

# THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN

## Transcript of the Public session of the Council meeting held on 11 December 2007

[NB: Decisions in square brackets and narrow type are taken from the unconfirmed minutes of Council and therefore are subject to amendment].

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## PUBLIC BUSINESS

### Present

President	Mr H Patel
Vice-President	Mr M Astbury
Treasurer	Mr A Gush
Mr S Acres	Ms S Agha
Mrs M Allan	Mr G Alexander
Mrs C Brown	Mr J Buisson
Mr S Churton	Dr B Curwain
Professor S Denyer	Mrs D Drury
Dr P Entwistle	Mr J Gentle
Mr J Hanlon	Mrs S Hikins
Mrs L Jacobs (until 07/114)	Mr R Jobling (until 07/113)
Mr J Jolley (until 07/113)	Mr A Kershaw
Mrs S Kilby	Professor B Michell
Mrs L Morgan	Mr G Phillips
Ms J Ramsey	Ms M Saunders (until 07/113)
Mr D Simpson	Mr D Thomson

### In attendance

Mr P Jones, Chairman Welsh Pharmacy Board and Mr F Owens, Vice-Chairman, Scottish Pharmacy Board.

Chief Executive & Registrar: Mr J Holmes

### 3. Welcome to guests

**Mr Hemant Patel, The President:** Good afternoon, Council. Firstly, I would like to begin by welcoming our guests. We have Susan Shelley, a secretary of the Oxfordshire Branch. We also have Miss Heena Bhakta, President of the BPSA.

We have a lengthy agenda. In spite of our late start, I hope that with your co-operation we will be able to make good progress today. Following the committee session this morning, the discussion of the Society's response to the Responsible Pharmacist consultation will take place this afternoon in public business. The papers for journalist colleagues will be made available to you as soon as we can in the next quarter of an hour. Further rearrangements of the agenda have been necessary to have key people here for discussions. I apologise, but at the time of preparing the agenda people's availability was not known. Items 8(a) and (b), referral to the Investigating Committee, will be taken tomorrow morning at nine o'clock. Agenda items 12, Recognition of Pharmacist Prescribers and use of post nominal initials, and item 13, CPD for new roles in NHS Pharmacy Services will be taken tomorrow as Peter Wilson will be available then. It will be preferable to take Regulation of Pharmacy Technicians today. Council business will close at 5.45, as we will be presenting Honorary Membership to Professor Schofield, former member of Council. For your information, I have arranged for copies of the recently published NPSA Design for Patient Safety booklets to be available to all Council members. I think that shows very good collaboration between the NPSA and the Society.

I would like to thank staff who have contributed to the booklet. It has been launched, as you know, and hopefully it will make the impact it deserved to in improving safety in community pharmacies.

#### **1. Apologies for Absence**

We have received a number of apologies. The first is from Rosemary Parr, Chairman of the Scottish Board, and also from Paul Bennett, Chairman of the English Board. We have here today Frank Owens, Vice-Chairman of the Scottish Pharmacy Board. David Carter sent a late apology this afternoon as his father has been taken to hospital.

#### **2. Declarations of interest**

Would Council members please indicate either a conflict of interest, or any interest, before the item is taken?

#### **4. Minutes of the public business part of the meetings of the Council held on 2 and 3 October 2007 and also 1 November 2007**

I will begin by saying that on the minute of 1 November, page 1, paper 07105, on fees for 2008, in error we indicated that Dr Entwistle declared an interest.

**Ms Averil Ridgway, Head of Secretariat:** I have one rather embarrassing minute, if I may mention it. In the minutes of 2 and 3 October, page 5, in the MHRA item in the fourth line down, POM means prescription-only medicine not pharmacist only medicine.

[With the following amendments, Minute 07/90, 2 October 2007, MHRA consultation letter MLX337 – personal sale of pseudoephedrine / ephedrine containing medicines by a pharmacist: “.....~~pharmacist~~ prescription only medicine.... ..”; Minute 07/105.1, 1 November 2007, Declaration of interests: Delete “Dr P Entwistle”; Council **resolved** that the minutes of the public business parts of the meetings held on 2 and 3 October 2007 and 1 November 2007 be received and agreed as a correct record.]

**The President:** Further training recommended! **(Laughter)**

#### **6. Chief Executive and Registrar's Report**

##### **(a) Pharmacy Regulation and Leadership Oversight Group (PRLOG)**

Can I invite you, Jeremy, to give us an update on PRLOG.

**Mr Jeremy Holmes, Chief Executive & Registrar:** PRLOG has had its second formal meeting, but we have had a number of offline discussions, both with the Chairman of PRLOG and the Chief Pharmacist, who leads one work stream, and Professor Peter Noyce, who leads the other work stream. I will ask Christine to update us through the paper that is in your pack.

**Mrs Christine Gray, Head of Corporate Governance:** I hope the paper is fairly self-explanatory. You will note that at a stakeholder briefing that the Department held on 19 November, they took the opportunity to give information about the Health and Social Care Bill and also the work of PRLOG. The terms of reference for PRLOG have been published on the Department's website. However, we were somewhat concerned when we saw the introduction to the terms of reference that you have in your paper, where you will see it refers to PRLOG's purpose as “*including overseeing the establishment of a leadership body for pharmacy which is fit for purpose to compliment the responsibilities of the General Pharmaceutical Council*”. That does not seem to fit with what the terms of reference themselves say, and the introduction was not included when the terms of reference were circulated to PRLOG. So the Chief Executive and Registrar has written to the Chairman of PRLOG expressing concern about that introduction to the terms of reference on the website. We have not heard back from the Chairman as yet. The only other thing to mention on this update is that the Department of Health has been looking at trying to revise the dates for PRLOG meetings in 2008, as some of them clash with half term. They may move the one on 22 February to 4 March, but the dates they have suggested do present some problems for both the President and the Chief Executive, so I have emailed them back saying do they want to look at it again, because there are some problems there.

**Chief Executive & Registrar:** Thank you, Christine.

**The President:** Are there any questions or comments? If not, we will move to (b).

[Council noted the report.]

**(b) Department of Health Professional Regulation and Patient Safety Programme**

**Chief Executive & Registrar:** You have C1 and you are probably familiar with the map on the back of the paper showing the working groups and those where we have representation. Just to update you, there is a Regulatory Body Policy leads group, which has been established, to facilitate input and output from the working groups. Eileen and Christine represent the Society on that group. A number of lay individuals and groups with an interest in regulation met at the offices of *Which* at the end of August.

One outcome from that meeting was a joint letter to Ben Bradshaw raising concerns about lack of lay involvement in the working groups. We are waiting for a response on that. The Department has published details of the working groups and their membership. Heidi Wright, our Head of Practice, has been appointed to the Clinical Governance Subgroup on tackling concerns locally. We have established our own Revalidation Advisory Group, as Council will recall from the October meeting, chaired by Peter Wilson, to provide input to the Government's Non-medical Revalidation Working Group and to facilitate communication with the Council and relevant stakeholders. It had its first meeting on 3 October. Obviously that is a crucial working group, because it is such an important interface between the General Pharmaceutical Council and the new professional leadership body.

**The President:** Are there any comments or questions on (b)? If not, we move to (c).

[Council noted the report.]

**(c) Independent Inquiry on the principles, functions and structures of the future professional body**

This is independent inquiry where the Society, like other bodies, will be making a submission. Work is progressing well and I will ask Chief Executive to add any comments he wishes to make.

**Chief Executive & Registrar:** You have Eileen's paper, C112, which gives you some important background on the process and progress of the Clarke Inquiry. We had useful discussion in Council's Committee session this morning. It is a very important Inquiry and we, as a Society, are putting a lot of emphasis on our own submission, but the Inquiry is taking evidence from a wide range of other stakeholders, and we look forward to that report, which will take a comprehensive view of opinions and evidence from the whole of pharmacy.

**The President:** Are there any questions or comments?

[Council noted the report.]

**(d) Council election 2008**

Council is asked to note paper 113 which has been circulated to you.

**Chief Executive & Registrar:** Paper 113 is on the Council election in 2008. Council is asked to note three things. First of all, those Council members whose term of office expires in 2008 are listed in section 2, although over the page there is a further section 2, just to confuse you. The first section 2 lists those Council members whose term of office expires in 2008. Secondly, the Council is asked to appoint Electoral Reform Ballot Services as the scrutineer for the Council election. They have been used for some considerable time, so you will be familiar with their services. Thirdly, the Council is asked to agree that the date from which newly elected or re-elected, and new appointed or re-appointed members of the Council take office in 2008 be one minute past midnight on 22 May.

**The President:** Can I ask you to note (i) and agree (ii) and (iii)?

**Mr John Gentle:** Before the Council was re-configured in 2005, it was never the case that more than a third of the Council changed at any one election. It may be unlikely, but there are 15 Council members here who may, for whatever reason, not be re-appointed. It strikes me as a cause for concern that up to 50 percent of the Council could change at any single election. Could we look at that, so that the terms of office are rigged so that does not happen again?

**The President:** Can we note your concern?

**Mr Graham Phillips:** We know that turnout for Council elections has been hovering at 18 to 22 percent for some considerable time. Given the momentous change, both within the profession and within this organisation, anything we can do to increase turnout would be valuable.

I know that we are under all sorts of other stresses and strains and competing resources. I acknowledge all those, but I wonder if we could do something a bit different and more innovative this year in terms of encouraging people to participate in democracy.

**The President:** We will note that point and I am sure people will take action. Council, you have agreed to note (i), agree (ii) as a scrutineers and (iii) to agree the date from which newly appointed or re-appointed members of Council take office in 2008.

[Council **noted (i)** the Council members whose term of office expired in 2008; **appointed (ii)**. Electoral Reform Ballot Services Limited as the scrutineer for the Council elections in 2008; and **agreed (iii)** that the date from which newly elected or re-elected and newly appointed or re-appointed members of the Council take office in 2008 would be 00.01hrs on Thursday 22 May 2008.]

**(e) Minutes circulated since the October meeting of Council**

Can we go to item 11? Have we received comments on minutes circulated since the October meeting? **(None)** With Council's permission, I would like to take the item on the responsible pharmacist that we discussed earlier on. Do you want to take that item later on or now?

[Council received the minutes of the following committees: Governance Committee - 19 September 2007; Law & Ethics Committee - 9 October 2007; Science Committee - 11 October 2007; English Pharmacy Board - 17 October 2007; Welsh Pharmacy Board - 11 October 2007; Scottish Pharmacy Board 24 October 2007.]

**11. The Responsible Pharmacist**

Doug will introduce the item.

**Mr Douglas Simpson:** My job is to remind everyone how we got to where we are today. There has been a general ambition that the role of pharmacists should develop to develop a more clinical role. Indeed, this is in the wish of Government. Andy Burn at the Conference the year before last stated explicitly that pharmacists now have a clinical role. It is that role which I think the whole of the profession want to see developed.

As a result of the wishes of Government and the wishes of the profession, a document was produced by Government on skill mix, about making better use of the pharmacy team in the pharmacy. This was consulted on. We presented our response to the skill mix document. One of the things that was conceded in the process was that pharmacists were not going to be able to develop their clinical role by being nailed to the dispensary bench all the time, but needed to be freed from that regular commitment of doing all the dispensing and spending all their time at the dispensing bench.

It was agreed that to develop a clinical role, pharmacists occasionally would have to leave the pharmacy for the provision of professional services and Council agreed that should be possible for short periods of time. The Society was not alone in this. Other bodies (the Company Chemists Association, the Pharmaceutical Services Negotiating Committee, the National Pharmacy Association amongst others) agreed that it would be reasonable for the pharmacist to leave their pharmacy for a short period of time to provide professional services. If we are seeing any kind of conservative views being expressed at the present time, I thought I would give you that piece of information by way of background.

As a result of the Society responding in this fashion to the Government on the skill mix issue, we had the Health Bill produced. The Health Bill is now the Health Act. This was based on the supposition, which I have mentioned already, that the pharmacist would not necessarily have to be in the pharmacy all the time. It was a big change but one the profession agreed on and it had been enacted in the Health Act. The Health Act is just an enabling measure, and an awful lot of work has to be done in putting flesh on bones.

We had a Health Bill working group (now the Health Act working group) looking at the regulations that would surround this issue of what is now the responsible pharmacist. One of the main things the Health Act did was to remove the concept of personal control and replace it with the concept of the responsible pharmacist.

Martin has been leading this project, coming up with proposals for how we might respond to the Government on the more detailed aspects of the measure. I hand over to Martin to explain the kind of job he has been doing.

**Mr Martin Astbury, The Vice-President:** I will outline what we have been doing to get to this position of producing this paper that is going forward as the Society's response. Since the inception of the group 18 months ago, the Health Act Working Group have met on seven occasions. Myself and Priya, the acting Head of Ethics and Secretary to the Law and Ethics Committee and the Health Act Working Group, have visited national boards, branches and regions giving presentations. We have also gathered information from all those sources. There was a consultation to the members in June of this year publicised in the *PJ* and the *C&D*. That was also available on the website, with details on the website, and you could submit via the website.

Comments were sought from the Veterinary Pharmacy Group, Hospital Pharmacy Group, Community Pharmacy Group and various groups that fed into this document. During the informal consultation part that the Department of Health had, a number of Council members attended those meetings, which were scattered in five or six different places throughout the UK where informal consultations by the Department of Health took place. We had Council members at most of those and members of staff. We also consulted with a number of other pharmacy organisations and had constructive dialogue with the Department of Health during that period. I will hand over to Priya.

**The President:** Martin, in terms of Scotland and Wales, what input did you get?

**Mr Martin Astbury:** All three of the Boards were able to input and all three of the Boards did take that opportunity.

**The President:** So this is a GB-wide response.

**Mr Martin Astbury:** Yes.

**Mr Douglas Simpson:** If I could continue. Martin having done his group, we have been through the draft response and put our stamp on it. That draft response has been agreed by the Law and Ethics Committee and is going to be put before you today and Priya is going to lead it.

**The President:** Before that, can I say a few words? I think this has been an important innovation and we have devoted a lot of resource in making sure that we got everything right first time. Both Martin and Doug have described the process. From my point of view, organising a large number of meetings over a period of time with large numbers of organisations, and taking all their comments on board goes to show how we have prepared our response. We have consulted people. This is not a group of five people sitting down dictating policy. From start to finish, it has been an 18-month process with probably over a hundred people inputting into the process. It is quite important to recognise that. In terms of process, does any Council member want to make a comment?

**Ms Jane Ramsey:** I have not been involved for 18 months because, as people will know, I am the newest lay member, only having been on Council for six months. I am also a member of the Law and Ethics Committee. I was sharing with colleagues this morning and felt I should say in public session today how impressed I have been as a new member and as a lay member of the Council around this whole process. It has been quite a privilege to watch colleagues in action, in terms of the development of the ideas, the commitment to getting it right, the arguments (in inverted commas) that have gone on intellectually between pharmacists and explaining those arguments to lay people like myself. As a layperson, I feel it is important to express the view that that perspective has certainly had an opportunity to be fully aired in this discussion.

I think the Society should feel proud of itself in the way it has actually come to a view on all these important issues for patients, because it is difficult for pharmacists and lay people alike, when they are trying to balance patient safety and convenience with a modernising agenda. I did think, as a relative newcomer, that the Society had got this right and had been particularly impressive in the way it has come to a view on all these very difficult issues.

**The President:** Are there any other comments? Welcome, Priya. You are making a debut today addressing the Council and guiding us through the document. Please proceed.

**Ms Priya Sejpal, Acting Head of Professional Ethics:** Good afternoon everybody. I am going to take you through the Responsible Pharmacist Consultation draft response in front of you today. There are somewhere in the region of about 45 questions, but hopefully a lot is already within current Council policy.

The actual draft response starts on page 9 of your paper. We start with the two-page introduction that aims to summarise what we have in our consultation response. We talk about the unique selling point of pharmacists, the need to ensure regulations are not overly burdensome and also highlight other areas of regulations, such as the controlled drugs and veterinary regulations which need to be considered when the Government looks at these regulations. That is the introduction in a nutshell.

Moving to the response itself, the first chapter in the consultation is titled *Pharmacy Procedures*. The pharmacy procedures, the pharmacy record and the chapter in relation to qualifications and experience, when you tie the three together, should provide a sound quality framework on which absence and being responsible for more than one pharmacy, and in the future remote supervision and supervision, should be based. In considering the response we have tried to ensure that that quality framework is in place.

The first question really has already been covered in the previous Council policy. Unless there are specific comments, I think we can potentially move on.

**Mr Graham Phillips:** I think this is an excellent paper and I agree with the comments that have been made earlier. There is so much in here that I can support; the clarity of it and way it has been argued. I have, as members will know, difficulty in two areas. The first is the description of a short-term absence from a pharmacy being two hours. It comes through at various places, but I am looking for example at page 10/33. In my own pharmacies, we use skill mix and technology in every possible way to free the pharmacists up to perform the maximum clinical role that that we can. But I can envisage no scenario in either my pharmacies or any other pharmacy in which one can safely remove the pharmacist. I believe a pharmacy without a pharmacist in it is not actually a pharmacy. I know to some extent it is a slippery slope argument. We have argued two rather than three hours. To be honest, whether it is two or three hours I do not think is particularly relevant. Once you get to significant periods of absence, it is very hard to defend it from there to half a day, to a day and so on and so forth. If we had the luxury that certain European nations have, both in terms of huge investment in technology and huge investment in terms of support staff (graduate technicians and that kind of scenario), then I could well imagine that we may look at this differently. But I see no prospect whatsoever of the injection of the necessary resources being made in order to provide that situation. It worries me that we go apace. It is not because I am Luddite about the requirements of practice. It is an on balance thing; where would the pharmacist do most good? The joy of community pharmacy -- and it is a joy to me -- is that you never know what is coming through the door next. You also do not know whether your most significant intervention on any one day will be an urgent requirement for a syringe driver, or it may be around a GSL medicine in a totally innocent scenario. It may revolve around giving a piece of public health advice on which no sale is made. It is the presence of the clinician in the pharmacy which guarantees the safety of the public. The whole value-add of community pharmacy is about the ready accessibility of a health professional. That is what the public has come to expect and that is what pharmacy means to the public. I think it is at our peril that we give that up. I think it could also be perceived as professional arrogance, as it is by no means clear to me, if the vast majority of public and patients out there, that a pharmacy would be running for two hours in the absence of a pharmacist, that they will be content with that. For those reasons and many more, I am in fundamental opposition to that.

**Mr Douglas Simpson:** Can I point out that this is the introduction Graham talked about. We have the specific chapter and recommendations further on in the paper. It is probably best to deal with the issues where they occur in the paper rather than discuss the introduction. It will come up later on in the item response to specific questions in the consultation document.

**Mr Graham Phillips:** There is one more general point around education. Do you want me to take that now or later?

**The President:** I think we will take points one at a time. Then if there is anything that needs to be said, we will come back to that. I would like to go to the first point, because it is a long paper, and we will need to spend time on each point. We will come back to anything that has been left out. Is that okay? **(Agreed)**

**Ms Priya Sejpal:** Moving to the questions, the first set of questions talks about the minimum areas that need to be covered in the pharmacy procedures. In the consultation document itself, there is a list of proposed minimum areas. In looking at the list proposed by the Department of Health, the Council's current policy is covered within those areas. There are some further proposed areas in the Department of Health's consultation that Council have not currently agreed, and they are put forward at the end of the page.

The Law and Ethics Committee recommended that the minimum procedures, over and above what Council have already agreed, should include arrangements for record-keeping, arrangements for when the responsible pharmacist is absent, arrangements for recording amendments to the procedures, arrangements for responding to complaints relating to the sale and supply of medicines, arrangements for responding to adverse incidents relating to the sale and supply of medicines and also arrangements for the transfer of responsibility for the pharmacy from the responsible pharmacist to an incoming responsible pharmacist.

Those were the areas proposed by the Department that were not covered in current Council policy, but the Health Act Working Group and Law and Ethics Committee felt they were important areas that needed to be covered in order to secure the safe and effective running of the pharmacy.

**The President:** Any questions on this section?

**Mrs Sue Kilby:** It is not about the specific section. First of all, I am pleased on the comments Jane made. I think a lawful lot of work has gone into the document. There is a lot of very good and useful information and a lot of thought that has gone into it. My only concern, on looking at it, is that I get lost, because there is so much information there. I would like to see the formatting of it changed somewhat, so there is highlighting of the really important bits – maybe bullet points in the way it is set out in the response. There are lots of good points in the two pages to start off with in the introduction. If it is set out slightly differently to highlight those points, then I think people reading it quickly will pick them up more easily. I am not criticising the arguments or what you have or have not done; it is the way the information is perhaps set out.

**Mr Douglas Simpson:** We are responding to a consultation document. The Department of Health asked a series of questions, so we are following a format which has dictated by the consultation process. If you want to do a summary that can be used as a commentary which is generally available, that is something the office would be happy to consider. It might be a good idea to consider that.

**The President:** So we are agreed. Next question, please.

**Ms Priya Sejpal:** The Department is proposing that pharmacy procedures can be set out either on paper or electronically. Here is a simple recommendation from Law and Ethics that pharmacy procedure should be able to be maintained electronically. **(Agreed)**

Following on from this, the Law and Ethics Committee are making a recommendation that the regulations should not specify the format of the pharmacy procedures. This is to ensure that there is some flexibility in approach to the procedures. Whilst the regulations should outline the content of the pharmacy procedures, the detail and format of these should be left to the responsible pharmacist. **(Agreed)**

The Department of Health posed a question around whether or not there was a need for the responsible pharmacist to sign off that they have checked and are happy with the pharmacy procedures. The Law and Ethics Committee make a number of proposals around reviewing pharmacy procedures. They did not feel it was necessary for the responsible pharmacist to literally sign off to say they are happy with the procedures. That is really based on the fact the Health Act requires a responsible pharmacist to secure the safe and effective running of the pharmacy and to establish and maintain procedures. In achieving that requirement, it is almost implicit that you would have been reviewing procedures and be satisfied with them without needing to place the unnecessary burden on the pharmacist to physically sign off to that effect. That is one of the proposals from the Law and Ethics Committee. **(Agreed)**

The Department is proposing that it would be more appropriate for guidance to be produced for the profession on the way in which procedures should be reviewed. The Law and Ethics Committee are recommending that it would be more appropriate for guidance to be produced on how to review pharmacy procedures, rather than for this to be outlined in regulations. **(Agreed)**

The Government did ask whether there were other proposals we wished to put forward. The Law and Ethics Committee recommended that in professional guidance we should require procedures to be reviewed at least annually and that procedures should be signed and dated to show that they have been reviewed. It is important to note that this annual review does not detract from the need to amend the procedures as and when necessary during the interim period, but that as a minimum procedures should be reviewed annually. **(Agreed)**

In addition, as it was felt there was an important role for superintendents and pharmacy owners to play, Law and Ethics were recommending that the superintendent pharmacist, or pharmacist owner, should sign a yearly declaration to state that appropriate procedures are in place. **(Agreed)**

**Mr John Hanlon:** I get the impression that much of this is agreed. It is only a suggestion, but if there are sections we do not agree with, would that perhaps get us through the business quicker?

**The President:** What has happened in the past is when we have missed anything out, people have come back and said "We did not have an opportunity to comment". I am happy to move, but what it shows is that everything is properly covered.

**Mr Graham Phillips:** This is so fundamental to the future of the profession that it is important for the profession to hear the debate on this. On this particular occasion, I think we are proceeding in the right way and I urge us to continue in the way we have.

**Mr Gerald Alexander:** It is so important to the profession that our voice is heard, that I think we do need to run through this. On a personal basis, I have had the privilege of being on the Health Act Working Group and Law and Ethics. Unlike Graham, I have had the privilege of the inside knowledge of what has gone on. It is easier for me to understand this, but I think we need at least to work through this. This was originally going to be in confidential business, but it is better it is in public business so the profession know what we think. I do have some points and I would like to come to them in the right place, but I think we want to air our views.

**The President:** Also the membership when they read the report will be aware that each point was carefully considered by the Council; it was not rubber-stamping exercise.

**Mrs Sue Kilby:** I think it is really important that we go through it for the simple reason that some of us may not be working so closely with community pharmacy at this time. We need to understand the arguments, because we are being approached by people working in community pharmacy, and we need to ensure that we give a consistent view from Council. That is the opportunity for us to hear the arguments so we can go out with one voice back to members when it is being discussed.

**The President:** I think we have agreed to proceed in the same manner. Priya, where are we?

**Ms Priya Sejpal:** Up to one of the final recommendations in chapter 3, page 16 at the top. Finally, the Law and Ethics Committee are recommending that guidance should contain a requirement for any amendment to the pharmacy procedure to be recorded with the reason for the amendment, the thinking behind it being that there was a need for an audit trail and also for potential inspection and monitoring purposes.

**Mr Graham Phillips:** I can understand the reasons behind this, but I am also concerned that it smacks of ivory tower thinking. Because if we have 40 SOPs operating, and we are required to create an archive of every single amendment to every single SOP, my concern is that -- I can see the legitimacy for it, but is it practical? A lot of what has been proposed is very sensible and very practical. To me this falls into the category of nice to do, but not *must do*. The risk is that people see this and find it impossible to comply, certainly given the current time and access to IT, and it undoes much other stuff in here which is practical and doable. On balance, I am opposed to this as a requirement. I think it is good practice but I would go no further than that.

**The President:** I would be surprised if the working group did not make that point at some stage. Priya, can you tell us what the thinking was?

**Ms Priya Sejpal:** The recommendation is for this to go into guidance not regulation. I think it was felt that, for example, it would make it easier for an incoming responsible pharmacist, rather than necessarily having to re-read the necessary SOPs, if they had been in the pharmacy before they could only have a check back to see what amendments had been. Therefore, the record would enable that.

**The President:** So it is guidance.

**Mr John Jolley:** It is normal practice in situations like this to keep a log of process deviations rather than amendments. I would strongly recommend that this be done. So in any case where the pharmacist is unable to follow the established procedure, in as much as anything in protecting the pharmacist from any subsequent action, he has a log where he keeps any deviations noted.

**The President:** We will note the point. I am sure there will be further consideration given.

**Professor Stephen Denyer:** In attempting to help the guidelines, I think there must be a consolidation phase on a relatively regular basis, where a series of amendments get entrapped in a new version of the SOP. Perhaps that is important to be included in the guidelines.

**The President:** We will take that on board. With those comments, can we agree the response? **(Agreed)**

**Ms Priya Sejpal:** The last question in chapter 3 has been drafted using current Council policy, with no further recommendations from Law and Ethics.

**The President:** Is that agreed? **(Agreed)** We are on page 17, Pharmacist record, chapter 4.

**Ms Priya Sejpal:** The proposals around minimum requirements for pharmacy record are in line with current Council policy. But one point of clarification for myself really. Our current Council policy states that pharmacy records must be available in the pharmacy. Law and Ethics have recommended that records could be held at another location, provided that the record is identifiable to the pharmacy in question and can be readily accessed for inspection and monitoring purposes.

**The President:** Is that agreed? **(Agreed)**

**Mr Graham Phillips:** I am not opposing this. Can you operationalise that for me? I want to be clear what it means in practice.

**Ms Priya Sejpal:** The idea is that ultimately the home of record as such, if it was electronic, would not necessarily need to be the database in the pharmacy, as long as it is identifiable to the pharmacy in question. If you were keeping a paper record for inspection and monitoring purposes, it is more than likely that would need to be in the pharmacy, but for electronic records it might be that they are held elsewhere.

**The President:** So we approve the response. **(Agreed)**

**Ms Priya Sejpal:** A number of other proposals were put forward by the Department of Health in terms of what needs to be included in the pharmacy record. The first proposal is whether or not there was a need for the pharmacy record to include the date on which the pharmacist became registered. The Law and Ethics Committee do not believe that is necessary; we already have the online register search.

**The President:** Can we approve the response? **(Agreed)**

**Ms Priya Sejpal:** The Law and Ethics Committee are recommending that the reason for the responsible pharmacist's absence should be recorded, as this would be necessary for an audit trail. **(Agreed)** Another proposal from the Department of Health was that the regulation should contain a requirement for any amendments to the pharmacy record to be kept and why these amendments were made. The Law and Ethics Committee do not agree that there should be a requirement for amendments to be recorded to the record and the reasons for it. It was felt that this was onerous.

**The President:** I am sure Council would agree this recommendation. **(Agreed)**

**Ms Priya Sejpal:** Finally, there was a proposal that the regulations should require the record to include information on other staff and other pharmacists who were working in the pharmacy other than the responsible pharmacist. The Law and Ethics Committee did not agree this recommendation and are recommending that you do not need to record this information in the record. The standards and guidance for pharmacists and pharmacy technicians in positions of authority do require clear lines of accountability to exist and for a retrievable audit trail of the healthcare professional taking responsibility for the provision of each pharmacy service. It was felt that a requirement to require that in the pharmacy record would be duplication. **(Agreed)**

The proposals around keeping pharmacy records electronically have been agreed by Council previously. In terms of the minimum periods for which pharmacy records should be kept, the Council's current policy is a minimum of five years. The Law and Ethics Committee are recommending that the records should be preserved for as long as is consistent with other regulations, so the five years potentially. **(Agreed)**

Moving on to chapter 5, this is the chapter that looks at absence of the responsible pharmacist from the pharmacy. There are a number of proposals put forward by the Government in the consultation, if I take you through them step by step. The first point to clarify is in the Government's consultation when they look at absence, they are looking to set a minimum amount of time for the responsible pharmacist to be in the pharmacy and a maximum amount of time for which they can be absent. When looking at these time periods, the Government are considering this per responsible pharmacist per shift. Say, for example, if you could be absent for two hours maximum, and you had two pharmacists in over a period of a day, they could both, during their shifts, be absent for two hours. In the proposals we are about to look at, the Law and Ethics Committee are recommending that the length of absence, and the minimum amount of time present in the pharmacy should be looked at per pharmacy per day, rather than per responsible pharmacist's shift. That would be the first recommendation from the Law and Ethics Committee. **(Agreed)**

Our current Council policy states that the responsible pharmacist must be present in the pharmacy for the large majority of time. The Law and Ethics Committee are recommending that the responsible pharmacist must be present in the pharmacy for substantially more than half of the time the pharmacy is open. In the Government's proposals around minimum presence in the pharmacy, the Government are proposing a minimum 50 percent; i.e. half the day. That is really why the Health Act working group and the Law and Ethics Committee recommend the use of the wording "substantially more than half". It was not felt that 50 percent was enough time.

**Mrs Sue Kilby:** Just a general comment. It might be a bit naïve and it is something I have raised before. With the responsible pharmacist it is obviously going to apply not just to community pharmacies but also to hospital pharmacies, because we have a quite a few registered hospital pharmacies. I wonder how this absence affects the hospital side and whether that has been discussed with people like Ray [Fitzpatrick, Chairman of the Hospital Pharmacists Group Committee]. I know Jeanette Howe, [Department of Health] has discussed it with the Hospital Group. I did not want to cut across anything that would have an impact on what they are doing.

**Ms Priya Sejpal:** I have shared this draft response with Ray and have received an email back saying he is broadly supportive of the proposals outlined in the consultation. The Council's current policy in respect of the fact that the regulations should not specify percentages of time – that is the Council's current policy. The Law and Ethics Committee and the draft response you have in front of you still state we do not believe a minimum percentage of time should be stated, but instead we should use the words "substantially more than half". However, it was felt that we should have a fallback position, for if they were to set this in regulation. The Law and Ethics Committee are recommending that if regulations were to specify minimum presence in the pharmacy, then this should be 75 percent of the working day. Our argument and our response will still clearly state that we do not believe a percentage should be stipulated, but if there is one, it should be 75 percent of the working day.

**Mr Gerald Alexander:** Only one point on the 'if' - "if regulations were to specify a percentage." I agree with what has been said – and I think I mentioned this in Law and Ethics – but I think the normal working day would need to be defined, because there are pharmacies that are open for 16 hours, if you are running a 100 hour pharmacy. Some of those pharmacies could be open with a pharmacist present for only 12 hours of the 16. I know it is in regulation and it would be in the NHS regulations. We are recommending that the maximum period of absence is two hours. But if that falls, and this is our fallback position, then I would suggest that if our fallback position is suggesting 75 percent, we should define what a normal working day is. A normal working day is probably no more than nine hours in a pharmacy. Therefore, if it is 75 percent, it should be a 75 percent of nine hours, not 75 percent of 16 hours.

**Mr Martin Astbury:** Just to clarify, this is the fallback position on the time period that there 'must' be a pharmacist present in the pharmacy. We are saying if the Government go with a percentage, we think that for 75 percent of a day there must be a pharmacist on the premises. I agree your point is a separate one, so far as the two hours, which we will talk about in a minute. That is altogether different and stands as a separate entity, which can be discussed in a minute. It is a completely appropriate view to put forward, as to what the working day is. The Health Act Working Group in the end went for the fact it was the opening period. We felt in NHS regulations they may stipulate something else, but we had to go for what we felt was the most workable, which was the official working day rather than core hours, which I think is what you were alluding to.

**Mr Gerald Alexander:** The point is the definition of what might be a normal working day, if you put that in.

**The President:** We will take your comments on board.

**Mrs Dorothy Drury:** Just to make sure these regulations do not cover official rotas and bank holidays, where obviously a pharmacist must be on the premises to cover special rotas.

**Ms Priya Sejpal:** In terms of these changes, the Health Act and the changes to the Medicines Act will be GB-wide. When the Government look at supervision, that is when the contractual arrangements under the NHS will also come into play. It would be my understanding that it would be at that point you would have to start looking at things like bank holidays, and the time periods which you suggest, rather than at this point in time, with the overall primary legislation and regulations.

**Mr Martin Astbury:** To clarify that, in order for the pharmacist to be absent, they have to be able to justify the absence. Therefore you would presume that they would not be able to justify it, if they were in that position. But if they could justify it, if there was a suitable emergency that required them out there, I am sure you would happily agree they should be doing other things. That is where one of the fallbacks is.

**Mr Graham Phillips:** I want to support what Mr Alexander had to say, because it could be a 24-hour day, in which case 75 percent is potentially six hours with no pharmacist present. I propose an amendment which says LEC recommends that if there is regulation of a specified percentage it should be 75 percent of the working day, up to a maximum of two hours. It is therefore consistent with the second part of our submission. Can I propose that as an amendment?

**Ms Priya Sejpal:** The Department is looking at a two-pronged approach to specifically stop the scenario you are suggesting. In a 16-hour day, if our proposals are taken forward, it would be 75 percent, so 12 hours minimum presence, but the regulations would also be saying a maximum of two hours absence. So implicitly out of a 16-hour day, you would only have absence for two hours. That is where the two-pronged approach is coming from. In order to be absent, you have to be able to comply with minimum presence, but you are also able to be gone for only the maximum amount of time. So 75 percent and two hours would only mean a two-hour absence in a 16-hour day. That is their two-pronged approach. My understanding from their consultation is that they are not going just for one aspect.

**Mr David Pruce, Director of Practice & Quality Improvement:** Just to clarify, the minimum percentage comes into play on short opening where you would not want, for example, a pharmacy that was open for three hours to be absent for two hours. The maximum amount of absence is much more important for long opening hours and, that is why there is such a two-pronged approach, because it covers both situations.

**The President:** I think there is no need for amendment.

**Mr Graham Phillips:** I appreciate you can de-couple them. I disagree. I think if you take my amendment, it addresses the scenario, and makes it absolutely explicit, because my amendment would deal with the scenario which David painted for us: 75 percent, up to a maximum of two hours.

**The President:** Do you have a seconder?

**Mr Gerald Alexander:** If it was a shorter opening period, David suggests two hours would be too long.

**Mr Graham Phillips:** I am saying up to 75 percent, up to a maximum of two hours, deals with both scenarios.

**The President:** I think the issue is clear. If there is no seconder, we will move on.

**Mr John Gentle:** I would support what Graham is saying in principle. 75 percent presence; therefore the absence would be 25 percent, but 25 percent or two hours, whichever is the shorter. I thank David for the clarification he just gave, because my concern would be for Saturdays, as many community pharmacies have Saturday morning openings, as opposed to all day openings on Saturday, with regard to doctors' surgeries being closed. Going back to what Dorothy said, in terms of what was termed as special openings (bank holiday and rotas), it seems to me we should consider whether we should include Saturdays in these absence procedures at all, on the basis that with doctors' surgeries being closed, Saturdays are not an ordinary day's worth of opening, compared to a Monday or ordinary weekday. If the surgery is closed, as it is in the vast majority of cases in England at the moment, and also Wales and Scotland I believe, community pharmacists are being faced with more and more unusual problems, out of the ordinary requests and a pharmacist's

absence on a Saturday could be of greater significance and have greater consequence than the absence of a pharmacist on a weekday. I wonder whether we should exclude Saturdays from the provision.

**The President:** Let me note the point.

**Dr Brian Curwain:** On the point of Saturdays, things may change. We know Government wishes to have surgeries open on Saturdays, and I do not think we should tie ourselves too rigidly at this stage. We are coming to the view that it is okay to be away for two hours. I am comfortable with this. I realise it is a compromise, for reasons which I will not describe now, but I think it is a necessary compromise. But are we saying anywhere that we do not anticipate that everyday, in any working week, or whatever period of time you choose, it is likely that a pharmacy will not have a pharmacist in it for 25 percent of the time or two hours? Is there a comment about that in this paper?

**Ms Priya Sejpal:** No, what we require and what is within current Council policy is that absence should be linked with need to adhere to professional requirements. So you should only be absent when having a rest break, or when undertaking professional services. Apologies, because there is a sentence missing from your paper which would be that the regulations should specify the need for the responsible pharmacist to justify their absence, but then you would have professional guidance to support what might be exemplified in terms of services. We have not specifically said that this should not be happening every day. The policy around this is absence per day, rather than per responsible pharmacist.

**Mrs Margaret Allan:** My question was answered when Dave came forward.

**Ms Priya Sejpal:** Just to clarify, the proposal here for minimum presence is that the regulations should not specify a percentage in regulations, but if that they were, we would have that 75 percent of the working day.

**The President:** Is that agreed, Council? **(Agreed)**

**Ms Priya Sejpal:** Taking absence from the other angle, Government propose a maximum period of absence of three hours. Our previous policy had stated that we believed pharmacists should only be absent for short periods of time, but we are now recommended by Law and Ethics Committee that a maximum absence of two hours to be permitted per working day.

**Mr Steve Churton:** I think what we need to make sure is that whatever absence of the pharmacist from the pharmacy we agree to, that absence is practical and productive. If you take into account many pharmacists might be travelling for half an hour to get to a point where they are providing their professional service, commuting time there and back is an hour, it only leaves them an hour to provide a professional service. We have to recognise there will be a push, I think, to make that time more productive. Therefore I would advocate we go with three hours.

**Mr Martin Astbury:** When we looked at it, to some extent we looked at it from the other angle. We felt how long would we actually be wanting a pharmacy to be running without a pharmacist. Therefore it was felt that if a longer period to travel and get to the place to offer this service was required, then at that stage you would probably want to get someone to come in and be the responsible pharmacist to enable them to do that. We felt that two hours was sufficient to be able to do what we felt was necessary, but for anything longer you would get someone else in as the responsible pharmacist.

**Mr Graham Phillips:** I made my points earlier on and I say those points should be addressed now regarding the two hour absence.

**Mr John Gentle:** Going back to the comments made before about whether this would become the norm in community pharmacies, that is where I have a real problem with this. You go back to the NPA slogan from a few years ago about *you can't ask a supermarket shelf what it recommends for your child's cough*. The point behind that slogan was that supermarkets do not have pharmacists and pharmacies do. I am seriously concerned that if this becomes -- **(Laughter)** Sorry. Frequently supermarkets *may* not.

**Mr Martin Astbury:** Can I ask you to use the example of a garage?

**Mr John Gentle:** A supermarket that does not have a pharmacist within it is the phrase I should have used. The point is that I am not in favour of a situation where pharmacies routinely operate without a pharmacist in

them. If this absence is going to be part of our recommendation, I would like us to assume that this is to be in urgent circumstances, *in extremis*, unusual circumstances or something that means that it will not become the norm. Because I have real concerns if community pharmacies the length and breadth of the country regularly open for a large percentage of their time without pharmacists in them.

**The President:** Any other comment?

**Professor Stephen Denyer:** I would like to observe that the pharmacy that is vacated by a responsible pharmacist will not be a Marie Celeste. There will be other professionals there who would be able to offer, I would suggest, a meaningful service to the community during that time but within constraints. Perhaps it is not quite as extreme as we envisage it.

**Mr Jonathan Buisson:** One of points the Department is trying to make with this legislation is that this is to cover things for quite a considerable period into the future into which we are not very good at gazing with our crystal balls, and that they want a bit of flexibility for the future. We are thinking of what is happening now in pharmacies and things may be different in the future and we may want this flexibility.

**Mr Graham Phillips:** I think I addressed the points earlier on, and there is no point in me reiterating them. My view is unchanged and I would like my disagreement recorded.

**The President:** Council, do you agree with the response before you?

**Mr John Gentle:** Can I clarify if we go through these points with a general eye, what exactly it means we are agreeing? For instance, if Graham or Steve raised a point, are these points going to be included, or are we agreeing this without those points? Are you asking people who have raised points to agree something?

**The President:** We are going section by section. At each point I am asking, does the Council approve the response? We are positively agreeing the responses rather than just concentrating on disagreements. There are some points which I have made which have been taken up in the guidance, which will be issued later on. There are other points which are made but there does not appear to be general support around the Council, and therefore they will not be taken up. But if the Council feels strongly that what is presented to them in the response is not what they want, then we will go to a vote and change. I am looking around the Council constantly to see if there is support for a particular point. I can understand that if you make a point and there is no support, then there will be disappointment. I understand that. That is why I allowed comments, so the individual has got a chance to take in other comments, before persisting in a particular way of thinking. If you still want to put it to a vote, I am very happy to do so. Do you want to put it to vote?

**Mr John Gentle:** Yes. It is the point about absence, which is covered in last two sections that I am particularly unhappy about.

**The President:** Can we take it one step at a time and we will put it to the Council to vote.

**Mr John Gentle:** President, if we put it to a vote, can we put it to named vote?

**The President:** I am very happy to do that, but first I would like Priya to reintroduce the item so everybody is aware what we are talking about, then we will take comments and then go to a vote.

**Mr John Gentle:** Can I point out that the request to put a named vote, this was originally confidential business and it has been moved to public business for obvious reasons. It seems rather silly then to hide the way Council members have voted. To put the vote into a public vote, as well as the discussion, seems to be commensurate with each other.

**The President:** We will come to that. Let us go step by step. Step one is reintroducing the item, so everybody is clear what we are talking about. Step two is comments from around the Council and step three is the vote. At that point, if you want a named vote, we will have to take a vote.

**Mr Martin Astbury:** On the process, I think Priya will reintroduce the motion, but I believe we have already had the discussion; the motion is there. I suggest, unless anyone has an amendment to propose, that we put that motion.

**The President:** I think it is very important. This is an important item and therefore I want everyone to know what they were voting for. I want absolutely no doubt in their minds. That is why I am asking for the item, because I know this is a controversial point and the profession will debate this at length. As soon as Priya has provided us with a hook, then we will carry on.

**Ms Priya Sejpal:** We started chapter 5 around absence, talking of the need to look at minimum presence within the pharmacy and maximum absence in relation to the working day of the pharmacy. It was agreed that the responsible pharmacist should be present in the pharmacy for substantially more than half the working day, and that if regulations were to specify this, then there should be 75 percent of the working day. I understand that was agreed. We then moved on to the maximum length of absence from the pharmacy of the responsible pharmacist. The proposal and recommendation from the Law and Ethics Committee is that this should be a maximum absence of two hours per working day.

**The President:** Ideally we would like pharmacists to be available to consult with the public at all times, but there are circumstances where the pharmacist needs to be off premises and that should be as minimal as possible.

**Professor Stephen Denyer:** I wanted to make the observation that we have set a working group to examine this. The reflections of the working group have undoubtedly had deep debate. What we are receiving is well articulated and built on lots of arguments. I am a little nervous if we determine to overthrow that good work without some cogent arguments put forward as to why we might dispute the proposals of two hours, 75 percent or whatever. Could I at least ask those who have a concern to be able to articulate very succinctly and successfully why there should be a concern?

**The President:** That is helpful. Doug, do you want to make a comment as Chairman of LEC?

**Mr Douglas Simpson:** I think I mentioned in my introduction that the Health Act was predicated on the pharmacist possibly being absent from the pharmacy for some time during the time the pharmacy is open. So if we are to vote against it now, it would be slightly ridiculous. The second point I would like to make is that it will not be compulsory to leave your pharmacy. **(Laughter)** You can, if you want to, stay there all the time. You can, as a pharmacy owner, insist that your pharmacists are present all the time. You can set up the system to suit you. Jonathan had it correct when he said we were trying to future-proof things. We do all manner of things. You can play a million tunes down a wire on to an Ipod, and that sort of thing -- I have not actually worked out how to use one myself yet! We have all sorts of possibilities of devices to help us with remote supervision in the future. We do not know what it is going to be like. We are trying to get away from the idea that you are going to have to be nailed to the dispensary bench all the time. We have had this debate once. It was decided one way and it would be ridiculous to go back on it now.

**Mrs Sue Kilby:** I would come back on what Doug has said, because I think my concern is the pressure that is going to be put on some of the members, because there seems to be some misunderstanding about this. I know several people working in community pharmacies for multiples at the present time where they have actually been told, "It's fine if you carry on and do all your services outside the pharmacy. You will be able to work outside the pharmacy, because the pharmacy can then be managed largely by the technicians." They have real concerns, because they do not feel happy about actually wanting to leave the pharmacy. They do not all have technicians. Some of them have dispensers and some do not, but they have real concerns about leaving their pharmacy. This is why I am saying we have to look and be thinking of the interests of those members, because they need to be put in a position where they do not feel as though they are being forced to do something which they feel is not right. That is why there are real problems in considering this. I am also very, very concerned about some of 100 hour pharmacies and whether there is adequate coverage in there. Likewise, there are problems with Saturday coverage in the area where I work, where there is not a pharmacist in some of the pharmacies on Saturdays in some of the multiples. So we do have big issues. It is looking at how can we manage it most effectively so our members are not put at risk, are not put under undue pressure to do things they do not feel comfortable doing. This is why there is so much debate around this point. It is looking at how we can cover everything. I heard what David said and I think his comments are very important about the short day. I also heard what Priya said. Okay, these things might be coming in the future. If they are, there is no reason why we cannot state it within this document at this present point in time, so we are flagging up what may be coming in the future around the two-pronged approach. Those are my thoughts and my comments.

**Ms Priya Sejpal:** In terms of looking at absence, I know there is no wish at all for patient safety to be compromised by having a pharmacist absent from the pharmacy, and we would not want to see ourselves in that situation. In terms of members being placed under pressure to leave the pharmacy, I think that is potentially a separate issue to this, in that it would need to be tackled separately and it is not a reason for absence to not being allowed. If that is something that is happening, it is something we need to look at through other avenues, such as the standards for pharmacists and pharmacy technicians in positions of authority, and looking at potentially having to strengthen those areas rather, than to maybe stop regulations to enable pharmacists that would like to leave the pharmacy to be able to do so, where they feel it is appropriate and does not compromise patient safety.

**The President:** This issue is important and quite emotional. Therefore, I am going to allow some extra time, because I would like to carry Council with me, so we have properly examined everything. But I would like to move to a vote as soon as possible.

**Mr Graham Phillips:** In terms of cogent argument, Stephen, I have been trying not to rehearse the arguments I made previously. You may not think they are cogent, but I do not think it is going to be helpful to Council for me to repeat what I said. I think those are cogent arguments. The only addition I would make is that in my pharmacies we have very well developed teams, including technicians at all levels who are absolutely superb and invaluable to our practice. If you were to speak to my technicians and ask them do they feel comfortable with operating a pharmacy for two hours in the absence of a pharmacist, I can guarantee you now that every single one of them would say no.

Doug, this is not about being tied to the dispensary bench, and I have never practised that way. I agree pharmacists tied to dispensary benches is a thing of the past, is Luddite and if we continue to practice on that basis, we negate almost all the value that we add. This is nothing to do with pharmacists being tied to dispensary benches or final checking or any of those Luddite things. This is about the fundamental value of having a pharmacist in the pharmacy, accessible to public need, to deal with whatever comes through the door -- and you never know what is going to come through the door; that is the joy of it, and it is a joy to me. You never know whether that intervention will be around something of huge significance or simply public health. It is the value of having that accessibility which we lose at our peril.

**The President:** Graham, I thought you were going to give us some alternative wording, but you have missed your chance.

**Mr Gerald Alexander:** I had the luxury, and I will say it again, to have sat on the Health Act Working Group, and I understand the points. I pay tribute to my colleagues. I have had the luxury of sitting on Law and Ethics under the chairmanship of Doug Simpson. Just to reinforce what Doug has said, and what Stephen has said, what is the point in going through the process, if Council is going to overturn something? I am not happy about that. So I fully support the workings of the Law and Ethics Group. What I want to say is that there seems to be a gross misunderstanding. The discussion that we are actually hinging upon here is moving away from the responsible pharmacist issue on to supervision, and we are not talking about supervision today. Another consultation will take place soon. We should understand there is a fundamental difference between supervision and the role of the responsible pharmacist. So unfortunately the ground is shifting and there seems to be a misunderstanding. The misunderstanding is that this legislation has been brought in to fix problem that personal control had. The problem of personal control was if a pharmacist was absent from a pharmacy, it was impossible for the pharmacy to sell a GSL medicine. That is it basically, basically. What is this guidance going to produce? It will mean that GSL medicines will be able to be sold in the absence of a pharmacist. It does not mean that we are going to sell P medicines. It does not mean that we are going to be dispensing POMs or dispensing or supplying. I think it is for the next consultation. When the next consultation takes place, we will be looking at SOPs that will define what is possible in the absence of a pharmacist. I think, as we have done here, we have tried to set the parameters of what we think is reasonable, in terms of what a pharmacist should be absent for a reasonable period and what could possibly take place in his absence or her absence. Hence I think what we should do is support the recommendations of the Law and Ethics Committee, which have been informed by the Health Act Working Group.

From a professional body point of view, the membership of the Royal Pharmaceutical Society should be grateful to the fact that this organisation spent countless hours examining all the possibilities within the Health Act. As Jane said earlier, we have examined individual layers. Therefore we have come to reasonable recommendations, I do not think honestly we need, John, to start taking votes on these issues.

I think if you are going to push it, I think you should, but I do not think it is that important. I think the major debate is going to come when the consultation is over supervision. This is defining the role of an individual who is in control of a pharmacy, and I think that is what we should understand.

**The President:** Thank you. What I would say about recommendations coming from the working groups or committees is that they are recommendations, carefully prepared recommendations. The Council is accountable to the membership and to Parliament. So it can accept, amend or delete anything, within reason. I think Stephen earlier on made a very good clear picture of what is needed to change the recommendation. There should be cogent argument against the recommendation for us to change our minds. I think that is what we are looking for. We have a number people wanting to speak and we have coffee waiting outside. I will take four more comments and put it to a vote, if necessary, but I hope it will not be.

**Professor Bob Michell:** I may have misunderstood this, because I certainly found it surprising. I thought this whole discussion hinged on the fact that the responsible pharmacist was being responsible in feeling that he or she could justify being away for two hours. But if I understood what Sue Kilby said correctly, I think she was implying that the responsible pharmacist could be dragooned into being absent against their judgement. That is something I certainly had not thought about. If it is true, it is deeply disturbing and it raises all sorts of issues. Whilst I respect the view that if two other groups have looked at this in huge detail, were those groups aware of the possibility of a responsible pharmacist being pressurised to leave the pharmacy against their judgement?

**Mr Martin Astbury:** Since May 2004, when the policy to allow absence for the three reasons that we said (emergencies, rest breaks and professional services) was put in place, certainly at that stage I put a declaration that I did not support that policy going forward. Since then, I have moved a long way, as we have developed policies to get to where we are now. The reason I have been able to move is because we have put lots of safeguards in place, lots of planks, to ensure that absence cannot be abused.

I have said right from the start that the important thing is that the regulations we put forward, or are proposing, are all taken en masse. Because if bits and bobs are taken, some of loopholes that I believe we have closed off may exist and therefore some of my concerns will come back. I hope that certainly what we have put together is balanced. The part of the justifiable is very important -- you have to be able justify it. For that reason, we got into the records and we have stated that you must state in records your reason for absence. At the moment, that is not Government policy. So we will be pushing very hard (and I mentioned this at Public Affairs the other day) and will be lobbying. I see it as a vital plank to make sure that the reason for absence is down, that you are justifying the absence and that it is being recorded. That is one part of the plank. Another part of the plank, which came from Law and Ethics, was the part relating to the pharmacists in positions of authority. That was a very important document which was put in place under the Code of Ethics. At some stage I am sure that section will be tested, where people, whether it be that someone is accused, as an area manager or a superintendent, of putting undue pressure on a pharmacist. That part of the Code of Ethics will be tested and somebody will be brought forward under that. I believe there are certainly powers under that Code of Ethics whereby, if a pharmacist does have undue pressure put on them, they should be able to fall back on those. I know it is still very difficult in practice. We have tried putting these things in place in order to stop it being abused. Do not get me wrong; I have been worried all along and I have moved a long way.

**Mr John Gentle:** As Stephen Denyer used to correct my microbiology essays at some time previously in a former life, I am used to him not regarding my arguments as cogent, but I will give it a go anyway. **(Laughter)** It seems to me that one of the strengths of community pharmacy is the ready availability of the scientifically trained health care professional on the high street, available to give advice to the public without fear or favour and without a prior appointment. That is absolutely vital and it is an important strength of the profession. I think the public have an expectation that that will be the case as well. I think the public will find it difficult to understand, when they go into pharmacies and they cannot get the services that they recommend, as do the Medicines Management Team in my PCT in Shropshire. They are increasingly concerned that when they agree a service with a community pharmacy, train and accredit the pharmacist to provide that, on days off, on absences and holidays, nobody else can be found to provide that, because there is not a replacement pharmacist who is accredited. There are several reasons why that accredited pharmacist being absent from that pharmacy, for whatever reason, will be unable to provide a service that the PCT pay for, that the PCT demand and that the PCT trained and will be simply unable to fulfil public expectations.

It seems to me that there will always be exceptions to the rule. So I am not in principle against a pharmacist leaving the pharmacy, as this paper says. What I am against is that practice becoming the norm.

I fear that it should not become the norm and widespread policy that pharmacies in the UK can open without a pharmacist present, and therefore a large proportion of their services will be unavailable. I feel it is disingenuous of Doug to make comments about being nailed to the dispensing bench, because in my pharmacy and in Graham's and I am sure in hundreds and maybe thousands of others the land over, those days are long gone. Pharmacists frequently appear on counters, get out from the dispensing bench and talk to customers and talk to patients. That is what they should be doing using expert clinical knowledge and counselling. That is what they are paid for under the new contract in England. I know it is different in Scotland.

**Mr Douglas Simpson:** It was a figure of speech.

**Mr John Gentle:** I meant Dave, not Doug. Dave voiced comments that the PSNC do not negotiate the contract in Scotland, so I just thought I would get my devolution bit in. It seems to me that these contractual obligations will be unable to be fulfilled. It has been said several times that this is future-proofing legislation. The future might be in five, ten or twenty years' time. I am concerned with this piece of legislation about the now. It may well be in the future this legislation will enable us to fulfil what we desire for the 2020 consultation, but that is a long way off. In the intervening time, I do not want to see legislation put in place that will cause the profession more problems than it will solve. In terms of Saturdays, I am not sure whether the Health Act Working Group or the Law and Ethics Group considered treating Saturdays different, and did consider weekday and weekend legislation, based on the fact that doctors surgeries are closed. As Brian pointed out, the Government may want them to open again. Well, it is the same Government that let them close in the first place, so I am not confident that will happen in the next five minutes. Again, we get the lag time between that legislation changing and the service provision in the meantime.

Finally on a point of process, if it is true that working parties consider everything and working parties are the be all and end all, and we should simply lay down and receive the legislation without revision, there is no point in Council meeting at all. We are here to revise that legislation on behalf of those who have elected us to do that. I served on working parties and on committees, and I appreciate the work that goes in, particularly on behalf of the staff, and Priya has obviously spent a lot of time with her colleagues on this. But it does not preclude any Council member here objecting to something that is there. It is a perfectly legitimate exercise for a Council member with a heartfelt plea, as I have and as I feel Graham has and one or two others around the table, to put this to the test. I do not want my concerns to be wiped away in a general aye. My final point and cogent argument is that I do not want the tower of pharmacy's achievements to be built higher and higher by losing the foundation stones.

**Mrs Lorna Jacobs:** I want to make my point succinctly. Professor Denyer raised the point that we need cogent arguments to go against the recommendations of two groups that have worked very hard and looked at this. They have become expert in a way that Council members, as a whole, cannot be. I think we should concentrate on the fact that the cogent reasons should, in general, be cogent reasons for thinking that the process that has been undertaken has not been satisfactory for a particular reason. I think the point that John raised about Saturdays, for example; has that group looked at is Saturday a special case? If the groups have looked at that, then the process has been appropriate. If the process has been appropriate, then we should be prepared to go with the recommendations, unless there is a very good reason to think the process in any particular aspect has been flawed; that an issue has not been considered; that experts for a particular view have not been considered. We should be very careful, otherwise people will not bother to take the working group seriously.

**The President:** I want to move away from the process. I think people have said what they need to say. Can we come back to the substantial point in front of us?

**Ms Marcia Saunders:** I think this has been a really fascinating debate and I think the working group has achieved a really very delicate balance between enhancing professionalism and safeguarding the public. It is quite a remarkable achievement. I think it is a very, very good report. I would certainly support Sue's suggestion that it be produced in some more digestible manner, as I think it is a good example of what the Council can do. I am very grateful to Gerald for the clarification that he made between supervision and responsibility, because that will remove any lingering doubts that I have. I really want to say thank you to Doug and Martin and the others. I think it is an excellent piece of work.

**The President:** We will have a vote, and if people want a named vote, we will have one.

**Mr Martin Astbury:** I do not know if this allays any of your fears. I pass this to Priya as something that we

would probably use to actually substantiate why we picked the two hours. I lifted it directly from the introduction. In the introduction it states: *"It is of paramount importance that patient safety is maintained. A unique selling point of pharmacy is that members of the public can seek expert advice about their medicines and health without the need for an appointment. It would be of concern to the Royal Pharmaceutical Society of Great Britain if this important quality of service were to be jeopardised by a pharmacy operating for more than two hours in a given day without the presence of responsible pharmacist."* I do not know if that helps at all.

**The President:** We will move to a vote now. Is there a proposer and a seconder for a named vote?

**Mr John Gentle:** This was put into public business rather than private for the reason that I would like it to be a named vote rather than an ordinary vote.

**Mrs Dorothy Drury:** I will second it.

**The President:** All those in favour of the proposal to have a named vote please show. **(Pause)**

**Ms Averil Ridgway:** *"On a motion of a member of the Council duly seconded names of members of the Council voting for and against a recommendation or resolution and those abstaining from voting will be recorded."* So it does not need a vote.

**The President:** All those in favour of the proposal to chapter 5.

**Ms Priya Sejpal:** The proposal for the maximum period of absence of two hours per working day.

**The President:** All those in favour. **(Vote taken: Carried)** We will take a break and return in 15 minutes.

**Professor Stephen Denyer:** If I can say, six and-a-half out of ten for John. That wasn't bad! **(Laughter)**

**(After a short break)**

**The President:** We are back in public business. Priya, can you take us through the paper you have produced for us?

**Ms Priya Sejpal:** Moving back to absence from the pharmacy by the responsible pharmacist, we are at page 21. One of the proposals in the Department of Health's consultation was, as we talked of earlier, the minimum presence of 50 percent and the maximum absence. There was a proposal that the length of absence could be increased, if there was the presence of a second pharmacist in the pharmacy. The Working Group and Law and Ethics Committee considered this and have recommended that where the responsible pharmacist is absent for more than the regulations allow (i.e. two hours), then the second pharmacist should become the responsible pharmacist. **(Agreed)**

We go to a series of conditions that also need to be met in relation to absence. The proposal is for the regulations to specify that the responsible pharmacist must be able to return to the pharmacy with reasonable promptness. Our current policy states pharmacists should be able to return without undue delay. The recommendation is to change the wording in line with the Department of Health's proposal. **(Agreed)**

There is a proposal for the regulations to require the responsible pharmacist to be readily contactable by pharmacy staff during periods of absence, but that the regulations should not specify how to remain contactable, and that this would be better placed in guidance. **(Agreed)**

Finally there is a proposal that if the responsible pharmacist is unable to maintain contact, they need to arrange for advice to be provided by another pharmacist. **(Agreed)**

Finally the Law and Ethics Committee have recommended that arrangements for advice have to be made in advance.

**Mr Graham Phillips:** I do not disagree with this in principle, but I am thinking about practicality. Let us suppose the responsible pharmacist is absent and, for whatever reason, delayed by a flat battery or whatever else. This is an absolute in circumstances where you may not be able to be able to guarantee it. Should there be a degree of flexibility to take into account life?

**Ms Priya Sejpal:** It could be that that is not in regulation. We do not have it currently worded in the regulations.

**Mr Graham Phillips:** I would just nuance the sentence to say “arrangements for another pharmacist must be made in advance wherever possible,” or something like that.

**Mr David Pruce:** If I may comment. The situation that I think Graham is suggesting is covered by a different mechanism whereby a pharmacist may provide cover. What we are talking about here is a pharmacist providing advice when a responsible pharmacist knows he will be uncontactable. There are provisions elsewhere for emergencies.

**Mr Martin Astbury:** On 22 did you put the recommendation that reasonable promptness should not be defined?

**Ms Priya Sejpal:** We are also recommending that the regulations should not define returning with reasonable promptness, and that this would be better advised on in guidance. **(Agreed)**

Finally on absence, the Law and Ethics Committee are recommending that how the responsible pharmacist is to arrange for another pharmacist to provide advice should be set out in guidance rather than regulation. **(Agreed)**

Chapter 6 goes on to look at the qualifications and experience needed to be the responsible pharmacist. There are a number proposals from the Law and Ethics Committee. If I take you to some of what has been discussed in the past and what was put forward to the Department, there are a number of ways of looking at this. One is that everybody should be able to be a responsible pharmacist on day one of joining the register. There were proposals put forward over and above undergraduate and pre-registration year. There was a need, anywhere between six months and five years plus, of training or competencies needed to be responsible pharmacists. One of the third views put across in consultation was all pharmacists should be able to be the responsible pharmacist at the point of joining the register, but there might be extra competencies required in order to be absent from the pharmacy, or responsible for more than one pharmacy.

**Mr Gerald Alexander:** Just to reinforce this, so everybody is under no illusion what this means, this is basically a new point, that in order to be absent, you have to have gone through this competency-based assessment. In other words, you are all capable of being responsible pharmacists, but you may decide, because you are not up to a certain standard, that you should not be absent. Therefore you could still be a responsible pharmacist, but you would not be able to be absent. This is slightly new and there is a nuance here that needs to be explained.

**The President:** I will take some comments then, Priya, if you take them at the end.

**Mr Graham Phillips:** Three points. On the last two paragraphs on page 24 it says: “*The Society believes that as currently a newly qualified pharmacist is competent to be in sole charge of the pharmacy,*” which is the current position. We could hardly say otherwise, because the ramifications would be severe.

That said, there is a debate around this. We have to recognise there is a debate around *is that right?* Certainly in my own experience of taking pre-regers and newly qualified pharmacists, I am increasingly anxious about it, because the practice of pharmacy has moved on so rapidly in the last ten years or so. I would like to flag up that there is a debate to be had here, and unless we address that debate, one does not want to undermine public confidence in the profession. There is real issue there and it does not help us to sweep the debate under the carpet. It then talks about leadership and management consequences. I think that is crucial and that is part of the whole education debate.

We have to be honest and say those competencies are not currently within the undergraduate syllabus. Some schools of pharmacy do a great deal, some do rather less and some do very little indeed on that. But we have to recognise that is fine; going forward you can prepare that, but that will take some years. We still have the existing profession, never having had those competencies, which would be great if we had a deanery structure or some equivalent of what medicine has in terms of getting people up to speed, but we do not. There is a big debate here, not simply about the whole of the undergraduate course, but the whole of CPD and revalidation going forward.

I think these are important points we need to make, because if we lose that, it will be very hard to deliver.

My third point is on the middle of page 25, which is an unconnected point. It says that the Society strongly opposes changes in qualifications that would lead to tiered levels of pharmacist, but goes on to support annotating the register. Surely by doing that, you are creating tiers of pharmacists. I am unclear what the differences are.

**Mr Jonathan Buisson:** I will echo Graham's last point, which is that all pharmacists are equally responsible, but some will have a certificate to say that they are more responsible than others, if we go through with this. The danger is that you are dividing sheep from goats. The practical difficulties of having a certificate of competence should not be underestimated. If we look at what has happened with MURs, which in effect needs a certificate to perform, this has not been universally adopted and took a considerable amount of time to bring in. We need to be careful of the dangers of the amount of work in bringing this in.

**The President:** At this stage, the only area where we have agreed annotation is prescribing pharmacists. We have not extended it beyond that. So far as I am aware, there are no plans to extend it anywhere else.

**Dr Sue Ambler, Acting Director, Education & Registration:** We are trying to pick up and flag that when we come to talk about supervision, and are referring to pharmacists leaving for protracted periods of time and the full business of pharmacy will be potentially going on in their absence, it is a very different set of circumstances to the one we are talking of here in relation to absences whilst only supplying GSL medicines. So we are trying to reserve our position for the future. When it comes to the supervision and the second batch of regulations, if we feel it is, and all the evidence in relation to risk is that that is a difference, we may at that point wish to put down a notation on the register. Yes, you are right; annotation would be something for the regulator. Whether the Society or the General Pharmaceutical Council would take it lightly if it was a patient safety issue; it would be a very different set of issues, and not something because it relies on having post registration experience. You could build it in, even if we had all the placements we wanted to. You would have to have experience. It is like becoming a surgeon. It is another level up from the point of registration and we would seriously have to consider it. We are merely flagging it up at this point. We are not saying it is to be a responsible pharmacist within the context of these regulations.

**Mr John Gentle:** I am a bit concerned about the practicalities of giving competency assessments to all these pharmacists. If there are twelve and-a-half thousand community pharmacies, give or take a few, we are going to need twelve and a half thousand certified competent pharmacists from day one of these proposals. I am worried how that is going to work out.

John recently made the comment about MUR and there is a good analogy with MUR training. What worries me is the way it was handled in England. Talking to Frank Owens earlier on today about the way that postgraduate education happens in Scotland, where it is all within the central control of NES, I think they have made a better job of it. I think if the Society can control these competency assessments and it is done through the Society, rather than given to a whole multiplicity of providers, although the quantity needed will cause a problem and maybe we will need a multiplicity of providers to allow this pragmatically to work.

There is one other point. In paragraph 24 of 33, it talks of: *"The RPSGB proposes that all pharmacists should be capable of becoming the responsible pharmacist at the point of joining the register."* Then the very top line of page 25 suggests *"The RPSGB does not believe these competencies can be acquired by education alone, but instead experience is fundamental."* It seems to me there is a contrast there, and there is a problem, because if you need experience to get these competencies, how can you be capable of doing it at the point of joining the register?

**The President:** We will come back to that point.

**Mr John Hanlon:** I think I know the answer, and I know this is a very important issue for pharmacists and for pharmacy, but I just ask the question. The points that have been raised around the table, were they raised with you prior to the meeting?

**Ms Priya Sejpal:** Not since the emails.

**Mr John Hanlon:** This is a perennial here. There are 30 people around the table. I am not saying these points are not important; they are important.

No-one is trying to stifle debate, but if you reflect on some of the points that have been made here, they could have been cleared up prior to today. It is not fair on the Council agenda, or on Council staff, that these rabbits keep getting pulled out of the hat. You, President, say it every time when the papers go out: "If you have points, speak to the lead staff member before the meeting." Every single time I am raising it at every single meeting. It never happens. Seriously, I am pleading with members of Council. Please reflect how you are operating. We will not get through the business if you continue like this.

**The President:** Thank you, John. It is a timely reminder at a crucial time. Thank you.

**Professor Stephen Denyer:** I think I am courageous to follow that. In fact, if I can reassure John, actually listening to one or two comments, which perhaps should not have been said, has helped me focus on a point or two I would like to make. It is a difficult balance, is it not, but I am going to say a couple of things, John. I feel uncomfortable as a head of school that graduates that come from school and go through registration take responsibility of sole charge. I am glad we will address that at a later stage. I feel uncomfortable listening to the discussions about competency to become a responsible pharmacist, because I think it is difficult to define the competencies. It will be difficult to test the competencies. It will be difficult to test them across a large body of practitioners. I think what we are talking about is the confidence that comes from experience that makes someone more likely to be able to exercise the role of responsible pharmacist. Perhaps if we are going to have any reflections on the document which will change or embellish it, I think we might argue that a period of experience, which does not need an annotation on the register, might suffice for the role of responsible pharmacist.

**The President:** A number points have been raised and we will try clear them one by one.

**Ms Priya Sejpal:** When we looked at qualifications and experience, if I read to you the original Council policy: *"Recognition of the requirements of the Code for pharmacists to work within their competence. There should not be currently any further qualifications required in order for a pharmacist to undertake the role of the responsible pharmacist. Pharmacists should be provided with training and support to be responsible pharmacist during their undergraduate training and pre-registration year, but there may be a need for a competency-based assessment."*

The proposals being put forward to you at the moment are that a pharmacist at the point of joining the register can secure the safe and effective running of the pharmacy, deal with the sale and supply of medicines, contractual obligations, standard operating systems etc., but there are extra competencies that are required to be absent or being responsible for more than one pharmacy. We have not stipulated in this response a specific time period. In fact the response strongly opposes a time period of six months or a year with the concern potentially that that then becomes all someone will think about is "in six months I can do X," and would then move away from the need to look at what competencies they need. The response does not wish to see an examination either, because that can also tend to detract from the competencies that might be required in order to be absent or be responsible for more than one pharmacy. In terms of the annotation to the register, if the Council were to agree that there were extra competencies required to be absent, or to be responsible for more than one pharmacy, the only way -- not the only way, but I would struggle to see how we could advise members of the public or employers of the difference between somebody that can be absent or somebody that cannot. Therefore, that would lead to annotation of the register. I do not know if I have addressed all points there. I am happy for you to come back to me.

**Mr Douglas Simpson:** These are matters of opinion. It is vital we get Council's opinion on all these issues. I would hate to think that 30 people will phone Priya and ask for changes to be made to the document as agreed by the Law and Ethics Committee. I would not want to it happen, as it would put a tremendous amount of work on the office.

**The President:** I just want to focus on the paper.

**Mr Gerald Alexander:** I am trying to be helpful. What I said before, and even Stephen did not quite take the nuance, is that no-one is being stopped from becoming a responsible pharmacist -- no-one. So on day one, you become a responsible pharmacist. But what we are saying is within a quality framework, which we are trying to address to protect the public, if a pharmacist were to be absent who is a responsible pharmacist, it probably would not be appropriate, day one or day two, to leave the pharmacy.

That is really all we are saying. We are saying if somebody becomes a responsible pharmacist very early in their career, then it seems reasonable they build up a certain level of experience in running that pharmacy before they leave it, even for the short period of time we have recommended. Hence this is a new point. If we understand that, I do not think it is too difficult. We are not saying we are going to make it impossible to become a responsible pharmacist with who can leave a pharmacy. It is something that will evolve over a period of time. It is trying to be helpful to the public. It is trying to raise standards within the profession and to meet a high standard within the framework of the Health Bill.

There is one other point that I wanted to make, as I thought it was very important. On page 9/33, it is only a drafting point and I was going to get to it at some point. The issue that the RPSGB believes that a pharmacist must only be responsible for one pharmacy at one time is a central issue that needs to be highlighted in this document. It is on the fourth paragraph of page 9 in our representation. What I would like to say is that that is lifted, and it should be lifted and highlighted, because it is central to our response, as is possibly the issue here, because of the misunderstandings that are taking place, and there are significant misunderstandings within the profession. There are areas here where certain levels of explanation to the profession are needed, and as a professional body that is what we are obliged to do: provide information to the profession. As we go forward, we are going to get blamed for all sorts of things by the profession because individuals do not understand what is being done. I think this is a particular point, as is the fact that one pharmacist must be responsible for only one pharmacy at a time. Those are central points of this response.

**The President:** I think you have highlighted a very important point. The document that is going to be prepared, we will try to include that point. As I say, I am happy to give you as much time as you want, but please, once we have agreed, do not try and reopen debates at another point in the document.

**Mr Martin Astbury:** I have to check if it is here, I know Sue mentioned that certainly at the moment no-one is saying in order for the absence to take place at this moment in time, where only GSLs would be able to be sold, no-one is saying that any new extra competencies would be required in order for that to happen. So at this stage we could go forward, as we are saying, that no new competencies are required; everyone is a responsible pharmacist and everyone is an equal responsible pharmacist – not some more equal than others, as I think Jonathan was alluding to. We have had research done which showed quite clearly that the new part of the responsible pharmacist is the absence part. It is clearly shown that there are extra additional competencies in order for the pharmacist to be absent, when extra things are happening around supervision and delegation and so on and so forth, which will come in the next tranche. So we need to reserve our position here, that we can, if necessary, annotate the register, and that in order to be absent you will need to have these extra competencies. So I urge you to support this. If I can also say, so far as process was concerned, the research was done and the education department then fed directly into Law and Ethics. I am obviously the Chairman of the Health Act working group and I would support fully these recommendations by the Law and Ethics Committee, but we were not able, because of the time process, to take it through the Health Act Working Group.

**Mr Graham Phillips:** I am still confused on one point, which is my third point I raised on the middle two paragraphs on page 25: *“The Society strongly opposes any change in qualifications.”* Does it and why does it? How does that relate to annotation of the register, which is to some extent creating two tiers?

**The President:** I thought Sue covered that point adequately earlier on. You can have a word with Sue later on. Council, can I ask you to accept the recommendation? **(Agreed)**

**Ms Priya Sejpal:** Following on from that, there were proposals for minimum periods of experience following registration, but obviously based on these conversations we are proposing a competency based assessment for only absence and being responsible for more than one pharmacy. There were then proposals around whether or not there were minimum periods of experience required for moving sectors -- say, for example, moving from the hospital sector into community pharmacy or vice versa. Law and Ethics Committee are recommending there should not be a specific time period or sector-based period before pharmacists can either return to practice or change sector. It was felt that the requirements of the Code to work within your competencies and to develop your skills and knowledge were sufficient, and that there was no need to stipulate any further requirements in regulations.

**The President:** Surely we can support this, can we not? **(Agreed)**

**Ms Priya Sejpal:** Moving to chapter 7, it discusses the concept of whether or not a responsible pharmacist can be responsible for more than one pharmacy. The Government have advised that this would only be in exceptional circumstances and have set out in the consultation two exceptional circumstances. The first is a temporary pharmacy and whether or not that would be a situation where a responsible pharmacist could be responsible for more than one pharmacy. The second is the automated machine. The Law and Ethics Committee recommend temporary pharmacists, and the example in the consultation was a pharmacy at a festival for example. The Law and Ethics Committee are recommending that temporary pharmacists should not form an exceptional circumstances where a responsible pharmacist can be responsible for more than one pharmacy. We already have procedures in place within our registration department for processing applications for temporary pharmacies, and it was not felt there was anything that was wrong with that situation. Therefore a temporary pharmacy should not be included as an exceptional circumstances.

**The President:** Is that agreed? **(Agreed)**

**Ms Priya Sejpal:** We currently have a policy set out around being responsible for more than one pharmacy. That policy is that there should only be one responsible pharmacist responsible for each pharmacy, and that a responsible pharmacist should not be responsible for more than one pharmacy. In current Council policy we did say if it were to go ahead in other fashion, this would only be for an automated machine or exceptional circumstances. That is just to reiterate our current policy. The consultation went on to look at certain specified conditions that would need to be met in order for a responsible pharmacist to be responsible for more than one pharmacy. It was when we started to look at these conditions that the Law and Ethics Committee considered that the automated machine should be thought of as separate to an exceptional circumstance. So the first proposal is that you would consider the automated machine separately to truly exceptional circumstances. **(Agreed)**

One of the recommendations put forward in the proposal is that the regulations should specify a requirement for the responsible pharmacist to exercise their statutory duty. The Law and Ethics Committee are recommending that the regulations should not specify a requirement for a responsible pharmacist to exercise their statutory duty. It was felt that since the responsible pharmacist's statutory duties are clearly set out in the Health Act, duplication in the regulations was not needed. **(Agreed)**

There were proposals around the staff that should be employed in the pharmacy. The Law and Ethics Committee are recommending that regulations should not specify what support staff should be available in the pharmacy. To give some background, in thinking about when a responsible pharmacist could be responsible for more than one pharmacy, when we looked at truly exceptional circumstances, the more recent floodings sprang to mind. There was a concern that by stipulating regulations of specific support staff that had to be present you would not necessarily be able to equip or to be able to serve the public in those circumstances, because your regulations would be preventing you from doing so.

**Mr Stephen Acres:** I apologise for not raising it before the meeting today, but it seems to fly in the face of patient safety that we should not leave somebody accountable within the department. I would perhaps advise that that should be a registered technician.

**Mr Martin Astbury:** I was actually supporting it, because the recommendation that the Health Act working group put forward was actually that a registered technician was present. One of the reasons behind that is even if we agree the Law and Ethics Committee's suggestion, the only thing that could actually take place under our current policies on what we are suggesting going forward for supervision, if there was neither a registered technician or a pharmacist present, would be the sale of GSLs anyway, so there should not be much going on in the pharmacy anyway under our current policies. For that reason, the Health Act Working Group felt there should be a registered person with accountability present.

**The President:** Doug, your Committee made changes following recommendations from the working group. Can you explain the reasons please?

**Mr Douglas Simpson:** Priya will tell me if I am wrong, but we are talking about emergency situations here. It would be very frustrating if a condition were set on meeting in an emergency which was very hard to achieve at the present time, because the number of registered technicians is not particularly high at the present time.

When there are more generally available, and the register was bigger, it would be appropriate to make that sort of condition. But it would be extremely frustrating in a dire emergency that you are prevented from meeting the needs of that emergency. Just pure practical issues at the present time, but not necessarily a future requirement.

**Mrs Lesley Morgan:** I take on board what Doug says. I was party to a lot of discussion in the working group, so I would support what the working group said, that we want a registered technician. There are people who are not registered or qualified in any way. Are they competent to take responsibility and are they going to be put under pressure? That gives added patient safety issues. I take on board what Doug says, so I am not sure if we could find some wording that would help us. If we say other people can do it, can they do it all the time? I wonder if we are then opening up floodgates.

**Mr David Pruce:** I think we have to differentiate between supervision and the responsible pharmacist. Here we are talking about a pharmacist taking responsibility for two pharmacies. Under the current regulations that pharmacist, if he was based in pharmacy A, would be able to provide a full pharmaceutical service. While in pharmacy A, pharmacy B would only be able to sell GSL medicines, while the pharmacist in pharmacy A was taking responsibility. Pharmacist A would be able to go to pharmacy B during his absence from pharmacy A to undertake things like dispensing urgent prescriptions, methadone prescriptions, etcetera. Essentially, we are looking at an emergency situation where a pharmacist is providing cover to two, but a limited service. When supervision requirements come in, that is the stage at which there may be a registered technician supervising activity in the second pharmacy and is able to sell P medicines and supply POMs. That is a later issue though. That was part of the thinking around the Law and Ethics decision to not put in any requirements for support staff in the second pharmacy. The activity would be very limited until supervision was addressed. For the sale of GSL medicines, we have already said in our response, a pharmacist may be absent for two hours and GSL sales continue. So the thinking was there was very little difference there, so far as the second pharmacy is concerned. That is how the thinking went.

**The President:** With that explanation, would you accept the recommendation? **(Agreed)** There were then questions about whether or not there should be a time period for which a pharmacist can be responsible for more than one pharmacy. Our current Council policy states that there should not be a specific time limit on how long a responsible pharmacist can be responsible for more than one pharmacy, but this should not be for prolonged periods of time. Law and Ethics Committee are recommending that the time period for which a responsible pharmacist can be responsible for more than one pharmacy should be in line with the time limits around absence. **(Agreed)**

Notification to the Royal Pharmaceutical Society of Great Britain is in line with current Council policy and finally the number pharmacies for which a pharmacist can be responsible for is in line with current Council policy. **(Agreed)**

**Mr Martin Astbury:** I mentioned before about the Public Affairs Planning Group the other day. This is another one of our policies where we differ from the Government, where we clearly stipulated what our policy is. Therefore again, we will be lobbying hard on this one to try and get the Department of Health to follow the policies that we have got.

**Ms Priya Sejjal:** Moving on, chapter 8 is around supervision by the responsible pharmacist in a pharmacy where he or she is not the responsible pharmacist. The response here is in line with current Council policy. **(Agreed)**

The final chapter is asking questions around the amount of time required to prepare for the changes that are outlined in the consultation. We have obviously highlighted that the length of time would depend on what changes are decided to be brought in, but that a recommendation of a 12 month period would be necessary to prepare for the introduction of these regulations. **(Agreed)**

We have recommended a phased approach in terms of the introductions of the responsible pharmacist in supervision requirements. My understanding of the thinking here is that by setting the quality framework around pharmacy procedures, records and introducing some areas of absence initially will enable the profession to become accustomed to those requirements before we the next draft of changes are introduced. **(Agreed)**

Finally the Government welcomed views on the need for guidance to support the introduction of these regulations. The Law and Ethics Committee are recommending that there is a need for guidance, which should be provided by the Society. We have stated that we envisage that any further professional guidance, whether mandatory or good practice, should be provided by the RPSGB in the form of standards and guidance documents and that that we welcome the opportunity to work closely with the Department of Health and other pharmacy bodies in drafting the content of any such documents. **(Agreed)**

**The President:** Before you go, Priya, can I say that in producing this document there was input from many people over 18 months, as I said earlier on. I would like to take the opportunity to publicly thank all those who contributed to the exercise, also those who were on the working group and the Law and Ethics Committee, and in particular to Martin, who chaired the working group, and Doug who chaired Law and Ethics Committee. A lot of hard work was done by dedicated staff who took the utmost care to make sure all areas were properly examined and supported the two chairmen and me here today. I would like to say particular thanks to Priya and Lynsey.

**Mrs Sue Kilby:** This will not come as any surprise to a lot of people around the table. What I really want is a very clear communication strategy around this, and communicating it in terms that the various stakeholders understand so that the messages are sent out very clearly, maybe to owners and to multiples, as to what it actually means, but also to members as well. This cannot be done just as a one-off exercise, but needs to be done repeatedly. It needs to link with everything else we are doing. There needs to be a full strategy on that. We need to look at different channels of communication to get the messages out. We are not just talking only to community pharmacy, but to hospital pharmacy and to primary care as well, and they are overlooked, because they do not read the C&D very often. We need to use all channels of communication and formats.

**The President:** I think your message, Sue, is loud and clear and it needs to be taken on board. I will invite Jeremy to comment.

**Chief Executive & Registrar:** It is a good point. This is not a one-hit-wonder. This is not one message. This has got to be a continual message so that the profession really understands what is going on, and they can mature their understanding to that as we move towards implementation. A rather cheeky request to our colleagues from the press over there, because we are in public business, that anything the press want to pick up from this discussion to reinforce those messages would be greatly welcomed.

**The President:** You mentioned a strategy. We will clarify the communication plan and how we are going to engage with the members sometime early in the New Year. We will come back to you with that.

**Mr Gerald Alexander:** I would like to talk to the press in a way. I think you need to know the amount of resources we have applied to our deliberations over 18 months, the number of hours and the number of individuals. This is what a professional body does. In this case, we are actually dealing with regulatory matters. We are giving our response to the Department of Health in order that they can write regulations, but as we go forward a professional body will need to advise a General Pharmaceutical Council in the way that we have looked at and examined these issues. I think the profession needs to know exactly what we do as a professional body, otherwise they will say, "It is just the Council making up rules, rubber-stamping things." That is not how we work. We put a lot of effort in. It has been a mammoth task. As long as the profession know that, then perhaps the way we move forward with the profession and professional body will be good for everybody, but I think they need to know it.

**The President:** Although this is about regulatory affairs, this is about making Britain the safest place in world to receive medicines. I would like to thank everybody for their efforts.

[On the recommendation of the Law & Ethics Committee, Council **agreed** the following.

*Procedures*

- i. that minimum procedures must include: record keeping, arrangements when the responsible pharmacist is absent, arrangements for recording amendments to the procedures, arrangements for responding to complaints relating to the sale and supply of medicines, arrangements for responding to adverse incidents relating to the sale and supply of medicines and arrangements for the transfer of responsibility for the pharmacy from one responsible pharmacist to another;
- ii. that pharmacy procedures should be able to be maintained electronically;  
that the regulations should not specify the format of the pharmacy procedures;

- iii. that the responsible pharmacist should not have to sign off to say they have checked and are content with the pharmacy procedures;
- iv. that the requirement to assess the need for procedures to be reviewed should be placed in good practice guidance;
- v. that guidance, in either the Code of Ethics or the supporting standards and guidance documents, is a more appropriate means of providing information and advice on the review of procedures;
- vi. that professional guidance should require procedures to be reviewed at least annually and that procedures should be signed and dated to indicate that they have been reviewed;
- vii. that the Superintendent or Pharmacy Owner should sign a yearly declaration to state that appropriate procedures are in place;
- viii. that guidance contains a requirement for any amendment made to the pharmacy procedure to be recorded, with the reason for the amendment;

#### *The Pharmacy record*

- ix. that records could be held at another location provided the record is identifiable to the pharmacy and can be readily accessed for inspection and monitoring purposes;
- x. that the regulations should not require the pharmacist's registration date to be recorded;
- xi. that the reason for the responsible pharmacist's absence from the pharmacy should be recorded;
- xii. that the regulations should not contain a requirement for the pharmacy record to include any amendment to the record and the reason for it;
- xiii. that the regulations should not require the record to include information on other staff and pharmacists working in the pharmacy;
- xiv. that records must be preserved for as long as is consistent with other regulations, for example CD Regulations;

#### *Absence from the Pharmacy*

- xv. that when considering length of absence and the minimum period of time a responsible pharmacist must be present in the pharmacy, this must be per pharmacy per day rather than per responsible pharmacist shift;
- xvi. that a responsible pharmacist must be present in the pharmacy for substantially more than half of the time the pharmacy is open;
- xvii. that if regulations were to specify a percentage, this should be 75% of the working day
- xix. that the maximum period of absence should be two hours;
- xx. that where a responsible pharmacist is to be absent for longer than regulations permit, another pharmacist must become the responsible pharmacist;
- xxi. that the regulations should not define 'return with reasonable promptness';
- xxii. that guidance should provide advice on the ways in which a responsible pharmacist can be readily contactable;
- xxiii. that where the responsible pharmacist is unable to maintain contact, they must arrange for another pharmacist to provide advice;
- xxiv. recommends that arrangements for another pharmacist to provide advice must be made in advance;
- xxv. that how the responsible pharmacist is to arrange for another pharmacist to provide advice should be set out in guidance;

#### *Qualifications and Experience*

- xxvi. that all pharmacists are eligible to be the responsible pharmacist at the point of joining the RPSGB Register, in so far as securing the safe and effective running of the pharmacy;
- xxvii. that there is a need for a competency-based assessment in order for the responsible pharmacist to be able to be absent and/or be responsible for more than one pharmacy;
- xxiii. that there is a need to annotate the Register to identify those pharmacists who have the requisite competencies to be absent and/or be responsible for more than one pharmacy;
- xxix. that the RPSGB assesses competency;
- xxx. that there must not be a specific time period or sector based period before pharmacists can return to practice or change the sector in which they work;

#### *One Pharmacy/One Responsible Pharmacist*

- xxxi. that temporary pharmacies, for example at festivals, should not form an exceptional circumstance where a responsible pharmacist can be responsible for more than one pharmacy;
- xxxii. that the automated machine should be considered separately to other truly exceptional circumstances;
- xxxiii. that the regulations should not specify a requirement for the responsible pharmacist to exercise their statutory duty;
- xxxiv. that the regulations must not specify what support staff should be available in the pharmacy;
- xxxv. that the time period for which a responsible pharmacist can be responsible for more than one pharmacy should be the same as the time limits on absence;

#### *Supervision by the Responsible Pharmacist in a Pharmacy where s/he is not the Responsible Pharmacist*

- xxxvi. that a 12 month period is necessary to prepare for the introduction of the responsible pharmacist Regulations;
- xxxvii. that a phased approach should be taken; and

xxxiii. that there is a need for guidance and this should be provided by the RPSGB.

Council, further agreed (xxxix) that a communications plan be developed to explain and promote the concept of the responsible pharmacist and the changes which would result from the implementation of the final regulations.]

#### **7. Staged payment of retention fees, proposed amendments to registration rules.**

Can I remind everybody the Council is fully committed to helping members make their payments in stages. However, we are constrained by what the Government allows us to do, and to present the item I would like to hand over the Treasurer.

**Mr Andrew Gush, The Treasurer:** I would like to present paper 7 and draw your attention to paper 7/12/C1 14, staged payment of fees; proposed amendment to registration rules. I would like to thank Sue Ambler, Andrew Gardiner and Gerald McEvilly for producing this excellent paper and recognise their determination to drive this work forward.

Staged payments are a priority to our members. Over 60 percent of submission to the fees consultation highlighted staged payments as desirable. So it must be, and it is, a priority of the Society. The purpose of the paper is to agree proposals for amendments to registration rules for consultation to enable collection of annual retention fees by staged payment. These are in appendix 1 of this paper.

The Council is asked to agree changes numbered 1 to 10. I will use this opportunity within public business to update you with the process and timeline which must be completed by August for staged payments to happen for 2009. Council defined our policy at the meeting on November 1<sup>st</sup> and also agreed that the Society would not be a rate determinant step in delivering this service to members for 2009's fee collection. Following this meeting, rules were drafted to reflect Council's policy and powers contained in the order. We have now reached stage three. Copies of the proposed changes have been sent to the Department of Health for its views. If the Council and Department of Health are content with the changes and the Department of Health are aware of the importance of the work, and so far have been very helpful and positive, the rules can then be formally accepted at the January meeting and consultation papers prepared.

Sue Ambler is confident that if the rules are approved at this point the consultation will be ready by the end of January. The consultation with members and relevant stakeholders will last for minimum 12 weeks. At the Council meeting for April, commentary on the consultation will be considered and amendments agreed where necessary. If the consultation is not finished in time for the meeting I will request Council to delegate to the Officers to sign off this work to keep it on track in terms of our timeline for success. Council will approve and make the rules in early June. The rules will have to be changed by the means of a statutory instrument drafted by our lawyers and agreed by the Department of Health lawyers and lodged with the Privy Council by late June 2008, as consideration can take up to eight weeks. It will then be laid down before Parliament for 28 days and subject, we are advised, probably by negative resolution, which means opinion is assumed to be positive, unless negative comment is made.

After this stage, the rules come into force and staged payments will be delivered to our members. The consultation will hopefully have told us when our members would prefer payments to be made. The first payment must be made by 1<sup>st</sup> January to meet regulation rules, so the first direct debit needs to be paid early enough before this date to allow members, who may have difficulties with their direct debits to be informed and helped. Today I commend to you changes in appendix 1, listed 1 to 10. I have received no comments on these changes before the meeting, but I would accept any comments or questions if necessary.

**The President:** I would ask that whatever was put on the screen be made available to the Council members.

**Mr Andrew Gush:** It has been made available to the press. Council members will have copies from the November meeting and the chart showing the timeline and process.

**The President:** Can we agree it for consultation? **(Agreed)**

**Dr Sue Ambler:** Although you are not actually agreeing them for consultation at the moment, as we have to get the agreement of the Department of Health lawyers. All you have done is to say that you are broadly content, but there will have to be a dialogue and they will have to come back to you before we go out for consultation.

We have done our bit now. That is the important point.

**The President:** Thank you. So we agree that we consult with the Department of Health.

**Mr Andrew Gush:** We are agreeing draft rules 1 to 10 to go out to consultation.

**The President:** I am hearing two different things.

**Mr Andrew Gush:** Sue, am I right in believing that these are draft changes which have been considered by the Department of Health at the moment. What we want to do is hear whether our members are content for the draft regulations to be represented as our views to go to the Department of Health.

**Dr Sue Ambler:** Sorry. It is further down on the paper, where it says we have to go to the Department of Health. Once this is drafted, we are expecting to have had comments back. We have to get a slot and get agreement of when the legislative slot will be, then we can go out to consultation.

**Mr Andrew Gush:** These are the draft rules we are agreeing.

**The President:** At this stage, it is premature to go to consultation.

**Dr Sue Ambler:** Yes. I really would not advise you do that.

**The President:** That is agreed. Can we go to item nine?

[Council agreed the proposed amendments to the Registration Rules as set out in the paper for discussion with the Department of Health and subsequent consultation having taken account of the Department's comments and the legislative timetable.]

#### **9. Student registration, responding to a consultation by the Department of Health.**

**Mr Graham Phillips:** There has been discussion at Education Committee for some time around student registration; whether we think it is appropriate, if it should happen at all, what should the modus operandi be and should we achieve consensus. In many ways, we pre-empted Department thinking, because when we were requested by the Department to give views, quite a lot of prior discussion had taken place. It seemed, on the face of it, a straightforward issue, but it is particularly complicated for pharmacy, because we have three groups of students: undergraduates, pre-reg and trainee pharmacy technicians as well. The circumstances are very different and one-size-fits-all would not work.

We did carry out a pretty comprehensive consultation with an independent analysis of all the responses. We used all our networks to try and garner people's views. This is all on the basis of risk to patients. In summary, the responses were that, on the basis of risk to patients, was that pharmacy undergraduate students should not be registered. Of course, this may be something that changes as courses becomes more clinical, but that is where we are currently. On the same basis of risk, but given the different circumstances that pertain, pre-registration students should be registered, so there is the difference. Again on the basis of risk, trainee pharmacy technicians should be registered. It has to do with the degree of patient contact.

Registration is only one possible option, and I guess two things apply. One is that we need look at alternative options and need to make sure we have done a sufficiently thorough job in drawing conclusions. We could look at practice mechanisms in schools of pharmacy and provide guidance. We could look at a students' charter for all students. We could require CRB checks for all students. These are the options. I think our conclusion -- and this is certainly the thought process at Education Committee -- is that we did not want pre-empt something, as that is quite a complicated and profound change to make, if we choose to make it. We currently feel we have not done entirely sufficient work to reach a firm conclusion. We are asking that Council agree that the education division does some more work on this subject. From my own point of view, I think it is important. Just because we may not have the regulatory agenda in place does not mean we cannot make progress. What has impressed me in the discussion we have had was both the willingness of schools of pharmacy and the willingness of students to agree to this. I do not know, Heena, if you want to express a BPSA view. Just because we do not have formal registration does not mean we cannot make progress. I would like us to pre-empt any legislative change and agree a voluntary situation in which we come together with students and schools of pharmacy and come up with a voluntary code. That voluntary code might ultimately be around not actual registration with the regulator but perhaps registration with a professional body. To me it feels more pre-emptive and much more supportive and is altogether is more attractive way to go. This is my personal view. I am happy to take questions, before we move to asking you to approve the appendix as

our response. Are there any questions for myself or Damian at this stage?

**Mrs Lorna Jacobs:** I had one fairly brief comment to make, in terms of the further work to be in consultation with stakeholders, that that should include patients and public. I understand that was not done before, but there is work that has been done in education with patients and public.

**Mr Graham Phillips:** Can I say, Lorna, that is a given and it is always a given.

**Mr Alan Kershaw:** I very much commend the approach in the paper. I do not necessarily want to suggest any changes to the drafting, but I want to make a point that seems important. Contrary to all the instincts of the professional regulator -- which is really to regulate everything that moves and register everything that moves -- I think that registration of students would be a poor step to achieve what we want to achieve.

There are a number of reasons for that. The main one is one of principle, which is that regulation is essentially, in the large part, about helping good practitioners to do better. We are talking of people who have not reached that stage. We are also talking about people who are in all sorts of senses not fully formed and not yet entering the profession. I think the full burden of regulation is unnecessary, and I do use that word 'burden' quite advisedly. I know it is not a word Ian Kennedy likes and I tend to prefer his models to others, but it is a burden at that stage.

Here we are really talking about issues of fitness to practise, conduct, discipline and so on. There I wonder what value would be added by a regulatory body moving in on what should be being done by the universities themselves. Where we need to do work is ensuring that all the schools of pharmacy have effective fitness to practise procedures for students and are prepared to use them; not with the full weight of the regulator, but in the sense of ensuring that problems are dealt with at an early stage, if there are problems, or incipient problems before they become them. Because the saddest thing you ever hear at a disciplinary tribunal is the comment "how did this person get into this profession in the first place?" In some cases, when problems are traceable back to student days, it is because the university was not prepared to do anything about it, because somehow or other their ancient statutes did not allow them to do that. They need to understand the need to do that, because they are training people not just to pass exams but to enter a profession.

Since we are in some sense delegating the right to say who goes into that profession, in the same way as we ensure the good and positive education that goes on in the pharmacy schools is proper to get people to registerable status through the criterion of accreditation work, in the same way I think we need to lay it on the schools of pharmacy, that they have a duty to ensure that people, while they may be perfectly capable of passing exams, are not given a ticket to enter the profession prematurely in a way that we would not want. I have very little research information on this beyond my own discussions in accreditation visits to pharmacy schools and with the members of the teams who are educators. But it seems to me there is a patchy approach across the schools to this kind of issue, and a reluctance in some cases to address the real issue, which is: should this person be allowed to enter the profession? Therefore the flip side of what we are saying is that it is not an option to have fitness to practise procedures and student health and conduct procedures, but a given and a requirement.

**Mr Graham Phillips:** Alan's points are well made, but I think they are covered by our strategy. I think I can give you reassurance on that. There is another form of sadness I would like to avoid which is of someone passing a pharmacy degree, but having committed such behaviour during the undergraduate years that we could not possibly register them. I want to avoid that one too.

**Mrs Lesley Morgan:** Graham did pick up my point but I want to come back to what Alan said. Not all of our registrants are trained in schools of pharmacy. Technicians in particular are trained by employers and training providers, who at the moment we do not have any control over necessarily. So I would like that we do more work in that area.

**Mr Graham Phillips:** Do I have support for our response as laid out at appendix A?

**Professor Stephen Denyer:** First, a word of assurance. I think it is important to know that whilst not all schools pharmacy have fitness to practise procedures in place, all heads of schools are charged by the Pharmaceutical Society to alert them if there are difficulties associated with some students. Sometimes it is a difficult thing to do, but I think the heads of schools do exercise that diligently. I think Graham made a passing comment to the role of the professional leadership body.

I think the heads of schools would strongly support the relationship between that body and its determination of charters or fitness to practise procedures. I think that would be a very constructive engagement with the future body.

**Mr Graham Phillips:** On the basis of that discussion, do we have your support for Appendix A becoming our response? **(Agreed)**

**The President:** Thank you, Damian, for all the work that has been done.

[Council agreed (i) the draft to the Department of Health as set out in the paper; (ii) that further work should be done by the Society in consultation with stakeholders before reaching a firm view about the usefulness of MPharm student registration and/or related measures, preregistration trainee pharmacist registration and/or related measures and of pre-registration trainee pharmacy technician registration and/or related measures; and (iii) that once a firm view had been established, it should be conveyed to the Department of Health.]

#### **14. Regulation of pharmacy technicians: amendment to interim appeals committee constitution and dealing with complaints against pharmacy technicians**

**The President:** I would like to move to item 14. The reason is that Janet Flint is not available tomorrow. We have paper C/126 in our agenda papers.

**Mrs Janet Flint, Head of Support Staff Regulation:** I would like to present this in two parts, because the recommendations relate to two different processes. The first recommendation relates to somebody coming on to the register where, under the new procedures, we undertake an assessment of good character prior to registration. In January 2005, the Council agreed the constitution of an Interim Appeals Committee that would hear an appeal in the event of somebody not being admitted to the Register. What we are recommending now is that, because time has moved on and the statutory committees are in place, the members have been trained and appointed, which includes pharmacy technicians. Instead of using the Interim Committee that we have used on one occasion in the past, we recommend moving towards the new procedures, so that we use the members of the Registration Appeals Committee, but they would not sit as the Registration Appeals Committee, but as an Interim Committee. That is the first recommendation I move. **(Agreed)**

**Mr Graham Phillips:** This may be very uncontentious. It seems straightforward and sensible stuff. Can we take the recommendations in one go? **(Agreed)**

**Mrs Janet Flint:** Thank you very much.

**The President:** I think this is uncontentious. Can I move the paper? **(Agreed)**

[Council agreed (i) that in the event of an appeal being received, the Interim Appeals Committee would be constituted from members of the Registration Appeals Committee, including the legally qualified chair; (ii) that in the event of a complaint being received against a technician on the voluntary register, the complaint would be investigated by a committee constituted from members of the statutory Investigating Committee; (iii) that in the event of a case being referred by the interim Investigating Committee for a full hearing, a committee would be established to consider the case constituted from members of the statutory Disciplinary Committee, including the legally qualified chair; and (iv) that in the event of a person being removed from the Voluntary Register of pharmacy technicians by an Interim Disciplinary Committee an appropriate mechanism would be put in place for that person to appeal against the decision.]

#### **10. Regulations, byelaws and guidance**

##### **(a) Guidance to underpin the draft regulations for the suspension and removal of Council members.**

**The President:** We asked Governance Committee to look at one or two things. To present that, I invite John Hanlon, Chairman of Governance Committee.

**Mr John Hanlon:** I realise that time is going on. I will speak briefly to (a) and pass you to Christine to deal with the other item. A very long time ago, when the world was young, we did go through the draft regulations. Council asked us to go away and look at guidance. This is a long, drawn out process, as you know, with our friends at the Privy Council. We have got to the stage where there is draft guidance. As I understand it, no-one has raised any issues in advance regarding the draft guidance. So unless there are questions, I would move that we accept the guidance.

**The President:** Is that agreed?

**Mrs Christine Gray, Head of Corporate Governance:** There are no unresolved issues, but Lorna raised a query with me, which I would like to draw to the attention of the Council about paragraph 4.3 in the guidance about mediation process, this is in the guidance itself. You will see that starts off: *“The process takes a maximum of two days.”* Lorna’s comment was that she was happy to have the two-day limit on the mediation process itself, but was concerned that this could be interpreted as meaning that once the decision was taken to go to mediation, the whole thing would have been concluded within two days. Whereas of course there would actually be a process during which arrangements would be made for mediation with the parties involved. Lorna asked if we could adjust the wording to make it clearer. We suggest that the first two bullets in paragraph 4.3 would read as follows. You would have a new first bullet saying if a decision is taken to opt for mediation, arrangements will be made for the mediation process in discussion with the parties involved. Then the second bullet would begin: *“The mediation process itself takes a maximum of two days”* and the rest as shown in your paper. That is the only change I have to put to you. I would emphasise this is guidance to help you understand the process. It is not binding on the Council, the Panel, the Registrar or anyone else. It is not part of the mandatory system of regulation. In any case, all relevant cases would need to be considered on individual merits. I am happy to deal with any questions or I am happy for Council to say if it will agree the guidance.

**The President:** It is a sensible suggestion. Are you agreed? **(Agreed)**

[With the proposed amendment and on the recommendation of the Governance Committee, Council agreed the proposed guidance as set out in the paper.]

**(b) Branch guidance under draft Regulations 15**

**Mr John Gentle:** The paper before you proposes, for the Council’s approval, a set of principles for running Society local branch and local branch committees and a procedure for transfer of members from one branch to another, to supersede the models rules which are scheduled into the byelaws. At the request of the Governance Committee, this paper was worked up by the office and approved for submission to Council by myself and David Carter, the other Council branch sponsor. I will hand over to Elaine, who will give you more background information on the paper.

**The President:** There is a comment on the paper.

**Mrs Sylvia Hikins:** A point of information. Are there areas of the GB where, if I were an individual member, I would not be covered by a branch?

**The President:** All areas are covered.

**Mrs Sylvia Hikins:** I am thinking of functioning branches. There is no no-branch area. I wonder what happens to members who live in an area where there may not be a functioning branch.

**The President:** If there are moribund branches, they will go to join an adjoining branch, or they do not do anything.

**Mrs Sylvia Hikins:** I wonder if there is no branch, or you think of a no-branch situation, when members might get some advantages. I was in a previous organisation where the branch structure did not cover the whole of the UK. It was not possible to do that. So you had members that lived in an area where there was not an active branch. What we did in recognition of that was to create what was called a “no branch”, and the headquarters or the centre would be responsible, if there was any information like branch information they would get. I am raising it as a possibility that might be considered with this paper.

**Mr John Gentle:** There are no areas of the country that are not members of the branch. However, there are some areas of the country where the branch committee currently or temporarily may not be active. Those areas are few and far between and are literally in single figures. Many of them are in metropolitan or urban areas, whereby other branches in neighbouring areas can take them over.

There is one in Lancashire, for instance, where the solution would be to merge the committees and have the merged committee running two branches as a single branch on a temporary measure. Sometimes branches fold and sometimes they are absorbed by other areas as well. What happens if a branch is not working actively is the staff in the office will offer a great deal of support in terms of administration, ideas and in some cases finance. They work hard to get the branch restarted. It tends to be fairly cyclical, thereby a new committee might come along, or a new member comes along and the branch gets reinvigorated. It does not happen often that a branch is moribund for more than a short period of time. Where that happens, members can be directed to joining branches.

**Mrs Sue Kilby:** Just as an aside, I am thinking of international members and people in the Forces, whether we need to think of these people in the context of this, or whether they are outside the whole branch system. It may be something to be considered for the future.

**The President:** I think we need to consider how we are going to deal with our overseas members. Has that been considered?

**Mrs Elaine Mulingani, Internal Governance Co-ordinator:** Not in the context of this paper, no. This paper was worked up as a joint effort by myself and Amanda King. As the paper says, the Council has recognised that the model rules as incorporated in the current byelaws are unhelpfully restrictive. That is why we have drafted these procedures and principles, together with the regulations that they will underpin, in a much more enabling fashion. Moreover, unlike the model rules they will not need Privy Council approval, and it will be easier and quicker to adjust them, if necessary. However, it is of course important to have such guidance in place and for it to be signed off by Council, given that the branches are part of the Society and the Society may bear ultimate responsibility for branch actions. Are there any questions or comments?

**The President:** Can we agree the draft guidance? **(Agreed)**

[On the recommendation of the Branch Sponsors, Council **approved** (i) the Principles for running an RPSGB Branch and Branch committee as set out in the paper, and (ii) the Procedure for transfer of members between Branches as set out in the paper.]

I propose we now adjourn, because I can see Mike Schofield has arrived.

#### **Presentation of Honorary Membership to Professor Michael Schofield**

**The President:** Michael, as you have heard many times, the Society was given the power to elect honorary members by virtue of its Royal Charter. We can elect people who have rendered distinguished service to this Society or to pharmacy.

Your career has been as a hospital manager and Health Authority Chief Executive, holding appointments in Manchester, Leeds, Liverpool and Rochdale and, on a part-time basis, at the Kings Fund College in London. You were Director of Health Services Management Unit at the University of Manchester for seven years. You also chaired two NHS Trusts in Bradford and Dorset and are a Past-President of the Institute of Health Services Management and a Past Chair of the National Association of Health Authorities and Trust. (NAAD), predecessor of the NHS Confederation. Other appointments included Independent Assessor for the Office of Commissioners for Public Appointments, Co-ordinator of the Health Sector Advisory Panel of Duke Street Capital, Deputy Chairman of the Board of the University of Nottingham, Chair of the National Liaison Group for the 50th Anniversary of the NHS and Council member of The Friends of Bradford Community Hospital.

You are an Honorary Professional Fellow at the University of Manchester and a Visiting Professor of Bournemouth University. You were awarded CBE in the New Year's Honours in 1999 for services to the NHS. In 1999 you were appointed as a lay member of the Society's Council, and throughout your eight years on Council you demonstrated a strong commitment to the Society and to the profession. Your services to the Society were exceptional, and the Council benefited enormously from your extensive experience of management and governance.

At Council meetings your contributions were always pertinent, well-grounded and informed by best practice from the wider world and frequently humorous. Your eight-year term of office has seen great changes for the Society with the granting of the new Royal Charter in 2004, and the coming into force of the Pharmacists and Pharmacy Technicians Order earlier this year. As we all know, times of change continue.

During your term as lay member of the Council you served as Chairman of the Infringements Committee and the Remuneration Committee. You were a member of Education, Science and Conference Committees and trustee of the Society's Benevolent Fund, Education and Parliamentary Funds and PTECO. You also served as member of the Publications and Journals Department Group and were a Council member appointee of the Publishing Board of Directors and in 2004 you became a trustee of the Pharmacy Practice Research Trust serving as Chairman of the Awards Panel.

Michael, we are grateful to you for your commitment to the Society and the profession of pharmacy. In recognition of this, it is now my great pleasure to ask you to accept your certificate of honorary membership of the Royal Pharmaceutical Society of Great Britain. **(Applause)**

**Professor Michael Schofield:** Thank you, Hemant, for those very kind words. I know that short speeches are very much appreciated in the Council chamber, so I am not going to go on and on. But I would like to say how I enjoyed my eight years on Council -- not every single minute, but mostly! **(Laughter)** Very enjoyable, and I have met some very nice people.

I am very pleased indeed to be still involved in the profession through membership of the Pharmacy Regulation and Leadership Oversight Group with yourself. That is going to be very interesting. Its main task is establishing the General Pharmaceutical Council, which I think will be very a important body for the profession, but obviously its work has implications for Royal Pharmaceutical Society of Great Britain, which I see as facing a sort of spaghetti junction of opportunities and challenges. I have every confidence that with the good sense of people on Council you will take the right road. I would like to say simply how very much this award is appreciated and to thank you everybody for the good times which we have had. I look forward to seeing you from time to time and to wish everybody all the best for the future. Thank you, President.

**The President:** Michael, of course you are invited to the Council dinner later this evening and I look forward to sharing a drink with you.

The President adjourned the public business of the meeting until the following day.