

YCFM event #2

“The Price of a Life – rationalising cost-effective medicine”

28th January 2010

BMA House, Tavistock Square

This is the information pack for the second event in the YCFM series on the 28th January at BMA House. We are providing you with an overview of some aspects of pharmaceutical policy in the UK to help you understand the issues that will be discussed.

Background

The UK pharmaceutical industry employs around 67,000 people and generates another 250,000 jobs in related industries, producing a positive trade balance of £6.2bn. Pharmaceutical companies carry out more than 25% of UK R&D.

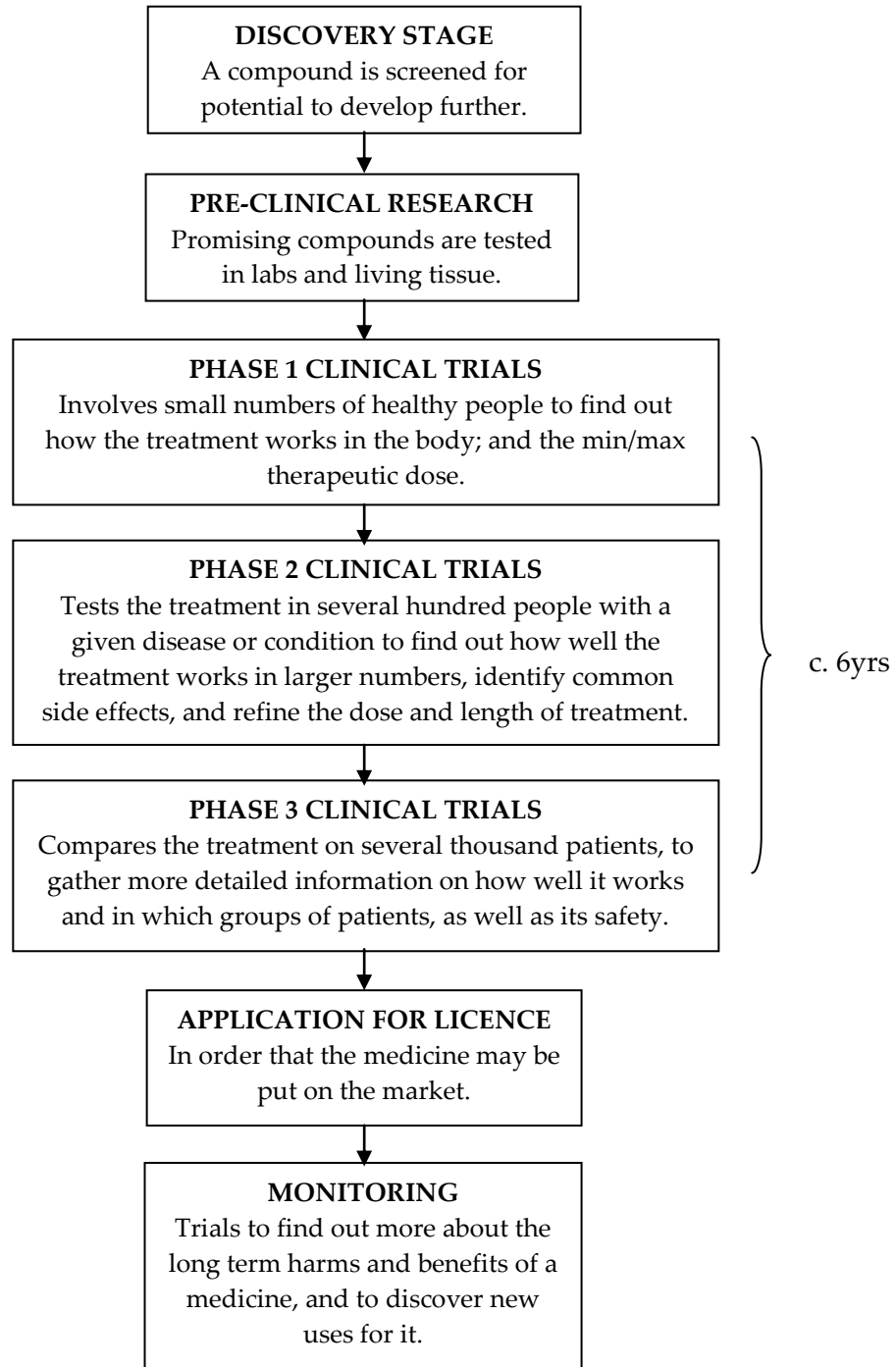
It takes an average of 10 years for a chemical compound to make the journey from the laboratory to a pharmacy shelf as a medicine, requiring both a great deal of skill and a great deal of money. On average, only one in 5,000 will end up as a prescription medicine.

To incentivise research, new compounds or areas for drug treatment can be protected (patented) for 20 years while development is taken forward. After this other companies can legitimately develop cheaper versions of the same medicine; called generics. The chart (fig.1) overleaf follows the typical process a drug follows from initial research to mainstream use. Regulation is provided by the UK-based Medicines and Healthcare products Regulatory Agency (MHRA) and EU-wide European Medicines Agency.

Once a drug is licensed for use in the UK, two further regulatory regimes come into play. First, the Pharmaceutical Price Regulation Scheme (PPRS, p.3), which regulates pharmaceutical prices/profits for branded drugs.

And second, that of the National Institute for Health and Clinical Excellence (NICE, p.5), which is responsible for deciding which treatments should be used in the NHS in England. Due to cost implications, not every new medicine will be widely available to all patients. NICE also issues evidence-based clinical guidelines.

Fig. 1.



Pharmaceutical pricing policy in the UK

Prescribing

British medical students, unlike their American counterparts, are taught to prescribe drugs by their generic, or recommended international non-proprietary name (rINN). These are designated by the World Health Organisation (WHO) to prevent confusion between different preparations of the same active substance.

However, UK doctors may subsequently write the branded name of the drug, reflecting a particular preparation, on the prescription or drug chart e.g. co-amoxiclav (generic) and Augmentin (brand).

Drugs can therefore be divided into two broad groups; branded and non-branded (generic).

The PPRS

The NHS spends approximately £11bn on drugs, accounting for around 10% of the total budget. 83% of this spending is on branded items. The prices of these medicines are controlled by the Pharmaceutical Price Regulation Scheme (PPRS).

The PPRS is a voluntary agreement between the Government and the pharmaceutical industry, typically of 5 years, to try and create a compromise between two differing objectives: obtaining medicines as cheaply as possible for the NHS while also encouraging R&D.

The pharmaceutical industry is represented in these negotiations by the Association of the British Pharmaceutical Industry (ABPI). This is a trade association for more than 90 companies in the UK which, combined, supply more than 80 per cent of the medicines prescribed in the NHS.

Broadly speaking, the PPRS works by regulating the annual profit of pharmaceutical companies to 21% of their capital.¹ Levels of profit greatly in excess of this will incur fines that the companies will have to pay back to the government and/or reduce prices.

In 2007, budgetary pressures and criticism from the Office of Fair Trading (OFT) prompted the Department of Health to renegotiate the 2005 PPRS early. The resulting 2009 PPRS introduced a 3.9% cut in the list price of branded medicines sold to the NHS from 1 February 2009 (and a further price cut of 1.9% in January 2010).

¹ The worldwide average profit is 14% of capital, thus this creates a strong incentive for companies to invest in the UK.

However, the 2009 PPRS also, for the first time, includes support for innovation and the uptake of new, cost-effective, medicine, increasing the R&D allowance from NHS sales to a maximum of 30%.

The 2009 PPRS also introduced two new initiatives:

- i. **Generic substitution.** This enables pharmacists and other dispensers to fulfil a prescription for a branded medicine by dispensing an equivalent generic medicine (though clinical judgement can override this).
- ii. **Flexible prices.** This enables pharmaceutical companies to supply medicines to the NHS at lower initial prices, with the option of higher prices if value is proven at a later date (this is only applicable for medicines that are subject to NICE appraisal).²

As part of this agreement, patient access schemes (PASs) can allow earlier NHS patient access to medicines that are not in the first instance found to be cost-effective by NICE.

National Institute for Health and Clinical Excellence (NICE)

Technology appraisals

Once a new drug/medical device is licensed for use, more than likely it will be assessed by NICE to determine whether or not it will be used within the NHS.³

Known as a **technology appraisal**, this assessment is based on a review of both clinical evidence (to measure how well the medicine or treatment works) and economic evidence (to measure value for money, i.e. how well the medicine or treatment works in relation to how much it will cost the NHS).

Key to this is an evaluation of the cost to the NHS of a given amount of improved quality of life (price per or Quality Adjusted Life Year or QALY) based on the proposed price of the drug. To help with this, NICE assembles specialist groups, representing a wide range of stakeholders including specialist clinicians, patients, healthcare workers and industry figures.

Generally, if a QALY is below a sliding threshold set by NICE (typically c.£ 30,000/QALY), the drug will be approved for use and Primary Care Trusts (PCTs), under the terms of the NHS Constitution, are then *obliged* to fund it for patients in need.

² Previously industry had freedom of pricing for new medicine (which it retains), but thereafter could not increase prices.

³ This ultimately depends on the Government referring the case to NICE.

If a QALY is below this threshold, the drug will not be approved for use within the NHS. However, this must be qualified. Following guidance issued by the Government in 2008, patients are allowed to pay top-up fees to use cancer drugs not deemed cost-effective by NICE, while continuing the rest of their treatment on the NHS.

Clinical guidelines and public health guidance

Although the public image of NICE is its role in technology appraisal, considerable amounts of its work – and impact on clinicians – is focused elsewhere:

- i. **Clinical guidelines** are recommendations by NICE on the appropriate treatment and care of people with specific diseases and conditions within the NHS. These are based on the best available evidence. While health professionals are expected to take it fully into account when deciding what treatments to give people, the guidelines do not replace their knowledge and skills.
- ii. **Public health guidance** contains recommendations for populations and individuals on activities, policies and strategies that can help prevent disease or improve health. The guidance may focus on a particular topic (such as smoking), a particular population (such as schoolchildren) or a particular setting (such as the workplace).
- iii. **Quality standards.** Following Lord Darzi's Next Stage Review (2008), NICE is tasked with developing independent standards of quality for the NHS relating to clinical effectiveness, patient safety and patient experience.

As part of this, it now recommends clinical indicators for inclusion in the pay-for-performance part of the GP contract, the Quality and Outcomes Framework.

Criticisms of NICE

Established in 1999, NICE has developed a worldwide reputation for its work in evaluating health interventions, but it has also come in for criticism from some quarters over:

- i. Transparency. In May 2008, NICE was [criticised in the Court of Appeal](#), which ruled that it should reveal the methodology of the computer models it uses to measure value for money.
- ii. The length of time taken to evaluate a new drug, which in the past has taken up to two years. During this time PCTs have been reluctant to fund these medicines; with the result that access for NHS patients has been delayed *vis-à-vis* other countries in a phenomenon called 'NICE blight'.

By way of response, NICE has now put in place a faster appraisal process for key new drugs which enables it to issue authoritative guidance on them within a few months of their UK launch.

- iii. Straitjacketing clinical decision making. There have been instances, such as NICE guidance issued on the management of lower back pain, where prominent clinicians [have objected to its recommendations](#).
- iv. A failure to end 'postcode lotteries' in prescribing. This is now being addressed by a patient's right, enshrined in the NHS Constitution, to have access to appropriate drugs approved by NICE. However, there are still issues arising as a result of devolved drug budgets, for example the Scottish Medicines Consortium (Scotland's version of NICE) recently approved an [arthritis](#) drug which NICE look set to turn down.

Our Guest Speakers

Professor Sir Michael Rawlins

Professor Sir Michael Rawlins has been chairman of NICE since it was founded in 1999. He holds an Honorary Professorship at the London School of Hygiene and Tropical Medicine, University of London and the University of Newcastle upon Tyne.

Sir Michael was the Ruth and Lionel Jacobson Professor of Clinical Pharmacology at the University of Newcastle upon Tyne from 1973 to 2006 whilst also consultant physician and consultant clinical pharmacologist to the Newcastle Hospitals NHS Trust. He has also been vice-chair of the Committee on the Safety of Medicines and chaired the Advisory Council on the Misuse of Drugs.

Dr Richard Barker

Dr Barker has been Director General of the Association of the British Pharmaceutical Industry since 2004. He is also a board member of EFPIA (the European industry association) and council member of IFPMA (the international equivalent).

He is Chairman of *Stem Cells for Safer Medicines*, a public-private partnership developing stem cell technology for predicting the safety profile of new medicines. Dr Barker is also on the board of Datapharm Communications, a new online initiative bringing medicines information to UK prescribers and patients, and a member of the TB Alliance.

His previous roles include leader of McKinsey's healthcare division, Chief Executive of Chiron Diagnostics and General Manager of IBM's Worldwide Healthcare Solutions business practice.

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Abbreviations

ABPI = Association of of the British Pharmaceutical Industry

DH = Department of Health

MHRA = Medicines and Healthcare products Regulatory Agency

NICE = National Institute of Health and Clinical Excellence

NHS = National Health Service

OFT = Office of Fair Trading

PCT = Primary Care Trust

PPRS = Pharmaceutical Price Regulation Scheme

QALY = Quality Adjusted Life Year

R&D = Research and Development

rINN = recommended international non-proprietary name

WHO = World Health Organisation

YCFM Steering Committee

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