Northern Ireland Assembly

Committee for Health, Social Services and Public Safety

OFFICIAL REPORT (Hansard)

Health and Social Care Bill: Legislative Consent Motion

25 January 2012

NORTHERN IRELAND ASSEMBLY

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Members present for all or part of the proceedings:
Ms Michelle Gildernew (Chairperson)
Mr Jim Wells (Deputy Chairperson)
Ms Paula Bradley
Mr Mickey Brady
Mr Gordon Dunne
Mr Mark H Durkan
Ms Pamela Lewis
Mr John McCallister
Mr Kieran McCarthy
Ms Sue Ramsey

Witnesses:

Mr Craig Allen	Department of Health, Social Services and Public Safety
Ms Shona Coy	Department of Health, Social Services and Public Safety
Dr Mike Mawhinney	Department of Health, Social Services and Public Safety
Mr Tony Wallace	Department of Health, Social Services and Public Safety

The Chairperson: I welcome Dr Mike Mawhinney, head of the medicines regulatory group in the Department; Mrs Shona Coy and Mr Tony Wallace who are also from the medicines regulatory group; and Mr Craig Allen from the legislation unit in the Department. You are very welcome, but we are intrigued as to why you need to come back to talk to us when a legislative consent motion was going ahead. Who wants to kick off?

Dr Mike Mawhinney (Department of Health, Social Services and Public Safety): Thank you. We are grateful to the Committee for hearing us today. This issue relates to a specific offence under the Medicines Act 1968. As the Chairperson is aware, some aspects of the position have changed since the briefing paper was submitted, but I will explain those as I go along.

The evidence relates to a proposed amendment to the 1968 Act, which will extend to Northern Ireland by means of a Health and Social Care Bill and will require a legislative consent motion to be debated in the Assembly. The Committee will be aware that the Health and Social Care Bill was introduced in the House of Commons in January 2011; and, in March 2011, the Assembly agreed a legislative consent motion on specific provisions of the Bill extending to Northern Ireland. It has now progressed through the House of Commons and is currently at Committee Stage in the House of Lords. There is now a

proposal to use the Bill as a vehicle to amend the Medicines Act in a matter relating to the supply of medicines.

Following the recent high-profile case of a pharmacist in GB called Elizabeth Lee, there has been concern among the pharmaceutical profession about the risk of criminalisation under the 1968 Act for making genuine dispensing errors with no aggravating features. Under the 1968 Act, an offence is committed when a medicinal product whose nature or quality is impaired in certain ways is sold or supplied against a prescription. Although that affects a range of healthcare professionals and retail sellers of medicines, the main effect is on pharmacists in their dispensing activities. That is a strict liability offence, which means that the existence of the offence does not depend on the person having a blameworthy state of mind.

The prosecuting bodies, the Medicines and Healthcare products Regulatory Agency (MHRA) in GB and we in the Department of Health, would not regard it as in the public interest to prosecute in such cases. However, the fear of prosecution is likely to result in reluctance on the part of pharmacists and others to report errors and is an associated loss of learning for the Health Service. The Government are seizing an opportunity that has arisen to amend the legislation via the Health and Social Care Bill to provide a due diligence clause, where, in the rare event of a prosecution being taken, a defendant could seek to establish that all due diligence had been exercised.

The availability of a due diligence defence is relatively common across legislative provisions, including the Consumer Protection Act 1987 and the Prescription Only Medicines (Human Use) Order 1997, which is already in a medicines-related piece of legislation and is operative here. It is in the mainstream of legal thinking and is reflected in the Law Commission's recent consultation paper 'Criminal Liability in Regulatory Contexts', where it is reported to be a fair defence. The proposed amendment would not disapply the current provisions but would permit a defendant to mount a defence where he has to establish, on the balance of probabilities, that due diligence had indeed been exercised. It therefore permits a defence while ensuring that the patient and the public are provided with continuing protection under the law.

I will now speak briefly on the timing and consultation issues, because they are important. Subsequent to the Elizabeth Lee case, there was widespread recognition that the law pertaining to dispensing errors was, indeed, in need of review. As a result, the Crown Prosecution Service and the Public Prosecution Service in Northern Ireland, with which we have worked very closely on this, agreed guidelines to ensure a consistent and appropriate response to dispensing errors here.

As a next step, consideration was given to introducing an amendment as part of the current Medicines Act review that we are undertaking. However, the powers used under that review were not an appropriate vehicle to effect those changes, so we could not do that. Consideration was given to using the then upcoming Health and Social Care Bill to effect change. However, in the interim period, Lord Clement-Jones introduced an amendment to the Bill, with the support of the Royal Pharmaceutical Society. That was withdrawn in the Lords on 19 December.

The Chairperson: What was withdrawn, the amendment or the support?

Dr Mawhinney: The amendment was withdrawn, because it was flawed; one of the reasons being that it did not extend to Northern Ireland, which would have been patently unfair to pharmacists here. That, however, opened a very small window of opportunity for us. There was an undertaking to push legislation to protect pharmacists and the public as quickly as possible, and that opportunity now exists with the Health and Social Care Bill.

By way of consultation, at the first possible opportunity, the Medicines and Healthcare products Regulatory Agency, the four UK Health Departments and the four Chief Pharmaceutical Officers discussed the proposals with the General Pharmaceutical Council (GPhC), the Royal Pharmaceutical Society (RPS), the Association of Pharmacy Technicians (APTUK), and, indeed, both wings of the Pharmaceutical Society of Northern Ireland (PSNI): the regulatory wing and the professional side. The meeting, which was held in early January this year, was very constructive, and the General Pharmaceutical Council subsequently issued a statement welcoming the Government's intention to legislate as well as the plans for a wider review of the sanctions and penalties under the Medicines

Act. A Northern Ireland National Pharmacy Association (NPA) representative and Community Pharmacy Northern Ireland (CPNI) were invited to those national discussions. The medicines regulatory group discussed those matters with officers from both those organisations and with the chairman of the professional forum of the Pharmaceutical Society of Northern Ireland.

At that time, accepting that CPNI would favour an immediate decriminalisation of the offence, all organisations were supportive of the current proposals as part of a programme of action. However, subsequent to our briefing paper, some GB representative bodies raised new concerns regarding the proposals late on Monday of this week; they were concerned about the burden of proof being placed on pharmacists if they got as far as court and that it might be an impossible defence. They were also concerned about the definition of due diligence. Those organisations have undertaken to discuss the matter further and have agreed to respond to the MHRA in a matter of days. However, in Northern Ireland, we have discussed those issues with CPNI, the PSNI regulator, the PSNI professional forum and the NPA, and we have received qualified support for the amendment from three of those organisations. The NPA will wait for a national decision on that, but it was speaking with us. They have, however, added a caveat to their agreement, namely that decriminalisation is their ultimate aim. I am happy to read out excerpts from their letters if you wish, Chairperson. There is that caveat, but they do support the amendment, and that is very important.

The MHRA remains fully committed to introducing this defence, and we believe that it is an optimal solution. It will protect pharmacists and the public and is an important step in the process. Some discussions are ongoing, particularly in GB, but support for the amendment is significant.

That is the current situation. Subject to the Committee's wish, we are content to apprise you further in person or in writing, but we seek your approval, in principle, for a legislative consent motion. The Department will be pleased to provide you with a legislative consent motion memorandum if one is required.

The Chairperson: We need the memorandum and the draft wording. I hope that they will follow this meeting.

Mr McCarthy: I am delighted to hear what you said. In your briefing paper you talk about a programme for action. May we have more detail on that and on MHRA's plans for a wider review of sanctions and penalties? What process will be pursued from now on in regard to calls for decriminalisation?

Dr Mawhinney: They are all one question, so I will answer them as one. There is a programme of action, and MHRA has undertaken to look further into the penalties and sanctions in the Medicines Act. Decriminalisation is a complex issue. It was explained in the Lords that this not only affects pharmacists; it also affects sellers of medicines and other healthcare professionals. The public needs to be protected as well, as do pharmacists. Therefore, to get it right, MHRA is keen to continue with the progress that we have made over recent years on this issue. I cannot guarantee that decriminalisation will be the final outcome; however, in a review of sanctions and penalties in the Medicines Act, section 67 will be covered and decriminalisation is certainly a possibility.

Mr McCarthy: I am glad to hear that you have had support from the different organisations.

The Chairperson: In the absence of any other burning questions, I thank Mike and his team. We are keen to see the wording of the legislative consent motion and the memorandum. If you get that to us, we will sign off on those next week.