BRITISH GENERIC MANUFACTURERS ASSOCIATION

Response by the British Generic Manufacturers Association (BGMA) to the Department of Health Consultation on Amendments to the Statutory Scheme to Control the Prices of Branded Health Service Medicines

The British Generic Manufacturers Association (BGMA) represents the interests of UK-based manufacturers and suppliers of generic and biosimilar medicines and promotes the development and understanding of the generic and biosimilars medicines industry in the UK. Our 26 members account for around 90% of the UK generic medicines market by volume.

Generic medicines are launched when the patent on a medicine produced by a research-based pharmaceutical (or originator) company expires. When a patent expires, generic manufacturers can produce equivalent versions that contain the same active ingredient. Generic medicines are tested by the medicines regulator (MHRA) to the same standards of safety and efficacy as the originator product. The high number of generic medicines manufacturers helps ensure that generic medicine prices are much less than those of the originator version under patent protection. Based on data from the NHS Information Centre data, we calculate that the use of generic medicines saved the NHS over £12billion in 2013-14. The average cost to the NHS of a generic medicine is £3.85, whilst the average cost of a branded medicine is £20.22. A 1% swing to generics usage from brand dispensing saves the NHS £160m.

Competition from generic medicines also stimulates the research-based pharmaceutical industry to develop new medicines (as generics capture the bulk of the market after patent expiry). Furthermore, in keeping medicines affordable for the Department of Health, this allows further investment in other healthcare priorities, and promotes innovation in the development of new medicines.

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RESPONSE BY THE BRITISH GENERIC MANUFACTURERS ASSOCIATION (BGMA) TO THE DEPARTMENT OF HEALTH CONSULTATION ON AMENDMENTS TO THE STATUTORY SCHEME TO CONTROL THE PRICES OF BRANDED HEALTH SERVICE MEDICINES

OVERVIEW AND ANALYSIS

We are opposed to an increase in the level of price cut applied to branded generic medicines by the Statutory Scheme because:

- Branded generic medicines are exposed to competition which already delivers far greater savings to the NHS as well as benefits for patients and so should be exempt from any further price cut.
- An enhanced price cut would hamper incremental innovation which leads to improved patient outcomes, and may have the effect of reducing competition, the key lever to reducing medicines prices.
- Any change would create uncertainty for companies, making the UK a less attractive market.
- The proposed change is not supported by clearly established, sound evidence.
- The Department's arguments on the basis of current PPRS planning fails to take into account the effect of future patent expiries reducing the cost of the branded medicines.
- A further price cut could lead to the withdrawal of some products from the market, reducing competition and patient benefits.

THE VALUE OF BRANDED GENERIC MEDICINES FOR PATIENTS AND THE NHS

The majority of branded generic and biosimilar medicines are identified by brand either because it is a requirement of the regulator—the MHRA—or because the product has a patient benefit beyond the common pharmacological effect of the active ingredient and the manufacturer wishes to differentiate the product so that prescribers may choose to access that additional patient benefit.

In each case, the brand is applied in the interests of patient. In the first case, there are some treatment areas, such as anti-epilepsy, where the MHRA requires a product to be marketed under a brand name. Similarly, a brand name is required by the marketing authorisation in the case of prolonged release formulations. This enables prescribers to maintain a patient on a specific manufacturer's brand in cases where small changes in the medicine being prescribed could lead to suboptimal clinical outcomes. In practice, prescribers exercise their clinical judgement and may often choose to prescribe these products by INN. In these cases, branded generic medicines compete with one another in the same way as unbranded generics, resulting in string downward pressure on prices,

In the second case, generic manufacturers will often undertake incremental innovation to enhance the clinical outcome of using the medicine. Innovation is not simply the preserve of companies developing new chemical entities. Indeed, generic medicine manufacturers may develop a new route of administration aimed at improving compliance levels or they may have developed a more effective version than the originator. These deliver improved health outcomes to patients and complement medicines optimisation. So that generic manufacturers, clinicians and patients, can differentiate these products so than prescribers may access that benefit for their patients, they will apply a brand name.

Biosimilar medicines also require a brand name and require significant further research and development investment to produce the product and then significant marketing investment to be able to compete with the originator and drive uptake. The uptake of biosimilars must not be discouraged (such as through additional cuts and pricing uncertainty) as this could deprive the NHS of hundreds of millions in savings and enhanced patient accessibility and benefits.

In these cases, branded generic medicines are operating in a multi-source market where competition applies downward pressure to the price. Indeed, a comparison of the reimbursement prices in the Drug Tariff between branded generic medicines that fall into the Statutory Scheme and reimbursement price of the originator or reference product shows the branded generic costs the NHS on average around 20% less. In addition, the effect of competition will have led to the originator reducing its price from when its product was under patent. As such, competition is already more effective in suppressing the selling price far beyond the maximum additional 10% price cut proposed in the consultation. Further cuts may question the viability of supply.

As such, if the Government does indeed opt to impose or establish the right to trigger a second reduction in prices, branded generic medicines should be exempt since they are exposed to competition which has already delivered far greater savings to the NHS.

We believe the annual market value for branded generics is in the range of £120m – £150m per year, though we note that only a small proportion is supplied by companies that fall within the statutory scheme.

HAMPERING INCREMENTAL INNOVATION WHICH LEADS TO IMPROVED PATIENT OUTCOMES

Uncertainty and reduced opportunity for making a sustainable return makes it more difficult for manufacturers to invest in innovation. Manufacturers of generic medicines carry out research and development on existing molecules to improve the concordance and efficacy of existing drugs. Companies invest – and apply a brand name to differentiate their generic version – because they could realise an increase in selling prices to the NHS where prescribers are persuaded of the patient benefits. They are less likely to undertake this work if they will or are likely to face an increase in the statutory scheme price cut.

It is important for the improvement of patient outcomes that this incremental innovation on single – and combination – products takes place. Indeed, as the generic medicines industry moves to develop and supply more complex molecules, in particular biosimilars, development of these medicines will cost more and confidence about future pricing ability will become even more important. Though their efforts are innovative, delivering enhanced patient outcomes, because these products are not NCEs (New Chemical Entities), they are subject to the price cut whereas NCEs resulting from innovation are not. This different approach does not reflect patient benefit derived from incremental innovation.

CREATING UNCERTAINTY FOR COMPANIES

We believe that the proposed amendments to the Statutory Scheme are disproportionate and contrary to expectation, serving to create uncertainty for medicines manufacturers. After bringing forward regulations to reduce prices by 15% to take effect at the start of this year, the proposals to allow for another price cut at some point in time will diminish the UK's reputation as a reliable partner for investment.

Many suppliers entered the statutory scheme for predictability so that they would know how much they would pay as part of DH limiting maximum selling prices, as opposed to the less predictable PPRS Payment system. However, further changes to the statutory scheme undermine this predictability.

The consultation wording allows for the flexibility for a 10% price cut at a yet-to-be-determined point in the future. Simply by establishing the right for Government to levy a further cut will create uncertainty for suppliers when trying to predict future market conditions and taking investment decisions.

PROPOSED CHANGES ARE UNDERPINNED BY EVIDENCE THAT IS NOT CLEARLY ESTABLISHED

The current PPRS set out a pricing regime for a five year period. Whilst PPRS sales have been in excess of the limit for the first two quarters, we question whether this is a long enough period of time to be able to form a clear view on the future level of the PPRS rebate.

PPRS MAY NOT TAKE INTO ACCOUNT FUTURE PATENT EXPIRIES

We question whether the PPRS Payment will rise beyond the equivalent of 15% of statutory scheme members' sales levels. Neither the consultation, nor the impact assessment, lay out clear cost comparison figures.

We also note that there are a number of products currently under patent which will lose their protection during the PPRS period. As such, prices will fall due to these products' "genericisation". We are not sure whether this has been calculated as part of the PPRS period forecasting as part of this consultation. It is crucial that the effect of generic competition at patent expiry is taken into account since it is the major driver for both innovation and cost containment.

CHANGES TO THE STATUTORY SCHEME COULD LEAD TO THE WITHDRAWAL OF SOME PRODUCTS FROM THE MARKET

For branded generic medicines that are already subject to the downward pressure of competition, an additional price cut, when taken with a growing number of regulations affecting the industry (EU API import requirement being just one), could lead to companies taking commercial decisions to withdraw from the market. This would damage competition, the central pressure point on the price of off-patent drugs.

PRICE ADJUSTMENT – COMMENT ON THE PROPOSED OPTIONS

1. COMMENTS ARE INVITED ON THE RANGE OF POTENTIAL PRICE ADJUSTMENTS

Whilst we appreciate the Department's need to control the NHS medicines budget, the Association considers conferring additional powers on the DH to limit the maximum price of medicines (supplied to the NHS starting prior to 1 December 2013) through the statutory scheme to be disproportionate and counterproductive.

The Association considers that it would be a huge and unprecedented challenge for manufacturers to accept an additional 10% decrease, on top of the 15% already secured from 1 January 2014 as a result of the 2013 Regulations. The consultation wording seems to allow for the flexibility for a 10% price cut at a yet-to-be-determined point in the future. Simply by establishing the right for Government to levy a further limit will create uncertainty for suppliers when trying to predict future market conditions.

ALIGNMENT WITH PPRS AND EFFECT ON THE PPRS

The Department aims to ensure the statutory scheme is in 'broad alliance with PPRS'… 'so that the price cut reflects at a minimum the level the companies would otherwise have paid in the PPRS'.

Under the proposals, the statutory scheme would appear to be being made more onerous than the PPRS with which to comply. Indeed, we question whether the projected PPRS payment will rise beyond 15% of suppliers' sales in the statutory scheme. The impact assessment does not seem to set out the quantifiable differences between the PPRS (projected rebate) and the statutory scheme.

Furthermore, the desire of the Department to increase price cuts to the statutory scheme seems - from the factors set out - to have been based just on two financial quarters of financial information (PPRS forecast growth vs actual rate in Q1 - Q2 this year: 3.87% to 5.5%). We question whether the evidence base is strong enough to impose a second round of price limits on the basis of this short period of growth. We understand that growth in medicines this year can be attributed to NHS specialised commissioning and the Cancer Drugs Fund, functions of government policy as much as companies pursuing commercial decisions. There will also be a number of drugs within the PPRS coming off patent over the period of the voluntary scheme's operation. Can DH be sure that this rebate growth trend will continue?

It is quite possible that making the statutory scheme more onerous will shift more suppliers into the PPRS – thereby destabilising the voluntary scheme, and affecting members of that scheme (by asking them to pay more in the rebate than was envisaged). Such a move would actually force up the costs of being in the PPRS, as opposed to aligning the statutory scheme with the PPRS.

The consultation document notes that DH is concerned about companies leaving the PPRS unless it makes the statutory scheme more stringent. To our knowledge, only one manufacturer has left the PPRS to join the statutory scheme. Indeed, it may be that some suppliers may have left the PPRS because they have deliberately de-branded generic medicines. These questions affect the viability of the impact assessment.

THE EFFECT ON BRANDED GENERICS

A further price cut will have a particularly negative effect on branded generics. Branded generics – unlike pharmaceuticals under patent – are already subject to the downward price pressure of competition, and as such, we believe further price controls are disproportionate.

Indeed, looking at the Association's Members who supply branded generics under the statutory scheme, the average reduction in their branded generics' tariff price compared to the originator's is around 20%, even before any discounts to pharmacy are taken into account. This does not take into account that the originator's price will have fallen as a result of competition.

Given the effect of competition on lowering prices far beyond the 10% maximum proposed limit quoted in the consultation, we call for branded generics to be exempted from this second price cut. Additionally, a further cut in the price of branded generics, when taken with increasing regulatory burdens, could make launching branded generics or maintaining existing ones less attractive.

Notably, innovation is not purely to be found in developing new chemical entities; incremental innovation plays an important role in improving patient outcomes on existing medicines. Yet, a second maximum selling price limit imposed on branded generics would discourage incremental innovation. Incremental innovation may include developing a new administration for example, which would then be marketed with a brand name, in order to increase concordance. Firms are less likely to focus on how the originator version can be improved upon if they could face a limit of up to 25% off their maximum selling prices imposed on their branded generics.

2. We welcome views on the above factors and any other considerations the Government should take into account when considering whether and to what extent further limits on the cost of branded health service medicines should be applied, for example the impact that any price adjustment might have on companies that are close to the £5m exemption threshold.

Longer term impacts on the UK's reputation as a place to do business

The uncertainty created by DH's proposed adjustments to the statutory scheme so soon after pricing arrangements were agreed in 2013 is likely to undermine the UK Government's reputation as a reliable partner for industry. This has much wider consequences about the UK's reputation as a life sciences centre, companies' willingness to invest in innovation, and launch and maintain medicines in the UK.

As noted, the generic medicines industry undertakes incremental innovation to improve the efficacy of or concordance with a product that has come off patent. Companies invest in this – and apply a brand name to differentiate their generic version – because they could realise a reasonable margin which potentially allows them to support the NHS by informing prescribers, and payers, of the benefits. They are less likely to undertake this work if they will or are likely to face an increased price cut through the statutory scheme. Suppliers of branded generics also include those that have had to apply a brand name to a generic because it is required by MHRA. They also risk facing an enhanced price limit when they have had no option but to deploy an invented name in order to get onto the market.

More widely, the generic medicines industry is having to spend more money to develop more complex products that are due to lose their patent protection. This is particularly the case for biosimilar medicines. Derived from living organisms, and whilst being more expensive than 'traditional generics', they offer very significant savings from the originator biopharmaceutical product. Owing to the increasing levels of investment required to bring a biosimilar to market (estimated at $150 - $250m vs $2 - 3m for a generic), it is even more important that companies are able to operate with pricing certainty.

Moving on from research and development investment, marketing investment must not be overlooked. In the UK, biosimilars companies manufacturing biosimilars will fall into the PPRS or statutory scheme; they will have to compete with the originator company products in order to take market share. An excellent example is human growth hormone (hGH) where providing product choice is central to NICE guidance on hGH.

In the UK, the hGH biosimilar is 18-57% cheaper than the originator products, but these savings for the NHS can only be realised by informing nurses and physicians of the benefits of the biosimilar (and the fact that it will have passed all regulatory checks). This requires marketing investment that will be reduced if the biosimilar is forced to take an additional price cut. Reduced investment means reduced growth of a lower priced produce and reduced savings to the NHS. Ultimately, this price cut to biosimilars will cost the NHS money.

Price adjustment on companies around the threshold

We oppose the proposed cuts, irrespective of the size of a company's sales to the NHS. However, looking specifically at the threshold figure, under these proposals, a company with just over £5m of annual sales to the NHS could receive 25% less than a company with sales under £5m.

Our suggestion would be that the current £5m threshold is complemented with a provision that companies over the £5m threshold but which offer low value unit sales prices under a certain amount continue to be exempt from the mandatory price cuts.

OTHER ISSUES

We note that the UK pricing system is used as a reference price in other countries. Manufacturers supplying on an international level may be reluctant to remain in the UK market when it helps suppress their prices in other jurisdictions.

STRENGTHENING THE INFORMATION REQUIREMENTS FOR ENFORCEMENT

3. SHOULD MANUFACTURERS AND SUPPLIERS BE REQUIRED TO RECORD AND KEEP INFORMATION ON ACTUAL SELLING PRICES OF BRANDED HEALTH SERVICE MEDICINES IN ORDER TO STRENGTHEN THE DEPARTMENT'S ABILITY TO ENFORCE THE SCHEME WHERE NECESSARY AND SUPPORT A FAIR AND CONSISTENT APPLICATION WHEN NECESSARY?

The Association is unsure of the Department's motives for seeking additional information. The current statutory scheme has reporting requirements where gross and net sales are made available.

Whilst selling prices could pinpoint when manufacturers are selling above list price, we consider that this would require more work from all parties to clamp down on what must be a very limited number of cases. As such, we are not clear why the Department is seeking this information. Indeed, we note that the Department currently enters into a bilateral dialogue where it has concerns.

However, if Department does indeed require more information to follow up with specific cases of suspected non-compliance, we support DH being able to ask for these additional details, such as selling prices. However, this information should only be required of specific suppliers in certain instances and the regulations should set out criteria for doing so.

4. DO YOU AGREE THAT MANUFACTURERS AND SUPPLIERS ALREADY RECORD THIS INFORMATION?

From our understanding, suppliers do record selling prices, but it would place considerable extra effort for companies to report these on an on-going basis. In addition, in order to distinguish sales into different channels e.g. hospital, retail, dispensing doctors, etc, information will be required from wholesalers as well as from the manufacturer.

5. Do you agree that manufacturers and suppliers should be required to supply this information on demand? If you have concerns regarding administrative burden, it would be helpful if you could provide a realistic level of costs for supplying the information.

The widespread supply of additional information is considered disproportionate of itself; and does not appear in the interests of protecting the public purse. Requiring the information in specific cases, where DH has clear reasons for doing so, might be a better, more proportionate way than requiring the information in all cases.

6. Do you agree that penalties should be applied to these new information requirements?

No.

Other Comments

7. Do you have any other comments about the consultation proposals?

Any changes should not take precedence over existing contracts or agreements to supply medicines in secondary care which were made using information available at the time.