BRITISH GENERIC MANUFACTURERS ASSOCIATION

SUSTAINABILITY: GENERICS AND THE NHS

An action plan

1. INTRODUCTION

1.1. BACKGROUND

1.1.1. The pharmaceutical industry in the UK, originator and generic, is amongst the most efficient in the world. The role of generics in driving this efficiency is of great importance. The UK is a prime example of the application of the Bangemann headroom principle: originator drugs receive a period of market exclusivity and appropriate levels of pricing that allow their developers to make a return on their research investment, following which the immediate onset of generic competition reduces the NHS's costs to create the financial headroom that means that it can afford to pay for newly developed drugs.

1.1.2. This virtuous circle has been and is likely to remain at the heart of government policies aimed at promoting research to develop new medicines to deal with unmet clinical need, whist constraining the growth of the drugs bill. Successive governments have created the market conditions for a large market share for the generic industry—currently 67% of all NHS prescription medicines by volume—and amongst the lowest prices in the developed world.

1.1.3. The conditions for the generic industry that create this outcome include low barriers to market entry, a non-branded INN market with automatic interchangeability of different manufacturers' versions of the same product, and freedom of pricing with prices constrained by the very competition that the other market features create.

1.2. BENEFITS OF GENERICS

1.2.1. The high volume, vibrant, competitive, multi-source market that these conditions drive is crucial to maintaining the benefits that generics bring to patients, the NHS and society as a whole. Those benefits include:

i. **Cost containment**: Reduction in price by 90% or more at patent expiry makes the drugs budget affordable. If the average cost of all NHS medicines was to be the average cost of brands, the drugs bill would be more than twice as high as it is.

ii. **Enhanced patient access to treatment**: Reducing the cost of medicines allows more patients to be treated and for new medicines to be funded.

iii. **Promotion of innovation**: Generic competition at patent expiry is a major driver for the originator sector to develop new products that will not face competition for many years: patent protection makes innovation affordable; generic competition makes it commercially essential.

iv. **Enhanced security of supply**: BAPW data show that 91.5% of orders placed by wholesalers for generic medicines are met within 24 hours by the manufacturer first contacted. This compares with 60% of orders for branded medicines. The multi-source nature of the generic market generates resilience.

1.3. NEXT STEPS

1.3.1. Following our paper of 16 December 2010 and our meeting with the Minister (Earl Howe) last year, we have, as the Minister asked, considered with officials those policies which generate the high volume, vibrant, competitive, multi-source market that underpins these benefits and we set out here proposals for work to be undertaken to define how further to maximise those benefits.

1.3.2. We recognise that not all of the policy areas referenced fall within the remit of the Department of Health. Where they do, we propose to progress them with DH; where they do not, we ask that DH facilitates introductions and discussions with the responsible Departments.

2. INTELLECTUAL PROPERTY

2.1. OBJECTIVE

2.1.1. The BGMA supports the effective and proper application of patent law and IPR generally. We seek an intellectual property regime that incentivises true innovation but which neither encourages nor facilitates originators to abuse IPR inappropriately to delay the launch of generic competition.

2.2. GENERAL

2.2.1. BGMA believes that this requires an acknowledgement that additional IPR should not necessarily be the default mechanism for legislators to incentivise pharmaceutical industry behaviour; and that a balance must be struck between the onset of generic competition and period of exclusivity: the more innovative and competitive US originator sector enjoys less IPR than its European counterparts. Cost and benefit and any additional IPR should be proportionate.

2.2.2. Fully to understand this balance, BGMA proposes a joint study by government and industry of the cost / benefit of the Paediatric Regulation as an example; and in the light of the results of that discussion of other means of incentivising behaviour by potentially more proportionate mechanisms. We should be pleased for DH to facilitate this discussion with MHRA and the involvement of BIS and the Intellectual Property Office.

2.3. EVERGREENING

2.3.1. Evergreening disrupts that balance between competition and exclusivity, making it more commercially attractive for originators to extend the exclusivity on their older products than to develop new ones.

2.3.2. We propose a review of the findings of the European Commission Sector Inquiry into the pharmaceutical industry[1] to ensure that, where those findings apply to the UK, any appropriate implementing action has been considered and taken to deal with the deficiencies identified by the European Commission. They identified "*practices [that] can delay generic entry and lead to healthcare systems and consumers paying more than they would otherwise have done for medicines*"[2]. This would be consistent with the findings of the House of Commons Health Select Committee report of March

[1] http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html
[2] http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/fact_sheet_2.pdf

2005 into the influence of the pharmaceutical industry[3] that "*We recommend a systematic review of so-called evergreening and other practices that impede the entry of generic drugs on to the market*"[4].

2.3.3. We propose that the review should make an assessment of the degree to which the actions of HMG and its agencies remedy the market deficiencies identified and make any appropriate recommendations for change. This could be based on benchmarking against the Commission's findings, and a review of examples which we would be able to bring forward.

2.4. PATENT LAW

2.4.1. The European Commission Sector Inquiry identified patent strategies and litigation as sometimes inappropriately delaying the onset of generic competition. Acknowledging some of these issues, the EPO has instituted a "raising the bar" exercise to prevent the granting of weak patents—ie, those that do not properly meet the tests of patentability—and has changed the rules around the granting of divisional patents. This will certainly help for patents issued in the future.

2.4.2. Other issues which we believe have the effect of inappropriately delaying the onset of generic competition are judicial and often national matters which may relate to the enforcement of older patents. We note too that the European Commission is now working on the detailed rules of procedure for the proposed Unified Patent Court. These in part cover similar issues, and we would welcome dialogue with BIS, the IPO and perhaps the Ministry of Justice to ensure that the necessary balance in the enforcement of IPR is created and maintained.

3. EXCLUSIVITY

3.1. The term of exclusive use provided by a patent can be followed on, in some circumstances, by different forms of exclusivity: Supplementary Protection Certificates, data exclusivity, and paediatric exclusivity. The last is an example where the cost and benefit may be disproportionate, and we suggest above than an analysis of this could inform future policy (see 2.2.2 above).

4. REGULATION

4.1. DEVELOPMENT

4.1.1. Since the costs fall on the Member States, the European Commission is frequently less sensitive to the financial impacts of regulation than industry, payers or national governments. This is particularly a concern in the UK because of the efficient nature of the market, and role of the NHS.

4.1.2. We should like to explore with government ways of better progressing the UK's interests in these negotiations, perhaps including earlier and clearer political statements of objectives to condition debate in Brussels, and more effective use of the impact assessment processes by all concerned, including industry.

4.2. IMPLEMENTATION

4.2.1. The MHRA has picked up the Red Tape Challenge with vigour and we propose to raise within that context *inter alia* the various measures raised in earlier discussions. We suggest that the Government adopts these as a benchmark.

[3] http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf
[4] Paragraph 374 of the report.

5. PRICING AND REIMBURSEMENT

5.1. We believe that the current level of generic competition and the operation of the market may be driving prices to an unsustainable level. This is important because of the need for increased investment in the development of more complex generic and biosimilar products in the near future, and to safeguard the essential multi-source nature of the UK generic market and the benefits that that brings.

5.2. To ensure that the industry is able to continue to play its essential societal role in the future, we propose that DH should conduct an analysis of Scheme M returns to show how, over time, the market price of generics has changed, and whether there have been any changes in the number of manufacturers marketing essential products. We propose a joint review by industry and government of these data; the likely impact of any changes observed; and any necessary ameliorating measures. We recognise that industry will have data, eg on the sources of API, that would need to be brought to bear in this review.

5.3. Subject to the outcome of this analysis, we continue to believe that the current Scheme M voluntary agreement provides the basis for an effective generic pricing and reimbursement mechanism. We should, however, like to discuss the scope for improvements in the light of that analysis.

5.4. We maintain dialogue with the four home countries on reimbursement issues; but we should like to note here the potential benefits for security of supply of the adoption of a UK wide reimbursement system, mirroring the scope of the PPRS.

6. PRESCRIBING AND DISPENSING RULES AND ADVICE

6.1. We believe that perhaps 15% of the market that could be generic is not, though there are currently no clear, reliable data. We propose a joint industry / DH study of the true market and methods of maximising generic use. This should be based on IMS and NHS data to give a full picture.

6.2. Misinformation campaigns, often around different indications or originator and generic MAs, which fall short of breaching competition or advertising law and regulations, are an increasing issue. We propose considering them at 2.3.3 above.

7. INDUSTRIAL POLICY

7.1. The generic industry is keen to play its part in the UK's future not only by constraining the NHS's costs, but also as an economic player. The intellectual property legislation that meant that much of the generic and API manufacturing base had to leave Western Europe to remain competitive has been amended. But those businesses that have invested elsewhere are unlikely to return, whilst those that remain here have to demonstrate the commercial advantage in doing so.

7.2. The increasing complexity of supply chains, consolidation of API suppliers, and the increased buying power of our customers all bring new challenges. Against this background, the UK is not an attractive location for generic development and manufacture. But the industry can contribute significantly to the country's economic activity: it is a major employer in some otherwise distressed areas.

7.3. The nascent biosimilars marketplace may offer more significant opportunities. However, it too faces challenges if it is to make the maximum contribution to the UK's economy.

7.4. We propose a discussion with government of the issues which could attract and sustain generic and biosimilar production in the UK; and of the Government's own objectives in this regard.