Further to the Public Accounts Committee (PAC) on the Care Quality Commission (CQC), I said I would write to you to explain in more detail why the pricing of some generic medicines have increased over the summer.

**Pricing arrangements for generic medicines**

Generic suppliers have freedom of pricing and we minimise barriers to market entry. Pharmacy contractors have every incentive to purchase below the price they are reimbursed by the NHS as we allow them to retain up to £800 million medicine margin per year as part of the Community Pharmacy Contractual Framework (CPCF) funding arrangements. The cheaper they source a product, the more medicine margin they keep individually, but to ensure that in totality it is not more than the £800 million we measure it annually and adjust the prices of the most common generic drugs accordingly.

These arrangements combined have been shown to deliver value for money for the NHS (e.g. by the National Audit Office report 2010) and the UK has some of the cheapest generic medicines in Europe, whilst typically maintaining a resilient supply.

**Reasons for prices increases**

However, since the summer a relatively small number of generic medicines have increased in price. My officials have identified the following reasons for the price increases:
• **Manufacturing and regulatory issues:**

Supply problems can occur for a number of reasons, such as manufacturing problems, difficulties in obtaining raw materials, distribution issues or regulatory problems. The UK has to compete with global markets for supply. When there is less available stock there is less competition and this can result in higher prices. Prices of products which are not directly affected by the supply issue can also rise. This is because it is a commodity market and manufacturers shift production in response to demand. Where DH is aware of supply issues affecting a generic medicine, we have a Medicine Supply Team, who work closely with the pharmaceutical industry, the Medicines and Healthcare products Regulatory Agency (MHRA) and the NHS in order to mitigate the impact on patient care.

Recently, the MHRA and other equivalent European regulators have partially suspended the licences of three large generic manufacturers in this country and in India due to serious concerns. Our Medicines Supply Team has been working with the MHRA so that in two out of the three regulatory cases, some supply of critical products from those manufacturers has been able to continue. However, while there is still supply of most products in the market, there is less stock available so it is inevitable prices have risen.

• **Fall in the Sterling:**

Most generics and their components come from abroad – as sterling falls, it costs more to purchase generics for the UK market. Since our generic prices are already so low manufacturers have little flexibility to absorb increased costs. So given the fall in the value of sterling it is inevitable that they will have to increase prices to compensate for this.

• **Other factors:**

Globally, changes in reimbursement systems, market forces and competition have been driving down generic drug prices for a number of years, and in particular manufacturers' margins have been challenged by consolidation of wholesale & retail channels in the USA. As a result, it is not uncommon for manufacturers to withdraw from certain markets with certain molecules when margins are no longer sustainable or indeed negative, and we have seen examples of this in our market. This then has the opposite effect of decreasing competition and capacity in the market, which in turn means prices rise, as we have seen in recent months in the UK.

As prices fluctuate more dramatically in the short term, wholesalers (who in many cases also own large chains of pharmacies) are more likely to change their
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Department  
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stockholding position on a frequent basis, and further compound the changes in market prices, including increases.

The introduction of new regulations, such as the Falsified Medicines Directive, is adding to the cost of manufacturing and handling, and potentially adds to cost pressures.

We will continue to investigate these, and other, as yet, less well defined anecdotal factors, some of which may be typical of “trading” environments.

The Department’s action to tackle the price increases

From next April we will have new statutory powers to require all actors in the supply chain to record, keep and provide us with information related to all their NHS products. This will enable us to:

- Gain greater transparency of the market; and
- Strengthen the current system for setting reimbursement prices for community pharmacy.

In the meantime

- My Chief Commercial Officer, Steve Oldfield, has met with all the larger wholesalers to discuss the problem and to ensure that the information they are currently giving us on a voluntary basis is accurate; and
- We are working with the Pharmaceutical Services Negotiating Committee (representative body of pharmacies) and the British Generic Manufacturers Association (representative body of generic manufacturers) to ensure reimbursement prices reflect the market as closely as possible.

I hope this reassures you that the Department is taking action to maintain supply where possible while at the same time ensuring that the NHS does not pay unjustified price increases.

Winter Funding

In the Autumn Budget the Chancellor announced an additional £337 million in 2017/18 to help ease pressure in the NHS this winter. The package will include more
hospital beds, community services, mental health services and urgent GP appointments to cope with the expected surge in winter demand.

Following intensive national engagement with systems, Pauline Philip, National Director for Urgent and Emergency Care wrote to all trusts on 15 December informing them of their individual allocation of this money. This will have enabled the trusts to start spending that money almost immediately. We are cognisant of the need to ensure this funding is being spent effectively and therefore NHS regional teams will be monitoring it on a fortnightly basis.

Of the £337 million winter fund, £150 million will fund the existing NHS plans to deal with a winter surge, with a further £50m from DH to follow.

The remaining £137m will be spent on new NHS measures including:

- Up to £60 million to ensure that more than 1,400 additional beds are available to cope with the heightened seasonal demand, on top of the 1,100 which have already been freed up through action to tackle delayed transfers of care. Further funding will also be made available to increase staffing in emergency departments.

- As much as £20 million to increase access to GPs over winter, including making more urgent GP appointments available 8am to 8pm over the holiday period.

- Up to £18 million for mental health services, such as providing additional liaison mental health staff who can relieve the burden on stretched A&E units by identifying patients in need of specialist treatment and referring them to more appropriate care more quickly.

- Around £4 million for Ambulance and 111 services, allowing them to increase the number of GPs, nurses, paramedics and other clinicians available to treat patients without sending them to hospital.

The extra £337 million is on top of the previously announced £100 million for A&E Departments and an additional £1 billion of funding to be spent on meeting social care needs, supporting the social care market and reducing pressure on the NHS this year.

As I said in the PAC hearing, we started preparing for winter earlier than ever before this year and have put in place robust plans to ensure the resilience of the NHS over
the coming months. This additional money from the Chancellor in the Autumn Budget is a welcome enhancement of those plans.

**Rapid Resolution and Redress**

The Committee previously requested an update on when the Government’s response to the public consultation on introducing a Rapid Resolution and Redress scheme for severe avoidable birth injuries would be published.

I am pleased to confirm that the Government’s Summary Response to the public consultation was published on 28\textsuperscript{th} November alongside the Secretary of State for Health’s refreshed Maternity Safety Strategy. Both the summary consultation response and the Maternity Safety Strategy can be accessed on gov.uk on the following links:


As previously noted, due to the technical complexity of policy development in this area and the need to ensure any final policy design can meet its objectives, this response is not a full policy proposal, but rather a summary of consultation responses received and a high level overview of next steps. We are now in the process of giving full consideration to points raised through the consultation and developing final policy proposals. We aim to present a final costed policy option with associated impact assessment for consideration in Spring 2018, and will look to develop the scheme, ideally from 2019.

We hope that you find this information helpful and stand ready to provide any further information as needed.

Yours sincerely,

SIR CHRIS WORMALD  
PERMANENT SECRETARY