Minutes of the Council meeting held on 13 September 2012 at 129 Lambeth Road, London SE1 7BT at 11.15am

Present

Bob Nicholls - Chair  Ray Jobling
Cathryn Brown       Liz Kay
Sarah Brown         Lesley Morgan
Soraya Dhillon      Keith Wilson
John Flook          Judy Worthington
Tina Funnell

In attendance

Duncan Rudkin (Chief Executive & Registrar)
Bernard Kelly (Director of Resources and Corporate Development)
Hugh Simpson (Director of Policy and Communications)
Christine Gray (Head of Governance)
Elaine Mulingani (Head of Private Office)
Francesca Chittenden (Council Secretary)
Viv Murch (Head of Organisational Development) – minutes 670 to 694
Terry Orford (Head of Customer Services) – minutes 686 to 687
Bernie Lunney (Head of Investigations and Case Management) – minutes 686 to 687
Priya Warner (Head of Standards and Fitness to Practise) – minute 676 to 680
Martha Pawluczyk (Registration and International Policy Manager) – minute 683 to 684

Attendance and Introductory Remarks

670 The Chair welcomed everyone to the Council meeting including the following observers: Aileen Bryson, RPS Scottish Policy and Practice Lead, Martin Astbury, President of the RPS and Francesca Rivers from the Pharmaceutical Journal.

Apologies for absence were received from Celia Davies, Gordon Dykes, and Peter Wilson.
DEclarations of interest

671  Cathryn Brown informed the Council that she was now working as a self-employed locum pharmacist. She had amended her Declaration of Interests accordingly.

671.1 Cathryn Brown and Elizabeth Kay declared an interest in items 6, 7 & 8, on the standards for registered pharmacies, as a locum pharmacist and a superintendent pharmacist respectively.

Minutes of the last meeting

672  The minutes of the meeting held on 14 June 2012 were agreed as a true record of the meeting subject to some minor amendments.

Matters arising

673  Under minute 642.3 Bob Nicholls (BN) confirmed that the 2011-12 Annual Report and accounts was laid before Parliament in Westminster and Scotland. Duncan Rudkin (DR) confirmed that the auditors had signed the accounts as a true and accurate record following Council’s approval in June.

673.1 Under minute 647 BN confirmed that a paper on the cash management policy would be presented to Council at its November meeting.

strategic plan 2013-2016

674  DR introduced paper 09.12/C/01 reminding Council that the strategic plan was due for submission to the Privy Council Office for laying before Parliament and the Scottish Parliament.

674.1 DR set out that the plan put forward for agreement by the Council was largely an updated version of 2012-15 plan that Council had agreed just one year previously. He drew members’ attention to the covering paper which set out the minimal changes that were proposed, which included an update to the context / history section of the plan and the addition of text regarding the progress which had been made with revalidation.

674.2 DR proposed that following completion of the 2013 member appointment process, the Council would have the opportunity to undertake a fuller review of the plan, in June 2013.

674.3 Council noted the emphasis on professionalism and professional responsibility throughout the plan and highlighted the need to make more
explicit the link between this and the key priorities.

674.4 Council also requested that the introduction be expanded to set out the rationale to the approach taken to update the 2012-2015 plan rather than undertake a full review.

675 The Council agreed the strategic plan for 2013-2016, subject to some additional drafting as set out above to be agreed by the Chair of Council.

REPORT ON THE GPhC CONSULTATION ‘MODERNISING PHARMACY REGULATION: DRAFT STANDARDS FOR REGISTERED PHARMACIES’

676 DR introduced report 09.12/C/02 and set out the context behind the introduction of standards for registered pharmacies. He reminded Council that the Pharmacy Order had been drafted in a way to enable the GPhC to transform the regulation of pharmacists, pharmacy technicians and pharmacy premises in a step by step manner. Focussing on implementation of the draft standards for registered pharmacies DR highlighted that the standards would not be fully enforced until after the rules had come into effect but that this would give those who must comply with the standards a significant lead in time.

676.1 HS drew the Council’s attention to the drafting amendments to the consultation report which had been made following the June Council meeting. He informed Council that the recommendation to incorporate the compliance indicators within a decision framework was partly made following a desire from consultees to understand better how inspectors would make decisions; publishing the decision framework as a public document would offer a transparent solution and avoid duplication of information. HS also informed Council that further legal advice had been sought in relation to the registration criteria and that any pharmacy supplying human medicine must be registered, including pharmacies supplying human medicines for use in animals. HS confirmed that the registration criteria had been updated and communications activity undertaken.

676.2 In response to a member query, HS confirmed that, although the consultation report did not include a glossary, further explanatory information would be available on the website.

676.3 In response to a member question, HS highlighted that the introduction of standards for registered pharmacies moved the focus away from the individual and focused on the pharmacy being compliant. He assured Council that transition planning would clearly communicate this change to
all of those who would be affected and that the wording in the response would be made more explicit to reflect this change and the focus on accountability.

676.4 In relation to self selection of pharmacy-only medicines, HS highlighted the three additional pre-conditions proposed before self-selection could be considered in order to provide additional assurance. The first proposal was that pharmacies would be required to submit to the GPhC advance notification before self selection could be enabled. This would enable the GPhC to monitor any decisions by owners and superintendents and ensure inspectors were able to take this into account. The second pre-condition around self selection was that guidance on compliance in this area would need to have been developed and communicated in advance. Finally, the GPhC would make clear that the prohibition on self-selection would remain in place until the full range of enforcement powers were at our disposal once the rules came into effect, which was not expected before October 2013 at the earliest.

676.5 DR drew attention to the sections of the paper summarising the options available to Council in relation to self selection of pharmacy medicines, including those which had been considered but which were not being recommended, namely (1) maintaining the approach contained in the consultation with no special provision in relation to this topic and (2) departing from the general approach of outcomes-focused standards by including within the standards a blanket proscription on enabling self-selection. Council confirmed that neither of the options was appropriate, for the reasons given in the paper.

677 The Council agreed
- the proposed response to the issues identified by the Council at their June meeting
- the proposed consultation report for publication.

STANDARDS FOR REGISTERED PHARMACIES

678 HS introduced report 09.12/C/03 containing the standards for registered pharmacies for approval.

678.1 Priya Warner (PW) reminded Council that following their approval the standards would be submitted to the Word Centre for plain English approval before publication.

678.2 It was noted that, in response to the Council’s previous comments, the issue of accessibility had been incorporated in standard 4.1. This recognised that accessibility of services was not confined to physical
accessibility of premises. Council requested a number of minor drafting amendments to the standards and asked whether the definition of safeguarding was sufficiently broad. HS and PW undertook to address the points raised.

678.3 The Council agreed:
- the standards for registered pharmacies, subject to minor drafting amendments
- to delegate approval of any additional required amendments to the Chair of Council
- to publish the standards widely as soon as the amendments had been finalised.

MANAGING THE TRANSITION: WORKING TOWARDS IMPLEMENTATION OF THE STANDARDS FOR REGISTERED PHARMACIES

679 HS introduced paper 09.12/C/04 setting out plans for communicating the standards and the transition schedule to allow familiarisation as to what would be expected and when full implementation would take place.

679.1 The Council recognised the rationale for introducing the new standards in advance of the decision framework and rules, so as to build understanding and enable owners and superintendents to familiarise themselves with the standards in advance of a new inspection model and full enforcement powers being in place. In relation to unlicensed medicines, the Council noted the conclusion that the supply of unlicensed, extemporaneously prepared methadone mixture in preference to an available licensed alternative was not compatible with the law in this area. There was a need for a managed transition, reflecting the need to act in a way which was consistent with the legal framework and the wider public interest.

680 The Council noted the paper and provided feedback on the approach proposed to managing the transition phase and work required in advance of full implementation.

ENHANCING OUR UNDERSTANDING OF ISSUES WITHIN THE PHARMACY TEAM

681 DR introduced paper 09.12/C/05. In setting the context in which the paper should be considered he drew Council’s attention to the changing workforce of the pharmacy team and the need to identify any potential issues within the workforce which may need to be resolved, and whether the issues were for the regulator to address. He reminded Council that the decision to register pharmacy technicians had been agreed before the establishment of the GPhC and that the two year transition period of registration for pharmacy technicians had now ended.
681.1 In addition to the introduction provided, HS set out that the information currently held was insufficient to provide the insight required to enable the GPhC to determine whether there were issues for the GPhC to resolve and insufficient to provide the understanding to respond strategically.

681.2 HS informed Council that the budget which had been approved by Council did include an allocation to cover the cost of the research proposed.

681.3 In response to a member question, HS confirmed that the GPhC would involve key stakeholders, including the centre for workforce intelligence and those considering workforce issues across GB, including the modernising pharmacy careers team and the Devolved Administrations, to ensure we maximise the impact of the survey.

681.4 In response to a further question, HS confirmed that part of the work proposed would address the collection of equality and diversity monitoring data. He assured Council that attention was being given to ensuring the data collected were relevant and that they would be used in a way that is fair to those with protected characteristics.

682 The Council agreed:
- the proposal to undertake an all registrant survey to enhance the GPhC’s information and evidence base
- the GPhC’s intention to assess the need for further work in relation to five key themes identified in the paper.

GPhC POLICY ON RETURN TO REGISTRATION

683 HS introduced report 09.12/C/06 reminding Council that the current transitional arrangements for those returning to registration ended on 26 September 2012.

683.1 Martha Pawluczyk (MP) confirmed that the policy would only apply to those who had left the register (this could be either the GPhC or RPSGB register) for a period of more than 12 months.

683.2 Council debated the technical aspects of the registration criteria and MP undertook to clarify these. Council also requested that the wording of the criteria be reviewed in order to make clearer who would be affected by the policy.

684 The Council agreed:
- the proposed updated policy for those returning to registration
- necessary consequential amendments to registration criteria documents for pharmacists and pharmacy technicians.
2013 COUNCIL AND COMMITTEE MEETING SCHEDULE

685 The Council agreed the 2013 schedule of meetings for the Council, Audit & Risk Committee and the Remuneration Committee.

PERFORMANCE MONITORING

686 DR introduced report 09.12/C/08 which Council was asked to note and comment on. DR informed Council that material on Continuing Professional Development (CPD) and accreditation that had been provided in June was not replicated in the September report as the data was activity reporting rather than performance monitoring information which was not yet available. He reminded Council that a workshop was to be held the following day to look at developing future performance monitoring reports.

686.1 Terry Orford (TO) confirmed that a process had been engineered to speed up the processing of grandparenting applications for pharmacy technician registration and that there were currently fewer than 80 outstanding. A target completion date to process those outstanding had been set for the end of September.

686.2 In response to a member question on the registration assessment, TO confirmed that of the 29 ‘requests to pass’ received, none had been granted in light of increased focus on ensuring that candidates were ‘fit to sit’ and through offering mitigations for issues arising on the day. In response to a further question, TO confirmed that three of the assessment centres offered facilities for adjustments and that feedback received indicated a 93.7% satisfactory rating.

686.3 Bernie Lunney (BL) confirmed that the Fitness to Practise (FtP) figures included all complaints received and not just those that progressed to a full case, she also confirmed that data was available on where referrals had come from and that this information would be included in the November performance monitoring report.

686.4 In response to a member question, BK informed Council that the increased legal costs were being monitored. In response to a further question, BK confirmed that administration costs were higher as a result of holding FtP cases in Birmingham but that legal costs were not affected by the change in location.

687 The Council noted the performance monitoring report.
COUNCIL FOR HEALTHCARE REGULATORY EXCELLENCE PERFORMANCE REPORT

688 DR introduced report 09.12/C/09 and highlighted that the GPhC fitness to practise (FtP) statistics referred to within the report were from the 2010-11 year and that the statistics, as could be seen from the previous report on the agenda, had improved significantly.

688.1 In response to a member query, DR confirmed that moving forward the GPhC intended to report on the same measures as used by the CHRE in considering the GPhC’s performance. DR also confirmed that the GPhC, following recommendation from the CHRE, would look at collecting data in relation to FtP at various stages of the process.

689 The Council noted the Council for Healthcare Regulatory Excellence performance report

CHIEF EXECUTIVE & REGISTRAR’S REPORT

690 All members whose terms of office would end in March 2013 declared an interest in relation to the 2013 Member appointments process as referred to within the report.

690.1 BN informed Council that the 2013 Council Member appointments process was on track and that the first advert would be published in the Sunday Times on 16th September.

DR informed Council that the Department for Health had announced that they would be looking at the scope for moving aspects of medicines legislation to fall under the remit of the pharmacy regulator.

691 The Council noted the report.

ANY OTHER NOTIFIED BUSINESS

692 There being no further public business, the public meeting closed at 3.05pm.

CONFIDENTIAL BUSINESS

DECLARATIONS OF INTEREST

693 No interests were declared
MINUTES OF THE LAST MEETING – CONFIDENTIAL SESSION

694 The Council confirmed the minutes of the confidential session of the 14th June 2012 Council meeting as an accurate record.

ANY OTHER NOTIFIED BUSINESS

There being no further confidential business, the meeting closed at 3.10pm.

Date of next meeting – 15 November 2012 - London