Fitness to Practise Committee, 23 May 2013

Nursing and Midwifery Council and General Pharmaceutical Council initial stages audit review

Executive summary and recommendations

Introduction
In December 2012 the Council for Healthcare Regulatory Excellence (now the Professional Standards Authority for Health and Social Care) published their findings following the audit of the initial stages of the fitness to practise process at the Nursing and Midwifery Council (NMC) and the General Pharmaceutical Council (GPhC). The HCPC Fitness to Practise Department has undertaken a review of the audits to assess what learning can be taken from them and applied to HCPC processes. Attached is a summary of that review and the action being taken by HCPC. Both audits follow the same general headings and themes and many areas overlap, therefore the review of both regulators is detailed in one document and follows the themes as set out by the PSA.

Decision
This paper is for information only. No decision is required.

Background information

The last CHRE audit of the initial stages of HCPC fitness to practise process was undertaken in December 2010. HCPC is audited by PSA on a three year cycle. The next audit is due to take place in June 2013.

Resource implications

None.

Financial implications

None.

Appendices

Review of the Professional Standards Authority audit of the Nursing and Midwifery Council and the General Pharmaceutical Council audits
Audit of the Nursing and Midwifery Council initial stages fitness to practise process
Audit of the General Pharmaceutical Council initial stages fitness to practise process

Date of paper

26 April 2013

Review of the Professional Standards Authority audit of the Nursing and Midwifery Council and the General Pharmaceutical Council

1. Introduction

A review has been undertaken of the Professional Standards Authority (PSA, formally CHRE) Nursing and Midwifery Council (NMC) and General Pharmaceutical Council's initial stages fitness to practise process audit report. The key points made by PSA in relation to each regulator are set out below with comment about what measures the HCPC has in place or areas of development planned for the future. The detailed findings of the PSA are set out in section 2 of each report. The full PSA reports are attached to this paper.

2. Risk assessment

2.1. NMC report paragraph 2.1 – 2.5

The PSA comments on the failure by the MNC to document risk assessments in some cases and insufficient reasons provided for not applying for an interim order.

2.2. GPhC report paragraph 2.1 – 2.2

The PSA comment that risk assessment is an area in which the GPhC performs well.

2.3. HCPC response

The HCPC approach to risk assessment requires the Case Manager to complete a risk assessment document at three key stages in the process. They are as follows:

- on allocation of the case;
- on receipt of significant further information; and
- at the time of drafting the allegation.

The form requires the Case Manager to rate the risk of the case as either A, B or C and explain why an interim order may or may not be required. An operational guidance document, Risk Profiling and Interim Orders, is provided to the team to explain what is required and how to assess and classify risk. To assist Case Managers, when a case is created in the case management system (CMS) a risk assessment action is automatically added to the case. Other mechanisms are currently being considered to further assist Case Managers in ensuring risk assessments are completed at all necessary points in the process.

The presence of risk assessments on case files has been audited as part of case file audits for a number of years. Where a lack of risk assessment is identified, this is addressed. In early 2013 a number of files were identified as not having timely risk assessments at all the required stages as set out above. As a result all live cases were reviewed to ensure that an up to date risk assessment was present. The number of new employees within department and the increase in case load as a

result of the transfer of social workers may have contributed to this. However, this has demonstrated that the file audit process is performing its required function in identifying issues enabling them to be addressed. Risk assessment is a very important area of work and this will be monitored closely in the coming months.

The file audit process monitors the presence of risk assessments and in addition to this, since January 2013 the content of risk assessment has also been reviewed to ensure that quality is maintained. The Investigations Managers review a small sample of risk assessments on a monthly basis to monitor the content and reasoning provided by Case Managers. This has only been in place for a short period and will be reviewed in due course to ensure the sample and frequency is adequate. Learning from this review will be fed back to individual Case Managers or form part of on-going training.

3. Gathering information / evidence

3.1. NMC report paragraph 2.6 – 2.10

The PSA identify three main areas where failings were identified:

(i) gathering sufficient information
The PSA provide examples of cases where further significant information could have been gathered to ensure that the correct decision was made.

(ii) acting on relevant information
A small number of cases were identified where the NMC had failed to take appropriate action following receipt of information.

(iii) closing a case before sufficient information has been obtained
A small number of cases were identified where the PSA considered further information should have been obtained prior to the closure of the case

3.2. GPhC report paragraph 2.3 – 2.8

The PSA refer to some cases in which the GPhC hadn't followed its guidance in relation to gathering further information. Good practice was noted in relation to further cases where the GPhC demonstrated robust processes were in place for gathering information and evidence.

3.3. HCPC response

The HCPC has a number of measures and safeguards in place to reduce the risk in the areas identified by the PSA. Case review meetings are held at least once per month at which Case Managers can discuss cases with their Case Team Manager and questions can be asked of the Case Manager about the investigation and the approach taken.

At the time the allegation is drafted to send to the Registrant, the Case Team Manager approves the allegation and in doing so reviews the case. This occurs in advance of the case being considered by an Investigating Committee Panel (ICP) and provides an opportunity for any missing information to be identified. When the case is being considered by the ICP it has the option of requesting further information if it considers that this would assist in making a case to answer decision.

It is important to note that at this stage in the process the panel is not making any finding of fact and is generally only provided with sufficient information to allow a case to answer or no case to answer decision to be reached.

Where the HCPC is aware of on-going employer action in relation to a registrant who has been the subject of a capability or disciplinary process (as in one of the examples cited by the PSA) the HCPC will keep the case open until conformation is received that the Registrant has successfully completed any recommendations and there are no fitness to practise concerns.

Where a decision is made to close a case prior to consideration by an ICP as the case is deemed not to meet the standard of acceptance, approval must be sought from a Case Team Manager. The CMS has an automatic approval process attached to these closure actions which requires a manager to review the action before it can be completed. This prevents cases from being closed without the appropriate review being undertaken. The Investigations Managers undertake a review of a sample of closure forms on a monthly basis to assess the quality of the content and reasons given for the closure.

An audit of cases closed prior to consideration by an ICP is also undertaken by a Quality Compliance Officer to ensure that all necessary actions have been undertaken and the case complies with the required process.

4. Evaluation and giving reasons for decisions

4.1. NMC report paragraph 2.11 – 2.17

The PSA found three areas for improvement, they are as follows:

(i) over-reliance on other organisations' investigations;
(ii) the use of clinical advice; and
(iii) decisions based on factual inaccuracies.

4.2. HCPC response

When a case is considered by the HCPC the action taken by another organisation, often an employer, will be taken into account when making a decision on a case, but the HCPC recognise that the remit of the HCPC differs to other organisations and decisions must be taken based on fitness to practise concerns rather than employment or other issues. For example, although an employer may be supportive of an employee and have measures in place to support them, it may be necessary to refer a case for a hearing and impose a conditions of practice order to formalise any arrangements in place.

As referred to in paragraph 3.3 above, the HCPC will keep a case open where there is an on-going employer process to ensure that all issues are resolved prior to the case being closed.

The HCPC has a process in place for obtaining profession specific advice from a registrant assessor in cases where particular issues arise which are likely to be outside the knowledge of the registrant panel member. In most cases specific advice is not required, however, this is an area that has been kept under review to ensure that it is used where appropriate. Refresher training was provided to the Case

Managers in May 2012 and the operating guidance was reviewed. The introduction of the Case Advancement Team allows cases of this nature, where more detailed investigation is required, to be identified and managed appropriately.

Case Managers and panels are always reminded that decisions should only be taken on the evidence available and inferences should not be drawn. ICP decisions are reviewed by a Quality Compliance Officer and feedback is incorporated into panel and team training.

5. Reasons for decisions and communication of decisions

5.1. NMC report paragraph 2.18 – 2.24

As a result of the audit the PSA identified the need for improvement in:

(i) the extent of the reasons provided for decisions; and
(ii) the way that decisions are communicated.

5.2. GPhC report paragraph 2.9 – 2.16

The PSA comment on two areas where recommendations for improvement are made:

(i) decision letters; and
(ii) quality control.

5.3. HCPC response

The HCPC Case to Answer Determinations Practice Note and the decision template that is provided for panels provide guidance on the drafting of decisions, giving reasons and the importance of doing so. The importance of providing reasons is emphasised during panel training and refresher training. An ICP co-ordinator is present at the panel meetings to ensure consistency and remind panels of the requirement to include sufficient reasons in their decisions.

All ICP decisions are reviewed by a Quality Compliance Officer following the panel meetings and a report is provided periodically to the Fitness to Practise Committee providing analysis on the review of the decisions (the most recent paper forms part of the Committee agenda for this meeting). Where improvements are identified during the review, this is fed into panel training and future developments to practice notes and templates. Between November 2012 and February 2013 the Investigations Managers attended all ICPs to brief panels on a number of issues including the importance of producing well-reasoned and detailed decisions

Where decisions are made by Case Managers and Case Team Managers to close a case without consideration by an ICP as the case does not meet the standard of acceptance, the case closure form should record the reasons for this. As part of the quality review undertaken by the Investigations Managers of the content of risk assessment forms referred to in paragraph 2.3 above, the content of case closure forms is also reviewed. Further information about the process for closing a case is provided at paragraph 3 above.

The HCPC process is to provide the registrant and complainant with a copy of the ICP decision following the meeting. The Case Manager is not able to add additional

reasons or detail to the decision provided by the panel and it is therefore important that, as referred to above, the panel provide adequate reasons in their decision.

Where a case is closed without consideration by an ICP, the reasons for that decision should be set out clearly in the letter sent to the registrant and complainant. In early 2013, a case was identified where this had not occurred and a new process was put in place in March 2013 whereby the closure letter should approved by a Case Team Manager to ensure that the reasons provided are adequate. The audit of cases closed without an ICP now checks that this approval has been sought.

The letters that are sent to registrants and complainants are drafted using templates letters which may need to be adapted by the Case Managers to ensure they are suitable for the individual case. The templates are stored within the CMS and some formatting issues have occurred as the system beds down which has resulted in some letters not having the correct font or lay out which we are working to address.

As part of the file audits which are undertaken, the quality of the content of letters is reviewed and feedback provided. As mentioned above some formatting issues have been identified and where any improvements to the content are highlighted, this is addressed with the Case Manager concerned.

6. Links between the NMC's FTP and Registration departments

6.1. NMC report paragraph 2.25 – 2.28

The PSA comment on some areas of the NMC process which require communication between the registration and FTP departments.

6.2. HCPC response

The HCPC processes differ to the NMC and so a direct comparison cannot be made between processes. Some of safeguards in place at HCPC include a monthly status audit to sure that those individuals under investigation or subject to a sanction have the correct registration status and a mechanism by which a registrant must have an 'Under investigation' status against their register entry in order for the case to be logged on the CMS. This prevents a case from being logged and the status change being forgotten.

7. Protecting the public

7.1. NMC report paragraph 2.29 – 2.30

The PSA provide some specific examples of cases where they do not consider that the NMC has ensured public protection.

7.2. HCPC response

In one case a concern about someone not yet on the register was not recorded to prevent the individual entering the register at a later date. The HCPC has a watch list in which details of concerns about individuals on yet on the register can be entered. Should the individual make a subsequent application a conflict will be highlighted to the Registration Department and the matter further received by the FTP Department.

Another case involved the NMC incorrectly removing an interim suspension order status from the register when, although one case against the registrant had been closed, a further case remained open and therefore the suspension order should have remained. The application and removal of statuses at HCPC is a manual process and therefore there is room for error. However, as set out at paragraph 6.2 above, an audit is undertaken on a monthly basis to ensure that the register is correct.

The PSA refer to one case where the reasoning of the panel not to refer a case was questioned. The process in place at the HCPC in relation to ICP decisions and review is set out in paragraph 5.3 above.

A further point involved the NMC's failure to refer cases to the Care Quality Commission. The HCPC has an MoU with the CQC and is in the process of implementing the MoU and ensuring that the appropriate reports are in place. Cases will be referred centrally by the Assurance and Development Team.

A case where a delay of 4.5 years had occurred is highlighted by the PSA where it appears no action was taken between 2006 and 2011. The measures in place at the HCPC is prevent such delay include monthly case review meetings between Case Managers and Case Team Managers, monthly statistics reporting the length of time cases have been open and case progression conferences whereby cases over 4 months old are highlighted for review by managers within the department.

8. Customer care

8.1. NMC report paragraph 2.31 – 2.35

The PSA identified a number of examples of poor customer care and deficiencies on the content and tone of communications.

8.2. GPhC report paragraph 2.17 – 2.19

The PSA comment on a number of cases where improvements could be made in the customer service provided and also noted that good examples were also identified in letters to stakeholders.

8.3. HCPC response

The HCPC provided stakeholder communication training to the whole FTP Department between February and April 2013 which focused on the importance of ensuring good communication with all those who come into contact with the department. An area of work being undertaken in 2013-14 looks at the experience of those who come into contact with the FTP Department and how this might be improved.

Those involved in a case should be kept informed of the progress of the case at regular intervals and the CMS provides Case Managers with actions to prompt them to review cases at least once a month. When a case reaches a certain stage, specific actions are added to the case automatically to prompt particular actions. For example, when an ICP date is set the ICP follow up action is applied to the case which is linked to a checklist of all the required steps to be undertaken. Contact is

maintained following an ICP and the Case Support Team ensure that parties and contacted every two months to update them on progress.

Other areas of work related to this are set out above, for example the audit of cases which includes a review of a sample of documentation sent and the CMS template issues encountered which are being addressed. We aim to keep cases loads at a level that allows Case Managers time to properly manager their case load and ensure accuracy. Where caseloads increase temporarily due for any reason we look to manage resources and put in place temporary measures such as overtime and additional support from the Case Support Team.

9. Guidance

9.1. NMC report paragraph 2.36 – 2.40

The PSA identified two areas where guidance could be strengthened, this related to linked cases and the sharing of the registrants response with the complainant. The PSA also identify a number of cases where the NMC has not followed its policies and procedures.

9.2. GPhC report paragraph 2.20 – 2.22

The PSA comment on the GPhC's good practice in reviewing its internal guidance and updating it as required. Two cases are highlighted as good examples of this approach and the on-going review process in place.

9.3. HCPC response

The HCPC has produced a Practice Note on the joinder of cases, however there is no specific operational guidance in this area about the practical management of such cases. A review will be undertaken of the operational guidance to assess whether any further information about joined of linked cases needs to be included.

The Committee and Council have been provided with a number of papers on the HCPC's approach to sharing the registrant's response over recent years. The approach adopted by the HCPC not to disclose the registrant's response to the complainant has been discussed and agreed at these meetings.

The HCPC has a number of policies and procedures in place and all team members are trained on these as part of their induction and as part of on-going training. Monitoring compliance forms part of the file audits that are undertaken and as part of on-going

Due to the complex nature of case work there are instances where policies are not correctly followed or errors are made. HCPC has a number of mechanisms in place to assist Case Managers in ensuring that procedures are followed and to identify issues when they occur. For example, some action on the CMS have due dates set to coincide with the timeframes in which the action should be performed and checklists are provided for key parts of the process to remind individuals of tasks that need to be undertaken. Where an issue is identified, measures are put in pace to provide training to individuals or the team as a whole and to rectify the errors that have occurred. An example of this is set out at paragraph 2.3 in relation to risk assessment.

Operating guidance and practice notes are regularly reviewed and updated when new issues come to light as areas of improvement are identified. Any updates are communicated to the team through team meetings, update emails and workshops.

10. Record keeping

10.1. NMC report paragraph 2.41 – 2.45

The PSA highlighted a number of examples of cases where cases had been closed on the case management system but the parties had not been informed that the case was closed, inconsistencies in dates recorded on the case management system and the paper file and inconsistencies in the documents held on the electronic and paper file.

10.2. GPhC report paragraph 2.23 – 2.27

The PSA noted that in some cases there were inconsistencies in the documents held on the electronic and paper file, documents were misfiled or were not recorded in chronological order.

10.3. HCPC response

When a case is identified for closure, a checklist action is applied to the case as a prompt for the tasks that need to be undertaken prior to closure. That action has to be performed before the case can be closed. The HCPC CMS is a paperless system and there are no longer any physical case files. All correspondence is scanned on receipt and allocated to the case by the Administration Team. There is a risk of correspondence being allocated to an incorrect case, however, processes are in place should any errors occur. File audits also provide a safeguard and are an opportunity to identify errors in the allocation of documents.

All outgoing letters and emails are produced in the CMS and printed and sent from that system at which point it is saved directly into the CMS case record. Therefore the issues cited above will not occur as there is only one version of the case file.

The existing case documents that were migrated into the CMS when the system went live did not enter the system in chronological order which can cause some difficulty when reviewing large case files. However this only applies to cases opened before April 2012 and as time progresses this becomes less of an issue as these cases are closed.

11. Timeliness and monitoring of progress

11.1. NMC report paragraph 2.46 – 2.54

The PSA commented on the areas of (i) active case management and (ii) timeliness. In particular, the PSA comment that there has been delay in listing cases for consideration by an ICP due to the absence of a Case Manager, with no process in place for other colleagues to present the case. The PSA also comment on delay due to the unavailability of a midwife panel member.

11.2. GPhC report paragraph 2.28 – 2.34

The PSA highlights an area of good practice in relation to a new process put in place by the GPhC which has resulted in the timely closure of cases where there are no fitness to practise concerns. The PSA also comment on some cases where delays had occurred, deadlines were not set for the provision of information and information was not chased.

11.3. HCPC response

The measures in place at the HCPC to review cases on a regular basis and monitor progress have been set out in the paragraphs above in relation to previous points.

In relation to ICPs the HCPC has a process in place for cases to be presented by other Case Managers in the department to reduce delays. For smaller professions where there are fewer panel members available, the HCPC has introduced the use of telephone conferencing to ensure that the attendance of registrant panel members can be assured, even where there are very few cases for that profession due for consideration. This also ensures best use of resources.

The standard of acceptance policy was reviewed in 2012 to provide further guidance on the types of cases that should and should not be considered as an allegation. Refresher training was provided to Case Team Managers on its application in late 2012 to ensure understanding and consistency in its application. The correct application of the standard of acceptance ensures prompt closure of cases that do not meet the standard of acceptance. The age of open cases is monitored on a monthly basis to ensure that this does not exceed the internal measure of 73% of cases being 5 months old or less.

The standard template letter used by HCPC to request information from third parties does not include a deadline for a response to be received and this will be reviewed.

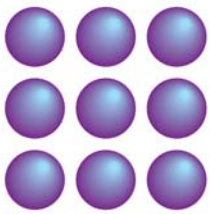
12. HCPC Recommendations

Following the review of the NMC and GPhC audits, the following areas of work have been identified for the HCPC to undertake in the coming months, some of which are already on-going.

- Review the approach taken to assessing the quality of the content of risk assessments;
- Keep the use of registrant assessors under review and ensure their use where appropriate;
- Continue to address the template formatting issues within the CMS to ensure that all letters use the correct font and formatted;
- Fully implement the Care Quality Commission MoU and ensure relevant cases are referred;
- Ensure caseloads remain at manageable levels to ensure quality and accuracy in case work;
- Review the need for operational guidance on managing linked and joined cases; and
- Review the standard letter for requesting further information and include a deadline for the response.

Audit of the Nursing and Midwifery Council's initial stages fitness to practise process

December 2012



council for healthcare regulatory excellence

About CHRE

The Council for Healthcare Regulatory Excellence promotes the health and well-being of patients and the public in the regulation of health and care professionals. We scrutinise and oversee the work of the nine regulatory bodies[1] that set standards for training and conduct of health and care professionals.

We share good practice and knowledge with the regulatory bodies, conduct research and introduce new ideas about regulation to the sector. We monitor policy in the UK and Europe and advise the four UK government health departments on issues relating to the regulation of health and care professionals. We are an independent body accountable to the UK Parliament.

Our aims

The Council for Healthcare Regulatory Excellence works to raise standards and encourage improvements in the registration and regulation of people who work in health and social care. We do this in order to promote the health, safety and well-being of patients, service users and other members of the public.

Our values

Our values and principles act as a framework for our decision-making. They are at the heart of who we are and how we would like to be seen by our partners. We are committed to being:

- focussed on the public interest
- independent
- fair
- transparent
- proportionate

Our values will be explicit in the way that we work; how we approach our oversight of the registration and regulation of those who work in health and social care, how we develop policy advice and how we engage with all our partners. We will be consistent in the application of our values in what we do.

We will become the Professional Standards Authority for Health and Social Care during 2012.

1 General Chiropractic Council (GCC), General Dental Council (GDC), General Medical Council (GMC), General Optical Council (GOC), General Osteopathic Council (GOsC), General Pharmaceutical Council (GPhC), Health and Care Professions Council (HCPC), Nursing and Midwifery Council (NMC), Pharmaceutical Society of Northern Ireland (PSNI)

Contents

1. Overall assessment

Introduction

1.1 In June/July 2012 we audited 100 cases that the Nursing and Midwifery Council (NMC) had closed at the initial stages of its fitness to practise (FTP) processes during the six month period 1 November 2011 to 30 April 2012.

1.2 In the initial stages of their FTP processes, the nine health and care professional regulatory bodies decide whether complaints received should be referred to a hearing in front of an FTP panel, whether some other action should be taken, or whether they should be closed.

1.3 Our overriding aim in conducting audits is to seek assurance that the health and care professional regulators are protecting patients and the public and maintaining the reputation of the professions and the system of regulation. We assessed whether the NMC achieved these aims in the particular cases we reviewed against the Casework Framework. We considered whether weaknesses in handling any of these cases might also suggest that the public might not be protected, or confidence not maintained, in future cases.

1.4 In our last audit report of the NMC dated November 2011, we summarised our findings as follows:

> *"…we found continuing areas of significant weaknesses in [the NMC's] handling of cases at the initial stages of the fitness to practise process. Many of the weaknesses are ones that we identified in previous audits. These weaknesses create risks for public protection and public/professional confidence in the regulatory process. We consider that there is some evidence of improvement in the quality and efficiency of the NMC's fitness to practise process in the last year….However we remain concerned about the extent of the weaknesses…"*

1.5 Our performance review report for 2011/2012 was also consistent with these findings and noted concerns related to the fitness to practise function in the areas of timeliness and progression of casework, the quality of decisions made and recorded, the quality of customer care, the quality of record keeping, the consistency of the on-going monitoring of risk and the quality of investigations. We said in this report that significant improvement would need to be achieved as a matter of urgency.

1.6 Since our last audit we have undertaken a strategic review of the NMC at the request of the Parliamentary Under Secretary of State at the Department of Health. The Strategic Review was not an audit. The Strategic Review report documents the troubled history of the NMC and also looks forward to make recommendations which aim to help the NMC tackle weaknesses in governance, decision-making and operational management. We anticipate that implementing the recommendations from the Strategic Review will therefore lead to improved findings in future audits.

1.7 We note that over the last two years the NMC has introduced numerous changes to its procedures aimed at improving quality assurance (see para 1.15 below). The cases we audited were subject to different internal procedures and those were not always consistently applied.

1.8 We hope that this audit report will be useful to the senior leadership team and operational staff with their programme of improvement aimed at raising standards in the FTP department.

Summary of findings

1.9 Many of the weaknesses from this year's audit are the same weaknesses that we identified in earlier audits. In response to our earlier audits the NMC said that it had implemented improvements and assured us that we would see improvements in later audits. We saw examples of better record keeping and correspondence in some cases, however we are concerned about the extent of the weaknesses identified during this audit including in cases opened since the NMC initiated its improvement programme in January 2011. In our view, our findings mean that we have not yet seen evidence that the improvements that have been initiated since January 2011 have resolved the problems we previously identified.

1.10 We found weaknesses in many areas of the Casework Framework (see Appendix 2). In our view the weaknesses we have identified in this audit, together with the evidence that improvements have not been entirely successful in resolving problems identified in previous audits, have the potential to create risks for public protection and damage public confidence in the NMC as a regulator. Full details of our findings are set out below, but in summary our findings are:

- Inadequate information gathering, giving rise to the risk that a robust investigation was not carried out before closing individual cases
- Insufficient explanations or inaccurate details being provided in decision letters sent to registrants and complainants, with the result that some may not have fully understood the reasons for the decisions made by the NMC and some may have been left with the perception that the quality of the investigation was not robust
- Poor examples of customer service and complaint handling. This damages the NMC's reputation and it might give rise to a concern that the NMC is not handling cases properly
- Failures to consistently follow the NMC's own policies and procedures
- Inconsistent approaches to record keeping, with the result that information on individual cases is not necessarily either easily accessible or held in one place
- Delays in the progression of cases and a lack of active case management resulting in avoidable delays.

1.11 We did see documented risk assessments in the eight cases we audited that were opened after the NMC changed its process in February 2012. We hope to see consistent compliance with this process for documenting risk assessments in future audits.

Method of auditing

1.12 We reviewed 100 cases that had been closed by the NMC between 1 November 2011 and 30 April 2012. These were selected from the cases that the NMC closed in this period without referring them for a hearing by either the Conduct and Competence Committee (CCC) or the Health Committee (HC)[2].

1.13 We selected 50 cases at random, which proportionally reflected the numbers of cases closed at each closure point within the initial stages of the NMC's fitness to practise (FTP) processes. The other 50 cases were selected at random from categories of cases that we considered to be 'higher risk'. That is to say that, in our view, there was a higher risk to the safeguarding of public protection if proper procedures were not followed in these cases. When auditing regulators we base our assessment of the risk associated with each case on the information we have gathered during previous audits, on the information we are provided with during our annual performance review of the regulators, on concerns that we receive about the performance of the regulators, as well as any other relevant information that comes to our attention.

1.14 In March 2010 the CHRE led a meeting of representatives from the nine health professional regulators to agree a 'Casework Framework'. This was a description of the key elements that should be present in the different stages of a good FTP process. A copy of this is at Appendix 2. When auditing a regulator, we assess the handling of a case against the elements of the Casework Framework.

1.15 In this year's audit we also looked for evidence of the effectiveness of the changes that have been introduced by the NMC since 2010 with the aim of improving its performance at the initial stages of the FTP process. These changes were: -

- November 2010 – the introduction of full case audits every two to four weeks, and monthly reviews of the oldest open cases to prevent delays in cases
- November 2010 – introduction of a new centralised filing system with a standard operating procedure to improve record keeping
- January 2011 – the introduction of the screening team comprising case workers, screening lawyers and clinical advisers, responsible for cases from receipt to their first consideration by the investigating committee. The case workers in the team review the case within 48 hours of receipt and if an interim order application is required, they refer the case to the screening lawyer

[2] We note that at least one of the cases was closed at a pre-meeting of the CCC

- January 2011 – the introduction of a new risk assessment process which introduced a formal and consistent approach to recording risk assessments

- March 2011 – the implementation of the policy to request a GP / nurse / occupational health reference and an employer reference in cases concerning criminal offences involving drugs and/or alcohol (where it is the registrant's first offence)

- March 2011 – the introduction of procedures to quality assure correspondence twice, return telephone and voicemails within 24 hours, acknowledge emails within 24 hours, provide a date for a substantive response within 20 working days, acknowledge letters and faxes within three working days and provide a date for a substantive response within 20 working days

- April 2011 – the introduction of closer monitoring of investigations carried out by external bodies

- May 2011 – the introduction of timeframes for solicitors undertaking investigations

- August 2011 – the implementation of the customer service pledge to improve customer care

- February 2012 – the introduction of an amended risk assessment procedure, requiring risk assessments to be documented.

The NMC's FTP framework

1.16 The structure of the NMC's FTP process means that there are two points at which cases may be closed without referral to a formal hearing in front of an FTP panel:

By NMC FTP staff without referral to the investigating committee

1.17 Rule 22 (5) of the NMC's statutory rules (The Nursing and Midwifery Order 2001 as amended) says that the NMC must refer to the relevant committee or person any allegation that is made to it 'in the form required'. The rules do not define what that phrase means. However, the NMC has defined it to mean that an allegation must identify the registrant (with contact details and PIN if possible), describe the incidents and be 'supported by appropriate evidence'. The NMC's processes permit staff in its FTP department to close cases which are not 'in the form required'. Decisions to close cases on that basis are made by the screening team. The screening team case workers make a recommendation to close a case - which is then reviewed and agreed by the screening team manager and screening team lawyer.

By the investigating committee (IC)

1.18 The IC's role is set out in legislation. The Nursing and Midwifery Order 2001 (section 26 (1) and (2)) explains that the committee's role is to:

'…consider in the light of the information which it has been able to obtain and any representations or other observations made to it under sub-paragraph (a) or (b) whether in its opinion in respect of an allegation of the kind mentioned in article 22(1)(a) [misconduct, lack of competence, conviction or a caution in the UK for a criminal offence, physical or mental health, or a determination by a body in the UK responsible under any enactment for the regulation of a health and social care profession to the effect that their fitness to practise is impaired, or a determination by a licensing body elsewhere to the same effect], there is a case to answer…'

1.19 The NMC IC's membership is made up of members of the nursing and midwifery professions and lay people.

1.20 In order to carry out its role, the IC assesses whether or not there is a 'realistic prospect' of a fitness to practise panel deciding that the registrant's fitness to practise is impaired, should the matter be referred to a formal panel hearing. To help the IC with this assessment, the committee can request that an investigation is conducted.

1.21 In the event that the IC decides not to refer a case for a hearing by an FTP panel, it may inform the registrant that the case may be taken into account in the consideration of any further allegation about them that is received by the NMC within three years of the decision not to refer the case for a hearing.[3.]

[3] NMC (Fitness to Practise) Rules Order of Council 2004 Rule (6)(1)

2. Detailed findings

Risk assessment

2.1 Robust risk assessment on receipt of a new case, and updating that risk assessment on receipt of new information, is an important part of public protection within a risk based regulatory approach. Unless the regulator has conducted a proper evaluation of risk, it is difficult to make sound judgements about whether regulatory action is necessary. In the context of the NMC's remit, risk assessments are required to support decisions about whether to take immediate action (to put in place an interim order) to prevent the registrant from practising without restriction while the allegation that their fitness to practise is impaired is being investigated. Robust and prompt risk assessment can also prompt the regulator to make a disclosure to an interested third party (e.g. another regulator) in order to safeguard public protection.

2.2 In our last audit we reported that the NMC introduced a formal and consistent approach to recording risk assessments in January 2011. We stated that we had seen evidence that this process was being followed in some, but not all, of the cases that we audited. In response to last year's audit, the NMC said that it had changed the screening assessment form to require staff to record the reasons for their decisions to alert/not to alert the investigating committee (IC) that an interim order might be required. In this audit we did not find a recorded risk assessment in 11 of the cases we reviewed that were opened after January 2011.

2.3 In response to our audit findings the NMC have said that the absence of a record does not mean that a risk assessment was not undertaken. In three of these 10 cases, for example, alerts on the case management system refer to an interim order being considered. The NMC have explained that between November 2011 and February 2012 risk assessments were being conducted but not necessarily recorded. For the avoidance of doubt we consider that, in the absence of a record, there is no evidence that the activity took place.

2.4 In one case that we audited we noted that a risk assessment had been conducted and while we do not disagree that an interim order was not required we do consider that there were insufficient reasons for the decision not to impose the interim order. The screening lawyer appeared to have ruled out an interim order because a year had passed since the incident leading to the referral to the NMC. In response to this the NMC have told us that comprehensive reasons for that decision were not recorded at the time but that, the time since the referral was only referenced as a factor and, the delay could not have been the reason for not proceeding with an interim order application. In the absence of documented reasons, it is not possible to determine the reasons an interim order was not applied. Failing to document reasons for key decisions means that the regulator may not be able to justify those decisions if challenged, nor will it be able to learn from any errors in its decision-making process.

2.5 The NMC have told us that formal risk assessment forms were introduced in February 2012 and that standard operating procedures have been amended,

with the result that staff now formally document the risk assessment of each case throughout its lifetime. We did see documented risk assessments in the eight cases we audited that were opened after February 2012. We will look for evidence of consistent compliance with this process in our next audit.

Gathering information/evidence

2.6 Information and evidence must be gathered at the correct point in the FTP process to enable effective decision making. The regulator must operate proactive processes for gathering information in order to ensure that the right information is available to be considered by the decision makers at the appropriate time. Our findings in this section of the audit report concern failings in three main areas (i) gathering sufficient information; (ii) acting on relevant information; and (iii) closing a case before sufficient information has been received.

(i) Gathering sufficient information

2.7 We found several cases where the NMC had failed to follow a robust process for gathering information/evidence. In these examples the failure to gather sufficient information meant that there was either a risk of the wrong decision being made, or a risk that the decision might have been based on inadequate reasons:

- In one case that we audited the NMC had contacted the registrant's employer to request the registrant's PIN number (a unique identifier for each nurse/midwife) so that the NMC could check its register. The employer refused, relying (without justification) on its duty of confidentiality to its employee. The NMC accepted the employer's refusal, rather than pursuing the request. The NMC accept that it was not right for the staff member to accept this refusal and have said they will deliver training to address this. In our view the appropriate action would have been for the case worker either to explain the reasons for the request and the NMC's remit, or to escalate the request

- Following the receipt of a report by a midwifery supervisor which related to the outcome of disciplinary proceedings about three midwives, the NMC failed to seek clarification about which recommendations in the report related to each of the three midwives. In addition, a letter from the employer said that one of the midwives had not yet completed her practice recommendation but did not specify which one. The NMC said that the available information suggested that there were no matters giving rise to an allegation of impaired fitness to practise. If the midwife had failed to complete the practice recommendation and the employer had concerns regarding her FtP, they would expect that such concerns would be highlighted. In our view it would be better regulatory practice for the NMC to have clarified this before closing the case

- In two cases that we audited better attempts could have been made by the NMC to clarify the facts and allegations in our view. The IC concluded that the evidence available was not sufficient to establish that there was a 'case to answer' in terms of there being a real prospect that the registrant's FTP

was currently impaired (see para 1.18). In one of these cases, the NMC had trouble with obtaining contact details despite repeated attempts. We also note that in the case of one witness, the NMC made unsuccessful attempts to make contact. Nonetheless, in both cases there were witnesses, who may have had relevant evidence to give, who did not provide statements. In our view, the IC would have been in a better position to reach a robust decision about whether or not there was a 'case to answer' if the NMC had attempted to clarify the facts and allegations from as many sources as possible

- In another case the NMC had not followed up on the outcome of a referral that had been made to the Independent Safeguarding Authority. We consider that this information would have been of benefit to the IC, particularly as the case involved a registrant who was employed to care for patients who were particularly vulnerable.

(ii) Acting on relevant information

2.8 Four cases we audited raised concerns about the NMC failing to act on information. They demonstrated that the NMC had failed to follow up on enquiries or had not passed on information appropriately. Conducting a robust investigation must involve ensuring that the right information is available to be considered by the decision makers at the appropriate.

- One case that we audited demonstrated that the NMC failed to instruct its solicitors to complete an investigation by carrying out the IC's instructions to investigate new and old allegations. It appeared from the audit of this case that this had been an error, rather than an intentional decision. We consider that systems should be in place to prevent such errors from occurring. Failing to follow the instructions of the IC may affect the quality of the investigation and also cause preventable case adjournments and delays

- In two cases that we audited the NMC had failed to provide the IC with the registrant's response to the allegations. This meant that the IC did not have all the information it needed in order to reach a robust decision. It was also a breach of the NMC's documented process, and a procedural failing that could have led to a successful legal challenge to the IC's decision on the grounds of unfairness to the registrant. Errors of this nature have the potential to damage confidence in the regulator

- In one case we audited the NMC had not provided its external lawyers with important information – that the registrant was currently subject to an interim suspension order. The NMC also failed to amend the allegations (which were wrongly recorded) despite the fact that the need for such amendment had been brought to the NMC's attention twice by IC members.

(iii) Closing a case before full information has been obtained

2.9 In our previous audit we identified five cases which had been closed prematurely. We expressed concern that the NMC could not reasonably have assured itself of the level of risk posed by the registrants before the decisions were taken to close the cases.

2.10 In this audit we identified four cases where we consider that the NMC should have obtained further information before taking the decision to close the case. Deferring the decision to close a case, pending receipt of sufficient information may be necessary in order to ensure that the right decision is made.

- In one case that we audited the NMC closed the case because the complainant did not wish to proceed with their complaint. The NMC's standard operating procedures require that in such circumstances it must consider whether it should proceed with the case in the public interest, whether there are any other lines of enquiry that could be pursued and whether the complaint could proceed without the complainant's cooperation. These are appropriate questions for a regulator to ask itself, given that its primary role is public protection and that requires the regulator to be proactive in investigating once it is aware of information indicating that a registrant's fitness to practise is impaired. There is no evidence that these issues were considered. In response to our feedback the NMC have told us that the amended version of its screening audit form requires case workers to document reasons for decisions taken. It is not clear to us how that measure will prevent a similar issue recurring in future, unless there is robust quality assurance of case workers' and screening lawyers' compliance and evaluation of the reasons they have documented for such decisions

- In one case the NMC lawyer had recommended closure of a case because the NMC could not access documents required to assess the case. In response to our feedback about this case the NMC have told us that they cannot investigate allegations without the consent of the relevant member of the public unless it considers there is an immediate risk to public protection. In our view the appropriate action for the NMC to take in this case would have been to use its statutory powers to gain the information it needed to fully consider the issues

- One case that we audited had been closed before the NMC had received a requested response from the registrant's employer and before the clinical records had been reviewed (even though one of the allegations was about whether appropriate treatment had been given). We acknowledge that when the clinical records were reviewed, they showed that there was no evidence to substantiate the allegations. Nonetheless, by failing to conduct the review before closing the case the NMC risked closing the case before it had gathered sufficient information and potentially reaching the wrong decision

- In one case that we audited the registrant had received a police caution for the offence of destroying and causing damage to property. The case was

closed by the IC on the basis that the matter did not relate to professional practice, the registrant had showed remorse and no concerns had been raised about the registrant in the reference from her employer. There was no evidence on the file that the NMC contacted the police to check the registrant's explanation about the offence. While the NMC did conduct a Police National Computer[4] (PNC) check in order to find out whether the registrant had any previous convictions, that did not provide any background information about the circumstances of the offence. In our view, the NMC should have contacted the police to obtain background information about the registrant's offence, in order to assess any risk to public protection.

Evaluation and giving reasons for decisions

2.11 A regulator's decisions must be able to stand up to scrutiny. We reviewed the quality of decision making in all the cases that we audited. We set out details about these cases in this section of the report.

2.12 We found areas for improvement in relation to (i) the reliance placed on other organisations' investigations; (ii) the use of clinical advice and; (iii) ensuring that decisions are not based on factual inaccuracies.

(i) Over-reliance on other organisations' investigations

2.13 The following three cases demonstrate the NMC's over-reliance on other organisations' investigations. We realise and accept that public bodies should be able to rely on each other and that it is proportionate to accept evidence and findings from external bodies. Since another organisation's investigation will have a different purpose or standards it cannot be fully relied on to address public protection considerations related to the fitness to practise of a registrant. This is an issue we have identified in previous audits. Two of the three cases below were closed after the publication of our last audit report and we are concerned that this indicates that the learning from our audit report has not been fully implemented.

- In the first case the IC referred to the findings that had been made during an employer's disciplinary process as a reason not to refer the case on to a hearing before the CCC or HC. In responding to our feedback about this case, the NMC have acknowledged that in principle panels must take their own decisions. The NMC said that it will continue to reinforce this message at training for panel members

- In the second case the NMC did not take action because the employer was initiating formal capability proceedings and had agreed to contact the NMC if any relevant concerns were raised. The employer was carrying out an assessment of the registrant's practice because concerns had been raised about their drug administration (which was relevant to the allegation being considered by the NMC). The IC closed the case and asked the employer

[4] Police National Computer: database containing information about people who have been convicted, cautioned or recently arrested

to contact the NMC once its formal capability proceedings had concluded if there were any concerns relevant to the NMC's remit. In response to our feedback on this case the NMC has confirmed that in these circumstances it would not monitor or follow up the outcome of the employer's proceedings and it would wait to see if the employer reported any concerns. We consider that, given the potential risks to public protection and the relevance of the employer's assessment of the registrant's practice to the allegations, it would have been better practice to have kept the case open until the NMC could satisfy itself that all the risks had been dealt with. We note that if the registrant had changed employer before the conclusion of the employer's capability proceedings there is no guarantee that the NMC would be notified to enable it to address risks to public protection arising from the registrant's lack of competence

- In the third case the NMC received a complaint about the registrant from the employer's safeguarding team at the outset of its investigation. The complainant provided a report at the end of the investigation which concluded that the allegations were unfounded. The NMC therefore closed the case on the basis that there was no evidence to support an allegation that the registrant's fitness to practise was impaired. When we audited the case we noted that the employer's report was brief and that its 11 appendices (including staff statements, care notes and police interviews) were not attached. In addition we noted that the employer's report did not refer to an interview with the patient (which we consider to be significant because there was a conflict of evidence between the registrant and another member of staff). In our view, there was insufficient information available at the date the NMC closed the case. The NMC should have requested the appendices to the report before a final decision was reached. In response to our feedback on this case the NMC told us that it would have no grounds to investigate if the complainant's investigation established that the allegations could not be substantiated. However the NMC must reach its own decision about whether or not there is evidence that a registrant's fitness to practise is impaired and it must base that decision on sufficient information.

(ii) The use of clinical advice

2.14 In January 2011 the NMC established a screening team which comprises case workers, screening lawyers and clinical advisers. This team is responsible for cases from the point of receipt. In this audit we looked for evidence that case workers were asking for clinical advice in relation to cases that were opened after January 2011. Clinical advice is likely to be useful in cases concerning allegations of impairment arising from lack of competence and in some cases concerning allegations of impairment arising from misconduct. It may be necessary for the purposes of conducting risk assessment in the early stages of an investigation and it may also help to inform decision makers considering issues relating to public protection and /or professional standards.

2.15 We audited three cases, opened since January 2011, that indicated the process for obtaining clinical advice and ensuring that the advice is used to inform decision making could be improved:

- In the first case the clinical advice report strayed from comments on clinical matters and expressed the advisor's personal view about the effect the case might have had on the registrant's behaviour, *"I don't believe that any of the registrants involved are likely to be faced with such a case again and if they are, they will know now the importance of antibiotics".* This statement was an assumption made by the advisor, rather than an evidence-based finding. As such, it may indicate that the adviser was not properly briefed prior to producing their report. The fact that it was not identified as an issue by the NMC also raises queries about the effectiveness of the quality assurance processes that are in operation

- In the second case the complainant had made allegations about the care provided to her mother by four nurses. We reviewed cases involving two of the four nurses involved (one of them concerning the ward manager and the other the matron). The clinical advice on the other two cases indicated that serious failings were made by the nurses in the two cases we audited (the ward manager and the matron). This clinical advice was not filed on the files of those two cases nor did it appear that any other clinical advice had been requested in respect of those cases. It is not evident that the IC, when considering the cases involving the ward manager and matron, were ever aware of the clinical advice or took it into account in making their decision although this was clearly relevant information

- In the third case the decision was based on the outcome of the registrant's employer's investigation and no clinical advice was obtained because the NMC screening lawyer took the view it was unnecessary as it was unlikely the case would result in a finding of impairment of the registrant's fitness to practise. We are of the view that the decision that clinical advice was not needed was wrong because the allegations related to a potential misdiagnosis and it therefore appears that a clinical adviser's opinion on the case would have been valuable.

(iii) Decisions based on factual inaccuracies

2.16 We reviewed four cases where we were concerned that decisions were unsound, because they were based on factual inaccuracies.

- In the first case the registrant had been convicted for possession of two bladed articles in a public place. The IC concluded that the registrant had addressed the concerns about her psychological wellbeing although there was no evidence to support that conclusion other than a GP report indicating the registrant had been referred for counselling (without any information as to the outcome of that referral). We also note that the IC had misinterpreted the GP report – wrongly stating that it established that the registrant had been subjected to a sexual assault. From our reading of the GP report we concluded that while the registrant had alleged that they had been the subject of a sexual assault, there was no evidence to substantiate that claim. The IC reached the conclusion that there was no real prospect of a finding of impairment of fitness to practise if the case was referred to a hearing, based in part on these inaccuracies. We were troubled by this given that, the registrant could also be said to have failed to demonstrate

insight as she had failed to surrender to custody, had expressed no remorse and in fact denied any wrongdoing

- In the second case the IC concluded that the registrant had undergone a period of supervised practice. While some evidence of supervised practice was provided to the IC, the report to the IC stated that, *"documentary evidence regarding … the extent to which the registrant completed the supervision required of her following the final written warning, is still missing"*

- In the third case we noted that the screening audit form (which is used to document reasons for closing cases at that stage) recorded that the reason for closure was that the employer had investigated the circumstances leading to the complaint. When we reviewed the file, it was evident that the employer was unaware of the circumstances leading to the complaint and had not investigated them. In response to our feedback on this case the NMC have told us that its processes have been amended to ensure that relevant information is received in response to requests for information. We are unclear about how that activity would prevent a future recurrence of this problem given that the nature of the employer's involvement was evident from the file and the case officer appears simply to have misunderstood the information

- Similarly, in the fourth case, the complainant had been advised in writing by the screening team that the concerns had been dealt with at a local level and therefore the NMC did not intend to take any action – however from our review of the file we were not able to identify any information indicating that the concerns had been dealt with locally.

2.17 The NMC advised us that these four letters were sent prior to training delivered to the IC in 2012, targeted training delivered to the screening team and the implementation of a process to ensure more detailed closure letters are sent out by the screening team following completion of a quality assurance audit. We would therefore expect to see effectiveness of this training in future audits.

2.18 Our feedback from this audit identified a need for improvements in relation to (i) the extent of the reasons provided for decisions and also (ii) the way that decisions are communicated in decision letters.

(i) Reasons for the decisions made

2.19 We found eight cases where, in our view, the reasons provided for the decisions reached were inadequately detailed:

- In three cases we audited the NMC decided that there was 'no case to answer' without setting out its reasons in sufficient detail. We note that we made a similar finding in relation to eight cases we reviewed in our last audit. In the first of these three cases the NMC did not explain how it had drawn its conclusion or set out what information had been weighed up. In the second case the IC appears to have accepted the legal advice that the evidence available was not sufficient to establish that there was a 'case to

answer'. There is no further explanation of the reasons behind the decision that was reached (that there was 'no case to answer'). In the third case the decision letter noted that the NMC's external lawyer had advised that as the NMC had been unable to obtain witness statements, there was no real prospect of the CCC making a finding of misconduct leading to impairment of fitness to practise. However the IC decision itself did not set out the reasons for the case closure

- In the fourth case the IC noted that it had been presented with two conflicting legal reports from internal and external solicitors. We noted that the decision letter did not set out the reasons why the IC preferred one report over the other

- In the fifth case the IC's decision letter did not document all the allegations that had been considered. This means it is possible that full reasons were not provided for all the decisions taken

- In the sixth case the IC did not explain the reasons for its conclusion that the registrant was not personally accountable for the failings identified, it did not outline which evidence it found persuasive, it did not explain why the realistic prospect test was not met, it did not explain why it had concluded that the registrant's failings had been remediated, it failed to reference the employer's investigation and it did not provide reasons for its conclusion that the registrant had demonstrated insight. The NMC said that training has been delivered to the IC and its ICs now sit with permanent IC secretaries. It is therefore hoped that this will resolve this issue.

2.20 In response to our findings in relation to these cases the NMC has said that it will deliver training to panel members in respect of their decision making. We note that in our progress review of the NMC that was published in January 2011 we reported that the NMC expected to complete a training needs analysis in March 2011, including providing training and events for FTP panel members (including IC members) focusing on drafting decisions and providing reasons. We recommend the NMC evaluates the success of this previous training initiative before implementing further training in response to this audit report and that it considers whether other measures may also be required.

(ii) Decision letters

2.21 In our audit we checked that decisions were properly communicated to complainants, registrants and other stakeholders. We identified delays with sending decision letters out (see Appendix 1) as well as issues with the content of the letters. We think it is particularly important to ensure decision letters are well-drafted and comprehensive because they are a key communication point between the regulator and the complainant, witnesses and the registrant(s) involved. Poorly drafted decision letters can be an indicator of inadequate quality control at the time of dispatch, as well as inadequate quality assurance. Poorly drafted letters may also damage the confidence of registrants, complainants and witnesses in the quality of the NMC's investigation.

2.22 In one case we audited, a letter we reviewed did not provide full information to the registrant about the decision to impose an interim order, nor did it provide full information about the requirements of the interim order. In particular, the letter omitted a particular recommendation, with the result that the registrant was unaware that she was required to undertake further medical testing until she herself reviewed the transcript of the hearing. This is a particularly serious concern given the potential impact for any review of the interim order of a failure to notify the registrant of the requirements that had been put in place. We note that the letter referred to above was sent out before March 2011.

2.23 The NMC has previously advised us that in March 2011 it introduced changes to ensure correspondence is quality checked twice before being sent out. We did see some examples of clearer correspondence in some cases. We highlight below some examples, related to cases closed after 1 November 2011, where the quality of correspondence could have been improved:

- One decision letter contained typographical errors and from which it appeared that words were missing

- One decision letter did not set out each allegation. We noted that the decision letter would have been improved if it had adopted the detail set out in the lawyer's report on the case

- One letter that was sent to the complainant in June 2010 to advise that the complaint was being referred to the IC and that clinical records were being sought. This would have raised an expectation that some form of investigation was taking place. A further letter was sent three months later, in September 2010, stating that the case was being passed to the case progression team for referral to the IC. However, the closure letter that was sent in November 2011 did not explain why the complaint was not in fact considered by the IC and in particular did not set out the reasons for the decision to close the case (and we noted that the decision appeared to have been based on advice from nursing and legal advisors)

- Two decision letters did not make it clear that the text of the letter been copied and pasted directly from the decision and reasons of the IC. The letters were therefore not tailored for their recipients and were not drafted in a user-friendly manner

- One decision letter, sent in April 2012, did not fully detail and address the allegations. When the complainant drew the NMC's attention to this, the NMC drafted a response indicating that further investigations would be initiated. We note that this correspondence was sent in August 2012

- One decision letter did not refer to the case being reopened or a record being placed on the WISER system (see para 2.26) if the registrant ever applied to be restored to the register. The NMC said that staff would be provided with refresher training on this issue and the case closure form would be amended to provide a prompt to staff to include this information in decision letters.

2.24 In this year's audit we saw some examples of better explanations and more detail provided in correspondence, therefore our findings (above) raise queries about the effectiveness of the quality checks introduced in March 2011. The NMC has told us in response to our feedback that it has amended its processes to achieve improvement in the quality of the decision letters it sends out. We will look for evidence of improvement in our next audit.

Links between the NMC's FTP and Registration departments

2.25 The NMC only has power to investigate fitness to practise concerns against individuals who are on its register. Preventing individuals who may not be fit to practise from being registered is an important aspect of the NMC's role in safeguarding public protection.

2.26 Information about the registration status of each registrant is stored on the WISER computer system. If a nurse/midwife has already left the register by the time the NMC hears about an allegation, the NMC has no power to take action unless they apply to re-join the register. In those circumstances, the NMC's procedure requires an 'under investigation' flag to be added to the individual's WISER record. The purpose of this is to ensure that the individual is not permitted to re-join the register until the allegation has been investigated. In our last audit report, we expressed concern about the interaction between the NMC's two main computer systems and the implications that this had for enabling it to deal adequately with allegations. In response to this, the NMC said it had put in place screening procedures to prevent a repeat of the problems our audit had identified. In this year's audit we saw one case where this new procedure did not appear to be working effectively (see para 2.30, 2nd bullet).

2.27 In addition, we found three cases which indicate the need for improved collaborative working between the Registration and FTP departments. We highlight these three cases below:

- In the first case the NMC staff had not complied with the request made by the Registrar's Advisory Group to obtain character references and a more in-depth statement from the registrant

- In the second case, the screening paralegal in the FTP team had contacted the Registration department to enquire whether a matter referred by the registrant's employer had been formally reviewed by the Registration team. It was confirmed that there had been an application for admission to the register and the matter was considered at the Registrar's Advisory Group. It was not apparent that the Registration team would have proactively informed the FTP team of the application for registration had the screening paralegal not contacted them

- In the third case the failure of the Registration team to respond to requests for information from the screening team meant that the screening team failed to meet their deadline.

2.28 In response to these issues the NMC have advised us that a training programme and consolidated standard operating procedure that deals with amendments to

the register will be devised. The NMC have also informed us that it is currently considering ways to improve and strengthen cross-directorate working. We will report further on this in our performance review of the NMC for 2012/2013.

Protecting the public

2.29 In our audits we look to see that the regulator's decision making at the initial stages of its FTP process is focussed on protecting the public, declaring and upholding professional standards and maintaining confidence in the profession and the system of regulation.

2.30 In the first two cases set out below, we concluded that the NMC failed to ensure the protection of the public. All the cases we highlight below raise particular concerns about risks to public protection (as well as other concerns):

- The regulator should have a system in place to ensure it can identify if complaints about fitness to practise are received while the registration process is going on. In one case it was alleged in December 2011 that a nursing graduate (working as a healthcare assistant who was applying for registration) had committed a serious act of dishonesty. The NMC carried out a check of the WISER system on 17 February 2012 and it was noted that the individual was not registered. The NMC therefore did not take action at this point because the individual was not a registrant. The Registration department then registered the individual on 23 February 2012, but this did not trigger a re-opening of the investigation in the FTP department. The NMC was notified by the complainant in April 2012 that the individual was now registered and seeking employment. The complainant contacted the NMC a month later claiming that the individual had recently been sectioned under the Mental Health Act and therefore should not be working with children. An alert (or flag) was only placed on WISER in June 2012 when a new referral was received, some four months after the individual had registered and two months after the complainant had contacted the NMC. This case indicates that the NMC failed to take appropriate action promptly on a number of different occasions once the individual was registered and this had the potential to lead to risks for public protection

- In the second case there were three different sets of allegations against the nurse, held on separate case files. The registrant had been made subject to an interim order of suspension as of October 2010 in relation to the first set of allegations, which concerned sexual misconduct. The Primary Care Trust (PCT), while investigating a separate matter, checked the NMC's register and noted that the nurse was suspended. In February 2011 the PCT made a complaint to the NMC that the registrant had been working as a nurse while subject to the suspension order. The NMC did not open an investigation into this matter until March 2011, although we note the PCT had first alerted the NMC to it in December 2010 and it made the formal complaint in February 2011. While this interim order was still in force, the third set of allegations was closed with a finding of 'no case to answer'. Following this closure, the NMC erroneously amended its register to remove the reference to the interim suspension order. The NMC did not

amend the register to correct this error until the PCT contacted them again the following day. It is not clear that the NMC would have identified the error itself. Incorrect amendment of the register could have exposed patients to the risk that a nurse who had previously worked while not eligible to do so (because they were under an interim suspension order) would have done so again. Following the audit, the NMC advised us that exception reports are now being run daily and a project has been commenced to ensure consistency between the case management system and WISER. Both of these measures are intended to enable such a situation to be identified and addressed immediately

- In another case we audited the IC appeared to have focussed its decision solely on the risk of repetition of the misconduct and did not appear to have properly considered the extent to which it might be necessary for a sanction to be imposed in order to declare and uphold professional standards or to maintain public confidence in the profession. The lawyer in the NMC's regulatory team flagged this up as part of the NMC's own internal systems for raising such concerns. The lawyer's view was that the IC had given undue weight to the fact that the registrant had repaid the money they had dishonestly obtained and that the IC had failed to take due account of the wider public interest, which meant that the case should properly have been referred for a hearing before the CCC. From our review of this case we agree with the lawyer's conclusions. The NMC's response to our feedback about this case is that it will flag up such cases to the IC. We recommend that the NMC considers whether there are other steps it might take to ensure that similar problems do not recur in future

- In another case we audited the NMC failed to advise the complainant that she might wish to refer her concerns to the Care Quality Commission (CQC) (her concerns would have fallen within the remit of this regulator). Our view is that the NMC should also have considered referring the matter to the CQC itself. In another case we audited the NMC notified the complainant that the NMC was referring the matter to the CQC but it is not evident that this referral ever took place. This means that two matters related to the quality and safety of patient care may not have been investigated as a result of the NMC's actions. The NMC have advised us that it is working on a central process to coordinate referrals to other regulatory bodies

- In another case that we audited there was an inordinate delay of 4.5 years. This was of particular concern as it was a high risk case. The documentation showed that no action had been taken by the NMC between July 2006 and January 2011. It is unclear how or why the delay with progressing this case was not identified by the NMC during this period. The regulatory legal team was instructed to investigate the case in January 2011, by which time the prospects of being able to gather all the required evidence had diminished due to the closure of the premises where the issues had occurred and the unavailability/unreliability of the witnesses' evidence, given the passage of time. Indeed the NMC's own legal advice stated: *"…even if all records were now available the delay caused thus far is of an order where witness recollection is likely to be compromised"*

- In the same case we noted that the complainant had alleged that the registrant was involved in two other issues relating to the death of service users and poor care delivery and had been referred to the NMC previously. The complainant said that considerable support and training had been offered to the registrant but there were continuing areas of serious concern. It is not clear if these other allegations were ever investigated by the NMC, which is a matter of serious concern as they may have indicated a pattern of incompetence/misconduct that might have put patients at risk.

Customer care

2.31 Good customer care is linked to maintaining confidence in regulation. In this section we outline our findings in relation to the contact the NMC has with registrants, complainants and other key stakeholders, such as witnesses, employers and PCTs. In particular we found areas for improvement in the timescales within which the NMC updated these stakeholders (see Appendix 1). We also found continued deficiencies in the content and tone of the NMC's communications.

2.32 Examples of poor customer care towards registrants included:

- A failure to notify the registrant that a case was open against them for five months
- A failure to apologise for the delay in progress in three cases
- A delay of four weeks in responding to correspondence from the registrant involved in one case who was complaining about the delays in her case being handled. We note that an apology was provided in the response from the NMC for the inactivity on the case for one year
- In one case that we audited the NMC had advised the registrant that the case would be considered by the IC when, in fact, the registrant had been already been struck off the register some months previously as the result of a different set of allegations and therefore, the NMC had no jurisdiction to take any further action against them
- Failing to provide an explanation for the IC meeting, at which the registrant's case would be considered, having been delayed in the same case.

2.33 Examples of poor customer care towards complainants include:

- A failure to apologise for the delay in progress in three cases
- Asking the complainant to help the NMC request an employment reference for the registrant and to help obtain a response from the registrant in one case, when this was clearly something the complainant (the registrant's sister) would not have been in the position to help with

- A failure to provide a written response to an enquiry about whether a complaint would be investigated. In this case, the NMC closed the case because the registrant was no longer on the register however, the complainant contacted the NMC when they became aware that the registrant had re-registered and asked whether the complaint would now be considered. The complainant contacted the NMC by telephone twice in one week to make this enquiry. The complainant was advised in the second call that the Registrar's Advisory Group was dealing with the matter, there were no FTP issues and the matter would not therefore be re-opened. It would have been better customer care for the NMC to have provided the complainant with a written response which would have prevented the complainant from having to contact the NMC to obtain an update

- A failure to respond to a complainant's letter in another case

- Advising the complainant to contact the CQC in circumstances where the original complaint letter had been copied to the CQC in the first place

- A failure to tailor standard letters which led to a request for one complainant's consent being repeated, although they had in fact already provided their consent. The standard letter advised the complainant that the case would not be progressed if consent was not provided and we note that, in any event, that statement is not correct as the NMC acknowledges that it can progress cases without consent where it is in the interests of public protection to do so. In the same case a letter sent to the bereaved complainant was not properly tailored and referred to the 'details of the experience and events' the complainant had provided, although she had in fact provided no such information. This was a case where the patient had died at the age of eight weeks. When cases involve particularly sensitive matters such as the death of a complainant's grandchild, it is particularly important to ensure that the regulator's communications are both sensitive and entirely accurate – the risk of failure is that the complainant may conclude that the regulator has not handled the case properly. In response to our feedback on this case the NMC have told us it will deliver training to staff about tailoring standard letters

- A failure to update the complainant's email address as per their request, with the result that information was sent to the wrong email address in one case.

2.34 Examples of poor customer care towards **other key stakeholders** include:

- A failure in one case to provide full information to the registrant's employer to enable them to respond to the request for information which led to a delay of several weeks. In response to our feedback about this case the NMC have told us that it has reviewed its approach to seeking this kind of information and now ensures it receives relevant information in response to requests for information from third parties

- Failure to tailor standard letters, leading to confusing information being sent out in three cases. In response to our feedback about this the NMC have

told us that staff will be trained on the importance of amending template letters as appropriate (See para 2.33 6th bullet). As this is an issue on which the NMC have previously provided training to staff, we recommend that they evaluate whether or not additional measures are necessary

- Providing inaccurate information to witnesses in one case. This included advising the witnesses that the IC had decided to refer the matter to the CCC, when the case had in fact been closed. The NMC wrote to apologise for this error two weeks later but unfortunately that letter contained further factual errors, despite having been through a quality assurance process. One of the witnesses subsequently wrote to the NMC to provide their availability for a future hearing. This indicated that the witness had not received the apology letter from the NMC explaining that the case had been closed. The NMC did not follow this up to confirm to the witness that attendance would not be required

- Delays in advising witnesses that they would not be required to attend a hearing. In one case this was done two months after the case had been closed and in another case, it was done 5 weeks after closure to one of the witnesses and it appears that one of the witnesses was in fact never informed. The NMC said that this occurred because staff misunderstood which letters the IC team were sending. This has now been identified and addressed

- A failure to provide updates to a registrant's employer following three separate requests; and, in another case, a failure to notify the employer of the outcome

- Delays in responding to a request for clarification of a decision letter. The IC had concluded that there was no evidence that the registrant had behaved inappropriately and therefore that, there was no real prospect that a finding of impairment would be made if the case were referred for a hearing. However the decision letter said, *"while the NMC does not condone [the Registrant]'s behaviour …"* implying that the registrant had behaved inappropriately. The employer wrote to the NMC to complain, because they found this statement unfair and misleading, given the IC's finding. The NMC did not respond for seven weeks. In its response the NMC apologised and said it had reviewed its practices to prevent similar recurrences.

2.35 Following our previous audit the NMC told us it had trained staff (during June and July 2011) on customer service, prior to implementation of the NMC's customer service pledge on 1 August 2011. This pledge had been sent out to registrants and complainants to explain the level of service they should expect and to signal the NMC's commitment to improving its customer service.

Guidance

2.36 It is good practice to have staff guidance documents and tools setting out the established policies and procedures, in order to ensure consistency and efficiency in case management. Our findings in this section of our report relate to

two particular aspects of case-handling. Firstly two areas where we identified that the NMC's established procedures could be strengthened particularly related to: the handling of linked cases and sharing the registrant's response with the complainant. We, secondly, comment on the evidence of the impact of the procedures that the NMC put in place following our last audit.

(i) Areas where procedures could be strengthened

Linked cases

2.37 Two or more cases may be linked because the allegations are brought by the same complainant, or because they involve the same registrant. The NMC have told us that linked cases are usually handled by the same case worker, but that it is inevitable that multiple case workers would need to handle a case at different stages of the FTP process. During our audit we noted the absence of a procedure (written or otherwise), to manage linked cases, which affected four of the cases we audited:

- In one case an alert had been placed on the case management system noting that the registrant had been the subject of a similar allegation the previous year. A request was therefore made for the case to be linked to the previous case so that the IC would be alerted to the other case. However that request was not complied with and the two cases were not linked on the case management system

- In one case the complainant became confused by the fact that she was corresponding with different case workers working on linked complaints

- In one case the complainant was written to by multiple members of staff who provided conflicting information about which issues were being taken forward by the NMC. (Further details about this case are provided at para 2.15, 2nd bullet)

- In one case correspondence with the complainant was saved on a case linked to the one we were auditing. This meant that the full chain of correspondence with the complainant was not saved in one place.

2.38 We note that the NMC has told us that it is currently considering the handling of linked cases and we hope that it will take account of our audit findings as part of that process.

Sharing the registrant's response with the complainant

2.39 We have previously reported on the benefits of sharing the registrant's response with the complainant. These include helping to bring information to light, establishing an accurate record of events to decide if a case should proceed to a fitness to practise hearing and potentially the early resolution of a case by providing clarification to the complainant. In two cases we audited we noted that information from the registrant had not been disclosed to the complainant in circumstances where there was a dispute about the facts. In response to our feedback the NMC have told us that they are considering their policy on

disclosure of the registrant's response in order to determine whether any amendment is required, bearing in mind its need to balance the impact on case progression with the need to have a fair process. We would invite the NMC to review whether or not the current policy is being complied with, in light of our findings, before considering whether or not any amendments to the policy are necessary. We would also invite the NMC to review our report on the benefits of sharing the registrant's response in considering its current policy further.

(ii) Inconsistent compliance with policies and procedures

2.40 Failure to monitor compliance effectively means that a regulator is not in the position to either identify systemic problems, or to take action about individual cases that have not been progressed appropriately and to take prompt remedial action. In this year's audit we considered the extent of compliance with established policies and procedures by the NMC's casework staff. In order to improve both the quality of its case-handling and stakeholder confidence in its processes, the NMC needs to improve by monitoring staff compliance with its own policies and procedures. We note below examples of cases where the NMC had inconsistently followed policies and procedures:

- In one case our own checks showed that the registrant had failed to disclose a caution when she registered and for up to four years afterwards. The NMC acknowledge that it failed to follow its own policy with regard to investigating failures to disclose criminal convictions and cautions in this case. In response to our feedback about this case the NMC have said that refresher training will be provided for staff

- In March 2011, the NMC changed its policy in relation to investigating 'first offences' of drink driving. Under the new policy, the NMC requests an employer and a GP/nurse/occupational health reference in order to confirm that the registrant is fit to practise. We welcome the NMC's commitment to introducing this policy, which is an area of good practice. We note one case where this policy was applicable and the policy was implemented. In our audit we found two cases that had been opened since this policy was put in place where such references had not been requested. We note that in both cases, the IC requested these references and one of the cases was opened in January 2011 and one in March 2011 when the policy was being embedded. Given this, we trust that we will see consistent compliance with this policy in future audits

- Decision letters do not appear to have effectively been quality checked twice (in line with procedures introduced in March 2011 (See para 2.23 - 2.24) leading to letters being sent out with inaccurate or incomplete information

- The NMC implemented a policy that customer service feedback forms should be sent out for cases that were closed or opened after 1 August 2011. The NMC told us, however, that staff had not routinely been sending the forms out and during our audit we identified at least three cases where forms had not been sent in relation to cases opened since 1 August 2011.

The NMC have addressed this matter by including a prompt in the decision letter to act as a prompt for staff

- Inconsistently meeting the requirement for acknowledging correspondence within 48 hours in line with procedures introduced in January 2011 (See Appendix 1)

- Inconsistently meeting the NMC's customer standard for updates to be provided every six weeks. (See Appendix 1)

Record keeping

2.41 We consider good record keeping to be essential for effective case handling and good quality decision making. In response to previous audits the NMC told us that new procedures were introduced in November 2010 to improve consistency in record keeping. In our last audit we found that these procedures were being inconsistently applied and we have similar findings to report in this audit.

2.42 During this audit we looked for evidence that information on each case was accessible from a single place and that there were comprehensive, clear and coherent case records.

2.43 We found 16 cases which had been recorded as closed on the case management system before the parties had been notified about the closure. In one additional case there was a delay of five months before the NMC notified the complainant about the closure of the case. In response to our feedback about these cases the NMC commented that in May 2012 it has made efforts to prevent recurrence. This included:

- Reminding staff that they must not send a decision letter until the case is closed on the case management system

- Introducing a KPI that states that a case should only be closed on CMS within five days of the event occurring and only when the decision letter has been sent

- Introducing a KPI that states that paper files should be archived within 10 days of the event and only where the decision letter has been sent

- Asking staff to advise managers when they identified that a decision letter has not been sent 10 days or more after the event in order that the delay can be recorded as a serious event review and investigated

- Requiring staff to complete the closure form which requires confirmation that a decision letter has been sent.

2.44 We found 17 cases in which there were inconsistencies in the dates of paper records and the dates recorded on the case management system. This mirrored one of the findings in our previous audit. In our previous audit report we commented on the wider impact of inaccurate data on the case management system, given that data from the system forms the basis of the NMC's reports to

its Council about its performance in the FTP function. In response to our feedback from this audit the NMC have said that it has already identified that this is an area where we need to focus attention. It is being addressed by managers and reinforced by focused quality assurance checks.

- We found 14 cases where either none or only some of the signed letters could be found on the case management system. We are concerned that without such scanned letters being on the case management system it is not possible to be certain about which letters have been sent

- We saw a number of cases where there had been a failure to keep copies of all relevant information on the case files. We made a similar finding in our previous audit – in response to which the NMC said that it would be too resource-intensive for staff to print and save documents from the case management system on to the paper file. In two cases we saw there was a failure to store all relevant information on the case management system in one case, and on the paper file in the other case. Of more concern is that we audited five cases that been opened after November 2010 where all relevant information had not been kept on the paper file and in one case, on either the paper file or the case management system.

2.45 In our previous audit we recommended that the NMC should take steps to expand its quality assurance of records management to ensure that performance in this area improves. While we saw some examples of better record keeping than in previous audits we reiterate this recommendation again this year.

Timeliness and monitoring of progress

2.46 It is essential to manage workflow evenly, because delays in one part of the process that cause backlogs will stress the system unless relieved quickly. In our previous audit we concluded that active case management could have avoided many of the delays identified in the cases we audited. Our findings in this section relate, firstly, to failings in active case management, resulting in delays and, secondly, the effectiveness of the recently introduced case audits and reviews in reducing delays.

(i) Active case management

2.47 We audited a number of cases where avoidable delays had occurred because the cases had not been actively managed. We set out below examples of these failings, which occurred both once cases were under consideration by the IC and at earlier stages of the investigation process:

Earlier stages of the case management process

- In one case we audited the NMC had failed to fully explain the reasons for its request for information to the employer it was requesting information from. This in turn led to an ambiguous response being received (which we note was not clarified prior to the IC reaching a decision). In response to our feedback about this case the NMC said that it has reviewed its

processes for seeking information and references from third parties, to ensure that requests are clear and unambiguous

- In another case there was a failure to request the next of kin's consent to obtain clinical records and this led to an avoidable delay. We recognise that this case was opened in 2006 and that the NMC has put in place different systems and processes since then to try and prevent these kinds of delays from happening. In another case the Chief Executive's office failed to respond at all to two requests for advice from the case worker about the next steps that should be taken on the case, which may also have contributed to the delay

- We audited five cases in which repeated requests for the same information (that had already been received) were made, which led to unnecessary delays. In one of these cases the same information had been requested on four occasions.

The Investigating Committee (IC) stage

- One case (which was opened in 2009) in which failure by NMC staff to follow the IC's instructions, led to repeated requests being made for the same information and avoidable delays

- Delays in the IC's consideration of cases, for various reasons:

    - Due to the unavailability of a midwife member of the IC (in one case). The NMC has told us that it has increased the pool of midwife IC members to prevent such delays recurring in future

    - Due to the case officer requesting that a case was not scheduled for an IC meeting before a certain date, to fit in with her annual leave, so she would have time to carry out the necessary redactions to the large bundles of evidence. In response to our feedback about this case the NMC have told us that it will direct staff not to make such requests in the future and ensure the manager works with the case officer to assist with workload management

    - Due to the case not being on the agenda in one case which led to a six week delay

    - In one case the reason for the delay remains unclear.

(ii) Timeliness

2.48 The NMC has taken action aimed at addressing this issue of timeliness by introducing full case audits every two to four weeks, as well as monthly reviews of the older cases. These measures were introduced with the aim of reducing delays and helping the NMC to identify cases where there had been a failure to take action within six weeks, or to progress the case every 12 weeks.

2.49 In this audit we looked at cases opened prior to the introduction of the additional monitoring measures introduced in November 2010, as well as cases opened since then. For cases opened both before and after November 2010 we noted delays in the following areas:

- Acknowledging correspondence
- Gathering information to commence or progress an investigation
- Progressing cases once new information was received
- Periods of inactivity
- Providing updates
- Chasing information
- Sending decision letters
- Notifying the registrant of the outcome of the IC
- Informing interested parties and witnesses of the outcome of the IC
- Notifying parties of the decision to close the case.

2.50 In addition, we list some additional areas of delay which occurred in five cases opened after November 2010.

- A delay of three months in verifying the identity of registrants in one case

- Delays caused by failing to follow up on a PNC check which led to needlessly requesting further information in one case

- In one case the registrant was suspended following an interim order hearing. The registrant was subsequently cleared of all police charges and the interim order was lifted. The NMC did not notify the registrant for a month that the interim order was lifted and that she could therefore practise unrestricted. In response to our feedback on this case the NMC have said that this delay was due to the high volume of cases it had at the time

- A delay of four weeks in responding to a request for an update to the registrant's representative.

2.51 We note that in one case we audited the NMC wrote to the registrant to apologise for the *"serious delay in the way in which matters have been progressed by the NMC"* and advised that they would arrange for a review to be carried out in order to establish why the delay had occurred. When the NMC looked into the case again in response to our audit findings, it was established that this review never took place. The failure to conduct this review undermines the NMC's commitment to prevent errors and delays from occurring. It is regrettable that the NMC did not have an effective system in place to make sure that such reviews took place. The NMC said that such an incident would now amount to a serious event review which is conducted whenever a required action is not undertaken in six weeks on a case and whenever no action is taken on a case for 12 weeks.

2.52 The NMC acknowledges some, but not all, of the delays we found in the audit and has not been able to provide explanations for many of the delays we identified. It is reasonable to assume, on balance, that the delays are indicative of delays across the NMC's entire caseload. It is not yet possible to make a finding about whether the learning has been properly implemented from the case

audits and reviews that have occurred, or whether the case audits and reviews have been effective in reducing delays in the progression of cases. This is because we have not seen enough cases to make this finding and in this year's audit we have continued to see delays in cases introduced before and after the case audits and reviews.

2.53 We summarise at Appendix 1 our detailed findings about delay.

2.54 Given our audit findings we consider that the timeliness and progression of casework is an area of improvement that the NMC should continue to prioritise. We hope to see marked improvements in this area in our next audit.

3. Recommendations

3.1 We recommend that the NMC reviews the impact of the case audits and serious event reviews that it introduced in 2010 and their effectiveness in driving improvements.

3.2 We recommend that the NMC reviews all our audit findings and implements robust remedial action. In particular we recommend that the NMC reviews:

- The consistency of information and evidence gathering – to ensure there is greater consistency around gathering sufficient information, that the right information is available to be considered by the decision makers at the appropriate time and to ensure that cases are only closed once full information has been obtained
- The evaluation and decision making processes – to ensure that decisions are made with consideration of the NMC's remit, clinical advice is properly taken into account and decisions are based on the correct facts
- The improvements that need to be made in relation to the reasoning provided for decisions that are made, as well as, in relation to the overall quality of decision letters
- Any improvements that can be made to the way that the registration and FTP functions work together
- The cases we have highlighted that raise concerns about public protection, in order to ensure that similar errors do not recur in future cases
- Ways in which procedures for dealing with linked cases and sharing the registrant's response with the complainant might be strengthened
- Ways to achieve improvements in the consistency of compliance with the NMC's own policies and procedures. This includes consistent issuing of customer service feedback forms
- How improvements can be made to customer care in light of the findings of this audit and the NMC's customer service pledge
- Methods of improving the standard of record keeping, in light of our findings
- Ways in which the NMC's case management can be improved in order to ensure cases are actively managed and delays are reduced or avoided altogether.

4. Appendix 1

Table comparing delays in cases opened before and after the NMC's case audits in November 2010

	Cases opened before November 2010	**Cases opened after November 2010**
A. Delays in acknowledging correspondence	Three weeks in one case and two months in another case	Failure to acknowledge in one case from 2012
B. Delays in gathering information to commence or progress an investigation	One year in one case	Three to six months in five cases
C. Delays in progressing cases once new information was received	Six months in one case	One month in three cases
D. Periods of inactivity	Two – eight months in seven cases from 2010 Of these seven cases, two experienced more than one period of inactivity so that the total delay in two of these cases was 10 and 19 months	Two weeks in one case from 2012 and two – 11 months in eight more historical cases Of these eight cases, two experienced more than one period of inactivity so that the total delay in two of these cases was five and six months
E. Delays in providing updates (where the customer service standard is for an update to be provided every six weeks)	Seven months to the registrant in two cases Almost one year to the registrant in two cases	Three months in one case Seven months to the registrant and complainant in two cases Eight months to the registrant in one case Eight months to the complainants in two cases
F. Delays in chasing for information	13 weeks in one case	Six and 12 weeks in three cases Failure to chase for requests for information leading to periods of inactivity on two further cases
G. Delays in sending decision letters	Seven and eight weeks in two cases	Five days to four months in three cases
H. Delays in notifying the registrant of the outcome of the IC (over the target of five days)	Four days in one case	Two days and four days in two cases

I. Delays in informing interested parties and witnesses of the outcome of ICs	Four weeks and seven months in two cases	Three weeks - seven months in five cases
J. Delays in notifying parties of the decision to close the case	12 months in one case	One – five months in five cases

5. Appendix 2: Fitness to practise casework framework – a CHRE audit tool

The purpose of this document is to provide CHRE with a standard framework as an aid in reviewing the quality of regulators' casework and related processes. The framework will be adapted and reviewed on an on-going basis.

Stage specific principles

Stage	Essential elements
Receipt of information	• There are no unnecessary tasks or hurdles for complainants/informants • Complaints/concerns are not screened out for unjustifiable procedural reasons • Provide clear information • Give a timely response, including acknowledgements • Seek clarification where necessary.
Risk assessment	*Documents/tools* • Guidance for caseworkers/decision makers • Clear indication of the nature of decisions that can be made by caseworkers and managers, including clear guidance and criteria describing categories of cases that can be closed by caseworkers, if this applies • Tools available for identifying interim orders/risk. *Actions* • Make appropriate and timely referral to Interim Orders Committee or equivalent • Make appropriate prioritisation • Consider any other previous information on registrant as far as powers permit • Record decisions and reasons for actions or for no action • Clear record of who decided to take action/no action.
Gathering information/ evidence	*Documents/tools* • Guidance for caseworkers/decision makers • Tools for investigation planning. *Actions* • Plan investigation/prioritise time frames • Gather sufficient, proportionate information to judge public interest • Give staff and decision makers access to appropriate expert advice where necessary • Liaise with parties (registrant/complainant/key witnesses/employers/other stakeholders) to gather/share/validate information as appropriate.

Evaluation/decision	*Documents/tools* • Guidance for decision makers, appropriately applied. *Actions* • Apply appropriate test to information, including when evaluating third party decisions and reports • Consider need for further information/advice. • Record and give sufficient reasons • Address all allegations and identified issues • Use clear plain English • Communicate decision to parties and other stakeholders as appropriate • Take any appropriate follow-up action (e.g. warnings/advice/link to registration record).

Overarching principles

Stage	Essential elements
Protecting the public	• Every stage should be focused on protecting the public and maintaining confidence in the profession and system of regulation.
Customer care	• Explain what the regulator can do and how, and what it means for each person • Create realistic expectations. • Treat all parties with courtesy and respect • Assist complainants who have language, literacy and health difficulties. • Inform parties of progress at appropriate stages.
Risk assessment	• Systems, timeframes and guidance exist to ensure on-going risk assessment during life of case • Take appropriate action in response to risk.
Guidance	• Comprehensive and appropriate guidance and tools exist for caseworkers and decision makers, to cover the whole process • Evidence of use by decision makers resulting in appropriate judgements.
Record keeping	• All information on a case is accessible in a single place. • There is a comprehensive, clear and coherent case record • There are links to the registration process to prevent inappropriate registration action • Previous history on registrant is easily accessible.
Timeliness and monitoring of progress	• Timely completion of casework at all stages • Systems for, and evidence of, active case management, including systems to track case progress and to address any delays or backlogs.

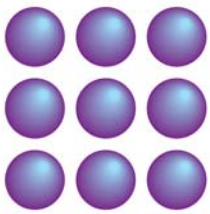
Council for Healthcare Regulatory Excellence
157-197 Buckingham Palace Road
London SW1W 9SP

Telephone: **020 7389 8030**
Fax: **020 7389 8040**
Email: **info@chre.org.uk**
Web: **www.chre.org.uk**

council for healthcare regulatory excellence

Audit of the General Pharmaceutical Council's initial stages fitness to practise process

December 2012



council for healthcare regulatory excellence

About CHRE

The Council for Healthcare Regulatory Excellence promotes the health and well-being of patients and the public in the regulation of health and care professionals. We scrutinise and oversee the work of the nine regulatory bodies[1] that set standards for training and conduct of health and care professionals.

We share good practice and knowledge with the regulatory bodies, conduct research and introduce new ideas about regulation to the sector. We monitor policy in the UK and Europe and advise the four UK government health departments on issues relating to the regulation of health and care professionals. We are an independent body accountable to the UK Parliament.

Our aims

The Council for Healthcare Regulatory Excellence works to raise standards and encourage improvements in the registration and regulation of people who work in health and social care. We do this in order to promote the health, safety and well-being of patients, service users and other members of the public.

Our values

Our values and principles act as a framework for our decision-making. They are at the heart of who we are and how we would like to be seen by our partners. We are committed to being:

- focussed on the public interest
- independent
- fair
- transparent
- proportionate

Our values will be explicit in the way that we work; how we approach our oversight of the registration and regulation of those who work in health and social care, how we develop policy advice and how we engage with all our partners. We will be consistent in the application of our values in what we do.

We will become the Professional Standards Authority for Health and Social Care during 2012.

1 General Chiropractic Council (GCC), General Dental Council (GDC), General Medical Council (GMC), General Optical Council (GOC), General Osteopathic Council (GOsC), General Pharmaceutical Council (GPhC), Health and Care Professions Council (HCPC), Nursing and Midwifery Council (NMC), Pharmaceutical Society of Northern Ireland (PSNI)

Contents

1. Overall assessment

Introduction

1.1 In September 2012 we audited 100 cases that the General Pharmaceutical Council (GPhC) had closed at the initial stages of its fitness to practise (FTP) processes during the six month period 1 February 2012 to 30 July 2012.

1.2 In the initial stages of their FTP processes, the nine health and care professional regulators decide whether complaints received should be referred to a hearing in front of an FTP Committee, whether some other action should be taken, or whether complaints should be closed.

1.3 Our overriding aim in conducting audits is to seek assurance that the regulators are protecting patients and the public and maintaining the reputation of the professions and the system of regulation. We assessed whether the GPhC achieved these aims in the particular cases we reviewed. We considered whether weaknesses in handling any of these cases might also suggest that the public might not be protected, or confidence not maintained, in future cases.

Summary of findings

1.4 In this audit we saw nothing that gave us cause for concern about the GPhC responsibilities for public protection and maintaining the reputation of the profession.

1.5 Risk assessment continued to be a strength and we found evidence of risk assessment in all of the cases we audited that the GPhC opened.

1.6 The robustness of the GPhC's investigation was also found to be a strength, although improvements could be made to the GPhC's record keeping as the robustness of the investigation was not always clear from the case files. This was particularly so with Stream 1 cases managed by the inspection team.

1.7 We noted particular good practice with the timeliness of casework, with 21 cases being closed well within the GPhC's targets for doing so.

1.8 Closure decisions were taken appropriately in all the cases we audited. This includes cases closed at the triage stage and Stream 1 cases managed by the inspection team which involve sign off of closure decisions by one person.

1.9 Improvements are yet to be seen in relation to record keeping. Improvements could also be made to the content of correspondence including the information provided in decision letters.

1.10 We welcome the quality assurance process and the review of letters, which the GPhC has introduced, aimed at making improvements in its case management. We look forward to seeing improvements in record keeping and correspondence together with continued strong practice in the areas of risk assessment and the timeliness of casework in our next audit of the GPhC.

Method of auditing

1.11 We reviewed 100 cases which had been closed by the GPhC at the initial stages of its FTP processes during the six month period from 1 February 2012 to 30 July 2012.

1.12 In March 2010 CHRE led a meeting of representatives from all of the nine health and care professional regulators to agree a 'casework framework'. This was a description of the key elements that should be present in the different stages of a good FTP process. A copy of this is at Annex 1. When auditing a regulator, we assess the handling of a case against the elements of the casework framework.

The GPhC's FTP framework

1.13 There are three distinct points within the GPhC's initial FTP process when cases may be closed without referral to a formal hearing in front of a FTP panel.

(i) Cases that fall outside the GPhC's jurisdiction

1.14 The earliest stage a case can be closed is at 'triage'. When a complaint is received, a manager within the FTP department will carry out a preliminary or initial assessment at the triage stage to determine whether to assess whether or not it falls within the GPhC's jurisdiction. Complaints will only fall within the GPhC's jurisdiction if they call into question a registrant's fitness to practise, or if they relate to registered pharmacy premises, disqualification of the body corporate or misuse of a restricted title linked to pharmacy.

(ii) Cases that do not fulfil the GPhC's threshold for referral to the IC

1.15 Where complaints fall within the GPhC's jurisdiction, FTP staff will arrange for further information to be obtained (this may be done by the GPhC's Inspection Team).

1.16 Once all the relevant information has been obtained, GPhC staff will assess whether or not the case fulfils the GPhC's 'threshold criteria' for referral to the Investigating Committee (IC). Cases that do not fulfil the threshold criteria for referral to the IC are closed. The GPhC may also issue advice to the registrant on closing a case without referral to the IC.

(iii) Cases that the IC decides should not be referred for a formal Hearing

1.17 If the case is deemed to have fulfilled the threshold criteria then a referral is made to the IC. The IC's membership is made up of both pharmaceutical professionals and lay people. The IC meets to decide whether allegations ought to be considered by the FTP Committee.

1.18 In order to carry out its role, the IC assesses whether there is a 'real prospect' that the FTP Committee would make a finding that the practitioner's FTP is impaired. The 'real prospect' test applies to both the factual allegations and the question of whether, if established, the facts would amount to impairment of the registrant's FTP. The IC must not refer any allegation to the FTP committee unless it is satisfied that there is a real prospect that the FTP committee will make a finding that the registrant's FTP is impaired.

1.19 In the event that the IC decides that the allegations ought not to be considered by the FTP committee, the IC may dispose of the case by:

- Sending an advice or warning letter to the registrant
- Agreeing undertakings from the registrant as to their future practice
- Initiating criminal proceedings or
- Dismissing the case.

Transitional arrangements

1.20 On 27 September 2010 the GPhC took over responsibility for the regulation of the pharmacy professions and pharmacy premises from the Royal Pharmaceutical Society of Great Britain (RPSGB). At that date, all open fitness to practise cases were transferred from the RPSGB to the GPhC.

1.21 The transitional provisions in the legislation that transferred regulatory responsibility from the RPSGB to the GPhC (the Pharmacy Order 2010) provide for the GPhC to dispose of fitness to practise cases that it inherited from the RPSGB as it considers "just". This applies to any cases that the GPHC received on transfer of regulatory responsibility, regardless of the stage of the fitness to practise process that each case had reached on that date.

1.22 Under transitional arrangements there is also a process for closing cases inherited from the Royal Pharmaceutical Society of Great Britain (RPSGB). The transitional provisions in the legislation that transferred regulatory responsibility from the RPSGB to the GPhC (the Pharmacy Order 2010) provide for the GPhC to dispose of FTP cases that it inherited from the RPSGB as it considers "just". This applies to any cases that the GPhC received on transfer of regulatory responsibility, regardless of the stage of the FTP process that each case had reached on that date.

1.23 The GPhC has developed a set of criteria to determine whether it is just to proceed with the case. The GPhC's Registrar makes the final decision about "just" disposal. The process to be followed in such cases is that whenever the FTP Manager considers it may be "just" to discontinue a particular case, views are sought from both the complainant and the registrant. The FTP Manager's recommendation to discontinue the case (as well as any submissions that the complainant or registrant have made about that recommendation) will then be considered by a Legacy Determination Group (LDG), which consists of senior members of GPhC staff. The LDG will make a recommendation to the Registrar about whether the case should be discontinued. If the Registrar decides that a case should be discontinued, the reasons for that decision are communicated to the complainant and the registrant.

1.24 The number of cases that the GPhC is handling under these transitional arrangements has reduced since our last audit of the GPhC. There were four such cases that were included in our audit sample.

2. Detailed findings

Risk assessment

2.1 Robust risk assessment on receipt of a new case, and updating that risk assessment on receipt of new information, is an important part of public protection within a risk based regulatory approach. The risk assessment enables the regulator to assess what action should be taken and how the case should be prioritised in order that the most serious cases are dealt with first. In some circumstances it will be necessary for the GPhC to take immediate action, by applying for an interim order, to prevent the registrant from practising unrestricted while the matter is undergoing investigation. Risk assessments can also be used to prompt disclosure to another organisation (such as an employer or another regulator) in the public interest.

2.2 We saw examples of completed risk assessments in every other case we audited. Risk assessment continues to be an area where the GPhC performs well.

Gathering information and evidence

2.3 Gathering the right information is essential for enabling the GPhC to ensure appropriate action is taken promptly. Information and evidence must be gathered at the correct point in the FTP process to support effective decision-making. The regulator must operate proactive processes for gathering information to ensure that the right information is available to be considered by the decision makers at the appropriate time.

2.4 We identified an area of improvement around the follow up of information where harm has been alleged. As part of the GPhC's threshold criteria the Registrar must consider whether there is evidence that the registrant's conduct or performance causes moderate or severe harm or death, which could or should have been avoided. The GPhC works with the definitions of harm developed by the National Patient Safety Agency (NPSA). In most cases we audited we saw that it was usual practice, where it was relevant to do so, to contact either a GP or a consultant to obtain confirmation about the degree and duration of harm suffered and to document this on file. We did audit three cases however where this was not done although we note that other information on the file suggested that there was no evidence of further harm in each of these cases. The GPhC said that it is in agreement that where there is an allegation of harm further enquiries should be undertaken to establish whether there is evidence of moderate to severe harm in accordance with the NPSA definitions. The GPhC said it will take this forward as learning points for the inspection and investigation teams and that the feedback from this audit will help identify appropriate training.

Investigation process for cases opened before 1 May 2012

2.5 The investigation process for cases opened before 1 May 2012 was that, the case was allocated to a case worker in the investigations team and also an inspector if that was deemed appropriate.

2.6 In the majority of the cases we audited we found robust processes in place for gathering information and evidence. We noted two examples of good practice in the following cases which were opened before 1 May 2012:

- In one case we saw attempts by the GPhC to seek evidence to make its own assessment of the case and not placing undue reliance on the police investigation. We noted that the GPhC asked additional questions to identify all possible lines of enquiry that were relevant for it to consider
- In a second case the inspector traced an ex-employee of the pharmacy to ensure they were informed of the dispensing error. This was because the dispensing error could not be attributed to a particular registrant and so the inspector wanted to share the learning from the case with all relevant staff.

New investigation process for cases after May 2012

2.7 The GPhC changed its process which affected all cases in our sample opened after 1 May 2012. In the new process, once it has been determined that the complaint is within the GPhC's jurisdiction, the case is allocated to Stream 1 or Stream 2 whereby:

- Stream 1 cases – relate to professional issues and dispensing incidents and on initial assessment are initially thought not to meet the threshold criteria. These cases are investigated and managed by the inspection team
- Stream 2 cases - do not relate to professional issues/dispensing incidents or are thought to meet the threshold criteria. These cases are investigated and managed by the investigation team, with input from the inspection team where appropriate.

2.8 In cases we audited that were opened after these procedural changes were introduced we found that processes for gathering information and evidence remained robust. We found examples in cases where the GPhC use the regionally based inspection team effectively to follow up on complaints, gather information and provide advice promptly.

Evaluation/Decision

2.9 A regulator's decisions must in themselves be able to stand up to scrutiny. We reviewed the quality of decision-making in all the cases that we audited. We set out our findings in relation to two aspects of the GPhC's processes for evaluation and decision-making: (i) decision letters; and (ii) quality control.

(i) Decision letters

2.10 We think it is particularly important to ensure decision letters are well drafted and comprehensive because they are a key communication point between the regulator and the complainant, witnesses and registrant(s) involved. Poorly drafted decision letters may also damage confidence amongst these stakeholders in the quality of the investigation.

2.11 We noted that in nine cases that met the criteria for closure with no further action, the inspector gave general advice during the course of the investigation and this advice was not described in closure letters. While these cases met the criteria for

closure with no further action and the advice given was therefore informal, we did find that the advice provided by inspectors was consistently of a high standard, tailored to the case and upheld and promoted professional standards. For this reason, we think that it would be informative for complainants to be aware of this advice. This is particularly so given that in one of these nine cases the complainant said they had consulted the GPhC's standards on the matter complained about and did not find the specific answer to their concern. We were pleased to note three cases where the inspector did correspond with the complainant to set out the advice provided to the registrant although this was not part of the standard process.

2.12 We noted 16 cases where the closure letters provided different information to the complainant and the registrant. In the letter to the complainant the complainant is advised that the allegations do not meet the threshold criteria and the letter to the registrant states that the case was not referred to the IC because there is no indication of impaired FTP. We acknowledge that the reasons for the closure are the same (if the threshold criteria have not been met then the allegations do not indicate impaired FTP) and that the registrant and complainant may need that explained in different ways. Nonetheless, in our view, it would appear more transparent for the same information to be provided. In response to our feedback the GPhC said that it would review its letter templates and we look forward to hearing the outcome of this review.

2.13 We noted four cases where we thought that further information could have been included in the decision letter:

- In the first case there was a file note setting out that the GPhC would write to the registrant and provide advice upon closure for the registrant to not practise unless she was fit to do so and to inform her employer of her health condition. This action was not, however, taken
- In the second case, the patient complained because the pharmacist had dispensed the correct medication but had not dispensed the specific brand highlighted on the prescription. A fuller explanation could have been provided (suitable for a member of the public) to help the complainant reconcile the explanation that, while the NHS regulations do not legally oblige a pharmacist to supply a brand, the pharmacist had been advised to read the NICE[2] guidelines which sets out that best practice is to prescribe the same brand of anti-epileptic drugs wherever possible
- The third case was closed with advice and the letter to the complainant sets out how the investigation was conducted. It does not set out the conclusions drawn from the investigation and does not provide an explanation about the reasons for closing the case with advice
- In the fourth case the decision letter to the complainant gives the indication that the registrant must accept the warning and if he does not, he will be referred to the FTP committee. The Pharmacy Order 2010 and the FTP Rules 2010 contain no requirement for the registrant to accept a warning in order for one to be issued. However, where the Registrant has not previously had an opportunity to make submissions on the disposal of the case by way

[2] National Institute for Health and Clinical Excellence (NICE) provide independent, authoritative and evidence-based guidance on the most effective ways to prevent, diagnose and treat disease and ill health, reducing inequalities and variation

of a warning the IC must adjourn to allow the registrant to indicate whether they would accept a warning. This was not communicated clearly in the decision letter although we note that the GPhC subsequently rectified this.

2.14 We note that the GPhC has fed these cases back as learning points to the team members involved. The GPhC advised us that it is undertaking a comprehensive review of its externally facing correspondence and is focusing on ensuring that the contents are customer focused and contain adequate information. This review will include specific consideration of whether the explanation provided in closure letters could be strengthened. We will look again at the quality of decision letters in our next audit of the GPhC.

(ii) Quality control

2.15 In our last audit of the GPhC we reported a concern that cases could be closed at the triage stage without checking/authorisation by a second decision maker. While we did not find any inappropriate closures in our last audit, or in this audit, we remain of the view that any closure decisions that are not subject to checking raise the risk of inconsistency in practice and inappropriate closures being made. While the GPhC continue to operate with one decision maker it has introduced a quality assurance scheme which focusses on key stages of the decision-making process. It has also introduced a series of internal audits to determine whether the triage process requires re-evaluation. The GPhC advised us that the quality assurance process has not identified any issues in respect of triage decisions. The GPhC has also advised us that it intends to pilot the use of a second decision maker at triage in a proportion of cases and it will commence this approach in 2013.

2.16 The new investigation process introduced in May 2012 sets out that once the inspector (Stream 1) or case worker (Stream 2) has completed the investigation, the threshold criteria are applied to determine whether a referral to the IC is necessary. Once the investigation is complete Stream 1 case closure decisions are signed off by one person whereas Stream 2 case closure decisions have dual sign off. In this audit we looked to see whether there were any inappropriate closures in Stream 1 closure decisions and we are pleased to report that we found no inappropriate closures.

Customer care

2.17 Good customer care is linked to maintaining confidence in regulation. Our findings in this section relate to the correspondence that the GPhC sends out to registrants and complainants. Our findings from this year's audit are summarised as follows:

- Delays in acknowledging correspondence in two cases
- Failure to set out the timelines for the investigation in one case and not informing the registrant of when he would next hear from the GPhC in one case. In another case, the registrants' solicitor emailed the GPhC to query the current position with the case. The response was sent the following day but it did not set out the timescales for the investigation, next steps or manage expectations. This was followed up with an email which noted the deadline for the response was due that day but also noted that, "we will accept any submissions received up until the meeting when this case will be considered (which is yet to be scheduled)." The GPhC acknowledge that this

is an example where customer care could have been improved and will feed this into its review of correspondence

- We found four cases where the registrant was not provided with an update within the service standard of three months. We note that the GPhC has reduced its service standard so that case workers are now required to provide updates to complainants every two months (rather than three months). We think this is a positive measure that indicates the GPhC's commitment to customer care
- In one case the registrant had sent an email to the GPhC saying that he understood that the application for rescission was refused as he had not responded to it. The GPhC had not responded to the registrant to explain that he had misunderstood this aspect of their process. Since receiving this feedback, the GPhC said that it would clarify this issue with the registrant
- We saw five cases where we thought it might have been better customer care for more information to have been provided earlier to better manage expectations:
    - In one case that was referred to the IC the registrant was advised that the case was being prepared for the IC and that the GPhC would be in touch again shortly. It was not until 10 weeks later, that the GPhC next communicated with the registrant to inform them of the details of the meeting and provide information regarding the IC process and role, details of the possible outcomes and the process for the registrant to make submissions
    - In another case a letter was sent on 13 April 2012 which provided information about the IC hearing but it did not set out which of the allegations were closed and which remained open
    - In two cases a medical report was received and not disclosed to the registrants for 34 weeks in one case and 23 weeks in the other
    - In one case the inspector made a file note following a call with the registrant that the registrant would be contacted in the 'near future'. The next communication with the registrant is a caution letter sent seven weeks later.
- In two cases the registrant was never informed by the RPSGB that he was under investigation. In one case this was potentially because the registrant was also the subject of a criminal investigation which the regulator did not want to prejudice. When the GPhC took over this case the decision letter was not sent to the registrant. In the second case the registrant was informed of the decision to discontinue the case and the registrant noted that she was not aware that an investigation had been underway for the past four years before receiving the outcome letter. It would have been better customer care for the GPhC to have informed the registrants once they had taken over these cases in our view
- In one case the complainant was informed of the decision and was advised that the registrants had received advice; the registrants were, however, not informed for another week. Since the complainant was in a working relationship with the registrants it would have been better customer care to have let the complainant know that the registrant would be sent a letter of

advice in due course or to have provided the same information at the same time

- We noted three cases where the complainant was not informed of the outcome and in one of these cases we note that the complainant was also the employer. The GPhC has noted that this was an oversight on the part of the inspector and has been raised as a learning point and more generally is now part of the training programme for the inspection team
- In cases that are closed with no further action the GPhC said that it is part of its routine procedure for the inspector to verbally communicate the outcome of the case to the registrant(s); however, a letter is not routinely sent. We do consider that it would be better customer care for the registrant to receive correspondence to confirm the outcome. Following the audit, the GPhC have advised us that a new template letter has already been developed.

2.18 In response to our audit, the GPhC advised that it is currently reviewing all template letters across its investigations, case management and hearings management teams and finalising a guidance document on letter writing to support staff with ensuring correspondence meets the requirements of the recipient. We welcome this review together with the GPhC's assurance that it will take our audit findings into account.

2.19 We noted good examples of letters to stakeholders in four cases that we audited. In these four cases the initial acknowledgement letters to registrants clearly set out an explanation of the process, signposted the registrant to sources of support and advice and provided the general perception that the GPhC is a supportive regulator to its registrants.

Guidance

2.20 It is good practice to have staff guidance documents and tools setting out the established policies and procedures in order to ensure consistency and efficiency in case management. The GPhC has a comprehensive set of guidance documents in place for staff and we have noted below two examples of the GPhC keeping the content of guidance documents under active review.

2.21 In one case we audited, the registrant was automatically removed from the register following failure to submit an FTP declaration and to renew his registration within the legislative timetable. He continued to work whilst unregistered until he was informed by his employer that he was not on the register, at which point he applied for restoration. The FTP department received information from the Registration department that the registrant may have been working whilst unregistered. There was some internal discussion on the file about how such cases should be disposed of and by which team. The GPhC advised us that it will be implementing a prosecution policy in 2013 to improve the consistency of decision-making and the gathering of documentation during the investigative process in cases where there is a lapsed registration and the registrant has continued to practise.

2.22 We noted two cases where misconduct was inextricably linked to the registrant's health concerns in that the misconduct arose out of the health condition. In both cases there was some internal discussion about how best to dispose of these cases. The GPhC has guidance on the use of voluntary undertakings but, at the time these cases were open, this did not cover cases where misconduct is

inextricably linked with the Registrant's health. The guidance in place at the time stated that undertakings "will not be appropriate" where the ill health of the registrant does not impact on fitness to practise. However the GPhC concluded in both cases that as there was an element of misconduct, the medical assessor's view should not preclude the GPhC from agreeing appropriate undertakings for a specified period to ensure that the registrant sustained recovery and that there was no repetition of the misconduct. In both cases the GPhC's medical assessor had also advised that the registrant's FTP was not impaired by reason of their ill health. Prior to this audit, the GPhC has reviewed and updated its guidance in light of the learning from these two cases. While we note that there was an element of delay while the correct course of action was being agreed, the final decision reached in both cases was supported with reasons on the file, took account of the public interest and weighed up the risks of the case.

Record keeping

2.23 We consider that good record keeping is essential for effective case handling and good quality decision-making. In line with the casework framework we checked to see that, (i) all information was accessible in a single place and (ii) there was a comprehensive, clear and coherent case record.

(i) All information is accessible in a single place

2.24 The GPhC aims for its paper file and its electronic case record to contain the same documents and for both to be a complete record of the case. We note the following however:

- We found 12 examples where correspondence or other documents were available on the paper file but not on the electronic case record and vice versa
- In two cases there was correspondence about an unrelated case which had been misfiled
- Two case files we audited appeared particularly disorganised and were not set out in chronological order limiting their usefulness as a reference tool in our view.

(ii) Comprehensive, clear and coherent case record

2.25 In general, we found that the reasons provided for decisions were well recorded on the case file. In one health case however, we saw that the case worker and the medical examiner considered that voluntary undertakings would be suitable. This issue of undertakings was not raised again and it was agreed that the case could be closed with no further action despite the GPhC asking the employer to confirm that a phased return to work would be workable in accordance with the recommendations in the medical report. It is not clear from the file why undertakings were considered and then ruled out. While we do not consider that the decision to take no further action was inappropriate we do consider that maintaining a comprehensive record of the reasons for decisions is essential for maintaining confidence in regulation and acts as a check for decision makers to ensure that the decisions themselves are robust. In response to this case, the GPhC said it was in

the process of reviewing health investigation procedures and it would be considering how to record decision-making around case disposal as part of that review.

2.26 We found 14 cases where a thorough and robust investigation had been conducted by the inspection team, however, all aspects of this investigation were not documented and therefore not evident from the file. Examples of this are as follows:

- In one case there was no record on file that a clinical opinion was sought to verify the patient's allegation that he suffered an adverse reaction as a result of being prescribed the incorrect brand of medication. In fact, the inspector had verbally confirmed with the patient's GP that the patient had not suffered an adverse reaction as a result of the change in brand, but this was not documented on the file. In a second case it appeared from the documents on file that the patient's symptoms fell within the definition of 'moderate harm' and therefore warranted referral to the IC. When we provided this feedback the GPhC was able to clarify that the inspector had spoken with the patient's GP and gastroenterologist who both concluded that it would be difficult to establish a direct link between the patient's symptoms and the dispensing error. This meant that the threshold criteria were not met and a referral to the IC was not required in this case
- In four cases there were undated and unsigned letters on file from the inspector and so it was unclear if these had been sent. The GPhC has confirmed that the letters were sent in all cases
- The absence of telephone attendance notes on the electronic case record in two cases and the absence of any record of a telephone call and/or faxes (although these are referred to in correspondence) in three cases
- The absence of a recorded update of correspondence with the registrant for a period of eight months and then three months in one case. We note that the investigator does recall being in regular contact with the registrant in this case
- In one case it appeared that an allegation relating to poor complaint handling had not been properly addressed because the report simply states, "[the registrant] does not believe that he was unhelpful towards [the complainant]". However in response to our feedback the GPhC noted that the inspector had spoken with the registrant on three occasions and so further information could have been recorded to indicate that this allegation had been followed up. In the same case the patient made an allegation that he was offered money to discourage him from complaining. From the file it does not appear that this matter was investigated but it is apparent from the further information received on this case that this allegation was investigated and there was no evidence to substantiate it
- In one case the GPhC's advocate was requesting further evidence to support an interim order in December 2010. From the file it appeared that nothing further happened for 29 weeks. In response to the feedback on this case the inspector confirmed that further evidence was sought straightaway

2.27 We note that it was one of our recommendations in last year's audit that the GPhC take active measures to improve the quality and consistency of its record keeping. The GPhC said that in May / June 2012 it implemented a quality assurance process

which includes file management and it is hoped that this will address the majority of the issues we have raised in relation to record keeping. It is hoped that the embedding of the new quality assurance process will enable the GPhC's record keeping to accurately reflect our finding about the robustness of investigations. We welcome the processes introduced to improve record keeping and we will look for evidence of improved record keeping in our next audit of the GPhC.

Timeliness and monitoring of progress

2.28 The timely progression of cases is one of the essential elements of a good FTP process. Our findings in this section are set out below in relation to (i) delays and (ii) active case management.

2.29 We note that the majority of the cases we audited met key performance indicators for closure. In particular we noted 21 cases which were dealt with, well within the targets for the completion of cases. 15 of these cases were Stream 1 cases that had been opened after the procedural changes were introduced in May 2012 and were managed by the inspection team. This is an area of good practice and indicates that the GPhC has successfully implemented a process aimed at improving the timescales for dealing with complaints. The findings below should therefore be considered in this context.

(i) Delays

2.30 Delays in the progress of cases create risks around undermining the confidence of key stakeholders in the regulator. In our audit we looked for the timely completion of casework at all stages. We also checked that the systems in place for active case management, tracking progress and addressing delays were effective and in use.

2.31 In our last audit of the GPhC we noted that some delays occurred as a result of a lack of resource in the FTP department, failures in internal communication and the absence of effective systems that provide active oversight of case progression. Since our last audit the GPhC has sought to address this by recruiting more staff, the introduction of its FTP database (June 2011) and by introducing its new process for investigation (May 2012) which is set out above (see para 2.7).

2.32 We noted that all examples of delay in this audit related to cases opened prior to the changes that the GPhC introduced to its processes in May 2012 which are aimed at making improvements in this area. Examples of delays in cases were:

- Delays in progress in six cases:
    - Four periods of delay of four, five, seven and then 32 weeks in one case and these delays meant that there was a five month delay from the conclusion of the investigation to informing the complainant and registrants about the outcome
    - A 36 week delay in progress in one case
    - A 29 week period of delay while case papers were being reviewed which we acknowledge involved complex issues in one case
    - A 15 week delay in progress which was due to the maternity leave and long term sickness of staff in one case

- A nine week delay in progress in one case which was due to the inspector having a large workload at the time
- An eight week delay in one case although we acknowledge that for some of this period the case worker was reviewing the large volume of documents of a legacy case
- Two periods of delay of seven weeks and then 10 weeks in one case

- Production of the inspector's report seven weeks after the site visit in one case and 10 weeks in another case which then took a further 10 weeks to sign off
- A delay of 21 weeks in considering this case at the IC once the decision was taken to refer the case. In response to this feedback the GPhC said that since May 2012 it has shortened its target timeframe for listing cases with the IC and has amended processes aimed at ensuring that the majority of cases can be listed with the IC within one month of the referral
- Three case were signed off for closure three, four and five weeks after the decisions were made respectively
- Closing one case 14 weeks after the registrant was due to return to work although we note that by this time the GPhC had received medical evidence confirming that there were no concerns about the registrant's return to practice
- Delays in sending decision letters in two cases by:
  - Two, three and five weeks after closure had been agreed in three cases
  - 21 weeks to the referrer of the decision, although we acknowledge that this letter was eventually sent because the GPhC had audited the case and identified for itself that this correspondence had not been sent
- In one case we audited, a pharmacist was alleged to have failed to ensure that a procedure was in place for the safe delivery of medicines. The pharmacist took remedial action following the incident to revise the standard operating procedures in place. The inspector visited the pharmacy and reviewed the changes put in place and took copies of the standard operating procedures. These were however then not placed before the IC panel and this was one of the reasons that led to an IC adjournment.

(ii) Active case management

2.33 We noted that in the letter sent by the GPhC requesting further information the GPhC did not routinely specify a deadline for providing this information. In our view this would support active management of cases and prevent avoidable delays. We note that the GPhC has indicated that its review of correspondence (see para 2.18) will incorporate the inclusion of dates and deadlines where relevant on correspondence.

2.34 We noted an absence of a process for actively chasing up information when information was requested by the GPhC in five cases. We note that all these cases

were opened prior to the GPhC changing its processes from 1 May 2012. We hope to observe more active case management in our next audit.

3. Conclusion and recommendations

3.1 Risk assessment continues to be a strength for the GPhC and we found evidence of risk assessment in all of the cases we audited that the GPhC opened. The robustness of the GPhC's investigation was also found to be a strength although improvements could be made to the GPhC's record keeping as the robustness of the investigation was not always evident from the case files. This was particularly so with Stream 1 cases managed by the inspection team. We noted particular good practice with the timeliness of casework with 21 cases being closed well within the GPhC's targets for doing so. Finally, we agreed with the closure decisions reached in all of the cases we audited. This includes all cases we audited that were closed at the triage stage and Stream 1 cases managed by the inspection team where one person is responsible for the sign off of closure decisions.

3.2 We recommend that the GPhC take steps to ensure consistency around cases where harm has been alleged so that further information is sought from the complainant and/or a clinician with relevant expertise (as appropriate) to agree the level of harm suffered.

3.3 We recommend that the GPhC continues to review the risks associated with having one person responsible for sign off in parts of its processes.

3.4 We recommend that the GPhC's takes into account the findings of this audit report and addresses the shortfalls we have identified when its quality assurance process (which includes file management and is aimed at making improvements in record keeping) is reviewed.

3.5 We recommend the GPhC continues to monitor its new processes to ensure that more active case management is present on cases to prevent undue delays which could undermine the confidence of stakeholders.

3.6 We recommend that the GPhC's review of its correspondence (aimed at ensuring letters are customer focused and contain adequate information) takes into account the findings of this audit report and addresses the shortfalls and strengths we have identified.

4. Annex 1: Fitness to practise casework framework – a CHRE audit tool

The purpose of this document is to provide CHRE with a standard framework as an aid in reviewing the quality of regulators' casework and related processes. The framework will be adapted and reviewed on an ongoing basis.

Stage specific principles

Stage	Essential elements
Receipt of information	• There are no unnecessary tasks or hurdles for complainants/informants • Complaints/concerns are not screened out for unjustifiable procedural reasons • Provide clear information • Give a timely response, including acknowledgements • Seek clarification where necessary.
Risk assessment	*Documents/tools* • Guidance for caseworkers/decision makers • Clear indication of the nature of decisions that can be made by caseworkers and managers, including clear guidance and criteria describing categories of cases that can be closed by caseworkers, if this applies • Tools available for identifying interim orders/risk. *Actions* • Make appropriate and timely referral to Interim Orders Committee or equivalent • Make appropriate prioritisation • Consider any other previous information on registrant as far as powers permit • Record decisions and reasons for actions or for no action • Clear record of who decided to take action/no action.

Stage	Essential elements
Gathering information/ evidence	*Documents/tools* • Guidance for caseworkers/decision makers • Tools for investigation planning. *Actions* • Plan investigation/prioritise time frames • Gather sufficient, proportionate information to judge public interest • Give staff and decision makers access to appropriate expert advice where necessary • Liaise with parties (registrant/complainant/key witnesses/employers/other stakeholders) to gather/share/validate information as appropriate.
Evaluation/decision	*Documents/tools* • Guidance for decision makers, appropriately applied. *Actions* • Apply appropriate test to information, including when evaluating third party decisions and reports • Consider need for further information/advice. • Record and give sufficient reasons • Address all allegations and identified issues • Use clear plain English • Communicate decision to parties and other stakeholders as appropriate • Take any appropriate follow-up action (e.g. warnings/advice/link to registration record).

Overarching principles

Stage	Essential elements
Protecting the public	• Every stage should be focused on protecting the public and maintaining confidence in the profession and system of regulation.
Customer care	• Explain what the regulator can do and how, and what it means for each person • Create realistic expectations. • Treat all parties with courtesy and respect • Assist complainants who have language, literacy and health difficulties. • Inform parties of progress at appropriate stages.
Risk assessment	• Systems, timeframes and guidance exist to ensure ongoing risk assessment during life of case • Take appropriate action in response to risk.
Guidance	• Comprehensive and appropriate guidance and tools exist for caseworkers and decision makers, to cover the whole process • Evidence of use by decision makers resulting in appropriate judgements.
Record keeping	• All information on a case is accessible in a single place. • There is a comprehensive, clear and coherent case record • There are links to the registration process to prevent inappropriate registration action • Previous history on registrant is easily accessible.
Timeliness and monitoring of progress	• Timely completion of casework at all stages • Systems for, and evidence of, active case management, including systems to track case progress and to address any delays or backlogs.

5. Annex 2: GPhC Threshold Criteria

The GPhC produced the following criteria.

The threshold criteria

5.1 Cases are not to be referred to the Investigating Committee unless one of the following statements is true:

Principle 1: Make patients your first concern

- There is evidence that the registrant's conduct or performance caused moderate or severe harm or death, which could and should have been avoided
- There is evidence that the registrant deliberately attempted to cause harm to patients and the public or others
- There is evidence that the registrant was reckless with the safety and wellbeing of others.

Principle 2: Use your professional judgment in the interests of patients and the public

- There is evidence that the registrant put their own interests, or those of a third party, before those of their patients
- There is evidence that the registrant culpably failed to act when necessary in order to protect the safety of patients.

Principle 3: Show respect for others

- There is evidence that the registrant failed to respect the human rights of patients, or demonstrated in their behaviour attitudes which are incompatible with registration as a pharmacy professional
- There is evidence that the registrant failed to maintain appropriate professional boundaries in their relationship with patients and/or others.

Principle 4: Encourage patients and the public to participate in decisions about their care

- There is evidence that the registrant damaged or put at significant risk the best interests of patients by failing to communicate appropriately with patients or others.

Principle 5: Develop your professional knowledge and competence

- There is evidence that the registrant practised outside of their current competence
- There is evidence that the registrant failed to maintain their knowledge and skills in a field relevant to their practice
- There is evidence of a course of conduct, which is likely to undermine public confidence in the profession generally or put patient safety at risk, if not challenged by the regulatory body.

Principle 6: Be honest and trustworthy

- There is evidence that the registrant behaved dishonestly
- There is evidence of behaviour on the part of the registrant which is likely to undermine public confidence in the profession generally, if not challenged by the regulatory body.

Principle 7: Take responsibility for your working practices

- There is evidence that the registrant has practised in a way that was systemically unsafe, or, has allowed or encouraged others to do so, where he or she has responsibilities for ensuring a safe system of working
- There is evidence of adverse physical or mental health which impairs the registrant's ability to practise safely or effectively.

If the Registrar is in doubt as to whether the above criteria have been met, he shall refer the case to the Investigating Committee.

6. Annex 3: GPhC legacy criteria

The GPhC produced the following guidance on how it would deal with cases inherited from the RPSGB:[3]

Just Disposal of Legacy Cases Guidance

1. Purpose

On the 21 July 2010 the Council of the General Pharmaceutical Council (GPhC) agreed the Just Disposal of Legacy Cases Policy.

The objective of this guidance document is to detail the procedure as to how the Fitness to Practise Division (FtP) will handle cases it inherits from the Royal Pharmaceutical Society of Great Britain (RPSGB) under the transitional provisions set out in the Pharmacy Order 2010 ("the 2010 Order").

2. Scope

The Just Disposal of Legacy Cases Policy applies to the following cases that must be transferred to the GPhC:

- *all cases that have not yet progressed to Investigating Committee including cases awaiting listing before the Investigating Committee;*
- *all cases where a decision has been taken by the Investigating Committee; or Disciplinary*
- *Committee (DC)/Health Committee (HC) in respect of interim order applications or*
- *otherwise by way of direct referral from the Registrar;*
- *all part-heard cases where the final decision has not been communicated to the pharmacy professional; including Disciplinary Committee and Health Committee decisions.*

According to Schedule 5, paragraph 12 of the Pharmacy Order 2010 the GPhC can dispose of the cases described above:

- *by using the relevant provisions in the Pharmacist and Pharmacy Technician Order 2007 ("the 2007 Order") or*
- *in line with the relevant provisions in the Pharmacy Order 2010 or*
- *in such other manner as it considers just.*

3. Procedure

3.1. Our approach to transitional cases relating to those on the practising register

The Just Disposal of Legacy Cases Policy will only apply to those cases the GPhC inherits from the RPSGB. It will not apply to those Fitness to Practise cases that GPhC receives after the appointed day.

3.1.1. Applying the criteria

[3] This is a reproduction of the GPhC document available at www.pharmacyregulation.org

The application of the legacy criteria will be entirely separate from the standard procedure for progressing Fitness to Practise cases as set out in the 2010 Order and the GPhC (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010 ("the 2010 Rules"). As such it sits outside the threshold criteria for determining whether a new case should proceed to the Investigating Committee and the decision to close a case because it is out of GPhC Fitness to Practise jurisdiction.

Pre IC Cases

The Case Manager / Investigator should review the case against the legacy criteria at the various decision making point at which the case has reached. For example, this could be at the point where the investigation has been completed but before the application of the threshold criteria has taken place.

The case manager / FtP Manager will determine whether the allegation / or information should be discontinued without referral to the IC. A record of this decision and the reasons must be recorded in the Just Disposal of Legacy Cases record of decision form (Practising Register at Appendix 1).

Post IC Cases

A review will take place by the FtP Manager / Case Manager of the case and a decision taken as to whether the case should be discontinued.
The criteria set out below are designed to assist with making this decision of both IC and DC cases. However, it is essential that each case should be considered individually and all relevant circumstances should be taken into consideration. The following should not be applied as a rigid set of rules or criteria when determining to proceed with the case to a hearing before either an Investigating Committee or a Fitness to Practise Committee of the GPhC, or having proceeded to a hearing, whether the case should nevertheless be discontinued.

The Case Manager / FtP Manager should consider that there is a presumption that there is a public interest in the ventilation in public of complaints that have a real prospect of establishing impairment of fitness to practise.

The following (non-exhaustive criteria) should be applied when determining whether a case may be discontinued or referred back to the Investigating Committee for rescission:

- *the length of any delay since the original allegation, and the reasons for the delay;*
- *the seriousness of risk of harm to the health and safety of the public*
- *the nature, gravity and seriousness of the allegations;*
- *the extent to which the pharmacy professional may have been prejudiced by the delay;*
- *whether the facts of the case involve important points of practice or principle;*
- *the state of the evidence and the likelihood of the charge(s) being proved;*
- *any witness difficulties and whether the evidence is likely to be weakened by the passage of time*
- *the individual circumstances of the pharmacy professional, including their health (for example have they retired etc.)*
- *the complainants' response (if any) to the proposed course of action*
- *whether there is a real prospect of establishing that the pharmacy professionals' fitness to practise is currently impaired.*

3.1.2. Cases that will not proceed to a hearing

It is important that the decision and reasons to discontinue a case is recorded by the Case Manager / Fitness to Practise Manager and is approved by the Registrar or his Delegated Officer. This should be recorded on the Just Disposal of Legacy Cases record of decision form (Practising Register at Appendix 1).

3.1.3. Cases that will proceed to a hearing

If the decision has been taken that the case should proceed to a hearing then the following
procedure describes which cases will be conducted in accordance with the relevant provisions of the 2007 Order or the 2010 Order as follows:
Where before the appointed day of the transfer:

1. An allegation of impairment of fitness to practise or disqualification has been brought to the attention of the Society and:
(i) The notice of referral to the Investigating Committee has been sent to the registrant concerned in accordance with rule 10 of the 2007 FtP Rules;

It shall be dealt with in accordance with the provisions under the 2007 Order and the associated rules there under.
Where before the appointed day of the transfer:

2. An allegation of fitness to practise or disqualification has been brought to the attention of
the Society and:

(i) Has not been referred to the Investigating Committee (or in the case of an interim order application, the Disciplinary Committee or Health Committee / or otherwise by direct referral from the Registrar) or
(ii) The notice of referral to the Investigating Committee has not been sent to the registrant concerned (where relevant)

It shall be dealt with in accordance with the provisions of the 2010 Order and the associated rules there under.

Where before the appointed day of the transfer:

3. (i) A case where the allegation of impairment of fitness to practise / disqualification has been referred from the Investigating Committee to the Disciplinary Committee (DC) or Health Committee (HC), (or in the DC or HC as a result of an interim order application or direct referral by the Registrar) and
(ii) The case has been listed for a hearing before the DC or HC (including those cases which have been adjourned or postponed)

The Fitness to Practise Committee of the GPhC will dispose of the case in accordance with the 2007 Order and the associated rules there under.

Where before the appointed day of the transfer:

4. (i) A case where the allegation of impairment of fitness to practise / disqualification has been referred from the Investigating Committee (or the DC or HC in an interim order application or direct referral by the Registrar) and
(ii) The case has not been listed for a hearing before either the DC or HC, then unless the person concerned has submitted written submissions requesting otherwise;

The Fitness to Practise Committee of the GPhC shall dispose of the case in accordance with the GPhC 2010 Order and the associated rules there under.

5. On the appointed day all existing review cases shall be dealt with in accordance with the 2007 Order and the associated rules there under with all subsequent reviews being dealt with under the 2010 Order and the associated rules there under.

If a decision has been taken to proceed with a case, then the standard procedure for progressing Fitness to Practise cases as set out in the 2010 Order and the GPhC (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010 ("the 2010 Rules") will apply.

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Council for Healthcare Regulatory Excellence
157-197 Buckingham Palace Road
London SW1W 9SP

Telephone: **020 7389 8030**
Fax: **020 7389 8040**
Email: **info@chre.org.uk**
Web: **www.chre.org.uk**