THE LICENSING OF MEDICINES IN THE UK
AND THEIR USE IN THE NHS

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This briefing is an update of SB 06-51 ‘The Licensing of Medicines in the UK and their use in the NHS’, published on 14 June 2006. It explains the process for licensing new drugs and treatments in the UK, and the process for issuing advice/guidance on their use in the NHS in Scotland compared to England and Wales.
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INTRODUCTION

There has been significant interest in the licensing of medicines in the UK and the subsequent guidance on their use in the NHS.

This briefing outlines both the process for licensing a medicine in the UK and the process for issuing guidance to the NHS in the use of such a medicine. It describes the role of the various bodies involved and also discusses where the ultimate responsibility for prescribing a medicine lies.

Figure 1 outlines the process for licensing medicines in the UK, and then the process for issuing guidance to the NHS in Scotland compared to England and Wales. These processes shall be discussed in detail below.

*Figure 1: The process for licensing a medicine and the issuing of guidance to the NHS on its use*

[Diagram showing the process for licensing a medicine and issuing guidance to the NHS on its use.]
PRIMACY OF MEDICAL PRACTITIONERS

It is important to note that despite the licensing procedures and guidance for the use of new treatments or a new use of an existing treatment, it is ultimately the decision of clinicians to decide whether or not a drug should be used in the treatment of their patient. In prescribing an unlicensed medicine the clinician must ensure a number of things, including:

- that the treatment is not a controlled drug
- that the clinician has consulted with and gained the consent of the patient
- that if the treatment does contain a controlled substance, that it has been granted a license for importation by the UK Home Office under the Misuse of Drugs Act 1971 (ch 38)

If a clinician feels that a particular unlicensed product would benefit their patient then they have to be prepared to take the full clinical and legal responsibility for the prescription, and as a result many clinicians will not prescribe a medicine that has not been licensed. Should they be prepared to prescribe the drug then it is also up to them to secure a supply and funding for their patient. In some cases the patient may choose to fund it themselves. However, for the NHS to fund such a treatment, the NHS board (in Scotland) or Primary Care Trust (in England and Wales), which employs the practitioner, would have to be prepared to fund the prescription. Generally, in Scotland, a NHS board’s Area Drug & Therapeutics Committee would be the most likely body that would consider the funding request and make a recommendation to the NHS board.

However, even if there is advice/guidance produced for a particular medicine, it does not override the individual responsibility of the clinician to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

LICENSING

The licensing of medicines is a reserved matter. Under the current legislative framework, a medicine is defined as something used in disease (whether it is used to prevent, treat or diagnose it), in anaesthesia, investigating conditions or interfering with the normal operation of the body. Numerous factors are considered in deciding whether a product is actually a medicine such as: what it contains; what it’s advertised or used for; the way it will be used; any particular targeting of the marketing information; and, what the promotional literature says.

In the UK, all medicines and medical devices for human and animal use are subject to a system of licensing laid down in EC legislation, the UK Medicines Act 1968 (ch 67) and other subsequent regulations. This is an area reserved to the UK Parliament. The control of medicines starts as soon as they are first discovered and tested, all the way through to when a company wants to change the conditions its products are approved for, such as changing the colour of the tablet, or what it is used for. Before a medicine gets to the stage of licensing it will, typically, have undergone 12 years of research and development. In this long process, the substances that were identified in basic research need to pass the pre-clinical & clinical tests. Pharmaceutical companies quite often research and test 10,000-30,000 different substances before one can be successfully licensed for use.

Following the development process the pharmaceutical company will seek a licence for the medicine. The purpose of the licensing process is to consider whether the medicine has a measurable effect against a comparator in a clinical trial (referred to as “efficacy”) and, whether, on balance, the drug is likely to have an acceptable level of safety and quality. There are two ways of obtaining a licence for the UK:

providing research and information services to the Scottish Parliament
• applying for a UK licence through the Medicines and Healthcare products Regulatory Agency (MHRA)
• applying for a European licence through the European Medicines Evaluation Agency (EMEA), which relates to all EU Member States

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA)
The MHRA was set up in April 2003 from a merger of the Medicines Control Agency and the Medical Devices Agency. It is an executive agency of the UK Department of Health, and is responsible for ensuring that medicines and medical devices work, and are acceptably safe.

The MHRA regulates a wide range of materials from medicines and medical devices to blood and therapeutic products/services that are derived from tissue engineering.

MHRA’s Commission on Human Medicines (CHM) assesses the application, and recommends whether the drug should get a licence or not. If it does then the product will receive its marketing authorisation and can be ‘launched’ ie the introduction of a new product or new indication to the market.

EUROPEAN MEDICINES EVALUATION AGENCY (EMEA)
The European Union (EU) established EMEA in 1995. Its main responsibility is the protection and promotion of public health, through the evaluation and supervision of medicines for human use. EMEA coordinates the evaluation and supervision of medicinal products throughout the EU, and is supported by the scientific resources of over 40 national competent authorities in 30 EU and EEA-EFTA (European Economic Area-European Free Trade Area) countries in a network of over 4,000 European experts.

EMEA began its activities when the European system for authorising medicinal products was introduced, providing for a centralised and a decentralised procedure. EMEA has a role in both, but is primarily involved in the centralised procedure. These processes are outlined below. However, it should be noted that there are some types of medicines that must be submitted for licensing: all biotechnology products, medicines for cancer, HIV/AIDS, diabetes, neurodegenerative disease and all orphan drugs.

Decentralised procedure
Under this procedure one member state assesses the application eg MHRA in the UK. If it recommends that the medicine be licensed, the other member states then either agree ie ‘mutually recognise’ the drug licence, or object. If all member states agree, the medicine is given marketing approval. If there is any disagreement, the Committee for Medicinal Products for Human Use (CPMP) will step in and arbitrate. It then advises the European Commission whether or not to license the medicine.

Centralised procedure
Where the centralised procedure is used, companies submit one single marketing authorisation application to EMEA. A single evaluation is carried out through CHMP, and if it concludes that quality, safety and efficacy of the medicinal product is sufficiently proven, it adopts a positive opinion. This is sent to the Commission to be transformed into a single market authorisation valid for the whole of the European Union. Following this, the product can be launched.

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1 The official permission from the regulatory authority (either the MHRA or the EMEA) to market/sell a product in the UK. This defines the indications for use as well as any contraindications and cautions to the use of the product.
2 It also has responsibility animal health and medicines for veterinary use, but this is not covered in this briefing.
Other EMEA Committees

Over recent years additional committees have been set up to undertake specific work on behalf of EMEA.

In 2001 the Committee on Orphan Medicinal Products (COMP) was established, charged with reviewing designation applications from persons or companies who intend to develop medicines for rare diseases (so-called ‘orphan drugs’), that affect fewer than 5 out of every 10,000 people in the EU. Given that pharmaceutical companies would not normally be able to make much profit from these medicines, because so few people would need them, they are eligible for a number of incentives, including:

- having to pay less in fees to license the medicine
- a longer time than usual when only they can market the medicine (market exclusivity)
- extra money for research and development

The Committee on Herbal Medicinal Products (HMPC) was established in 2004 and provides scientific opinions on traditional herbal medicines.

USE OF LICENSED MEDICINES IN THE NHS

Once a medicine has been licensed many clinicians will prefer to await official advice/guidance before prescribing it. It is important to note that NHS advice/guidance is not the same as licensing and it has no effect on the licence status of the medicine. The licensing process considers quality, efficacy and safety, whilst NHS advice/guidance considers the clinical effectiveness\(^3\) and cost effectiveness\(^4\) of the medicine.

It is the process for producing this advice/guidance that causes the most confusion and debate. Guidance over the use of licensed drugs in the NHS in Scotland is a devolved matter. However, there is a level of joint working that takes place between the organisations responsible for issuing this advice/guidance across the UK.

KEY ORGANISATIONS

In Scotland, the principal organisations for producing advice/guidance are the Scottish Medicines Consortium (SMC) and NHS Quality Improvement Scotland (NHS QIS), whilst in England and Wales it is the National Institute for Health and Clinical Excellence (NICE).

The SMC, under the umbrella of NHS QIS, advises on the clinical effectiveness and cost effectiveness of all newly licensed medicines (please see below). It is composed of members from the NHS boards and is managed and supported by an executive team and secretariat.

NHS QIS is a special health board. It provides a national service, but rather than managing health services directly, it works with and supports other organisations that do. NHS QIS is the lead organisation in NHS Scotland for improving the quality of healthcare delivered. Its roles include providing clear advice and guidance to NHSScotland on effective clinical practice. It is also an umbrella for other organisations that work to improve the quality of healthcare.

NICE was first set up in 1999 and its role reviewed and expanded in 2005. It is responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health in England and Wales. As part of its role it produces technology appraisals, which

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\(^3\) How the drug will be used in practice and how it compares to the existing treatment.

\(^4\) Whether or not it is good value for money.
offer guidance on the use of selected new and existing medicines and treatments within the NHS in England and Wales. The NHS in England and Wales is obliged to adhere to NICE guidance.

PROCESSES IN SCOTLAND AND ENGLAND & WALES FOR PRODUCING ADVICE

SMC, NHS QIS and NICE organisations have their own processes for developing guidance, but, as shown in Figure 1, above, there is a level of cooperation between the two bodies. Thus, to outline the process for developing advice/guidance for NHS boards in Scotland it is crucial to describe both processes.

When a medicine is licensed

The following section describes the processes employed in both Scotland and England in producing guidance when a medicine receives its license.

Scotland

The Scottish Medicines Consortium (SMC) advises NHS boards and their Area Drug and Therapeutic Committees (ADTCs) on the use of all new medicines, new indications and new formulations as soon as possible after they are licensed by MHRA or EMEA. It is important to note that the SMC does not issue advice on medical devices, vaccines, branded generic drugs, non-prescription-only medicines, blood products, plasma substitutes and diagnostic drugs.

The SMC was established in October 2001 and considers medicines licensed since January 2002. Prior to this decisions on which new medicines to approve were taken by the local ADTCs, which resulted in the possibility of wide variation in the provision of new medicines across Scotland and involved much duplication of effort. Thus, the SMC was created to help reduce “postcode prescribing”. The SMC is made up of representatives of all ADTCs, other health professionals, the pharmaceutical industry and patient representatives. The SMC process for producing its advice is illustrated in Figure 2:

![Figure 2: SMC Processes and Timelines](source: Dear et al (2007))

Source: Dear et al (2007)
In summary, the SMC first requires pharmaceutical companies to complete a New Product Submission form. In order that advice can be published soon after the product becomes available for use the submission needs to be made before product license. SMC then undertakes a clinical, scientific and cost-effectiveness rapid assessment of the company’s submission, and will issue advice on its use. The SMC process is more fully discussed in a paper by Dear et al (2007).

NHS QIS (2006, p 6) states that SMC advice on unique medicines accepted for use for specific conditions are obligatory and must be introduced in NHSScotland to an agreed national programme. Medicines that are accepted for use for conditions where alternative drug treatments already exist are subject to local NHS board decisions; these are the majority of SMC decisions with only one unique drug in the last three years.

In time, SMC advice may be superseded by the advice of a NICE multiple technology appraisal (MTA) (see below) if it is endorsed by NHS QIS. The Scottish Government expects NHS boards in Scotland to implement advice from the SMC and guidance from NHS QIS.

England and Wales

As outlined in Figure 1, above, NICE only considers medicines referred to it by UK Ministers. NICE produces initial guidance for selected medicines through its single technology appraisal (STA) process. This is a recent development that only started in mid-2006. Prior to this, there was no such procedure, and this meant newly licensed medicines had to wait for the full evaluation process (see below) to be undertaken. Given the SMC remit in Scotland for dealing with newly licensed medicines this often led to advice being issued in Scotland a significant time before that in England.

Therefore, NICE introduced its STA process, which is a more rapid process for assessing drugs and other treatments to sit alongside its standard process. The process for evaluating drugs is similar to that of SMC. NHS QIS (2006, p 7) notes that the STA process covers all health technologies and enables single new drugs, and existing drugs with new indications to be assessed more rapidly than its fuller evaluation process. This means NICE can produce faster guidance for England and Wales on a small number of selected drugs chosen by the UK Department of Health which have already been recently licensed.

NICE STAs have no formal status in Scotland, though NHS QIS publishes them on its website for information. This was confirmed in 2007 through a Health Department Letter by the then Scottish Executive (2007a).

It should be noted that in a recent report into NICE by the House of Commons Health Select Committee (2007, para 200) it recommended that NICE should examine all new medicines when they have been licensed (as happens in Scotland through the SMC). In its response the UK Department of Health (2008, p 3) said it would reflect on the recommendations further, though noted that such a proposal may lead to a longer fuller evaluation process and noted how the development of the STA process was a recognition of the need to produce faster guidance.

Following the publication of initial advice

As outlined in Figure 1, above, in some circumstances, SMC advice may be superseded if NHS QIS endorses a NICE Multiple Technology Appraisals (MTA) relevant to the product or condition to be treated as being valid for Scotland. The MTA process is a fuller evaluation process that NICE undertakes for new medicines, in addition to its STA process.
Multiple Technology Appraisal process
The Multiple Technology Appraisal process undertaken by NICE is briefly outlined in Figure 3.

The process itself can take up to 54 weeks to be completed, though in some cases it has taken much longer than this depending on whether the decision of NICE is appealed. As discussed above it is the length of time of the NICE MTA process that has often been criticised, particularly given the delay to patients who may benefit from new treatments. This was especially the case when there was no STA process.

Figure 3: The NICE Multiple Technology Appraisal Process

<table>
<thead>
<tr>
<th>Provisional appraisal topics chosen</th>
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<tr>
<td>The Department of Health produces a list of provisional appraisal topics.</td>
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<table>
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<tr>
<th>Consultees and commentators identified</th>
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<tr>
<td>National organisations including groups representing patients and carers, bodies representing health professionals, manufacturers and research groups.</td>
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<tr>
<th>Scope prepared</th>
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<tr>
<td>NICE works with the Department of Health to develop a scope. This document sets out what the appraisal will cover and the questions that need to be asked. Consultees and commentators comment on the draft scope.</td>
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<table>
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<tr>
<th>Appraisal topic referred</th>
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<tr>
<td>The Department of Health refers technology appraisal topics to NICE.</td>
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<tr>
<th>Assessment report prepared</th>
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<tr>
<td>NICE commissions an independent academic centre to review published evidence on the technology and prepare an assessment report. Consultees and commentators are invited to comment on the report. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents. Commentator organisations include manufacturers of the products with which the technology is being compared, NHS Quality Improvement Scotland (see below) and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.</td>
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<tr>
<th>Evaluation report prepared</th>
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<tr>
<td>The assessment report and comments on it are drawn together in the evaluation report.</td>
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<tr>
<th>Appraisal consultation document (ACD) produced</th>
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<tr>
<td>An independent appraisal committee considers the evaluation report. It hears evidence from nominated clinical experts, patients and carers, before making its first recommendations in the ACD. Consultees and commentators have four weeks to comment on the ACD. The ACD is also made available online so health professionals and members of the public can comment on it.</td>
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<th>Final appraisal determination (FAD) produced</th>
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<tr>
<td>The independent appraisal committee considers the comments on the ACD, then makes its final recommendations in the FAD. The FAD is submitted to NICE for approval. Consultees can appeal against the final recommendations in the FAD.</td>
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</table>
Guidance issued
If there are no appeals, or an appeal is not upheld, the final recommendations are issued as NICE guidance.

Source: NICE, Developing NICE technology appraisals. [Online]

**NICE Multiple Technology Appraisals and their use in Scotland**

NHS QIS is involved in the NICE appraisal process, with one Scottish expert being assigned to a MTA throughout the whole process. In addition, a group of 4-5 experts reviews the draft NICE MTA. This means that NHS QIS is in a position to publish its guidance on the MTA at the time NICE publishes its final MTA advice on a particular drug.

NHS QIS (2003) notes that when considering the suitability of the NICE MTA for Scotland, it takes into account the following:

- the principles and values of NHS Scotland
- epidemiology (frequency, distribution and stage at presentation)
- structure and provision of services
- other implications for NHS Scotland eg rural issues, predicted uptake, existing advice from the SMC

NHS QIS (2006, p 7) notes that it will then advise NHS Boards on whether the MTA is valid for Scotland or not. If the MTA is deemed to be valid for Scotland, it supersedes any relevant SMC guidance, and, as a result, the NHS in Scotland should take account of the advice and ensure that recommended drugs and treatment are made available to meet clinical need. If the MTA should not be deemed valid for Scotland it would then be discussed with Scottish Government Health Directorate, though to date this has never occurred.

One point of interest is the extent to which SMC advice mirrors that of NICE MTAs for the same medicines and indications. Dear et al (2007, p 23) considered the 35 cases between 2002 and 2006 where SMC and NICE MTA looked at essentially the same medicines and indications. They found that decisions from SMC had been generated on average 12 months earlier, and the recommendation from NICE has been the same as that at SMC in all but six cases.

**FURTHER CONSIDERATIONS**

There are a number of issues that commonly arise from the process of issuing guidance, including the status of all guidance in terms of NHS Boards in Scotland and the capability of NHS Boards to make a decision contrary to the guidance in exceptional circumstances.

**The status of advice from SMC and NICE MTAs**

NHS Boards are responsible for the delivery of health care services in their areas, based on local need. The Scottish Executive expects NHS Boards in Scotland to follow advice from the SMC and guidance from NHS QIS. On the SMC website it states:

“The Minister for Health and Community Care has publicly stated that “NHSScotland should take account of the advice and evidence from the SMC and ensure that recommended medicines are made available to meet clinical need””.

However, ultimately, the decision to use the advice/guidance rests with the individual clinician. Indeed the SMC website further states:
“Individual clinicians should take account of SMC’s advice when exercising their clinical judgement, unless there is evidence to justify not doing so in the light of particular circumstances of an individual patient.”

As regards the use of MTAs deemed valid for use in Scotland by NHS QIS the advice is the same:

“For NHS QIS-validated MTAs, NHSScotland should take account of the advice from NHS QIS and ensure that recommended drugs and treatment are made available to meet clinical need.” (NHS QIS, 2006).

**The exercising of judgement by NHS Boards in cases of an exceptional circumstance**

An area of recent controversy has concerned the ability of NHS boards to determine that a particular patient is an “exceptional case”. Examples of this have usually surrounded NHS boards deciding to pay for a medicine that is not recommended for use by SMC or NHS QIS.

As discussed at the beginning of this briefing, it is up to an individual clinician to determine the treatment for their patient. If they believe that a particular medicine, which has not been recommended for use in the NHS, would be of benefit to their patient the main issue then becomes how it will be paid for. One option is for patients to fund such treatments themselves. However, this can often be extremely expensive, and would mean the patient has to become a private patient. The consultant contract explicitly states that a patient cannot be treated as a NHS patient and a private patient for the same episode. Guidance on this was issued by the Chief Medical Officer for Scotland in February 2007 (Scottish Executive, 2007b).

Another option is for the clinician to ask the NHS board to pay for the treatment despite it not being recommended for use. They will make representations to their NHS board setting out their reasons for believing their patient is an exceptional case and why they would benefit from the medicine in question. It should be noted that, as illustrated below, there are no rules that define exceptional status. However, the patient should be:

a) significantly different to the general population of patients with the condition in question
b) likely to gain more benefit from the medicine than the average patient

NHS Boards may have their own procedures for dealing with such decisions, but one method employed is for such representations to be made, initially, to a NHS board’s Area Drug and Therapeutic Committee, which would consider the case. It would then make a recommendation to the full NHS board. In coming to a decision, NHS boards should take account of the recommendations of SMC and NHS QIS.

In a recent answer to a Parliamentary Question, the Minister for Public Health, Shona Robison MSP, stated:

“NHS boards should have processes in place to determine their prescribing policy on medicines, including consideration of requests by clinicians to prescribe medicines not approved by the Scottish Medicines Consortium. Each request should be considered on its individual merit. The department has not issued national guidance governing consideration of “exceptional case” medicines requests.” (Scottish Parliament, 2008).

This was further explained by the Cabinet Secretary for Health and Wellbeing, Nicola Sturgeon MSP, in answer to an oral question concerning a particular case:
“...it is essential to have in place a system for approving new drugs, and that that system must be expert led and evidence based. In Scotland, the process is conducted primarily through the Scottish Medicines Consortium. New evidence will always be considered, because it is vital that decisions should always be taken on a clinical basis...I confirm that, when the Scottish Medicines Consortium has not approved a drug, it is open to any clinician to put the argument to a health board that a particular patient is an exceptional case.” (Scottish Parliament, 2007).

**SIGN Guidelines**

A common question is how NHS QIS appraisal guidance relates to the Scottish Intercollegiate Guidelines Network (SIGN) guidelines. SIGN is now a part of NHS QIS and the Guidelines are designed to provide advice to clinicians on how to treat particular clinical conditions, rather than the use of individual medicines. NHS QIS (2006, p 2) states:

“SIGN has the responsibility to produce clinical guidelines for NHSScotland. The evidence-based guidelines developed by SIGN are derived from a systematic review of the scientific evidence followed by the considered judgement of the guideline development group. SIGN guidelines provide recommendations for effective and safe practice in the management of clinical conditions where variations in practice are known to occur and where effective care may not be delivered uniformly throughout Scotland.”

As regards their status, SIGN guidelines should be taken into account when services are being developed. NHS QIS (2006, p 2) notes that their implementation is the responsibility of NHS Boards and their operating divisions. In addition, they provide the evidence base for many of the standards developed by NHS QIS. When elements of SIGN guidelines are incorporated into NHS QIS “essential” standards, they are obligatory.

In terms of their relationship with advice from the SMC and that contained in NICE MTAs deemed valid for use in the Scotland by NHS QIS, SIGN Guidelines will take account of that advice. It should be noted that SIGN is concerned with the efficacy of the treatment and not the cost-effectiveness, which, as discussed above, is one of the main considerations of the SMC advice and NICE MTAs. An agreement has recently been published between SMC and SIGN concerning the relationship between SMC advice and SIGN guidelines (Scottish Medicines Consortium, 2008).

**Use of local formularies**

In Scotland, after SMC advice has been issued to local NHS boards and their Area Drug and Therapeutics Committees (ADTCs), the ADTC makes a decision on local implementation and inclusion of the product in the local formulary. The British National Formulary (BNF) contains a comprehensive list of medicines available for use throughout the UK. Local formularies, however, contain a more limited list of medicines, chosen on the basis of clinical effectiveness, cost effectiveness, comparative safety and patient acceptability. Local formularies generally cover medicines recommended for use in both hospitals and general practice and fulfil the vast majority of prescribing requirements. In considering SMC advice, local Health Boards and their ADTCs can decide whether to add the new medicine to their formulary if it is a new agent or an improvement on existing treatments. ADTCs may choose not to include the medicine on their formulary if it has no advantages over existing formulary choices.
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