Northern Ireland Assembly

Committee for Health, Social Services and Public Safety

OFFICIAL REPORT (Hansard)

Human Medicines Regulations 2012

20 June 2012

NORTHERN IRELAND ASSEMBLY

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Members present for all or part of the proceedings:
Ms Sue Ramsey (Chairperson)
Mr Jim Wells (Deputy Chairperson)
Ms Paula Bradley
Mr Mickey Brady
Ms Pam Brown
Mr Gordon Dunne
Ms Michelle Gildernew
Mr John McCallister
Mr Kieran McCarthy
Mr Conall McDevitt

Witness:
Mr Seamus Camplisson Department of Health, Social Services and Public Safety

The Chairperson: Seamus, you are very welcome. Will you deal with the concerns of the Belfast Health Initiative?

Mr Seamus Camplisson (Department of Health, Social Services and Public Safety): Yes, I will. I work in the health protection branch of the Department of Health, Social Services and Public Safety (DHSSPS) and have been working with colleagues in the pharmaceutical advice and services branch and with the Medicines and Healthcare products Regulatory Agency (MHRA) on the Human Medicines Regulations 2012. Members will have seen a letter to the Committee Clerk from my colleague Karen Savage, dated 18 June. Members will also have seen a letter from the Minister to the Committee, dated 23 December, which gives the background to the Human Medicines Regulations 2012 and their purposes. The primary purpose of the regulations is to consolidate existing UK medicines legislation and make it more user-friendly and less bureaucratic. The goal has been to simplify the law without changing its effect.

The regulations run to around 300 pages and include six quite minor policy changes. I will give members a flavour of the tweaks, which are concerned with issues such as the removal of statutory warnings, the review process for licensing decisions, the sale, supply and administration exemptions, the removal of a pharmacy wholesale dealing exemption, patient group directions and the optimisation of medicines use. The only other new issue in the regulations is part 10, which transposes the European pharmacovigilance directive 2010 into UK law. The only new offences are contained in part 11. There are 24 new offences, which were agreed by the Executive last month. None of the changes affects the regulation of homeopathic medicines.

The open letter to MLAs from the Belfast Health Initiative refers to section 10 of an MHRA proposal, which is presumably a reference to section 10 of the Medicines Act 1968. I will briefly explain what section 10 does. It provides for exemptions with regard to manufacturer's licences and marketing authorisations. To make a medicine, a manufacturer's licence is required, and a medicine requires a marketing authorisation before it can be placed on the market. If someone goes into a pharmacy and describes his or her symptoms, a pharmacist can make up a medicine for that person. Section 10 allows a pharmacist to make up and provide an unlicensed medicine. That must be done on the basis of an in-person consultation between a customer and a pharmacist. If I may, I will quote from section 10(4):

"Without prejudice to the preceding subsections, the restrictions imposed by sections 7 and 8 of this Act do not apply to anything which is done in a registered pharmacy by or under the supervision of a pharmacist and consists of—

(a)preparing or dispensing a medicinal product for administration to a person where the pharmacist is requested by or on behalf of that person to do so in accordance with the pharmacist's own judgment as to the treatment required, and that person is present in the pharmacy at the time of the request in pursuance of which that product is prepared or dispensed".

The purpose of section 10 is to allow a pharmacist to use his or her professional skills and judgement to prepare something for a customer or patient.

The MHRA ran a public consultation on the consolidation project between October 2011 and January 2012 and received 103 responses from the homeopathic medicines sector. Some of the responses asked for the section 10 exemption to be widened, so that, for example, unlicensed homeopathic medicines could be bought and sold online or over the phone without a consultation in person. The MHRA considered the representations and concluded that it was not possible to consolidate sections 10 and 15 of the Act safely without compromising their legal effect. In other words, section 10 of the Medicines Act 1968 will remain on the statute book unaltered by the regulations.

The consolidation project, of which the Human Medicines Regulations 2012 are the product, is not intended to change either the current regulatory status of regulations that govern homeopathic medicinal products or their sale or supply. There is a regulatory framework for homeopathic medicines with three categories of permits for products. Those are product licences of right, which were granted to products in use before the 1968 Act; certificates of registration under the 1992 simplified registration scheme; and authorisations granted under the national rules scheme 2006. In effect, that amounts to a licensing system for homeopathic remedies.

In summary, the six policy changes to which the regulations will give effect are minor adjustments, and it makes sense to use this opportunity to update and improve the law on those details. Similarly, the regulations were deemed to be a suitable vehicle for transposing the pharmacovigilance directive into UK law. To widen the exemption in section 10(4) of the Medicines Act 1968 would be a significant departure from the existing legislation. That should not be done without a thorough consideration of the possible consequences of any proposed changes and a full consultation on any options that might be considered. That is a matter for further discussion and correspondence, which, in the first instance, would be between the homeopathic medicines sector and the MHRA, and beyond that with the pharmaceutical sector and the wider healthcare sector.

The Chairperson: Thank you for that. Members received copies of the Belfast Health Initiative letter that refers to face-to-face contact with pharmacists. However, the letter goes on to state that there are only five homeopathic pharmacies in the UK and none in Northern Ireland. How does the fact that no homeopathic pharmacy operates here make it easier for somebody to have a face-to-face consultation with a pharmacist?

Mr Camplisson: I have no knowledge of how homeopathic medicines are currently bought and sold, but there will be no change to whatever happens now. The letter states:

"the enforcement of section 10 in its current form will have serious consequences".

Draw your own conclusions about the current enforcement of section 10. If —

The Chairperson: Are you saying that there will be no change to how it currently sits?

Mr Camplisson: There will be no change at all that will affect homeopathic medicines.

The Chairperson: I suggest that we park the issue and tell the Belfast Health Initiative that that is what we are being told. Sorry, I have just been advised by the Committee Clerk that we cannot do that because the regulations need to be signed.

Mr McDevitt: I hear what Seamus says, and this is a very technical argument on which I do not feel awfully confident to challenge him, to be honest. However, if you contend, as clearly as you appear to, that this has no material impact on the current situation for people who avail themselves of, or provide, homeopathic treatment, would it be appropriate and will you provide a definitive comfort letter to that effect?

The Chairperson: Sorry, will you say that again?

Mr McDevitt: I asked Seamus whether he would be happy to provide a definitive comfort letter to that effect. Perhaps we could secure that. If an issue then arose, it would be technical and may be for the courts rather than the Assembly.

Mr Camplisson: This is Westminster legislation; it is a statutory instrument and part of the co-signatory arrangements that arise from the Medicines Act 1968, so the regulations will be co-signed by Minister Poots and the Secretary of State for Health. We expect that to happen next week.

The Chairperson: That is our dilemma, but if we get that comfort letter as quickly as possible —

Mr McDevitt: In that case, if there is a timescale, the Committee Clerk may want to —

The Committee Clerk: As far as I am aware, the Committee does not formally approve a statutory instrument; it does not go through the House like a normal statutory rule, which is subject to negative resolution.

Mr McDevitt: In that case, it would serve natural justice for Seamus to provide the Belfast Health Initiative with a letter in advance of the signing off.

Mr Camplisson: I would be happy to.

The Chairperson: Yes, and copy us into it.

Mr Camplisson: By all means, yes.

The Chairperson: Are members agreed?

Ms Gildernew: I am sure that many of us, the Queen and many Popes have used homeopathy for different things. The Belfast Health Initiative was concerned enough to write to us, so that letter, and perhaps further clarification, is needed. I hope that you will make yourself available to the group if it needs to hear that explanation, because its members are very concerned, as was I when read their letter.

The Chairperson: Are members agreed?

Members indicated assent.

The Chairperson: Thanks very much for coming here at short notice, Seamus.