Lewis Macdonald MSP
Convener of the Health and Sport Committee
Scottish Parliament
Edinburgh EH99 1SP

24th February 2020

Dear Mr Macdonald,

Health and Sport Committee – Supply and Demand for Medicines

Thank you for providing NHS National Services Scotland with the opportunity to input into the Health and Sport Committee inquiry into the supply and demand for medicines in Scotland.

International Comparisons of Generic Medicine Prices

The committee asked for more information on international comparisons that have been undertaken on generic medicine prices.

There are methodological challenges associated with undertaking price comparisons for pharmaceuticals, for example managing the risk of sample selection bias, ensuring appropriate use of exchange rates or purchasing power parities for currency conversion and ensuring that the pricing information used is representative given differences in market characteristics across countries. Whilst the results of individual studies need to be interpreted in this context, generally recent studies from different authors using different methodological approaches have indicated that the UK is performing comparatively well.

Recent studies include:

- A 2019 independent report compiled by the economics consulting company, Oxera[1] that was funded by the British Generic Manufacturers Association (BGMA). This compared ex-factory gate prices of generic medicines across five European countries and found that prices in the UK were generally lower than the other countries studied.
- A 2017 report by the London School of Economics and Political Science[2] compared prices of 200 off-patent medicines in 13 European countries. The study found that UK ex-manufacturer prices were significantly lower than all other countries surveyed however the

[1] Oxera Consulting LLP, 2019. The supply of generic medicines in the UK. A study by Oxera - Prepared for The British Generic Manufacturers Association. Available online.

[2] Wouters OJ, Kanavos PG, McKee M, 2017. Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending. Millbank Quarterly. Sep;95(3):554-601. (link)

authors cautioned that there was a risk of bias linked to the representativeness of the products reviewed.

- In October 2019 at the 'PreP [HIV Pre-Exposure Prophylaxis] in Europe' summit in Warsaw, an analyst from the European Centre for Disease Prevention and Control (ECDC) presented comparative pricing information for the HIV treatment and prevention medicine, tenofovir disoproxil with emtricitabine from 23 countries in Europe and central Asia. Whilst prices in individual countries were anonymised due to confidentiality restrictions, the price in effect in Scotland was in the lower quartile of reported prices.

Tendering for the Supply of Primary Care Dispensed Medicines

The committee asked for more information on the NHS National Services Scotland view that there is not currently a strong case for moving to central procurement of all primary care dispensed medicines at this time and specifically, the reason for this given the context of the NHS reimbursing pharmacies more than the medicine purchase price.

Where a medicine is prescribed by generic name, the focus of price competition is the community pharmacy sourcing decision; community pharmacies have freedom to purchase from any supplier and can respond quickly to changes in market circumstance, for example the entry of a new supplier offering a lower price.

The NHS reimburses pharmacies for medicines dispensed at a price higher than the cost to the pharmacy of purchasing the product (as illustrated in figure 1); this is by design and a key reason for the effectiveness of the current arrangements. Community pharmacies retain the difference between the pharmacy purchase price for a medicine and the fixed Drug Tariff reimbursement price; this incentivises pharmacies to source medicines at the lowest available prices which creates the price competition that drives down prices being charged by wholesalers and manufacturers.

Figure 1: The Anatomy of a Generic Medicine Price

Pharmacy purchasers range from individual independent pharmacies to large pharmacy chains. Pharmacies can boost their buying power by aggregating their demand through buying groups; there are numerous buying groups operating within the UK.

The margin retained by pharmacies forms part of the core funding for the community pharmacy service in Scotland. The level of community pharmacy purchase profit is closely monitored on an ongoing basis through invoice inquiries with adjustments made to the reimbursement arrangements where necessary to ensure delivery at agreed levels. NHS Circular PCA(P) (2019) (13) provides a summary of the 2019/2020 remuneration arrangements. The total agreed funding

for community pharmacies and the proportion of that funding delivered to community pharmacies through purchase profit income rather than other approaches such as fees and allowances is a policy decision.

The arrangements for ongoing monitoring of pharmacy purchase profit income and managing the associated reimbursement price adjustments are key to ensuring that the NHS benefits from efficient community pharmacy purchasing. The Health Service Medical Supplies (Costs) Act 2017 enhanced the UK Government's powers to collect information on the sale and purchase of health service products by manufacturers and wholesalers. There is provision in the Act for the Department of Health and Social Care to share pricing information collected with the Scottish Government and NHS National Services Scotland for defined purposes including reimbursement price setting; this information flow has still to be implemented. This enhanced access to supply chain pricing information has the potential to strengthen the current arrangements.

The current arrangements in place in Scotland and central procurement are both 'free-market' approaches that create a pro-competitive environment for generic medicines. The focus on competition through both methods is believed to be why the recent Oxera[1] report into generic medicines prices found that UK prices were closer to countries in the study that made use of centralised tendering than those countries that applied regulatory approaches to control pricing.

A small number of countries in Europe tender for outpatient medicines, with a focus on generics. There are a number of published reviews of the experience to date including by researchers at the London School of Economics[3] and the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies[4]. A concern cited in both of these reviews was that moving to a single central purchaser could lead to concentration of supply; risks associated with reducing the number of suppliers in a market include increasing the risk of supply problems and reducing price competition. These are both factors which can lead to higher prices over the long term. Tender conditions (e.g. number of suppliers; length of award etc.) would need to be designed to manage this risk with the desire for low prices balanced with the need to ensure continuity of supply of medicines. A key benefit of the established approach in primary care is that it encourages plurality of supply.

Although there is not currently strong evidence available to support a case for system-wide change, there are scenarios where tendering for medicines supplied in the community could offer benefits. In 2016/2017, central procurement of flu vaccines and distribution to GP practices was successfully implemented. Previously community pharmacies purchased vaccines and distributed these locally to GPs. Flu vaccines are made to order each year using complex manufacturing processes; there are regularly supply delays. Central procurement enabled both access to competitive pricing and central oversight and control of stock to enhance management of delays in supply.

An area which may benefit from central procurement is off-patent 'speciality' generics which are currently supplied to patients via hospital supply routes. This includes certain off-patent cancer and HIV medicines. The market context for these products is different to the high volume, relatively low cost generics traditionally supplied through community pharmacies. As these products are currently predominantly supplied through hospitals, manufacturer pricing policies are influenced by established regional hospital tender arrangements across the UK and the supply requirements built into those contracts. Central procurement may enable improved patient access to these medicines through community pharmacies by bringing pricing into alignment with secondary care.

[3] Kanavos P, Seeley E and Vandoros S, 2009. Tender systems for outpatient pharmaceuticals in the European Union: evidence from the Netherlands, Germany and Belgium. Enterprise and Industry, European Commission, Brussels, Belgium.
[4] Vogler S, Gombocz M, Zimmermann, N, 2017. Tendering for off-patent outpatient medicines: lessons learned from experiences in Belgium, Denmark and the Netherlands. Journal of Pharmaceutical Health Services Research. 8(3):147–158.

Significantly higher prices in primary care for affected products is currently a barrier to supply via community pharmacies.

As both the established primary care pricing arrangements and central procurement use competition to help control costs, neither approach is effective in the absence of competition, for example single-source generics. The strengthening of the UK Government's pricing powers through the Health Service Medicines (Cost) Act 2017 has the potential to support the control of pricing where competition is limited.

In the case of brand:brand competition, for example therapeutic competition in in-patent markets, the focus of competition is the prescribing rather than the dispensing decision; the community pharmacy needs to source the specific supplier's product specified on the prescription. Supplementary to the Drug Tariff reimbursement arrangements, there are national rebate arrangements in place with pharmaceutical companies for certain branded medicines. These are managed by National Services Scotland on behalf of Health Boards and provide a route for pharmaceutical companies to offer competitive pricing to NHS Scotland for medicines dispensed in primary care whilst maintaining the confidentiality of their pricing arrangements. This approach is only feasible for branded medicines.

Outcome and Value Based Pricing

The committee requested an NHS National Services Scotland perspective on outcomes-based pricing and value-based pricing, specifically whether this should be adopted, how it could be assessed and what would be the main challenges in doing so.

Outcomes-based Pricing: Where there is significant uncertainty about a medicine's cost-effectiveness at the point of health technology assessment and the relevant outcome can be objectively measured within a reasonable timeframe, an outcomes-based pricing agreement is one approach which could enable the NHS to manage the risk that the medicine is not cost-effective. For example, a pharmaceutical company rebating the cost of the medicine if an individual patient does not achieve a defined clinical outcome.

There is an established route for companies to propose outcomes-based pricing schemes for consideration in the SMC process; the Patient Access Scheme Assessment Group (PASAG) operates independently from SMC and in advance of the SMC decision considers the acceptability of schemes for implementation in Scotland.

Outcomes-based pricing schemes are accepted by exception where there is clear justification for the need for complex arrangements. NHS IT Systems are not sufficiently developed to routinely automate the collection and reporting of data required to administer outcomes-based pricing schemes; the cumulative burden and financial risk to the NHS of using manual processes to manage a significant number of complex schemes would be untenable. This may change in future; building on work undertaken by the Data Scoping Taskforce, the Scottish Government is leading work to improve the quality and capture of medicines use and outcomes data.

Another key consideration in implementing pricing schemes which link the medicine price to an individual patient's clinical outcome is information governance; any complex pricing arrangement must be compliant with the General Data Protection Regulation (GDPR) and Caldicott guidance.

Complex pricing arrangements can also create longer-term financial risks for the NHS, for example obscuring pricing information can impact on price competition between therapeutic alternatives over the long-run.

PASAG reviews pricing proposals to assess their feasibility and to ensure that available NHS capacity to administer schemes is prioritised to those that will offer the greatest benefits to the NHS. New regulatory approaches that speed up medicines access from a regulatory perspective are increasing the number of products where there is uncertainty surrounding cost-effectiveness at the point of market access and where outcomes-based pricing could offer a solution. PASAG is working with the SMC to consider lessons learned from recent assessments and to consider how the review of outcomes-based pricing proposals could be better aligned with the SMC process.

There are other approaches which, subject to the product context, can also help manage uncertainty about a medicine's cost-effectiveness. This includes 'interim acceptance' which is already implemented as a decision option for medicines with an EMA conditional marketing authorisation with consideration actively being given by SMC to extending use of this provision *and* price reductions.

Value-based Pricing: The UK Government has reserved responsibility for the pricing of medicines; responsibility for medicines access policy is devolved to the Scottish Government. There are established 'Value Based Access' arrangements in place across the UK. Whilst under the provisions in the 'Voluntary Scheme for Branded Medicines Pricing and Access' (VPAS), manufacturers are free to set the price of their medicine at the point of market access, the health technology assessment process (e.g. SMC in Scotland and NICE in England) incentivises manufacturers to set their effective price to the NHS at a level that enables a medicine to be accepted for use by the NHS.

In 2014, following a review of the SMC process, changes were made to the SMC decision-making rules to reduce consideration of cost-effectiveness, as one element of overall value, when assessing medicines for rare conditions and end of life medicines. Since then, there have been a number of instances where the price that a company has offered to secure market access in Scotland has been higher than the price offered in England. This is directly linked to differences in health technology assessment (HTA) processes.

The 2019 VPAS Agreement included a clause, "Scheme Members will work with purchasing authorities to achieve comparable arrangements that provide an acceptable value proposition in each part of the UK". Whilst the majority of companies are offering Scotland comparable commercial arrangements to England, there are a small number of companies continuing to levy higher prices for equivalent market access. This clause is an important safeguard that would help ensure that Scotland is not financially disadvantaged from considering a broader or different value criteria than England. Work is on-going to implement the VPAS provision.

Please let me know if you require any further information,

Kind regards,

Lindsay McClure
Associate Director – Medicines Pricing and Supply
Procurement, Commissioning and Facilities