

Royal Pharmaceutical Society of Great Britain

Transcript of the Public session of the Council meeting held on Tuesday 2 February 2010 at 1 Lambeth High Street, London, SE1 7JN.

[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

COUNCIL MEETING

Present

President	Mr S Churton
Vice-President	Mr M Astbury
Treasurer	Mr J Gentle
Mr S Acres	Ms S Agha
Mr G Alexander	Mrs M Allan
Professor N Barber	Mrs K Blair
Mr D Carter	Mrs D Drury
Dr P Entwistle	Ms S Hikins
Mrs L Jacobs	Mr J Jolley
Mr A Kershaw	Miss Y Liddell
Dr T Learoyd	Mrs S Kilby
Professor B Michell	Mrs A Moore
Ms M Saunders	Mr D Thomson
Mrs V Turner	

In attendance

Ms Mair Davies, representative from the Welsh Pharmacy Board; Mrs Sandra Melville, representative from the Scottish Pharmacy Board; Mr Graham Phillips from the English Pharmacy Board (Wednesday 3 February 2010 only) and Mr Jeremy Holmes, Chief Executive & Registrar

Mr Steve Churton, The President: We are now in public business.

1. Welcome to guests

The President: First of all, just to welcome a few people, Sandra Melville representing the Scottish Board today, Mair Davies representing the Welsh Board, and it says Graham Phillips over there but I think he is here tomorrow. I think, Martin, you are representing the English Board for today's proceedings.

2. Apologies for absence

The President: Apologies received from Graeme Hall and Jane Ramsay. Everybody else should be present, I think, today.

3. Declaration of interests

The President: Declaration of interests, just to remind as usual Council members to make declarations of interest as appropriate before each agenda item.

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Before we move to the published agenda today, I would just like to take a moment to pay my respects to a previous Society President and one of the most famous pharmacists of our generation, Professor Arnold Beckett OBE, who died aged 89 sadly this week.

Perhaps most well known for his work on drug testing in sport, he was a former member of the International Olympic Committee's Medical Commission, Head of the School of Pharmacy at King's College, London for many years, Chairman of the Board of Pharmaceutical Sciences and a member of the Medicinal Commission of the International Olympic Committee.

Dr Beckett registered with the Society in 1941 and went on to be elected to the Society's Council in 1966. He became Vice President in 1979 and was elected President in 1981 for one term. He continued to serve on the Council before leaving in 1990.

His work as one of the most respected pharmacists include publishing 465 research papers, patenting many products in markets throughout the world and being the joint founding editor of the distinguished International Journal of Medicinal Chemistry. As well as honorary doctorates and many and national and international awards, Professor Beckett awarded an OBE for his contributions.

I am sure that members of Council will joint me in recognising Professor Beckett's outstanding services to pharmacy and in sending condolences to his family and friends. Thank you, Council.

4. Minutes of the public business part of the meeting of Council held on 1 and 2 December 2009

The President: Moving on to item 4 now on the agenda, which is minutes of the public part of the meeting held on 1 and 2 December, you have the minutes of that meeting before you. Are we content -- sorry, I beg your pardon.

Ms Martyn Schofield, Corporate Secretariat: Kay Blair was missed off but she did attend.

The President: I was just about to say, are we content? Kay, I am sure you were going to mention that you were missed off the minutes. Are we content, apart from that, where a correction will be made, that they present a fair and accurate record of our discussion. John?

Mr John Jolley: I wrote to Jeremy. There is an omission in the Transitional Working Group account in that I expressed the concern that I had in the delay in applying for charity status for the museum. There is no mention of that discussion at all in the minutes and I would ask that that be included because we will be making reference to that during the course of today's meeting.

The President: Is that 09/144?

Mr John Jolley: 09/144.

The President: OK, thank you. Any other comments on the accuracy of the minutes? OK. Thank you. We will accept those.

[Ms Martyn Schofield, Corporate Secretariat, advised Council that Mrs Kay Blair had been listed as absent when she had been in attendance.]

[Council resolved

that the minutes of the public business part of the meeting held on 1 & 2 December 2009, subject to the above amendment, be received and agreed as a correct record].

5. Matters arising from the public business part of the minutes not specifically included in the agenda

The President: Matters arising from them not included in the agenda. I have not been notified of any matters arising.

Mr John Jolley: Again, I communicated to Jeremy concern that there is still an ongoing delay in applying for charitable status for the museum. This was first identified as a requirement back in 2007 because it is in fact a way in which the museum may get external funding from other than the Society and, as such, be able to secure its financial viability.

The President: John, do you have a preference to where that discussion takes place in the agenda?

Mr John Jolley: As I say, it crops up in a number of spots during the course of the agenda but I just want to register that particular point because I do think it is now an urgent requirement that we look to get charitable status for the museum.

The President: I am sure we will pick it up then as we go through. Sue?

Mrs Sue Kilby: I have to declare an interest here. It is item number 22, about affixing the seal to our fellowship -- is that going to be taken up?

The President: Hold on. Which page are we on in the minutes?

Mrs Sue Kilby: In the minutes, page 3.

The President: Page 3?

Mrs Sue Kilby: Yes, item 22.

The President: This is the public minutes we are talking about.

Mrs Sue Kilby: That is in the -- I have got the public business, members designated as members' of the Society --

The President: We are not looking at the minutes, Sue, not the agenda, minutes of the last meeting.

Mrs Sue Kilby: I am sorry. I am trying to work out where we are.

The President: All right. OK. On to -- David?

Mr David Thomson: Can I give an update on the transfer of the overseas appointments? Council may be pleased to note that we have had one registration of interest for support but since it came from a dispensing doctor's practice we have declined to make any further --

The President: Thank you, David, for that.

Professional leadership matters

6. Generic substitution

The President: On to item 6 on today's agenda which is the discussion on generic substitution. Council will be aware that the English Board are to submit on this consultation and we thought it would be very useful for the Council to consider the issue today. We have got Heidi and is Neil around?

Ms Heidi Wright, English Practice & Policy Lead: He will a little bit delayed because he is

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in another meeting upstairs. He said he would get here as soon as he could.

The President: But you are happy to lead us for the time being?

Ms Heidi Wright: Yes.

The President: I would like, if possible, to suggest that we have a timed discussion here of 45 minutes otherwise we will get behind for the day. So we have a fair amount to get through and I will ask that Heidi kick the process off for us.

Ms Heidi Wright: I am assuming everybody has read the consultation. I will quickly summarise. Basically, generic substitution, there are three options suggested by the Department of Health: option one, do nothing, keep it as it is now. Option two is to have a list of items that cannot be substituted. Option three is a list of items that can be generically substituted. The Department of Health have gone for option three. Within options two and three you can neither as a prescriber opt in nor opt out. So if you have a list, and this is where it gets very confusing, if you have a list of medicines that cannot be generically substituted, if you write a brand name, you can then as a prescriber say it has to be dispensed as the brand by opting out. Similarly, for option three, you would have a list of medicines that can be generically substituted and if you write the brand and it is on that list you can opt out of that as well. So basically you can opt in or opt out and you can do that by either ticking a box on the prescription, is one of the options. The other option is an endorsement by each item which again is the preferred item from the Department of Health.

Basically, the Department of Health are saying they would like to have a list of medicines that can be generically substituted and have about 40 items on that list to begin it and the list can be expanded over time and having an opt-out option and having that as an endorsement by each item.

So that is it in summary. Really the discussion I wanted to focus around three points. The first one is do we agree with the option put forward as option three by the Department of Health with the opt-out by endorsement? If not, why not, and what are our reasons for perhaps going for other options or maybe coming up with a fourth option, as in Wales? Then the other part of the discussion I would like to focus around professional discretion, pharmacists' professional discretion, and then look at any other issues that anyone may want to raise.

The President: Thank you. So on the option three question, first of all? Alison?

Mrs Alison Moore: I probably should not speak because I am not based in England. I just wondered what the pricing and cost implications to pharmacists are of some of these options. For example, if a doctor, a prescriber, sorry, does not opt out so enables a medicine to be generically substituted, and the pharmacist chooses not to do that generic substitution because they feel that it is better for the patient for whatever reason that they clinically decide, are they going to be financially penalised for that decision? Are they going to be paid as if they had given a generic or are they able to exercise professional discretion because I think one of the things I feel most strongly about this is that whatever method is chosen, the pharmacist should be able to be reimbursed for what they supply as long as they have got justification for supplying that particular product. So, you know, linking it in with all the drug tariffs stuff and part 8 and everything else, is there anything in there because I could not see anything when I looked at all that mentioned reimbursement and that has got to be a key part of this surely.

Ms Heidi Wright: There is very little in there about reimbursement and obviously that would form part of our response and that is why we brought up the other item around professional discretion.

The President: An important point. Thank you, Alison. Dorothy?

Mrs Dorothy Drury: Two points. I would have preferred where it says generic substitution that it said for human medicines, and maybe Bob can back me up, so that we know it is not attempting veterinary medicines and the cascade system. Secondly, I am just a bit concerned that we move from the term pharmacist to dispenser in some of the discussion.

The President: Bob, did you want to pick up on that?

Professor Bob Michell: I was going to raise the point at minute 44. Although this is all about the NHS, it is worth reiterating, because it will form the usual habit, that under almost no circumstances is it likely that a generic substitution of a veterinary medicine would be lawful because you have to consider the cascade and, on the whole, it is unlikely that there would be a generic alternative to a licensed veterinary product. So I think the default position should be that you cannot do it, and the advice would be that if you are going to do it you would be well advised to consult a veterinary surgeon.

The President: Thank you. Is that a stretch, Tristan, or just a hand up?

Dr Tristan Learoyd: A stretch and a hand.

The President: A stretch and a hand, right. Alan?

Mr Alan Kershaw: Thank you. The words "patients" and the "public" are pretty well non-existent in this document except that as an afterthought patients' views will have to be sought as part of some consultation when the Department have decided what they are going to do following this consultation. So I wonder, first of all, what are the views of the Society's patient liaison group on this and can we know those before we are asked to make a decision? Really it seems to me a missed opportunity because I have no problem with the concept of generic substitution but it would be a great opportunity, this, to extend the public's education about this sort of thing and help to focus on what they are really taking. So the focus of the paper is entirely economic as far as I can see and I would like to know a little bit more.

The President: Thank you. Gerald and then Margaret.

Mr Gerald Alexander: First of all, I think the savings that the Department of Health will make from this are fairly modest. I think if you look at the document on page 6, it tells us that 83 per cent of prescription items were prescribed generically and made up, and so on and so forth. The remaining 17 per cent of prescription items were prescribed and dispensed by brand names. It says the great majority of these drugs are available only as branded products, but 5 per cent, so what we are looking at is 5 per cent of 17 per cent of 9 billion which is quite modest. I think it is less than 1 per cent. So we are looking at perhaps £50 million savings for the Department of Health which, in the scale of things, £72 million, I think, is relatively small.

Where that impacts upon community pharmacy, that is the problem. It is the impact that it has on us and it has on the relationship that we have with our patients. Our patients need to be assured that they are getting a good and unbiased service from community pharmacy. So it could be argued, and I think this does not happen really in -- generic substitution is not going to affect the way that hospitals operate. I cannot see that there is any issue relating to that.

So my concern, it does not matter which option you go to, is that the current proposal should only be accepted with assurances that pharmacy/patient relationships and pharmacy/GP relationships will not be damaged and that patient care will not suffer, and that pharmacists will not face financial loss as a result of their work in this respect.

I think some patients only accept a familiar brand. This policy could leave pharmacists in a

difficult situation needing to choose either to dispense the brand with a financial loss or to give a generic knowing that the patient might not take it.

So those are the issues and I think we should focus on that. I think we have all been in favour of the move towards generic substitution over the years but seeing as the GPs have already switched virtually to 83 per cent and there is only another 17 per cent to go, it is not such a big issue. I really think that the Department of Health should be consulting with the GPs to encourage them to work more towards the prescribing of generics so that that small element that is actually still being prescribed in a proprietary way could be changed. So I think the emphasis should be there otherwise the pharmacist is going to be at the receiving end of the unfortunate relationship that could evolve between pharmacist and patient and I think, from the Royal Pharmaceutical Society's perspective, we should be consulting with our group that deals in public patient involvement before the consultation response is written and that patients should have some sort of view in our response.

The President: Thank you, Gerald. Margaret?

Mrs Margaret Allan: Thank you, President. I just wanted to expand slightly on the Welsh Board's decision to actually say that we should not go for any of the options, whether it is option three or two or one. Basically, I think we all around this table would agree with the principle of generic substitution. It is professionally right that pharmacists are more than capable of being able to decide whether there is an opportunity to substitute a generic with all the knowledge of medicines that we have.

We feel that this is just a quick fix by the Department of Health to try and solve a problem that they perceive they have rather than actually more of a long-term strategy to solve the legislative problems that we have around shackling community pharmacists to actually make generic substitutions by being shackled by having to actually dispense always what is exactly on the prescription without being able to make a professional judgment as to what is right both for the NHS but also for the patient. So we would say that that is what needs to happen rather than this short-term quick fix measure.

Whether you go for option three or two, they are both operationally extremely complex. There is a huge reliance on the GP getting it right. GPs do not have much time to do what they do anyhow and worrying about whether they tick a box or not is just crazy. It is going to put even more information on a prescription. Where does that match with patient safety? We are trying to ensure that we get the medicines right. If we are trying to read all these other bits and pieces that are on the script, that does not fit in with patient safety.

We do not think there is any credence really in the cost benefit. Certainly, there is no value in Wales. We would not even look at it. We have got something like about 97 per cent where GPs are using generics so there is no way it would be a cost benefit issue within Wales.

So fundamentally those are the reasons why we said no, we do not want to go with any of the options, but we do go along with the principle of value for money for the NHS, but we feel that we need to try and resolve the legislative problem that we have where we cannot generically substitute within the community.

The President: Thank you, Margaret. Val and then Sue.

Mrs Valerie Turner: I have to admit most of what I was going to say is in agreement with what Margaret has just said in that we want to be able to substitute but I really do not think we will be helping our members if we went along with option three in the way it is because it just leaves us open to the government saying you will give a generic unless it is endorsed otherwise because that is all you will be paid for. If you give the brand, you will then have to go through the complicated regime of getting the script amended which will then cause deterioration in relationships both with patients and with doctors. A doctor who is currently

prescribing on the computerised system, and if he is prescribing branded, is going to continue prescribing branded medicines and using an endorsement. It is the GPs that need to be trained, the ones that are causing the problems. That is where the problems lie.

Other areas where we get the branded coming through are on handwritten prescriptions and they are the ones that we all know what the doctor really means but the word is too long and they are too lazy. They write the shorter brand name and we all know that really we could just as easily give the generic and that is what we really would like to do. I cannot support the options that they have put down.

The President: What bells would be put in there to resolve your particular issue?

Mrs Valerie Turner: I would just like -- it is difficult to say. I just feel we would like to be able to substitute where we know that there is no issue for the brand being given or the generic being given. It is professional judgment. It is a legislative thing, and I realise that, but that is what I would like to see, yes, an ability to substitute. We have all been faced with the problems of a branded antibiotic, not available, the patient needs it but they can have a generic. We all know the generic will work as well as the brand in that particular case but it gets complicated in that at the moment you have to contact the prescriber. We want to be able to just use our professional judgment and give the generic but I do not want to be the person in the middle between the prescriber and the patient trying to sort out whether the prescriber really wants the person to have the brand, you know, have they just missed off the endorsement or have they just put the endorsement on as a matter of practice? I just do not like that idea at all.

The President: Sue?

Mrs Sue Kilby: I have got a number of issues, first about the actual consultation. It does not really seem to have actually included pharmacy in the actual way it is actually written. It has considered doctors and paid a passing interest to patients but actually the pharmacists are the ones that will be dispensing these prescriptions especially as there is a statement in here to say it excludes dispensing doctors. I do have an issue about this, about excluding dispensing doctors, because I think it could actually lead to variation and differentiation and the whole range of issues about whether patients are actually part of the dispensing list or not part of the dispensing list. I think we do need to think about that very carefully as to which products they have or do not actually have.

I am also really concerned because I can see that this is being driven by cost but actually the biggest thing that wastes the cost is actually around the waste of medicines not being used appropriately. One of the biggest problems we actually have, and I know Nick knows all about this, is all to do with concordance and actually getting things written correctly and actually safely and appropriately. I think that this actually is coming from the wrong perspective and actually what we ought to be looking at is actually trying to improve the actual use of medicines and making sure there is reduction in waste, and that ought to be something that pharmacy -- we ought to be flagging up.

I have concerns about some of the products that they are actually listing in here. One of them is around Salbutamol inhaler. I know it is routinely used as a generic but often patients get used to using a set product and what I would not want is patients to actually move from one to another without being counselled appropriately. We do need to have that built in somewhere.

The other issue that we have is things like lactose intolerance and whether patients -- moving from one generic to another, when in fact they specifically have been actually put on a product because of their lactose intolerance. Maybe pharmacists are not aware of that and they do not know about it and they do not consider it. So I think it is not quite as straightforward as it might first appear.

In principle, I am not against the idea of actually having a restricted list where this is applied to

but I think we have to think carefully about what is actually on this list. I think pharmacy must insist, as a professional body, that we are actually involved in drawing up that list and it should be consistent with the views of the profession as to what is actually acceptable. This has not necessarily picked up what is actually being deemed as being appropriate from the guidance that came out last year because, in fact, in there they were saying that the inhalers should be -- you should have continuous products as far as the patient was concerned. So they obviously have not reflected and referred to that.

So I do have concerns about where we are actually going with this and whether this is the most appropriate way of actually trying to make savings. This is clearly what it actually is, it is actually a savings exercise, and it is very unclear as to how much savings we are actually going to make from it.

The issues with endorsements and whether we can actually include it, I totally agree with what Heidi has said. As a profession, we must have the authority to actually override what comes through on a prescription because we know most prescriptions are actually repeat prescriptions and they have never ever seen any healthcare professional and, in fact, they have been generated by the practice staff so they may not be aware of the subtle issues and they may well miss some of the changes. So therefore, as the healthcare professional, we must have some authority to amend what is actually on that prescription and we must also not be penalised for making that decision as well.

So that is my thoughts at the moment.

The President: Thank you, Sue. David?

Mr David Thomson: President, it is recognised that this is part of another process that started last year, a phase in the PPRS negotiations, and there were some stakeholder events held in England last year. Surely there must have been some mention of this at that time. It might be useful to get an insight as to what that debate was about and what points were agreed.

I would also like to know what intelligence is being gained from a similar process that will start in Scotland and Wales with the respective governments as well because it will not be just dealt with in England. It will have a knock-on effect elsewhere. I think it would be useful to get an awareness of those likely debates so that we can inform our response.

I think we are only being asked about the concept of generics and substitution, not perhaps the mechanics of it. That in turn will be developed elsewhere. Some aspects, both financial implications, will be taken up by other bodies that have an interest in that area. So I think it is looking at the professional thing. In that, I do not think the document is strong enough or there is the potential to influence an outcome that might suggest that pharmacists are given the diagnosis at the outset. The choice of product is made by the pharmacist increasingly is what you find in hospital nowadays as well. I think there is other aspects about if we are looking at systems looking at changing cost reduction, it could influence the drug tariff amendments more quickly to affect the market prices that are there currently.

So there is a whole raft of things that we may or may not want to touch on but it touches on the surface of it. Thank you.

The President: Tristan?

Dr Tristan Learoyd: Are any of these based on proposals from other countries or methods employed in other countries? I think is it the Australian method they have generic substitution, is that correct?

Ms Heidi Wright: It does say that some other countries are already doing it across Europe.

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Dr Tristan Learoyd: Do you know the net loss to the businesses?

Ms Heidi Wright: I do not know, not personally.

Dr Tristan Learoyd: The view from industry, and I have spoken to some people from industry, pharmacists, they said that out of all of the options, if they had to choose one it would be three. That is because there is a definitive list there but they said that they would like the definitive list to be based on sound safety data. The concerns that they had included the variation in the colour composition of solid dosage forms, patient acceptability and compliance and the psychological effect, the effect of varying formulants on bio-availability in the generics, and they also expressed concerns over the close monitoring of overseas generic supplies to guarantee their safety and compatibility with other generics in the same group. There is also a concern over non-pharmacist dispensaries' ability with regard to professional discretion and there is also a concern about the carer's ability in care homes to administer inconsistent generic substitutes, and I think Professor Barber will probably know more than me on that.

The President: Tristan, can I clarify, did you say non-pharmacist dispensaries?

Dr Tristan Learoyd: Yes, I think they were referring to doctors' dispensaries so with regard to professional discretion in that case.

The President: Thank you. Phillida?

Dr Phillida Entwistle: Two comments, if I may, on whatever response to whatever option we choose. Going back to the dispensing doctors, I have unfortunately lots of personal experience of this. They routinely generically substitute already. They leave the decision as to whether or not it should be done to their dispensing assistants in the dispensary. When I queried whether this was a sensible thing to be doing I was told it was because they had limited availability of space in which to store a range of drugs so they generically substitute to help themselves. I think that should be -- I think we should have a swipe at the dispensing doctors in whatever response we do.

My second point is about this being an England only event. There are borders between us and Wales and particularly in my case Scotland. I just wonder whether the issue relates to the location of the prescriber or the location of the dispenser because people do move across.

The President: That is a good question. Mair, I am sorry to have taken so long to get to you.

Ms Mair Davies: Firstly, a point of information. There was surprise in Wales when this came out of an English document because the Welsh Assembly government are accepting it to be a GB document, not an England only document, and this is currently being considered by the Assembly, so that is in answer to David's question. They are considering it.

Margaret has given you an overview of exactly how we debated it in Wales and, indeed, we have got 97 per cent generic prescribing there already. The big issues for us were the professional judgment and that pharmacists should be able to make the professional judgment for generic substitution. We are in support of the principle there.

Going to Sue's issue, there is no consideration to the implication for pharmacy practice within this document at all, and I am a bit concerned about the working relationships between pharmacists and doctors and patients. We had a big debate about those as well and I think patients in particular are not considered at all in here.

I do not want to go back over what Margaret has said but we did not think any of these options should be considered.

The President: Thank you. Sylvia and then Alison.

Mrs Sylvia Hikins: Thank you. Just a couple of points. Regarding from the patient's point of view, I think it is very important that the NHS gets best value for money and, whatever is prescribed, that there is no lessening of medicinal effectiveness.

I do actually think that pharmacists do have an educative role when it comes to medicines and patients and therefore if there is a generic substitution which is appropriate, that the pharmacist, and probably already does, is part of educative role in, if you like, weaning a patient off a particular brand name and on to something else.

There will be savings for the NHS in this and it saddens me that the English part of the NHS government has stepped away from free prescriptions for England although they are in Scotland and Wales. If we are going to get £72 million of savings from this, I hope a case might be made and perhaps supported by this august body to suggest that we should have free prescribing in the UK.

Presumably, as we screw down individual prescription costs, we are going to have an increased number of cases where in fact those paying for a prescription in England, which is nearly £8 an item now, are probably pay well over the odds for the actual cost of the product that they are being given which I think, you know, is a pretty difficult situation to be in if you are a patient on a low income. It would be interesting to see some costings as to the cost now of the prescription scheme because one of the arguments was that it cost more to administer than it would be to give free prescriptions.

So I do not know whether we could put a little plug in there somewhere about that.

The President: Thank you. Alison?

Mrs Alison Moore: I am probably going back to some of Margaret's and Val's points but, just to expand on them, when I am working in a community pharmacy, the times when I want to do a generic substitution are either when I cannot get hold of the brand that has been prescribed, which is commonly when it has been a branded generic actually rather than an original brand or, as Val has said before, when it is a handwritten prescription that has either come from an out-of-hours or when a GP has gone and done a home visit or, quite commonly where I am, from a hospital outpatient department. In most of those three circumstances, those brands are not intentionally prescribed, they are prescribed because that is the name that has come readily to mind. We all know that as soon as we phone the prescriber, they say "Yes, of course you can swap it, it is not an issue", and the actual issue is the faffing about trying to get the new prescription written, not the substitution. Those are the situations in which we would like to be able to make a substitution.

Those situations cannot be addressed by lists, either lists of things that can be prescribed and swapped or by lists of things that cannot be, because we should all know as pharmacists what cannot be swapped because we should know what is not generically equivalent and what is because we are trained as pharmacists. We should know that already. I think perhaps one of the problems with this document is, as Dorothy said at the beginning, it refers to dispensers, not pharmacists. Dispensers maybe should not be making those decisions but pharmacists should and can and if this document referred to pharmacists, and it is the pharmacists' professional responsibility to make that decision, and we emphasise that in our response, I think that is an appropriate distinction to make, that it is the pharmacist that is carrying the can for any decision that they make to substitute something and they can justify the circumstances and the reasons why they have made that substitution. As a knock-on effect there might be a few savings but I think the purpose of this would be to make life easier for the patients and for the prescribers and for the pharmacists in those types of situations where we really struggle, just bureaucratically, to fulfil a prescription. Those are the

circumstances, I think, that we should be pushing for generic substitution. If we can say that, yes, it will bring savings and we are happy to welcome those savings, but from our perspective the purpose of this would be to increase our standing as professionals, I think that is the important point to put across.

The President: Thank you, Alison. A number of nods around the table. Sandra wants to make a point and then Lorna, thank you.

Mrs Sandra Melville: I really just wanted to add my endorsement to the Welsh point of view that Alison has been saying and to add that having moved from working in community for 15 years to hospital practice I found it incredibly refreshing not to be hindered by having to give -- if somebody writes a trade name because they could spell Losec and not Omeprazole It happens all the time. You get to use your professional discretion and it seems that this is trying to use the pharmacy profession to get the doctors to prescribe better. I think the whole way of looking at it is not the right way of looking at it. It is not the perspective that should be taken and it should really be about the pharmacist being free to use their discretion to substitute when they can.

The President: Thank you. Lorna?

Mrs Lorna Jacobs: Thank you. Everyone has made most of the points. I admit that it is about not merely doctors having professional discretion but pharmacists having professional discretion, and I look at the heading above paragraph 31 that talks about prescriber autonomy and then later down dispensing flexibilities. These are not terms in the same category. What about pharmacists' autonomy? I think that is a really, really important point that you have to make. This is sticking plaster legislation and really, if you focus much more on pharmacists having dispensing autonomy, then the government will find that the savings will be made and the patient safety and the patient compliance will all be wrapped up much more effectively than doctor autonomy, dispenser do as you are told.

In paragraph 44, in this scenario, "the dispenser can only supply a generic against", it actually is not clear where the "only" belongs. Does it mean that in this scenario the pharmacist must supply a generic, he can only supply a generic or can he supply a generic only in this situation? I think that is actually a bit indicative of their muddled thinking.

The President: Thank you, Lorna. Steve and Bob.

Mr Steve Acres: I just find it quite amazing really that the government should produce a paper like building on strengths to deliver in the future where they are talking about giving more clinical responsibility, more of a clinical role to pharmacists. This seems to be going in completely the opposite direction. It is taking that clinical freedom away.

The second point I want to make very briefly was around dispensers and generic substitution. I would be very against moving forward with allowing technicians or dispensing doctors' assistants to go down that particular route.

The President: Thank you, Steve. Bob?

Professor Bob Michell: Thank you, President. I came into the discussion open-minded, mildly minded to accept option three. Listening to the arguments around the table I now take a quite different view, which is this: I would like to look strategically at what is in the best interests of patients and what will most enable pharmacists to deliver an expanded and beneficial role in healthcare. The answer to that is not to make them function as accountants on behalf of the NHS because the main harm that that will do is to worsen their relationship with GPs and quite frankly, at the moment, the relationship with GPs in many instances, not all, still seems to be in the Palaeolithic stage compared with hospitals. We really do need the sort of trust and partnership relationship which is developing very fruitfully in hospitals and so

it should not be a matter of a pharmacist intervening because there is a checklist, it should be a matter of a pharmacist intervening as a matter of their trained professional judgment, and that is a judgment which they have and other forms of dispensers do not have.

If you want to save money for the Health Service, save it from where it has been mostly profusely wasted and that is the GPs. The GPs have looted the Health Service.

After years of being underpaid for providing an extremely good service, they have now succeeded in pulling the extraordinary trick of being vastly overpaid at the same time as abandoning many of their most important responsibilities. Frankly, a lot of people must envy them for pulling that trick, but the fact is that their dereliction of duty over out-of-hours care is costing patient welfare hugely but it is also costing the NHS hugely, not least in cluttering up A&E with patients who are trying to escape the abominable out-of-hours arrangements which their GP practice is providing. Frankly, if these overpaid and luxuriously employed people cannot prescribe properly, that needs to be the pressure point. If they cannot tell the difference between the generic and the brand name, and is it because they are getting nice free gifties from the people who supply the brand name, then that is the point to intervene because trying to intervene via pharmacist pressure will simply undermine the chances for a constructive professional relationship between the two. We do not want an economic or policeman's relationship between the two. That is not in patient interest in the long term.

The President: Thank you very much, Bob. John?

Mr John Gentle, The Treasurer: It is getting a bit like "Have I got news for you", this. We have just send the lawyers scrambling upstairs to review their books before Bob's speech goes on the website.

Gerald commented on the amount of savings and Margaret particularly in Wales said that the savings would be minimal. There will be some savings and I suppose £50 million is relatively small but it is nice if you can save it, I suppose.

It seems to me though that it is a professional freedom for pharmacists to change things that I would support this for. Comments that Margaret made and Val made, and in particular that Alison made, the scenario that it is the Boxing Day rota and you are scrabbling around for an hour trying to find a GP to get him to change Amoxil to Amoxicillin for a one-off antibiotic prescription, there is no benefit to the patient in getting the brand here. It is the hassle factor that we have here and we know what the GP will say, as has been pointed out.

In terms of patient safety, it is the kind of thing that routinely goes on in hospitals and I do not see why it is safe in hospitals and not safe for pharmacists to do something similar in the community.

The government have made this paper particularly and unnecessarily complex around items 30 to 50 in particular. I do not think, for instance, that we need to say on the form we need to inform patients about section 17(d) of the drug tariff on the form. It is completely unnecessary to put these kinds of things on the prescription form. What is the patient benefit? It will confuse them, they will not understand it. I could not see that.

The scenario where a doctor might prescribe two items by brand, and one to be changed and the other one not, I am struggling to understand where this is going to come from and why you cannot write one generically and one branded otherwise. The sections where they are talking about how can we work out where the doctor can initial three of the five items but not the other two items, it seems to be almost like the Dangerous Dogs Act, this, where they have looked for the worst case possible scenario and written the legislation for when things go wrong and not written the legislation for when pharmacists and doctors can work to the benefit of the patients and cost basis of the NHS. So from that aspect it seems to be strange legislation.

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We are talking about branded prescribing but within generic prescribing. It is common in my pharmacy to get prescriptions for either Amlodipine, either Amlodipine Besilate or Amlodipine Maleate. Now, a prescription for Amlodipine can be provided by either of the generic salts. They are all bio-equivalent and this is why a list, in my view, would help because it would save the pharmacist having to go round and check for two salts he would be unfamiliar with. Put them on a list and let the MHRA argue about bio-equivalence.

I would go further and say the pharmacist reform comes in here. When you are looking at something like Ramipril, which is available in tablet form and capsule form, as long as the patient is happy to take either, I do not see why the pharmacist should be stopped from supplying either, particularly when one costs three times the cost of the other. It seems to me to be a daft system to put legislation in place to stop the pharmacist doing that. If it is to allow that to happen, then fine, I think we should be going down that road.

So the point of the list is I think it will save time and it will save problems debating bio-equivalence issues and it will make life easier and that is why I would like this legislation if it makes my life easier and it makes me make the patients' life easier, whereby I do not have to spend time hassling doctors, because they do not appreciate it. They say "Of course, what are you phoning me about that for? Why don't you just do it?" They do not understand why we are calling them, it takes time, effort and money. So I think we should be looking for the quickest and easiest way that we can allow pharmacists to do this and it seems to me that this paper and option three in particular is probably the solution although it is not perfect.

The President: Thank you, John. Briefly, Sue, if you could.

Mrs Sue Kilby: Very briefly, can I support what John actually says? I know Alison says that we all know when to be able to change from the brand to generic. Actually we may know that around this table, we may think we actually know when we can actually do it, when we can do it safely, but actually when you actually talk to people out there -- and I have to declare an interest because I have worked in a blue chip company and I have also worked in a generic company and I have also done qualitative research around this area and actually looked for definitive lists on products that you can change from one to another and actually there are very few lists around. The only one I came across is the one that was updated from the North-west MI centre and, in fact, I think there does need to be some guidance and that is why it is useful to have a list to provide guidance to the profession as to what can be done in terms of safety and what should be actually excluded because, as an organisation, we have never really defined a definitive list and there are more complex products that are actually coming off patent such as the biologics that I would not want to be switched in some cases unless we are pretty certain what we are doing.

The other important element of it is actually ensuring that the patient is appropriately counselled when you are actually making switches from one product to another because there is a lot of people who are totally unaware that there are variations in the generics. It can be within about 90 to 120 of the original. People do not realise that. Products can go up and down so you could be on 90 on one generic, you could be on 120 on the other, and the difference in the two is actually significant with some products. Not all pharmacists are aware of this. You know, what are the issues? So I think it is important there is an agreed list if we are actually going to go ahead with this. It may not be ideal but I would strongly endorse what was said.

Finally, what Bob was saying about GPs, yes, but the other problem is actually unfortunately patients do not always take them and that is where the biggest waste actually occurs and we need to do more work about trying to improve concordance and adherence with medication. I think pharmacists have a huge role around this. This also links back into changing from one product to another and ensuring that they are properly counselled when they switch from one product to another.

The President: Thank you, Sue. Alison and then Jeremy and then we will close.

Mrs Alison Moore: Just to quickly come back on the list thing, personally I would not support a list of drugs you could generically substitute or drugs you could not but I do see John's point about having a list of things which are generically equivalent to each other. That does not mean you can or cannot substitute them, so not as a list of these are the products you are allowed to substitute, these are the products you are not, but to have a list saying Amlodipine Maleate and Besilate are both the same, you can interchange them if you wish. That would be a useful list to have and I think that is a distinctly different type of a list, just to be able to say, yes, Ramipril tablets and capsules are interchangeable, don't worry about it. For somebody else to have made that decision would be a very useful thing indeed. The things that I have had to generically substitute recently, after discussions with the GPs, have not been on this list and those are the things that come up time and time again for me and they are not even on the list of top 40 so it is -- you know --

The President: Jeremy?

Mr Jerney Holmes, The Chief Executive & Registrar: I think this is quite a symbolic discussion at a pragmatic level. It may be that option three is the least imperfect of the options put forward but I like the qualification that Alison and John have raised, which is a different kind of list, a list of products that are interchangeable, so you have got some reassurance that a substitution is appropriate.

I think behind that pragmatic discussion there is a very strong theme of professional judgment coming out here and it has echoes of the way in which the boards responded to the consultation on the GPHC standards. Actually we do not want to be confined. The profession needs the flexibility to exercise its professional judgment. So rather than detailed prescriptive requirements there needs to be a recognition that pharmacists have the skills to exercise that judgment in a professional capacity. That requires trust amongst the other players in this particular piece of action, particularly GPs. So I propose that we build this into the work that we are doing with the Royal College of General Practitioners such that they understand the professional skills that pharmacists have and the way in which those skills can be exercised in the process of generic substitution and raise this game above that of lists and confines such that the ambition of the White Paper, as Steve mentioned, can be realised and pharmacists can become true clinical professionals.

The President: Thank you, Jeremy. Well said. Marcia?

Ms Marcia Saunders: I think Jeremy's summary is really, really helpful and I am glad you made the point about the Royal College of GPs because three colleagues have made some very generalised colleagues about GPs and I know they are largely for rhetorical purposes but there are good GPs and there are bad GPs and in fact the characterisation by no means represents the vast majority of GPs whom I know.

The President: Thank you, Marcia. Have you got what you need, Heidi, or probably more than you need?

Ms Heidi Wright: Probably more than I need. It has been really, really useful to hear everyone's discussion. The other thing I will say is it will be the English Pharmacy Board that will be submitting the response to this consultation. If you have got any other issues, arguments, anything else that you would like to put forward, if you could get that to me by the end of this week, that would be really good because we have got an English Pharmacy Board meeting next week with the new Board.

The only other thing I would say around professional discretion, just to play devil's advocate, it probably comes with liability issues as well. So that is the other thing to consider around that.

The President: Alan, did you want to make a point?

Mr Alan Kershaw: I just wondered, what was the answer to my question about what were the views of the Society's public liaison group?

The President: I do not know whether we have taken those views.

Ms Heidi Wright: We have not.

The President: We have not but we will do.

Ms Heidi Wright: The response does not have to go into until the end of March. We probably should have looked at them earlier but we have not so we will.

The President: Kay?

Mrs Kay Blair: Just a very quick question, if I may. If the English Board were to adopt the recommendation of the Welsh Board, would the expectation be that the Department would actually rethink this or is there any views about what might happen if that scenario unfolded?

Ms Heidi Wright: I do not know.

The President: It is a matter for the Department to consider when it gets all its submissions, Kay, but --

Mrs Kay Blair: There was nothing in the past that would lead you to believe it might act one way or the other?

The President: No. Thank you for a good discussion. There are some common themes emerging, clearly. The key one for me is we should be trusting pharmacists' ability to do professional judgment here. Pharmacists need guidance and information to support and inform that professional judgment. The primary focus should be on the patient in terms of benefit and safety, the secondary focus on cost savings, and actually the practical implications of implementation also need to be considered. That would be my summation of the discussion. Thank you very much, Council. Thank you, Heidi, for your contribution.

[Council agreed that generic substitution should be applied when the professional judgement of the pharmacist considered it appropriate; when it was in the best interest of the patient; when there were sound financial reasons for the substitution and when practical reasons dictated substitution. Option 3 in the consultation represented the closest response applicable to the Society but, akin to the Welsh Pharmacy Board's response, needed to be amended to include the professional judgement of pharmacists and the trust of general practitioners.]

*[Council
received
i. the report].*

7. Implications of the revisions of EU distribution directive and the MHRA consultation (MLX 365)

The President: I am going to move straight on, if I may, to item 7, which is concerning implications of revisions to the EU distribution directive and MHRA MLX 365. John and Gerald have kindly agreed to lead us through this consultation. Again, Heidi will stay with us here to feed back comments into the consultation process and response to the MLX conversation. I am not too sure, John, you are going first, are you? Thank you very much.

Mr John Jolley: Thank you for this opportunity to review this MLX 365 consultation paper. This consultation paper impacts both on pharmacy, all sectors of pharmacy, and certainly we will benefit from having this discussion. It also has knock-on implications on the European

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regulatory strategy which you certainly must be aware of before reaching any of the conclusions.

Each year there is an annual review of those regulatory provisions affecting the development, manufacture, distribution, marketing of all pharmaceutical medicines and also pharmacological activities. A brief outline of the European programme, each year there is a meeting held at Horseferry Circus here in Canary Wharf, which is the centre for the former EMEA. The first piece of news is that this particular organisation will no longer be called the EMEA, it will be just called the European Medicines Agency, from 8 December, an important point to note because, of course, it affects all the e-mail contacts within the organisation and, in fact, those are live at the moment.

The meeting that was held on 2 December, as I say, is an annual meeting. It covers and includes representatives from all 27 member states' regulatory authorities plus one or two extra and, in fact, on 2 December there were representatives from the Turkish regulatory authority there as well. It also includes various interested parties, European organisations, and in fact my inclusion was on behalf of EIPG and certainly the information then needs to be cascaded throughout the European organisations and PGEU and EHPG are also informed.

Basically, we identify those regulatory provisions which require amendment during the course of the year. The major European Directive 2001/83 is the collective directive which applies to all regulatory factors within the pharmaceutical industry.

There are three basic statutory instruments. There is a regulation where EMA will issue a particular directive on member states and they are mandatory. There is no discussion. They become immediate law. The directive is an advisory document initially and when it is published it then allowed two years for each member state to implement the provisions of that directive into their national regulations and those are then mandatory on people within the country. There is a third category, which is guidelines, which are more prescriptive and more detailed aspects of each direction.

So a meeting was held in November 2008 and, just to give you some explanation, these were the key issues that were identified at that meeting. First of all, the issue of patient access to medicines information was detailed and various provisions allowing for quality information on prescription only medicines provided for and industry contact to patients. Secondly, anti-counterfeit medicines, this has been for some time a key issue and a requirement to have authentication processes that would track and trace the distribution of medicines throughout the European Community were identified as being required and authentication of medicines to detect possible counterfeits. Automated checking of dispensing medicines was also a pre-requisite.

Gerald will shortly give you further detail that PGU have considered in all of these aspects.

The third area was in pharmaco-vigilance and various measures to improve the monitoring of safety of medicines within patients, again, throughout the Community were destined as a basic requirement. Although elaborate, that provision will be coming into play.

As regards the December 2 meeting, the highlights from that meeting were first of all that there is planned a revision for good distribution practice. All of these measures have not yet been started and will actually be discussed during the course of the year. This is where it becomes most important that we are aware of what ongoing discussions are taking place before considering our response to MLX 365.

The first requirement is that all regulatory authorities are to consider a more cost effective method for the distribution of medicines. This is very much blue sky research which is looking into the ways that medicines may be distributed throughout the European Community. There are various suggestions that automated systems be taken up in order to improve the cost effectiveness of the method of distribution. Certainly, automated dispensing systems are

heavily featured within this and how those can be integrated into the distribution pattern.

I will say at this point, these are long-term measures so that they will not actually be implemented next year. However, the ground rules are being set at this point of time to agree what is the best method and most cost effective method of getting prescription medicines to the patient.

The second issue is quality management systems within the supply chain. There are many issues with regard to what is referred to in European speak as the falsification of medicines. These form two particular areas. One is the counterfeiting measures where certain manufacturers will deliberately go out of their way to falsify the production of medicines. The other and increasing incidence is where active ingredients are supplied to established manufacturers which have been contaminated or tampered with in some way for particular financial gain. There are some notable cases in this and, in fact, those of you who remember the last Olympic games in Beijing, there were great issues with regards to the introduction of Melamine which chemically when added to a product will give an artificially high protein level to the product that is manufactured. There have been similarly a number of other cases, most notably on the case of low molecular weight Heparin where contaminants were added to that product in order to give, again, a false assay result. Various generic products have been put on the banned list from a generic manufacturer in India, Ranbaxy, where deliberate adulteration was taking place and where test results were incorrectly manipulated to give a false impression, all for capital gain.

There is also, in the Ranbaxy case, various issues regarding the nature of the manufacture and possible cross-contamination with beta lactam products from antibiotic manufacture which again has resulted in certainly the FDA banning 15 of the Ranbaxy products into the US. European regulations are likely to take account of that.

The European Medicines Agency wish that a project be ongoing in order to guarantee the security of medicines entering into the legitimate supply chain for prescription medicines and there will be certainly various measures in order to establish quite clearly a quality management system which is appropriate to medicines production.

One of the key factors which certainly we will see within this regulatory framework is the provision for assigning particular individuals with key responsibilities in various parts of the process. This we have known as certainly the qualified person who currently has responsibilities in the area for active pharmaceutical ingredient production as well as commercial manufacture, distribution and in clinical trials. That remit is likely to be expanded so as to make not just companies responsible but individuals working within those companies accountable. This clearly cannot be done outside of the European Community and so measures are being taken in order to establish who is key responsible for importing products from outside of the European Community into any medicines which may be used within the European Community.

Now, with specific regard to the MLX 365, and I think this is where the majority of the discussion will hopefully help Heidi in making her representation, I do not propose to say a lot at this stage about this other than to just outline what MLX 365 is asking us to do. It first of all gives us a do nothing option. If we move on, the second option, various controls are proposed, controls on wholesaler dealers. These wholesaler dealers do not apply exclusively to those wholesalers. They will apply also to every community pharmacy which has at this point in time a right to wholesale up to 5 per cent of their total turnover. Certainly, measures and controls are being suggested in this paper that will impact on that.

There are various controls on the nominated responsible person who has to be nominated on a wholesaler dealer's licence. These controls are fairly basic in that there are extensions and requirements which the existing responsible person requires to be able to be carried out. There are additional controls on storage and transit of medicines because, again, concerns

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are being raised about the nature of much of our transit and storage, particularly within pharmacies where drugs are not being stored in accordance with the manufacturers' recommended storage conditions, which might well affect the stability and shelf life of a particular product. As such, there are implications both to community practice and hospital practice. Finally, there are various measures proposed which introduce criminal sanctions should there be any deviation from the measures which are proposed.

There is then a further option three which specifically addresses the responsible person and I think perhaps, as a profession, this is the one area that we should have greatest concern over. One of the measures that is being provided is that because of the importance of this responsible person and because of the large number of non-pharmacists who may wish to be nominated as responsible persons in this area, the MHRA are actually proposing that they introduce a qualification which they will certify for such members. At the moment, within the regulations for wholesalers' dealers, there is a recommendation that the responsible person should preferably be a pharmacist and, if not a pharmacist, should have undergone a requisite course on the nature and safety of medicines. The second factor is that all responsible persons must carry out a supervised course of practical experience which, in effect, is no different from what current arrangements apply, except that those people who are have qualified as eligible to be nominated on a licence as a qualified person are no longer given an exemption in these provisions.

Now, all of that added up, then the particular consultation paper suggests that there would no longer be a need for the responsible person to be registered to any professional organisation because the MHRA are suggesting that such people, because they are taking over the certification, will not deem it necessary that those responsible persons be preferably a pharmacist. You can probably gather from the tone of what I have said that I am not wholly in agreement with their proposal.

That is a very brief outline of the major areas. Perhaps I can hand over to Gerald to give some further explanation of the European strategy for 2009 and what actions have been taken and to also then give some comment on the MLX 365.

Mr Gerald Alexander: John, thank you very much. Before I go into this one, because I have identified some gaps that the consultation will create difficulties for community and hospital pharmacists, just to let you know about the -- John refers to the EU strategy on medicines. The EU Commission is consulting and has been since 2008 on a pharmaceutical package. The pharmaceutical package, as John on one of his slides mentioned, was about information to patients, pharmaco-vigilance proposals and an anti-counterfeiting Directive. The Directive would change Directive 2001/83 which is a major piece of pharmaceutical legislation that exists in Europe and, as I have been the PG representative from this Council to PGU, which is an organisation which represents community pharmacy and the 27 member states are members of PGU, PGU of course has a interest in lobbying, perhaps might be the best way of putting it, the European Commission given the advice of its member associations to suggest changes to that legislation.

The current legislation is likely not to change in relation to information to patients. It seems that information to patient legislation is going nowhere and therefore it will happen at some time but it will not happen in 2010. The information to patients, the industry was trying to lobby very heavily to get information directly to patients and that does not sit very well with the medical and pharmaceutical professions across Europe. It is probably better that patients receive clinical information from healthcare professionals.

So I think the European commissioners understood that and it is now on the back burner. It does not mean to say it will not come back because it probably will do. All of this stuff is slightly cyclical.

The pharmaco-vigilance proposals, just in a nutshell, are about adverse drug reaction

reporting. We have got a fairly reasonably sophisticated system in the UK and pharmacists are actually able to report adverse drug reactions in addition to the medical profession and I think patients also can report. In Europe, I think in Sweden, for instance, pharmacists cannot report adverse drug reactions. So there is a time lag there and they were quite surprised when I suggested it was a good thing that patients could report directly adverse drug reactions.

The pharmaco-vigilance proposals take into account medication error reporting as well which is something that -- Wendy is not here at the moment but medication error has been something we have been dealing with, within the Society and within UK pharmacy, for some years and again we are quite advanced, I think, compared to the rest of Europe.

The proposals that the PGU have made to pharmaco-vigilance changes literally have been accepted by the rapporteur for the EU Commission. I cannot think -- I think it is an English MEP but I am hopeless with names so I have forgotten that. So the pharmaco-vigilance proposals are going ahead and will probably reach UK legislation and law later on.

The anti-counterfeiting Directive is the piece of work that has been going on for a long time and PGU has been making representations to the rapporteur, who is a Ms Mathias, who is from Portugal. She is one of the far left members of the European Parliament but she is dealing with the issues of that. The key issues about anti-counterfeiting are to try and make safe the medicines that reach the European market and that patients receive medicines safely or pharmacies receive them.

The issues that PGU has in relation to the internet are that internet -- that is the major source of counterfeit medicines reaching people and that is where the problems occur. Most medicines that are counterfeited are traded. John talked about manufacturers. I think we should talk about those people who supply counterfeit medicines as being nothing but traders because they are not regulated. It is purely for financial gain and it is criminal.

There is lots of information that I have provided to Jeremy and to the staff in relation to the WHO and the information that they have provided but, just taking you to the issues of the anti-counterfeiting Directive, the anti-counterfeiting Directive also has within it the potential for another piece of work, which is called the medicines authentication work that goes with it. It is authenticating medicines within the pharmacy through some form of electronic recognition method, for instance, a radio frequency identification or a two-dimensional bar code.

Those are pieces of work that are going on. There is also another piece of work that is going on through the EDQM, which is the Council of Europe, which works out of Strasbourg which represents the 53 states aligned to the Council of Europe, and they are currently conducting a trial on some sort of medicines authentication technology system. They are conducting a trial. So that piece of work is going on.

Where PGU perhaps differs from the proposals in the anti-counterfeiting Directive, and would suggest that member states have their own individual medicines authentication technology recognition system, it is really down to the member states, and it should not be imposed by the EU Commission because, for instance, in Spain they have a different view of what they call track and trace. It is tracing the medicine from the manufacturer right to the point of supply in the pharmacy. So it may not be necessary to actually conduct a complete track and trace system right the way through from manufacture to supply to the patient. From the point of view of patient safety it is probably enough as far as some member states are concerned, I think probably enough as far as the UK is concerned, to make sure that medicines reach the patient safely through the pharmacy via prescription.

So those are the three pieces of work that are going on. I am sorry about that. I typed up that really quickly. I left off the 'A' off the slide. It should be MHRA consultation, which is the

medicines healthcare regulation agency. I can do things too quickly on a computer and I think everybody knows that so I apologise for that in advance.

This consultation really fits reasonably within the overall work that is going on in Europe but this is measures to strengthen the supply chain within the UK. One could argue what is necessary and what is not. Thank you, Martyn, for giving me this. Which one do I press, the one on the right? OK. Look at that. That is the one. I will go back one and I will say this consultation follows on from last year's consultation and Sadia answered the consultation on behalf of the Society at the beginning of 2009, I believe. I think that was called MLX 357 or 257, I cannot remember. This consultation is all about plans to implement most of the changes by April 2010. The changes planned include to remove the £35,000 turnover concession regarding reduced fees, tightening on wholesaler dealers including, and this is where John has already mentioned, fit and proper persons, criminal checks, payment in advance for fees and licences, introduce due diligence obligation and each body corporate at a wholesaler site must have a wholesale dealer's licence which cannot be transferred. Responsible persons, John has already talked about that, so introduction of minimum training standards, introduction of code of practice, the MHRA to hold a list of those responsible persons, and I think probably we would all agree that those responsible persons should be pharmacists. Introduce due diligence, require each site of multi-site wholesalers to nominate a responsible person. Import for export, operators must check authenticity and provenance of medicines and keep records. This sort of fits with the EU situation. The wholesalers must know where the medicines come from in the first place before they redistribute them. The MHRA has the authority to inspect premises, records and take samples. Transit, storage, place a legal obligation on those contracting for storage and transport to ensure probity.

I put this all on to one slide and unfortunately perhaps in hindsight it would have been easier to separate it but these are the issues for pharmacy. This is where it becomes difficult for community pharmacists and hospital pharmacy to restrict the use of section 10.7. 10.7 is to emergencies that are occasional, a small quantity and not for profit. This is the Medicines Act legislation 1968, is that correct, Sarah? Thank you. This is the area that pharmacy actually works within currently. So it was found that section 10.7 was not compatible with EU legislation, hence the very tight restriction. So EU legislation, the Department of Health has decided that the exemption that pharmacists are currently able to work within was not compatible with EU legislation. I am not going to comment on lawyers at the Department because you probably all know my feelings about English language testing, but we will move away from that.

So this applies to hospitals and could affect the movement of hospital services into primary care. Will there be public health implications if this comes into force? I think we might need to consider that. Pharmacies wishing to trade larger amounts will be obliged to hold wholesale dealer licences and comply with all requirements. So the small scale operation is, in effect, going to be banned and this is where it becomes a problem.

So pharmacists will need to hold that wholesale dealers licence as the reduced fee is being removed. I do not think any of us would probably welcome that if we were trying to supply local practices with medicines. They would need to issue guidance on the safe disposal and exchange of unwanted and near expiry stock to be regulated by Royal Pharmaceutical Society inspectors, soon to be the GPHC inspectors, issue guidance for the disposal of unused and discarded packaging in pharmacies, which is quite interesting because it could mean that pharmacies would literally have to shred all the cartons that are currently being thrown away before you re-dispense it to a monitored dosage system which could be just in case somebody goes around the back of your pharmacy and jumps into the bin and finds some interesting packaging so they can replicate it to produce a counterfeit medicine. I hardly think that is likely but, anyway, this is what is being suggested.

I am sorry, where was I? That almost seemed like a joke but it was not. Issue guidance. Introduce targeted and risk-based inspections by the Society inspectors or soon to become

the other inspectors. It is to be assumed that this will include checking whether pharmacies are supplying wholesalers. So that is another issue. Criminal sanction, John has already talked about. I do not think I need to go into that.

The implications for pharmacy, this is really perhaps the important bit. It will not be cost effective for a community pharmacist to hold a wholesale dealer's licence if only supplying small amounts, for instance, to doctors' practices. A lot of GPs hold accounts with community pharmacies and community pharmacies make supplies to doctors. Those small scale supplies, in effect, would be banned under this so where would GPs receive their medicines from in the future? They would have to go to some form of wholesaler outside. The current figure I think is 17.37 for a small scale dealer's licence. That is the value of it. I think the proposal is £35,000. So this could affect relationships with GPs and other healthcare professionals including care homes and hospices, who are currently supplied under the exemption, 10.7. Increase the burden of regulation if you have to obtain an wholesale dealer's licence and include responsible person training, not a pharmacist, we will forget that. Increased inspections, increased costs associated with the destruction of packaging. What about waste from other sources, care homes, hospital wards, GP surgeries? When we dump the medicines in our bins we normally just throw the packaging away. Now the packaging will have to be disposed of in another way so I would say this is an increase in the regulatory burden. Inability to supply anyone apart from other pharmacies to meet patient need under the very limited 10.7 exemption.

That is it really. I think those are the gaps that I think we need to think about in terms of this consultation. What I might suggest is that -- I have thought about it. If pharmacy were to have a special exemption where they could supply other healthcare professionals, not necessarily a wholesale exemption, but the supply of healthcare professionals who administer medicines, that could apply to prescribing nurses, general practitioners. The sort of measures to strengthen the supply chain would not be too bad but there are some restricting implications with this consultation and if it goes through by April 2010 I think community pharmacy and hospital pharmacy will have a great deal of difficulty. So I think we need to highlight those issues.

The President: Thank you, Gerald. Thank you, John, as well. Could you get that last slide back up by any chance? I thought that was very useful. We can just talk about some of the issues as it affects pharmacy. John, you wanted to have a word.

The Treasurer: Yes. I think it is very laudable that the MHRA and the government are looking at counterfeit medicines. If you look around sub-Saharan Africa, and certainly West Africa, places like Nigeria and Ghana, and look at the medicines markets there they are rife with counterfeit medicines and you are lucky if you get something that actually says what it -- Ronseal do not make medicines in Africa, basically, which is unfortunate. What frightens me here though is this simply will not do what is intended to do. Has it never occurred to the government that if it is attempting to stop counterfeits getting into the supply chain, that medicines in a pharmacy are already in the supply chain? Therefore whatever that pharmacy does with them, any legislation affecting that cannot possibly affect counterfeits getting into the supply chain because we are talking about here medicines that are already there. So it seems to me if that had occurred to the government to start with, they may not have done this. That is not why they are doing this. There is something disingenuous slightly there and I suspect it has probably got more to do with wholesaling of medicines and stopping Pharmacists wholesaling medicines. It seems that the man who thought of British jobs for British workers is now assisting on British tablets for British patients and, whether that is lawful under EU law or not, I am not quite sure. The government seems to play fast and loose with its interpretation of EU law. Over language legislation it seems that whilst language testing is allowed the government does not seem to like that bit of EU law and this bit of EU law, after seven or eight years after it was implemented they have finally woken up to the fact that maybe they should implement this and wish they had not bothered.

What really concerns me though is in community pharmacy whereby an awful lot of small scale trading goes on, the odd box of tablets here, the odd bit of tablets there, and it helps. There are two other pharmacies in the town where I work and we are continually swapping medications to help each other out in supplying patients.

Now, this legislation talks about exempting those kinds of supplies on the basis that if they are not for profit and if they are small scale, and I suspect they will be brought in on some kind of named patient basis, it is going to mean an inordinate amount of form filling for no real great benefit and certainly no patient benefit safety and it will not affect counterfeiting medicines. So if those kinds of sales could be exempted from this, and some kind of redemption that Gerald was talking about, about supplying other professionals, other pharmacies, that would be fine. We have got no intention of applying for a wholesale licence for something like under £20,000 worth of trade a year. It seems to be absolutely pointless. This seems to be something that is extremely burdensome. It is interesting that in the legislation and in the government's response to it they do seem to be talking about not applying this to hospitals because applying this to hospitals might be too burdensome and onerous. Now, if they are prepared not to supply it to hospitals on that basis can they please apply this criteria to community pharmacy because that would be extremely welcome and a welcome change from this particular government.

The President: Thank you, John. Sue?

Mrs Sue Kilby: Thank you. I think there has been a lot of different issues that have actually been raised here with the two discussions that we have actually had. One we have had about the whole integrity of the supply chain and there is a lot of points where pharmacy or the Society ought to be responding and actually raising the profile, everything from obviously the whole issue about bar codes, the types of bar codes, and being able to track medicines through. I think some of us will remember that we have actually had presentations by Agate who are able to actually check the product at the final dispensing. They could not introduce that process within the UK because we did not actually have enough information on the packages that were coming through but the process has been introduced into Belgium. So there are issues around that.

Now, I know in the veterinary market we have actually been tracking through from beginning to end for some time, have we not, Bob? I know when the veterinary medicines regulations were introduced there were some concerns about what was going to happen in community pharmacy because they were not actually able to do it.

So we do probably need to look at the integrity of the supply chain. There are issues about what is actually happening to some wholesalers. Probably I think we need to think about whether we should be pushing for the responsible person being a pharmacist, and flagging this up as to whether this is appropriate or not. In the hospital sector where we have quite a lot of wholesalers some of them are relatively small but some of them are quite large and I am working with one who is a very large wholesaler and we actually do have a pharmacist who is nominally the responsible pharmacist but I am aware that in a lot of places the techs are effectively actually running the show so there are some slight issues and debate around area. Obviously, I am strongly in support of having pharmacists where possible to actually be the responsible person.

I think there's also issues around QPs as well and where they are going to actually sit in the future and trying to push more strongly that they should be pharmacists and supporting the whole process of QPs being pharmacists and understanding the actual supply chain from the point of view of pharmacy. I think we ought to be having a voice as the Society going forward and the professional body going forward around QPs and RPs. So I think this is something that the professional organisation ought to be picking up on.

I also think that honestly there are issues about medicines information to patients and making

sure that they are able to access information from reliable sources as well. The problem is by saying that we are not actually going to directly promote products to patients is fine but we have only got to go abroad and go to the States, for example, and we actually immediately see that products are being promoted directly to patients. Most people have access to the internet either directly or through libraries these days so, again, they can find information that way as well. So we have got to think about how we manage this situation and being able to signpost people to reliable sources of information.

There are obviously issues about if the section 10.7 is actually removed and clearly around community pharmacies because what we do not want is for patient care to actually suffer as a result of this section being actually removed.

There are issues obviously and concerns that certain organisations have been perhaps exporting medicines and I do not know whether this has been one reason why this has been introduced at the present point in time. I could not possibly comment on that. There are a lot of issues and I just wonder whether we ought to do some sort of risk assessment and actually highlight and pick up the number of points and look at whether some of these things ought to be taken forward and actually go on to perhaps work streams. There is clearly too many to actually do the whole discussion justice at this point in time.

The President: Thank you, Sue.

Mrs Sue Kilby: That is my comments.

The President: Marcia and then Lorna.

Ms Marcia Saunders: Firstly, I want to declare a interest. It is in the Register. I do some work in the MHRA. It is not related to this.

I have two very specific questions. One was whether John or Gerald could just explain the rationale for the responsible person not being a pharmacist, what rationale is given for that? Second, and this just displays by ignorance, could you spell out, Gerald, in one of your slides you said that it would create difficulties in movement from hospital to community, to primary care, if you could explain that.

Mr John Jolley: Can I suggest I take the first part and Gerald take the second part? Custom and practice at the moment allows that the responsible person can be somebody who has undergone a period of not less than 12 months' theoretical training on the storage and distribution of medicines and, particularly, the safety of medicines as well as the 12-month period of practical experience. As such, a number of non-pharmacists have been allowed into the situation but the regulation does state that, if there is a preference, the position of responsible person should be a registered pharmacist because quite clearly they have the knowledge.

Now then, the provision of this MLX allows for the nomination of deputies to the responsible person where there are more than one distribution site, there being one deputy to each distribution site. These deputies work under the specific direction of the responsible person and do not necessarily need to be a pharmacist providing that that pharmacist who is a responsible person has got an effective quality management system in place and that they are accountable to. That is the basic issue as far as responsible persons are concerned. The option three, the amendment to allow the MHRA to train their own responsible persons, who should not necessarily be pharmacists, I would strongly influence and my belief is that that should not be the case. Leave the responsible job in the hands of a pharmacist but allow the deputies to be non-pharmacists.

The President: Thank you, John. Gerald on the second point?

Mr Gerald Alexander: I think the little bit you are referring to, Marcia, is this applies to hospitals and could affect the movement of hospital services into primary care. I am not talking about big movements of hospital services into primary care but there are some services that take place, the supply to I think it could be to patients which could be deemed to be wholesale dealing, I think, where prescriptions are not necessarily written because everything -- I think --(inaudible)-- feeling finds its way into primary care. There are other areas of commercial activity, very small scale, which would affect patients. I am trying to think of issues like -- I do not know whether appliances like colostomy bags or things like that, I am not absolutely positive about that. I cannot give you a definitive answer.

Forgive me, President, although I have suggested gaps, I did not actually really talk about my personal feelings. Perhaps I can come back to that later.

The President: Lorna and then Alison.

Mrs Lorna Jacobs: This was actually more on the business of the responsible persons and my understanding of the role is quite limited. I was thinking that if the MHRA are talking about training and keeping a list and saying that they are fit and proper persons, then that list really only has validity if you also have all the other bits that go with that, which is a process to say is somebody fit to do their job and having a disciplinary process and a code of conduct, and all the rest of, i.e. the regulated profession? Do the MHRA really, if they want to keep the list, do they want all the other rubbish that goes with it, the administration and cost, that would go with that? Is it not easier to say these people must be part of the regulated profession and therefore the list will be a list that is properly maintained and, if somebody is on that list, then it means something, not merely that they did the training at some period of time and there is no evidence that they are up to date or fit and proper. I would, of course, suggest that a pharmacist should be the proper person and that should be the regulated profession but by default, if that fell, it should be somebody who is regulated in some way.

The President: Alison?

Mrs Alison Moore: I wanted to say, first of all, that this is an area that I am not particularly familiar with and it is a shame we could not have had some sort of background paper as well as those presentations because I have struggled to take all that new information in and to be able to then formulate it, think about it and provide you with any kind of feedback. So that is no disrespect to Gerald or John who have done very well with this but if we could have had some kind of background information as well in writing, I personally would have found that quite helpful so I could have thought through some of the issues before the meeting.

Bearing that in mind, what I am about to say might be a load of rubbish so I apologise if it is not actually relevant. One of the things that we were asking about and were talking about was this wholesale supply that pharmacists often do to GP practices and other such places and I do not know if one of the options for the MHRA is look at the system that they currently use in Scotland whereby usually pharmacies supply the GP surgeries under the NHS and it is not, as far as I am aware -- I was just checking the data before. I do not think that is counted as wholesale dealing, it is an NHS supply, and whether there are any ways of doing similar things with care homes and hospices and other organisations. I do not know and I could be talking rubbish if I am because I might not have understood the implications.

The President: Thank you, Alison. It is a fair point about the papers. Gerald, did you want to respond?

Mr Gerald Alexander: Just the issue of the papers. I think Jeremy understands. I talked about changes of staffing and that is why John and I were asked to bring this issue to Council. So I do not normally present and worry about things like that but Martyn has got a whole series of handouts that I have passed on to Martyn for printing and they are all PGU statements on the various issues, medicines authentication technology, pharmaco-vigilance

proposals, information to patient proposals and the anti-counterfeiting Directive. Also there is a briefing note for people like us to go and talk to parliamentarians about in relation to the key issues. They say for PGU but I think it is key issues for patients, where patients are put at risk through the supply chain being breached through counterfeit medicines reaching the supply chain. That is a pretty limited circumstance within community pharmacy across Europe. I mean, other countries have been penetrated by counterfeit medicines but there is a very big issue relating to how patients in member states receive medicines via the internet. We talked about it at Law and Ethics but that is the sort of legal stuff that we have been involved in. It is legal in the UK, Germany and one or two other countries, I cannot remember which ones, in Holland, to actually order medicines over the internet via a prescription. It works; it is feasible.

The problem patients have is that when patients go onto the internet they do not know what is a legal site and what is not a legal site and what is authentic and what is not.

So we have got to be concerned about dangerous medicines reaching patients which would have untold catastrophic effects on patients and how is that prevented?

Now, it is up to member states whether they want to allow internet trading or internet pharmacy or not. Internet trading will always take place. You will always find there are websites way outside of Europe that are purporting to be pharmacies or pharmaceutical providers and individuals who read the internet or always look at the internet will always find the offers. We have probably all seen the SPAM in our e-mail boxes, what you can only buy, and the catastrophic effects that could occur as a result of somebody purchasing that. I think the Royal Pharmaceutical Society has been involved in that rat advert. I had the pleasure of suggesting that they play the rat advert just before lunch at the last PGU general assembly and I think, as usual, one of my clangers, but I think it hit home. The rat advert, you sometimes go to the cinema and see this individual pulling the rat out of his mouth. It is all very dramatic but patients need to know the dangers associated with counterfeit products which ultimately could have catastrophic consequences.

All of the efforts across Europe are to reduce the availability of counterfeit medicines into the supply chain and we should wholly support those measures. This MLX consultation is just one small part of it. It could be construed by some of our colleagues here that this consultation is perhaps just to strengthen the supply chain but to make it awfully difficult to wholesale medicines, in other words, to export medicines out of this country, because there is a lot of parallel exporting. So I will not go on to that but I can understand where this consultation is coming from. I do not think our colleagues in community and hospital pharmacy should be hamstrung by restrictions where we were once able to use an exemption in the Medicines Act to supply our professional colleagues. So I think we should still be asking for limited activity in that respect without any penalties relating to purchasing a wholesale dealer's licence.

The President: Thank you, Gerald.

Mr John Jolley: Just in the interests of time, and I notice we are well into the lunch break at the moment, could I make a suggestion that Martyn has copies of the actual MLX, that they be electronically sent to each member of Council and that we invite members of Council to make any further comments that have not already been made back to Heidi?

The President: That is a good suggestion, John.

Mr John Jolley: The only thing is that the response has to be in by no later than 12 March so we would have to set a closing date of say the end of February for that.

Mr Gerald Alexander: From a background point of view, for Alison, all of these handouts are available, telling you about the PGU comments on the anti-counterfeiting Directive.

The President: So my suggestion is that we do as John suggests, sending the MLX around and also we can send that briefing paper around that Gerald made reference to.

Mr Gerald Alexander: I think Martyn may have that.

The President: I think that encapsulates what a lot of people may need to know. I think that is a very interesting discussion. I think Heidi has probably got, again, more than enough to go away with. Can I thank John and Gerald for their time spent in preparation and presenting today. I think the one key issue that I have taken out of this, there are several, but one is the key issue is about wholesale dealer's licence and the practical implications on pharmacy. I think that is really the issue that will go right to the heart of many of our members in terms of their understanding of what the implications of this are. So thank you again for that. I am proposing now we break for lunch and we will catch up and start again at 2.00 pm. Thank you.

[A key point was made about the wholesaler licence in the consultation, as many pharmacies were accustomed to the minor scale "wholesale" supply of medicines to assist local colleagues to meet the needs of their patients. It is extremely unlikely that pharmacists would apply for a wholesaler licence for a custom and practice worth less than perhaps £20,000 per annum, and, if implemented, the suggestion in the consultation would lead to unnecessary patient inconvenience.

Council members were requested to email Ms Heidi Wright, English Practice & Policy Lead, by the end of February 2010 with any further comments to be included in the MLX 365 consultation response.

[Council

received

i. the report].

(Luncheon adjournment)

8. Homeopathic and herbal remedies

The President: We are on item 8 of the agenda, homeopathic and herbal remedies. This is paper 2 and Jayne will kick us off with this paper. Thank you, Jayne, for coming in. I know you are not feeling well so thank you for coming.

Professor Jayne Lawrence, Scientific Adviser: If I cough please excuse me. I think I have got the flu that everybody else has had sometime this year.

I just want to give you a very quick brief background to this paper and just say that for the past year or so Science Committee have been doing a very extensive review looking into all the scientific and clinical evidence surrounding homeopathy. I should acknowledge that most of this work has been done by Dr Colin Cable, who probably most of you know is in the Scottish office. He is our pharmaceutical sciences information adviser but he was unable to be with us so I am presenting the paper today.

Based on the work that Colin did, Science Committee came to the conclusion that there was no scientific or clinical evidence to support the use of homeopathy. For those of us who are old enough to remember, that actually agrees with the only time the Council has ever made a statement on homeopathy and that was back in June 1986 and they said exactly the same thing, there was no scientific evidence to support its use.

I would also just like to take a second and say that I am actually very grateful for the work that Science Committee did around homeopathy because just before Christmas we were asked at quite short notice to present evidence, oral and written, to the Science and Technology Select Committee on the scientific basis of homeopathy. Because we had done all that work in the Science Committee, we were actually able to make a very informed response so, first of all, I thank Science Committee but it does actually show the importance of having involvement in

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the professional body by learned people who are able to call upon their expertise when we need it.

Just as a very small aside, a lot of you may have seen the news over the weekend, I think it is called the Merseyside Sceptic, had a campaign for 10 23 -- I was a bit slow there -- Avogadro's dilution. That is the number -- when you have diluted beyond that you have no molecules present which is why it was used for that particular campaign. I believe the reason that weekend was chosen for the stunt of this overdose with homeopathic preparations was because the Select Committee were due to report this week. That apparently has now been delayed to mid-February. So you will find those results out fairly soon.

I do not intend to go to the paper in an awful lot of paper but what the Science Committee found, or Colin found and informed the Science Committee, there is a huge amount of confusion out there between what a herbal and homeopathic preparation actually is. One of the things we thought would be useful for the pharmacist was to actually make those differences very clear to them so that they would be informed if patients came in to speak to them. This was the reason for appendix 2.

Now, I think it is really important to say that obviously appendix 2 cannot go out in the form it is. It needs to go out with accompanying notes that make it very clear what the view of the Society is and that the comments contained, particularly under homeopathic remedies, are actually homeopaths' view on the particular formulations and were not giving credence to some other philosophies that are actually contained in that particular paper. So I think that is very important. We should have appended those notes and I apologise for not doing that but those notes will go out with documents if obviously Council believe that is something that is useful for the membership.

Another thing in relation to this and, again, we want to bring this before Council, it was very clear that a lot of preparations that were denoted as being homeopathic would not be what most of us would understand as being homeopathic because they actually contain large amounts of what a homeopath would call a material amount which, for the scientist, is very hard to understand what that means, but large amounts of material actually in the preparation. Now, that actually has a huge patient safety issue and the Science Committee were concerned about this because the view is that homeopathic preparations contain no material so, as a consequence they are safe, in inverted commas. Obviously, if preparations do contain material amounts they become equivalent to herbal medicine in that there is now potential for interactions. So we propose that this is perhaps something that the new professional body or the professional body would like to take further and explore with a view to resolving this issue and hopefully improving patient safety.

The President: Thank you, Jayne. Sue and then John and then Sylvia.

Mrs Sue Kilby: First of all, I would really like to thank you for such an excellent paper. It clarifies a lot of points in my mind and brings to the attention, especially the comment about it actually containing some active materials, because generally speaking you tend to think that they do not. So I think it is an excellent piece of work.

I have one or two comments on appendix 2. I am pleased to say that it is data that would not go out in this form. Obviously, one bit is around no known side effects because if there are active ingredients in there, potentially there could be interaction. The other bit is actually about informing healthcare professionals. As far as my hospital is concerned, we actually ask them to bring all medicines especially as patients are confused as to whether they are herbal or homeopathic medicines. I would still like them to bring all medicines even if they are homeopathic because then we can actually check. If they do not understand, they do not know, I would rather see them and we have got the information there.

The President: John?

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Mr John Jolley: I would also like to echo my compliments to Jayne for an excellent paper. I am very glad that you added that rider that, in addition to appendix 1 and 2 which you propose putting on the website, there should be a statement saying that basically there is still no scientific evidence to support the use of homeopathic medicines. I do not feel that there are sufficient pharmacists currently aware of this fact and I think certainly Council needs to re-emphasise that point very strongly because in certain areas of practice homeopathic medicines are even being prescribed for the treatment of malaria which is beyond the placebo effect, it is not going to do anybody any harm. There is a confusion out in the profession that homeopathic medicines represent yet another one of the complementary medicines.

You referred to a demonstration. Now, Steve's blushes, he probably knows full well about this, this was a demonstration of people who were blatantly taking whole containers of homeopathic medicines outside a number of Boots branches. Paul Bennett, who is the professional standards director, in his response, stated that "We know that many people believe in the benefits of complementary medicines". Yes, I know, but he then goes on to say, "and we aim to offer the products. We know what our customers want." But is a homeopathic remedy a complementary medicine? I think one good point about your analysis, it distinguishes between homeopathic and herbal remedies, which I do not want to classify in this area at all, but we need to be far more prescriptive, advice to all pharmacists, as to what homeopathic medicines represent.

One thing you omitted to mention, and I will have no hesitation in saying, you have actually appeared before the Select Committee which is currently reviewing homeopathic medicines and from our earlier discussions I am very, very pleased with the messages that you took to that Select Committee. Can we please also have those messages out to all members of the profession so there can be clearly no doubt in any pharmacist's mind that homeopathic medicines are not yet another product within the complementary medicine field and that there is no scientific evidence for their use.

The President: Thank you, John. Sylvia?

Mrs Sylvia Hikins: Thank you. I wanted to pick up on what John has just said. This is a very good paper, excellent. The Mersey Sceptics, although they focus on Merseyside, of course the demonstrations were outside Boots pharmacies around the country in major cities and, as John said, they gulped down great masses of this stuff. We do not think there was any ill effect although who knows.

I think the important thing on this is that the fact that these medicines appear on Boots shelves in a major pharmacy retailer sort of legitimises it which I think is a bit of pity really. The Observer report said, and this is the bit that I want to raise, someone from Boots, a spokesperson from Boots, said that they follow the guidelines issued by the RPSGB. So my question is do we have guidelines around homeopathic medicines? What are these guidelines that the Boots spokesperson alluded to?

The President: I have to declare an interest. I could not possibly comment.

Professor Jayne Lawrence: I assume that they mean the Code of Ethics and the associated documents. The Code of Ethics does not mention any specifically about homeopathic preparations but there is a section in Safe and Effective Use of Medicines that actually do mention about these preparations and it says quite clearly in there that you should not advise on these medicines unless you had had appropriate training. So I am assuming that there had been appropriate training to pharmacists.

The President: Phillida?

Dr Phillida Entwistle: Thank you. This is a great advice help to pharmacists but at Science

Committee we did discuss how we could take it further to the public. One of the things that was suggested was that we created some sort of poster which would be displayed by people like Boots near to where they are selling these products with a few cogent points about them so that the customer can read them before they buy them. The most cogent point to makes seems to me to be the penultimate paragraph in homeopathic remedies in appendix 2. If that were on a poster which starts off the way in which they work is not known and there is no scientific evidence, I think that would be very helpful to the public before they purchased them.

The President: Thank you, Phillida. Lorna?

Mrs Lorna Jacobs: I was going to ask the question is this for pharmacists or for patients or for both? If it is on the website, will the patients, the public, also have access to it? If so, it might be better to just do two versions, one that has been through patients to see they do understand some of the language involved. The last bit about the herbal medicines, the two sentences there, again, as a lay person, the two sentences seem to me somewhat contradictory.

“There is a dearth of scientific evidence to support the efficacy of most herbal medicines and many herbal products have not been evaluated.”

“There is evidence for the efficacy of some herbal products in specific conditions.”

Now, I sort of see the difference but it comes across a bit contradictory.

Also in the homeopathic side, there are statements that we would put on our website, the greater the dilution of a remedy, the more potent and effective it becomes. I am concerned that that is effectively the statement that the Society is making about a homeopathic medicine. The more dilute, the more energy it imparted and the more effective the remedy.

The President: I think that is why we need to be clear in the statement that Jayne alluded to that it is not our position.

Mrs Lorna Jacobs: Yes.

Professor Jayne Lawrence: I certainly take your point about patient proofing it in terms of reading. I think that is a very good point.

Mrs Lorna Jacobs: Yes, and I think that the business about whether we are saying these statements or homeopaths are saying them should also be patient proofed.

Professor Jayne Lawrence: Yes, I agree totally.

Mrs Lorna Jacobs: Whatever rider you make you check that patients see it in that light.

Professor Jayne Lawrence: Yes, thank you.

The President: John?

The Treasurer: Thank you. Where to start really. One of the problems with the Code of Ethics when it talks about the safe and effective use of medicines may well be the fact that these products are not medicines legally. They are sold as foods. So you could argue that although they are called homeopathic remedies or homeopathic medicines they are not legally medicines and therefore the Code of Ethics may not be seen to apply if we are talking about safe and effective use of medicines which legally these are not, apart from those that are licensed by the MHRA which surely must have had a day off when they licensed them. I find that somewhat bizarre. I am glad to see that Jayne will clarify that that third column on

homeopathic remedies in appendix 2 will be amended and as clearly as possible, I think, because if we are talking -- the comment that Lorna made about serial dilution, ensuring the efficacy of the remedy, it reads to me more like Harry Potter's spell book rather than a scientific treatise on effective medicines. As you may well have gathered by now, I am not awfully fond of scientists and this is a scientific organisation and in other areas would stress the fact that science underpins community pharmacy, hospital pharmacy, and in those circumstances it is very difficult for this organisation to come out and promote or even accede to the use of homeopathy as a credible medicines treatment.

As well as the MHRA I am staggered under section 3 that the Cochrane review missed a paper that was fairly critical in assaying whether these products were in fact homeopathic or not. You would have thought that establishing them as homeopathic products in the first place might have been one of the first things they did before they reviewed it as a successful trial. I am wondering whether the same guy at the MHRA is also working for the Cochrane review and they had an away day together on that one, I am not sure.

The main point, I think, is to establish that when we put this appendix 2 out, and Jayne has said she will do, it is made absolutely clear that the Pharmaceutical Society of Great Britain does not endorse anything in column 3 in appendix 2.

The President: Alison?

Mrs Alison Moore: I will echo those comments about the second column first before I say anything else because maybe within the text all the time saying homeopaths believe that, you know, in all the little bits, so that nobody can just look at one box and think that is our opinion might help a little bit.

My main point was actually to go back to what Sylvia said about the Pharmaceutical Society being quoted in respect of their – personally, I find it embarrassing if that is the case. I think it is partly propagated by the fact that at the moment our policy is to say that there is no scientific evidence to say that they are effective. That is not the same thing as saying the Pharmaceutical Society does not endorse the use of homeopathic products because there is no evidence to say that they are effective. We do not do the first bit, we just say the second bit, and that leads people to be able to say, "Oh well, they have not said do not use them, they have just said there is no evidence that they are effective", and I wonder if, even at this meeting or at a subsequent meeting, we can keep looking at this and see if we cannot come up with a better policy than there is no evidence for their use because that really is just sitting on the fence and I just do not feel it is appropriate anymore for us to keep doing that.

Professor Jayne Lawrence: Can I just make a very quick answer? The problem is there is not a policy. The Society presently does not have a policy.

Mrs Alison Moore: --(inaudible)--

Professor Jayne Lawrence: Yes, I agree and I think that is really big problem so it is something that ought to be resolved, I agree.

The President: It is on this point Marcia?

Ms Marcia Saunders: Yes, it is on this point. When I was a member of the Science Committee for two years about three years ago we did a lot of work on guidelines around homeopathy and my understanding was that something was put out and it was very clear that these were not medicines, it was very clear that people needed to protect patients from believing that they were medicines. Just also on that point I also saw Paul Bennett quoted as saying that indeed there was no evidence for -- I think, personally, he should have said we sell hairspray too, but never mind. Shall I go on to the other point I was going to make?

The President: Yes.

Ms Marcia Saunders: Which is I agree completely with John that we should substitute the word “products” for “medicines” in our own material as well and not actually keep using the word “medicines” there.

Then, finally, I hope that the new professional body will support the efforts that are currently being made to get NICE to take a look at homeopathic products.

The President: Thank you, Marcia.

Professor Jayne Lawrence: Can I just say something quickly on that? There is a petition, number 10 petition, at the moment if anybody is interested that you can sign up that is specifically asking NICE to look at the efficacy of these particular types of medicines, if anybody wants to join.

The Treasurer: Products. You said medicines.

Professor Jayne Lawrence: Sorry.

The President: Mair:

Ms Mair Davies: Just to remind you, these are still prescribed on the NHS by doctors and pharmacists, I think, are going to have quite an ethical dilemma when this goes out and a prescription comes in and we need to give thought to that.

The President: OK. Alison, on that?

Mrs Alison Moore: Yes, on that. Just to comment that I am aware of several circumstances when GPs prescribe things that I do not necessarily personally agree with the use of, that that is a dilemma that one faces on more than one occasion and not just related to homeopathy.

The President: Steve and then Dorothy

Mr Steve Acres: It was really just a presentational issue really. I was glad to hear Jayne saying that there was going to be a covering letter that clarified the Society’s position.

In appendix 2, if you look at the second page of appendix 2, page 9 of 9, and you look at the top two boxes, if you were somebody who was uninformed and reading those particular boxes, you might assume that homeopathic products are the right thing to do. I just wondered if presentationally whether you should have two separate fact sheets rather than a comparative table because of the way people might see that.

The President: Thank you. Dorothy?

Mrs Dorothy Drury: As has already been said, these are allowable on FP10s and I have had to dispense them so there is a difference between selling products, and you would be endorsing them, and having to dispense them. We could not really refuse to dispense a homeopathic medicine.

The President: Bob?

Professor Bob Michell: Thank you, President. The issue, first of all, about whether we call them medicines or not, people do call them medicines. I think it is going to be very difficult to actually change that. What I think is more important, these two appendices I think are mostly extremely useful in making it clear to pharmacists and all sorts of other people that the difference between a herbal and a homeopathic is actually quite subtle in some cases.

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If we do it for public consumption, then I think there is something else that needs to go with it and to be very prominent, and it is to emphasise this: that the medicines which patients normally receive on the NHS have been subject to extensive and expensive testing to show that they work and within reason that they are safe just to get them registered and these days increasingly they also have to be subject to additional scrutiny from NICE. None of this applies to homeopathic remedies. There is no evidence based patient protection. That is the first thing.

The second thing, which has already been referred to, is the issue of prescribing them and therefore, in other words, availability off the NHS budget. I realise they are not necessarily the most expensive of medicines but what it does --

The Treasurer: Products. It starts here, Bob, it starts here.

Professor Bob Michell: I do not think the prescribing of nostrums on the NHS budget is ethically acceptable for the reason I have already hinted at. You cannot have a two-tier system in which patients may be denied drugs for which there is excellent evidence of efficacy. It just does not happen to be in the British culture or under British approval or yet approved by NICE, or whatever it is, but there are many medicines which are efficacious which patients cannot have and on the other hand to be spending NHS money on nostrums that, by any of these criteria, have no evidence of efficacy at all. I think that is going to be very important in future because, first of all, there is a growing pressure that these products or nostrums should be available on the NHS and whatever is said ahead of the election it is quite clear that the NHS budget is going to be hugely curtailed after the next election and it is therefore extremely important that not a penny is wasted on substances that have no proven efficacy whatsoever.

The President: David, sorry to keep you waiting.

Mr David Thomson: Thank you, President. Just to indicate I work in a Health Board area that has a homeopathic hospital with the main medical lead on that being very active in the area one of these papers has cited as a reference in the document. So we have a lot of involvement with homeopathic treatments and the hospital has a six-month waiting list. It is one of the few areas that still has a waiting list. That might be a form of treatment under homeopathic laws in itself but it attracts a huge amount of public interest. Patients' choice is that they want to be treated homeopathically and that generates prescriptions which are dispensed by pharmacies within the Glasgow conurbation.

It also generates a huge amount of OTC sales as well for these products. We are aware of unscrupulous practitioners in the area as well that supply white tablets claiming to be homeopathic tablets and they charge an extortionate amount of money for the equivalent product that can be bought for £2 or £3 OTC. They charge about £30 for the same product. The fact that pharmacy is involved brings a degree of legitimacy to the service. It also brings a safety and standard to it as well which, from a patient's perspective, is quite useful. It is not endorsing or encouraging the use of the treatment but it brings a safety standard which I think we need to respect rather than dismiss as being inappropriate.

The President: Thank you, David. John, do you want to come back?

The Treasurer: Yes, just briefly, I appreciate what Bob says about people using the word "medicines" in common parlance. However, I do not think that we should carry that on and I think we should start to use the word "product" instead of even "remedy" which it says here because I struggle to justify the word "remedy" along with "medicine" because it is not a remedy. So I think in our official documentation we should start to change the terminology and hopefully that will spread.

With regards to Boots also sell hairspray, we do, but at least they have some decency to put some hairspray in the tin, whereas with 30c Arnica that has no Arnica in it, I am wondering whether the consumer legislation should start to investigate this because it is a breach of some consumer Act surely and maybe the DTI can show an interest instead of competition in pharmacies which they do not belong there.

I think Alison's comments about stating that we do not endorse these products' use, and that the question is we have no policy on it, if we have no policy on it, it is surely true that we do not endorse their use, so I think it is legitimate for us to use that phrase and to preface our comments with that.

Just a final comment, I think where we could give some advice is to the people organising mass demonstrations outside these Boots stores. They surely missed the point. If only one person were to demonstrate it would probably be far more effective and perhaps we should advise them so.

The President: Thank you, John. With that, I think we will move on. Subject to the amendments that were talked about, Council are happy for these appendices to go onto the website. (Agreed) Thank you. Thank you to Jayne for coming in and also to Colin.

Mrs Alison Moore: I just remembered something. It has just occurred to me that somebody had e-mailed me to say that -- I do not know what the policy was but they quoted me a link from the Society's website and said this is currently the Society's guidance on homeopathy, asking if it could be taken off because they felt it was inappropriate. I was just to ask, are we planning on replacing whatever we currently have on homeopathy on the website with this information?

Professor Jayne Lawrence: I believe the only thing we have got is a science fact sheet which I think was before my time on Science Committee and that says quite categorically there is no scientific evidence of a pharmacological basis for that.

The President: We can review what is there to make sure we are happy with it. Bob?

Professor Bob Michell: There was a You and Yours on homeopathy and I think complementary medicine in general and the Society declined to be interviewed and the statement that was made by one of the commentators was that that was a pity because the Society had excellent guidelines on the subject. Now, what they meant by that, I do not know, but someone in the programme thought that we had something excellent, so we do need to track down what that was.

The President: We have actually finished this item but I will allow two more comments. David and then John.

Mr David Thomson: Just a quick one President, thank you. We have a book in the pharmaceutical press, publications on homeopathy as well, so I think there is a potential conflict of interest in some respects.

The President: John?

Mr John Jolley: What I wanted to say was I think all of these measures could be taken up, Jayne's suggestion, the Council should have a definitive policy with regards to homeopathic products.

The President: Thank you, John.

Mr John Jolley: The sooner we can have such a policy, whether we need to wait until the next Council meeting in order to ratify that or whether Jayne can actually put the relevant

information forward and send it round to us for virtual ratification, the sooner the better.

The President: I will leave Jayne to have a think about how best to do that. Thank you, Jayne.

[Council made several amendments to the guidance including clarity over which group of people made the assertions as to the effectiveness of the products and for the guidance to be suitable for patients and the public. Council also asked that Professor Lawrence's evidence to the Select Committee on this matter be published].

*[Council
approved*

i. appendices 1 & 2, subject to the amendments made at the meeting].

9. Sharing of the OLR research with the National Pharmacy Boards and Assembly

The President: Moving on to item 9 on the agenda, which is paper three, the sharing of the OLR research information with the National Pharmacy Boards and Assembly and Howard will just lead on this. Howard?

Mr Howard Duff, Director of England: Good afternoon, Council.

Mrs Sue Kilby: Can I declare an interest?

The President: I am sorry?

Mrs Sue Kilby: Can we declare an interest?

The President: As members of the National Board? If would you like to, yes.

Mrs Sue Kilby: OK. I would like to declare an interest as being part of the Boards as to whether these are going to be shared.

The Treasurer: I have already seen it, Sue.

Mrs Sue Kilby: It is just that effectively whether we have to declare that interest.

The President: That is fine. Howard?

Mr Howard Duff: Thank you. The paper is quite straightforward and it seeks your consent to provide the OLR research that was presented to you two years ago in February 2008 to the National Pharmacy Boards and the Assembly. This will be in order to provide the Assembly and National Boards with important information with which to discharge their future leadership functions as part of a professional leadership body. The documents will still be designated as confidential and so they are for the personal use of Board and Assembly members.

You will remember that the OLR research was around providing information about member perceptions of the Society, a SWAT analysis of what was potentially something that members wanted, to understand how the members felt about the Society, and what services they may seek in future and the parameters of payment that they would consider.

There was also -- it was cut, chopped and diced, I think is the correct term, by members of sector, employment, status, age and location. So it is quite a simple request, Council.

The President: Are Council content with this? (Agreed) Thank you, Howard.

[Council
agreed

i. that the OLR research be provided to the National Pharmacy Boards and Assembly].

10. Transitional working group

The President: We go on to the next agenda item, transitional working group, paper 4, and Howard again to take us through the report.

Mr Howard Duff: Thank you. I would like to present the latest TWG consolidated report which is appendix 1 attached to this paper. As usual I will go through the amber sections on the report providing a bit of background to Council on that. After that, Catherine Duggan will provide some further information on the science and research work stream and that relates to the appendices 2 through 5 that is also attached.

So now looking through the RAG report on the first page we are all green. On the second page we come to the information and advisory service. This has been running at amber for a while. We have had significant problems with recruitment but I must say now that things look very different up on the third floor compared to the status in November. We are a full team now. We are fully recruited. The team are all together and they are very much acting as a team. So I think we are going to be continuing as green in future. It is worthwhile providing an update on that.

In terms of LPF, the first actual amber, this is amber for the reason that we have not completely identified the LPF geographies within the London area. We are out for discussion now on splitting London into six LPFs and we expect that to be resolved within the next month.

There is also a potential that the pilot for the virtual LPFs, which is also part of the website project, may be delayed to some extent but we are still on course to meet the commitment for all LPFs having at least a virtual space by 1 April.

Under professional support tools, this is the same team as the information and advisory service, so having got the team in place for the IAS pilot the team are now concentrating on looking at the professional support tools that we will produce and we are planning to launch this service in that area in March.

The other amber is the visual document for pharmacy which, you may be aware, is undergoing a further iteration at the moment to become more aspirational, more ambitious, and would benefit from some professional writing, so that is the stage of the vision.

Moving on to the third page, the first amber is around local leadership. There are a couple of aspects of local leadership, a couple of which form another of the second wave of commitments around identification of local PR spokespersons and that is associated with identification of leaders among LPFs. Then there is also the work around developing new leaders and we are intending to wrap that up into a single process going forward.

I will take mentoring and the last item, return to practice, together because essentially they have a common cause as a reason why they are amber, which is that we have lost the project managers for both of those areas. In the first one, mentoring, we are running pilots and we still expect pilots to be delivering results in this quarter. The common solution is actually the arrival of Nina Barnett on a part-time secondment to us who, I think, Catherine will be asking to head up both of these projects going forward, which is quite an exciting prospect really. So I think the return to practice will still remain amber for a while but I think we can get back on to green with the mentoring project fairly soon.

That just leaves the science and research that I think we have allowed quite a bit of time to so I will hand over to Catherine.

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Mrs Sue Kilby: Can I ask some questions of Howard or are we not taking questions?

The President: Ask them if you would like to just on the points Howard has mentioned and we will get on to science and research.

Mrs Sue Kilby: There is a couple of things. One question I am been asked is who is leading on leadership within the organisation now that Ann Adams has actually left?

Another issue is around what information an advisory service will actually be covering. Will they be providing guidance on interpretation of the various acts of pharmacy and what will that actually mean? Is it more of a basic information service?

Thirdly, the issue around the LPFs, as Howard well knows, there are still issues I think in the South-east as well because we still have not got our act together down here, and one of the members of Council will support me on that as well. So it is not just London at the moment that has not sorted things out.

The President: If we have the details, Sue, we will have them now. If not, we will come back to you on the ones we have not got details on.

Mr Howard Duff: Starting with the third one, I think there are issues across the country with LPFs. What I meant by that is that we have got a working geography everywhere except for London. I think there are some branches that are still lagging behind in terms of seeking membership meetings to discuss the new LPFs. So I think everyone outside London, we have got a working basis, a framework that we can go forward on. We have held back in London because of some of the personalities involved.

I will pass the second one back to Catherine but the first one was around leadership and in the new structure I think leadership is something that is embedded in very many of the job descriptions. Predominantly, the country directors have that as part of their role. In terms of this, this is about an aspect of delivering a small part of that which is around how we deal with the leadership locally and how we foster that.

The Chief Executive & Registrar: Could I just add to that? We now have our five LPF facilitators in post and they are up to speed and out there with the branches and with the emergent LPFs and a key part of their role is identifying the local leaders, movers and shakers. That is a resource that is going to make it a lot easier.

Mrs Sue Kilby: Do we know who those LPF facilitators are? I actually do not know who they are.

The Chief Executive & Registrar: We can give you a list of names, three in England, one in Scotland, one in Wales.

Mrs Sue Kilby: Thank you.

The President: Catherine?

Dr Catherine Duggan, Director of Professional development & support: Thank you Steve. Good afternoon, colleagues. In response to your question, Sue, around the IAS service, the spec of course will cover a wide variety of queries and questions that the profession will have. I think the interesting thing really to remember is that it will be providing professional advice as opposed to the right or the wrong answer. There will be obviously information, data, things that are handy to know, and then there will be different layers of information and advice that progress, if you like, as the questions become more complex. We have got a triage system in place at the moment which we are triaging and additionally

through more established partnership working with some of our other specialist organisations, not just clinical but our scientists and our industry colleagues and such like, we are hoping that appropriate people can be sought and brought into the fold to answer really specialist pertinent issues. So it is under development at the moment but we will have a core information service that will then, I think, probably build on as we move forward.

Mrs Sue Kilby: Thank you.

The President: Catherine, are you going to take us through some science and research --

Dr Catherine Duggan: I am, indeed. Thank you, Steve. The science and research work stream, we thought we would do an overview for you, bearing in mind the science and research work stream as part of the TWG overall work streams was set up a little later than the others, it was set up in May and the work stream itself, the scope and depth of the project, was agreed in June. We reported some progress late last year. This progress report now focuses on what we have done from December onwards and I have Jane and Beth with me as well for some more in-depth questions, should they arise.

A summary then, we provided you with on page 5 of 27, and I do not intend to go through this in much depth, only to say that you will see that there is quite a few strands that seem to mirror many of the other work streams in TWG, namely, about engagement, collaboration, working out how you might take practice research forward. There is a capacity issue in our profession. How would we address this? How would we make it more relevant and aspirational for all sectors of the profession to be involved in research? Alongside that, what support can we give them through some research tool kits?

We have also set up an expert advisory panel, more of which anon, and identified what members might need from research or what they feel is appropriate for us to offer.

Then how we might integrate science into the RPS. So there is a point at the bottom of page 5 which talks about local science forums. Now, whether these exist separately is not decided yet but it is a view that science should be part of all the LPFs moving forward.

We then have on page 7 of 27 given you a project brief so it takes you through the imperative for why this work is important, the fact that we are thinking about building capacity, so it is not something that is isolated from the profession taking place in our universities or the PLB, and it is something that the profession can hold and build themselves towards and then, additionally, how we might foster and engage with the pharmacy practice research community.

The project goals, I think, also tap into what Sue was mentioning earlier on which is about the issue of --(inaudible)-- it is really about how we can embrace the expertise that exist in the profession around science and research and tap into that most effectively. Jayne's example through the homeopathy briefing was a good way of showing that actually when you are asked to an expert panel, an advisory panel, you have to do it pretty quickly. You have to be able to access those experts in the profession pretty quickly. We are lucky to have some of that expertise in the PLB but we have got a science profession out there as well.

So the work has been very productive over the recent months. Just to take you through the objectives, you will have seen those on page 8, and then the project scope. Really it is about identifying those stakeholders and seeing what we can deliver moving forward.

I will then take you briefly to page 9 of 27 where we are thinking about future-proofing this. There are two main elements around the business case. The first is to future-proof the transitional ideas that are emerging from this work stream. So this work stream is in transition at the moment and it is over and above the research and science provision that we deliver at the present time as well.

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The thing that we really need to just highlight is that that is proposing that we have expertise that we can tap into and we have a good research and science strategy moving forward, all of which will be identified against the risks to the profession if we do not do it, the benefits to the profession if we do, and the potentials for resource. These will be decisions for the new Boards and the Assembly to make going forward.

So I think what we have done is identified through this work stream two strands of work, what we need to continue to do that is worthy in science and research, and also what we might do differently or as well as and we are going to have a good risk benefit analysis of this take to take forward to the new Boards for them to make the decisions.

I think that is probably where I will stop and take any questions. Thank you.

The President: Thank you, Catherine. Gerald?

Mr Gerald Alexander: Just one or two small questions, President. Firstly, I picked up on the document on 5 where you talked about a document outlining an expert advisory panel and you have mentioned that, Catherine. So I say who are the expert advisory panel and who do they advise and in what circumstances?

Dr Catherine Duggan: At this present time they are an expert advisory panel advising us, if you like, on what the PLB should be delivering moving forward and details of who is on that Panel, I do apologise, are on page 11 of 27 -- I am sorry, that is the project team. The expert panel, the stakeholder group is proposing the work of the expert panel moving forward.

Mr Gerald Alexander: What is their experience in terms of research?

Professor Jayne Lawrence: Can Beth answer it because that is the work she has been developing?

Mrs Margaret Allan: Basically, the expert panel is being set up in light of the fact that we will lose our Committee structures but we need to ensure that we still have strong expertise in terms of science and that science from social science through to basic science informing the Assembly and the Boards in the work that they do.

We have recently take the concept of the expert panel to the Board to see how they see it working with them and we are going to recruit some people in a transition role to develop the idea, work out how we are going to get people on that Board, the nomination system, the criteria for those people because they really will be the leaders in the field, the experts, and one of those issues will be the range of disciplines that we need and the criteria for getting on that panel. We obviously want to use the expertise that is in existing Committee structures and external groups already established as well but it is about creating an effective mechanism for enabling the governance of the organisation to work properly and leadership in terms of being able to speak authoritatively maybe on ad hoc occasions but also being proactive.

Mr Gerald Alexander: Thank you. There is another little question. On page 10 of 27, under stakeholder management, you intend to involve a various list of stakeholders, is that right? It says so. It says stakeholders inside the Society and then it says stakeholders with links. That is sort of the intention, is it not?

Dr Catherine Duggan: Yes.

Mr Gerald Alexander: So what do you think the future viability of the pharmacy practice research trust is?

The President: Who are you addressing the question to, Gerald?

Mrs Margaret Allan: Catherine.

Dr Catherine Duggan: I think the stakeholders were advised the direction of the PLB in terms of research and science and the future of the PPRT falls kind of across that and its own trust status and charitable status itself so it is almost two separate issues, if you like.

Mr Gerald Alexander: No, where I am going is the fact that if you are involving a group that potentially is not going to be viable or there in the future as a result of changes, then I am asking you whether you think their funding is viable for the future?

The President: Jeremy?

The Chief Executive & Registrar: Yes, thank you. I think we need to draw a distinction between involving groups who are active now and taking any view on their future viability. I think it is for those groups themselves to decide whether they have an agenda they can fulfil and, if so, how they are going to do it. I think it would be inappropriate for Catherine or any of my colleagues to comment on the viability of any of those groups going forward but we are involving them because they are active now.

Mr Gerald Alexander: Thank you, Jeremy. I will perhaps leave some further questions to later in the Council meeting, thank you.

The President: John?

Mr John Jolley: I am very pleased to see the reaction to our last Council meeting where we were talking about continuance of the Science Committee and what group would take on the existing role. Certainly, the arrangements look very good indeed. However, I think it is important that in appointing members to this expert advisory panel we should ensure that they are truly experts in the particular field that we want to be able to negotiate on or to prepare information on. They need not necessarily be pharmacists, they need not necessarily be members of any of the National Boards. They more than likely will be external. Furthermore, they may not necessarily be permanent members of an advisory board. Providing we have sufficient resource within the new PLB to do the necessary horizon scanning to be able to identify what are those topics and, quite clearly, we have had a long debate about homeopathic products, which in hindsight worked out well for us because in the future we are going to have to be able to spot in advance where these contentious areas are so that the next time there is a publication in the Lancet which brings up an outcry we have actually got pre-prepared an expert in the background who can talk authoritatively on a particular subject and that we can roll him out. That does not come without a lot of preparation and planning. So my one plea would be, yes, an expert advisory group. Let us plan it well in advance. Let us make sure that we get the true opinion leaders, and I am not talking about people who may have had an interest, I am talking about people who have led the research on that particular field, so we can talk authoritatively so that when approached by government we can give an expert view because at the end of the day our objectives must be we are the specialists on medicines and our foundation is in science, quite apart from anything else. Thank you.

The President: Thank you, John. Sue?

Mrs Sue Kilby: Coming back on this and about being leadership and really being true leadership, I do not really need to say anything to the two of you but obviously being well aware it is not just UK and we need to be aware of what is actually happening in the wider world, so to speak, especially within Europe and America and Japan, and what is coming actually through and we need to establish contacts with some of these leaders as well so that we can have informed views and opinions before they are hitting the UK press.

The President: Thank you, Sue. Bob?

Professor Bob Mitchell: I have a question on page 17, please. I have a simple question on page 17 under (iv). Lay involvement in the context of the Pharmaceutical Society is easy to understand. It means you are not a pharmacist. In the context of science, I wonder whether it is intended to mean lay in the sense of not a pharmacist or lay in the broader sense of not a scientist at all?

Mrs Margaret Allan: I think of lay as a broad brush term for patient, public and lay. At the moment there are layers of involvement that you would have in terms of research both in say commissioning the research and having peer review which would be -- if it was relevant to patient review, depending on the topic or the topic of the subject, it may be more to have public or it might be more relevant to have lay. So I think I am using lay to cover all three at the moment, depending on the topic of the research that is being investigated.

Professor Bob Michell: I do not see anywhere in here yet any specific identification of horizon scanning issues where there may be a collision between what is scientifically justifiable and what is politically acceptable, the human equivalent of badger culling, if you like. One example would be that sooner or later there will be clear evidence from pharmacogenetics that a certain set of genetic groupings may not benefit from particular life-saving drug where others do and with budgets being tight, et cetera, there could therefore be a ruling that this drug should be acceptable for certain genetic criteria and not for others and we do not have to discuss today but just imagine if that genetic difference corresponds to an ethnic difference. So it seems to me that there should be some particular provision for looking well ahead towards issues where science is going to collide with politics because those are the issues that need the most time to get a refined view point.

The President: Thank you, Bob. Any more questions for Catherine and the team? Thank you. I was intending to say a few words about TWG today so now seems to be an appropriate time to say them.

I just remind Council that TWG has a membership of five members of Council, including the officers, one former Council member and six National Pharmacy Board members. It is chaired by Jeremy and was tasked by Council to oversee the process of transition to the PLB.

I suppose I should declare an interest here as a member of TWG but I really just want to place on record what I consider that TWG and their work streams have done and that is really an outstanding job over the months that they have been in operation. Throughout the whole process, we have been very careful to recognise the importance of inclusivity, transparency and efficiency. Firstly, inclusivity. No one, and I really mean no one, who has expressed a wish to support the work of the TWG has been turned away. Indeed, I am pleased to say that there were several Council and Board members who have made very welcome and valuable contributions to the work and I am personally very grateful to them for doing so and for their commitment to the processes and the outputs.

We have actively sought contributions from all sectors of the profession and beyond and from those at every career stage. We have built very strong relationships with other pharmacy organisations and with specialist groups and advanced practitioners.

We now have nearly 400 pioneers whose contribution has been invaluable to support the work streams, to define, to test and to refine the products and services that have been developed and, in fact, I have written personally to over 300 of those pioneers.

As far as transparency is concerned, I think it is fair to say that we recognised at a very early stage in the process the need for appropriate transparency and good communication and we established a public domain website dedicated to the work and output of TWG and, to date, I

can report to Council that we have had 44,000 unique visitors to that site, that is over 90 per cent of the Register, 70,000 hits in total and 4,500 hits every week, so it is a very well used website.

We have held two major stakeholder days and provided countless opportunities for stakeholders to input into the thinking of the work streams. Council have been provided with copies of all the work stream briefs and asked for input and every work stream lead has personally reported to Council at least once on their brief and progress against it.

Every Council meeting has had a standing agenda item to update Council using the RAG report we have been through today. All agendas and action points are freely available to anyone to view on the pharmacy PLB website.

Thousands of pharmacists have signed up to receive frequent e-mail updates and all members for whom we have e-mail addresses are regularly e-mailed whether they have asked to be or not, frankly.

23 full page in-depth articles on deliverables and outputs of the work streams have been carried by the PJ and over 40 pages of advertorial have been placed in the PJ and The Chemist and Druggist. Every opportunity has been taken to make use of the branch and regional networks to communicate the progress being made as we move towards establishing the LPFs. The first and second wave 100-day commitments have all been based really on outputs from the work of TWG and its work streams.

Finally, efficiency. This has been and continues to be an exceptionally complex programme of activity. To ensure the efficiency of the programme and to deliver on track and on time, the TWG has had to move with pace and pragmatism. Thousands of decisions have been taken during the course of this programme and virtually all of these have not been brought to Council. It has simply not been feasible, necessary or desirable to do so and Council should not expect or want to be involved in all these decisions. However, we have very carefully considered those occasions where it is right and proper that Council should be involved and we have brought such issues to its attention. So, for example, Council has been involved in discussing and commenting on the business plans and the financial sensitivity modelling, the branding of RPS, the organisational design and limited liability structures, the drafting of the vision for the profession and the over-arching governance arrangements which are on today's agenda to discuss.

Similarly, we have considered which decisions it is right to reserve for the Assembly of the new RPS to consider. There will be a great many important issues which fall into this category including, I might say, the pharmacy practice research agenda which is entirely appropriate for the new professional body to comment on.

So why am I mentioning all these things today? First and foremost because I actually feel very strongly that Council should appreciate how hard people are working and I think we should be making encouraging and appreciative noises for a job well done. Secondly, because the work of TWG is now being embedded into the day jobs of the functional directors and heads of the teams who will continue to deliver the outputs. Therefore, the work of TWG is rightly coming to an end and Council needs to be aware of this. Finally, because I want to place on record the thanks of this Council for the efforts which members of the TWG, the work stream leads, their teams and members from every corner of the profession are making to secure the future of this organisation. It is not overstating the case, I think, that without this effort this organisation as a professional leadership body of our profession would not be fit for purpose or maybe even exist at all after the separation in a few months' time and I genuinely believe that as a Council we should be hugely grateful to the many who have supported this process and I would ask Council members to join me in recording our thanks on the record to all those involved. Thank you very much.

(Applause)

The President: Thank you very much to Catherine, Howard and the team. Thank you very much.

Mrs Sue Kilby: One of my concerns I raise continually is about the ongoing management of the education agenda which is not directly covered within these work streams. I am concerned that a lot of the education contacts and support is within the regulatory side and really I am very concerned about what support we are going to be giving going forward about pre-reg, what contacts and links we have actually got with the schools of pharmacy because that is mainly going through on the GPharmC side and I just think that I am not quite sure where that is actually fitting into the organisation going forward and how that will actually be managed. Perhaps Jeremy can answer me on that.

The Chief Executive & Registrar: Yes, a good question. Thank you, Sue. The first thing is we are very actively engaged with the schools and particularly with CuHoPs and with the BPSA, and Patrick is leading on that work because that is potential recruiting ground for membership of the professional body. I say potential because the creation of a membership category for students and pre-regs is subject to a special resolution, as you know. If that resolution were to be passed, we need to have already established the right kind of relationships with the schools, with the BPSA and with individual students. So Patrick is doing some very energetic and very productive work on that.

The second is the work that Catherine and her team are doing and we are looking for a career ladder for pharmacy that takes pharmacists right from their early days as an MPharm student, through their pre-reg, through to registration, through to the support they need if they wish to get involved in advanced and specialist practice and the appropriate designations associated with that. That career ladder is a fundamental part of the professional development and support work because at the moment it is sorely lacking and a professional leadership body's role in developing that, I think, is absolutely imperative.

Mrs Sue Kilby: It is the support for pre-reg tutors and taking on some of that work currently covered by some of the education division in the regulatory side that I have got particular concerns about who is actually going to be managing that support and link when we move into the professional body because I cannot see if somebody who is actually necessarily doing that. I can understand that Patrick is actually obviously actively canvassing for new members and providing support and obviously, with my interest with the BPSA, I have got to totally support and encourage the inclusion of students and pre-regs as soon as possible on that. It is actually some of the work that is actually being undertaken by Wendy's team which unfortunately we will not necessarily be able to access if the professional body -- once the GPharmC separates off and it is really looking at how that is actually going to be managed and transferred to support it going forward, Jeremy.

The Chief Executive & Registrar: We are on that case, Sue. We are working closely with the pre-reg team, with Joanne Martin and her colleagues in regulation. I think it is worth saying that there are a number of areas where the work of TWG can absorb support, for example, for pre-reg tutors. So mentoring is one such where actually we want more pre-reg tutors and a lot of pre-reg tutors need support, and one channel, one mechanism, for that support to be provided is through mentoring. There are other mechanisms too but we are working very closely with the pre-reg team and regulation.

Professor Bob Michell: I share Sue's concern. I was not going to raise it today. I have raised it before and since it has come up I would be interested to know what Nick feels about it because my concern is this: I would not expect, and I might be wrong, but I would not expect it to be part of the GPharmC's priorities to take a really horizon scanning view of education and what it can mean to the future, the long-term future, of pharmacy and healthcare delivery. I think that is beyond their immediate and more obvious commitments. If

we look to parallel professions, yes, the GMC with tomorrow's doctors has evolved a lot of very constructive pressures on medical education but I think it would be reasonable to say that a lot of the impetus for that actually came from the Royal Colleges and we do not have the equivalent of the Royal Colleges. Certainly, in my own area, I could name five or six major improvements in veterinary education which, of course, were implemented with the RCVS as the regulator but they actually came from the vision, the research and the energy of the professional body over many years.

So I share Sue's concern that I think the PLB, for the sake of pharmacy and actually for patients, will need to have a very active but different interest in education and, of course, the relationship with the schools of pharmacy and the universities will be crucial to that.

The President: Thank you, Bob.

[The President thanked members of the Transitional Working Group for their outstanding work on ensuring the setting up of the Society post demerger.

*Council
received
i. the report].*

Regulatory matters

11. CHRE Performance Review 2009/2010: submission of draft self-assessment

The President: We are going to move on now to item 11, regulatory matters, and ask Wendy to step up. CHRE performance report for 2009/2010. It is paper five.

Mrs Wendy Harris, Deputy Registrar & Director of Regulation: Thank you, President, and good afternoon, Council. I have to offer apologies for bringing it to you at this late date but there is a reason for this. If I can refer you to paragraph 3 of the accompanying paper, you will see that the timetable is actually a parliamentary timetable. We seem to be caught up in so many parliamentary timetables at the moment in regulation but for the process for the CHRE review we get short notice of the information required to prepare it and submit it and we do have to submit it by that date and unfortunately it did not fall into line with the dates of the Law and Ethics Committee or of Council. So you will see that myself and Jeremy agreed the content that the staff in regulation had pulled together because it had to be with CHRE by 17 December. It then went to the Law and Ethics Committee at the beginning of January and has is now brought to you for your approval. In sending it to CHRE we did put with the caveat that it was pending approval of this Council so it has not been sent with your approval at all.

There is a slight variation in this year, one in terms of the compact nature of the formatting of our response, and I attribute that completely to Stewart Heiney who has moved into a new role in regulation as stakeholder liaison with responsibility for CHRE and the magnificent work he has done in pulling that together but, secondly, that CHRE themselves have now started to refine their process and have asked us really to focus on where the performance has changed from last year rather than reporting on everything under each of the standards that they are looking at.

So with that in mind I just wanted to flag probably two or three points that I would like to promote to you rather than go through everything and then ask that you do approve it.

Firstly, one of the key things we were able to report is the significant achievement of bringing the case management system on line, in time, and under the budget. I know, Marcia, our thanks to you for being the Council representative on that project. That is working very well indeed.

The second is that we have now been able to reduce our Investigating Committee hearings

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down to one day a month because we are getting a thorough at the front end now of complaints coming in and are able to use the non-referral criteria and other methods for dealing and disposing of those cases rather than moving them forward. We have still got some that are still waiting in a queue to get to Disciplinary Committee but we are now getting the through-put right.

The third is that we have taken on a inspector to monitor undertakings because this is another sanction that the open to ourselves and the Committees, that a registrant will make undertakings in terms of the type of practice and to help support them it means an inspector can go on visit and gain that assurance that can be provided back to any Committee or such that has set those undertakings to move it forward.

Last of all, again, and this is down to Stuart's process, he set in train a review of all the recommendations made to all of the regulators and all of the best practice that was described from all of the regulators and measured us against it to ensure that we were then able to demonstrate that we had learned from the CHRE process.

So, like I say, it has been a very thorough process this time. I am very happy to commend this to you. It just demonstrates the excellent work that is happening in regulation at the moment. Thank you.

The President: Thank you, Wendy. I am rather hopeful that Council will not have any questions on 200 pages of a report but if anybody has got any burning questions, shout now. Can I take it that we can approve this? (*Agreed*) Thank you. Could you thank Stuart on behalf of Council? Thank you very much, Stewart. Well done, a good job. Thank you very much.

[Council approved

i. the Society's self-assessment for the 2009/10 CHRE Performance Review].

13. English language competency of EEA pharmacists - update

The President: Let us move on now to item 123, verbal update on English language competency testing. Wendy?

Mrs Wendy Harris: Thank you. If Council will recall, we wrote to the Department of Health sharing all of the legal advice that we had had and making the proposal on the need for English language testing of EEA applicants. This is just to update you subsequent to that letter. The Department of Health has let it be known to us that they are considering the letter but we have not received a response from them at this moment in time.

Council also asked that we send further letters, one to the British Medical Association. If you remember, Council in October discussed the doctor that the CQC report had found on and more recently in the press through the GMC hearing. We have received a letter from the BMA and I will not read it in full although I am sure it can be made available to you but just to quote some final sentences:

"Thus the BMA is in agreement with the Royal Pharmaceutical Society and finds the legal opinion of Mr James Flynn QC to be very interesting.

The BMA also calls for the directive to be revised in order to introduce a legal duty on all medical regulators to share registration and fitness to practise information proactively with other regulators in Europe.

Regulatory authorities have established initiatives such as the healthcare professionals crossing border initiative to ensure that national regulatory authorities are able to work collaboratively. It is imperative that this work is continued and developed further.

The BMA will focus on these three aspects of the directive during the revision process and looks forward to working with the Royal Pharmaceutical Society on such issues

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of mutual concern.”
So we have another professional body there.

We have also been in touch with the CQC who we also wrote to. David Pruce wrote to them, again, following the same discussion at Council. Regrettably, CQC have informed us that they have not been able to locate the letter so we are redrafting for the President to sign whilst he is here for Council and we will re-issue that letter to CQC. Thank you.

The President: Thank you, Wendy. Any comments or questions to Wendy? Thank you very much indeed.

[Mrs Wendy Harris, Deputy Registrar and Director of Regulation, advised Council that the Department of Health had not replied to her letter on the legal advice obtained by the Society on this issue, but were still considering its contents. The British Medical Association had written to advise that they were in agreement with the views of the Society in seeking English language competency of EEA pharmacists. The letter written to the Care Quality Commission had not been received by that organisation and so a replacement would be sent.

The President thanked Mrs Harris for her update].

14. GPhC Education and Registration consultation

The President: We are now moving on to item 14, GPhC education and registration consultation, paper 6 in your pack. Wendy?

Mrs Wendy Harris: I would like to defer, if I may, to Alan who chaired the Council working group to respond on this.

The President: Thank you, Alan.

Mr Alan Kershaw: Thank you. The paper is self-explanatory and the consultation paper is in here. I have to say our group found it remarkably difficult to penetrate the drafting of this. It is not helpfully written and questions are not helpfully formulated. Nonetheless, we made up our own minds what they were trying to ask us and have done the response which you find on pages 21 onwards of this document.

I am not going to take you through all of these. There is nothing I particularly want to highlight so I would be happy to take questions.

The President: Thank you, Alan. Bob?

Professor Bob Michell: A question and a comment on page 23, GPhC should give full consideration as to whether the number of resits is limited to two instead of three. I am not very sympathetic to the line that we are taking here because I could see the same argument being used far more powerfully vis à vis the driving test. There are far more inept drivers killing people than inept pharmacists so I would say why not argue that someone who cannot pass the driving test at the fifth attempt should not be allowed to take it again for ten years, or whatever.

More usefully, and I think more relevantly, if we are going to go down that line I would like to know if there is any evidence of a relationship between the number of attempts and subsequent conduct infringements or complaints because, if there is, then I am happy to support. If there is not, then I think we are being a bit puritanical.

The President: Alan?

Mr Alan Kershaw: I would just like to explain what we were driving at there. I do not think Bob is inviting us to argue for an unlimited number of attempts at the exam, as with the driving test, but the point we were making is that there should be a limitation, that we believe the

present three, possibly four, is too many, and what we were pointing up was the illogic of the consultation paper's argument which appeared to suggest, if you look at it, it says that the norm in UK further education is one attempt and one resit and then appeared to follow from that the logic therefore is that pharmacists should get three attempts. So we thought GPhC should be invited to explore that over time, that was all. There was no intention to argue that we had reached a position where two was the limit.

Professor Bob Michell: Leave aside what the limit is. I still reiterate my question. We are talking more and more about evidence-based policy and so the issue here is not what the norm is anywhere else, the issue is: is there any evidence that those who require more resits, having qualified, demonstrate any evidence of subsequent endangerment to the public?

The President: Wendy?

Mrs Wendy Harris: Thank you. There was a study that has been published recently, and by recent the latter half of last year, by Manchester University that has undertaken a review of student conduct and behaviour through their undergraduate time and subsequent training and the correlation between then fitness to practise cases in later years. The output from that is that it is suggested that there is a correlation of two to one, that for every student where there are concerns over conduct or in terms of how they conduct themselves during their training years, they are twice as likely, if those terms exist, to come in front of an FTP than they would do if there were not concerns otherwise.

Professor Bob Michell: I am sorry, I do not want to prolong this because I think everybody knows what I am talking about. It is interesting and it is suggestive but it is not the same thing. The question I am asking is capable of a quantitative answer. Over the years have those who have required repeated attempts at their final exam subsequently, in their careers, been more prone than the average to complaints or other infringements of conduct?

The President: Can I just ask, does anybody else have any issues about this particular question that Bob is raising that would lead us to change the words in this submission? Lorna, on this point?

Mrs Lorna Jacobs: Yes. I have similar concerns to Bob. We have regularly had to address the issue and it is one of the most uncomfortable bits of being a Council member. Taking the comparator, I took three times to pass my test and I have not had any problems in the so many years since I have been driving. I would urge that if the view is that this is the level we have to stick to, that we should give some consideration to whether this should be a lifetime ban, that you have two attempts in your lifetime. What and how people behave and address issues when they are 20, 25 may be very different from how they address issues and focus their studies when they are 45. I think that it just seems to me to be inappropriate that decisions that people take at 25 should bar them from a profession for the rest of their lives.

The President: Thank you, Lorna. Martin?

Mr Martin Astbury, The Vice President: I must admit, I would prefer staying with the status quo of three. I think with the first retake you tend to be -- assuming you have gone down the normal route, you take it a couple of months afterwards, whereas the further retake, the way the system is at the moment you go for a further six months' training. So there is a difference of this extra training to be able to do it and then probably at that point I can see where we are with the three if that is where the limit is, but I think two is unduly clamping down.

The President: Gerald and then Alan.

Mr Gerald Alexander: Yes, thank you, President. As part of the working group, obviously I would wish to support what is written here, but I think Bob raises a very interesting question and I think that is some work the GPhC will need to conduct in order to inform its thinking in

the future. So it may be we should be putting that into the response. I think although we say unsure, we fully support the proposal that the number of attempts should be limited. It is limited at the moment and we do fully support that position. I think there is no question about it. I think Alan and I had some interesting discussion in the working group and I think he was slightly more right of centre than me but that is neither here nor there.

The interesting point, I think, is that I did sort of draw this to the attention of the working group, that because the arrangements for the MPharm and the pre-reg are not integrated at present, I suggested, and I cannot remember what the response was amongst the group, that arrangements should perhaps stay the same until such time that the in-service arrangements for practice were integrated into a five-year programme. So, in other words, I suggested that the status quo would probably be a good thing until such time that we review or the GPhC education procedures review changes in the educational arrangements which involve an integrated course. I am not saying that is where we should be going. I am just saying if it ever gets to that point, that is when the number of attempts should be looked at by the GPhC and they should decide on how patient safety would be best served by limiting the number of places. So I am not actually saying one, two, three or four, or anything, I am just saying it is not the appropriate time to look at the number of attempts until the programme of a five-year programme is looked at holistically. I do not know whether that captures our discussion, Alan.

Mr Alan Kershaw: It is not for me to decide anyway but I think -- let us be very clear on what we are saying because what is proposed in the consultation is not, with respect to Martin, the status quo. What is proposed is three with no fourth attempt. I am perfectly happy to support that because I think some of us may be, given the reaction we have to individual cases we have to deal with at the moment.

If the Council want us to say that we are content with the proposal that there is a limit of three, in other words, the third one effectively becomes the exceptional one, what had struck me in the paper was that it was not logical in saying that in further education you are normally allowed one plus one. Why should we be more lenient? Therefore we should have three. It just seemed rather strange and I thought maybe they should do the calculations paper. However, Bob's suggestion about research, that is absolutely fine, but let us be very clear on what we are asking if that is to be looked into. I am not sure that data is available. The fact that it is not available does not mean there is not a problem and there is not a necessary correlation between conduct cases and earlier inability to pass an exam. We are talking about different things. So it is not just about your competence in the profession, your ethical understanding later on and your ability to abide by ethical codes, and so on, which may well be tested in the exam in the beginning but is not normally a reason for resits. So we would need to be very clear that the information we get is going to tell us what we want. So let us just take that point on board.

If the general feeling is that we should say that we support the proposal in the paper, then by all means let us say that. I have got no axe to grind.

The President: Sylvia and then Sue.

Mrs Sylvia Hikins: Thank you. I think we cannot take this bit of the discussion, question 9, out of what is being suggested in question 8. I have long had some qualms about the nature of the pre-reg exam. It worries me when we have a testing system that we can fail a person for just 1%, particularly on something say like a calculation. I suspect 1% either way does not really make any difference down the line of how good a professional is and a practice is.

So I was really pleased to see the suggestion here, the suggestion that we change the term from examination to assessment, and that there should be more of a focus on experiential learning rather than focusing on one exam. Now, if that happens, I am quite happy for the one plus the resit because I think that will redress then what I see is a flaw in the present

system. Otherwise, until that happens, I really do not mind whether it is two or three. I certainly would not want a possibility of a fourth attempt because I think that is too much.

The President: Thank you. Sue?

Mrs Sue Kilby: We actually discussed this paper, this consultation, I think, at the Education Committee and the view was that we were accepting the three attempts on this. Obviously, there was a very low number for the fourth attempt and that is why we decided to go with the third attempt and leave it with three attempts. So I am quite surprised it has actually come through recommending two attempts because, as I say, the --

Mr Alan Kershaw: It is not recommending two attempts.

Mrs Sue Kilby: Well, suggesting two attempts. The view of the Education Committee was three attempts was acceptable.

The other point is I believe in law, in LPCs, is it the LPC that you are actually able to have three attempts for that, the first and two repeats, the law exams?

Mr Alan Kershaw: I do not know but I would not regard that as a model for anything.

Mrs Sue Kilby: All right, OK.

The President: Bob, do you want to come back?

Professor Bob Michell: Thank you, Chairman. I am very happy with the reduction from four to three. It was the reduction to two which I felt was tight. I think there is something which we could add to that support which might be helpful and save some trouble. For however long it is that I have been on Council and heard these fourth attempt pleas, I would say that in the considerable majority the third attempt should never have been attempted because there were quite clear stresses that even if the stress prevented the candidate from seeing that they should not be taking this exam, there should have been someone close to the candidate able to say, "Look, you are not up to this at the moment. You may want to take it now but you will be much safer deferring your attempt." Even though there are warnings in our existing literature, I do think that somehow there should be an absolutely resoundingly scary warning to candidates that the third attempt is the final attempt and if they have the slightest doubt as to their fitness to perform on the day to the best of their abilities, the safer option is to withdraw and re-enter later.

The President: It sounds as though we are converging around the number three on this. Sorry, Tristan --

Dr Tristan Learoyd: Just to pick up on a point that Sue actually raised, in the university system you tend to see -- you have one exam, quickly followed by a resit if you fail that exam, and then there will be a further resit normally a year after. So it fits in nicely with the university system. I have got some other points. Do you want me to raise them in a bit?

The President: Yes. So, Alan, could I ask you to redraft the answer to that along the lines of our discussion but converging on three? Points of other relevance on this consultation. Tristan, kick us off.

Dr Tristan Learoyd: Looking at -- apart from the GPhC, at 3.1 they have put "In particular it must be 52 weeks long". That is in regard to EC Directive 2005/36. I do not actually think it says 52 weeks long in there. It specifies 26 weeks but it does not mention a 52-week period in there so we might need to just check on that.

Then, on to appendix 2 --

Mr Gerald Alexander: I think it says the latter requirement which means the 26 weeks is in-service training. That is the minimum.

Dr Tristan Learoyd: What I would say is 26 is regarded as a minimum but does not specify 52. I just wonder if we have put in there it must be 52, whether that does not leave us with future flexibility we might need for modifications to the course.

On appendix 2, midway down it talks about:

“The GPhC may wish to consider this in further light of any changes to the roles and responsibilities of pharmacy technicians.”

Now, I am particularly nervous about what that is insinuating in there, the roles and responsibilities of pharmacy technicians.

Mr Alan Kershaw: Which page is that?

Dr Tristan Learoyd: That is on 21 of 24 in appendix 2. I have concerns over that particular line there.

The President: Which line again, Tristan, to be clear?

Dr Tristan Learoyd: “The GPhC may wish to consider further in light of any changes to the roles and responsibilities of pharmacy technicians.”

It is a vague statement and I would regard it as a vague statement. Do you want me to continue with the other little bits and pieces?

Mr Alan Kershaw: We can answer that. I will let Steve do that.

Mr Steve Acres: I think that is just about -- the whole point of that paragraph was around some of the training and particularly the assessment of pharmacy technicians that is done by distance learning where the employer may pay but also maybe an assessor for the student and sign off any work that goes forward to an awarding body. The bit about any changes to roles was just the fact that any training needs to address any changes in roles for pharmacy technicians which may come in the future, extended roles.

Dr Tristan Learoyd: OK. Then, on to page 22 of 24, there is a bit where it says “Agree”, which is the third paragraph from the bottom, and it talks about the competence in teaching skills and communication with regards to pre-registration tutors. The bit I would find about that is how we go about assessing the competencies in a cost effective manner and whether we have seen any data from the GPhC on how they are going to go about this. I was just interested in that.

The President: Wendy, do you have any detail? Alan?

Mr Alan Kershaw: We are simply putting down the marker for them that since the consultation paper invites comment on the proposal that pre-registration tutors should be subject to standards, that when those standards are drawn up they should include not just the ability to do the job but the ability to teach it. How that is assessed is a matter for the GPhC but it is only another form of how we ask when we accredit pharmacy schools, we would ask them what support is given to their teachers in teaching skills and support the development of that. That is all. It is no more than that and I do not think we are in a position right now to say you should do this in a certain way.

Dr Tristan Learoyd: OK. It is just the concern would be there if they were all --(inaudible)--

on that part and the financial implications for the businesses.

The President: Just on that, I am sorry, Tristan, Sue wants to just come in on that point.

Mrs Sue Kilby: I have always had a quite strong view that if someone was a pre-registration tutor that part of their role is actually to develop professional aspects of the pre-registration student so that when they come onto the Register they have awareness of their professional responsibilities. Actually, and I declare an interest here, I would actually like to see something in there where we are actually encouraging that these pre-registration tutors are actually members of the professional body.

The President: An interesting thought.

Mrs Sue Kilby: I do not see why we should not put it in there unless, of course, people are not happy with them being members of the professional body.

The President: Your final point, Tristan.

Dr Tristan Learoyd: The final point I would like to raise was on page 23 of 24. It is again the third paragraph down. It talks about:

“In the future this may be a longer process which involves an assessment as only a partial component.”

Just to avoid committing ourselves to anything, I just wonder whether we could insert the words “may differ somewhat and involve assessment as only a partial component” just so we do not commit ourselves to any particular point there, just to leave it open again for flexibility.

The President: So with those draft -- I am sorry, Alan.

Mr Alan Kershaw: I am sorry, Jeremy wants to make a point. I just wanted to pick up one point now I have heard the comments. There is just one point on question 6 on that page which Wendy can probably clarify straightaway that had not occurred to me or to us in the group. The requirement that pharmacists should have to have practised for three years in a particular sector before being allowed to apply to become a tutor in that sector, we suggest the procedures clarify whether it is a continuous three year period. In other words, you cannot have breaks during it.

The other point that occurred to me later was that it needs to be clarified whether this all has to be in the UK and there may be a straightforward answer to that because it may be we cannot actually prescribe that.

Mrs Wendy Harris: If the pharmacist is on our Register it will be irrespective of their origin of their training so we cannot distinguish between an overseas qualified pharmacist and a UK qualified pharmacist for certain.

The President: Jeremy?

The Chief Executive & Registrar: Thank you, Steve. Just two points I wanted to draw to Council's attention. The first is that the consultation document refers to a deadline of 25 January. In fact, the deadline is 15 February so we are still well inside that deadline. The second thing is on the draft response, that is page 21 of 24, paragraph 5 refers to a separate response being submitted by the National Boards of the Society. We have seen this as predominantly a regulatory response and therefore something that should be led and signed off by Council and the working group that Alan is chairing but it may well be appropriate for the Boards to have sight of this and to provide input in the same way that Council has just provided input to the English Board's response on generic substitution. So I do not see this

as a two-parter in the same way that we responded to the GPhC standards. This is really a regulatory response from Council but I think it would be appropriate for the Boards to have sight of that and the new Board members, who have been in post for just over 24 hours, some of them have expressed a desire to see this and to comment on it and I would ask for Council's agreement for that to happen and if there are any substantive points for them to go back to the working group via Alan as Chair. Would Council be happy for that to happen?

The President: Alison?

Mrs Alison Moore: It depends who is going to sign the final version off. Is that going to go back the officers' group and Steve for final sign off?

The President: The proposal is that the response that Alan and the working group are responsible for would be signed off by the officers. Are Council happy with the suggestion from Jeremy? (Agreed) Are we happy for Alan as Chair to make the amendments, the drafting changes and for the officers to sign that off. (Agreed)

Thank you very much. With that we will break for tea and be back at 4.00 pm, please.

(Short adjournment)

The President: Thank you, Council.

[Council agreed that the National Pharmacy Boards be given the opportunity to input into the response, although it was a regulatory issue.]

*Council
agreed*

i. that the Officers Group sign off the response prior to submission].

15. GPhc Rules; options for future consultation response

The President: We are on item 15, the General Pharmaceutical Council rules; options for future consultation response. This is paper 7 in your pack and Wendy will lead us through this. Wendy?

Mrs Wendy Harris: Thank you, again, President. Council, I do apologise. You are probably feeling that you have got consultation fatigue in terms of the GPhC at the moment but this one is to try and get us a little ahead of the curve. You will notice that I have recorded in there that actually we do not know when the rules consultation will take place. We do know that it has to happen before GPhC opens its doors. The rules are those detailed pieces of operational function, statutory function, that the regulator must discharge.

I wanted to consult with you because obviously when we get down to this level of detail the staff who work in regulation are focused on this absolutely. They crawl all over it to make sure that whatever is being described in the rules, that they will have to then work to, is understandable, that either reflects current practice or there is an understandable move to a different kind of practice that is underpinned by the content of the Pharmacy Order linking that then across to the standards that will be enforced across the registrants.

So, in hoping that we can make this as pain-free as possible for you given, like I say, previous consultations as well, and to save effort rather than so there is not a duplication of effort by Council members, I was proposing to you that you receive the study, the critique, that the staff will produce on each of the sets of rules and I have put in the options that could come to the Council, it could go to the working group that Council has formed to respond to the Order and the standards and education procedures or, indeed, it could go to officers. I have put the options there for you and my recommendation, but would be very interested in your views on this, is that you do agree that it is the staff that will prepare all of this but they will prepare

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looking at the significant changes, not every single detail and change where there is just a nuance in terms of placement of commas and full stops which can often be so important, but that the staff do that and then it is provided to the Council working group who have just recently been looking at all of the standards and the procedures for them to agree on your behalf or for them to submit to Council for ratification and agreement when the moment arises.

Like I say, I am talking somewhat hypothetically to you because I really do not have any indication of when the rules may be released for consultation.

Just one final point to make, and my apologies, on paragraph 1.1 I made an error in drafting and in the list of rules could you strike out in your copy "premises" and substitute that with "appeals". That was my mistake when I was drafting it and I did not spot it when I was proof reading it. That is the list, six sets of rules that will come our way, no known date, but it will be sometime within the next four to six weeks, I suspect, and with a two to three-month turn around.

The President: Thank you, Wendy. Phillida, did you want to comment?

Dr Phillida Entwistle: Yes. I presume you are recommending option 4? Of those two, I would be OK with that as long as it was the working group that was reconstituted because I do not think this is appropriate for the officers' group, I do not think there is any element of urgency about it. I do not think it falls within the remit of the officers' group on leadership. What I do think it requires is some input from somebody with experience on fitness to practise matters. Obviously, what we are trying to achieve, as you said earlier, is a regulatory response and we want to end up with a workable and relevant outcome within the parameters which we have always discussed in this Council. So the working group, certainly, but not the officers.

The President: Thank you, Phillida. Just for information, I think that is where the officers got to as well in their thinking. Seema?

Miss Seema Agha: There was a suggestion whether it would be helpful for me to attend the meeting with the working group to assist with the rules work.

The President: Alan, do you have a view as to whether you would welcome Seema's input?

Mr Alan Kershaw: Not at all. At the moment I am still not convinced we will necessarily have to meet but what we do need to know is that when the staff have been through the immense amount of detail here, that they have a way of bringing issues to a group to digest this on behalf of the Council. It certainly does not belong here in the full Council, I would suggest. I think it is not a good use of everyone's time. As to -- I am entirely neutral on whether we have got enough at the moment or not but if there were a need for some specific -- I think it remains to be seen what is in these things but if there were a need for some specific direct experience of the fitness to practise procedures here, then I have no objection to the suggestion.

The President: Thank you, Alan. Sue, did you want to raise something?

Mrs Sue Kilby: I do not know, are we looking purely and simply from a regulatory perspective or also from a professional point of view as well? I am not sure what the consultation is. Is this coming down as being a deed done as far as what is happening in the GPharmC and you are looking for advice and guidance on that or are we having a consultation that is actually going out to wider organisations?

Mrs Wendy Harris: The rules to be made, they are consulted upon, but the detail of these is really how we the staff in regulation discharge the function. So it will say, for an example, the

rules on the Statutory Committees will say there shall be a Fitness to Practise Committee, and it shall comprise one Chair, one Deputy Chair, two lay, two professional. It is in that level of detail. So a lot of it will actually replicate what we do now. It is not the sort of thing that I would expect there to be -- rules ain't sexy. They are not going to exercise a great deal of people unless you are really focused on that level of detail. So I am not suspecting that even the GPhC will be overwhelmed with responses to it but I was only expecting this to be a regulatory response because it is around how do we discharge the function.

The President: Alison? I am sorry, Alison. Jeremy wanted to come in on that point.

The Chief Executive & Registrar: I am sorry, if I may just add to that, that is absolutely right what Wendy said. It was a functional mechanism to enable the GPhC to put into operation what it is required to do. It needs rules to do that and those rules need to have been consulted on but it is a very different kind of consultation as compared to, for example, the standards consultation where there is a very strong professional interest. This is really a technical exercise to get the right mechanism in place and, as such, it is just about portering the current regulatory machinery to the new GPhC machinery.

Mrs Sue Kilby: I was just thinking around CPD, that was all, and around how that would fit and if there was a need to consider it from the professional side if we are going to be linking back across and that was what I was thinking about.

Mrs Wendy Harris: Thank you, Sue. That has prompted me. The CPD rules are actually not going to come out in this tranche. Of all of those listed, the department, with their solicitors, have drafted all of the rules with the exception of CPD and they are expecting those to be done later on once GPhC has opened its doors. So we will have five out of the six sets to look at in, like I say, four to six weeks' time, but not CPD. My apologies for not flagging that to you sooner.

Mrs Sue Kilby: Thank you.

The President: Alison?

Mrs Alison Moore: I am perfectly happy with what you are proposing. I just want to clarify, at the top of page 2, (iv) that we are recommending says as (ii), which is the one where they do the detailed differences and I thought when you were speaking verbally you said it was going to be as (iii), which is the one where they do the significant differences.

Mrs Wendy Harris: Thank you.

Mrs Alison Moore: Thank you. I just thought if we are agreeing to it formally, we should --

The President: Which one are we agreeing to?

Mrs Wendy Harris: Alison is quite correct. Again, that is drafting. I am sorry, this is a picnic. The problem is in the chair, not in the computer.

The President: Not this Chair?

Mrs Wendy Harris: No, this chair here. I am sorry, President, I take the blame. Alison is absolutely correct. It is as I put in (iii), which is only the significant differences brought to the attention of the Council working group.

The President: Is Council content with that proposal? (Agreed) Thank you very much, Council. Thank you, Wendy.

*Council
agreed*

- i. *option (iv) that regulatory staff review each and every set of Rules and provide a critique of the differences between the current and proposed Rules but that only the major differences be brought to the attention of the GPhC Standards Working Group, in the draft consultation response.*

FOR NOTING

16. The Three Year Rule

*[Council
noted the report that had been circulated at 10.02/C/08].*

17. Statutory Committees statistical report

*[Council
noted the report that had been circulated at 10.02/C/09].*

18. Law & Ethics Committee 2005-2010

The President: There are three papers for noting, paper 8 on the three year rule, paper 9 on the Statutory Committee statistical report, and I would just like to just thank Jeanne and her team for producing that excellent report for us again. If could you pass our thanks back to her, Wendy, that would be great, thank you. Paper 10, item 18, the Law & Ethics Committee 2005-2010, it sounds like the life and times of and a Mastermind subject, but I think it is an excellent piece of work. I would like to thank Priya for putting that together and actually I would like to thank Law & Ethics Committee for suggesting that happens. I would like to thank specifically the Committee members of Law & Ethics, both past and present, especially the Chairs, for overseeing the work during this period. The Chairs over this period have been Pat Hall, Doug Simpson and of course David. So thank you very much indeed all of you and thank you for the great work in putting that report together. Thank you.

*[Council
noted*

- i. *the report that had been circulated at 10.02/C/10].*

Organisational matters

19. Chief Executive & Registrar's report

a) Minutes of committees circulated since the December 2009 meeting of Council

The President: On now to organisational matters, item 19, the Chief Executive & Registrar's report.

The Chief Executive & Registrar: Thank you, Steve. There is only one item under there which is a matter of report for the Council to receive the minutes of the Governance Committee in November and the Education Committee in November. All of those are on the micro-site.

The President: Thank you, Jeremy.

*[Council
received*

- i. *the minutes of the Governance Committee held on 18 November 2009 and Education Committee held on 18 November 2009].*

20. Policy governance structure for the professional leadership body

The President: Item 20, which is paper 11, policy governance and structure for the professional leadership body. Michele, thank you.

Mrs Michele Savage, Professional leadership governance adviser: Good afternoon, Council. I have been asked to bring the proposed policy governance structure for the PLB to you for comment. We felt it was important that you had the opportunity to comment on this governance structure. I would emphasise though however that it is for the Assembly to agree this structure and obviously a lot of work has gone on taking it to this stage.

Ultimately, it is for the Assembly to decide is this the structure they want? It is not set in stone and I would say that I think moving forward that governance policies as a matter of course should be reviewed regularly and I would expect that the governance structure that whatever the Assembly decide they want to take forward should be reviewed after a year after the demerger just to make sure that it is fit for purpose. I think what you think you might want might not be what is working well in a year's time and I think we do need to get into a regular review process, particularly as we move through the first five years of the PLB. I think that is very, very important.

I am just going to really pick out what I think are some of the main points and can I just bring you to section 2 where it says the governance model on page 1? It says here the Society has adopted the Carver model of governance. That should not be on there because, as I have said, it is the Assembly that is adopting it and nothing has been adopted as yet. So if you could delete that and forget you saw that, that is incorrect, and I apologise, I should have taken that out. I think sometimes with papers you see what you want to see rather than what is actually there.

The policy governance sits very well with what the prospectus proposed for the MPBs with the Assembly being the strategic body and the MPBs being the main drivers.

Just moving through what we have with governance policy, I know there has been some concern raised about how you, how the Assembly, will make sure that and the MPBs that the staff are doing what they want. Now, I think there is some confusion sometimes over what is managing what the staff are doing and actually monitoring and I think where we probably need to get a lot cleverer is about the information that staff provide to the Assembly and the National Pharmacy Boards which enable you to ask the right questions to ensure that the policies that you are asking the staff to implement are delivering what you, as a professional body, want to deliver so that it is quantifiable, that you have outcomes. I think there is a big piece of work to be undertaken around that as to getting back to basics and looking at the papers that we, as the staff, bring to you so that they actually give you what you want to do.

So I think we need to be very clear that there is a distinction between managing the policy process and monitoring the process and I think this is one of the things that the policy governance does.

Just moving on through the paper, I think most of it is fairly straightforward. I understand there has been some discussion around the role of members in governance which is page 8. What I would say in this is that I think you need to think that what is going to be moving forward is going to be very different to what you have now. You are going to be a professional leadership body and you are going to want to be a strong influencing body in the national arena, whether it is with other health bodies or with politicians as well, and I think that is when the collective responsibility really comes into play as well.

I know there have been some issues over some of the wording around if you publicly dissent you should consider your position. I think that is good governance and I actually think that is probably going to be more that is going to unite the Assembly and the National Pharmacy Boards rather than divide because I think a number of the big issues over the years where there has been considerable debate within Council and the National Pharmacy Boards have been things that have been more associated with regulatory issues. I think moving forward that is not going to be the issue because you are going to be united behind that as well.

The paper has been to Governance Committee and that was one of the words -- I actually had everybody resigning which probably was a bit over the top and probably was not the best thing I could really have put in but after discussing with Governance we felt that it should be in there so that people should consider their position and if they were comfortable with what they were doing, absolutely fine, but all we were asking was that they reconsider their position.

So really probably what I want from you today is to get some comments that I can then take forward to the National Pharmacy Boards' induction day next week, which will be discussed by all of them, and to the shadow Assembly as well. So I think it is important that what you have got to say moves forward to the next body. You have the experience of how the Society has worked over the years and your views on governance and I just think it would be very useful for me to take these forward.

The President: Thank you, Michele. Just as a bit of background to this paper, I was asked that this paper should come to Council and I was very pleased that it should do so for the reasons that Michele has outlined. Although it will be for the Assembly to decide upon their governance arrangements, I do think it would be very helpful for the Assembly to hear any comments from this Council based upon our expertise in this area. So I do want an open discussion on this. We just need to appreciate that it is not for the Council to agree this, it is to comment on, to assist the Assembly in agreeing their governance structures for the new body. Who would like to kick off? Sylvia, Lorna and then Kay.

Mrs Sylvia Hikins: Thank you. My question is around openness and transparency, particularly in relation to the professional body membership. The two questions are do you intend for at least the Assembly meetings for a member of the professional leadership body to be able to sit and listen? I think this is the arrangement here, is it not? If I was a member and I wanted to just come and sit in the back and listen to the proceedings I could do that. That is question one. Will that be the way the Assembly operates and could that percolate to the Boards as well? The second question is, is there any intention to have a website and at least put the minutes or the proceedings of the Assembly on a website?

The Chief Executive & Registrar: Thank you, Sylvia. First of all, I should say our intention, my intention, is different to what the intention of the Assembly might be, which is the important intention. I would very much hope that the Assembly will be open to members and, indeed, the Board meetings already are open to members, and I would very much hope that the minutes of those meetings are available on the website. Ultimately, it is for them to decide. It is the Assembly and the Boards who will decide. I would express my view in the way I have done just now but they will make the decision.

The President: Lorna?

Mrs Lorna Jacobs: Thank you. I would just like to add to what Michele said on the points in item 5. This matter has been to the Governance Committee and we had the benefit of two external governance advisers, Paul Jervis and Tony Ashmore, and this was the recommendation of the Governance Committee. Now, clearly, it is, as everyone said, for the Assembly to make their own decision on it but I would like to issue what I would consider a health warning. If the Assembly choose not to recognise the collective responsibility in this way, that will have implications in the view of the experts and in my view. It will have implications on how the professional body is perceived by external bodies and the people you wish to influence. As I recall, that was one of the strongest things that came out of TransCom, was that you want the professional body to be able to influence Department of Health and ministers and other policy-making situations. How you conduct yourselves in public and accept collective responsibility will have a significant impact on how the professional body is perceived and its ability to have clout. If you do not accept it and there are constant letters in the PJ dissenting from decisions that the Assembly has made or at local practice forums, then you run the risk of being seen as a group of people permanently chasing their own tails, changing decisions and just having a lot of internal dissent again. I

really, really hope you will rise to the challenge of accepting collective responsibility so that you can carry the weight that you deserve with those opinion leaders.

The President: Thank you, Lorna. Kay?

Mrs Kay Blair: I find this paper really interesting and I was particularly interested in page 2 of 10 when we were talking about the model and the role of the Chief Executive and Directors in the Assembly. I can totally understand in the governance model, because the Assembly is the oversight and the monitoring, but the way it was worded gave me some concerns that the Chief Exec and the Exec team might be slightly subservient to the Assembly. I have always worked on boards where they have not been like the Assembly, it is a different role, et cetera, but where the Chief Exec and the Finance Director or key Directors are an equal part of the Board. I suppose I understand the governance model but I would like some reassurance that this will be an inclusive model that actually does take account of the stature and stance of the Chief Exec.

The President: Michele?

Mrs Michele Savage: In this paper it does actually say that the Chief Executive is not subordinate to the Assembly. I cannot quite find it but I know it is in there somewhat. We had had that discussion at the Governance Committee as well and it was one of the points that were made. I do not know whether you want to say anything more about it, Lorna.

Mrs Lorna Jacobs: That tends to be more what the NHS does with their boards where you have boards with executives and non-executives. This is the newer model and it can also work. They are slightly different ways but this is more of ensuring that the Assembly has a more strategic role and gets less involved in the operational matters, I think.

The President: On that point, Marcia.

Ms Marcia Saunders: I think I actually agree with Kay. I think you should delete all references to Carver in this as a further reference. The Carver reference model actually does not state -- it is interpreted in a number of ways. It does not state that executives cannot be members of boards or at least it is not usually interpreted that way. Unitary boards very often and very successfully follow the Carver model. That is on a point of clarification. I happen to be very comfortable with the way that Kay describes the operation of a board as well.

Mrs Michele Savage: Can I just come back on that? We have had some discussions about -- Carver model ending up being in here and actually what we want is a governance structure for the Royal Pharmaceutical Society and I think, as we have moved from talking about the PLB, we are now going back to talking about the RPSGB and I think we need to change the name of that. As Marcia said, it is not Carver in its pure form, it cannot be because we are unique, aren't we, amongst bodies? So I think that is important and Martin and I had a chat about this a little bit earlier.

Just coming back to Kay's point, page 6 of 10, 4.1, it says here "The Chief Executive is not subordinate to the Chair of the Assembly" so maybe we need to take out "Chair" there. Is that what you are suggesting on that, Kay?

Mrs Kay Blair: I think I am happy with that. I do not want the impression to be given that the Chief exec is not an important part of this team and it seemed to me really page 2, that you know, they have the right to be heard. I mean --

Mrs Michele Savage: I think some of this is language and I think as we sort of move forward, I still think we have got a little way to go with this yet, so I think that is something we can take on board and I will certainly take those comments on board.

The President: Thank you. Alison, sorry to keep you waiting.

Mrs Alison Moore: The first thing I wanted to say was that I would wholly endorse Michele's comment about reviewing this policy governance on a regular basis. I think that is a very healthy thing for the new organisation to do.

Also whether this paper is adapted or not or whether it is a case of this paper goes to the Assembly as it is with a variety of views from Council appended to it, I do not have any strong feelings about, as long as the Assembly are made aware of the views that were held up in Council and, if there are areas of controversy where there is no agreement, that those areas are highlighted to the Assembly. I think one of my concerns is they are going to have an awful lot of papers presented to them at the beginning with a lot of quick decisions that they are going to have to make and I would not like anything to be rushed through without them having the time to be aware of what we consider might be the potential risks.

Having said all that, I am sorry, but I want to go back to page 8 which is the bit not really about collective responsibility, I do not disagree with any member taking collective responsibility for decisions, but I still feel that -- I will rephrase. I will start from the beginning. I think that it is very important that the members of the new body or the members of the Pharmaceutical Society, the ordinary members, have trust and trust their Board members and trust their Assembly members. I also think it is very important that the Board and Assembly members behave appropriately in public and towards each other and in meetings. I think personally that that trust will be best recognised by allowing those members on the Assembly and on the Boards a freedom of speech both within and outside of the Assembly meetings as long as they have behavioural contracts, there is some sort of a code of conduct that says that they are not going to behave inappropriately towards each other, they are not going to slag each other off in public, but I think to not allow elected members the opportunity to just a disagree with each other, to me, removes that element of trust. I think a normal member of the Society will not trust a Board member that they think is always saying whatever the policy is because that is the only thing they are allowed to say. They will not know when they can believe them and believe that they are speaking honestly and when they think they are just towing the party line. They will not know the difference because they will always be agreeing with Society policy. That is the slight problem I have with this. I think there is a difference between taking a legal responsibility for a decision that a Council has made or an Assembly. I think it is perfectly fine and I think all people sign up to that when they start. Having to agree with every decision that is made once it has been made, without time limit on this, and without any ability to say actually that decision was made and although I will take responsibility for that decision I do not personally agree with it, and being polite about the way it is disagreed with, I cannot see why that should be allowed and I would like the Assembly to have the opportunity to consider that.

The President: Bob, is it on that point?

Professor Bob Michell: Exactly on that point. I share Alison's concerns and I do not think it is a small point, I think it is an enormous point. I think it is an enormous point because the primary purpose of this particular body is not to be the regulator anymore but to be the spokesman of the profession or spokesperson of the profession.

If we look on page 10 at bullet points 4 and 5, I see serious problems, especially in bullet point 4.

“Act collectively in discharging the functions of the governance body ..”

No problem.

“ .. abiding by ..”

Certainly:

“ .. and supporting any decisions made.”

That is the whole problem with our national government. That is why people cannot be bothered to put their shoes on, on election day, because they know that MPs, once they go into the sausage machine, come out as sausages. The point is there will in the future be divisive issues of great concern to the membership in which the split of opinion within the profession may be fairly even. So you have someone who may have been elected in order to campaign on a particular point and if they fail in their first attempt to change the policy, or whatever it is, it is perfectly understandable that they must abide by that decision but it is not understandable that they should have a compulsory Damascus experience and cease to campaign on the point. In fact, this seems to me to be very different to the current position which, as I have always understood it, is that if there is a Council policy with which you do not agree, the existing obligation is to properly state the Council position and to explain why you differ in your view. I think that is a much healthier way of approaching it and I think it is far more important when it is a representative body rather than a regulator. Yes, I know from the point of view of political activity you need to present a united front but I do not think that can be at the expense of suppressing the proper democratic expression of a wish for change.

The President: Do you want to say something, Michele?

Mrs Michele Savage: Yes, I did. I take on board what Alison and Bob have said. I do think looking at this, there is a slight contradiction between what is said in the role of the members in governance, section 5, and bullet point 5 where we are saying in here:

“Support publicly the policies of the Society, and where appropriate, explaining fairly any contrary views considered.”

I think there is a bit of a mismatch there with those two sections. So I do need to look at those because I think what bullet point 5 is saying is exactly what Alison is saying, you support the collective decision, but you are explaining the other views put forward as Alison has done on a number of occasions, but saying this was a decision but this was the view that I put forward, and I think that is what bullet point 5 is saying, which is not necessarily what it is saying in section 5. So there is a bit of a mismatch there that I do need to go and look at.

Professor Bob Michell: May I say support is a dangerous word there. Abide is an appropriate word. It means you accept but you are in minority but there is a collective decision. I do not think it should imply that, for example, in the future discussion you would necessarily support the view. You feel you are elected to secure change; you do not necessarily secure change at the first attempt.

The President: Marcia?

Ms Marcia Saunders: It is also on this point. I actually do agree with Alison. I know she is surprised, on this particular one, because we debated it quite a lot previously. I do agree in the way that she has described it. I think that the problem -- I think that the actual issue is about taking responsibility for the decision and we all do have to take responsibility for decisions that are taken in organisation of which we are a member and we are in the minority. We still have to take responsibility for it. The problem arises if we cannot state our own position and I think, the way Alison described it, you can state your position.

The other problem that arises though is when opposition becomes obsessive and terrier-like and what you are going to do is try to overturn it at the next meeting. That is usually dealt with by having something in the standing orders that says a decision will stand for X number of meetings or months, and it is usually something like two or three meetings, depending on how frequently things are, but a decision will stand for a particular period, and there are models for that. I would suggest that making sure that something of that sort is written in is fine but I think Alison described the situation very well.

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Mrs Michele Savage: Just to come back on that, Marcia is quite right, our standing orders that we have at the moment say that and Martin and I have looked at the standing orders on that and there is probably no reason why those could not be re-adopted for the Assembly, obviously subject to their agreement as well.

I do think that I probably need to look at these two things again just to see where I end up and take your comments forward and maybe there needs to be a slightly amended version that goes forward to the Boards and the shadow Assembly.

The President: Gerald and then David.

Mr Gerald Alexander: I think the comments that Marcia, Alison and Bob have made make very good sense for freedom of speech and good debate. I am sure that the current model that exists in our governance handbook is not too far offbeat.

I just want to go back a stage to the actual governance model itself and to take a leaf out of David Thomson's book. I would like to talk about devolution, which is very unusual, and the fact that three National Boards exist. We are talking about an Assembly which I hope will not be a mark 2 Council of the Royal Pharmaceutical Society, it will be something slightly different. From what I understand and recall, we are thinking about an Assembly meeting maybe twice a year, perhaps three times a year, I do not know, if my understanding is reasonable.

So given that understanding, if I were to think about the model of governance and the separation between the role of the staff, the management and the staff, and the Boards and the Assembly for setting strategy and broad objectives, which is talked about right on the front page, "Management is charged with implementing strategy and achieving the objectives that are set", i.e. management determines how the organisation achieves its objectives, I am pretty happy with that as long as it is done properly. That is where governance comes in. That makes good sense. Therefore, it is the duty of the individuals on the Assembly or the National Boards to challenge and hold the executive to account should those objectives not be met. That is probably what we would all agree here and it is with a slight variation of issues related to cabinet responsibility. If we go a bit further on it says:

"Ultimately all bodies within governance account to a governing body. A Chief Executive is appointed by and receives instructions from and accounts to the governing body. The Chief Executive appoints staff .."

So the issue is there is this accountability framework. Now, we have got three National Boards and an Assembly. Do you not think it reasonable that the Chief Executive actually is accountable to the National Boards also or is it the Directors that look after the National Boards that are accountable? I just wonder, because the Assembly is only going to meet maybe two or three times a year, how is the accountability going to be met? I just pose that question.

The President: Jeremy?

The Chief Executive & Registrar: Thank you. Well, first of all, I would see the country Directors as accountable to the Chief Executive. Yes, they have to work closely with the Boards and particularly with the Board Chairs but in terms of line management it is very clear to me that they report to the Chief Exec. That is important because if there is an issue between a Board member and a country Director, the appropriate escalation of that is to the Chief Executive. That is, as it were, the next level up of management responsibility.

The Chief Executive has to be accountable to a body. I do not think the Chief Executive can be accountable to four bodies. So if you take the hierarchy, then it ought to be the Assembly

to which the Chief Executive is accountable.

Mr Gerald Alexander: OK, that is fine. I am sure there will be some concerns about issues in the future that a National Board would like to positively take forward and if the Chair of the National Board felt -- I know that the Chair will probably sit on the Assembly. I cannot remember if they do or if they do not. The issue is the Assembly does not meet that often and if there is an issue over the lack of implementation of a particular policy, how is that responsibility to be met?

The President: My view would be that the Chair of the Board would liaise with the lead Director for that country to resolve that issue and if that could not be resolved through that route that would be escalated to the Chief Executive.

Mr Gerald Alexander: Going back to Lord Fraser of Carmyllie, the idea about National Boards was that they would actually deal with matters relating to their various countries, and there has got to be some sort of autonomy from a National Board to be able to deal with those national issues. My issue with this is that the reporting structure is only back to the Assembly and not back to the National Board. I understand that but I think there needs to be some mechanism in place that actually strengthens the position of the National Board in relation to the way the executive function. I do not know whether you have any thoughts on that.

The Chief Executive & Registrar: Could I just point out that the Assembly is composed predominantly of members of the National Boards, including all the Chairs, the Vice Chair of the English Board, and indeed five other members of the English Board. So it is, in that sense, the Boards working in concert and, to my mind, that is the ultimate point of governance and responsibility to the Chief Exec.

Mr Gerald Alexander: President, I really should not be talking about it here and I am not going to be talking about a specific, but it is the reporting structure. We, as a Council, expect certain elements of information to be laid before us in order that strategy and policy that has taken place in the past is implemented. I am sure, Jeremy, you would accept that any information that comes across your desk would always be passed back to us if you felt that a particular policy or initiative was not able to be met. I am referring to a research and -- just a research strategy issue that is historic and I just feel that the reporting mechanism is vital to any successful professional body or any over-arching body.

The President: I think the reporting mechanism is important and the lines of communication are important.

Mr Gerald Alexander: There is a point, you know, President, that perhaps I would like to make but it is not now obviously, but I am talking about this in the grand scheme of things. The grand scheme of things is ends and means and that is what the Carver governance model is about. The end is the point that we have all agreed on and the means are carried out by the Chief Executive and the staff. Should there be any deviation or change from that end point, then you would expect reasonably, as a member of a governing body, to find out directly from the Chief Executive such reports. That is the issue that I am really referring to. I am not referring to the decisions that are made, I just want to make sure that Councils are actually informed of changes in process that actually lead to different end points.

The President: As you are aware, Gerald, you will get opportunity to talk about that in more detail in confidential business.

Mr Gerald Alexander: That is the specific --

The President: You will get the opportunity to talk about it in confidential business.

Mr Gerald Alexander: It is purely an issue --

The President: Confidential business. David?

Mr David Thomson: Thank you President. Thank you, Michele. The paper illustrates a model of best practice that has been tried and tested and refined over the years and I think the new bodies would do well to accept wise counsel and continue that refinement as they evolve as well.

There are two specific points. The first one is on clarification on the charitable trusts. Can we be more specific about what they actually entail, just for clarification, or is it just a general statement?

Mrs Michele Savage: It is a general statement. I am talking to Catherine about the charitable trusts and what that will entail. It is just giving a top level view on the governance of that at the moment but I can come back to you on that at the Boards.

Mr David Thomson: The second point, and I am not sure it is covered in the induction programme, but the Nolan principles and even the Carver principles, we talk about them, but I do not think many of the new members might have seen them. Would you cover that?

Mrs Michele Savage: That will be covered on the induction days, if I remember rightly. We will be going through the whole policy governance, the Nolan principles within -- I think it is the afternoon session when I come up there.

Mr David Thomson: Thank you.

The President: Dorothy and then Alan.

Mrs Dorothy Drury: I would like to support Alison and Bob and Marcia. It would be wonderful if everybody could just agree, and if there was 14 of us and we had 14 and we all exactly want the same, but there must be a point when we have seven want one and six want the other and obviously the majority has got to be what is followed but I think that you have to be able, you know, then that something is not such a majority decision and that is when we have probably had problems as a Council. You have to go on the majority decision but that you could give a reason why you think differently.

The President: Thank you, Dorothy. Alan?

Mr Alan Kershaw: Thank you. Just to be completely relentless on this point about dissent, there are really three categories, here, are there not? There are unanimous decisions which you agreed with and therefore you can promote and support, there are majority decisions where you may or may not be in the majority but where you are bound by the code to explain the balance anyway that some thought this and some thought that and this is what we decided, and there are ones where, however it was decided, you disagree with and you have given notice that you are going to express dissent on a personal basis. So I think any recasting needs to consider all those situations.

The President: Thank you, Alan. Steve?

Mr Steve Acres: Just to pick up the same point about dissent, freedom of speech, call it whatever you like, it is really about balance, isn't it? If one or two people decide that they want to talk against the Assembly policy and they have got a reasonable reason for doing so, and it appears in the press, people will see that there is reasonable debate and that will be fine. The problem is that if there are lots of people doing it all of the time that the balance tips in the wrong direction and the credibility of the organisation goes down the pan, so it is really just to get a balance.

The President: Martin?

The Vice President: As someone who has been elected onto the new Board, I have just been in listening mode here and I am going to continue to stay in listening mode and not comment.

The President: Sue, are you in listening mode?

Mrs Sue Kilby: No. I have listened and a lot of it -- well, obviously I have got to declare an interest as an elected member of the English Board. It is actually not directly to do with what is on the piece of paper here but it is just my thoughts because we are supposed to be looking at having some sort of partnership arrangement, agreement, with some external organisations and I am just wondering how they fit into this as well, which level you would actually involve them in negotiations of actually performing those links with some of the other groups that are around that we have been in discussions with or I have been led to believe there have been discussions with, and how they are actually going to link into -- I am not obviously specifically thinking of the College of Pharmacy Practice but you have been talking and discussing with people like the UKCPA and other special interest groups. Are you thinking that the partnership will be at the Assembly level or is it going to be at Board level? We have not actually thought of that in which case if we have not thought of that, then fine. It is just I am not sure how they fit into this point and where the governance is going to be.

The President: Jeremy?

The Chief Executive & Registrar: I do not think this is so much a governance question, Sue, as an operational question. I think when there is a working partnership which might be embodied in MOU and that is consistent with a strategy that the Assembly and the Boards have set out and agreed with the executive, then it becomes an operational matter as to how you are going to implement that strategy. So I do not see this as a connection between the governance body for the Assembly or the PLB and the governance body for another organisation. I think that is at the executive and operational level but within the constraints and parameters of a strategy agreed by the Assembly and the National Boards.

Mrs Sue Kilby: So the decisions will be -- it will be left to --(inaudible)--

The President: John?

The Treasurer: I think when you are looking at these things what you try and do or what I try and do anyway is try and think of a particular situation and how it would apply. The one that concerns me, if we do not allow any kind of dissent clause or any kind of dissent may be probably too strong a word, a disagreement cause, is assisted suicide. Now, if the Council were to vote for an assisted suicide policy or the Council to recommend that pharmacists were to take part in one, I do not mean vote for each other or anything like that, if one of the Council members was, for instance, a devout Roman Catholic who may take great umbrage at being forced to defend publicly a policy that their religion opposes them to, part of the debate in the run-up to the election, there were a series of questions posed to candidates in Wales and in and around Scotland. I think they were slightly different between England, Scotland and Wales, but one of the questions posed to English candidates was "Would you support the retention of a conscience clause?" I think everybody who was successful at that considered they would. Now, that does not sit easily with any kind of dissent if you are allowing a conscience clause and there are several issues you may want to apply that to. It currently applies controversially in some respects to the provision of EHC in community pharmacies but it would apply to any kind of involvement with an assisted suicide policy in the future and I think that is something we should bear in mind.

The President: Tristan?

Dr Tristan Learoyd: There is two points. One of them is on page 2, it talks about:

“The Assembly agrees overall strategy and top level objectives ..”

It still sounds as though things are coming in from the top when I think the idea is that the professional body has been sold as a prophet of hypothesis and hope where it comes from the bottom. So we are still not getting that quite right.

The President: I am sorry, I do not understand what you have just said. Could you explain it?

Dr Tristan Learoyd: I will contextualise what I have just said. To the detriment of this Council, one of the things that I have seen coming onto this Council and being part of it for nine months is that it has been a control and command culture or it has been perceived as control and command. Now, two of the reasons or one of the main reasons why I was elected twice at a young age was because I have attacked that point, that it has been control and command, and that the --(inaudible)-- is that the Council does not listen. If we have a clause or we continue with the code of conduct which says that certain individuals cannot voice their opinions and we do not have transparency, then it will continue to be viewed as ‘big brother’ or as a body that does not listen. I think it is to all our detriment if we have a professional body that is seen not to listen. I think one of the ways that we can combat that is to have a liability clause or a disclaimer which protects the Society from libel or from exchanges with external third parties who are wanting to prosecute the RPSGB because of what an individual Council member or Assembly member or Board member said but I do not think we should go to the point where we are inhibiting fellow professionals from using what is normally their best judgment in giving their arguments across on representative bodies.

One of the other things that underpins the idea behind this professional body and the way it has been sold is that it will be based on science, practice and research but research is based on freedom of expression so therefore, if we are a science based profession, we are therefore based essentially on freedom of expression which is embedded in the research which then would be central to our future success.

So my view would be that we need to remove as much of the governance as possible so that the Society can function in a manner that it will not be held accountable to third parties but so we can allow freedom of expression. You may hold your pen up at laugh, Lorna, you may do that, but I honestly think that this is the best policy

The President: Tristan, I think Lorna is trying to catch my attention and make a point. Lorna?

Mrs Lorna Jacobs: Thank you. It may be very nice to have a situation where anyone can express their views freely. Freedom of expression is an excellent policy and I would not wish in any sense to move away from that. But we are in a society where people do have liabilities for what they say. It might be nice to have a situation where the Society is not liable for the actions --

The President: Tristan, it might be polite if you listened to Lorna’s response having posed the question.

Dr Tristan Learoyd: I sincerely apologise, for the record, and I am now. You have my full attention.

Mrs Lorna Jacobs: It would be nice to have a situation where people were not -- the Society was not liable for the actions of members of its Assembly. That is not the society in which we live and it would be nice if we might choose to ask the government to make such a law. That will not happen. We live in the real world. If members of the Assembly or the Boards make

statements in public they, and in some situations the Society, will be liable for those statements.

What governance is trying to do is to ensure that people behave in appropriate ways with respect for the organisation, for other members of the Assembly and the Boards and to ensure that the organisation is able to function and to achieve its objectives as well as possible. So the governance is not there to shackle people, it is not there to stifle debate. What it is trying to do is to encourage debate and then, when a decision has been made, enable the executive to get on and action that decision promptly without feeling that they will then be undermined by people making further representations to try and get that decision reversed so that the organisation is not --(inaudible)-- the system directly.

Dr Tristan Learoyd: Can I just come back on that when you say there is no legislation with regard to freedom of expression and refer you to the European Convention on Human Rights where it is actually one of the rights that is instilled into that particular Convention.

The President: Sylvia?

Mrs Sylvia Hikins: Thank you. Freedom is a bit like truth, is it not? There are various shades and ways of coming at it. There was a well known philosopher in the 1930s who said freedom is the recognition of necessity. I would have thought it was very necessary for a professional body to think about what its purpose is and its purpose is, of course, to be inclusive with its members and to allow debate and all of that on issues, but beyond that its purpose is as it has got no regulatory basis to be an enormous pressure group to bring about changes within the practice of pharmacy and related professions. It is going to do that by engaging other organisations with it and that is a big responsibility. So it seems to me that, unlike the members of that Society that can probably more or less say what they like because that is part of an inclusive response, when you consult people can respond and say what they want and that is part of being inclusive with members being part of the decision making, but when it goes through the processes and the decisions have been made by Boards and Assemblies, by and large, unless it really is a strongly moral issue, the members of those Assemblies and Boards should stick with it. If they do not like it, if they actively engage publicly against the decision of a Board of which they are part, then they should do what, for example, members of the government have done in the past over Iraq, like Claire Short, resign and campaign around the issue. So I support what Lorna has said 100 per cent.

The President: Yvonne and then Gerald.

Ms Yvonne Liddell: We all need freedom of speech. We all come from different walks of life and we all bring something different to this table. I have not been on Council as long as some and Tristan has not been on as long as me and without fellow Council members' direction when I first started, I probably would not still be here because it was quite difficult.

We have clinical governance in our day-to-day life which we all seem to have no problem following. The way I see it, it is there for protection as well as anything else. We all should be mature enough. In the Assembly and the Pharmacy Boards, or whatever, we are all adults. Nobody has to be on absolutely everything. Part of being in this room is that we do not all agree and that is why we represent our members very, very well. That should continue. Nobody wants a room full of people that agree with absolutely everything or what is the point. The whole point is that everyone should be able to listen to each other, vote the same, agree, but do it in a mature way, but governance is there to help everyone. It is protection and we all need it. We all follow it every single day and without it we would be totally lost and chaotic.

The President: Thank you, Yvonne. Gerald?

Mr Gerald Alexander: I am sorry to come back but this point is quite interesting. I think maybe you should define the role of a skilful Chair in your governance arrangements. A

skilful Chair would be able to identify areas of disagreement and perhaps it might not be best to come to a firm conclusion where perhaps amongst the group of individuals discussing issues they might agree to disagree. In fact, a skilful Chair could identify where there is division and there are perhaps two schools of thought, especially if it was the issue that John raised about end of life care. It could be quite an emotive topic to deal with and I can see where Tristan is coming from and I completely agree with Lorna and Sylvia. You have to have some rules and you have to have some means of organising the way that you publicise your discussions. So the skilful Chair will need to maintain credibility of the organisation. If that skilful Chair can maintain credibility of the organisation by allowing sometimes, and I am not saying every time, members to agree to disagree, you could have two minority reports. There is no reason why not but it is up to that individual to be skilful enough to identify those issues where there are some serious disagreements. It probably is not best to come to a vote on an issue such as that on a seven to six basis.

So I would implore the new professional body, when it gets going under the new Charter, just to consider how a meeting is chaired and the outcomes and if they feel that it is impossible to reach a conclusion, it is probably better that you do not actually have a specific policy which promotes one point of view but alienates a whole group of members and Assembly members or National Board members around the table. That is it really.

The President: Any more comments that might – Marcia?

Ms Marcia Saunders: I just can never entertain a discussion about governance without mentioning the money. Fundamentally, this will be a governing body and one of its absolutely fundamental roles is the sound stewardship of the members' money and actually making sure that the time is spent profitably and that policy is clear and that there are clear outcomes and objectives are achieved. It is not actually just a debating chamber.

The President: Sandra?

Mrs Sandra Melville: Could I just say I think it has been very useful having been involved in TWG and we got involved in this governance paper. It is very useful listening to all the comments. I have to say that Steve hit the nail on the head when he said it is about balance. I think we cannot have a gagging clause or we will lose credibility. At the same time we cannot be seen to be squabbling or we lose credibility. It is about balance and I think Michele has done a very good job of trying to capture that. We have all thought about that as everything that has been gone into the paper to bring it to where it is now.

My question is for Michele. I do think it has been very, very interesting listening to all these points of view. Where does this go now? What are you going to do with these comments? Where does the paper go from here?

Mrs Michele Savage: The papers are being discussed at the induction days next week at the three newly elected Boards. I will capture all these comments and hopefully get those round to the Board members in the next couple of days so they have got those as well as the Council paper and the other policy governance.

I am asking that the National Pharmacy Boards discuss it and then make recommendations with comments to the shadow Assembly for their meeting on 2 March where, again, it will be discussed and at that stage hopefully we will come up with something because by that time it will be the newly elected members that will have had a say and of course a number of them will not have been involved in this discussion because they have been on Council and they have not been at Board level.

So it is important that we -- hopefully eventually we will come up with something which is addresses everybody's concerns and people are comfortable with going forward, but that is where I am heading.

The President: That is right, Michele. I am sure that the Assembly will welcome the comments that have been made around this room today. It was very helpful. Thank you very much. Thank you, Michele.

Mr Alan Kershaw: Have we taken all the points? There is a point in the code which Michele knows about which she can take us through.

Mrs Michele Savage: Yes, I have addressed that and it is now removed so you will be happy.

The President: We have not dealt with it. Have you dealt with it off line, Alan?

Mrs Michele Savage: We came to the same conclusion.

The President: Would you like to tell Council?

Mrs Michele Savage: Alan raised a concern over, let me just get to it, on the code of conduct, bullet point 2, where it says:

“Are in good standing professionally, including with the Society and any other professional body or regulator of which they are a member or registrant ..”

And then it goes on to say:

“ .. are not subject to any disciplinary allegations that have been referred to an investigating committee (or equivalent), or adverse finding resulting from a disciplinary process.”

That is a bit complicated and actually we just felt that it just needed to stop where it says “registrant” because if you are in good standing professionally that should cover it all with whichever registrant. I changed it after Alan and then you changed it to exactly the same as well. So is everybody comfortable with that?

Mr Alan Kershaw: That is fine. It is not just the complexity, it is the point of principle that in the second half it introduces the idea of having to stand down if there is an allegation against you which is a bit of a hostage to fortune.

The President: Thank you very much, Council. Thank you, Michele. Item 21, we are going to defer to confidential business when we reach that point. That is the Resource Management Committee report.

[Mrs Lorna Jacobs, Chairman of Governance Committee, emphasised the importance of collective responsibility in ensuring the reputation of the Society going forward. In discussion there were mixed views about what ‘collective responsibility’ should entail as there was a concern about stifling freedom of speech. Several Council members advised that the Code of Conduct and the inclusion of the Standing Order that stopped a topic being re-considered within a short time period would ensure that members could still register their dissent in an appropriate manner. The role of Chairman was also discussed as a person able to identify division and steer the discussion to a ‘agree to disagree’ conclusion.]

Council

i. requested that their comments be added to the policy governance report to be considered by the Assembly].

22. Members designated as Fellows of the Society by the Panel of Fellows under Regulations Section 12

The President: We now move, therefore, to item 22, and I am declaring a personal interest, as I am sure will Martin, Sue and David. I will leave Jeremy to chair.

The Transcript of the public meeting of the Council is not the formal record of the meeting. The formal meeting comprises the papers presented to the meeting and the minutes subsequently approved. The policy of the RPSGB is actively debated at the meeting. The views expressed in the transcript do not necessarily represent the Society’s agreed policy.

The Chief Executive & Registrar: Is Council happy for me to chair this item? We are still quorate. Thank you. Council will recall the members designated as Fellows by the Panel of Fellows and I am seeking Council's permission to apply the common seal to the fellowship certificates. This is a ceremonial procedure but an important one and I think the Fellows whose certificates are ready and waiting would be very grateful if that seal were to be applied. Do I have your agreement to that? (Agreed) Thank you very much.

*[Council
resolved*

- i. that the Common Seal of the Society be affixed to the certificates of those Fellows designated in 2009].*

FOR NOTING

23. Council update

*[Council
noted the report that had been circulated at 10.02/C/13].*

24. National Pharmacy Boards elections 2010

The Chief Executive & Registrar: If Council is happy I can just draw your attention to the noting items, the Council update. If there are any points on the Council update, I am sure Martyn would be happy to receive those.

The President: Thank you. For noting, item 23, which is paper 13, Council update, and paper 14, which is item 24, to note the results of the elections to the National Boards. Congratulations to Martin, John, David, sue, Tristan, Sandra and Mark in his absence as well for being re-elected. Commiserations to Nick and to David. Suitable eulogies will follow in March, I am sure, for that.

*[Council
noted the report that had been circulated at 10.02/C/14].*

*[Council
elected*

- i. Mr David Carter as the Council member representative to the English Pharmacy Board].*

25. Any other business

The President: Any other business in public business. I have had no notification.

I beg your pardon, Val. I know I missed somebody.

None notified, AOB. I was going to try and press ahead with confidential business but I do not think we will because we have worked hard today so we will adjourn at this point and we will return at 9.00 am tomorrow morning. There is a light supper upstairs at 6.30 for those of you who wish to partake. Thank you, Council.