Minutes

PIAG
Patient Information Advisory Group

PIAG 5-02/2008

Meeting held on Monday 20th October 2008

Present:
Members: Professor Dame Joan Higgins (Chair), Mrs Pauline Brown, Dr Patrick Coyle, Dr Tricia Cresswell, Dr Fiona Douglas, Ms Ros Levenson, Mr Michael Hake, Ms Susan Parroy, Professor Sir Denis Pereira-Gray, Dr Mark Taylor, Mr Terence Wiseman.

In attendance: Ms Victoria Cox (*Secretariat*), Ms Natasha Dunkley (*Secretariat*), Mr Ian Johnstone (*NIGB Secretariat*), Ms Melanie Kingston (*Secretariat*), Mr Paul Eveson (*Department of Health*) and Ms Karen Thomson (*Secretariat*).

1. Welcome and Apologies for absence

1.1 Apologies for absence were received from Professor Mike Catchpole, Ms Stephanie Ellis and Professor Roy McClelland.

1.2 Ms Victoria Cox was welcomed to the meeting as a new member of the PIAG Secretariat.

1.3 **Declaration of Interests**

Mr Michael Hake declared an interest in agenda item 8 [PIAG 5-07/2008] because of his role as a Commissioner for the Healthcare Commission and as a member of their Confidentiality Committee.

2. Minutes of last meeting

2.1 Minutes of the previous meeting held on 9th September 2008 [PIAG 5-02/2008] were agreed to be an accurate record, subject to minor amendments.

3. Secretariat report

The Secretariat report [PIAG 5-03/2008] was received and its contents noted.

3.1 Redfern Inquiry – Implications of draft judgment

It was reported that the draft judgment broadly supported the Advisory Group's view that confidentiality survives death and that in relation to the purposes of the Redfern Enquiry,

the public interest would be sufficient to warrant the disclosure of confidential patient information. There was therefore no dispute about the outcome of the judgment. There were, however, a number of key points arising from the draft judgment that raised implications for the way the Advisory Group assessed applications for approval.

The first is that the judge did not give a definitive answer on the question of whether confidentiality survives death but rather that this was likely to be the expectation of "the man in the street". The judge therefore agreed that it was at least arguable that confidentiality survives death and therefore that there needs to be justification for the disclosure of confidential patient information after a person's death. He also agreed that there was nothing prohibiting the use of Section 251 to provide a shield to disclosing bodies in relation to the deceased. In relation to the Redfern Enquiry he felt it more appropriate to utilise the public interest in stead of Section 251 because the Enquiry was not the type of purpose that had been anticipated in the drafting of the legislation and because the data had been generated in the private sector in the context of employment and again this may not have been anticipated by the drafters of Section 251.

This gives rise to questions about data generated within the independent sector, where the treatment has been commissioned by the NHS, and about the use of NHS data by independent sector data processing organisations and where new information had been generated through analysis. Although PIAG's role includes consideration of information generated within health services in relation to its advisory role, there was concern that this could mean that this data then fall outwith PIAG's purview in terms of how it is subsequently used or disclosed to others. Members agreed that more focus should be placed on resolving issues related to NHS-commissioned care within the independent sector. Members were of the view that, following precedent set by research ethics committees; if care had been commissioned by the NHS then it constituted NHS service and fell within remit. Members acknowledged that account would not have been taken of such considerations by the judge, as they were not relevant for the particular circumstances of this case. It was proposed that there should be a move towards resolving this issue proactively.

Action: **Ian Johnstone to raise issue with Harry Cayton, the Chair of the shadow NIGB.**

In the judgment, disclosure was permitted under the grounds of the public interest therefore there were no major implications arising from this point. Members noted that caution should be exercised when assessing whether the purpose of an activity fell within the scope of 'medical purposes' and to seek a legal view if in any doubt.

3.2 Collaborative working with the Human Fertilisation and Embryology Authority

It was reported that the Human Fertilisation and Embryology (HFE) Bill was currently passing through Parliament and included provision for disclosure of currently 'protected information' on the HFEA Register to be disclosed for medical research purposes. It was noted that, if the Bill was enacted with these provisions in tact, section 251 powers would apply from enactment, as a transitional arrangement prior to Regulations. It is possible that such applications could be submitted to the Advisory Group in December. It was noted that the HFEA representative should attend initially as an observer, but the Advisory Group could seek their views on relevant studies. Once PIAG has formally transferred to being a Committee of the NIGB, there should be scope to co-opt members from the HFEA to assist with this work.

Action: Secretariat to invite HFEA member to the next Advisory Group meeting, if appropriate

The Secretariat reported that they had attended a HFEA workshop event on 11th September 2008, which was to identify the needs of researchers in relation to HFE data. A meeting took place between the DH, HFEA and PIAG Secretariat on 15th September 2008 to discuss information issues and how PIAG and the HFEA might work together to streamline application processes for access to HFE protected information for research purposes. It was noted that under the Bill, regulations would establish the HFEA as the body with responsibility for approving applications for access to this data, but that one of the proposals being considered was that this responsibility be delegated to PIAG for data relating to treatment provided in England and Wales. In many instances researchers would need to apply to PIAG in any case, for approval to link HFE and other confidential patient data, without consent. Additionally, PIAG's view could be sought for UK-wide studies. This would minimise the number of approvals that would specifically need to be considered by HFEA. It was reported that the HFEA were in the process of developing consent procedures for data collected from October 2009 which would address these issues in future but not that of the large volume of data already collected.

3.3 Integrated Research Application System

The Secretariat had received a request from the IRAS Board asking the Advisory Group if it would be willing to stipulate that, from now on, the preferred route for research applications should be via IRAS. It was noted that this did not preclude consideration of applications submitted on the current form, but that the website would direct research applicants to IRAS in place of the current PIAG form. The current application form and guidance would remain on the PIAG website for non-research applicants, at least for the time being. It would be possible for non-research applicants to utilise IRAS for PIAG applications but the Secrerariat need to review the application form to ensure it is appropriate for this purpose.

Members agreed that IRAS should become the preferred route for research applications.

Action: Secretariat to notify NRES of PIAG view on use of IRAS

3.4 Research Capability Programme

It was reported that the documents for the programme had been published on the NHS Connecting for Health website. These included PD18, which outlined the role of Honest Brokers and Safe Havens (Agenda item 8). A further document on Patient Consent (PD15) was tabled and members agreed to discuss this and other relevant programme documents at the December meeting

3.5 Research Capability Programme PPI Meeting

Representatives from PIAG and the NIGB had attended a meeting with the patient and public involvement representatives involved in the Research Capability Programme (RCP) Board. The purpose of the meeting was to form a link between lay members involved in different aspects of the RCP and with other bodies with an interest in the RCP and to consider issues with respect to the nature of engagement with patient and lay members within the Programme. It was noted that a follow up meeting was planned and that Marlene Winfield, Director of patient and public involvement in NHS Connecting for Health, had been invited to attend.

3.6 Extensions approved by Chair action

Evaluation for screening for colorectal cancer [4-07(j)/2002]

An extension had been requested but which the Advisory Group had been unable to approve in June because clarification was needed about what additional information was being sought. Further detail had been provided which made it clear that the applicant was not seeking additional information but wanted to undertake a data-cleansing exercise by seeking the same information directly from hospitals rather than relying solely on data provided by cancer registries. The request was reviewed by two members and the Chair, and was approved by Chair's action.

4. Chair's report

4.1 Complaint

Members were informed that the complaint discussed at the last meeting had been investigated. A letter from the Chair offering our apologies and explaining what would be done to address the procedural shortcomings had been sent to the applicant.

The Chair provided a further update on the complaint and that a letter had been drafted on behalf of Ben Bradshaw (Minister of Health).

4.2 Panorama programme

It was reported that the BBC would be showing a Panorama programme on issues related to personal data and there would be a short segment on the disclosure to and use of confidential patient information by the Dr Foster Unit (DFU) at Imperial College. This disclosure was undertaken with PIAG approval . It was noted this would be shown on Monday 27th October 2008. It was agreed that, should a response be needed, this would be approved by the Chair.

Action: Chair and Secretariat to prepare a response to the programme if necessary

4.3 Draft NHS Constitution

Members discussed the particular pledge under Informed Consent within the Draft Constitution, and noted that there appeared to be a lack of transparency between the Executive Summary and actual detail contained within the Draft Constitution.

Members were informed that the acting Chair of the NIGB had written to the Secretary of State regarding NIGB views, and the PIAG Chair would be writing to the BMJ. Following discussion, it was agreed that the Chair would also formally write to the Secretary of State to express PIAG concerns and the view that the section should be withdrawn to allow for a fully informed debate on the proposal.

The Advisory Group discussed the legal status of the Draft NHS Constitution and proposed the view that it represented a summary of existing legal rights, with additional pledges. A claim could not be made against a breach of the Constitution; however, it could be taken into consideration in the event of a breach of an existing legal right. Members were uncertain of the definitive legal status of the document and requested clarification.

Action: Secretariat to identify legal status of Draft NHS Constitution

4.4 Review of PIAG processes

The Chair reported that as part of the move across to the NIGB, it had seemed timely to undertake a review of PIAG processes. An external body would be commissioned to carry out the review and would be likely to want to speak to Members and the Secretariat as well as a number of applicants and other stakeholders. The Chair clarified that the review would also look at resourcing issues.

4.5 National Information Governance Board

The Chair invited Mr Johnstone to update the Advisory Group on the transitional arrangements. Mr Johnstone reported that the NIGB would be given a briefing in

November on the role of the statutory body. It was noted that the Regulations to establish the NIGB were due to complete their passage through Parliament on 27th October 2008. It was expected that the appointment of the Chair of the NIGB would be formally announced in November. The NIGB would also consider terms of reference for the new Committee in November but that these would not be approved until December along with membership of the new Committee. It was noted that PIAG would continue to operate until 31st December 2008.

4.6 Proposed article about the role of PIAG

The Chair thanked Professor Sir Denis Pereira-Gray and the other members that had contributed to this article and reported that it was nearing completion.

5. Database Monitoring Sub-Group (DMsG) Report

The Chair of the DMsG provided a verbal update to the Advisory Group.

5.1 Review of HES fields

An initial review of HES fields for identifiable, sensitive and non-sensitive data items had been completed with helpful assistance from a NHS Information Centre representative. The outcome from this exercise would be likely to lead to more applications, and Advisory Group lay members from PIAG who sat on DMsG agreed that it had been a worthwhile exercise that would be beneficial to repeat at intervals. Further work would be required to implement the changes and to communicate these changes to HES applicants on the PIAG and HESonline websites.

5.2 Applications

Members were informed that DMsG had received a number of repeat applications where the initial application often sought non-identifiable data, and sequential applications would lead to the data becoming identifiable. Such applications would need to be directed to apply for S251 approval to PIAG. Members expressed the view that DMsG appeared to be moving forward positively.

5.3. Communications

The Advisory Group noted that a dedicated section of the PIAG web pages had been established for DMsG. It was clarified that DMsG would need to remain within the NIGB as it would enable the workload for PIAG's successor committee to remain manageable.

6. New Applications for Section 251 support

6.1 Summary of Fast-track applications

No fast-track applications had been received since the last Advisory Group meeting

6.2 National Kidney Care Audit [PIAG 5-06(b)/2008]

This audit was designed to measure how renal services compared when viewed against the Renal National Service Framework, and to identify healthcare associated infection (HCAI) rates linked with vascular access in comparison to the national average. Support under section 251 was requested as the study required access to large numbers of patient identifiable information without consent, in order to check the information against the Personal Demographic Service (PDS) and to link to HCAI data from the Health Protection Agency (HPA) and HES data.

The Advisory Group approved the application as the importance of carrying out work in this area was recognised. Members noted that user involvement was very good and that the data would be held for one year after the audit had been completed (until 2012). Members also noted that the cohort consisted of approximately 20,000 patients and that it would not be practicable to obtain consent due to this large number. Discussions centered on whether the extent of patient identifiable data required was necessary. Members expressed concern that the application stated that surname was required as NHS number was not routinely held on the on the Health Protection Agency (HPA) lab-base database. Members noted this reason was frequently cited by applicants and that the HPA receive a large proportion of data from laboratories and these traditionally do not use NHS number.

Action: Secretariat to write to the HPA asking that they undertake batch tracing of NHS numbers for this study and also to seek to implement use of NHS numbers across all areas of relevant work.

This approval was subject to the following conditions:

- The Advisory Group approved the use of patient surname for 12 months only. During this period, the HPA should carry out batch tracing of NHS numbers through the NHS Strategic Tracing Service or the Personal Demographics Service. After the first 12 months, within this study, the NHS number should be used wherever feasible or the surname only used where the NHS number could not be obtained or validated.

- Amendments to the patient information leaflet, as follows:

    - The section under ‘Keeping Information Safe’ should be simplified to state how the information will be stored (also see linked point below);

    - Under a separate heading, explicit inclusion of the right to opt-out and how to access this mechanism;

- Details included on how identifiable the data would be in the initial collection phase;
- Details provided on how long the data will be retained (until 2012);
- The wording under the 'Vascular Access' section to be put in lay persons language e.g. 'getting to your veins'.

Additionally, the Advisory Group noted that due to the statistically high proportion of ethnic minority communities likely to fall within the cohort, provision should be made to accommodate those who would not have English as their first language.

Action: Secretariat to advise the applicant of the Advisory Group's decision

6.3. Case-control studies of psychiatric in-patients and those discharged [PIAG 5-06(c)/2008]

The purpose of this study was to identify the characteristics and specific risk factors for suicide occurring early in admission and post-discharge so as to develop risk assessment tools for use in clinical practice. Section 251 approval was sought as the study required access to the National Confidential Inquiries database and HES data in order to identify patients who committed suicide, and control groups.

The application was approved following extensive discussion by the Advisory Group. A key issue involved the extent of data required to identify the control group. It was agreed that the DMsG Chair would review the HES form to confirm whether the extensiveness of identifiable data was, in fact, necessary.

Action: DMsG Chair to review HES form

Members also considered the sensitive characteristics of the cohort and noted that in relation to the control group, the seeking of consent could potentially be harmful to the patient. Members expressed the view that if asked to seek consent from the control group, the clinician would be likely, and appropriately, to exclude high-risk patients from the study, which would lead to selection bias. Members noted that some changes to the application had been requested by the REC and agreed that PIAG should have sight of the amendments for checking via the Chair.

Advisory Group members were persuaded that in this instance, it would not be practicable to seek consent from the control-group cohort on the grounds that the seeking of consent could lead to an increased risk of harm to the patient.

The Advisory Group additionally noted that the age range of the cohort specified from age 10 upwards. Members expressed concern over this aspect and proposed that including children would make the issue of seeking consent from parents difficult, and as this sub-

cohort would be likely to include very small numbers, children should be excluded from the study.

The approval was therefore subject to the following condition:

- That children should be excluded from the study and that the age range of the cohorts should not include any participants aged under 18. Members agreed that seeking consent from this vulnerable cohort was inappropriate. In relation to children, Members agreed that it was likely to involve very small numbers and therefore would be of questionable validity given that the issues in the 10-14 and 14-18 age groups would not be explored in detail within the study. Any linked study relating to children should involve a separate application to PIAG.

Following this application, Members discussed the benefits to setting up a separate, non-business meeting to discuss the issues raised within these areas. The principal areas that Members felt should be covered were the vulnerability of patients in a mental health setting and the need to take particular care about overruling any withdrawal of consent.

Action: Secretariat to identify feasibility of setting up meeting to discuss issues raised by application

Action: Secretariat to advise the applicant of the Advisory Group's decision

6.4 Use of atropine in differentiating aetiology of syncope [PIAG 5-06(d)/2008]

This retrospective review was designed to investigate the usefulness of atropine in differentiating between different types of syncope in order to identify whether the result of the test influenced management of the patient. Support under section 251 was requested due to required access to patient notes in order to extract clinical data by a researcher outside of the clinical care team.

The Advisory Group did not approve this application. The Advisory Group considered the study to be sensible and of benefit to patients, however, it was the Advisory Group's view that the study constituted a clinical audit rather than research as atropine is already prescribed as part of routine clinical care, therefore a clinical review could be carried out as part of the Trusts clinical governance procedures.

Members advised that the clinician involved in providing routine care should complete the proforma and provide year of birth rather than full date of birth. Alternatively, the clinician involved in providing care to the cohort should seek patient consent for the disclosure of confidential patient information to those outside of the clinical care team..

Action: Secretariat to advise the applicant of the Advisory Group's decision

6.5 Teenage and Young Adult (TYA) cancer: the patient journey experience [PIAG 5-06(e)/2008]

This application sought to identify levels of national variation in patient pathways for TYAs using cancer registry data from 2001 onwards to identify whether the level of age-appropriate care influenced survival rates. Support under section 251 was requested as the study involved access to cancer registry data, in combination with HES data, in order to examine the impact of 2005 NICE guidance on improving outcomes for young people with cancer.

The Advisory Group approved the application on the grounds that the applicant would be in receipt of de-identified data and therefore it was borderline as to whether section 251 support would be required.

Members were generally supportive and welcomed the good use of user involvement in the development of the study.

Action: Secretariat to advise the applicant of the Advisory Group's decision

6.6 Development of Guidelines for prevention of violence in mental health settings [PIAG 5-06(f)/2008]

This study was designed to combine literature reviews, policy and focus group experiences to develop guidelines to aid decision-making for staff working with potentially violent mental health service users. Support under section 251 was requested as the study required access to service user case notes and incident reports in order to identify practical interventions and assessment tools currently in operation.

The application was reviewed initially by eleven Advisory Group members. The Advisory Group were unable to approve the application at the meeting. Members agreed, as a decision on the application could potentially set a precedent, that the application be deferred to the meeting on the 8th December for further consideration that would allow it to be reviewed by all members of the Advisory Group. The Advisory Group discussed at great length the issue of the public interest in improving staff safety, balanced against the rights afforded to the individuals in the cohort.

In order to aid the Advisory Group in reaching a view, it was agreed the following information should be provided:

- Further clarity over the security of information; once the information had been extracted by the research nurse onto the code breaker sheet further detail would be required as to where and how it would be stored;

- Advisory Group members noted that for those patients that had not been discharged, there would be ample opportunity to seek consent. Members noted the response to the query sheet and requested a copy of the invitation letter and information sheet. Confirmation of the status of the research nurse should also be provided;

- Members also noted that consideration should be given to demonstrating the possibility of bias and the seeking of consent versus non-consent through the carrying out of a pilot study;

- Clarification on whether part of the purpose of the study was to evaluate whether guidelines were being implemented;

- Expansion of the user involvement stage to test the acceptability of the use of data without consent / overriding dissent (Please note that the definition of user involvement here did not necessarily mean people who were violent now but who had been in the past).

Action: Secretariat to advise the applicant of the Advisory Group's decision

6.7 GP Practice Market Share Analysis [PIAG 5-06 (g)/2008]

It was reported that this application had been withdrawn by the applicant, following discussion with the Secretariat, with the intention that a revised application would be submitted at a later date.

7. National NHS Patient Survey Programme

7.1 Discussion paper from the Healthcare Commission Surveys team [PIAG 5-07/2008]

Members discussed a briefing note from the Healthcare Commission related to the National Patient Survey Programme and two proposed options sending out survey questionnaires to patients. The first option involved the approved survey contractor sending pre-packed information to the trust, who would identify relevant patients, according to redefined criteria, label and send out the packs to patients and who would provide pseudonymised data on the whole cohort to the approved contractor. Patients would then give consent for the use of the data by the contractor by returning the questionnaires. The second option involved the approved contractor receiving confidential patient information from trusts for them to identify the relevant cohort and send out the questionnaires. The briefing paper proposed that this could be done through the issuing of a honorary contract between the Trust and the survey contractor. The argument for using an approved contractor for the whole process, is so that no bias is introduced through trusts selecting the relevant patients and because such organisations are better equipped to manage the process of sending out reminders etc. Members agreed

that the first option should be used and were not persuaded of the necessity to use the second option as there did not appear to be sufficient grounds to warrant the disclosure of confidential information without consent in such circumstances when other approaches that did not involve breaching confidentiality were practicable. Members did not feel that adequate explanation had been given for why option 1 was not feasible. Members noted that the Healthcare Commission and its successor body had responsibility for monitoring information governance standards within health and social care, and therefore it must be seen not only to be operating within these standards but also to promote and model best practice, as it was likely that Trusts would follow the practices it set. Members asked the Secretariat to discuss the issue with the newly appointed Healthcare Commission Information Governance Manager.

Action: Secretariat to discuss these issues further with the Healthcare Commission's Information governance manager

8. Research Capability Programme

8.1 PD18 – Case for "Honest Broker" and "Safe Haven" Services to support research [PIAG 5-08/2008]

The Chair introduced this paper, which had been published recently along with other Research Capability Programme documents on the NHS Connecting for Health website, and explained its background. The Chair reminded newer members of the meeting arranged in March with major stakeholders, including the Department of Health Research & Development Department and the Wellcome Trust, to discuss issues related to the identification of potential research participants. The Chair also reported that additionally, a breakfast meeting had previously taken place with Professor Sally Davies where reassurance had been provided that the Research Capability Programme would come back to PIAG with proposals for how the core issue of consent for access to confidential information might be resolved. It was noted that these documents had been published without opportunity for PIAG to provide input. The Chair invited Members to provide initial comments on the paper.

The paper was discussed at length and a number of issues were noted; a principal concern was the fact that the document, had not been written in accessible language and consequently was unlikely to be understood by members of the general public. This was of particular concern as Members felt that one purpose of the paper should be to increase the trust and confidence of patients and the public in the handling of their identifiable information. The failure to present the document in a comprehensible form and the lack of a mechanism to show how this could be measured was not sufficiently defined within the document.

Members discussed the issue of defining what is meant by 'honest broker' and 'safe haven' and the need for honest brokers to have a secure legal basis for their access to confidential patient information, either through consent such as that undertaken by UK Biobank or via a statutory basis. It was reported that the NIGB would sign-off the criteria for honest brokers and safe havens. Key to the success of any honest broker service would be public trust and confidence in the service to safeguard the confidential patient information with which it was entrusted. Members wondered how the gathering of patient and public expectations would be maintained throughout the life of the honest broker service, which would be central to maintaining such public trust and confidence. This would further need to be supported with information being provided both about how patients' information was being used either for their interests as patients or the public interest and the oversight of such uses. This requirement would appear to be missing from the proposed criteria.

The Advisory Group noted that on page 32 an independent report had been produced by the Academy of Medical Sciences setting out the benefits of use of personal information for research purposes. It was agreed that evidence presenting all sides of the issue should have been presented in the document in order to provide a balanced approach. Related to this, the AMS report asserted that the difficulties of undertaking epidemiological and other data-based research were so great as to prevent such research from taking place. Members agreed that it would be helpful if some illustrative cases of studies that researchers would like to do but had been prevented from doing.

Members noted that the paper proposed setting up a mechanism to establish classes of approval for research. Members expressed concern as a mechanism for approvals is currently in place via PIAG that currently meets the requirements of the activity, balancing the public interest against the extent of the breach of confidentiality for each study. Members recommended that if the view was that the PIAG mechanism was not sufficient, then reasons and evidence for this view should be cited as the document was not clear as to why there was a need to change or how a balanced judgment might be achieved otherwise.

Advisory Group members felt that most researchers, handled patient identifiable information responsibly, however, a key issue was that PIAG did not consider researchers to have an equivalent duty of confidentiality to that owed by healthcare professionals. The duty of confidentiality is enshrined both within healthcare professionals' contract of employment, and codes of practice from their professional registering bodies, with breaches potentially leading to a prohibition in practice. An equivalent duty of confidentiality is a requirement of the Data Protection Act, so this is an important issue to be considered. Also the previous custom and practice of allowing researchers access to confidential patient information through honorary contracts. Such contracts have no force in law and are not therefore a substitute for confidentiality forming part of a substantive contract of employment and enforceable through discipliniary procedures.

Another issue that was identified and that relates to the Data Protection Act, was that of subject access rights, where the data controller was not the Honest Broker and how the process to support subject access rights would be managed.

The Advisory Group noted that a significant delay in research applications had been caused by Trust R & D departments and the requirement for researchers to approach and obtain approval from each R & D department and therefore that PIAG was not the primary source of administrative burden or delays for researchers. This also raised the possibility that researcher dissatisfaction with the processes involved in navigating appropriate approvals led to general statements and further evidence as to precise bottlenecks should be identified.

Some factual inaccuracies were noted within the paper, such as the omission that PIAG had strong lay membership, and that DMsG was part of PIAG and therefore would transfer with PIAG into the NIGB structure.

Action: Chair to write to Professor Sir Alex Markham to inform him of the factual inaccuracies within paper

9. Future meetings for 2008

Monday 08 December 2008

10. NIGB Ethics and Confidentiality Committee meetings 2009

It was noted that the 2009 meeting dates for the proposed Ethics and Confidentiality Committee, which would be responsible for considering applications under Section 251 of the NHS Act, would be circulated shortly.