

## 3.2 *DH guiding principles* checklist for all decision-making or advisory committees/groups

The *DH guiding principles* give a starting point against which decision-making or advisory groups can review their policies and procedures. The checklist here is based on these principles and should be used by PCTs and the following groups to review the policies and processes which support their defined functions.

- Priorities Committees or equivalent (see [Section 2.3.1](#))
- APCs or equivalent (see [Section 2.3.1](#))
- SCGs making recommendations about medicines or treatments (see [Section 2.3.2](#))
- Supra PCT collaborative committees or groups making recommendations about medicines or treatments (see [Section 2.3.2](#))
- Clinical Networks making recommendations about medicines or treatments
- Provider Trust DTCs or equivalent (see [Section 2.3.3](#))

**A separate health check for groups considering IFRs can be found in [Section 3.5](#).**

### **Overall picture (SCOPE of *DH guiding principles*)**

The *DH 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 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 WCC 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.

- Is there a clear map of where the group fits in the overall structure (whole system) for PCT decision-making and policy development around medicines and treatments?
- Is the group clear about the context in which decisions/recommendations are being made?
- Are existing and potential collaborative arrangements understood by the relevant Boards and the individual decision-making/advisory groups?

### **Governance and accountability (*DH guiding principle 1*)**

**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.

- Has the relevant Board formally agreed the remit of the group? Is there clarity about the status of decisions made, i.e. is the group decision-making or advisory?
- Is the authority and accountability for decision-making clearly defined and fully communicated?
- If the group has delegated authority, is it operating within the PCTs governance framework?
- Does the group have a clearly designated remit, lines of accountability and governance arrangements? Does the group have clear terms of reference?
- Does the membership of the group appropriately reflect the decisions it is being asked to take? Is there an appropriate mix of clinical and managerial professionals?
- Do members have the appropriate range of skills? Is there access to adequate ongoing training and resources to support the committees' work? Do members have designated time?
- If necessary, how are additional specialist skills accessed?
- Is there a defined quorum? How is decision-making formalised (e.g. voting for consensus)?

- Does the group have a policy which defines conflicts of interest, how to declare them and what happens if interests are not declared? Is this open to public scrutiny?
- Are governance arrangements and resources in place to support audit of the group's activities, both in terms of internal functions and outcomes of decisions/recommendations?

### Procedures (DH guiding principle 2)

**PCTs should:** Establish a set of robust decision-making procedures which, where appropriate, allow recommendations to be developed through collaboration across PCTs.

- Does the group have a set of standard procedures? Would they enable a group of competent people to make the best decision, based on the available information at that time?
- What provision is there for identifying and meeting the training and development needs of group members?
- Have decision-making procedures been agreed by the relevant Board(s)?
- Are there resources to support/commission the activities which underpin effective decision-making; for example, horizon scanning, evidence appraisal? Do these activities have procedures and policies in place?
- How are agendas set? What does the group consider? Is there provision for proactive and reactive agenda items?
- Does the group accept submissions, how are they structured, who can submit?
- Are there procedures for re-visiting decisions based on subsequent evidence; for example, where treatment outcomes are poor, or new clinical trials emerge? How is this highlighted?
- Are there procedures to manage urgent requests clearly linked to other groups where appropriate?

### Criteria for decision-making (DH guiding principle 3)

**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.

- Does the decision-making group have a set of defined criteria to be considered in decision making? Are these publicly available?
- How are ethical considerations incorporated into decision making?
- Are there policies on other potential influencing factors; for example, innovation, precedents, weak/insufficient/conflicting evidence?
- Does the group have access to the best available evidence? How is the evidence base for decisions identified, accessed and used?

### Documentation (DH guiding principle 4)

**PCTs should:** Document thoroughly the application of decision-making procedures and the rationale for each decision.

- Does the group have publicly available and accessible documentation which describes how decisions are made?
- Are decisions minuted with clear rationale, decision points and action required?
- Is the validity and relevance of the clinical evidence base clearly documented?
- Are there standard templates for agendas, minutes, submissions (with supporting notes)?
- Is the minimum documentation for urgent requests defined?
- Is there a record of how decision-making procedures were applied, and the rationale for each decision which can be reviewed and/or audited?

### **TIMELINESS (DH guiding principle 5)**

**PCTs should:** Make decisions in a reasonable and practical timeframe, but without compromising the minimum process requirements, even when requests are urgent.

- Does the group have a policy which defines timely decision-making and communication of outcomes? Does this vary depending on the nature of the decisions?
- Where, due to unusual or unexpected circumstances, defined timeframes are unlikely to be achievable, is this explained to the relevant stakeholders and a realistic timeframe proposed?

### **IFR APPEALS PROCESS (DH guiding principle 6)**

**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.

See IFR policy health check, **Section 3.5** for detailed guidance.

### **ENGAGEMENT (DH guiding principle 7)**

**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.

- How does the group engage with stakeholders about prioritisation, the different decision-making processes and how they can best provide input?
- How does the group engage with wider stakeholder groups including, for example, local authorities and the pharmaceutical industry?
- How are patients and the public involved in the development of decision-making processes?

### **COMMUNICATION (DH guiding principle 8)**

**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.

- Is the remit of the group and how it functions well understood by Provider Trusts and clinicians likely to be using it to request medicines and treatments for their patients? How is this evaluated?
- Is there a framework for the timely and effective dissemination of decisions; for example, detailing method, frequency, format and recipients?
- Is responsibility assigned for communicating decisions (including where appropriate to patients, the NHS community and the public)?
- Is communication in a style and format that is appropriate to the target audience? How is this evaluated?

### **IMPLEMENTATION AND PROCESS IMPROVEMENT (DH guiding principle 9)**

**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.

- Is there a clear process for ensuring funding decisions are incorporated into contracting and procurement procedures?
- Is there a framework for the implementation and monitoring of decisions? Does the group assign responsibility for implementation and/or monitoring?
- How does the group monitor decisions to ensure that criteria for decision-making are being consistently applied? What is the feedback mechanism?
- How are decisions/policy kept up-to-date as new evidence emerges?
- Is there an assurance process to monitor the effectiveness of the committee and to enable learning to be incorporated into future process improvements?
- Does the group have performance indicators? How are these developed and reviewed?