Minutes of the **Council** meeting held on **12 September 2013** at
129 Lambeth Road, London, at 10.15am

*Minutes of the public session*

**Present**
- Bob Nicholls – Chair
- Sarah Brown
- Soraya Dhillon
- Gordon Dykes
- Mary Elford
- Tina Funnell
- Mohammed Hussain

**Apologies**
- David Prince

**In attendance**
- Duncan Rudkin (Chief Executive and Registrar)
- Hugh Simpson (Director of Policy and Communications)
- Bernard Kelly (Director of Resources and Customer Services)
- Claire Bryce Smith (Director of Inspection and Fitness to Practise)
- Vivienne Murch (Head of Organisational Development & People Strategy)
- Damian Day (Head of Education & Registration Policy)
- Lyn Wibberley (Head of Executive Office)
- Matthew Hayday (Head of Governance)
- Paula Woodward (Council Secretary)
- Nigel Clarke (Chair, Learning Outcomes Review Group), minutes 66 to 66.10 only

57. **ATTENDANCE AND INTRODUCTORY REMARKS**

57.1. The Chair welcomed members and staff attending the meeting. The Chair also welcomed a number of public observers including Mair Davies of the RPS.
57.2. The Chair reported that Nigel Clarke (NC) had been appointed Chair-designate by the Privy Council. He outlined the new Chair’s background and reported that NC would participate in the appointments process for the new Council members. The Chair also reported that NC would attend the meeting for item 12 in his role as chair of the Learning Outcomes Review Group, as had been planned prior to his appointment to the Council.

57.3. The Chair also reported that Mary Elford had been appointed to the board of Health Education England, and that Mohammed Hussain had been appointed Chair of the Local Professional Pharmacy Network - West Yorkshire Area Team.

58. **DECLARATIONS OF INTEREST**

58.1. The following interests were declared:

- **Item 9: Update on guidance and Rules**
  Liz Kay, Berwyn Owen, Mohammed Hussain declared interests as superintendents of registered pharmacies.

- **Item 10: Performance monitoring**
  Soraya Dhillon and Keith Wilson declared interests as employees of Universities with schools of pharmacy.

- **Item 12: Revised Learning Outcomes**
  Soraya Dhillon and Keith Wilson declared interests as employees of Universities with schools of pharmacy.

- **Item 16: Direct Debit indemnity arrangements**
  Sarah Brown, Tina Funnell, Liz Kay and Keith Wilson declared interests as signatories to the current indemnity scheme.

59. **MINUTES OF THE PUBLIC SESSION OF THE PREVIOUS MEETING**

59.1. The minutes of the public session of the meeting held on 13 June 2013 were agreed as a true record.

60. **MATTERS ARISING**

60.1. In relation to the concerns raised about the language skills of health professionals (minute 42.3) Duncan Rudkin (DR) reported that a European Directive had been drafted which aimed to clarify the regulators’ powers to check language competence. The Directive’s progress would be monitored and reported to the Council in due course.

61. **STRATEGIC PLAN 2014-17**

61.1. Duncan Rudkin introduced paper 09.13/C/01 by drawing members’ attention to the key considerations and resources implications.
61.2. A number of members commented that the proposed plan fully reflected the Council’s aims for the next stage of the organisation’s development and welcomed the direction outlined and the language used in the document. During the subsequent discussion, the Council noted that the GPhC operated as part of a complex system and that care should be taken to prevent duplication and unnecessary burden on those regulated. It was also noted that the plan would have to be sufficiently flexible to adapt to external factors in order to remain effective.

61.3. DR advised the Council that the organisation would have to invest in and develop its capacity and capability in order to implement the plan. DR reported that a draft report had already been prepared by independent consultants focusing on data, information and knowledge management which would go some way toward shaping that development. The consultants’ final report would be made available to Council in due course.

61.4. Responding to a question about the financial implications of the plan, Bernard Kelly (BK) informed the Council that cost projections would be prepared as more detailed plans were developed. However, it was clear that the organisation’s current resources would need to be reviewed to ensure that they were aligned with the ambitions of the strategic plan. Equally, the organisation’s level of reserves would need to be reviewed to reflect the projected increase in activity.

61.5. BK also reported that although an information strategy would be a key part of the plan, it was clear that the organisation needed to increase capability in relation to data, information and knowledge in order to achieve the ambitions set out in the strategic plan.

61.6. The Council agreed the strategic plan as set out in draft at Appendix 1 of paper 09.13/C/01 subject to a minor change to the text. It further approved its preparation for laying before Westminster and Scottish Parliaments and its publication.

62. MID STAFFORDSHIRE PUBLIC INQUIRY (FRANCIS REPORT): UPDATE ON KEY ISSUES FOR PHARMACY REGULATION

62.1. Hugh Simpson (HS) introduced paper 09.13/C/02 by reminding the Council of its previous discussions. He drew members’ attention to the work undertaken to embed the key themes agreed by Council into the organisation’s strategic and corporate planning work. HS explained that the annex to the paper provided an overview of the work identified, mapped against key recommendations from the Francis report, to provide assurance to Council that work was underway.

62.2. The Council discussed the scope of the paper and noted that, while pharmacy was not highlighted as a key concern within the Francis report,
there were important lessons for all health regulators. The Council noted that other reports, including those led by Sir Bruce Keogh and Don Berwick, had developed key themes further, particularly the need to focus on issues of culture.

62.3. A member asked how the GPhC would work with other organisations to develop networks that would foster the development of a culture focussed on patients. HS reported that the aim was to establish a series of Memoranda of Understanding and that these discussions had already started, focussing on information sharing and operational relationships.

62.4. DR also reported that an update on the GPhC’s response to the report would be sent to ministers and key stakeholders with a copy of the new strategic plan.

62.5. DR informed the Council that the lessons from the Francis report would be embedded into the organisation’s ongoing work. Progress would be presented to Council as part of the usual performance assurance reporting, with an update paper presented in six months time.

62.6. The Council noted the paper on the Mid Staffordshire Public Inquiry.

63. FURTHER DEVELOPING OUR APPROACH TO MODERNISING PHARMACY REGULATION

63.1. HS introduced paper 09.13/C/03 by referring to the issues discussed in the previous item and informed members that the approach taken by the GPhC had been reinforced by the conclusions of the recent Berwick report.

63.2. The Council discussed the key principles set out in the paper and suggested that the bulleted paragraphs in section two should be broadened to include registrants and working with other organisations.

63.3. The Council noted the paper.

64. NEW INSPECTION MODEL

64.1. Claire Bryce Smith (CBS) introduced paper 09.13/C/04 by summarising the key points in the paper.

64.2. Members who had participated in the Inspection Development Advisory Group (IDAG) reported that the new inspection model, including the labels and their descriptions, had undergone a thorough examination, with feedback received from both public and registrants throughout the new model’s development. Members noted that the introduction of the model would be the next milestone in the application of the Standards agreed by Council in 2012.

64.3. Responding to members’ questions, CBS informed the Council that the inspection model would be evaluated externally. Members noted that it was
important to be clear about the strategic and operational objectives by which the model will be evaluated. On the matter of publication of inspection reports in advance of the Rules being in place, DR informed the Council that legal advice would be sought to clarify the GPhC’s position.

64.4. CBS explained that improvement action plans would be used during the prototype phase where pharmacies were judged to be poor and, in some cases, those judged to be satisfactory, to secure improvements where standards had not been met. She reminded Council that a fitness to practise investigation could also be carried out if appropriate.

64.5. A member asked whether pharmacy compliance rates were expected to be similar to registrants’ CPD compliance rates. CBS explained that it would not be easy to make such a comparison as pharmacy standards were a wider assessment.

64.6. The Council discussed the proposed inspection labels and suggested that the descriptions which explain them could benefit from minor adjustments. CBS informed the Council that further testing of the descriptions with patients and stakeholder groups is being carried out as part of the roll-out. Members also noted that designating a ‘poor’ label to a pharmacy would only be the start of the process to ensure improvements were made and patients protected.

64.7. The Council noted:
   i. the readiness of the inspection model for the first stage of the nationwide roll-out in November; and
   ii. the aspects of the model which will be operational from November 2013 and further work required after that.

64.8. The Council agreed inspection labels for the outcome of an inspection for testing as part of the first stage of the nationwide roll-out.

65. REGISTERED PHARMACIES: UPDATE ON GUIDANCE AND RULES

65.1. DR introduced paper 09.13/C/05 and reminded the Council that the Pharmacy Order makes it necessary for the Standards to be set out as part of the Rules. They would therefore have to be included in the proposed consultation. HS reported that this would provide an opportunity for an internal review of the drafting of the Standards in light of key external developments, particularly the Francis Report, as well as an opportunity for further comment from stakeholders.

65.2. HS drew members’ attention to the section of the paper regarding guidance for pharmacies preparing medicines in a registered pharmacy without the need for a manufacturer’s licence. HS reported that, following the receipt of further legal advice, guidance was now being drafted to explain how
pharmacies preparing medicines in accordance with a prescription for an individual patient (including the preparation of extemporaneously prepared methadone) must mitigate risks to patients and meet the standards for registered pharmacies. The new approach to inspection would check this activity, where appropriate.

65.3. Regarding guidance for internet pharmacies, HS reported that the scope had been revised to cover medicines supplied via all methods of distance selling. However, a number of complex legal issues, including cross-border retail and European Union (EU) legislation, needed to be considered before finalising the guidance. He also reported that discussions had been taking place with the MHRA, the Royal Pharmaceutical Society and others in order to develop the most effective policy and guidance on this issue.

65.4. Regarding guidance on the supply of P medicines, the Council noted recent discussions and debate about how medicines could be supplied safely within pharmacy, including concerns raised by a recent report from Which?. DR reported that the GPhC was keen to take a positive role in the debate and a background paper on the safe supply of Pharmacy medicines would be released shortly. There would also be further opportunities for the Council to receive wider comments during the upcoming consultation on the Rules for registered pharmacies.

65.5. Regarding the approach to the consultation on Rules, members noted that the timetable may be subject change as the process involved external parties such as Privy Council advisers. However, it remained the intention to bring a further paper to Council in November, setting out the consultation proposals in more detail.

65.6. The Council agreed the revised scope of the three guidance documents to support the standards for registered pharmacies and the proposed approach to the consultation on Rules.

66. Revised Learning Outcomes for the Initial Education and Training of Pharmacists

66.1. The Council agreed to take this item out of turn. Nigel Clarke (NC), chair of the Learning Outcomes Review Group, joined the meeting at 1pm.

66.2. Damian Day (DD) introduced paper 09.13/C/08. He reported that the revised learning outcomes for the MPharm degree were the first of a series of planned changes to update pharmacy education standards. DD reminded members that much of the education framework had been inherited from the former regulator and that changes were needed to ensure that the standards kept pace with pharmacy practice during a period of rapid development.

66.3. NC reported that the group’s key concern was to ensure that the public was protected while taking into account the impact of any changes on colleges,
tutors and students. NC informed the Council that it was also crucial that employers fully understood the proposals and were able to support them during and following their implementation.

66.4. NC informed the Council that representatives from England, Scotland and Wales had participated in the group’s work. He also reported that the review had taken account of the findings of the Francis Report and that representatives from the Department of Health, Health Education England and the Pharmaceutical Society of Northern Ireland had observed the Review Group’s deliberations. In addition, Council was told that the learning outcomes had already been considered by a scrutiny group convened by the Pharmacy Schools Council.

66.5. The Council discussed the proposed changes with a particular focus on the transition from the current course structures to the new. The Council noted that there was now a much greater emphasis on conduct, ethics and patient welfare, in addition to the continuing need to ensure students gained a comprehensive understanding of medicines. The Council expressed the view that the report clearly demonstrated the need to update other elements of pharmacy education such as pre-registration.

66.6. A number of Council members asked about the measures being taken to ensure that higher education institutions were fully consulted and their needs understood. DD assured the Council that a full consultation and implementation plan was being prepared taking into consideration issues such as funding, the different approaches being taken in the countries of the UK, and the need to carefully manage the transition to the five year MPharm degree. During the discussion, Council members suggested a number of issues that should also be considered such as prescribing and acute hospital training.

66.7. Responding to a member’s comment about the need to ensure the changes were implemented in a timely fashion, DD replied that this would be addressed as part of the implementation plan. DR commented that the revised learning outcomes set the standards for entry into the profession and that changes to other aspects of the education framework would support those standards.

66.8. The Chair thanked Nigel Clarke and the other participants in the Learning Outcomes Review Group for a thorough and thoughtful report.

66.9. The Council agreed that the new learning outcomes set out in the paper were contemporary and fit for purpose and should form the basis for a full consultation at a date to be decided. The Council requested that a further paper be presented in early 2014 to provide an update on progress.

66.10. NC left the meeting at 1:45pm.
67. **PERFORMANCE MONITORING**

67.1. DR introduced the report (paper 09.13/C/06) and invited members’ questions and comments.

67.2. Regarding the number of individuals requesting adjustments at assessment centres, DD reported that it was not clear why Sunderland reported no adjustments while other centres reported double figures. DD undertook to investigate and to report to members via email.

67.3. Regarding the financial implications of statutory appeals, BK informed members that a contingency set aside in the budget had been more than sufficient to cover such costs to date.

67.4. Claire Bryce-Smith (CBS) confirmed that the reasons for delays in dealing with fitness to practise cases covered those caused by both internal and external factors. The Council noted that it was important to continue to make every effort to reduce the delays.

67.5. DD introduced the Board of Assessors report by reminding members that these were the first assessments to use the updated question bank. He reported that, over time, questions became familiar to students and needed to be revised but that ‘anchor’ questions were used to allow comparison between different cohorts. While this resulted in a dip in pass rates, this was not unusual and other accreditation bodies had experienced similar results when new questions were introduced. The most important point was that the pass standard had been shown to be consistent and fair.

67.6. Members discussed the report and suggested that more detailed analysis would be helpful in understanding the differences in pass rates between different groups. Members also noted that the Board of Assessors had raised a number of learning points as a result of concerns about the answers some candidates gave to some questions. DR reported that these would be highlighted in a future edition of Regulate.

67.7. The Council noted the performance monitoring report. The Council also asked that a further paper, examining the Board of Assessors findings in more detail, be presented in due course.

68. **PROFESSIONAL STANDARDS AUTHORITY (PSA) PERFORMANCE REVIEW REPORT 2012-13**

68.1. DR introduced the report (paper 09.13/C/07) by drawing the Council’s attention to some of the key points. In response to a member’s question, DR reported that the information security case set out in the report had now been closed by the Information Commissioner.
68.2. DR informed members that the executive would report back to the PSA on progress against the points raised. He also reported that the PSA was undertaking a review of its performance reporting.

68.3. The Council noted the report.

69. **CHIEF EXECUTIVE & REGISTRAR’S REPORT**

69.1. DR introduced paper 09.13/C/09 by reporting that he and the Chair had attended a further Rebalancing Board meeting where more progress had been made regarding superintendents and responsible pharmacists.

69.2. DR informed the Council that the workshop arranged jointly with the RPS and aimed primarily at pharmacy organisations following the Which? report, would be used as the basis for discussions at the next GPhC Council workshop in October.

69.3. The Council noted the report.

70. **REMUNERATION OF INVESTIGATING COMMITTEE CHAIRS AND DEPUTY CHAIRS**

70.1. Viv Murch (VM) introduced paper 09.13/C/10 and reported that the matter had been omitted in error from a paper presented to Council in June. She reported that the Remuneration Committee had agreed the slight increase at its June meeting and that it was in line with changes to the fees of other associates.

70.2. The Council agreed that:

   i. the fee for Investigating Committee chairs and deputy chairs should be increased by £6 from £330 to £336; and

   ii. the effective date for the increase should be 1 June 2013.

71. **COUNCIL AND COMMITTEE SCHEDULE FOR 2014**

71.1. Paula Woodward confirmed that the chair designate had been given a list of the proposed dates set out in paper 09.13/C/11 and had indicated that he could meet them. She informed the Council that the Remuneration Committee shown as scheduled for October 2014 would in fact be held on the same date in September.

71.2. The Council agreed the schedule of 2014 Council, Audit and Risk Committee and Remuneration Committee meeting dates set out in the paper.
72. **DIRECT DEBIT INDEMNITY ARRANGEMENTS**

72.1. BK introduced paper 09.13/C/12 and informed the Council that the proposed arrangements removed the personal liability from four current Council members. The new indemnity, if agreed, would be undertaken by the GPhC as a corporate body and would therefore require the application of the seal.

72.2. The Council agreed to:

   i. the replacement of the existing personal indemnities given by five members of Council, by a body corporate indemnity given by GPhC; and

   ii. the application of GPhC’s seal to the new deed of indemnity.

73. **ANY OTHER PUBLIC BUSINESS**

73.1. The Chair confirmed that the meeting was moving into confidential business since some matters to be discussed named individuals and were commercially confidential.

73.2. There being no further business, the part of the meeting that was held in public closed at 2:25pm.

**DATE OF NEXT MEETING**

Thursday 14 November 2013