Northern Ireland
Assembly

COMMITTEE FOR HEALTH, SOCIAL SERVICES AND PUBLIC SAFETY

OFFICIAL REPORT
(Hansard)

Pharmacy (NI) Order 1976 (Amendment) Order (NI) 2011

7 December 2011

NORTHERN IRELAND ASSEMBLY

COMMITTEE FOR HEALTH, SOCIAL SERVICES AND PUBLIC SAFETY

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Members present for all or part of the proceedings:
Ms Michelle Gildernew (Chairperson)
Ms Michaela Boyle
Mr Mickey Brady
Mr Gordon Dunne
Mr Mark H Durkan
Mr Sam Gardiner
Ms Pam Lewis
Mr John McCallister
Mr Kieran McCarthy

Witnesses:

Mr David Best	)	
Ms Shona Coy	)	Department of Health, Social Services and Public Safety
Dr Norman Morrow	)	

The Chairperson:

I welcome Dr Norman Morrow, who is the chief pharmaceutical officer in the Department of Health, Social Services and Public Safety. This is the first time that you have been to the Committee in the new mandate, so you are very welcome indeed. I also welcome David Best, who is the assistant director of human resources, and Shona Coy, who is the principal pharmaceutical officer. Fáilte romhaibh. It is great that you are here. Thank you for coming to Newry. We are great believers in getting out and about, and we also believe in the Department

getting out and about to see us. I am delighted that you are here. Norman, you are going to make a short presentation, after which there will be questions from members.

Dr Norman Morrow (Department of Health, Social Services and Public Safety): Thank you very much, Chair. Thank you for the invitation to speak to the Committee today.

I am conscious that, as the Chair pointed out, this work started under a previous Administration, and although some members of the Committee will be aware of it, it may be new to others. Therefore, I hope that the initial briefing that we gave you was helpful in providing some clarification. I assure Committee members that this is not the only opportunity that you may have to talk about the matter. If you agree to the amendment order being put before the Assembly, the Examiner of Statutory Rules will report back to the Committee, which would give you another opportunity to discuss the matter with officials, should you want them to come back. I want to make that clear at this stage.

I want to mention two things by way of introductory comment. First, the Pharmaceutical Society of Northern Ireland has been anxious to have this new legislation on the statute book to fulfil the demands of modern regulation. We have obviously worked very closely with the society in creating the legislation, and the society has been supportive of it.

The other thing that I should point out at this time is that the proposed legislation is exclusive to the regulation of pharmacists and does not relate to any contractual matters associated with the provision of pharmaceutical services. The legislation is concerned with the governance of the profession, independent of practice situations. So, it is purely about the way that some of my colleagues and I are regulated and the way that we behave as professional people.

I will give you a little bit of background and introduce you to the key elements of change that are being proposed to the Pharmacy (Northern Ireland) Order 1976. Over the past 10 years, there has been a substantial change to the whole regulatory landscape, particularly among the health professions. Two reviews stand out: one to do with the medical profession and the other to do with non-medical professions. Those were complemented by the Government's response to the recommendations of the fifth report of the Shipman inquiry and to the recommendations of the Ayling, Neale and Kerr/Haslam inquiries. That resulted in a publication about safeguarding patients, which set out a range of measures to improve and enhance clinical governance in the

NHS.

This legislation is coming forward against that background and, in particular, that of a further White Paper that was produced in response to the two reviews of medical and non-medical professions entitled, 'Trust, Assurance and Safety: The Regulation of Health Professionals in the 21st Century'. That set out a programme of reform in the United Kingdom for the regulation of the health professions. It is in that context that we are making changes in this amendment order. The idea is to modernise and strengthen the regulation of pharmacists in Northern Ireland and to ensure public, patient and professional confidence in the regulatory system. I emphasise that the whole point of this is to provide an assurance about patient safety and public protection. That is fundamentally what underpins the legislation.

We have also taken account of a more recently published command paper entitled, 'Enabling Excellence: Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers'. That sets out plans to have a more proportionate and effective system of regulation, which devolves more power to regulators but is balanced by a new accountability to government in how they exercise those freedoms. It also gives further emphasis to employers and commissioners allied to clinical governance, discipline and quality assurance matters. Indeed, it emphasises the need for regulators to work with providers to assure that governance.

That is the broad context in which the legislation is being brought forward. Its underpinning is to have a proportional, rational approach to regulation in the context of protecting the public.

I will move on to the profession itself. In our briefing to you, we noted, as is required, the situation in GB. The Royal Pharmaceutical Society of Great Britain has had both regulatory and professional leadership functions, but, following the White Paper, since September 2010, it has been split into the General Pharmaceutical Council and the Royal Pharmaceutical Society. The General Pharmaceutical Council is responsible for the regulation of pharmacists, for pharmacy technicians and the registration of pharmacy premises. The Royal Pharmaceutical Society has migrated to be a professional leadership body. Although there are, of course, working relationships between those two organisations, they are independent bodies with different accountability and governance arrangements and are separately funded. That is the situation in GB.

The Pharmaceutical Society of Northern Ireland was established in 1925 and was similar to its GB counterpart in as much as it had responsibility for the regulation of its pharmacist members and was — and is — the leadership body of the profession here. Its powers are substantially governed by the Pharmacy (Northern Ireland) Order 1976. Obviously, that is now 35 years old and was established at a different time in a different context. The proposed legislation seeks to address shortcomings in the existing legislation in order that the public are appropriately protected.

In Northern Ireland, no decision has been taken on separating the regulatory and professional functions of the society, but it has been recognised by both the society and the Council for Healthcare Regulatory Excellence (CHRE) — the regulator of the regulators — that there is an ongoing need to update the statutory framework in Northern Ireland to better meet the demands of better regulation. The CHRE has made that clear in its reports. It is in that context that the Department has been taking forward the changes in association with the society so that it can meet the demands of modern regulation, and that is the purpose of the amendment order.

Taking the legislation forward involves two stages. The first is the laying of the draft order with the Assembly. Of course, that is subject to the Committee's approval and, indeed, ultimately, that of the Assembly. I will come on to discuss the draft order, which gives us the powers to make various regulations. The second stage is the development of the regulations, setting out the more detailed legislative requirements.

We have been through quite a substantial part of the first phase in as much as we have consulted on the draft Pharmacy (Northern Ireland) Order 1976 (Amendment) Order (Northern Ireland) 2011. That is a bit of a mouthful. That consultation ran from March to June this year, and we have published a consultation report, which you will have seen notified in our briefing to you. We had a very positive response to the consultation, and that is reflected in the consultation report. If and when the proposed amendment order is agreed, the next stage is to consult on the proposed draft regulations, which will set out the more detailed regulatory provisions.

I turn now to the specifics of the order and the amendments that it makes. One amendment reconstitutes the society's council. The present council has 23 members; that would be replaced by a council consisting of seven pharmacists and seven lay members. It is in the spirit of the White Paper to balance the professional and lay membership. That council would be appointed,

rather than elected by the membership. Secondly, the amendment order would place a duty on the council to set and publish standards for the safe and effective practice of pharmacy, which it would be necessary for pharmacists to maintain. That would become an open document, setting out the standards to which people would work. Partly related to that, thirdly, a duty would be placed on the council to set standards for continuing professional development among practitioners or registrants, including a mandatory requirement for pharmacists to complete an annual declaration regarding their compliance with that requirement. So, that is about updating oneself.

Fourthly, it reconstitutes the society's statutory committee, which is really its disciplinary committee, and extends the range of sanctions available to it. The statutory committee would be empowered to deal with cases by issuing warnings or advice, and it may suspend pharmacists or attach conditions to their practise. Ultimately, it may direct that a pharmacist be struck off. It has that power already, but I will come back to that in a moment. So, the order reconstitutes the statutory committee and gives it a range of sanctions.

The amendment order also creates a scrutiny committee with a range of sanctions, including the power to issue warnings and advice. That is designed to provide an initial screening of cases, allowing them either to be dealt with directly or to be referred to the statutory committee. So, it creates a stepwise process in that.

Finally, we intend to repeal article 18 of the existing order, which creates the power to consider health cases. Article 18 currently gives the head of the Department of Health powers to direct that a pharmacist be struck off if that pharmacist is suffering from a physical or mental disability that renders them unfit to have their name on the register. That power has been in place for 35 years, but it is difficult to enact, and we are changing it. The society is in a much better position to do that and to provide for qualified clinical advisers.

In summary, the provisions described provide a much more constructive approach to professional regulation, particularly by introducing greater proportionality to the fitness-to-practise process. For the first time, the society will be able to meaningfully consider health-related cases and to use medically qualified clinical advisers in that process. Until now, the statutory committee has had the ability only to employ the ultimate sanction: erasure of names from the register. That is now complemented by a range of disciplinary and restorative measures.

It will have a range of sanctions that it can avail itself of. It may, for example, insist that a pharmacist does some retraining.

I know that that is a lot of material, but I hope that it has given you a sense of the direction in which we are travelling. We commend the amendment order to you for approval. I am happy to take questions.

The Chairperson:

Thank you, Norman. I have a couple of questions myself, but I want to repeat to members what Norman said at the beginning. This does not relate to any contractual matters associated with the provision of pharmaceutical services. If anybody starts to ask about contracts, I will cut them off in their prime. We have very little time, and we want to get stuck into the crux of it.

Norman, is the annual report likely to be very unwieldy? We will likely hear from pharmacists if they are being asked to do something that will take them a lot of time or is very bureaucratic. Tell me a wee bit about that. I welcome the continuing professional development element of it. It is important that all health professionals are able to undertake that. Finally, can we ensure gender and geographical balance on the scrutiny committee?

Dr N Morrow:

I will start with annual reports. The Council for Healthcare Regulatory Excellence is committed and carries out an annual assessment of each body under its ambit. It produces and publishes annual reports on the performance of the regulators, which go to Government.

The Chairperson:

So each pharmacist does not have to produce an annual report.

Dr N Morrow:

I will deal with that when we discuss continuing professional development. It is not an annual report but it is an assessment, if you like, from CHRE about the performance of each regulator for which it has responsibility. A report is produced every year.

Given that the legislation will make provision for continuing professional development to be a mandatory process, it would perhaps be helpful to describe what currently happens. I am a

registrant of the society, so I am required to maintain a portfolio of evidence of continuing professional development. I have a voluntary responsibility to do that and to declare to the society that I have carried it out. As part of the society's monitoring of that process, it can ask to examine my portfolio to ensure that it fulfils its current requirements. At the moment, that is set in a voluntary system. However, the legislation will make it mandatory, and it will be akin to other regulators. I am already doing it, so in that sense it will not change. However, it offers the society more power to be able to regulate that as a formally required activity. As a pharmacist, I think that it is right that we should have a requirement for continuing professional development.

The Chairperson:

So do I. It is important because pharmacists deal with very vulnerable people.

Dr N Morrow:

That is independent of the practice environment.

Mr Dunne:

We are certainly impressed with what we have seen during our visit today. We pass on our thanks and appreciation to all the staff with whom we have dealt. We will probably talk about that later.

Does the statutory rule come before the Assembly shortly? From the Minister's letter, I understand that he is talking about laying it before the Assembly before Christmas. Is that right?

Mr David Best (Department of Health, Social Services and Public Safety):

It will be subject to the Committee's approval. There will be some time restrictions about any subsequent regulations. However, we are in your hands.

Dr N Morrow:

If the statutory rule goes through this stage, it will have to be debated on the Floor of the Assembly.

The Chairperson:

What are the chances of getting it in the Order Paper? We have only next Monday and Tuesday before the Christmas recess.

Mr McCallister:

It is not in the Order Paper.

Mr Gardiner:

I doubt whether we would get it in now.

The Chairperson:

I doubt whether we could get it in now for debate next week, especially —

Mr Best:

It will certainly not be debated.

Dr N Morrow:

No, the legislation has to be laid. It comes to the Committee first, and then it has to be laid. The Examiner of Statutory Rules will report back to you, which is why I mentioned that at the beginning.

The Chairperson:

It is debated after that.

Mr Dunne:

It will probably not happen.

Mr Gardiner:

We are talking about Christmas so you can expect this about July. *[Laughter.]*

Mr Dunne:

You mentioned continuing professional development. Were you referring to pharmacists in an organisation or the entire staff?

Dr N Morrow:

It is pharmacists. It is only the registrants of the society. Currently, only pharmacists are registrants.

Mr Dunne:

Pharmacists have to show continuing professional development and have evidence of that?

Dr N Morrow:

Yes.

Mr Dunne:

In the main, is that happening at present?

Dr N Morrow:

Yes.

Mr Dunne:

It is not currently a statutory requirement, but it will be. Obviously, the council will be more streamlined with 14 members rather than 23. Will that be a positive move?

Dr N Morrow:

It is critical that the regulator gets a balance between professional and lay members so that the public feel that their interests are properly represented. Historically — I am not talking about Northern Ireland but about the generality of professional regulation — the public have felt that there has not been enough lay membership on some regulatory bodies. The regulation is designed to balance that and ensure the expression of a reasonable public interest.

Mr Dunne:

The briefing paper states that a duty will be placed:

"on the Council to set and publish standards for the safe and effective practice of pharmacy".

Publishing standards is one thing but ensuring that people comply with them is a completely different issue. How will that be monitored and audited?

Dr N Morrow:

Currently, a pharmaceutical inspectorate routinely monitors the standard of premises. In many ways, the standards provide the reference points against which anybody's practice can be judged. If people come to the society about a case against them, those standards will be the reference

point by which they will be judged. As well as the inspectorate, which deals with pharmacy premises, there is a mechanism whereby people can bring a complaint to the society.

Mr Dunne:

What assurance is there for the public that pharmacists are carrying out their daily business to the required standards?

Dr N Morrow:

There are probably two ways to look at that. One way —

The Chairperson:

Norman, will you keep your answers a wee bit shorter? I am very conscious of time. Please be succinct.

Dr N Morrow:

One way is through the inspectorate, which carries out regular examinations of premises and procedures. There are standard operating procedures —

Mr Dunne:

Does the inspectorate look at procedures as well as buildings?

Dr N Morrow:

There are procedures as well. There is an opportunity for the Health and Social Care Board, as the commissioner, to look at standards and the performance it wants through contractual agreements. There are two ways to ensure the desired quality: the legal professional imperative and the contractual arrangements. It is pretty much the same in other arenas, and, in fact, some arenas do not have an inspectorate.

Mr McCarthy:

You said that all members of the new council will be appointed and that you would like grass-roots representation. Why have you been barring elected representatives, who are the people on the ground? Do you have something against elected representatives?

Dr N Morrow:

I do not think that I said "grass roots". All that I was trying to say is that the new council will be made up of seven pharmacists and seven laypeople so that there will a balance between professional and lay interests. At present, council members are elected, and the difference is that people will now be appointed. The White Paper stated that councils should be appointed rather than elected. For continuity's sake, we have made some provision outwith the legislation for some pharmacist members of the current council to be able to move over initially to the new council.

The Chairperson:

So the seven laypeople will be appointed by the Minister, unlike the education and library boards, where there is a provision for elected representatives to be part of the laypeople representation.

Mr McCarthy:

The Community Pharmacy NI (CPNI) response mentioned a couple of issues: an extension to the 14 days in which to supply information and the fitness of chemists to practise. What do you have to say about those matters?

The Chairperson:

Before Norman answers, Michaela will ask her supplementary question, and Sam will ask his question. Norman, you can wrap up and respond to those questions in one-line answers.

Ms Boyle:

Will the council of 50% laypeople and 50% professional people be voluntary or will people be paid? If yes, where will the money come from?

Mr Gardiner:

I do not have a question. I want to thank Dr Morrow for his presentation. He has a good way of going about the issue because it protects people and is in the interest of the public. I welcome those changes.

The Chairperson:

I am guillotining the session now, unless someone else wants to ask a question. There are no more questions, Norman, so you can respond.

Dr N Morrow:

I understand that there will be daily remuneration for council members.

Mr McCarthy:

I mentioned the CPNI's concerns about the 14 days in which to supply information. Its members would like 28 days.

Ms Shona Coy (Department of Health, Social Services and Public Safety):

We expect the society to impose such a timescale in which to request information in exceptional circumstances only. We expect that it will be used only in very rare circumstances. Other regulatory bodies use the 14-day timeline, but we do not expect it to be used routinely. We expect that information will come in through the usual type of investigation procedures, and the timeline would be used only if an investigation were being hampered.

Mr McCarthy:

So you are not moving from 14 days.

Ms Coy:

No.

The Chairperson:

Thank you for attending. I am sorry that I had to rush you at the end, but we have a lot of business to get through today.