

From the Permanent Secretary
Sir Chris Wormald



Department
of Health &
Social Care

Meg Hillier MP
Chair of the Committee of Public Accounts
House of Commons
14 Tothill Street
London
SW1H 9NB

39 Victoria Street
London
SW1H 0EU

21 December 2018

Dear Chair

Price increases for generic medications report

I am writing to the Committee about the report, *Price increases for generic medications*, which was published on 12 October. On 13 December the Government published its response to the report in the form of a Treasury minute, which addressed recommendations three and five in detail. This letter provides a fuller response to recommendations one, two and four as requested by the Committee.

Recommendation One: The Department should, by December 2018, share with the Committee its plan for maintaining the supply of medicines pre- and post-the UK's exit from the European Union, and confirm how it will ensure that patients will be able to obtain the medicines they need.

The Department has been preparing for the UK's exit from the EU including for a scenario in which the UK leaves the EU without a deal. To ensure the continuity of supply of medicines the Department has taken the following actions:

1. The Department has been working with the pharmaceutical industry in the EU Exit Medicines Supply Industry Collaborative Group to prepare for the UK's exit from the EU.
2. The Department has undertaken an analysis of the supply chain for medicines which identifies those products that are imported from the EU and the European Economic Area (EEA). Without a deal, the supply chains for these products may be affected by changes to border processes and procedures.
3. The Department has issued guidance for the regulation of medicines on how to prepare for the UK's exit from the EU if there is no deal, including in relation to batch testing and Qualified Person (QP) release, which you can find here: <https://www.gov.uk/government/collections/how-to-prepare-if-the-uk-leaves-the-eu-with-no-deal#regulating-medicines-and-medical-equipment>
4. The Department has asked all pharmaceutical companies that supply the UK with prescription only and pharmacy medicines from, or via, the EEA, to inform the



Department of their contingency plans and ensure they have a minimum of six weeks' additional supply in the UK, over and above their business as usual operational buffer stocks.

5. The Department has agreed that medicines and medical products will be prioritised at the border to ensure that the flow of all these products will continue unimpeded after 29 March 2019. The Department is working with the Department of Transport to implement the arrangements.
6. The Department is funding warehouse space for additional storage space for stockpiled medicines to support the Department's contingency planning.
7. The Department has written to all NHS organisations, GPs, community pharmacies and other service providers, advising them, amongst other things, that they do not need to take any steps to stockpile additional medicines or write longer prescriptions.
8. The Department has consulted on modifications to MHRA legislation and regulatory processes if there is no deal in which case the MHRA would be a stand-alone medicines, clinical trials and medical devices regulator, taking any decisions and carrying out any functions which are currently taken or carried out at EU-level.
9. To improve the Department's information about the increasing number of supply problems, from 1 January 2019 holders of Marketing Authorisations will be required to notify the Department of shortages under the Health Service Products (Provision and Disclosure of Information) Regulations 2018. This legal requirement will replace the current joint best practice guidelines published by the Department and the pharmaceutical industry.
10. The Department, in consultation with stakeholder representative bodies, is also progressing some changes to legislation before the UK leaves the EU, in particular to introduce the possibility of a 'serious shortage protocol'. The protocol would enable pharmacists to dispense a reduced quantity, an alternative dosage form, a therapeutic equivalent or a generic equivalent as indicated in the protocol without liaising with the prescriber. Any protocol would be developed with input from clinicians, supporting pharmacists to exercise their professional judgment in supplying an alternative medicine that is both available and suitable. As such, the protocol would support the management of serious shortages across the NHS.

Recommendation Two: The Department and NHS England should, by December 2018, establish clear and timely information flows between each other and local bodies to identify and inform about generic medicine supply and/or pricing issues, and write to the Committee to explain what they have done to ensure this. These information flows should include how clinicians can obtain greater transparency of the price of the generic medicines they prescribe.



The information flows between the Department and the NHS on medicines supply issues, pricing and reimbursement, including concessionary prices have been improved and continue to improve.

Sharing information on supply problems

The Department and NHS England work closely together on minimising the impact of medicines supply problems on patients. The Department has initiated the circulation of monthly updates about supply issues affecting primary care to the NHS, including to clinical commissioning groups (CCGs) and six-weekly updates for hospitals and other secondary care providers, tailored to secondary care systems. These reports are also uploaded to the Specialist Pharmacy Services (SPS) website which NHS staff can access. In between these reports, the Department uses established networks to communicate any new significant supply issue so that messages can then be cascaded to a local level. There are also systems in place to cascade messages quickly across the NHS if needed including the Central Alerting System (CAS), a web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others. The Department also take the initiative to liaise with specialist clinical groups, patient groups and other relevant networks to share information about supply issues that may affected specific patient groups.

Sharing information regarding concessionary prices

For concessionary prices the Department has started to inform NHS England directly each time it sets a concessionary price. This includes the concessionary price itself but also an estimate of the cost impact to the NHS. This enables NHS England and CCGs to better understand the cost pressure.

Sharing information regarding pricing

Prescribers already have access to information about pricing. When general practitioners (GPs) and other primary care prescribers prescribe a medicine, their IT system will show the Drug Tariff list price for that medicine. In addition, CCGs' medicines management/optimisation teams support primary care prescribers with cost effective prescribing. This includes utilising IT clinical decision support tools that enable prescribers to select a more cost-effective option at the point of prescribing. CCGs also provide regular financial reports on prescribing and medicines optimisation indicators, utilising dashboards to highlight the variation in generic prescribing from a national level, down to GP practice level.

Regional Medicines Optimisation Committees (RMOCs) have been set up to provide advice and recommendations on the optimal use of medicines across health economies, thereby reducing variation in prescribing and medicines waste, whilst also improving health outcomes and value. Within hospitals and other NHS providers, intelligence on price changes and expert guidance on the most cost-



effective medicines to be used to support patient care is provided by the organisation's pharmacy service. This ensures medical practitioners are fully supported in the diagnosis and care of their patients. Specialist clinical pharmacy services both deliver clinical expertise to support doctors but also, through medicines management and cost reporting processes, ensure that, where relevant or influenceable by prescribers, required changes are identified and communicated to them. This may include information relating to price, availability or clinical choice of medicine. Analytical tools, such as the NHS Improvement Model Hospital and the commercial analytical system Rx-Info Define, are used to monitor for price changes, growth and savings opportunities.

Recommendation Four: The Department should, by December 2018, write to the Committee to set out the full range of actions it can take to address rises in the price of generic medicines, and what skills and capacity it has put in place to use its new powers.

Whereas the prices of branded medicines are controlled, for unbranded generic medicines the Department relies on a competitive market, without any barriers to market entry, to drive prices down. This generally works well and has led to some of the lowest prices in Europe. However, there are situations where we see price rises, sometimes significant. Two different scenarios can be distinguished.

The first scenario is that described in the National Audit Office (NAO) report where, for example, there might be a supply problem which in turn leads to an increased price as a result of decreased supply or the costlier branded medicines being the only products available. A higher price in response to constrained supply is to be expected in a generally competitive market. In these cases, the Department sets a concessionary price for an unbranded generic medicine, as a temporary measure, to ensure that patients continue to get their medicines and that community pharmacies are reimbursed fairly for the products they dispense. Typically, supply increases again, and prices get driven down again.

The second scenario is when there is only one supplier of the medicine so there is no competition to drive the price down and suppliers charge prices that appear unreasonable. Where there are concerns of breaches of competition law, the Department asks the Competition and Markets Authority (CMA) to consider investigating such medicines. The CMA currently has three ongoing excessive pricing cases (phenytoin capsules, hydrocortisone tablets and liothyronine tablets) and the Department provides the CMA with the evidence needed to progress these cases.

It is the second scenario that the Department intends to use its own powers to limit prices for. To support these powers the Department:

- Is monitoring prices to determine where price increases have been sustained and where the market has corrected itself.



- Has Amended the Health Service Medical Supplies (Costs) Act 2017, so that the Secretary of State can now
 - a. give a direction to limit the price of any health service medicine that is not covered by the voluntary scheme, currently the Pharmaceutical Pricing Regulation Scheme (PPRS); and
 - b. make regulations to require companies to provide, amongst other things, information about the cost of bringing a product to market.
- Has published the Health Service Products (Provision and Disclosure of Information) Regulations 2018. These Regulations enable the Department to obtain information, including about manufacturing and supply costs of health service products. Information obtained under the Regulations will help the Department consider whether the cost of manufacturing a product bears any relation to the price at which it is sold.

The powers to limit prices can only be implemented following a consultation of the relevant industry bodies. The Department is therefore developing a framework for the use of its price limiting powers and is preparing an industry consultation to be released early 2019. The framework will set out what factors the Department proposes to consider when setting the price of a generic medicines and what process the Department will follow. As part of this work the skills and capacity required are also being considered.

Yours sincerely,

SIR CHRIS WORMALD
PERMANENT SECRETARY