

Danish Ministry of Health and Prevention

**Analysis of Hospital
Pharmaceuticals**

Country Report - England

March 2009

COWI



COWI A/S

Parallelvej 2
DK-2800 Kongens Lyngby
Denmark

Tel +45 45 97 22 11

Fax +45 45 97 22 12

www.cowi.com

Danish Ministry of Health and Prevention

Analysis of Hospital Pharmaceuticals

Country Report - England/Wales

March 2009

1 Introduction

The UK hospital system

NHS hospital trusts (also known as an acute trust) provides secondary care services. In England there are 175 acute trusts.

The NHS is financed mainly through general taxation in combination with national insurance contributions¹. The NHS (National Health System) is the publicly funded health care system in England

Definition of hospital pharmaceuticals

In England/Wales the following definition of hospital pharmaceuticals can be applied:

*Pharmaceuticals which are purchased by hospitals and used for treatment of hospital patients, which may be either inpatients or outpatients.*²

The survey and interviewees

This survey covers the NHS in England and Wales, and the visits were performed over 1 day at a meeting with key professionals within the area of hospital pharmaceuticals. The interviewees were from the Department of Health (DH) and National Health Service (NHS) - London & Eastern Pharmacy Services.

COWI performed the interview and the interviewees were:

- David Kullman, Medicines, Pharmacy & Industry Group, Department of Health
- Kevan Wind, responsible for advising NHS trusts and Primary Care Trusts (PCTs) on purchasing pharmaceuticals in London & East of England Regions.
- Matt Harpur, Medicines, Pharmacy & Industry Group, Department of Health

The meeting took place at the Department of Health in London on the 22nd of January 2009. The visit in United Kingdom (UK) was performed by 3 consultants from COWI.

¹ Departemental Report 2006. The Department of Health.

² Hospital supply pharmaceuticals to some clinics (where there is direct supply to the patients), to prisons, and to walk-in clinics.

Legislation and organisation

2 Regulation and legislation

The sale and supply of medicines in the UK is controlled by the Medicines Act 1968 which is currently under revision.

Error! Reference source not found. The financing of hospital pharmaceuticals is the responsibility of NHS acute trusts, which own the acute hospitals.

The hospitals are configured as NHS acute trusts. Some acute trusts are regional or national centres for more specialised care. Acute trusts can also provide services in the community, for example through health centres, clinics or in people's homes. The trusts agreements for pharmaceuticals also cover clinics even though they are not hospitals. Furthermore, prisons and polyclinics (out-patients' clinic) are covered³.

The trust will have a hospital pharmacy as part of its organisation. Trusts covering more than one site may have multiple hospital pharmacies. The hospital pharmacy will typically dispense medicines for individual inpatients, provide medicines to wards and dispense medicines to outpatients who have attended the hospital's outpatient clinics and who have received a prescription. The Primary Care Trusts (PCTs) commission hospital services for their local area from acute hospitals.

NHS hospitals provide pharmaceuticals for inpatients and some outpatients. Inpatients are supplied with their medicines free of charge and outpatients pay a prescription charge (as per the rules that are applied in primary care).

Hospitals may contract out a service to a third party provider, e.g. for its outpatients dispensing, for homecare or banding services, and for independent sector treatment centres (ISTCs)⁴ that are treating NHS patients and can access NHS-PASA (National Health Service Purchasing and Supply Agency's) contracts. This business is distinct from the primary care sector and involves treatment of NHS patients that are 'hospital' patients in terms of prescribing responsibility.

³ Prisons can access NHS-PASA contracts but are moving towards a GP prescribing community pharmacy supply model, e.g. the prisoner is treated as if the person was in his/her own home. Arrangements for supply of medicines to polyclinics has yet to be finalised but will probably vary across the country.

⁴ Independent sector treatment centres (ISTCs) are private-sector owned treatment centres contracted within NHS.

Financing of hospital pharmaceuticals The hospital pharmaceuticals are publicly financed by the National Health System (NHS).

The acute hospitals are configured as NHS acute trusts (foundation and non-foundation). Foundation status allows more financial flexibility for the trust. The NHS acute hospital service is mainly a public system both in terms of financing (through taxes) and delivery (ownership of hospitals).

Price regulation Manufacturers and suppliers are free to set the prices of new major branded pharmaceuticals at launch. UK (not only England/Wales) uses an indirect control framework called Pharmaceutical Price Regulation Scheme (PPRS) framework to regulate prices. The PPRS covers all branded prescription pharmaceuticals including pharmaceuticals sold to hospitals. Pharmaceuticals sold under generic names are not covered by the PPRS.

The work of Pharmaceutical Price Regulation Scheme (PPRS) includes two main components:

Profit controls. The profit controls sets a maximum level for the profits that a company may earn from the supply of branded drugs to the NHS. If the pharmaceutical companies exceed this level they will be required to repay the excess profits to the Department of Health. The profit control also enables the pharmaceutical companies to increase prices if profits are assessed by the Department as below a given minimum.

Price controls. The price control system gives the pharmaceutical companies the freedom to set the initial price of new active substances but impose restrictions on price increases. They also comprise price cuts which are agreed at the time of renegotiations. The pharmaceutical companies have some flexibility in deciding which pharmaceutical products to target in cutting prices. This system is known as price modulation.

The prices of other new branded products that are not new active substances have to be negotiated with the Department of Health. The NHS list price of existing products may only be increased with the Department of Health's agreement if the criteria for price increases set out in the agreement are met⁵.

A profit framework is fixed for each individual manufacturer. The PPRS covers about 80% (by value) of pharmaceuticals dispensed in the NHS⁶.

The profit control and price control are evaluated and renegotiated approximately every 5 years,

⁵ Under the terms of the new PPRS, from 2009 there will be flexibility for drug companies to increase or decrease the original list price of a drug if new evidence or a new indication comes to light that changes the value of a drug to the NHS. NICE would then consider whether the drug is cost-effective at the new price.

⁶ Negotiated periodically between DH and The Association of the British Pharmaceutical Industry (ABPI).

The PPRS scheme is not seen as a regulatory mechanism. It is best thought of as an attempt to exercise buyer power in the purchase of prescription pharmaceuticals by the NHS across the UK (Office of Fair Trading, 2007).⁷ All major companies chose to join the 1999 and 2005 PPRS.

⁷ Office of Fair Trade. The Pharmaceutical Price Regulation Scheme - An OFT market study. Office of Fair Trading, 2007.

3 Market place and purchasing

Hospital pharmacies purchasing

Each trust negotiates their prices with the manufactures.

Locally purchasing groups

On top of that every trust is represented on a purchasing group by a pharmacist or technician, these pharmacy staff meet locally and regularly to align procurement standards and approaches, and to exploit the purchasing power of their collective trusts, representing the interests of the trusts' budget holders, clinicians and relationships with PCTs. The resulting business is either aggregated at a regional level (for branded products) through 14 geographically based pharmacy purchasing groups, or at a national level (for generic and near patent expiry products) through the 6 SCEP award groups.⁸

To maximise NHS leverage and to minimise duplication of effort, NHS trusts aggregate their purchasing power on a collective basis (though their pharmacy purchasing groups). The National Health Service Purchasing and Supply Agency's (NHS-PASA) then competitively tenders this business in line with EU directives. Trusts agree their award decisions and NHS-PASA then manages the resulting framework agreements on behalf of the NHS trusts and their purchasing groups.

National purchasing and supply agency (NHS-PASA)

The National Health Service Purchasing and Supply Agency's (NHS-PASA), established in April 2000, is an executive agency of the Department of Health and provides strategic guidance on procurement. NHS-PASA acts as centre of expertise, knowledge and excellence in purchasing and supply matters for the health services. The NHS-PASA working with the pharmaceutical community from secondary care trusts is in a key position to advice on policy and the strategic direction of procurement.

NHS-PASA administers a database, Pharmex that contains all purchasing prices in England. The individual hospital purchaser can then benchmark their prices for hospital pharmaceuticals with other trusts prices, and use that in the negotiating procedure with the pharmaceutical companies.

The tendering procedure

The tendering process is as follows

⁸ SCEP is the The Supply Excellence Programme that has the objective to restructure the NHS supply chain to gain efficiencies and improve the effectiveness of supply management in the NHS.

- Pharmacists agree which drugs to tender for
- NHS Supplies place advert in OJEC (Official Journal of European Communities)
- NHS Supplies send tender documents to relevant suppliers
- Suppliers complete and return tenders
- NHS Supplies prepare adjudication documents
- Pharmacists adjudicate
- NHS Supplies notify suppliers (successful & not)
- Suppliers notify wholesalers
- Pharmacy Systems Changed
- Contract Starts

Competition

The pharmaceutical market is divided into pharmaceuticals with generic competition and into pharmaceuticals where only "Brands" are available. Generics are further subdivided into community type products (e.g. oral omeprazole) where the hospital market is a small proportion of the total and the supply risk is low, and hospital only products (e.g. injections) where the market has to be managed strategically. Where strategic management is required the hospital market is split into 6 groups. For community type products the award is normally made to a single supplier. A strategic process is used towards the manufacturers as they are provided with the indicative prices that contracts were awarded at the last procurement round.

For brand pharmaceuticals in a limited range of markets England, Wales have successfully used therapeutic tendering in EPO products, Growth hormones, low-heparins and bolus toxins. Savings in this area have been substantial and patient's care has been transferred from primary to secondary care if the costs in that sector are lower.

In some cases contracts are given to pharmaceutical companies even though they are not offering the lowest prices. This is done for strategic reasons to keep the competition in the market.

The role of value-added

The principal of value-added plays an important role in England and Wales in some markets. Value-added can for instance be sponsoring of a nurse. This is a good deal for the trusts, but it inhibits the penetration of generics into the market.

Reference prices

A specialised commission in London has managed to force the manufactures to reduce the cost on HIV pharmaceuticals to London.

Home care delivery services

Home care services provided by private companies is subject to VAT. Thus, the delivery services are not subject to VAT. E.g. services such as delivering dialysis equipment for "renal-patients" is offered by manufactures in return for the trust buying their products.

Delivery of hospital pharmaceutical

Delivery arrangements to hospitals are complex and individual to companies. Some deliver direct, some use pharmaceutical wholesalers and some have agency arrangements with wholesalers.

4 Professional management/clinics

NICE and treatment guidelines

In its assessment of clinical and cost-effectiveness The National Institute for Health and Clinical Excellence (NICE) makes use of health economic analyses and QALYs to form its recommendations. In practice NICE will also include additional factors such as social value judgments. NICE also recently announced adjustments to their appraisal methodology to widen access to drugs for end-of-life conditions. As a result, changes to NICE's Technology Appraisal methodology have been made that will allow greater flexibility on how NICE makes recommendations on the use of medicines that extend life at the end of life in treating certain rarer conditions. NICE's recommendations are issued to the NHS and offer guidance on the clinical and cost-effectiveness of drugs and new therapies. NICE guidance is applicable to both the hospital and community/primary care settings. There is a three month statutory funding direction on PCTs to fund NICE positively appraised drugs.

Hospital Drug and Therapeutics Committees are expected to follow NICE's recommendations regarding the cost-effectiveness of medicines. NICE only appraise a limited number of medicines. However, most major drugs are appraised by NICE and all new cancer drugs are as a rule appraised.

Therapeutic committees

The trusts and purchasing agencies work closely with the therapeutic committees. All acute trusts have a committee responsible for making decisions on medicines use within the trust, often referred to as the Drug and Therapeutics Committee. The committee is a mechanism for securing the commitment of clinicians to a rationalized system of medicines usage. Decisions reached by the Drug and Therapeutics Committee are used to inform the trust's preferred list of medicines, usually referred to as 'The Formulary'. The Formulary will contain medicines that the trust has identified as necessary to meet the clinical needs of its patients. Generally the committee takes responsibility for decisions on new drugs but it will also review the use of existing and already approved drugs.

The membership of the Drug and Therapeutics Committee is multidisciplinary. Besides representatives from the trust there will usually be input from the local health community (GP and pharmaceutical adviser) as well as a patient representative or lay member.

5 Expenditure and medicine prices

In UK medicines dispensed by a community pharmacist against a prescription have no VAT. Hospitals pay VAT, while there is no VAT on pharmaceuticals in primary care. Pharmaceuticals prescribed at hospitals are subject to VAT at a standard rate of 15%.