

THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN

Transcript of the Public session of the Council meeting held on 6 June 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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Present

President	Mr H Patel
Vice-President	Mr G Alexander
Treasurer	Mr J Jolley
Mr S Acres	Ms S Agha
Mr M Astbury	Mrs C Brown
Mr J Buisson	Mr D Carter
Mr S Churton	Dr B Curwain
Professor S Denyer	Mrs D Drury
Dr P Entwistle	Mr J Gentle
Mr A Gush	Mr J Hanlon
Mrs S Hikins	Mrs L Jacobs
Mr R Jobling	Mr A Kershaw
Mrs S Kilby	Professor B Michell (until item 07.06/C/63)
Mrs L Morgan	Mr G Phillips
Ms J Ramsey	Ms M Saunders
Mr D Simpson	Mr D Thomson

In attendance

Mr P Jones, Chairman Welsh Pharmacy Board and Dr RM Parr, Chairman, Scottish Pharmacy Board

PUBLIC BUSINESS

The President, Mr Hemant Patel: Good morning Council.

5. Election of the Society's Officers for 2007-2008

The Secretary and Registrar will take the chair for this item.

Secretary & Registrar, Miss Ann Lewis: We come first to the election for the office of President. One nomination has been received for the office from Mr Patel. I would like to ask the nominators to formally make and second the nomination.

Mr David Thomson: I wish to nominate Hemant Patel for the position of President.

Mr Douglas Simpson: I would like to second Mr Patel for the office of President.

Secretary & Registrar: Will Council please affirm this? **(Agreed)**

Mr Patel is duly elected as President for the year 2007 and 2008.

The President: Thank you, Council. I will say a few words after the election of my fellow officers. Can we go to the next item, which is nomination for the Vice-President?

Mr Jonathan Buisson: I would like to nominate Brian Curwain.

Mrs Sylvia Hikins: I would like to second Brian Curwain for Vice-President.

Mrs Dorothy Drury: I would like to nominate Martin Astbury for Vice-President.

The President: Do you have a seconder?

Mr David Carter: I would like to second Martin Astbury for Vice-President.

The President: Are there any other nominations for Vice-President? If not, can we get the ballots ready for the election, please? Whilst the ballot is being prepared, everyone would have noted that the current Vice-President, Gerald Alexander, has not offered himself for the post of Vice-President, or any of the Officers this year. I have worked with Gerald for many years, particularly in the last two where, as Vice-President, he has been a supportive member of the Officers Group and personal adviser. Particularly during the Carter Working Party discussions, I found his contribution extremely valuable. Gerald has served on the Council for over five years, two years as Vice-President. He is an active member of the Council and I am glad that he is going to continue to remain on the Council. I would urge him after this year to consider standing again for one of the posts of the Officers in the coming years. We will need all the help and expertise available to us. The next two or three years are quite tricky. Gerald, would you like to say anything?

Mr Gerald Alexander: No thank you, President. I think everybody knows.

Ms Marcia Saunders: I would like to propose a vote of thanks to Gerald for his work over the past two years that I have been here. **(Applause)**

The President: After the election of the Treasurer and other members to support the Officers' team, we will have a short break before resuming the rest of the agenda. There is an item carried over from yesterday and hopefully we will be able to clear all items relating to public business before coffee time.

Mr Douglas Simpson: What is the item left over?

The President: From the Secretary and Registrar's Report, an item on special resolutions, which is item 10 on your agenda paper. Also item 13 on your agenda from referrals from the Governance Committee. We will be coming back to items 29 and 30, which related to two items where we had brief discussions in Committee session.

There were 29 votes cast. Martin Astbury is elected Vice-President for 2007/2008. **(Applause)**

Can we proceed to the election of the Treasurer? The current Treasurer, John Jolley, has come to his end of term. He has served three years, which is the maximum allowed under our governance. Please join me in thanking John who, like Gerald, has been a very supportive member of Officers Group and also during the Carter Working Party. He chaired the support group that helped the four nominees to do the job that they were able to do. John, thank you very much for your contribution as Treasurer. You are still on the Council, so that is good to see. **(Applause)**

Secretary & Registrar: President, at the end of voting for the Treasurer, we need to record the votes for the election in the minutes, so we will record them when the two are completed.

The President: May I have nominations for the post of Treasurer for 2007/2008?

Mr David Thomson: I would like to propose Andrew Gush.

Mrs Lelsey Morgan: I would like to second Mr Gush's nomination.

Professor Stephen Denyer: I would like to propose Brian Curwain.

Mrs Sylvia Hikins: I would like to second Brian Curwain.

The President: Any other nominations for the post of Treasurer? If not, can we get the ballot papers circulated? **(Vote taken)**

Mr Douglas Simpson: Just to fill in time, I note that the box that is being used for ballot is a relic from Bloomsbury Square, as I am! **(Laughter)**

Mr Jonathan Buisson: Both will be stuffed and gifted to the museum in due course! **(Laughter)**

The President: Again, 29 votes were cast. Andrew Gush is the new Treasurer for 2007/2008. **(Applause)**

Secretary & Registrar: Votes cast for the Vice-President were Brian Curwain 12 and Martin Astbury 17. In the election for Treasurer, the votes were as follows: Brian Curwain 11 and Andrew Gush 18.

6. Election of lay member of Council

The President: We go to item 6, which is the election of a lay member of Council and an additional member of Council to work with the officers. May I ask for nominations for a lay member of Council to work with the officers?

Professor Alistair Michell: I would like to nominate Phillida Entwistle.

Mr Graham Phillips: I would like to second the nomination of Phillida Entwistle.

Ms Marcia Saunders: I would like to nominate Alan Kershaw.

Mr Ray Jobling: I would like to second Alan Kershaw.

The President: While the papers are collected, can I take this opportunity to welcome our branch observers? I note that Preeti Sharma, from Hounslow and District Branch, is at the meeting today. Welcome.

Again, 29 votes were cast. Phillida Entwistle 17, Alan Kershaw 12. So will you join me in congratulating Phillida. **(Applause)**

Bob has served on the Officers Group for the last two years. Last year he notified the Council that he only wanted to serve for two years. Bob, do you want to say something?

Professor Alistair Michell: It has been a privilege and pleasure to work alongside the Officers team and I admire their commitment in uniquely difficult times; far more difficult than during the blood bath of the Charter debate, for example. It is important that the lay member is not an Officer but works with them as a critical friend. I can think of no-one better to do this than Phillida. In a number of settings, especially Infringements, I have admired her ability to listen carefully, think hard and deliver wise, crisp, concise insight. I think she is exactly who we need to encourage Council and warn them where appropriate.

The President: Can I have nominations, please?

Mr Andrew Gush: I wish to nominate David Thomson for the position of Council member to work with the Officers Group.

Dr Phillida Entwistle: I would like to second that.

Mrs Lorna Jacobs: I would like to nominate Jonathan Buisson.

Mr Ray Jobling: I second that.

The President: Whilst the ballot is being counted, it would be useful if the outgoing Treasurer is given an opportunity to say something.

Mr John Jolley: Thank you very much indeed, President, I wish to thank all members of Council for giving me the opportunity to be the Treasurer for the last three years. It has had its moments and certainly various issues have highlighted the importance of the financial management within the Society. I wish my successor, Andrew Gush, every success in the future. I am afraid, in handing over to Andrew, he is going to have one or two major challenges to achieve, but nevertheless I will certainly give him whatever support I can in terms of my past experience and wish him the very best of luck. **(Applause)**

The President: The additional member of Council to work with the Officers Group for 2007/2008 is David Thomson, who polled 17 votes and Jonathan 12.

The President: Can I ask the former Vice-President to hand over the chain to the new Vice-President, please? Council, we have elected a team of Officers and two Council members to support the Officers in their work. We will now take a ten-minute break and resume at ten o'clock.

Mr Graham Phillips: Forgive me, President, for briefly interrupting. I do not want the opportunity to go past without paying tribute to Bob and the work that he has done for us over the past few years. He has said very generous things about Phillida and I would say all those things about Bob. Bob has brought firstly the ability to hold a mirror up to you and allow you to see yourself as others do and secondly to act as a critical friend. He has been through difficult times himself, yet throughout the period he has played the role with absolute perfection. I express extreme gratitude to him for the work he has done on behalf of all of us. **(Applause)**

The President: I think it would be appropriate that I give the new Officers an opportunity to say something. Treasurer, do you want to say something?

The Treasurer, Mr Andrew Gush: I feel honoured and privileged to be selected as Treasurer and you have my full commitment in terms of time, in terms of the task of delivering the best for Council members and to deliver for all our members as well. I would like to thank you again for selecting me. **(Applause)**

The Vice-President, Mr Martin Astbury: When I joined Council four year ago as *Joe Bloggs, pharmacist*, I felt all pharmacists should aspire to be on Council. Here I feel is where we can actually make a large difference for patients and pharmacy. All the members of this Council work very hard to aspire towards to that aim and I once again renew my vow to do the best I can in this job. **(Applause)**

The President: Council, thank you once again for electing me President of the Society. I congratulate the successful candidates and my commiserations to Brian. I wish him better luck next time. I must also thank all the members of Council who have supported me with words of encouragement, time and made themselves available when I needed their help and also members of staff. I think since January, particularly during the Carter Working Party discussions, I have found their help invaluable. I think too that the Council and membership often underestimate the dedication and hard work that is done by staff.

I am very proud of the achievements of this Society and also recognise a need for change. We are excellent in a number of areas: education, training and CPD support, strategy for the pharmacy profession, developing a better picture of the pharmacy workforce, practice research, pharmacy publications and -- despite all the criticisms -- influencing Government and legislation. This can be improved on, but there are good examples of success which must not be ignored or forgotten. However, more could be done in professional development and raising standards, developing leadership skills at a local level and exciting new roles in public health and clinical areas. More could be done to support branches, pharmacy students and retired members.

I want the Society and the future professional body to have a cradle-to-grave relationship with our pharmacists that is mutually supportive and beneficial. I still want to bring back the members who left the Society in anger in the recent years.

This year we must take some action to correct the sad situation we find ourselves in and re-establish our reputation as a caring membership organisation.

I stated and Council supported my ambition to help make Britain the safest place in the world to receive medicines. I intend to take advantage of growing support, both within the profession and outside. So by basing our work on doing social good and putting the public first, our position in the wider world as healthcare professional is more valued.

This takes me to the linked point of our style of working. Our style of working must become more friendly, inclusive, persuasive and open. The regulatory role has done us no favours in this area, and we have much work to do in this area. As President of the Society at this historic time of great and rapid change, which will see the separation of dual roles, I intend to focus on a number of key tasks. These are:

- To keep sight on our purpose and continue to serve members and the public.
- To maintain the Society's strategic functions, core and leadership services before handing over to the General Pharmaceutical Council and a future professional body respectively.
- Without delay to mandate the emergence of change effectively and start to separate the professional role and regulatory role.
- To better support and engage the branches and members and continue to engage with other pharmacy bodies.
- To communicate with members, branches and others.

Whilst focussing on key tasks, it is important that we must also in parallel be cognisant of risks which may blow us away from our desired objectives.

The risks are:

- That we are will lose sight of the wider regulatory and professional development and leadership agenda.
- That we fail to adequately manage resources;
- That over focus on change will distract us from delivering our core tasks to the highest standard and as a result our credibility will be damaged.
- That we become focussed on the process of change and not the purpose of change.

We have a clear and strong sense of purpose. What the profession and others will be watching for is consistent application of values, whether the Society is membership focussed or not, and whether we are paying attention to detail. There has never been a greater need for transparency, accountability to members overtly demonstrating we are not only listening to members, but supporting them nationally and locally to realise their aspirations.

New Officers and Council, with support from members and staff, must aim to create a successful change for the Society that will result in the formation of a new professional body and a General Pharmaceutical Council. This means that we must have a clear focus on priorities which Council must establish, a careful planning of our activities, attention to process review of internal and external communication, strengthen strategy and relationships. The most precious of these is relationships with members.

By the time of BPC in September, we must come up with a plan to better support members old and new and win their trust, so we can become authoritative voice for members of this Society in the wider world. I look forward to working with you all and taking the profession forward with a secure future and responsive professional body that membership is craving for and very much deserves. Thank you. **(Applause)**

We will break now.

(After a short break)

The President: Colleagues, we are in public business, we will go to the next outstanding item, item (d) of the Secretary and Registrar's report.

(d) Regulations on special resolutions

Secretary & Registrar: The Council is asked to consider paper C/51, the Regulations on Special Resolutions, and to agree that the regulations be gazetted. Perhaps I can ask Elaine Mulingani, Internal Governance Co-ordinator, to introduce the paper.

Mrs Elaine Mulingani, Internal Governance Co-ordinator: Thank you, Secretary and Registrar. The Council agreed the draft regulations concerning special resolutions in March. We have now received initial comments from Privy Council advisers. They are content with the draft and we now seek Council's agreement that the draft be gazetted.

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

[Council agreed that the regulation on special resolutions be gazetted.]

13. Referrals from the Governance Committee.**(a) Draft guidance to support special resolutions**

Mr John Hanlon: We have just agreed the gazetting of the resolutions. If you remember, when we had the discussion on these resolutions, the real meat and drink of what they are about is in the guidance. Council were aware of the view they wanted to see the guidance and see what information was provided to members to allow them to interpret the resolutions. I think that is a good principle, and it is the intention to follow that as we go through the tortuous process of getting regulations in place for the Section 60 Order.

What happens now with the guidance is that there may well be some amendments, if there is change to the regulations proposed. It is highly unlikely, but if there are minor changes, could they come back to Governance and not Council, so we could crack on with this? With that caveat, there may be minor changes to the governance, if the Council is content to agree to it going forward.

The President: Do you agree the draft guidance? **(Agreed)**

Mr Douglas Simpson: Quite considerable power seems to be given to the independent scrutineer to have a major role in the conduct of meetings, asking people to leave and this kind of thing. I have never seen this idea in relation to a Society meeting. It is usually up to the chairman of the meeting or the President to deal with matters of misbehaviour. I wondered what the rationale was of having a fourth person there as a fourth official, if you like.

Mrs Elaine Mulingani: We did base this guidance on a number of examples of good practice from other chartered bodies, but also I think the feeling of Governance Committee was that they did want to have an independent scrutineer to have this final power to ensure governance was completely above board. So that was the wish of the Committee, but obviously it is up to Council.

Mr John Hanlon: Could I perhaps add that it was thought this was a good idea, because it protected the President of the meeting if he had this independence. It would be used *in extremis*, but it would be useful for the President if he were chairing the meeting.

Mr Douglas Simpson: I think it would be put the chairman in a difficult position. He would not know if he was in charge or not. I have reservations, but I will not attempt to hold the paper up.

Secretary & Registrar: Having been there to support Presidents through a number of these meetings, I think we need to think this is a very important provision. I think having independence is an advantage. Many procedures have changed, but this is a very important procedure which the Council and Society would have. Therefore, I think the Chairman of Governance makes it clear it protects office-holders.

The President: This is work in progress. If you have further comments, direct them to Elaine to be fed to the Governance Committee.

Mr Jonathan Buisson: Would this be somebody from the Electoral Reform Society or that ilk?

Mrs Elaine Mulingani: Yes. That is what we have in mind.

The President: With that, can we agree the draft document in front of us? **(Agreed)**

[Council agreed the guidance to underpin the draft regulation on Special Resolutions.]

29. Implementation of new recognition of professional qualification Directive, Directive 2005/36/EC.

Secretary & Registrar: The Council has considered these matters and they wished this to be brought forward to the public agenda, so it can be clearly on the record in public business. For the benefit of the Council, I would like to remind you of the business and considerations which the Council made. The Council considered the draft response to the Department for Education and Skills (DfES) limited consultation on Regulations implementing the new Recognition of Professional Qualifications Directive, which is Directive 2005/36/EC.

The Council expressed grave concern at the impact of the EU Directive, in particular the absence of any requirement for visiting practitioners to Britain to comply with CPD requirements which applied to all of those who are on the practising register. It was noted that this was in stark contrast to the reforms of health regulation which were to tighten up these requirements for the protection of the public and patients.

Professor Bob Michell, who is a lay member of the Council, considered it completely unacceptable that there was to be no capacity to require these visiting practitioners to comply with CPD, let alone revalidation. He pointed out that the driving force for reform in the UK was the Shipman Report, and noted that the GMC's proposals at the time regarding CPD and revalidation attracted serious criticism from Dame Janet's inquiry. For Government, EU conformity may be the driving force, but for a healthcare regulator it has to be patient safety. Those DfES proposals, judged by the criteria established by the Shipman Report, did not protect the public or patients.

Mr Alan Kershaw, lay member, said that there were serious dangers in this and real safety issues at stake. There was no assurance that other European countries were as advanced as the UK in their requirements for CPD and revalidation. It must be made clear to ministers that this is a very serious issue and that the Society has grave doubts as to how this can be safely implemented.

Professor Stephen Denyer, academic pharmacist, recognising the dangers and urged a robust response outlining the impact against the stark clarity shown by reference to Shipman.

The Council agreed a draft response, subject to the comments of Council members as stated, and noted firstly, the proposals did not meet the principle that regulators must protect the public and patients. Secondly, that there were potentially serious safety issues and risks. Thirdly, the contradiction with the stringent requirements for CPD and revalidation for UK practitioners was unacceptable. Fourthly, the Society would continue to work with the other UK regulators to urge the Government to take notice of the serious concerns and safety risks.

President, I have confirmed with both Professor Michell and Professor Denyer, the words that I have repeated on their behalf before they left the meeting.

Secondly, we will be considering the Department of Health's regulations -- these are the DfES limited consultation - in July. That is what the Council wished to have in public. There may be other comments to be made, but I hope I have captured the tenor of the discussions yesterday.

The President: Thank you, Ann. The summary is, in my view, an accurate summary of the Council discussion. What I would like to ask for -- we have an open discussion -- is what are the next steps after this? What would you be doing?

Mrs Martha Pawluczyk, Head of Overseas Registration: What I am proposing is to look at the DH regulations that I have received, refer to DfES regulations -- they are dovetailing together.

DH regulations will be the regulations that actually amend the Pharmacists and Pharmacy Technicians Order to set up a three-part register to accommodate visiting EEA pharmacists and pharmacy technicians on to a third part of the register.

A paper on those proposals will come to Council also in July. The closing date for the DfES regulations consultation is 3rd August and the closing date for the DH regulation consultation is 17th August. So at the July meeting, I would have thought we could see the implementing legislation in the round, so to speak, and ensure that there are no further loopholes. Something may have been plugged, but I very much doubt it.

Secretary & Registrar: I think, President, at this stage we can share Council's views and concerns with the other regulators with whom we have been working closely. I am sure they will share the views that have been expressed here and can only add weight to them. There is more than one Minister involved in this and before we take it further, so far as that is concerned, we should have the opportunity of a comparison with the DH regulations. I think the first point is to share it with other regulators.

The President: Is it worth sharing it with CHRE?

Secretary & Registrar: Yes.

Ms Marcia Saunders: That exchange has mostly answered my question, which was about how do we influence upwards, if you like. In particular, how do we influence the Department of Health? I wanted to say I think many people -- certainly it was expressed by Bob Michell, Alan Kershaw and Stephen Denyer -- feel that there is probably a need to get concerns about patient safety into the national arena, perhaps through members of Parliament and perhaps through the press and other agencies as well.

The President: I will invite Graham, as Chairman of Communications, to comment on it later on.

Mrs Lorna Jacobs: I wanted to clarify. The issues that have been discussed relate to CPD, but the other issues I would like to come through strongly is the limit on information that can be exchanged in terms of people's practice. It only relates to legality of service providers' establishment, disciplinary matters or criminal sanctions, and it appears to exclude information about poor performance or health and whether conditions have been imposed on the regulations on registration in the home country. So where you can have a practitioner who has conditions imposed in one country, those conditions cannot then be imposed in Britain and I think that is as serious and needs highlighting.

Mrs Martha Pawluczyk: I am hoping that there is something in the Department of Health consultation that may address that. That was an issue that was raised in our meeting with Lord Hunt and AURE, and it has been an issue that we have raised with the DH in all our meetings with them. It does seem to create a perverse incentive for a practitioner to move to a jurisdiction where his practice would be unlimited. Whereas, it would be limited in the Member State from which he originates.

Mrs Sylvia Hikins: I accept that the Society will be working with other regulators and applying pressure, but I think we have a duty to raise awareness in a wider arena. I am thinking particularly of members of Parliament. We have a constituency system. Our MPs represent a constituency. As we have said, if this goes through there is a real danger to patient and public safety. I would like to see somehow the Council determine to communicate with MPs, the last four points of Ann's statement, which I think are the essence of what we want to convey. We need to do it in a briefing, an email or something like that, at an appropriate time. I really think we ought to go beyond what has been suggested this morning to raise awareness.

The President: We will note the point and come back to it.

Secretary & Registrar: I think it is a very good point to make. The local branches are already talking to their MPs about various matters. It is the sort of thing that could be effectively disseminated face to face with local MPs, either by Council members directly talking to their own MP, but I know they have made contact with them -- but also at a local level where it can have most impact.

Mr John Hanlon: I support what my fellow lay members have said about this. I think as a regulator in the public interest this is inimical to the public interest and if it was brought in, it would cause serious concerns about safety in relation to pharmacy practice in this country. I support what Sylvia said. I do think we have to go public on this. I think just a shot across the bows to go public, to say, "If you brought this in, we think this would actually damage patient safety". I think that is the view certainly of all the lay members around this table.

Mrs Cathryn Brown: I am conscious we are working with other UK health regulators, but we are not the only pharmacy regulator in Europe. Have we been in contact with them? How do they feel about accepting this?

Mrs Martha Pawluczyk: We do not have a forum of pharmacy regulators across Europe. There is a recognition of the Mobility Group of the Pharmacy Group in Europe, which I have been attending. I met recently with my counterpart from the French Board of Pharmacists, the regulator in France. They have similar concerns about temporary service provision to us. We have been assured by both the Department of Health representatives and DfES that they have put all our concerns to the EU Commission, when they have been discussing implementation and transposition of this. There is mileage in going directly to the Commission possibly, because there are instances where we had hoped that a particular Article in the Directive could be interpreted in such a way that CPD could be a requirement.

There are other moves across Europe which are led by the GMC on information exchange on fitness to practise issues, the Health Professions Crossing Borders Project, which my colleagues, Peter Burley and Phillip Green, the Deputy Registrar and Director of Education and Registration, have been attending. It has got a lot of cross-Directorate work with Fitness to Practise in relation to the sort of information that we can exchange across borders. So information exchange follows the professional that moves.

Ultimately I think that the GMC, GDC and NHS have benefited from professionals moving. The majority of people who move are competent and caring and are not running away from fitness to practise. But the concern is that there are loopholes in this, so a professional who may have fitness to practise proceedings in one Member State may move to avoid consequences.

Mr Jonathan Buisson: When we discussed this at the Education Committee, one suggestion that was made, not entirely in jest, was not just that we go public, but almost that we go nuclear and start briefing people like the Daily Mail and Daily Express. *You see how the foreign Shipmans are coming over here and the EU says we can do nothing about it.* You can imagine the headlines. The Department of Health might have a change of heart on this.

Mr Ray Jobling: I wanted to add another lay member's voice to those who have expressed great concern on the issue. I think people might be initially misled if they were to think this is simply about recognition of professional qualifications in a rather DfES sense. It really is much more central to the concerns of the Department of Health and public safety. Martha is right to give weight here to the fitness to practise issues which are contained within this. CPD is extremely important, but also those concerns. There is a telling phrase in the documentation we have got about "the Society does not believe that some of these provisions are sufficiently robust to protect members of the public and patients from rogue practitioners". If we can use phrases like that in our public statements, I think people will take a great deal of notice of it. It is very important to get across to people that the public concern is unanimous and goes across both lay and professional members.

Mr Gerald Alexander: First of all, I am not a lay member of Council, but a pharmacist. I would like to support the views lay members have expressed at this Council table. As a pharmacist, we manage risk within our environment and I think pharmacists are compliant with regulation. What concerns me is that we are removing the safety net in relation to patients. The James T Reason Swiss Cheese model of risk springs to mind, where there could be one rogue element that would actually get through the safety net, through the Swiss cheese.

Frankly, just to echo views of Council members who have already spoken, we need to robustly represent ourselves to MPs and to the public at large and we need to slow down the implementation of this Directive. In fact, what I am saying is we should robustly resist the implementation. If I was to express any credentials of being left or right wing, I think we have lost our sovereignty to the EU. I believe this country is very compliant in implementing EU Directives, where others in Europe are not. I think the views we have taken need to be expressed widely to the public and to MPs and we should resist the implementation of this EU Directive. There is no question that we wish to make this country the safest place to receive medicines. If we are going to stick to that vision, how can we accept this EU Directive in its present form?

The President: Would you go further than resist and defy the Directive?

Mr Gerald Alexander: Yes.

Mr John Jolley: The European Industrial Pharmacists Group for the last two years now have been progressing this issue of CPD through all of its member associations throughout Europe - I must say with not with a great deal of success. Particularly, some Orders, [4 words removed for legal reasons] seem very reluctant to comply with the more rigorous requirements of CPD, preferring much the continuing educational route. There is provision within a European Directive affecting the manufacture of product which requires some components of CPD to be complied with, but they are very minimal. I would hold very little hope that many of the European States would meet anything like our requirements for CPD. To this end, I think I would go as far as resisting any attempt to implement regulation. I cannot see why, on an issue like this where there is public safety at risk, we should in any way compromise our particular intentions by allowing people who have not complied with these practices. So yes, I would resist.

The President: What about defy?

Mr John Jolley: Defy.

Miss Seema Agha: This was an issue I wanted to raise yesterday, which Bob expanded on regarding the language competence in paragraph 45. I think it is a very fundamental issue. The Directive says that you cannot be required to take a language test as a condition of registration in a host Member State. I think Martha was saying that that is to be left to employers to be dealt with. Those of us who have been members of the Infringements Committee know that language has been an issue to fitness to practise. It has been brought through a disciplinary process for the regulator to address, so it cannot be satisfactory that you leave it to an employer to deal with language, which is fundamental. Communication is fundamental to patient and the practitioner. It cannot be left to an employer. It has to be central to any fitness to practise issue. Other regulators, the Law Society, the GMC -- for example, doctors coming from a foreign jurisdiction are required to do linguistic tests as part of any conversions. Is that the case for other jurisdictions and not for EEA, where there are language issues? I want to understand what the differences are and what the justification is, because we know there are problems out there. The regulator has been asked to deal with language issues.

Mrs Martha Pawluczyk: We, like the GMC, language test wherever and whenever it is possible for us to do so. We have specific power in the Pharmacists and Pharmacy Technicians Order now that clarifies the ability of the Society to require people who are non-exempt to be language tested. So all EEA nationals are exempt from regulator language testing. Europe will argue that it is not a blanket exemption. If we could differentiate the sector of the profession that a practitioner was going to, we could make a proportionate language test. It cannot be a blanket test to everybody, but it is something that AURE is working on. There is a language working group as part of AURE, led by Richard Marchant, who I believe is their head of policy regulation. I am a member of that group.

We will be working with them and the Department of Health to see how far we can language test and what we can say about language testing and how we can advise employers and PCTs on the sort of language testing that could be carried out. Perhaps not all of you know; AURE is the Alliance of UK Health Regulators on Europe. It represents all the health and social care professions in the UK, and the Society is a member of that body.

Mr Alan Kershaw: Looking at the proposals here, to an outsider it is going to look very detailed and rather abstruse. It is very important, if we are going to convince opinion formers on this, that we get across to them that it is not just an abstruse matter of regulatory theology (although it is). It goes to the heart of what registration is all about and it represents a potential real danger to real people. That is very important. We need to simplify the message, as far as we can, for the general consumption while getting across a very detailed analysis of why we think this is potentially very dangerous.

It is worth pointing out something that I think came through in discussion yesterday. There is a serious mismatch between this and everything the Government purports to be saying in the White Paper about healthcare regulation, where the whole trend for the last five years has been to tighten and strengthen, and at the same time allowing a potential loophole of this kind. The peripatetic practitioner, who potentially leaves a trail of havoc behind them, moving from one job to another where no-one is really in a position to pick up the pieces, is a problem enough within one country, let alone across 20 or more. It is an important point to get across. Mismatch and potential dangers from areas we know very little about are the key message.

Ms Marcia Saunders: I agree with Alan about needing to simplify. Indeed, I wanted to utter a slight note of caution. I think we have to be absolutely focussed on patient safety in this and be very, very careful that we do not allow ourselves to be cast into the light of people who have particular views on European legislation, or indeed who might want to restrict practice. There is always a danger, thinking about what the headline might look like: *Pharmaceutical Society wishes to defy legislation, or wishes to restrict entry from Europe*. That is not what it is about. It is about our unanimous, lay and pharmacy concern for patient safety. We should be simple, snappy and clear about this, particularly in the briefing we give to the regional groups, and make sure that in their discussions with MPs they do not become cast in that light, because that could actually be quite counter-productive.

Mr Graham Phillips: It may be we go so far as refusing to implement this Directive, but I do think we need to be guided by Martha, who has unique expertise, and allow her time to analyse the latest information which has arrived with her only very recently.

It is important to recognise that lay members do not have the sole concern for patient safety and that the professional members are equally concerned. I would not want to see that put in a divisive way; it is a common concern, as indeed it should be. We should not make a knee-jerk reaction. I am concerned that sudden emails to MPs at the moment will look like that. We have common cause both with other regulators and indeed patient and professional groups. I think we should work together with them in a more sophisticated and more nuanced way. We use our political capital up sparingly and at great risk, particularly at a time when there are all sorts of other debates going on (given the recent letter to the Journal and the future of this organisation). Let us please use our political capital very sparingly. What I would like to do is allow Martha to continue her deliberations and advise us and take it to the Communications Group and produce a mature but decisive response. I hope the Council will agree to that.

The President: Is the Council agreeable to that?

Mr John Hanlon: I do not think so, is the honest answer, President. I want to propose that we go to a vote on this.

The President: Can you explain what you want to see happen, John?

Mr John Hanlon: I will be guided by other lay and pharmacist members on this, but I think there is a clear view around the table that we want to go public on this and we want to brief MPs on this. It is not a knee-jerk reaction.

This is doing the job that a regulator, in the public interest, should be doing. It is saying, *if you go ahead with this, you will put patients at risk*. We should be making this public now in case, in their folly, they go ahead with this.

Mr Graham Phillips: I was not suggesting that we should not pursue this, or that we should not pursue it in a public way. I want to ensure exactly what the problem is, give Martha the opportunity to

do any further analysis and not react in a knee-jerk way. It does not mean I am devaluing the significance of it, I just think it would be more effective if we have a mature response and we work with others, rather than going it alone. I think that will put the Society much more in the forefront of this. I am not suggesting we do nothing at all.

Mrs Martha Pawluczyk: We have before us the implementing DfES regulations. Those are based on Directive 2005/36. They implement the general system of recognition which I think strengthens patient safety, as it allows us to do a competitive assessment of qualification. It implements the temporary service provisions for all the professions governed by the general system of recognition; so all the Health Professional regulated professions (e.g. osteopathy) and pharmacy technicians, which will concern us. The Department of Health regulations that have just literally hit our desks implement the visiting practitioner provisions for pharmacists and amend sections of the Pharmacists and Pharmacy Technicians Order to enable that to take place. They actually do relate to the DfES regulations, so there is mileage in realising that they would most likely say very much the same as the DfES regulations, because they are based on the same bit of European legislation, but there may be slightly different nuances. I have not had a chance to look at that. The statement we have made is important I think because on CPD, DfES are the lead implementer and it is clear from the Department of Health that they take the lead from DfES on this. So that position is not going to change.

With regard to fitness to practise issues, I do not know how that is going to change and the impact and the relationship of visiting practitioners to our fitness to practise part of the Order. We are going to have meetings across directorates with members of staff at the Society, in fitness to practise and education and registration and governance, to have a look at how all these bits of legislation dovetail together. That will come to you as a whole in July. It is really up to Council to decide what they want to do.

Secretary & Registrar: I want to support everything that has been said, but particularly Graham's comment. Through bringing this debate into the public arena, we are beginning to make that dissemination of views. That will be in our report of this Council meeting. The Council have been very well briefed in order to have this debate. I think Graham makes a good point in that what I was suggesting is the way in which we can actually cascade that information, but it will mean that anybody who is talking about it will have also to be very well briefed, because they are complex regulations. It is quite a complex issue to discuss and you then have to summarise that into something which is pretty easily assimilated. So I think it needs to be carefully prepared. From this meeting, we have quite a lot we can disseminate into the press now. From that, we can consider how we might develop the argument at different levels.

Professor Stephen Denyer: I apologise coming into the debate a little late, but listening to in particular Graham's advice and comments, I am one for a considered response, but also one for an urgent response where required. One of the things that has characterised this Society in the past is sometimes we have not responded in as timely a manner as some other professional organisations express concerns over matters. Perhaps I can urge that we discuss with our common professionals with urgency how we might put forward a combined commentary, because that will carry even more power and weight than one from a single organisation.

Mrs Sylvia Hikins: I would not want us to be really soft on this. I understand the concerns around the Council Chamber, but I would still like to leave the Chamber today with some decision being made on our communication strategy. I think we have to be really timely on this.

From that point of view, I welcome the comments from our new Director of Communications, if she feels she can comment what would be timely.

I think there is something to be said for communicating to MPs, who are constituency representatives, that there are loopholes in the Directive of which we have grave concern around patient safety. We could then direct them to our website to read more about it, or put some proviso that they could find out more, taking up the points that Ann made. I am not happy just to say leave it to a communications group and see how things go. I think there is a strong feeling around the table that we have to take a stronger line on this issue than we have on previous issues.

Secretary & Registrar: I think the issues which I read out capture the tone of the Council's discussion following that. I think what is absolutely clear from the discussion following it is that whilst some of those comments are specific to people, all of the lay members (I think almost without exception) have spoken to support those thoughts and we need to make that clear, together with all the professional members. Deborah Oliver has only been with us two days, but if she were able to make a comment on how we might best disseminate this right now, probably based on that written text, that might be helpful.

Ms Deborah Oliver, Interim Director, Public Affairs & Communications: Hello everybody. This is actually day three now! I think I would appreciate some advice, because I am obviously new to this area, but I think there is a clear brief about the concerns that the Council has on this issue. What I am not so clear about is what the end outcomes are that you want. Once you have raised a concern about public safety, what actually do you want to happen? Once you have got the awareness and everybody talking about the issue, what do you want to happen as a result of the debate? I will definitely be guided by colleagues and their experience, particularly Graham's views, on how to take this forward.

The President: Martha would be able to help us with what exactly we want to replace some of this, because I am sure that has been communicated to AURE and to other regulators. Do you want to comment, Martha?

Mrs Martha Pawluczyk: Possibly a statement on our website, if this is implemented, "This category of registrant does not undertake CPD". I do not know. I actually feel, the Government having signed up to European Directives -- and it is a Directive that, whether we implement or not, comes into force on 20th October -- I think it is a way of trying to mitigate what we may need to do. On 21st October I may receive an application from somebody wishing to provide a temporary service as a pharmacist in this country. I think we need to ensure that we have robust procedures which are legal to actually deal with that situation in the public and patient interest.

The President: Can I invite Sue Ambler to augment what has already been said?

Dr Sue Ambler: What we would be looking for as an outcome is that we could ensure parity across the registration process, so that there was no difference and so that we could interpret the Directive in that way, rather than end up with a situation where we potentially have part of our register where the quality assurance that we have in place across fitness to practise and the qualification and health is different in some way.

The President: Thank you very much, Deborah?

Mr Jonathan Buisson: I echo, as Sue says, that the best outcome is all registrants are the same. We cannot have a second class group of registrants. That is what we are really upset about, the idea of that. Again, I echo what Stephen said. I think we should work with the other regulators because a joint statement from all regulators saying "We are all pissed off about this" will be more effective than just us. But on the other hand, I would also say to them, "We are now prepared to go public with this. Are you going to join us?"

The President: Can I remind the Council that we are in public business?

Mr Alan Kershaw: Sue has made the point I was going to make, that the overall aim is to be sure that we can apply equivalent safeguards to any pharmacist practising in this country.

But there is another level which is that we are seeking acceptance by the Government of the detailed modifications that we need to see before we can be sure of that.

Dr Phillida Entwistle: I think the assurance of the outcomes we want are to be absolutely sure that the people who are going to be acting as pharmacists in the country can speak the language competently, have continuing competence in practice and also that the qualifications which they have produced as evidence are valid, because there is vibrant market in forged certificates of this sort.

I also think that this may not be a sensible time of the year to start on the MPs. We may start with the health correspondents of the broadsheets, who are quite interested in this.

Mr Ray Jobling: The key to the professional patient, the professional public relationship, is one of trust and confidence. What strikes me about this is that it is bound, as it hits the fan, to undermine confidence. How can it be the case that if you go to a pharmacist and you see, say, Martin Astbury there, that you believe him to be much more firmly regulated than pharmacist X, who is facing you. You have lost confidence in pharmacist X, who may be fine, honest, well qualified, etcetera. This is not the way. On how we say it and when we say it, we should take professional guidance. It would be good to have all of the other regulators with us, and I hope they are going to react as robustly as we are. I feel very cheered by the fact that the medicines specialists feel very strongly about this and feel strongly about public safety.

Mr Graham Phillips: If people think I was arguing for doing nothing, I can assure them that is not the case. What I am arguing for is let us be quite clear about our position and quite clear about the outcome we are seeking. Let us be quite clear about the best way to pursue it and let us pursue it with urgency. My proposal is that we work up the messages and we see if we can work with other regulators and patient interest groups and lead something. I believe that is more effective than emailing MPs.

Secretary & Registrar: I think Martha indicated we have spoken to other colleagues in Europe. I think the point was well made by Catherine. Just to explain, across Europe the competent authority (i.e. the person who is regulating) varies. So it is not the UK pattern. It is different in different countries. So we can liaise with many of them, but in some cases it is the government who is the regulator.

Mrs Sylvia Hikins: Just for the record, I wanted to make clear that I was not saying we do one thing or the other. Of course we must do what Graham suggested; it is absolutely right and proper. All I was suggesting, as part of our raising awareness campaign, is that we email MPs to draw their attention to loopholes in Directive. That is all I was suggesting.

The President: Whether we email or communicate with MPs, the point is that we should be communicating with MPs. In terms of action points, we have taken comments on board. We have had this debate in public. We will be working up a communication plan involving other regulators. I will be writing to the acting Chairman of CRHE -- because I sit there as a representative of the Society, nominee of the Society -- and ask her for her support, which I think will be forthcoming. We will take steps with advice from our PR company to see what we can do in terms of alerting the MPs and the press. Is that agreed? **(Agreed)**

Ms Marcia Saunders: Like John, I would like to formally capture the fact that this is a unanimous view of this organisation, and I would propose a show of hands to that effect.

The President: All those in favour, please show. **(Vote taken)** It is unanimous.

30. Measures to address issues in qualifications for exempt applicants under Directive 2005/36/EC

Mrs Martha Pawluczyk: This Council have agreed the form that these applicants are going to use to apply to register yesterday and in August of 2006 the assessment process that these applicants will undertake.

This paper is to agree what the compensatory measure will be, once the comparative assessment of their qualification and work experience against a national requirement for registration have been undertaken. In the draft DfES regulations that are before you, that actually sets into legislation the comparative exercise for general system recognition. It states also the sort of compensatory measure that can be applied to this category of applicant. These applicants can be required -- there is a substantially different matter -- to undertake either an adaptation period with assessments or an aptitude test. They cannot be required to undertake both, and the aptitude test has to be a bespoke test which sets out to test the substantially different gap between their qualifications and experience and the national requirements for registration.

The paper here proposes that if the comparative assessment identifies gaps, that those should be addressed by way of an adaptation period with assessment, where there is a period of workplace assessment, against the Society's performance standards, undertaken under the supervision of a pharmacist, approved by the Society, preferably as a prereg tutor and at pharmacy premises approved for the purpose of pre-registration stage.

It is further proposed that the applicant pay a fee as a preregistration trainee pharmacist to cover the cost of training manuals, administrative support etcetera. The applicant would be required to produce evidence to satisfy the Registrar and the tutor that the gaps identified had been addressed. The assessors would point the trainee to learning material produced by CPPE and the NPA, where knowledge gaps could be rectified. Evidence of having undertaken that additional workshop, seminar and distance learning would have to be provided to the tutor, because the tutor workplace supervising pharmacist would be required to produce and provide the Registrar with assessments against performance standards and provide the evidence that any knowledge gaps identified had been addressed. That is the proposal. The paper sets out the resource implications for an adaptation period, which would be cost neutral to the Society, and the substantial resource application, if an aptitude test were formulated for testing and being a compensation measure. So the recommendations are as set out in the paper and the Council is asked to approve, approve or not.

Mr Jonathan Buisson: Before we get into debate, can you clarify; persons who are exempt applicants, are these pharmacists registered within another Member State, or is this pharmacy technicians within a Member State or outside Member States, both or whatever? Which group of potential people are we talking about?

Mrs Martha Pawluczyk: In this paper it is pharmacists only. It is pharmacists who fall under the two categories in the Article 10 cases of the Directive. They will be pharmacists who have qualified in Europe before a particular reference date and their training does not comply with the minimum training requirements set out in the Directive. They will also be those people who have not undertaken the three consecutive years of practice which the Directive permits people or pharmacists who have got non-compliant qualifications with minimum training requirements to rectify that non-compliance. So they do not have the so-called acquired rights. They are also persons who have had a third country qualification recognised in a Member State and then have worked as a pharmacist in the recognising Member State for three years. The description of an exempt person is broader than just an EEA national and an exempt person is defined in the Pharmacists and Pharmacy Technicians order and is set out in the paper refers to a national of European State other than the United Kingdom, a national of the United Kingdom who is exercising a community right. An example of that would be, for instance, if as a British national I had qualified in France, and I wished to come to this country, I would have the same right as a French national to have my French qualification recognised in this country. Then European law extends nationality rights to persons who are not nationals of Europe, but have a community right to be treated as if they are European nationals. That extends mainly to spouses of an EEA national. They have the rights under European legislation to be treated as if they are EEA nationals for the purpose of free movement and recognition of the Society.

Mr Graham Phillips: I hate to say this now, but I think Appendix 1, page 5/6 makes the position admirably clear. It is a minefield, yet Martha has given us a clear steer here. I was rather hoping we could move straight to the recommendations on page 4 and adopt them, rather than having a long debate. Is there support for that? **(Agreed)**

Mrs Dorothy Drury: I am concerned that there could be a postgraduate holiday when somebody could have a degree in this country and do a prereg year abroad. I would like to know if the prereg year abroad is the same as here, because I have seen the post folio of our students here, and all the competencies that are checked off, and they examine everything. I would want to know that it is the same if you qualify in Greece or Hungary or wherever the prereg year.

Mrs Martha Pawluczyk: I do not know whether it is the same. We have a four-year degree programme and then a one-year pre-registration training periods. That means that our entire qualification, the certificate of registration with the Society is the qualification which complies with the Directive. In lots of other member states, the in-service training is an integral part of their degree, so they have a five-year degree, six months of which is in-service training and it is part of the university

programme. That is the programme in the majority of States. We have had applicants who have completed a four-year degree here. I am aware of one who has gone to Germany. In Germany there is a year of training in order to sit the final state examination. That is then the qualification which is listed in the annex. The competent authority in Germany would write to us and say this person has a four-year pharmacy qualification and in-service training which complies with the minimum training requirements, and they would be holders of a listed qualification and we, as a competent authority, would be required to accept it. What we do here is we do actually check that the individual has not entered pre-registration training here and had not sat any of the pre-registration exams and was using that as a loophole. We would be seeking legal advice as to how we would progress an application, should that eventuality occur.

The President: Graham, do you want to put your proposal, then we can break for coffee?

Mr Graham Phillips: I would like to move that we accept the recommendations half-way down page 406 in the paper.

The President: Is that agreed? **(Agreed)** We will break and resume at 11.30.

[Council agreed that for exempt applicants for establishment who possess a relevant EEA pharmacy qualification not covered by *The Approved European Pharmacy Qualifications Order of Council 2007*, where the comparison of their qualification with the national requirements for registration reveals 'substantially different matters' the Society should (i) require such applicants to complete a period of adaptation with assessment as opposed to an aptitude test, (ii) require the adaptation period to be undertaken under the supervision of a pharmacist approved by the Society (preferably as a preregistration tutor) and at pharmacy premises approved for the purpose of preregistration training, and (iii) use the Society's preregistration Performance Standards as the basis against which assessments will be completed during the required period of adaptation.]

(After a short break)

18. Another other business

Mr Jonathan Buisson: I am raising this issue which was brought to my attention by David Miller, one of my colleagues on the English Pharmacy Board. It is an issue about the registration of pharmacists, or pharmacists when they get to the point of registration and the documentation relating thereto. So it is not really an English Board matter; it is both a GB and a regulatory matter. I have received a comprehensive briefing on this from the Education Department, for which I am very grateful. I am grateful to David for raising this matter with me and I am grateful to the Education Department for this. The matter in hand relates to the amount of documentation. There is a comprehensive selection of documentation that the pre-registration people have to produce in order to register and who validates this documentation. In particular there is a requirement that if the applicant is proving their identity in the form of a passport, a copy of it has to be countersigned by a notary. I believe this attracts a fee of between £60.00 to £65.00 as an additional cost. Virtually all of the other documentation which is to be produced can be countersigned by the preregistration tutor. There are even situations where the pre-registration tutor, had they known the person for a significant point in time, could countersign the photographs from which the passport was produced, but not the resulting passport.

The Section 60 Order and the relevant rules, which we may have passed, were mostly discussed in February and March, quite possibly at a time when our minds were on other things. I am grateful to David for bringing this up.

I am not a pre-registration tutor or an expert on how these things would work in the field; he is and he is looking at it from the bottom up. The Section 60 Order gives the Registrar considerable discretion in what evidence is accepted. I was hoping that this might be exercised in this case, but the briefing I have received suggests that the Registrar is not able to exercise considerable discretion around this particular issue. David may wish to circulate the briefing notes to you. I wanted to raise this formally and have something read onto the record about it. It may take the place of a briefing.

Dr Peter Wilson, Head of Post-Registration : Thank you, President. We had a conversation about this yesterday. The situation appeared to me that we have a member of the English Pharmacy Board who has raised the issue with Jonathan who has brought it to Council under AOB.

Jonathan is quite correct. The decision on the documentary evidence to be supplied by a pre-registration graduate who applies to register for the first time as a pharmacist were set out in rules which Council agreed in February. The administrative arrangements for implementing the rules were put before Council and agreed in March of this year.

The regulations and requirements are stronger than they used to be. They are in line with the identity requirements of other healthcare regulators. They are in fact not as draconian as the requirements of some of the regulators. They are not as draconian, for example, as the PSNI has for its new registrants. The purpose is to manage the increasing problem of identity fraud. There is no history in our profession of people who are not qualified to register as pharmacists gaining entry to the register. That is not the case in other healthcare professions. There have been a number of significant cases in medicine of people obtaining registration with the GMC and practising for a number of years, putting patients at risk and it then proving very difficult to gather sufficient evidence to de-bar them from practising. So the requirements which you agreed in March are designed to reduce, as far as we can, the possibility that somebody should provide fraudulent identity information and register as a pharmacist, and potentially then remain registered for a significant number of years, practising and putting patients at risk.

So that is the situation as we are at the moment and those are the requirements which you have agreed. They have not yet been implemented. They will be implemented for the registration of pre-registration trainees who successfully pass the registration exam and apply to enter the profession this summer. The request from David Miller comes from one individual in the north-west who has discussed concerns with a few pharmacists and their trainees in the hospital service in the north-west, if I understand the correspondence correctly. We are not subject to an onslaught from the profession at this point.

My suggestion is as follows. We cannot change the requirements on pre-registration trainees who wish to register this summer. We have to go ahead and implement that. We cannot change it. All the forms have been printed and will be distributed. If the Council decides they do wish to readdress the registration identity requirements, that is something which you will have to discuss. You will have to take account of the fact that you would be changing the rigour of that aspect of regulation at a time when the Society is under the spotlight. I would suggest that if you want to do that, then an opportune moment to do that would be when we know the outcome of the registration of pre-registration trainees in 2007. I leave it there for the moment, President.

The President: I think we have now got the comment on record. Are you satisfied with that, Jonathan?

Mr Jonathan Buisson: Yes. We are here where we are. Let it run for a year and let us know if there are any problems that are encountered during this year's registration season.

The President: Can I thank observers. We are now moving to confidential business.

The President closed the public business part of the Council meeting.