BGMA note on existing process by which Government scrutinises and may regulate generic prices

1. Normally the prices for generic medicines are controlled by competition between manufacturers and respond to supply and demand to keep the market supplied in full. Generic medicines prescribed through the NHS and dispensed by a community pharmacy in England account for roughly 80%[1] of the volume of medicines in primary care at 40% of the cost[2] of the primary care drugs bill.

2. Generic competition is effective at keeping prices low: it saves the NHS over £18bn a year[3] or 11%[4] of the NHS's entire annual operating budget. Oxera compared the actual manufacturer selling prices of generics in the UK to a number of European countries and found that UK prices were on average consistently the lowest over a multi-year period[5].

<u>Government recognition that generic competition works</u>

3. NHS primary care prescribed unbranded generics[6] are regulated by competitive pressure, which in addition to delivering significant savings, also provide security of supply through a multi-source market. The Department of Health and Social Care has not commented much in recent years on the pricing of generic medicines. Where it has, it has affirmed that this model works successfully:

> "Where unbranded generic medicines can enter the market, the Department's view is that effective competition between manufacturers/suppliers acts as an effective means of cost control, ensuring NHS patients have access to crucial medicines at a price which balances the need to secure best value for the NHS with the need to ensure the reliable availability of high quality products.
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> "The Department recognises that allowing freedom of pricing encourages competition, leads to quicker entry to market and has led to the UK paying some of the lowest prices in Europe for unbranded generic medicines.

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[1] Table 5, excluding data on dressings and appliances, Prescription Cost Analysis, NHS BSA, June 2024; https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fnhsbsa-opendata.s3.eu-west-2.amazonaws.com%2Fpca%2Fpca_additional_tables_2023_24_v001.xlsx&wdOrigin=BROWSELINK; https://media.nhsbsa.nhs.uk/news/nhs-launches-latest-report-on-prescribing-costs

[2] Note that this is the reimbursement cost, which includes the pharmacy margin and distribution costs. Oxera found that on average, roughly half of the reimbursement price accounted for the manufacturer selling price. *"The supply of generic medicines in the UK"*, Oxera, 2019.

[3] Based on every script was being fulfilled and reimbursed at the average brand price. Prescription Cost Analysis, NHS BSA, June 2024: https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fnhsbsa-opendata.s3.eu-west-2.amazonaws.com%2Fpca%2Fpca_additional_tables_2023_24_v001.xlsx&wdOrigin=BROWSELINK; https://media.nhsbsa.nhs.uk/news/nhs-launches-latest-report-on-prescribing-costs

[4] £18bn is 11% of the NHS England budget for 2024/25, £162.5bn; https://assets.publishing.service.gov.uk/media/6568909c5936bb00133167cc/E02982473_Autumn_Statement_Nov_23_Accessible_Final.pdf

[5] "*The supply of generic medicines in the UK*", Oxera, 2019.

[6] Secondary care medicines are nearly exclusively procured through NHS tenders, and branded medicines supplied to either primary or secondary care have their maximum selling price approved by DHSC. An unbranded generic is a generic presentation where the licence does not carry a specific brand name, nor is it marketed with a brand name. Branded generics, biosimilars and originator licensed medicines do carry a brand name to differentiate the product for clinical and/or commercial reasons.

"…The Department is committed to allowing freedom of pricing for unbranded generic medicines where there is effective competition. This means that the Department will allow any changes in market prices to be influenced by existing market mechanisms and that where there is effective competition the Department will not interfere in the operation of the market. What effective competition means will need to be judged on a case by-case basis[7]".

Most recently, DHSC has stated:

"For unbranded (medicines), also known as generic medicines, DHSC relies on competition to keep prices down which has led to some of the lowest prices in Europe. At the same time we have relatively resilient supply. This allows prices to react to the market. For example, in an international market, this ensures that when demand is high and supply is low, prices in the UK can increase to help secure the availability of medicines for UK patients[8]".

4. From time to time, there are cases where supply shocks or product innovation may cause a lack of competition. This can include the company that originally invented the product having left the market. Such instances of a lack of competition are often temporary.

<u>Existing system of Government price scrutiny and control powers</u>

5. Underpinning this system of price regulation based on competition is an established process of scrutiny performed by DHSC covering the entire supply chain for all NHS-prescribed unbranded generic medicines in primary care. The Government's powers are enshrined in law[9] and it has powers to set prices[10]. DHSC legally requires manufacturers, as well as others in the supply chain, such as wholesalers and pharmacies, to provide volumes and prices for all generic medicines sales on a quarterly basis.

6. Where DHSC wishes to scrutinise prices charged in the supply chain for a presentation, it is BGMA's understanding based on the DHSC's consultation response[11] preceding the secondary legislation – which gave full effect to the statutory provision of information by companies to Government – that DHSC may have "regard to a range of factors when deciding whether to control the price which may be charged by any manufacturer or supplier for the supply of an unbranded generic medicine". The DHSC consultation response noted that the range of factors included:

- "The direct and indirect costs associated with the medicine.
- The pricing history of the medicine.
- The price of the medicine elsewhere.
- The volume of use.
- Any regulatory requirements.
- Any investments in and innovation of the medicine.
- An appropriate margin for manufacturers and suppliers including wholesalers."

[7] "*Legal requirements to provide information about health service products*", a consultation response by the DHSC, June 2018.
[8] A DHSC response to a public petition that achieved over 10,000 signatures calling for a national UK manufacturer of essential, off-patent, generic medicines within the NHS, December 2021.
[9] The Health Services Medical Supplies (Costs) Act 2017; The Health Service Products (Provision and Disclosure of Information) Regulations 2018.
[10] Section 262, NHS Act 2006.
[11] "*Legal requirements to provide information about health service products*", a consultation response by the DHSC, June 2018.

7. The DHSC consultation response did not go into detail about how these factors may be measured. However, noting that each medicine market will likely have their own unique characteristics, DHSC – and indeed companies – may use a number of the following measurements where available:

    - Prices for the originator product approved by DHSC, adjusted for inflation since approval.
    - Prices for similar branded products approved by DHSC, adjusted for inflation since approval.
    - Prices for products in similar therapeutic areas offering a similar economic value approved by DHSC, adjusted for inflation since approval.
    - Prices approved by NICE for similar clinical outcomes.

8. It is worth noting that prior to DHSC putting the provision of volumes and sales data on a statutory putting, a number of manufacturers supplied this information on a voluntary basis through Scheme M[12], with the data used by DHSC to inform the setting of reimbursement prices. Scheme M ceased on 30 June 2019. While clearly historic, it noted that "in its examination of the reasonableness of a Scheme (M) member's costs and prices, the Department would have regard to factors such as the following":

    - "Trends in previous prices reported by the Scheme member and other companies for the same product.
    - Any special features of the Scheme member's operation with particular reference to any integration of a Scheme member with any wholesalers and/or pharmacists and any associated transfer prices.
    - Any ratios inferred from the Scheme member's non-generics business.
    - Each Scheme member's reported costs and profit margins and the average of other similar companies.
    - Information from external sources that relate to the generics industry across companies".

9. The DHSC may informally approach a manufacturer to understand its justification and seek supporting evidence for the selling price charged for a particular product or presentation.

10. Where a manufacturer wishes to continue to sell its product at the initial level charged and DHSC has concerns with this, (or where DHSC does not wish to make an informal request), then DHSC is able to make a formal information request under the Health Medical Supplies (Costs) Act. Following a formal request, the provision of information under this formal request and the ensuing discussions between DHSC and the manufacturer, the Secretary of State may use his or her powers to set the price of the product that can be charged[13].

11. It is also understood by BGMA that the Competition and Markets Authority may choose to initiate investigations separate to this DHSC scrutiny process to assure itself that the taxpayer is getting value for money. In doing so, the CMA may choose to assess potential excessive pricing using different models and measures, and companies will also need to be mindful of this.

[12] "*Revised long-term arrangements for reimbursement of generic medicines, Scheme M*", March 2010.
[13] Section 262, NHS Act 2006.