National Audit Office

Report
by the Comptroller
and Auditor General

Department of Health & Social Care

Investigation into NHS spending on generic medicines in primary care

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Key facts

£3.5bn

estimated amount the NHS spent on generic medicines in primary care in 2016-17, including a target £800 million contribution to pharmacies

709

number of price concessions that the Department of Health & Social Care (the Department) granted in 2017-18, up from 282 in 2016-17

£315m

National Audit Office estimate of the net spend on concessionary priced medicines in primary care in 2017-18 (over and above the amount that would have been paid via lower Drug Tariff prices)

Seven times	the increase between the net spend on price concessions for generic medicines in primary care in 2017-18, compared with 2016-17
81%	proportion of spending on generic medicines that is in primary care, 2016-17
3,000	number of concessionary pricing requests made by pharmacists in November 2017; before May 2017, the monthly figure was fewer than 150 requests
£800 million	agreed annual margin retained by pharmacies as part of their funding to provide NHS pharmacy services. This is the difference between the price at which a pharmacy purchases a medicine and the price that the NHS reimburses the pharmacy when the medicine is dispensed.

Glossary of key terms

‘Generic’ and ‘branded’ medicines – New medicines, generally marketed under their brand name, have patents that are protected for a minimum of 20 years. During this time, no other company can manufacture or market the medicine. At the end of this time-period other companies can manufacture and market the same medicine under its generic name, typically selling it at a lower price.

Drug Tariff price – Each month the Department publishes the Drug Tariff. This sets out what pharmacies in primary care will be reimbursed for the cost of each generic medicine they dispense for an NHS prescription.

Concessionary prices – If pharmacies in primary care cannot purchase a medicine at, or under, the Drug Tariff price, the Department can set a higher ‘concessionary’ reimbursement price for that month.

What this investigation is about

1 During 2017, the prices of certain medicines purchased by pharmacies for the NHS increased unexpectedly. This placed what NHS England described as a "significant unbudgeted pressure" on clinical commissioning groups. In 2017-18, the net spend on the affected medicines totalled an estimated £315 million, nearly seven times greater than the equivalent spend in 2016-17. During 2017-18, the costs of certain individual medicines increased more than tenfold.

2 The medicines affected by these price increases were 'generic' medicines. Medicines can be 'branded' or 'generic'. Branded medicines are medicines sold under the name given by the company that made them. New medicines have patents that are protected for a minimum of 20 years, and are generally marketed under their brand name. During that time, no other company can manufacture or market the medicine. At the end of this period, other companies can manufacture and market the medicine under its generic name, typically selling it at a lower price. In 2016-17, the NHS spent an estimated £4.3 billion, or 28% of total medicine expenditure, on generic medicines.

3 This investigation sets out the facts in relation to:

- NHS spending on generic medicines, and the 2017-18 increase in spending on certain generic medicines;
- possible causes of the price increases in the market for generic medicines; and
- how the Department of Health & Social Care (the Department) and its arm's-length bodies responded to the price increases.

4 This investigation focuses on primary care, where most spending on generic medicines is incurred. It is intended to be the first report in a wider programme of work on medicines.

Summary

Key findings

The increase in prices of certain generic medicines

1 **The NHS spent an estimated £4.3 billion on generic medicines in 2016-17, of which most was spent in primary care.** In 2016-17, the spend on generic medicines in primary care was £3.5 billion.[1] In primary care, pharmacies buy medicines from wholesalers or manufacturers who determine their own prices. The Department of Health & Social Care (the Department) does not set the price of generic medicines. Instead the Department reimburses pharmacies set amounts for the medicines they dispense, which are published in the Drug Tariff. If pharmacies cannot get a medicine at this set amount, the Department can use a mechanism called concessionary prices. This allows it to reimburse pharmacies at a temporarily higher price than the Drug Tariff price (paragraphs 1.2 and 1.8).

2 **The prices of certain generic medicines increased unexpectedly in 2017-18.** There was an unprecedented increase in the number of requests from pharmacies for concessionary prices. These increased from fewer than 150 a month before May 2017 to a peak of 3,000 in November 2017. In 2017-18, the Department granted 709 concessionary prices, up from 282 in 2016-17 (paragraphs 2.1 and 2.2).

3 **The price increases resulted in additional unforeseen costs for clinical commissioning groups.** Clinical commissioning groups are ultimately responsible for expenditure on medicines for their patient population. We estimated the net spend on concessionary priced medicines at £315 million in 2017-18 (that is, over and above what would have been spent if the Drug Tariff price applied). This was seven times greater than the equivalent spend in 2016-17. Ten medicines accounted for around half of this net spend. The cost of certain medicines increased more than tenfold: for example, at its peak, the concessionary price for Quetiapine 100mg tablets was £113.10, 70 times higher than its previous set price of £1.59. In October 2017, NHS England began forecasting an end-of-year overspend across clinical commissioning groups, partly due to the issues in the generics market. In May 2018, NHS England reported an unaudited end-of-year deficit of around £250 million among clinical commissioning groups (paragraphs 2.3 to 2.6).

1 This includes an agreed £800 million contribution to pharmacies.

Causes of price increases

4 **The Department identified three main factors that may have caused the price increases but cannot fully verify or quantify these.** These include the suspension of some manufacturers' licences and a fall in the value of sterling. Our analysis indicates that the Department identified a direct relationship between price increases and shortages for four out of 10 medicines subject to concessionary pricing in October 2017. (paragraphs 3.7 to 3.9).

5 **Analysis by the Department in November 2017 identified unexpected increases in wholesalers' margins.** The Department undertook analysis to understand what was happening in the market. It identified increases in manufacturers' prices, but also unexpected increases in wholesalers' margins in 2017, which it could not fully explain. The NHS will not be able to get back the expenditure due to the increase in manufacturer and wholesaler prices. The Department's analysis also showed that the concessionary prices it had granted were set higher than necessary above wholesalers' selling prices. It estimated that this amounted to £86.3 million of additional costs for clinical commissioning groups in 2017-18, which it expects to be recouped in subsequent years through the established reimbursement mechanisms. The Department subsequently changed its calculation of concessionary prices, basing this on manufacturers' rather than wholesalers' prices (paragraphs 3.10 and 3.11).

How the Department and its arm's-length bodies responded to the price increases

6 **The Department told us it took action to maintain the supply of those generic medicines on concessionary prices for patients in 2017-18.** The Department is responsible for ensuring the supply of medicines. Its actions included: liaising with manufacturers to identify whether supplies were available; permitting one manufacturer whose licence was suspended to supply certain medicines considered critical and releasing supplies of one medicine from a centrally held stockpile (paragraph 3.3).

7 **The Department received intelligence from a variety of sources about potential impacts of the price increases.** This included information about how supply issues were affecting pharmacies' ability to obtain medicines, although the Department does not know how many patients experienced problems getting their prescriptions. We also heard concerns from the Pharmaceutical Services Negotiating Committee about the impact of price increases on its sector (paragraphs 3.4 and 3.5).

8 **The Department will have new powers to control the price of generic medicines, which are due to come into force from July 2018.** Following some high-profile cases of issues with the price of some generic medicines (before 2017-18), new legislation has strengthened the Department's powers to control the price of generic medicines. The legislation also introduced mandatory information-sharing arrangements. Before July 2018, the Department had to rely on voluntary arrangements, which limited its ability to identify and respond to the recent price increases. However, its new powers are untested and will require sufficient resources (paragraphs 3.12 to 3.15).