patients' and consumers' organisation representatives at all levels of the Agency's work, including more participation of patient experts in scientific advisory group meetings, an increase in the number of Committee for Medicinal Products for Human Use consultations, participation of patient representatives within the Pharmacovigilance Working Party and an enhanced participation in the review of EMA documents, including package leaflets for new medicines prior to authorisation,

The focus during the next two years will be on revising the 'Framework of interaction' which will include the role of patients within the scientific committees, the involvement of patients in benefit/risk evaluation and a strategy for training and support.

European Medicines Agency invites feedback on plans to revise existing guidelines on biosimilar medicines and influenza vaccines

The European Medicines Agency has published two concept papers for a three-month consultation period.

The papers seek stakeholders' views on the need to revise:

- the guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues;
- the series of guidelines in place for influenza vaccines.

Feedback for both concept papers can be submitted until the end of December 2011.

Once all feedback has been reviewed, the Agency will start the revision of the guidelines as appropriate.

Please click here and here to view online

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