**GEDLING PRIMARY CARE TRUST**
**DIRECTORATE OF PUBLIC HEALTH & PARTNERSHIPS**

# INTRODUCING NEW TECHNOLOGIES AND PHARMACEUTICAL PRODUCTS INTO THE NHS

## INTRODUCTION

This paper gives a brief overview of the process through which new products for use by patients are regulated, both at national and at local level. The items concerned include all new pharmaceutical products that may or may not require a prescription, and new devices such as different types of cardiac pacemakers.

## CLINICAL TRIALS

New pharmaceutical products must go through three phases of trials:

Phase I: After a potential candidate drug is identified and checked on animals, it is first given to healthy volunteers. This enables optimum doses to be calculated and any potential side effects to be noted.

Phase 2: The new drug is then enlisted into a formal clinical trial, either comparing it to a placebo or the existing best practice treatment regime. At this stage the drug is only available for patients within the approved trials or possibly on a named patient basis. All such trials must be approved by the Ethics Committees of the Trusts and/or PCTs in which they are being carried out.
The development to Phase 2 trials is usually a number of years.

Phase 3 [Post-marketing surveillance]: Once the drug has been shown to be safe and effective in Phase 2 trials, the manufacturer will apply for a licence (see below) and the drug becomes available for use by prescribers. However, for the initial period of its release, prescribers are asked to pay particular attention to any side effects reported by patients and to inform the Committee on Safety of Medicines (CSM) using the 'yellow card' available in all copies of the British National Formulary (BNF) or on line through the CSM website. These new drugs are listed in the BNF with a black triangle beside their name and a comment that there is limited experience on the use of the product and a request that ALL suspected adverse reactions should be reported.

## MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA)

This government organisation is responsible for the licensing of all pharmaceutical and health care technological products. Safety, quality and efficacy are the only criteria on which legislation to control medicines for human use are founded. When applying for a licence, the pharmaceutical company will submit evidence to the MHRA. The CSM, within the MHRA, will

review the application and produce an independent assessment. The CSM may recommend:

- That a licence is granted
- The application is accepted subject to specific modifications
- The application is rejected, again for specific reasons

A licence will be granted if the medicine is of acceptable quality, safe and effective. The Medicines Act specifically excludes from the licensing criteria any consideration of comparative efficacy. The MHRA is therefore obliged to licence a safe drug of acceptable quality even if it is less affective for a given condition than its potential rivals.

The licence for a new drug will specify

- The particular indications for which it may be used
- The age group

The licensing process is expensive for the manufacturer, not only in terms of the charges made by the MHRA but also the costs of assembling the evidence. For some drugs it may therefore not be worth the companies' time in this country, resulting in so-called 'orphan' drugs. An example of this is melatonin, widely used to regulate sleep patterns especially in children with Attention Deficit Hyperactivity Disorder.

In other cases, a drug may be licensed for one indication, but also used for another. Especially if the drug is out of patent, there is no financial advantage to the manufacturer to pay to extend the licence.

The main issue in respect of licensing is, however, in prescribing for children. Because of the ethical difficulties and additional expense, few trials are done in children and many of the drugs prescribed for them are therefore technically unlicensed for use on children under the age of 12. Prescribers are therefore advised to ensure they prescribe in accordance with national best practice.

The MHRA licenses new devices according the relevant European Community Directives, which state that any device must be safe and fit for their intended purpose prior to marketing. It is also introducing similar systems for herbal and homeopathic remedies.

## NATIONAL INSTITUTE FOR HEALTH & CLINICAL EXCELLENCE (NICE)

The National Institute for Health and Clinical Excellence (NICE) was formed on 1st April 2005, when the existing National Institute for Clinical Excellence took on the functions of the Health Development Agency to create a single excellence-in-practice organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.

NICE produces guidance in three areas of health:

- Public Health: guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
- Health Technologies: guidance on the use of new and existing medicines, treatments and procedures within the NHS
- Clinical practice: guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.

If a drug or device is currently being appraised by NICE, NHS organisations should make decisions on its use locally. Local Government and NHS organisations are expected to take account of NICE public health guidance in taking action to achieve the targets set out in the 'Choosing Health' White Paper and in the development of local area agreements.

NICE is asked to look at particular drugs and devices when there is uncertainty about the value of a drug or device or when prescribing practices vary across the country. Once NICE publishes guidance, health professionals and the organisations that employ them are expected to take it into account fully when deciding what treatments to give people. Local NHS organisations normally have three months from the date of publication of each technology appraisal guidance to provide funding and resources to implement that guidance.

## LOCAL PROCEDURES

Within the Greater Nottingham Health Community, all newly licensed drugs are reviewed by the Area Prescribing Committee and coded in a 'Traffic Light' system, summarised in the table below.

| Colour | Description |
|---|---|
| Grey | Drugs that have yet to be reviewed by the Hospital Trusts Drug and Therapeutics Committees and whose role is therefore not yet known locally |
| Red | Drugs that are classified as suitable for prescribing only by hospital specialists |
| Amber 1 | Drugs that are prescribed in accordance with a local Shared Care Protocol (SCP), initiated by secondary care clinicians and continued by primary care staff. |
| Amber 2 | Drugs that are initiated only on the recommendation of secondary care clinicians but prescribed by primary care clinicians, without an SCP |
| Green | Drugs that may be started in either primary or secondary care. |

There is a clear process to follow for all secondary care clinicians who wish to use a new pharmaceutical product. Consultants are expected to complete an application to have the drug considered at the Trusts' Drug and Therapeutics Committee (DTC), for which they should have directorate support. One off applications to try a very new drug can be agreed for up to 2 patients in discussion with the Chair of the DTC. However, General practitioners, as

independent contractors, can technically prescribe any licensed medication. The traffic light system is therefore advisory and recommends best practice.

The APC also reviews NICE guidance as it is issued monthly and may make recommendations about how it should be implemented locally. However the decision on how this is done is up to each PCT. In Gedling, all NICE Guidance is considered by the Clinical Effectiveness Group, which decides:

- Whether the guidance is relevant to primary care
- If it is relevant, which staff group needs to be made aware of it and the best mechanism to ensure this
- How the implementation of the guidance should be monitored locally
- This information is then given to the Integrated Governance Committee.

**FUNDING ISSUES**

Most new drugs and procedures within secondary care are covered by the overall tariff price within 'Payment by Results' or the annual uplift awarded to the relevant Trust. For those specialist drugs and devices that are outside tariff, the annual planning process will identify appropriate increases, often at a level above that of an individual PCT, e.g. through the Mid Trent Cancer Network or Trentcomm for specialised commissioning.

Funding for pharmaceutical trials is covered by either the pharmaceutical industry or the Trust's Research and Development allocation.

Within primary care, the implications of new drugs are incorporated into the allocation for the prescribing budget on an annual basis.

**RECOMMENDATION**

The Board is asked to note this report and comment on the implications**.**

Mary Corcoran
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10th March 2006