



Northern Ireland
Assembly

**COMMITTEE FOR
HEALTH, SOCIAL SERVICES AND
PUBLIC SAFETY**

**OFFICIAL REPORT
(Hansard)**

**The Health and Personal Social Services
(General Medical Services Contracts)
(Prescription of Drugs Etc) (Amendment)
Regulations (Northern Ireland) 2011**

21 September 2011

NORTHERN IRELAND ASSEMBLY

**COMMITTEE FOR
HEALTH, SOCIAL SERVICES
AND PUBLIC SAFETY**

**The Health and Personal Social Services (General Medical
Services Contracts) (Prescription of Drugs Etc) (Amendment)
Regulations (Northern Ireland) 2011**

21 September 2011

Members present for all or part of the proceedings:

Ms Michelle Gildernew (Chairperson)
Mr Jim Wells (Deputy Chairperson)
Ms Michaela Boyle
Ms Paula Bradley
Mr Mickey Brady
Mr Gordon Dunne
Mrs Pam Lewis
Mr John McCallister
Mr Kieran McCarthy

Witnesses:

Ms Margaret Glass) Department of Health, Social Services and Public Safety
Ms Cathy Harrison)

The Chairperson:

I welcome Cathy Harrison, a principal pharmaceutical officer in the Department's pharmaceutical directorate, and Margaret Glass, from its pharmacy and prescribing branch. You are very welcome. The evidence session will follow the same format as the previous one: please give us a short presentation on the purpose of the legislation, and I will then take questions from Members. Thanks a million. Tá fáilte romhat.

Ms Margaret Glass (Department of Health, Social Services and Public Safety):

Thank you. The purpose of our being here today is to discuss the SL1 letter that you have already received. Essentially, the proposed statutory rule is to allow us to amend the Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) Regulations (Northern Ireland) 2004. As you said yourself, it has a similarly snappy title, which I will not bother repeating.

The legislation was made in 2004, and there are two schedules to it. Schedule 1 is a very long list of drugs and medicines that doctors cannot prescribe under their general medical services (GMS) contract. Schedule 2, which is the one that we are interested in, is shorter but lists drugs that, under certain circumstances, can be prescribed. It is schedule 2 that we are looking to amend.

At the moment, schedule 2 allows two antiviral drugs, Tamiflu and Relenza. I will let Cathy give you their technical names, because I am afraid that I cannot pronounce them. The schedule allows for those drugs to be prescribed on certain occasions to certain groups — the occasion being when the Chief Medical Officer says that influenza is circulating in the community. When that happens, two groups can receive those drugs, and they fall into two categories. The first category is those at clinical risk; for example, someone who is diabetic or has heart disease. The second category includes the pregnant and the over-65s. The legislation proposes to extend the list to people who are under 65 years old — everyone over 65 is covered regardless — but who would be at medical risk if they were to get influenza. Therefore, it is really widening the categories of who can receive those drugs.

If the legislation is not amended, it will put doctors who would want to prescribe those drugs outside the terms and conditions of their contract. Basically, we are updating the list to tidy up that situation. We consulted on the matter, and the Committee was advised in advance of that consultation in May. It was a targeted consultation, but we had it publicly on our website. We got five responses, and there is a consultation report at annex A of the SL1. Basically, everyone is in favour of us updating the list.

In addition, because we have had a bit of time, we had to amend the legislation in 2009 and in 2010. That was done quickly, because of the situation. We have since had more time to consult on amending the list, so we took the opportunity to have a close look at the legislation. As with

everything, when you take a close look, you find typing mistakes and some things in the wrong order. There are things that no longer need to be there, so we are also using this as an opportunity to include a new schedule to tidy up those little anomalies.

Cathy will now cover the background to this matter, and how we communicate with GPs about the change.

Mr McCarthy:

Will she use the technical names for the drugs that you cannot pronounce? *[Laughter]* I could not do it, either.

Ms Cathy Harrison (Department of Health, Social Services and Public Safety):

The medicines involved in this change are the antiviral drugs oseltamivir and zanamivir. Oseltamivir is manufactured by Roche and is marketed in the UK as Tamiflu. That is available as capsules and suspension for oral use. Zanamivir is manufactured by GlaxoSmithKline and is marketed by Relenza, which is in a dry power for inhalation. Tamiflu and Relenza are licensed for the treatment and prevention of the symptoms of flu. The prescribing of those medicines, as Margaret said, is restricted to the weeks of the year when the levels of the seasonal flu virus circulating in the community are highest. That is to prevent overuse of those medicines and to reduce the risk of resistance to them developing.

Until now, only the patient groups identified in schedule 2 to the 2004 regulations have been able to be prescribed those antivirals by GPs under the terms of their contract. The change that we are proposing will enable GPs to prescribe antivirals to any patient whom they consider to be at risk of developing medical complications from flu. An example of a person who would benefit from the changes would be someone under the age of 65 with no underlying health problems, who would otherwise be considered healthy, and who presents at their GP with worrying and worsening flu symptoms. There is evidence of that happening during the 2009 swine flu outbreak and last year's normal seasonal flu period.

The person presenting to the GP may have a severe cough, difficulty breathing, persistent or recurring fever and, sometimes, bloody sputum. In that situation, pneumonia would be the GP's concern, because that is the most serious complication of flu. At that point, the use of antivirals may avoid the condition escalating to pneumonia developing and the potential admission to

hospital that that would cause.

In the absence of changes to schedule 2, GPs might, in the past, have referred such patients to hospital, because there is no restriction on the prescribing or supply of medicines, including antivirals, in hospitals.

Prescriptions for the antiviral medicines will be allowed to be dispensed at community pharmacies as normal, and they will source their stock through the usual wholesalers. The annual number and cost of prescriptions for antivirals is low. For example, in 2010, around 1,400 were issued in primary care, at a cost of around £11,000. Therefore, it is not anticipated that increasing the availability of antivirals will have a significant impact on the number of patients seeking care from their GP. Such people would already be going to their GP; it just helps the GP manage their care more effectively and quicker.

We believe that any impact is more likely to be a consequence of the type of flu virus that is circulating than as a result of any change to the legislation. If more people are suffering from flu, that will result in higher numbers seeking help. Within the next few weeks, the Department will issue a chief professionals' letter explaining the changes to all GPs and the wider health and social care sector.

I hope that that was a useful update for the Committee. We are happy to take questions or clarify any of those points.

The Chairperson:

That was helpful and useful.

Mr McCarthy:

To be brief, what is the score with the use of generic medicines? We are all trying to keep down the cost.

Ms Harrison:

The relevant medicines prescribed would be generic — as oseltamivir or zanamivir — but they are still under patent, so the brand names to which we referred are the only ones available at the moment. One of the products — Tamiflu — is due to come off patent in the next few years.

Mr Wells:

Given the figures that you quoted, they are not that dear anyhow.

Ms Harrison:

No, they are not. The different preparations vary, but they cost £10 to £14 a pack.

Ms Boyle:

I suppose that this is part of the prevention that we talked about earlier. Doctors need to refer and to have the flexibility to prescribe Tamiflu. We are getting at those target groups that are not at high risk, so the measures will keep people out of hospital and are part of being preventative. You cannot argue with that.

Ms P Bradley:

I forget what I was going to say. My mind is blank. Move on to somebody else. Sorry; it is my age.

The Chairperson:

I welcome the proposed change as well. As is stated in your paper, it may add a small cost to primary care, but it will save an awful lot in secondary care. Anything that helps us to manage the flu outbreaks is to be welcomed. Is that it, Paula? Did I ask your question?

Ms P Bradley:

It was related to that, yes.

The Chairperson:

It sounds as though we are fairly content to progress. Paula, do you want to come in on your point now?

Ms P Bradley:

Yes. People were hospitalised with the virus. In which age groups were those people? They were not all over 65 or pregnant. There was an age group there that —

Ms Harrison:

— were otherwise healthy adults, yes.

Ms P Bradley:

Very healthy people ended up in hospital. It was not the over-65s or pregnant women who did not get but that age group.

The Chairperson:

Hopefully, a certain amount of information has been extrapolated by now from last year's event. In my Department in the previous mandate, the Department of Agriculture and Rural Development (DARD), I dealt with disease issues, so I had a lot of sympathy for then Minister McGimpsey in how he tried to handle the swine flu issue. I had a certain understanding of where he was coming from.

I was concerned about the impact on pregnant women, but I was also concerned about the impact on young people with special needs. Do we have more evidence on how we can help that group of people protect themselves and on how those families affected can protect their precious children? There were heartbreaking deaths last year across these islands of people who were very vulnerable.

Ms Harrison:

The first line of defence is the seasonal flu vaccination programme, in which pregnant women are now included. Many children with special needs will also have underlying conditions, which means that they will fall into the risk groups and qualify for a vaccine. The regulations will pick up anyone who falls outside that by giving access to antivirals.

The Chairperson:

At this stage, are recent findings in the South about narcolepsy still merely assumptions? Is evidence developing of a link? To explain properly, I am not saying that we should not do this, for I would still rather have a child who has a condition as a result of receiving potentially life-saving medication. There are times when risk factors must be weighed up, but I understand that some link was established between narcolepsy and the swine flu jab. Is that accurate?

Ms Harrison:

The swine flu injection involved was used in pandemics. Those cases of adverse events involving narcolepsy are being monitored centrally in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA).

Mr Wells:

It is worth saying that, when I was Chairperson last year, one of the issues that we dealt with was the large number of expectant mothers who had not been vaccinated. Somebody quoted that something like 22 million vaccinations had been given out without there being a single example of any side effects. Therefore, it was madness for ladies who were expecting or expecting to expect not to be vaccinated. Having been through two winters of it, I would like to think that very few people are left in that position. One reason that last year's outbreak was so much less severe than the previous year was that so many people had been vaccinated, so there were fewer potential flu targets. I like to think that the message will go out from the Committee that any woman in that position should have the vaccination immediately.

The Chairperson:

Yes. OK, I think that that is it. You got the easy touch today. Thanks a million for coming and explaining that to us.