

## Pharmaceutical System in the UK



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## Disclaimer

Conflict of interest: Nothing to disclose

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## National Health Service

- NHS provides universal access to healthcare based on medical need rather than ability to pay.
- World's largest publicly funded health service responsible for great majority of healthcare in UK.
- Since devolution in 1999, responsibility for healthcare in Scotland, Wales and Northern Ireland transferred to devolved administrations.
- Services similar in most respects but differences.

## Medicines Expenditure

- Most frequently and widely used NHS treatment accounting for some 12% of NHS expenditure.
- NHS spending on drugs (England only) 2009-10
  - £7.9 billion Primary/community Care (Out-patient)
  - £4.0 billion Secondary/hospital Care (In-patient)
  - £11.9 billion Total

## Pharmaceutical System Overview

- New medicines developed by pharmaceutical companies
- Licensed (marketing authorisation) by EMA/MHRA
- Decisions on NHS price and reimbursement by Department of Health
- Medicines prescribed and dispensed to patients
- Clinical- and cost-effectiveness assessed by NICE
- Prescribers supported by NPC/prescribing advisors

## Licensing

- Marketing authorisation before a medicine can be marketed.
- Medicines licensed for use by the European Medicines Agency (EMA) or the UK Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health.
- Safety, quality and efficacy criteria.

## Pricing - brands

- Pharmaceutical Price Regulation Scheme is the pricing system for **branded** NHS medicines.
- Controls prices through regulating profits that pharmaceutical companies allowed to make on sales to the NHS.
- A balance between value for money for the NHS and a fair return for industry to enable it to research, develop and market new and improved medicines.

## Pricing - brands

- Freedom of pricing for innovative products (new active substances).
- Sets NHS list price (community and hospitals) i.e. price at which community pharmacists reimbursed.
- Hospitals may be able to purchase medicines under contract at a discount.
- NHS list price includes margin for distribution.

## Pricing - generics

- Prices of generic medicines set by market
- Freedom of pricing subject to maximum of reference product at patent expiry
- High generic prescribing rates – 83% prescriptions written generically by volume (England)

## Reimbursement

- No separate reimbursement system.
- Most medicines granted automatic (100%) NHS reimbursement after Marketing Authorisation and price approval.
- Small number on negative list and restricted list – only prescribable for certain patients/certain circumstances.
- Community pharmacists reimbursed for medicines and paid for provision of dispensing services.

## Reimbursement

- Paid according to drug prices, fees and allowances, published monthly in the Drug Tariff.
- Branded medicines at NHS list price set by PPRS.
- Generic medicines set using different mechanisms either using factory gate information on volume and sales or weighted average of price lists.
- Discount clawback scale (average 10%) deducted from reimbursement prices and retained margin contributes to cost of service provision.

## Reimbursement

- NHS Prescription Services reimburse pharmacies for prescriptions dispensed in the community.
- Hospitals purchase medicines locally against framework agreements awarded by the Department of Health Commercial Medicines Unit at either national or regional levels.

## Future changes

- Department of Health consultation on 'A new value-based approach to the pricing of branded medicines' December 2010.
- To be introduced at the expiry of current PPRS at end 2013.
- To promote greater innovation and access and a closer link between NHS price paid and value.

## Patient co-payments

- In England, fixed co-payment (standard prescription charge) per item (£7.40). Also Pre-payment certificates (season ticket).
- Exemptions (e.g. age, income, medical exemptions) – over 90% free at point of delivery.
- Prescription charges abolished in Scotland, Wales and N.Ireland.
- No payment for NHS medicines in hospitals.

## NICE Guidance

- National Institute for Health and Clinical Excellence (NICE) - guidance on the promotion of good health and the prevention and treatment of ill health for the NHS in England and Wales.
- Evidence-based recommendations on clinical and cost-effectiveness on most new medicines through technology appraisal guidance.
- Statutory funding direction requires NHS to put in place funding for drugs positively appraised by NICE within 3 months of final guidance.



## Prescriber support

- National Prescribing Centre (NPC) (now part of NICE) promotes and supports high quality cost-effective prescribing and medicines management across the NHS.
- Network of prescribing advisors (primary care) provide guidance to prescribers on cost-effective prescribing of medicines.
- Information on NHS list prices of medicines.

## Strengths

- PPRS
  - freedom of pricing = early launch of medicines
  - 5 year agreement = stability and predictability
  - 'Light touch' regulation
- High generic prescribing rates and competitive market
- NHS - focus from single structure
- NICE – regulatory excellence
- MHRA – world leader
- High level government-industry dialogue

## Any questions?

- Further information on:
  - Licensing at [www.mhra.gov.uk](http://www.mhra.gov.uk)
  - Regulation of prices at [www.dh.gov.uk/pprs](http://www.dh.gov.uk/pprs)
  - Clinical and cost-effectiveness at [www.nice.org.uk](http://www.nice.org.uk)
  - Cost-effective prescribing at [www.npc.nhs.uk](http://www.npc.nhs.uk)
- Thank you.

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