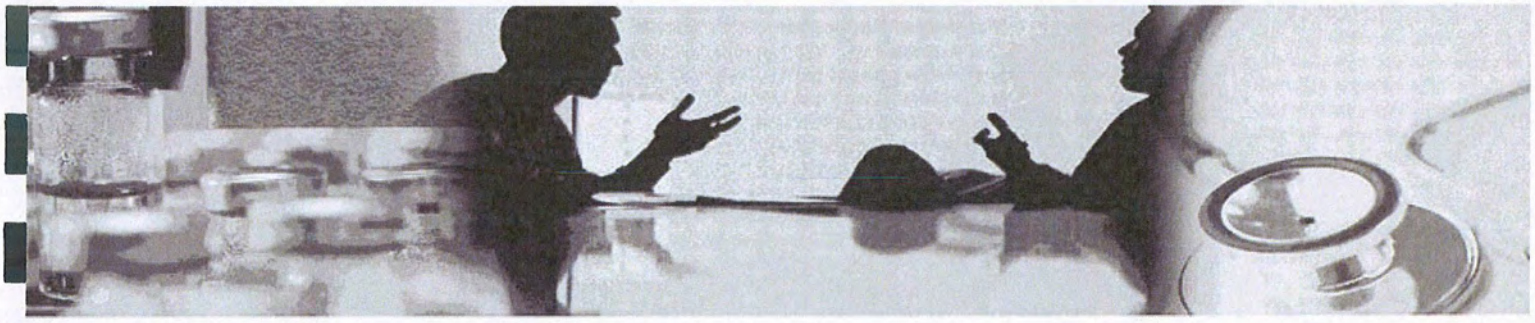
NPC

National Prescribing Centre

Defining Guiding Principles for Processes supporting Local Decision Making about Medicines

Final Report



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A. Introduction

During the consultation process for the Next Stage Review and the Consultation on the NHS Constitution, it was decided that there was a need to support processes for local decision making about medicines in PCTs across England. Currently, the only national guidance on decision making on medicines is developed by NICE and covers a specified range of products and indications. National guidance for decision making on medicines not appraised by NICE, has been limited to general commissioning support and is not specific to medicines.

PCTs are under a duty to promote a comprehensive health service which is available to the entire community based on clinical need, not the ability to pay. Like all public authorities, PCTs are required to operate within finite budgets and, therefore, have to prioritise some treatments over others according to the needs of local communities. However, in the absence of a national framework, local priority decisions have led to variations in responses between PCTs and this, on occasions, has given rise to concern.

The NHS Constitution aims to address variations in the availability of medicines and treatments resulting from inconsistency in local decision-making processes, whilst accepting natural variation will exist, and is appropriate, in order to meet the differing health care needs of local populations.

To date, local decisions about medicines have been discussed at local Area Prescribing or Medicines Management Committees, and by Trust Drugs and Therapeutics Committees (or their equivalents). Some PCTs collaborate with other organisations in order to pool skills and resource and there are also formal collaborative networks covering specific disease areas, for example in cancer or cardiac disease. In a few cases, mainly for rare and/or complex disorders, the development of recommendations and decision making are delegated to National or SHA-level groups.

Decision making about medicines occurs routinely as part of the annual operating plan development process, at the same time as all other healthcare products, treatments and services are considered and prioritised by the PCT to meet the needs of their local population. PCTs should, therefore, have a set of commissioning policies to cover decisions on the majority of medicines.

It is however likely that, during the year, there will still be some requests for medicines not covered by these commissioning policies. PCTs, therefore, need to be able to make additional types of decisions about medicines, on a basis that is fair and consistent with their core prioritisation processes and with the decision-making processes of other PCTs. For example:

- In-year development of additional commissioning policies where a significant number of requests for a medicine are expected
- Review of funding requests for a medicine for a specific patient for whom the existing policies may not be appropriate.

As part of the Next Stage Review, the Consultation on the NHS Constitution and the Government's response to Professor Mike Richards' report about NHS patients who wish to pay for additional private drugs, the Department of Health has laid out what the public can expect from local decision making on medicines. Consequently, the Department of Health has commissioned the roll out of a number of national work streams, including the development of these Guiding Principles, to support PCTs in the development and refinement of their local processes and procedures for decision making about medicines.

The purpose of these Guiding Principles is, therefore, to improve the consistency and quality of local decision making on medicines and to reassure patients that there will be a common, rational framework within which such decisions should be made.

B. Guiding Principles for Processes supporting Local Decision Making about Medicines

THE GUIDING PRINCIPLES

FOR PROCESSES SUPPORTING LOCAL DECISION MAKING ABOUT MEDICINES

The Guiding Principles should always be considered within the context set out by the overarching **SCOPING STATEMENT.**

Underneath the Scoping Statement there are nine Guiding Principles for PCTs to take account of when developing and refining their local decision-making processes. These Principles address the following issues:

1. **GOVERNANCE AND ACCOUNTABILITY**
2. **PROCEDURES**
3. **CRITERIA FOR DECISION MAKING**
4. **DOCUMENTATION**
5. **TIMELINESS**
6. **APPEALS PROCESS**
7. **ENGAGEMENT**
8. **COMMUNICATION**
9. **IMPLEMENTATION AND PROCESS IMPROVEMENT**

THE GUIDING PRINCIPLES

FOR PROCESSES SUPPORTING LOCAL DECISION MAKING ABOUT MEDICINES

SCOPING STATEMENT

The guiding principles have been developed to support local decision making about medicines. This includes decisions on medicines made as part of the development of the annual operating plan as well as consideration of in-year service developments and individual funding requests (IFRs). The principles are designed to cover decision making across primary and secondary care on all medicines not, or not yet, appraised by NICE. While these principles are directed at PCTs, they should equally apply to any collaborative arrangements PCTs may choose to adopt.

Local decisions about medicines should be made in the context of, and be consistent with, national policies including World Class Commissioning and local priorities, prioritisation processes and governance frameworks. Decisions should take into consideration clinical and cost effectiveness relative to other interventions commissioned by the PCT for its population, as well as the available budget.

PCTs should:

1. Establish decision-making groups, with a clearly designated focus of accountability, which include a locally-defined mix of members with the appropriate range of skills
2. Establish a set of robust decision-making procedures which, where appropriate, allow recommendations to be developed through collaboration across PCTs
3. Define clearly, and then consistently apply, standard criteria for decision making. Decisions should be based on the best available evidence, take into account the appropriate ethical frameworks and comply with statutory requirements.
4. Document thoroughly the application of decision-making procedures and the rationale for each decision
5. Make decisions in a reasonable and practical timeframe, but without compromising the minimum process requirements, even when requests are urgent
6. Establish an appeals process for decisions made on individual funding requests, including clearly defined grounds for appeal, independent of the original process and open to patients and their clinicians
7. Take reasonable steps to engage with stakeholders including the wider NHS, patients and the public to help increase understanding of local priority setting about medicines
8. Communicate clearly with stakeholders including the wider NHS, patients and the public. Communication should include the processes, decisions and the rationale for decisions, while maintaining appropriate confidentiality
9. Establish assurance processes to monitor the application and performance of decision-making arrangements, and to enable learning to be incorporated into future process improvements

C. Context for the Focus Group Series Workstream developing the Guiding Principles

Decisions on whether medicines should be funded can be made either at a national level, by NICE, or locally by PCTs. Where NICE has appraised a product, national guidance applies. Where NICE has not appraised a product, there is a wide range of national information and policy direction supporting the development of local commissioning. However, to date, none of this information has been specifically focused on the development of processes to support local decision making on medicines.

Since 1999, NICE has worked to appraise products and produce national guidance. If NICE recommends a treatment in a Technology Appraisal, PCTs must make funding available for the treatment within three months of its publication, unless the Secretary of State directs otherwise.[1] This requirement was recently confirmed by clause 4.14 of the Consultation on the NHS Constitution which says:

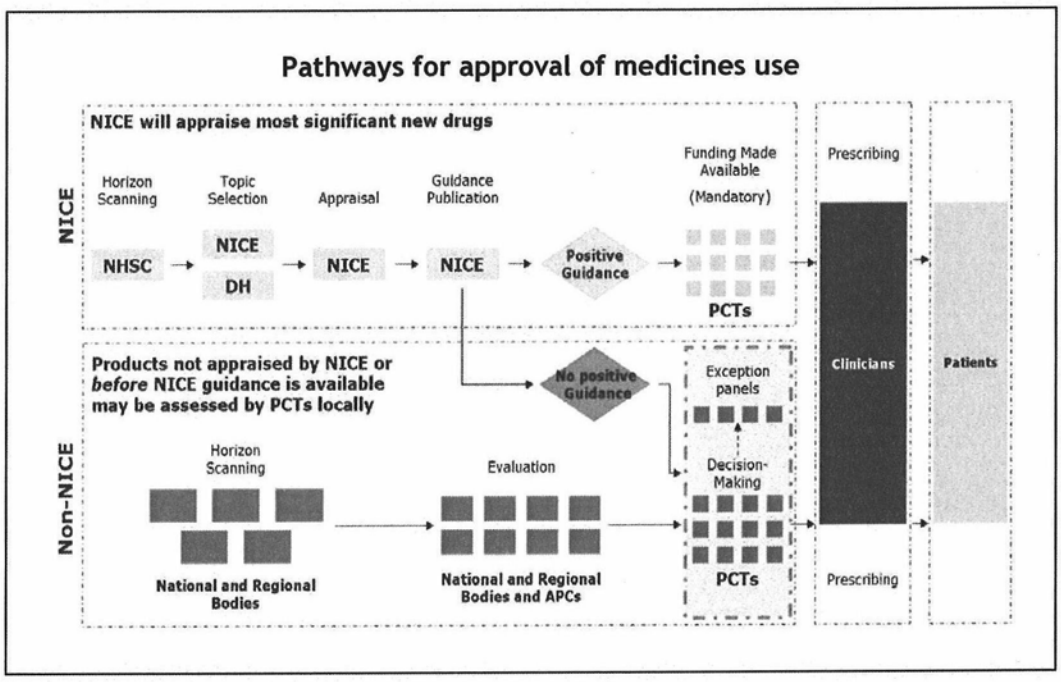
Nationally approved treatments, drugs and programmes

"You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you."

Specific guidance from DH adds that lack of positive NICE guidance is not in itself sufficient reason to withhold treatment.[2]

"It is not acceptable for the local NHS to cite a lack of NICE guidance as the sole reason for not providing a treatment. A key role of the NHS has been, and will continue to be, to make decisions about the use of new pharmaceuticals. NICE does not exist to 'kite mark' all the drugs which are licensed for use in the UK. Therefore, the NHS will have to continue to make informed decisions about the use of these drugs."

However, for medicines where there is no positive NICE guidance, other NHS priorities and processes are relevant. Most medicines use is approved through two different pathways as illustrated below:



In addition, there are several overarching policies and principles which provide guidance to local decision makers, including the core principles of the NHS, World Class commissioning, the Next Stage Review and the NHS Constitution.

The **NHS core principles**[3] were developed to uphold the founding ideals of the NHS and were relaunched in July 2000, to reflect the needs of the modernised NHS. These principles give a basic context for decision making by PCTs on all topics. More recently, the principles have been updated as part of the Consultation on the NHS Constitution[4]:

Principles That Guide the NHS (in the Draft NHS Constitution)

"Seven key principles guide the NHS in all it does. They are underpinned by core NHS values which have been derived from extensive discussions with staff, patients and the public.

1. The NHS provides a comprehensive service, available to all

2. Access to NHS services is based on clinical need, not an individual's ability to pay.

3. The NHS aspires to high standards of excellence and professionalism

4. NHS services must reflect the needs and preferences of patients, their families and their carers.

5. The NHS works across organisational boundaries and in partnership with other organisations in the interest of patients, local communities and the wider population.

6. The NHS is committed to providing best value for taxpayers' money and the most effective and fair use of finite resources.

7. The NHS is accountable to the public, communities and patients that it serves.

A second key national policy which provides guidance on the selection of services, which are commissioned by a PCT, is the **World Class Commissioning** (WCC) initiative. The WCC Assurance Framework[5] lays out a number of commissioning competencies that are directly relevant to the current work, including:

- *"prioritise investment according to local needs, service requirements and the values of the NHS"* (Competency 6)
- *"proactively build continuous and meaningful engagement with the public and patients to shape services and improve health"* (Competency 3)
- *"lead continuous and meaningful engagement of all clinicians to inform strategy and drive quality, service design and resource utilisation"* (Competency 4)
- *"promote and specify continuous improvements in quality and outcomes through clinical and provider innovation and configuration"* (Competency 8)

Within the specific competency indicators, the WCC framework lists developing investment plans to address areas of greatest inequality; deploying innovative approaches to achieve high levels of engagement of hard-to-reach patient and public groups; engaging clinicians representing all healthcare and well-being delivery methods (e.g. social care); monitoring findings, such as prescribing choices, as well as the impacts of specific initiatives on clinical quality and outcomes.

The present work has been developed to complement and build on the WCC framework.

Most recently, the Next Stage Review and the Consultation on the NHS Constitution have laid out the plans for the future direction of the NHS.

The **Next Stage Review**[6] proposes "*guaranteed patient access to the most clinically and cost effective drugs and treatments*" (p16). This is described in more detail in section 3 of the Next Stage Review. Specifically relevant to this work, are chapters 47 and 48 which recognise the concerns of patients and the public due to "*unexplained variation in the way local decisions are made*" and the right, through the Constitution to "*expect rational local decisions on funding of new drugs and treatments*".

Next Stage Review: Ensuring access to the most effective treatments

Chapter 46. *Patients want the most effective treatments, and staff want to be able to provide them. As the NHS becomes more personal, patients and the public want to be assured that the most clinically and cost effective treatments are available everywhere. During this Review, patients and the public were very clear that they had zero tolerance for variations in access to the most effective treatments. The National Institute for Health and Clinical Excellence (NICE), established in 1999, has developed a worldwide reputation for its work in evaluating health interventions. It has highly regarded, transparent processes for assessing new, licensed drugs and medical technologies to determine clinical and cost effectiveness.*

Chapter 47. *It has sometimes taken too long for NICE appraisal guidance to be made available on newly licensed drugs. Guidance has often been published two years or more after a new drug's launch, though 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. Whilst all primary care trusts have a legal duty to fund drugs that have been positively appraised by NICE, we recognise that patients and the public are concerned that there remains unexplained variation in the way local decisions are made on the funding of new drugs before the appraisal takes place, or where no guidance is issued.*

Chapter 48. *We will take steps to end this so-called 'postcode lottery' for new drugs and treatments. Through the NHS Constitution we will make explicit the right of NHS patients everywhere to positively NICE-appraised drugs and treatments, where their doctor judges that these would be of benefit. The Constitution will also make clear the right of patients to expect rational local decisions on funding of new drugs and treatments. Open and honest explanation will be due if the local NHS decides not to fund a drug or treatment that patient and clinician feel would be appropriate.*

...

Chapter 51. *Looking to the future, we will strengthen the horizon scanning process for new medicines in development. We will involve the industry systematically to support better forward planning and to develop ways of measuring the uptake of clinically and cost effective medicines once introduced. For new clinical technologies, we will simplify the way in which they pass from development into wider use by creating a single evaluation pathway, and will develop ways to benchmark and monitor their successful uptake.*

These plans from the Next Stage Review were laid out in the **Consultation on the NHS Constitution**[4] as a right (4.14) covering local decisions on other drugs (outside of NICE), and gives some initial guidance on the way that the public and patients can expect decisions to be made locally:

Nationally approved treatments, drugs and programmes

"You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you."

To help support the NHS in delivering on this commitment, the National Prescribing Centre (NPC) initiated three work streams at the request of the NHS Chief Executive:

1. A detailed **baseline survey** of existing PCT arrangements, both for initial funding decisions on new medicines, and for considering exceptions to commissioning policies once these have been established;

2. Development of a **set of public-facing "guiding principles"** that PCTs might be expected to use or reflect in their decision-making processes; and

3. Development of a **PCT decision-making handbook** as good practice guidance and support for consistent local decision-making processes and governance.

The second work stream has been approached by applying the focus group methodology presented in this report. This work has been led by the NPC on behalf of the Department of Health (DH) in order to support the development of local processes for decision making about medicines.

This work covers decision making on medicines within the context of development of the annual operating plan, including the prioritisation and commissioning process to develop a local commissioning policy, as well as for medicines where no policy exists (in-year service developments and IFRs). The present work is applicable primarily to the consideration of funding of medicines across both primary and secondary care, but may also relate to the funding of non-drug treatments.

D. The Guiding Principles and Supporting Information

0. Scoping Statement

Final high-level statement of scope	**The guiding principles have been developed to support local decision making about medicines. This includes decisions on medicines made as part of the development of the annual operating plan as well as consideration of in-year service developments and individual funding requests (IFRs). The principles are designed to cover decision making across primary and secondary care on all medicines not, or not yet, appraised by NICE. While these principles are directed at PCTs, they should equally apply to any collaborative arrangements PCTs may choose to adopt.** **Local decisions about medicines should be made in the context of, and be consistent with, national policies including World Class Commissioning and local priorities, prioritisation processes and governance frameworks. Decisions should take into consideration clinical and cost effectiveness relative to other interventions commissioned by the PCT for its population, as well as the available budget.**

Supporting Information:

- These guiding principles should apply to decision making related to medicines, undertaken:
  - as part of the development of the annual operating plan
  - as in-year service developments
  - as IFRs

- Medicines should be reviewed in the context of World Class Commissioning and the PCT's overall service priorities
- Medicines not appraised by NICE should be considered for inclusion in the prioritisation process
- Medicines should be reviewed on a proactive basis, where possible, rather than reacting to multiple IFRs
- Decisions should be regularly revisited, based on subsequent evidence. Not every decision will be revisited every year.
- Disinvestments should be considered along with investments.
- Coordination and communication of decision making should be established between primary and secondary care and also specialised services
- SHAs should play a key role in facilitating, supporting and monitoring the decision-making processes

1. Governance and accountability

Final high-level principle	**PCTs should establish decision-making groups, with a clearly designated focus of accountability, which include a locally-defined mix of members with the appropriate range of skills**

Supporting Information:

- Decision making on medicines needs to be an integral part of each PCT's commissioning processes
- Terms of reference should be set for all decision-making and related groups, and included within the formal governance framework of the PCT
- Across decision-making and related groups, defined membership should include a balanced mix of clinically and managerially-focused professionals and lay persons, with representation likely to include:
  - Medicines Management
  - Public Health specialists
  - Commissioning specialists
  - Healthcare professionals
  - Lay representatives
  - PCT finance
  - Primary and secondary care representatives
- People involved in decision making across primary and secondary care should be adequately resourced and encompass, or have access to, the required set of skills. Support should include ongoing, targeted training of the relevant people
- Any potential conflicts of interest should be declared, recorded and a report made available for public scrutiny
- Clear agendas should be set, including proactive and reactive items

- There should be a pre-defined quorum for each decision-making activity
- Authority for decision making and budgetary control should be defined with a clear link to the accountable person; e.g. PCT Chief Executive, on behalf of the PCT Board, through the PCT's scheme of delegation of powers
- Any delegated decision-making authority should operate within the PCTs' formal governance frameworks
- Governance arrangements and resources should be in place to support internal audit
- Existing or potential collaborative arrangements should be understood by the decision-making group and the PCT Board

2. Procedures

Final high-level principle	**PCTs should establish a set of robust decision-making procedures which, where appropriate, allow recommendations to be developed through collaboration across PCTs**

Supporting Information:

- Standard procedures should be established by the PCT for making decisions on medicines, as required in the NHS Constitution
- The procedures should enable a group of competent persons to make the best decision, based on the available information at that time
- Board approval should be required for all decision-making procedures
- Procedures should consider the need for collaboration between PCTs, in order to allow efficient use of the expertise required to develop recommendations
- Recommendations developed in collaboration should serve as a basis for decision making by the PCT. Decisions can only be made by the PCT, or on behalf of the PCT through appropriately delegated authority
- Procedures should focus on reviewing interventions proactively (including those medicines flagged during horizon scanning) to maximise the proportion of topics considered as part of the development of the annual operating plan. Where topics emerge and need to be managed in year, the service development route should be considered first. Only where this is not appropriate, should the IFR route be used.
- It is intended that the primary approach to horizon scanning and clinical and cost effectiveness information sourcing will be developed at a national level, based on a single horizon scanning database and NHS Evidence

- Procedures should be established for re-visiting decisions based on subsequent evidence, such as new clinical trials.

- Clear separation should exist between commissioning procedures which prioritise treatments for the whole, or subset, of the PCT population and those procedures dealing with individual patients.

- There should be clear procedures to:

  - identify whether an IFR requires a service development or should be treated as an individual case

  - determine the approach to multiple IFRs for the same treatment

- Separate procedures should be established for urgent individual requests, including clearly defined, minimum procedural requirements and a means of ensuring that urgent decisions do not set precedents or automatically create local policy

3. Criteria for decision making

Final high-level principle	**PCTs should define clearly, and then consistently apply, standard criteria for decision making. Decisions should be based on the best available evidence, take into account the appropriate ethical frameworks and comply with statutory requirements.**

Supporting Information:

- A consistent and reasonable set of factual criteria should be considered in evaluations, including:
  - National guidance and priorities (e.g. NICE)
  - Relative cost and clinical effectiveness and strength of evidence
  - Patient safety
  - PCT opportunity cost or foregone benefit
  - Local priorities
  - Available resources

- Clear policy should be developed locally for handling other potential influencing factors including, for example:
  - Individual patient care needs
  - Innovation
  - Precedents
  - Weak/insufficient/conflicting evidence

- The best available evidence should be identified, accessed and used appropriately by decision-making and related groups, using their judgement and exercising discretion.

- Grounds for appropriate IFRs should be clearly defined by the PCT and communicated effectively to all relevant stakeholders, including Trusts and clinicians

- An efficient process for submitting IFRs should be clearly defined by the PCT and communicated effectively to all relevant stakeholders, including Trusts and clinicians

4. Documentation

Final high-level principle	**PCTs should document thoroughly the application of decision-making procedures and the rationale for each decision**

Supporting Information:

- Documents describing decision-making processes should be clearly laid out and publicly accessible
- Type, format and detail of information should be standardised by the PCT
- Decisions should be minuted with clear rationale, decision points and action required, thus demonstrating that the procedures and criteria have been followed
- The validity and relevance of the clinical evidence-base should be clearly documented
- The minimum documentation required for urgent decisions should be clearly pre-defined by PCTs
- A PCT's form for submitting an IFR should be kept concise, but allow sufficient information to be collected to minimise the need for additional information requests. Where appropriate, neighbouring PCTs should work together to help standardise information requirements
- Communications with patients and their clinicians should be consistent with minuted detail

5. Timeliness

Final high-level principle	**PCTs should make decisions in a reasonable and practical timeframe, but without compromising the minimum process requirements, even when requests are urgent**

Supporting Information:

- Defined timeframes for decision making and communication of outcomes should be set out publicly by PCTs
- Timeframes should be set according to case type, e.g. service developments, urgent/less urgent individual requests
- Defined timeframes should be set by PCTs for their appeals process
- Where, due to unusual or unexpected circumstances, defined timeframes are unlikely to be achievable, this should be explained to the relevant stakeholders and a realistic timeframe proposed

6. Appeals process

Final high-level principle	**PCTs should establish an appeals process for decisions made on individual funding requests, including clearly defined grounds for appeal, independent of the original process and open to patients and their clinicians**

Supporting Information:

- The appeals process should be consistent with the rest of the decision-making guidelines and procedures
- The grounds for appeals on decisions made on IFRs should be clearly laid out.
- Where there is significant new evidence, at the time of a potential appeal, the request should normally go back to the original panel for re-consideration
- Appeals committee membership should be defined as independent from the original decision-making group, but be able to access expert evidence as required

7. Engagement

Final high-level principle	**PCTs should take reasonable steps to engage with stakeholders including the wider NHS, patients and the public to help increase understanding of local priority setting about medicines**

Supporting Information:

- PCTs should take reasonable steps to provide an explanation to the public on the need for PCT prioritisation due to local health outcome choices and finite budgets
- Stakeholders need to understand how prioritisation works, the different decision-making processes and how they can best provide effective input
- Reasonable steps should be taken by PCTs to develop a clear means of engagement, where necessary, with wider stakeholder groups including, for example, local authorities and the pharmaceutical industry

8. Communication

Final high-level principle	**PCTs should communicate clearly with stakeholders including the wider NHS, patients and the public. Communication should include the processes, decisions and the rationale for decisions, while maintaining appropriate confidentiality**

Supporting Information:

- Public access should be provided to decision-making policies, procedures and criteria
- Frameworks should be established for the timely and effective dissemination of decisions (for example: detailing method, frequency, format, recipients)
- Local policy should be developed, identifying who will be responsible for communicating different types of decisions to patients and, where appropriate, to the NHS community and the public
- Decisions should be communicated to the NHS community and patients in a way that does not compromise any individual patient's confidentiality
- For IFRs, there should be a defined process to allow clear, accessible, consistent and timely communications with patients and their clinicians
- Decisions made on IFRs, along with the rationale for those decisions, should be communicated to patients in a timely and sensitive manner. This communication should be carried out face to face where possible, by an appropriate person, who is competent to explain the complexities of the specific information in terms the individual can understand
- Effective communication is a two-way process.

9. Implementation and process improvement

Final high-level principle	**PCTs should establish assurance processes to monitor the application and performance of decision-making arrangements and to enable learning to be incorporated into future process improvements**

Supporting Information:

- PCTs should assign responsibility for the implementation of procedures and monitoring of decisions
- Learning should be incorporated into practice, in alignment with local performance management processes
- PCT decision making about medicines should form part of the wider commissioning assurance arrangements managed by the SHA, in accordance with the World Class Commissioning framework

E. Appendices

1. Definitions

Area Prescribing Committees (APCs) and **Medicines Management Committees** (MMCs) were used during the focus group discussions as generic terms encompassing those local 'strategic' committees, whose members include primary and secondary care commissioners and providers working together to develop a consistent health community approach to medicines management. These committees have a range of remits but typically consider the implementation of NICE guidance and manage the introduction of new medicines. They comprise pharmacists, GPs and other clinicians, consultants in public health, commissioners, prescribing advisors, administrative support officers, and in some cases lay representatives. There are a wide range of names used locally for Area Prescribing and Medicines Management Committees.

Specialised services are high-cost, low-volume interventions, provided in relatively few specialist centres (usually in larger hospitals). There are currently 36 services defined as being specialised, typically complex/chronic conditions, which require a critical mass of patients to make treatment centres cost-effective and to optimise the level of patient care. These services are therefore best planned for catchment populations greater than one million people. As a result, PCTs group together to commission such services collectively, which allows them to share the financial risk of funding expensive and unpredictable activity. Specialised services are either commissioned on a regional basis, by the 10 Specialised Commissioning Groups (SCGs), or on a national basis by the National Commissioning Group (NCG), in the case of particularly rare conditions. Each SCG acts on behalf of a population of about five million people and formally designates specific providers to provide specific specialised services, based on a nationally agreed set of criteria.

The **Annual Operating Plan** is one of the planning tools utilised by PCTs. It sets out the developments planned over the following 12 months to improve local health and wellbeing in response to local and national priorities.

As part of this planning process, each PCT carries out a population-based, relative-benefit value assessment of all available interventions, including medicines without positive NICE guidance, in order to prioritise interventions and optimise the use of the available budget. According to the WCC assurance framework, PCT Boards are expected to select health outcomes from the assurance toolkit and submit their choices to the SHA. The selected outcomes should reflect the health needs of the local population and the PCT's strategic priorities, and should have been agreed with their partners and stakeholders (including the public, patients, clinicians, and community colleagues). The approved health outcomes then become the basis of the annual funding prioritisation, which informs both investment and disinvestment decisions, and against which all newly available interventions are considered.

An **individual funding request** (IFR) is a request to fund, for an individual, an episode of healthcare that currently falls outside existing contracts. The funding request may be asking for any type of healthcare: a service, a piece of equipment or aid, a specific treatment or medicine. In contrast to annual prioritisation and in-year service development decisions, appropriate IFRs are considered on an individual patient, rather than population, basis. There are two main categories of appropriate IFR: Firstly, where patients fall outside an existing generic or treatment-specific policy where an unusual circumstance applies to the individual. Secondly, for patients with a very rare clinical condition. Using the IFR process is inappropriate where they represent requests for service developments (e.g. effectively a group of IFRs relating to a newly licensed drug), or in cases where there is no evidence that a particular individual will gain comparatively greater clinical benefit. Evidence for additional clinical benefit needs to accompany requests that fall outside an existing PCT commissioning policy not to provide a treatment. The question for consideration is then whether the evidence is sufficient to justify the patient receiving funding when others have been excluded. This is usually decided based on clinical differences and evidence that the patient will benefit from the treatment more than the normal range of response.

In-year service developments involve commissioning a new service, or modifying an existing service, during a financial year. The specific criteria, which need to be satisfied in order for a treatment to qualify for consideration as an in-year service development, are typically established locally and can vary across PCTs. The

investment decision is made outside of the annual operating plan development processes, usually where an immediate need arises, which could include:

- the introduction of a newly available intervention of high strategic importance;
- the introduction of a new product with an improved cost-effectiveness profile;
- the avoidance of a significant risk;
- the need for immediate compliance with newly introduced legal requirements; or
- the need for urgent remedial action.

Opportunity cost is an economic concept that underlies health care priority setting and relates to physical resources such as qualified staff or money. It is derived from the understanding that investing such resources in a particular way means they cannot be invested elsewhere. In the context of finite health care budgets, for example, this means that any new development results in the loss of opportunity or benefit from not doing something else. It is, therefore, key that during priority setting the costs and benefits of interventions are considered in relation to those of the other possible alternatives.

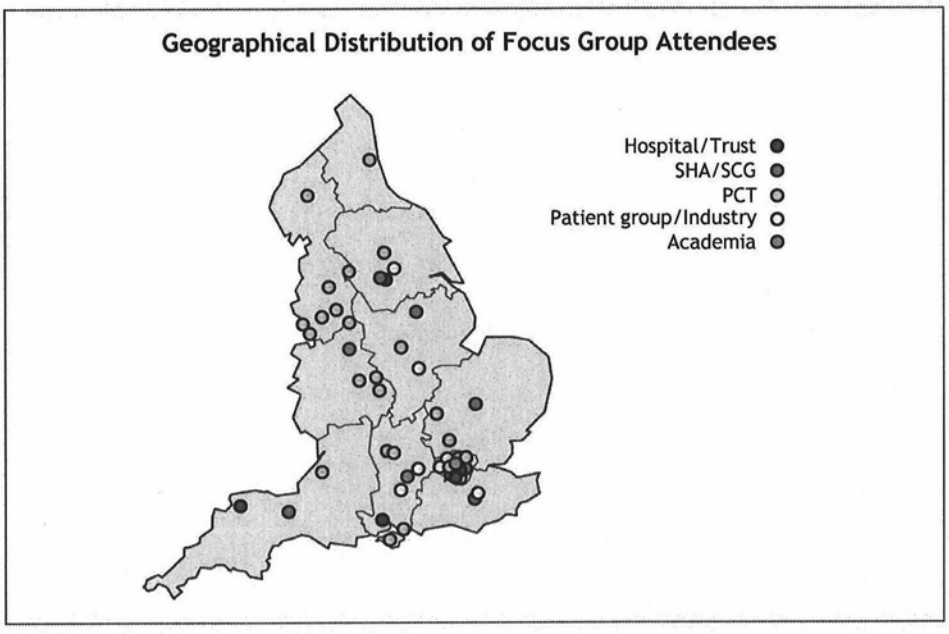
2. Glossary

APC	- Area Prescribing Committee
CPH	- Consultant in Public Health
DTC	- Drug and Therapeutics Committee
IFR	- Individual Funding Request
MMC	- Medicines Management Committee
NCG	- National Commissioning Group
NSCG	- National Specialised Commissioning Group
NICE	- National Institute for Health and Clinical Excellence
NPC	- National Prescribing Centre
PBC	- Practice-Based Commissioning
PCT	- Primary Care Trust
PEC	- Professional Executive Committee
PH	- Public Health
SCG	- Specialised Commissioning Group
SHA	- Strategic Health Authority
WCC	- World Class Commissioning

3. Methodology

This document reflects the contributions made in a series of focus group discussions supporting the development of the Guiding Principles. The four focus groups were held during September 2008, and a broad range of stakeholders, with a variety of perspectives on the NHS, were invited to take part. Between 15 and 20 stakeholders participated in each workshop. The attendees included one or more representatives from each of the following categories:

- Academic Representative
- Academic Legal Representative
- APC Member/Chair
- Commissioning Group Lead (PCT)
- Community Pharmacist
- Director of Acute Commissioning
- Director of Prescribing and Medicines Management
- Ethics Representative
- GP
- Consultant Physician
- Healthcare Strategy Consultant Manager
- Lay / Patient / Public Representative
- Medical Information Organisation Representative
- New Drugs Pharmacist
- NHS Alliance and Primary Care Pharmacists' Association (PCPA)
- NHS Alliance representative on PBC
- NICE Representative
- Regional Medicine Information Specialist (SCG Representative)
- PBC Group Representative
- PCT Chief Executive
- PCT Commissioner (Senior)
- PCT Director of Finance
- PCT Lead for Healthcare Priorities
- PEC Member (Medical)
- Pharmaceutical Adviser / Head of Medicines Management
- Pharmaceutical Industry Representative
- Pharmaceutical PH Representative
- Public Health Director / Consultant (PCT)
- Public Health Director / Consultant (SCG)
- Trust senior DTC member
- Regional Director Public Health (SHA)
- Regional Healthcare Manager
- SHA Representative
- Trust Consultant / Registrar (Medical)
- Public Health Policy Legal Advisor



Each focus group event was structured according to the following agenda:

- Introductions, objectives and scope (NPC Representative)
- Overview of current decision-making processes (Facilitator presentation)
- Review of draft guiding principles (Facilitator presentation)
- Refine and test the draft principles - initial feedback (Plenary session)
- Refine and test the draft principles - applying the principles in practice (Break-out sessions)
- Break-out group feedback and implications (Plenary session)
- Summary and conclusions (Facilitator presentation)
- Closing words and next steps (NPC Representative)

During each half-day event, the focus group participants were introduced to the context of this work and the set of guiding principles in development. Following this scene-setting and introduction to the work, a plenary discussion was held to bring out some of the immediate high-level issues. After that, the participants were split into three groups in order to consider whether the set of principles captured all relevant points to the appropriate level of detail, as well as to explore and test the practicality of each guiding principle.

The first focus group was presented with a set of initial draft principles, developed by an expert group during the first phase of the work. During this and consecutive sessions, participants were invited to put forward any additional principles which they felt should be considered for inclusion by the plenary group. The principles included in the set, along with their wording, were adapted throughout the focus group series to reflect comments from previous events.

Each session concluded in a plenary discussion where the views of each break-out group were presented. Any additional principles brought forward were analysed and the potential impacts of their inclusion into the set were explored.

A variety of viewpoints were raised and debated, and a broad range of opportunities and challenges were highlighted for further analysis, including a number of points that were to be fed into the work stream developing a best-practice handbook.

Two legal advisors specialising in public health policy also contributed to this process.

4. References

1 NATIONAL HEALTH SERVICE ACT 1977 (Directions to Primary Care Trusts and NHS trusts in England concerning Arrangements for the Funding of Technology Appraisal Guidance from the National Institute for Clinical Excellence (NICE), July 2003), http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_4083088

2 Speech by Jane Kennedy MP, Minister of State for Quality and Patient Safety (December 2005) NICE Conference, http://www.dh.gov.uk/en/News/Speeches/Speecheslist/DH_4125786

3 NHS Main Website, http://www.nhs.uk/aboutnhs/CorePrinciples/Pages/NHSCorePrinciples.aspx

4 Consultation on the NHS Constitution (June 2008), http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_085812

5 World Class Commissioning Assurance Handbook (June 2008), http://www.dh.gov.uk/en/Managingyourorganisation/Commissioning/Worldclasscommissioning/Assurance/index.htm

6 Next Stage Review Final Report (June 2008), http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085825

Priorities Steering Group, 10th February 2009 **12/2009**

Proposal for a review of PCT funding exceptions in South Central

Introduction

This proposal has been requested by the Directors of Commissioning in South Central. While each PCT has its own processes for deciding whether to fund 'exceptions', and wants to keep them local, there is also a need to demonstrate consistency across South Central PCTs, to avoid a 'postcode lottery' and to reduce the risk of decisions being challenged.

The essential questions to be answered by the proposed piece of work are:
1. Are the **processes** for approving / rejecting 'exceptions' similar across South Central PCTs?
2. Are the **criteria** for approving / rejecting 'exceptions' similar across South Central PCTs?
3. Are the criteria **applied** in similar ways in each South Central PCT?

The following recent documents contain national guidance relevant to the first two questions (regarding processes and criteria for approving / rejecting 'exceptions'):
- National Prescribing Centre / Department of Health, Jan 2009. Defining guiding principles for processes supporting local decision making about medicines.
- National Prescribing Centre / Department of Health, Dec 2008. Making clear and transparent local decisions about medicines and treatments: a handbook. (Currently only available as a working draft – in confidence.)
- NHS Confederation, March 2008. Priority setting: managing individual funding requests.

Proposed approaches

PHRU will liaise with nominated leads in each PCT, who will ensure that the necessary PCT documents and data are supplied to PHRU in a timely fashion, and be available for follow-up.

	Scope	Method	PHRU days required	Timescale	Requirements of each PCT
A	Assess the extent to which each PCT conforms to the NPC / DH guiding principles on: 1 Governance and accountability 2 Procedures 3 Criteria for decision making 4 Documentation 6 Appeals Process	Desk-top review of each PCTs' written policies, procedures and criteria, seeking clarification from PCT leads where required. Where there are obvious variations between PCTs PHRU will contact the PCT leads to seek some indication of the rationale and to assess the legitimacy of local variation.	10	March or April 09 – July 09	PCT leads will supply current relevant documents and respond to follow-up enquiries from PHRU.

B	Quantitative assessment of the extent to which criteria are applied in similar ways in each PCT	Compare South Central PCTs using the following indicators: • Total number of enquiries / initial requests around IFR received by PCT, per 1,000 population • Number of requests that proceed to the Exceptional Case Panel as IFRs, per 1,000 population • % of IFRs that are approved • % of IFR refusals that are appealed • % of IFR appeals that are successful	2	March or April 09 – July 09	PCT leads will supply the enquiries / initial requests / IFR data to PHRU for analysis.
C	Qualitative assessment of the extent to which criteria are applied in similar ways in each PCT	Set up two 'dummy' cases that each PCT will take through its own process. Once complete, all related documentation including notes of meetings etc to be forwarded to PHRU for analysis. PHRU will test for consistency of outcomes across PCTs and, for each PCT, consistency of processes and application of criteria with PCT written policies and procedures.	9	July 09 – Sept 09	PCTs will complete the 'dummy' process and supply all related documentation to PHRU for analysis.
D	Assess the extent to which each PCT conforms to the NPC / DH guiding principles on: 5 Timeliness 7 Stakeholder engagement 8 Communication	Desk-top review of each PCTs' written policies, procedures and criteria, seeking clarification from PCT leads where required. Where there are obvious variations between PCTs PHRU will seek some indication from the PCTs of the rationale, to assess legitimacy of local variation.	7	March or April 09 – July 09	PCT leads will supply current relevant documents and respond to follow-up enquiries from PHRU.

Deliverable

PHRU will produce a single report for the Directors of Commissioning, which will include the assessments of each PCT. PHRU will retain ownership of the methodology used.