

Flow chart – pharmaceutical system in the UK in the in- and out-patient sector

New medicine

MARKETING AUTHORISATION

European Medicines Agency (EMA) or Medicines and Healthcare products Regulatory Agency (MHRA)

Task: Decision on marketing authorisation/licensing.

Criteria: Safety, quality and efficacy. (Directive 2001/83/EC relating to medicinal products for human use amended by Directives 2002/98/EC, 2003/63/EC, 2004/24/EC and 2004/27/EC).

MHRA also responsible for classification of medicines; post-marketing surveillance; ensuring compliance with statutory obligations e.g. advertising and distribution; and pharmacovigilance.

VIGILANCE

PRICING AND REIMBURSEMENT

Department of Health – Medicines Pharmacy and Industry Group

Task: Setting of National Health Service (NHS) list price/reimbursement price.

Criteria: The prices of branded prescription medicines supplied to the NHS are controlled by the Pharmaceutical Price Regulation Scheme (PPRS). NHS list price includes margin for distribution. The Drug Tariff sets the reimbursement prices for generic medicines. Hospitals may be able to purchase medicines under contract at a discount to the NHS list price.

There are no separate pricing and reimbursement mechanisms and the great majority of medicines prescribed on the NHS are granted automatic (100%) reimbursement.

OUT-PATIENT

IN-PATIENT

Department of Health – Medicines Pharmacy and Industry Group

All medicines that can be prescribed on the NHS are fully reimbursed except those on a negative list and those on a restricted list which may only be prescribed for certain patients and in certain circumstances (Schedules 1 and 2 to the NHS (General Medical services Contracts) (Prescription of Drugs etc) Regulations 2004).

Hospital Pharmaceutical and Therapeutic Committees

Task: Draw up a formulary of medicines that can be prescribed in the hospital although normally arrangements for exceptions.

Hospital pharmacy purchasing groups and Department of Health NHS CMU

In England, hospitals purchase most medicines centrally through hospital pharmacy purchasing groups via NHS CMU framework contracts or locally through individual NHS trusts or hospitals.

DISTRIBUTION

Pharmaceutical companies

Task: Supply medicines via wholesalers or direct to pharmacies and hospitals

OUT-PATIENT

Wholesalers

Wholesale margin not regulated – negotiated with pharmaceutical companies

IN-PATIENT

Community pharmacies

Pharmacy mark up not regulated – regulated with wholesalers

NHS Hospitals

Patients

In England, a fixed co-payment (standard prescription charge) for each item supplied but exemptions.

Patients

No payment for NHS medicines.

NHS Prescription Services

Task: Reimburse pharmacies for NHS prescriptions dispensed

GUIDANCE

National Institute for Health and Clinical Excellence (NICE)

Task: Provides the NHS (in England and Wales) with evidence-based recommendations on the clinical and cost effectiveness of most new drugs through its technology appraisal guidance.

Criteria: Technology appraisal guidance is based on a review of clinical and economic evidence. Clinical evidence measures how well the medicine or treatment works - the health benefits. The economic evidence shows how well the medicine or treatment works in relation to how much it costs the NHS and whether it represents value for money.