





United Kingdom

Department of Health, Cathleen Schulte, cathleen.schulte@dh.gsi.gov.uk, +44 20 7972 6539

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

Out patient

Pricing policies for medicines

Maximum prices (manufacturer price/reimbursement price/NHS list price) of branded **medicines** are set in line with requirements of the voluntary Pharmaceutical Price Regulation Scheme (PPRS) or statutory regulations (the Health Service Branded Medicines (Control of Prices and Supply of Information)(No.2) Regulations 2008 and the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007). Manufacturers are required to seek agreement on the proposed maximum price from the Department of Health prior to launch. Products containing a New Active Substance have freedom of pricing.

The 2014 PPRS operates until the end of 2018 through a cap on the vast majority of National Health Service spend on branded medicines. For any expenditure above the agreed level, companies in the PPRS make quarterly percentage payments to the Department of Health on their net sales. Companies which are not members of the voluntary scheme are subject to statutory regulations and are required to apply a 15% price cut to products that were on the market on 1 December 2013.

The prices of **generic medicines** are set by the market. Generic manufacturers have freedom of pricing subject to a maximum of the reference product at the point of patent expiry. Part VIII of the Drug Tariff lists the reimbursement price of many generic drugs in the community.

Wholesale remuneration

The reimbursement price includes margins for the wholesaler and pharmacist. These are not fixed, so it is not possible to derive the ex-factory price. Historically, the margin for branded medicines was nominally 12.5% off the NHS list price but, in practice, it varied as it was negotiated between the manufacturer and wholesaler. Changes to the way medicines are distributed e.g. Direct to Pharmacy (DTP) schemes or a restricted number of wholesalers mean that this average figure is no longer accurate for many medicines. In addition, Part II of the Drug Tariff lists medicines for which a discount is not deducted when reimbursing pharmacy contractors

Pharmacy remuneration

Most new medicines are granted automatic full reimbursement following market authorisation and pricing approval. In the community, any product may be prescribed for a patient and it will be reimbursed on the NHS except for a small number on a negative list - Part XVIIIA of the Drug Tariff.

The NHS list price excludes VAT. Medicines supplied to hospitals and community pharmacies are subject to VAT at the standard rate (20%). Medicines dispensed by a community pharmacist against a prescription are zero-rated for VAT (which means that the patient pays no VAT and the pharmacy can recover the VAT paid when buying the medicines). Sales of over-the-counter (OTC) medicines are also subject to VAT at the standard rate.

The Department of Health is currently running a 12-week public consultation on proposals to reform the statutory scheme regulations. More details on the Department's proposals can be found at:

https://www.gov.uk/government/consultations/pricing-of-branded-health-servicemedicines

<u>Positive / negative list</u>
There is no positive list. Most new medicines are granted automatic full reimbursement following market authorisation and pricing approval. In the community, any product may be prescribed for a patient and it will be reimbursed on the NHS except for a small number on a negative list (Part XVIIIA of the Drug Tariff).

Reference price system
The UK does not operate reference pricing.

From 1 April 2015 the prescription charge in England increased to £8.20 per item. Prescription charges do not currently apply in Wales, Scotland and Northern Ireland.

Mechanisms for vulnerable groups

No charges are paid by children under 16 (or full time students under 19), pregnant women, people aged 60 or over, people with certain medical conditions or people on Overall, about 90% of prescription items are dispensed free. Those people who do pay charges and who need prescriptions regularly may buy a prepayment certificate, which entitles them to free prescriptions for a fixed period. The cost of the pre-payment certificate is £29.10 for a 3-month and £104.00 for an annual certificate.

Pricing policies for medicines

As in the outpatient sector, maximum prices of branded medicines are set in line with requirements of the voluntary Pharmaceutical Price Regulation Scheme (PPRS) or statutory scheme. In addition, companies that are members of the PPRS have the option to propose a patient access scheme (PAS) in the context of a NICE appraisal of a medicine. A PAS is an arrangement agreed between the Department of Health (with input from NICE) and a company to improve the cost-effectiveness of a medicine without affecting the agreed maximum (list) price. There are a number of different types of PAS, but the most common and preferred model is a discount scheme.

Wholesale remuneration

Not applicable.

Pharmacy remuneration

Costs of medicines for in-patients are covered by a tariff price, which includes an element for medicines.

The NHS list price excludes <u>VAT</u>. Medicines supplied to hospitals are subject to VAT at the standard rate (20%).

Reforms

The Department of Health is currently running a 12-week public consultation on proposals to reform the statutory scheme regulations. More details on the Department's proposals can be found at:

s://www.gov.uk/government/consultations/pricing-of-branded-healthservice-medicines

Reimbursement of medicines

Most new medicines are granted automatic full reimbursement following market authorisation and approval of the NHS list price by the Department of Health.

<u>Hospital formularies</u>
Formularies have been in place in the majority of NHS hospitals for many years, sometimes shared arrangements are in place. Each hospital will normally have their own formulary of active substances, and as a result, the formal and number of items on each list will vary significantly – as a minimum medicines approved by NICE are on this list. Generic substitution is normally practised with these lists, with the exception of products with narrow therapeutic indices and variable bioavailability. The formularies are continually updated, and depending on hospital policy, are overhauled every 1 to 2 years.

Co-payment in hospitals

Not applicable.

Mechanisms for vulnerable groups

Not applicable.

In June 2014, the Health Secretary appointed Lord Carter to chair the NHS Procurement and Efficiency Board. In June 2015, the Department of Health published Lord Carter's independent, interim report which, among other areas, made recommendations for efficiencies in hospital pharmacy and medicines optimisation. Lord Carter's report is available at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/4342 02/carter-interim-report.pdf