

Council meeting 12 April 2012

04.12/C/13

Public business

Chief Executive & Registrar's report

Purpose

To keep the Council abreast of significant recent meetings and developments.

Recommendation

The Council is asked to note this paper.

1.0 Recent meetings

1.1 Listed in Appendix 1 is a non-exhaustive selection of significant meetings held during the two months since the last Council meeting.

1.2 Council members are reminded to liaise with the office before accepting external invitations to speak on behalf of the GPhC, in order to minimise overlap and to ensure they have the most up-to-date supporting material.

2.0 Dispensing errors

2.1 Council members will be aware that Lord Clement-Jones had submitted amendments to the draft Health and Social Care Bill that, if accepted, would have made provision for a 'due diligence' defence for pharmacy professionals and others in relation to dispensing errors.

2.2 These amendments were reached on the last day of the Report stage in the House of Lords. Lord Clement-Jones withdrew his amendments after receiving further reassurances from the Minister, Earl Howe, regarding the planned MHRA review of sanctions and penalties under the Medicines Act. In doing so,

Lord Clement-Jones noted that the GPhC had been supportive of the proposed amendment, but there was as yet no consensus with the pharmacy professional bodies as to the best way legally of formulating a defence that would meet these objectives. It was therefore the unanimous view not to amend the legislation now, but to wait for the promised review by MHRA.

2.3 In responding, Earl Howe said that both he and ministerial colleagues were determined to address the concerns of pharmacists and pharmacy technicians regarding dispensing errors, and that they wanted to see a learning culture so that helpful lessons were learned, while making sure that any changes continued to give patients protection. The Minister said that the MHRA aimed to establish the scope and membership of the review by September 2012 and that they would also look to introduce an independent element to the review, as it would be a challenging task to achieve a suitable balance between the roles of medicines legislation and professional regulation.

2.4 Key pharmacy bodies (the Royal Pharmaceutical Society, the Pharmacists' Defence Association, Pharmacy Voice, the Guild of Healthcare Pharmacists, the Independent Pharmacists' Federation and the Pharmaceutical Services Negotiating Committee) subsequently issued a joint press release in response to these developments, in which they regretted that a solution had not yet been found, but welcomed the commitment from the government to taking the work forward to a timetable. They explained that after taking legal opinion, it they had felt unable to support the idea of a 'due diligence defence' in law, and were pleased that this had been put to one side in favour of a timetable for addressing the fundamentals at the heart of this matter.

3.0 **Council for Healthcare Regulatory Excellence (CHRE)**

3.1 *Priority changes to Pharmacy Order 2010/Efficiency/effectiveness review*
Council will recall agreeing in January the GPhC's 'wishlist' of changes we would like to see made to the Pharmacy Order 2010 in advance of the Law Commission's more fundamental review. This was duly submitted to the Department of Health. The Department had previously made it clear that any legislative changes in advance of the Law Commission's work would need to be justified on the basis that they would lead to greater efficiency and effectiveness, amongst other criteria. Therefore, it asked CHRE for advice on the submissions from the GPhC and other regulators, within the context of CHRE's ongoing efficiency and effectiveness review of the regulators.

3.2 CHRE has now provided the Department of Health with an interim update on progress of the review, in which they note that their advisers, the Centre for Health Service Economics and Organisation, are using the data submitted by

the regulators to analyse the scale and scope for potential efficiencies across the regulators. The update also listed those of the regulators' proposals for priority legislative change that CHRE would advise the Department to consider further. All of the GPhC's proposals fell into this category. CHRE provided this advice in anticipation of further policy development work by regulators and the Department ahead of a full public consultation on any section 60 order.

3.3 CHRE noted in the advice that any section 60 order amendment would be unlikely to be operational for approximately two years, and that therefore, while proposals would lead to improvements in regulation, these would not be felt for some time. Given this, CHRE expected that regulators would do all they could to improve their processes and demonstrate good practice through more timely interventions that would not rely on legislative change. This would include such actions as:

- ongoing reviews and audits of processes
- thorough quality assurance
- working and collaborating with others to share good practice
- amending rules where necessary, with the support of the Department.

CHRE intends to submit its final advice to the Department in May 2012.

3.4 *Implementation of CHRE's powers to investigate complaints against the regulators*

Section 28 of the NHS Reform and Health Care Professions Act 2002 included provision for CHRE to investigate complaints about the way the regulators exercise their functions. This provision has never been commenced but, in *Enabling Excellence*, the Government made it clear that it planned to enact it. The Department of Health has now asked CHRE to provide advice on how this function might be implemented, in order to inform its drafting of the regulations (which will be consulted on in due course).

3.5 CHRE duly produced an outline of how Section 28 might work in practice, and has sought views from the regulators on its proposed approach. In essence, CHRE is suggesting that it will:

"investigate concerns that are raised to us about the regulatory bodies where there is an allegation, supported by sufficient information, about an administrative or policy matter which we judge presents a wider threat to public protection and/or confidence in regulation. Further:

- *Anybody can raise a concern to us (including the Authority itself), however we will not investigate matters raised by a registrant relating to his or her own registrant status*

- *We will not consider matters where there is solely a disagreement over a fitness to practise decision*
- *The regulatory body in question will ordinarily be given the first opportunity to respond to the concern raised, before the Authority will consider the matter in detail*
- *Concerns raised with the Authority may be used to inform other areas of our work in scrutinising the regulators.”*

3.6 In light of the tight deadline for reply, we produced and sent a preliminary response in which we:

- noted that the issue needed to be seen in the context of the much wider question about strengthened accountability of the regulators which was currently being considered within the Law Commissions' consultation.
- agreed that any such mechanism would need to be limited to avoid CHRE from being overwhelmed (while noting that the original parliamentary debates on the relevant legislative clauses suggested that it would cover a rather wider range of circumstances than that proposed by CHRE);
- sought further information on how CHRE would see this working alongside the regulator's own complaints policies and processes;
- pointed out that it was hard to comment on the approach without further understanding of the issues CHRE think the powers would be used to address, or the thresholds for decision making and how judgements would be made about what would constitute a wider threat to patient safety or confidence in regulation; and
- suggested formal or informal discussion to explore these issues further.

We will keep the Council informed of progress in this area.

3.7 *Preparing for the Professional Standards Authority role on Council member appointments*

Council members are aware of plans for the Privy Council to delegate the process of making Council member appointments to the regulators, with the Privy Council retaining responsibility for actually making the appointments. CHRE will become the Professional Standards Authority (PSA) and will be tasked with assisting the Privy Council in the exercise of its power to make Council member appointments. CHRE is preparing proposed standards and guidance on the appointments processes to be undertaken by the regulators.

3.8 The Council submitted comments on the proposed arrangements in June 2011. We now understand that CHRE is expecting to take on its new responsibilities in relation to Council appointments in advance of the transition to the PSA, namely from 2 July 2012. CHRE has advised that it expects to consult on its draft standards and guidance in late April. We will circulate the consultation document to Council members for comment.

4.0 **Registered pharmacies consultation**

4.1 We are now half way through the 13 week consultation and our engagement process is well under way. We have arranged consultation events with a wide range of key stakeholders, including local pharmacy forums, local pharmaceutical committees, primary care commissioning organisations, superintendents, pharmacy owners, and health councils, right across England, Wales and Scotland. An external organisation has also been commissioned to run three facilitated, half day, patient and public involvement events -- one in each of the countries in which we regulate. GPhC attendees are being supported with a detailed information pack.

4.2 We have received over 120 responses so far, online and in hard copy. Moreover, GPhC staff working as facilitators and note takers at engagement events are capturing discussions, key points and questions, and providing feedback direct to the policy team.

5.0 **Consultations**

5.1 A list of active consultations with which the organisation is or is not engaging is included at Appendix 1.

Recommendation

The Council is asked to note this paper.

Duncan Rudkin, Chief Executive & Registrar
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23 March 2012

Appendix 1**List of Meetings**

Listed below is a non-exhaustive selection of significant meetings held during the two months since the last Council meeting. Initials are as follows: Bob Nicholls (RMN), Duncan Rudkin (DR), Hilary Lloyd (HL), Bernard Kelly (BK), Hugh Simpson (HS), Elaine Mulingani (EM):

Chair:

- King's Fund Board Leadership Programme Seminar - *Are we there yet? Progress on the £20 billion 'Nicholson challenge'*
- Health Regulators Chair's meeting
- Health Education England Steering Group meeting
- Oliver Colville MP, Vice Chair All Party Pharmacy Group – briefing meeting on registered pharmacies consultation (with HS)
- Modernising Pharmacy Careers Board meeting (AM only)
- Council for Healthcare Regulatory Excellence (CHRE) Regulators' Forum (with DR)
- CEO & Chair, Royal Pharmaceutical Society (RPS) – update meeting (with DR)
- Medical Education England Board meeting
- Registered premises consultation event - Pharmacy Voice/Company Chemists' Association professional practice group meeting (with HS, HL)
- Professional Adviser for Regulation and Workforce Standards, Scottish Health Directorates – Update meeting
- RPS Scottish Board Chair & Director for Scotland – update meeting
- CEO, Community Pharmacy Scotland – update meeting
- Director of Pharmacy, NHS Education for Scotland – update meeting
- Community Pharmacy Scotland - Centenary Celebratory dinner
- RPS Healthy Living Pharmacies summit meeting
- Pharmacy Voice Stakeholder Engagement Meeting (with DR)
- Pharmacy and Public Health Forum meeting

Staff:

- Registered Pharmacies consultation Scottish event (DR, EM, HL)
- Tim Spencer-Lane, Law Commission (DR, EM)
- Registered Pharmacies Consultation Welsh event (HS)
- CEO, Royal Pharmaceutical Society (RPS) -- update meeting (DR)
- Council for Healthcare Regulatory Excellence (CHRE) senior staff – meeting on performance review (DR, EM, HL, HS)
- Pharmaceutical Society of Northern Ireland (PSNI) – discussion re: MoU

- implementation (EM)
- CHRE Regulators Forum (DR with RMN)
 - Regulators' Chief Executives' Steering Group (DR)
 - Regulators' Directors of Resources Meeting (BK)
 - Department of Health Working Group considering the future role and functions of Controlled Drugs Accountable Officers (HL)
 - CEO & Chair, RPS – update meeting (DR, with RMN)
 - Registered premises consultation event - Pharmacy Voice/Company Chemists' Association Professional practice group meeting (HL, HS with RMN)
 - Associate Director Medicines Management, NHS South of England – meeting to discuss overlap between FTP and professional/contractual issues (DR, HS)
 - Legal and regulatory pharmacy conference (DR)
 - Associate Director Medicines Management, NHS South of England – update on planning for NHS Commissioning Board performance management arrangements for pharmacy in England (DR, HS)
 - Chief Executives General Medical Council, Nursing & Midwifery Council & PSNI –medicines and professional regulation meeting DR, HS)
 - Pharmacy Voice Stakeholder Engagement Meeting (with RMN)
 - Medicines & Healthcare products Regulatory Agency senior staff – meeting to discuss respective roles (DR, HS, HL)
 - Macmillan Cancer Support workshop - *Lost in Translation?* (HS)
 - RPS senior staff – update meeting (DR, EM, HS)
 - CEO, CHRE (DR)
 - Interim Medical Director, Senior Adviser and Adviser, National Clinical Assessment Service (DR)
 - British Pharmaceutical Students' Association Conference (DR)

Appendix 2

Consultations (week ending 16/03/2012)

Consultations on which a final office decision is pending are in italics.

Title	By	Summary	Deadline	Response
Proposals to reform and modernise the NHS (Pharmaceutical Services) Regulations 1992.	Welsh Assembly Government	This consultation sets out proposals to amend the process by which applications to provide NHS pharmaceutical services are determined. http://wales.gov.uk/consultations/healthsocialcare/proposals/?lang=en	27 April 2012	Darren Hughes (Lead)
Modernisation of the GDC's fitness to practise procedures	General Dental Council	The consultation focuses on the possible introduction of case examiners to undertake a statutory role in the decision making process. We are currently seeking views from key stakeholders and would like to ask for your feedback about the proposals. http://www.gdc-uk.org/GDCcalendar/Consultations/Pages/Modernisation-of-the-GDC%27s-Fitness-to-Practise-procedures.aspx	30 April 2012	Priya Warner Recommendation not to respond
Standards for members of NHS boards and governing bodies in England.	Council for Healthcare Regulatory Excellence	This consultation paper seeks your views on our draft Standards. These have been developed through review of existing standards and other relevant guidelines and through extensive discussion with key stakeholders across the healthcare sector. http://www.chre.org.uk/satellite/413/	10 April 2012	Christine Gray Lead
Review of the Accreditation Standards for Pharmacy Degree Programs	Australian Pharmacy Council	The Australian Pharmacy Council will be holding public consultation workshops in several capital cities between March and May 2012 to discuss the Review of the Accreditation Standards for Pharmacy Degree Programs. http://pharmacycouncil.org.au/content/index.php?id=37	11 May 2012	Damian Day Recommendation not to respond

Review of NHS Pharmaceutical Care of Patients in the Community in Scotland Evidence Gathering Exercise	Scottish Government	The review will focus on the needs of patients and the NHS; current arrangements for providing NHS Pharmaceutical Services across Scotland; their fitness for purpose; and sustainability into the future.	4 May 2010	Lynsey Cleland (Lead)
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