Price increases for generic medications


Report, together with formal minutes relating to the report

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The Committee of Public Accounts

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Summary

During 2017, the prices of certain generic medicines purchased by community pharmacies for the NHS increased unexpectedly, affecting an unusually high number of medicines. Although the Department of Health & Social Care (the Department) and its arms-length bodies took action to ensure patients continued to receive the medicines they needed, it was slow to take action to manage the financial impact. Clinical commissioning groups bore the brunt of this unexpected increase in costs, which contributed substantially to their end-of-year overspend of around £250 million in 2017–18. While we received no evidence that any patients were harmed, some patients did have difficulties obtaining medicines and pharmacists had to go to greater lengths to secure medicines in short supply. The Department’s ability to deal with any future reoccurrence of these issues, in a more timely and effective manner, hinges on its 2017 powers and accompanying regulations introduced from July 2018. We were not convinced that the Department had a clear plan on how it would use the new powers. Also, the Department could not assure us of its plans to safeguard the supply of medicines after the UK has exited the European Union, which is worrying given that this exit is fast approaching.
Introduction

Medicines can be ‘branded’ or ‘generic’. New medicines are generally marketed under their brand name and their patents are protected for around 20 years. During that time, no other company can manufacture or market the medicine. After this, other companies can manufacture and market the same medicine under its generic name, usually at a lower price. Generic medicines are commonly prescribed to patients in the community: of the £4.3 billion that the NHS spent on generic medicines in 2016–17, 81% was in primary care. Community pharmacies buy medicines on behalf of the NHS, for which they are then reimbursed. For generic medicines, the Department’s policy is to rely on competition in the market between suppliers of generic medicines to control their price. The Department does not set the price of generic medicines, but does set the amount that community pharmacies will be reimbursed by the NHS (the ‘reimbursement price’). Clinical commissioning groups pay for these medicines out of the funding they receive from NHS England. Despite being the main purchaser of these medicines in the UK, the NHS has relatively limited influence over how much they cost in what is a global market.

During 2017–18, the costs of certain generic medicines increased substantially partly as a result of two large medicine manufacturers having their production suspended because of quality issues. One example of price rises was for a mental health medicine called Quetiapine: its reimbursement price for 100mg tablets peaked at £113.10, 70 times higher than the previous reimbursement price of £1.59.
Conclusions and recommendations

1. The NHS had to spend additional money, time and effort, for those generic medicines affected by the price rises in 2017, to make sure patients got the medicines they needed. Where pharmacies have trouble buying a generic medicine at the normal reimbursement price, the Department can agree to pay a higher price temporarily. In 2017–18, NHS England spent an additional £315 million to fund higher prices for generic medicines, seven times higher than the previous year. Some of these medicines were in short supply during the year and the Department took action to maintain the supply. For example, it released a cancer medicine from its stockpile of essential medicines during 2017–18 to ensure that the medicine remained available to patients. While no instances of patient harm have come to light, we were concerned to hear about the frustration and distress some patients experienced, and the extra efforts that pharmacies had to make to get medicines that were in short supply. The manufacture of medicines relies on importing ingredients from outside the UK. The UK’s exit from the European Union therefore poses further challenges to the supply of medicines, particularly for medicines with a short shelf-life.

Recommendation: 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.

2. There were clear signs that prices of certain medicines were increasing from June 2017, but the Department failed to take any action to manage costs until November. Before June 2017, on average the Department agreed to pay higher reimbursement prices for 26 medicines a month. In June this increased to 38 medicines and continued to rise, peaking at 91 in November. The Department told us it became aware of the price rises in summer 2017 but did not have the information it needed to take action. For the financial impact of the price rises, the Department relied on NHS England to alert it, which in turn relied on clinical commissioning groups. The Department will depend on this same process to take action should future pricing issues arise. We heard from a pharmacy representative that rumours about stock shortages during 2017 may have exacerbated the supply issues due to panic-buying. Although better information is available to GPs, clinicians in hospitals generally do not know the price of the medicines they prescribe, meaning they cannot make fully informed decisions about what they prescribe or understand the influence of their prescriptions on the budgets of their pharmacies.

Recommendation: 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.

3. The price rises for certain generic medicines during 2017 contributed substantially to clinical commissioning groups’ end-of-year overspend. Clinical commissioning groups ended 2017–18 with an overspend of around £250 million. NHS England attributed the majority of this overspend to the unexpected price
increases in generic medicines. The Department told us that, overall, spend on
generic medicines did decrease slightly in 2017–18, which it put down to clinical
commissioning groups making savings on other areas of spending on generic
medicines. It told us that it expects clinical commissioning groups to manage cost
pressures within their allocated spending levels for the year. However, NHS England
has advised clinical commissioning groups that they should not budget for similar
pricing pressures in 2018–19.

Recommendation: The Department and NHS England should, by December 2018,
release updated guidance to clinical commissioning groups that sets out their
contingency plans to mitigate the financial impact on clinical commissioning
groups if there is a repeat of these unforeseen price increases.

4. The Department has not yet set out how it will use its new powers, should similar
prices rises happen again. The price increases happened at a time when there were
ongoing concerns about the generics market, with recent investigations by the
Competition and Markets Authority into instances of suspected anti-competitive
behaviour by generic medicines suppliers. The Department has acquired new
powers, under 2017 legislation and new regulations published in 2018, to collect
information about the market for generic medicines. The legislation also removed
a loophole through which some suppliers of generic medicines were exempt from
existing price control powers, which allow the Secretary of State to step in and limit
prices. However, the Department did not tell us the full range of actions it could use,
beyond the collection of information, to address similar price rises in the future. The
Department recognises the challenge it faces in getting right the implementation,
and making the best use, of its new powers to gather information, identify issues in
the generics market, and control price where needed.

Recommendation: 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.

5. We are yet to be convinced that the Department’s new powers, and accompanying
regulations, are sufficient to enable it to act effectively should similar price
rises happen again. The regulations introduced in 2018 make it mandatory for
companies to provide quarterly information on the medicines they sell. They also
give the Department the right to request additional information within two days if it
thinks there are issues with the supply or pricing of medicines sold by that company.
However, the new regulations allow companies to give “reasonable estimates” of
how much they buy and sell medicines for in some cases, rather than actual figures,
limiting the accuracy of the information available to the Department. Companies are
also required to notify the Department if they intend to stop supplying a medicine,
or they expect a supply shortage. But this only applies if the company itself judges
that its actions will affect patients, and does not give the Department any control
over which medicines companies notify it about. We also raised concerns about the
high prices the NHS has paid for ‘specials’, which are medicines prepared to meet the
needs of individual patients. However, the regulations only enable the Department
to collect routine quarterly data on a minority of these medicines.
Recommendation: The Department should, by September 2019, ensure that the first annual review of the regulations includes an assessment of how well the provisions for companies providing estimates and notifying the Department of an impending shortage are working, as well as the application of new information collection powers to ‘specials’ medicines.
1 Impact on the NHS and the supply of medicines

1. On the basis of a report by the Comptroller and Auditor General, we took evidence from the Department for Health & Social Care (the Department), NHS England, and the Medicines and Healthcare products Regulatory Agency on spending on generic medicines by the NHS. We also took evidence from the Pharmaceutical Services Negotiating Committee (which represents community pharmacies), the British Generic Manufacturers Association, and a Deputy Director of Medical Education from Imperial College.

2. Medicines can be ‘branded’ or ‘generic’. New medicines, generally marketed under their brand name, have patents protected for around 20 years. After this time, other companies can manufacture and market the same medicine under its generic name, usually at a lower price. Generic medicines are medicines which are no longer on patent.

3. Generic medicines are commonly prescribed by GPs. GP prescriptions for generic medicines accounted for 81% of the total £4.3 billion that the NHS spent on generic medicines in 2016–17. Community pharmacies buy medicines on behalf of the NHS, for which they are then reimbursed. For these generic medicines, the Department’s policy is to rely on competition in the market between suppliers of generic medicines to control their price. The Department does not set the price of generic medicines, but does set the amount that community pharmacies will be reimbursed by the NHS (the ‘reimbursement price’). Clinical commissioning groups pay for these medicines out of the funding they receive from NHS England.

4. The Department, the British Generic Manufacturers Association, and the Pharmaceutical Services Negotiating Committee agreed that, for most generic medicines, relying on competition in the market to set the prices generally serves the NHS well. Research suggests that the UK enjoys comparatively low prices. However, as a purchaser the NHS has relatively limited influence over prices in what is a global market, with the UK making up around 2.6% of the world market value.

5. During 2017–18, the reimbursement prices of some generic medicines increased substantially. These medicines are used to treat a range of conditions, from high blood pressure to mental health conditions. One example of the extent of the price increases was for a mental health medicine called Quetiapine. The reimbursement price for Quetiapine 100mg tablets reached £113.10 at its peak, compared with a previous price of £1.59.

Maintaining supply of medicines

6. The Department asserted that it has to balance maintaining the supply of medicines to patients with obtaining a good price for the tax payer. Where pharmacies have trouble buying a generic medicine at the normal reimbursement price, the Department has an

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1 Report by the Comptroller and Auditor General, Investigation into NHS spending on generic medicines in primary care, Session 2017-19, HC 1122, 8 June 2018
2 Q 1; C&AG’s Report, para 1.1
3 C&AG’s Report, paras 1.5, 1.7
4 Qq 23, 24, 59, 76, 78
5 C&AG’s Report, paras 1.3, 1.7
6 C&AG’s Report, paras 2, 2.4
established mechanism where it will temporarily pay pharmacies a higher reimbursement price. The Department used this during 2017–18 to allow reimbursement prices to rise at a time when it considered supply was under threat. Its view is that the mechanism to grant a temporary higher price worked, as it avoided patient harm, but came at a financial cost. The NAO estimated the additional cost to the NHS was £315 million in 2017–18, seven times higher than the equivalent spend in the previous year. The Department also took other action to maintain supply, including releasing a medicine to treat cancer from its emergency stockpile.

7. Although we did not receive evidence to suggest that any patients were harmed during 2017–18, we were nonetheless concerned to hear about the frustration and distress some patients experienced in obtaining their medicines. The representative from the Pharmaceutical Services Negotiating Committee (PSNC) told us about one case where a patient could only obtain one week’s supply of their breast cancer drug at a time as the pharmacy could only get limited amounts and had to ration its supplies. We also heard about the impact of the price rises on community pharmacies. The PSNC told us of the burden on pharmacies: the extra effort required to get medicines and the actions they took to minimise the impact on patients. This included contacting GPs to suggest an alternative medicine or ways of filling a prescription (e.g. if 20mg tablets had been prescribed and were unavailable, whether they could supply 2 x 10mg tablets), and rationing supplies to patients. It also reported that pharmacies had to dispense medicines not knowing how much money they would get back from the NHS, creating financial uncertainty against a backdrop of reduced government funding to the sector.

8. The Department told us that the UK’s exit from the European Union is not expected to affect where the NHS obtains its medicines as the vast majority are made outside of the European Union. As the British Generics Manufacturer Association explained, the UK is heavily dependent on active ingredients coming from India and China. However, the Department told us that it is currently looking at how it can mitigate against any supply issues which could arise in response to the UK’s exit from the European Union, for example getting medicines into the country. The Department explained that this contingency planning includes looking at more general threats to supply, such as events in other countries. For example, the British Generics Manufacturers Association told us about a previous strike at a port in India affecting supplies of active ingredients used to manufacture medicines which created a shortage. The Department told us that different medicines, for example those with a short shelf-life, require different solutions, so there is no ‘one size fits all’ plan. The Department was unable, however, to provide us with any detail of its plans, or to assure us and the public about the supply of medicines in the event of a ‘no deal’ exit.

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7 Qq 62, 65; C&AG’s Report, paras 1.8, 2.3
8 C&AG’s Report, para 3.3
9 Qq 11, 111
10 Qq 6–8; Pharmaceutical Services Negotiating (GEN0008), paras 28–30
11 Qq 36, 85
12 Qq 23, 88, 90, 94
13 Qq 94 –97
Access and availability of information about the market

9. Before June 2017, on average the Department agreed to pay higher reimbursement prices for 26 medicines a month. In June 2017 this increased to 38 and peaked at 91 in November 2017. Clinical commissioning groups alerted NHS England to the increasing price of some generic medicines in July 2017, and NHS England subsequently informed the Department of the financial pressure in September 2017. The Department told us that this process, where local areas first raise the issue, is the most important trigger for it to take action should future issues arise. Regarding the price increases in 2017, the Department admitted that it began to see prices increasing in the summer, but asserted that it did not know how best to take action because it did not have the information to understand what was happening until the end of October. In November 2017, the Department undertook an investigation and data analysis into the causes of the price increases. It attributed the price increases to turbulence in the market arising for a series of events which included two large medicine manufacturers having their production suspended because of quality issues. The Department also identified changes in other countries’ markets causing downward pressure on UK prices and the fall in the value of sterling as contributing factors to the price increases.

10. We received written evidence from a community pharmacy owner which suggested that many of the shortages in 2017–18 may have been caused by rumours about short supplies. They told us that this created a “self-fulfilling prophecy”, leading pharmacies to buy more stock than normal to get through the period of supposed shortage. The representative from the PSNC acknowledged that this does happen but told us that it is not within its remit to ask pharmacies to avoid panic buying.

11. We asked how doctors are alerted to increases in the prices of generic medicines and how, or whether, they factor in the cost of a medicine into their decisions when prescribing medicines. Imperial College told us that generally hospital doctors do not know the costs of the medicines they prescribe. He told us that he was unaware that the cost of a medicine called hydrocortisone had increased from about £1 a month to £100 a month until he prescribed it for a private patient, who said they could not afford it. He told us that for these types of ‘outlier’ medicines, generic medicines which go against the general picture of a low cost and good value market, it would be helpful if clinicians knew the price of the medicine in advance of prescribing it. The PSNC told us that the situation is different among GPs as they have a large amount of data and information available to them, and clinical commissioning groups monitor local prescribing. It also said that community pharmacists, who dispense the medicines GPs prescribe, want better access to information and timelier price data.
Clinical commissioning groups’ spend on generic medicines

12. Clinical commissioning groups are allocated money by NHS England to pay for medicines for their local population. From October 2017, NHS England started including the impact of the price increases on clinical commissioning groups’ budgets in its financial reports, directly linking a forecast overspend by clinical commissioning groups to the price increases. At the time, NHS England described the price increases as a “significant unbudgeted pressure.” Following its analysis in November 2017, the Department also realised that it was setting reimbursement prices paid to pharmacies higher than necessary and changed the way it calculated the reimbursement price, reducing the amount the NHS paid. In May 2018, NHS England reported that clinical commissioning groups ended 2017–18 with an unaudited overspend of around £250 million.

13. The Department told us that overall spending on generic medicines prescribed in the community had decreased slightly in 2017–18. However, clinical commissioning groups still had to spend more money on medicines than they had planned to. NHS England told us that clinical commissioning groups absorbed some of the costs themselves, including using unexpected savings from other parts of their generic medicine budget. NHS Clinical Commissioners, a national membership organisation for clinical commissioning groups, submitted written evidence that its members, in responding to the pressures, had to make difficult decisions to try to stay within budget, including reductions in the availability of treatments and services.

14. In February 2018, NHS England advised clinical commissioning groups not to plan for a continuation of the pricing pressures in 2018–19. More generally, the Department told us that it expects clinical commissioning groups to manage these pressures across the year and that there is not extra money in the health system for this. We highlighted, however, that clinical commissioning groups do not have control over the price of medicines.

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21 C&AG’s Report, paras 3, 2.5
22 C&AG Report, para 2.5, 2.6
23 C&AG’s Report, para 2.6, 3.11
24 Qq 73, 74, 155; C&AG’s Report, para 2.6
25 NHS Clinical Commissioners (GEN0005), para 3
26 C&AG’s Report, para 3.6
27 Qq 75, 156, 157
2  The Department’s new and additional powers

15. The Department acquired new powers, under the Health Service Medical Supplies (Costs) Act 2017, to collect information about the market for generic medicines. In 2018, it published regulations (the Health Service Products (Provision and Disclosure of Information) Regulations), which set out what its new powers mean in practice, including what information the Department can collect and under what circumstances. The legislation also removed a loophole through which some suppliers of generic medicines were exempt from existing price control powers, which now allow the Secretary of State to step in and limit prices.28

Implementing the new powers

16. The price increases and supply issues happened at a time when there were ongoing concerns about the generics market. The NAO report summarises some of the Competition and Markets Authority’s recent investigations into instances of suspected excessive and unfair pricing. These included cases where companies had allegedly de-branded a medicine to make it generic and, at the time, no longer subject to price control and then used their market dominance to increase prices unfairly.29

17. We heard from the British Generic Manufacturers Association that there will always be outliers in how much suppliers charge for generic medicines, where competition does not appear to drive down the price, but that a better system was needed to address them.30 The Department told us that the reason it asked Parliament to grant its new powers was because of weaknesses in its information gathering powers and a lack of transparency in the market. As we heard, these weaknesses included a time-lag in the Department receiving information from suppliers, which the Department told us delayed its ability to take action in response to price rises during 2017.31

18. The British Generic Manufacturers Association told us that it expects the Department’s new powers will allow the types of cases which have previously been referred to the Competition and Markets Authority to be resolved much more easily and efficiently. For example, the Department will be able to collect additional information within two days if it has any concerns rather than having to wait three months. The British Generic Manufacturers Association also told us that the Department can use this information to first try to resolve issues, with the option to still refer cases to the Competition and Markets Authority.32 The Department similarly told us that it expects to use its new powers to spot trends in the prices for generic drugs and investigate what is causing them much more quickly. The Department recognised that its main challenge is now implementing its new powers properly to get the best out of them. It told us that it was committed to ensuring that its powers are used effectively, so that data is swiftly and properly analysed so the

28 C&AG Report, paras 3.13, 3.15
29 C&AG Report, para 3.12
30 Q 47
31 Qq 65, 66
32 Qq 50, 158
Department can take the right action against those who are not complying. However, aside from the collection of information and using this to investigate what is happening, the Department did not tell us the full range of actions it was planning to use.\(^{33}\)

### Effectiveness of the new powers

19. The new regulations make it mandatory for companies to provide the Department with information on the medicines they sell, replacing the previously voluntary arrangements.\(^ {34}\) The Department explained that where it has specific concerns it will be able to request additional information within two days. However, we were concerned to hear that companies are able in some cases to give the Department “reasonable estimates” of how much they buy and sell medicines for, rather than actual figures, potentially limiting the accuracy of the information. The regulations also make it mandatory for companies to notify the Department if they intend to stop supplying medicines, or expect a supply shortage. However, this requirement only applies if a company itself judges that its actions will affect patients, and does not give the Department any control over which medicines companies notify it about. The Department wrote to us after the session to say it was planning to issue further guidance to companies. The Department acknowledged that while the legislation increases its powers it is not the whole answer.\(^ {35}\)

20. We also raised concerns about ‘specials’: medicines prepared to meet the needs of individual patients, for example in liquid form for patients unable to swallow tablets. Since only a minority of specials have set reimbursement prices we asked the Department what it can do to ensure that pharmacies buy the more cost-effective product. For the majority of specials, pharmacies are instead reimbursed either the price they paid or the cost of the ingredients. The Department told us that it is currently looking at its options to ensure that the NHS pays the best available price for specials and plans to consult on these at the end of the year.\(^ {36}\) However, while the Department confirmed that under the new regulations it can ask for additional information about any ‘specials’, we remain concerned that the provision of routine quarterly information collection for ‘specials’ is limited to the minority with set reimbursement prices.

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\(^{33}\) Qq 65, 66, 118, 119, 124, 158–161

\(^{34}\) Q q 65; C&AG’s Report, paras 3.8, 3.9, 3.15

\(^{35}\) Q 118, 131, 152; Ev XXX Letter from the Permanent Secretary at the Department of Health & Social Care

\(^{36}\) Qq 49, 118, 140–143, 147; C&AG’s Report para 3.14
Draft Report (Price Increases for Generic Medications), proposed by the Chair, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 20 read and agreed to.

Introduction agreed to.

Conclusions and recommendations agreed to.

Summary agreed to.

Resolved, That the Report be the Sixty - Second of the Committee to the House.

Ordered, That the Chair make the Report to the House.

Ordered, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

[Adjourned till Wednesday 10 October at 1:30pm]
Witnesses

The following witnesses gave evidence. Transcripts can be viewed on the inquiry publications page of the Committee’s website.

Wednesday 4 July 2018

Mark Burdon, Regional Representative, North East and Cumbria, Pharmaceutical Services Negotiating Committee; Warwick Smith, Director General, British Association of Generic Manufacturers; and Professor Karim Meeran, Deputy Director of Medical Education, Imperial College. Sir Chris Wormald, Permanent Secretary, Department of Health and Social Care; Steve Oldfield, Chief Commercial Officer, Department of Health and Social Care; Dr Bruce Warner, Deputy Chief Pharmaceutical Officer, NHS England; and Dr Ian Hudson, Chief Executive, Medicines and Healthcare Products Regulatory Agency.

Published written evidence

The following written evidence was received and can be viewed on the inquiry publications page of the Committee’s website.

GE numbers are generated by the evidence processing system and so may not be complete.

1  ABPI (GEN0010)
2  British Generic Manufacturers Association (BGMA) (GEN0011)
3  Mr Michael Hewitson (GEN0009)
4  National Pharmacy Association (NPA) (GEN0012)
5  NHSCC (GEN0005)
6  Pharmaceutical Services Negotiating Committee (GEN0008)
List of Reports from the Committee during the current session

All publications from the Committee are available on the [publications page](https://www.committee's website). The reference number of the Government’s response to each Report is printed in brackets after the HC printing number.

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