Northern Ireland Assembly

Committee for Health

OFFICIAL REPORT (Hansard)

Human Medicines Regulations and Misuse of Drugs Regulations: Department of Health

29 February 2024

NORTHERN IRELAND ASSEMBLY

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Members present for all or part of the proceedings:
Ms Liz Kimmins (Chairperson)
Mr Danny Donnelly (Deputy Chairperson)
Mr Alan Chambers
Mrs Linda Dillon
Mrs Diane Dodds
Miss Órlaithí Flynn
Miss Nuala McAllister
Mr Colin McGrath
Mr Alan Robinson

Witnesses:

Mr Martin Coleman	Department of Health
Mr Chris Garland	Department of Health
Mr Gary Maxwell	Department of Health
Ms Karen Simpson	Department of Health
Mr Canice Ward	Department of Health

The Chairperson (Ms Kimmins): In attendance today are Canice Ward, head of the medicines regulatory group; Chris Garland, senior principal pharmaceutical officer; Karen Simpson, head of the medicines legislation unit; Martin Coleman, head of the vaccination and screening policy branch; and Gary Maxwell, head of health development policy.

Ms Karen Simpson (Department of Health): We start with the Human Medicines (Amendments Relating to Coronavirus and Influenza) Regulations (Northern Ireland) 2024. Thank you for the opportunity to brief the Health Committee today. I will give an opening statement on the SL1 that relates to extending temporary provisions in the human medicines regulations that were introduced in 2020 to support the COVID-19 and extended flu vaccination programmes. This will be a summary overview, as full details have been provided to the Committee in a written report. I will then pass to my colleague Canice Ward, head of the medicines regulatory group, who will give an opening statement on the misuse of drugs regulations.

The human medicines regulations or "HMRs" govern the arrangements for the licensing, manufacture, wholesale dealing and sale or supply of medicines for human use. The Committee has been informed of the current proposal to amend regulations 3A, 19 and 247A of the HMRs in order to support the ongoing delivery of COVID-19 and flu vaccinations in Northern Ireland.

Regulation 3A enables trained healthcare professionals or staff under the supervision of healthcare professionals to conduct the final stage of assembly, preparation and labelling of COVID-19 vaccines without additional marketing authorisations or manufacturers' licences being required. That is important because, as COVID-19 vaccinations are not available as prefilled syringes, each vaccine that is administered continues to require final-stage preparation before administration to the patient.

Regulation 19 allows COVID-19 and influenza vaccines to be moved between vaccine providers without the need for a wholesale dealer's licence, and regulation 247A enables the use of an extended workforce that is legally and safely able to administer a COVID-19 or influenza vaccine without the input of a prescriber, using an approved protocol. Regulations 3A and 19 have sunset provisions, which means that they will cease to have effect in Northern Ireland on 1 April 2024 unless they are extended from 31 March 2024. Regulation 247A is permitted for use only during a pandemic.

It is acknowledged that a permanent solution needs to be put in place, and we are working with our counterparts in England, Scotland and Wales to undertake consideration of longer-term mechanisms that can be deployed. In the short term, however, at a time when COVID-19 continues to be prevalent, there is an ongoing need to support the continued safe and effective supply, distribution and administration of COVID-19 and flu vaccines by maintaining the three provisions until April 2026.

With regard to Assembly procedures, the HMRs are made under powers in the Medicines and Medical Devices Act 2021. The Department of Health in Northern Ireland is named in that Act as the appropriate authority in recognition of the fact that the regulation of medicines is a matter that is devolved to Northern Ireland. The Department of Health and Social Care (DHSC) in England laid a statutory instrument on 10 January 2024 to amend regulations 3A, 19 and 247A by extending them to 1 April 2026, but that will apply only in Great Britain and will come into operation on 31 March 2024. We wish to lay an equivalent statutory rule that will come into place at the same time in order that there is no detrimental impact on the spring COVID-19 booster programme, which is to commence in April 2024. We would welcome the Committee's support on that statutory rule.

The regulations will be subject to the draft affirmative procedure and will be laid before and approved by resolution of the Northern Ireland Assembly. Therefore, an Assembly debate on the regulations will be required, and we have provisionally scheduled that for 19 March.

I will now pass to Canice, who will discuss the misuse of drugs regulations.

The Chairperson (Ms Kimmins): Thank you, Karen.

Mr Canice Ward (Department of Health): Do you want me to move on to the brief on the misuse of drugs regulations, or would you like to ask questions on the first set?

The Chairperson (Ms Kimmins): Are there any questions, or do you want to go ahead?

Miss McAllister: We will take them all.

The Chairperson (Ms Kimmins): We are happy to go ahead.

Mr Ward: Thank you. Thanks for the opportunity to brief the Committee on the two SL1s relating to the control of a number of dangerous drugs under the misuse of drugs legislation in Northern Ireland.

The drugs under consideration include 15 synthetic opioids, including nitazenes; three stimulants — diphenidine, ephenidine and methoxyphenidine; a synthetic cannabinoid receptor agonist called cumyl-PeGaClone; and a benzodiazepine called remimazolam. The proposal is to schedule those 20 substances under the Misuse of Drugs Regulations (Northern Ireland) 2002 and to designate them under the Misuse of Drugs (Designation) (Amendment) Order (Northern Ireland) 2001, with the exception of the benzodiazepine, remimazolam.

The Department provided a briefing to the Committee before the meeting, but I thought that it might be useful to give a bit of background on how those drugs become controlled across the UK. The UK-wide Misuse of Drugs Act 1971 places controls on drugs that are considered dangerous or otherwise harmful, hence the name "controlled drugs". Under the Misuse of Drugs Act, those drugs are classified as class A, B and C, which, I am sure, you are aware of, according to their abuse potential, harmfulness or dangerousness when they are misused. The most dangerous drugs are placed in

class A. The classification under the Act provides a framework for criminal or penal purposes, and the Act is a reserved matter, with any changes being taken through the UK Parliament.

Some drugs under the Misuse of Drugs Act are beneficial or have a therapeutic use. That legitimate use of controlled drugs is a devolved matter and is enabled through the Misuse of Drugs Regulations (Northern Ireland) 2002, which we hope to amend today. GB has separate but, essentially, analogous regulations.

The Misuse of Drugs Regulations (Northern Ireland) 2002 define the class of persons who may possess, supply or produce controlled drugs when acting in their capacity as a professional. For example, a pharmacist, doctor or nurse can supply or prescribe diazepam or morphine, which are controlled drugs, when acting in a professional capacity. That is enabled through the misuse of drugs regulations. In the regulations, the controlled drugs are placed in five schedules according to their harmfulness or use in a medicinal setting. Schedule 1 has the most tightly controlled drugs, which have no recognised medical use, and schedule 5 includes those with lesser controls.

Under the Misuse of Drugs Act, the Advisory Council on the Misuse of Drugs (ACMD) was set up, which advises the UK and NI Governments on dangerous drugs or drugs that are of concern across the UK. Among other things, the ACMD makes recommendations on how tightly the drugs should be controlled, first, under the Act, and, secondly, under the regulations to allow or disallow lawful use. Following a recommendation and advice from the Advisory Council the UK Government recently put forward an amending Order to the Misuse of Drugs Act that will control the aforementioned 20 dangerous drugs, due to the emergence of harm across the UK and internationally.

The drugs pose serious acute health risks, and there have been a number of involvements in fatal or near-fatal overdoses, including in Northern Ireland. In tandem with recommendations to put controls on the drugs under the Act, the ACMD made recommendations about their controls under the devolved misuse of drugs regulations to further restrict their use in any legitimate settings. Consequently, an amendment to the Misuse of Drugs Regulations (Northern Ireland) 2002 is required in order to implement the ACMD advice in Northern Ireland. Essentially, the amendment that we hope to make will replicate amendments taken forward by the Home Office in GB across England, Scotland and Wales. It will place the drugs in schedule 1 to the misuse of drugs regulations, meaning that there can be no use of them across the healthcare setting because there is no recognised use of them.

In tandem with that, the ACMD recommended that the substances be designated under the Act, because they have no legitimate use. As a result, we hope to make an amendment to the Misuse of Drugs (Designation) Order (Northern Ireland) 2001, which will mean that they will not have any recognised use and that no person can be in possession of them or use them for any reason except under licence from the Department. For example, forensic scientists or people wanting to test the drugs can do so if they are licensed to do so. Similar amendments are being made to the equivalent designation Orders in GB.

For the next step, subject to the Committee's agreement, we propose to lay the statutory rules as soon as possible so that they come into operation on 20 March, which would tie in with the controls under the Misuse of Drugs Act and equivalent legislation across GB. A letter will be issued to key stakeholders in Northern Ireland to make them aware of any changes that may come into effect in relation to the drugs.

Thank you for your time. I am happy to answer any questions.

The Chairperson (Ms Kimmins): Thank you. Do members have any questions?

Mr Donnelly: From my reading of the briefing paper, they are synthetic drugs that are cheaply produced, mass-produced and brought into the drug market in order to bring on the same effects for which people take narcotics. Drugs such as nitazenes in particular are quite a health hazard, in that people who inject opioids, particularly heroin users, are finding nitazenes in the heroin supply — is that correct? — and that is leading to increased deaths among heroin users. Have nitazenes been a factor in deaths in Northern Ireland among the injecting drug-use population?

Mr Ward: We are acutely aware of the numbers. I cannot give you the numbers, but nitazenes certainly have been detected in Northern Ireland. To give you a bit of background on the cause, the normal heroin trade and supply comes from Afghanistan, but the Taliban have stopped it somewhat. The nitazenes are filling the gap. They are extremely potent — up to 500 times more potent than

heroin — so you need only a very small amount to get an equivalent dose. Hence, there have been some fatal overdoses. Nitazenes have been detected, but I do not have the numbers.

Mr Donnelly: From what I understand, they are more resistant to naloxone as well.

Mr Ward: I think that that is just to do with the potency, really.

Mr Donnelly: Can drug supplies be tested for nitazenes? Can a drug user test his supply for that?

Mr Ward: I do not think that a drug user could do it. There are labs — forensic science or commercial labs — that could test for nitazenes, but I do not think that an individual user or misuser could test for that.

Mr Donnelly: Is it something that they could do in an overdose prevention centre?

Mr Ward: It could be done if we had an overdose prevention centre and there were adequate lab facilities there to detect nitazenes. They are present in minuscule amounts to give the same effect, as you will appreciate, but they are detectable, just not at an individual level. It would take lab equipment to do that.

Mr Donnelly: So a user could have his drug supply tested, which could detect those nitazenes and show up whether it would be a dangerous dose potentially?

Mr Ward: In theory, yes.

Mr Donnelly: No problem. Thank you very much.

Mrs Dodds: I have a question on the movement of COVID-related medicines and vaccines. Why do we need to extend that to 2026, given that we have now been using them for a considerable period? Can we not adopt more conventional methods of using them? I do not know the answer; I just want to know why we need to extend unusual methods of dealing with drugs for COVID vaccines. Why do we need to do that, given that we have been doing it for some time?

I have a secondary question. It almost begs the question of whether we will continue to give COVID vaccines for a considerable time into the future. Does anybody have any comment to make on that?

Mr Chris Garland (Department of Health): Yes. On the first question, you are absolutely right: we are progressing through the pandemic. However, in large part, the deployment of COVID vaccines is determined by the physical characteristics of the vaccines. As we outlined in the briefing, COVID vaccines are not currently available as prefilled syringes; they are available as multi-dose preparations, multi-dose vials, which require a manipulation at the point of administration to the patient. They are also, in large part, distributed in the frozen state through the supply chain. The flexibilities that we hope to extend will help us to continue to support the deployment as we, hopefully, transition towards more user-friendly prefilled syringes that are distributed at fridge temperatures, much more like other vaccines.

As regards the movement of vaccines between vaccine providers, the normal safeguards are that a wholesale dealer's licence is required for the movement of vaccines, as with any other medicine, between one provider and another. Those provisions during the programme have been useful in that they have allowed movement of vaccine under controlled health service conditions in circumstances to avoid excess wastage of vaccine. That has had significant benefits in helping us to ensure that we make the best use of the vaccine availability that we have. As I said, we hope for a further time-bound extension while we work with our colleagues across the UK in the Department of Health and Social Care and the other Administrations on a longer-term solution.

Mrs Dodds: So you are saying that you want an interim solution of two years in order to regularise what you are doing and bring it more into line with how you might expect other vaccines, such as the flu vaccine, to be used. I suppose that the technology has to progress in order to do that.

Mr Garland: Yes. The vaccines that we use for the COVID-19 programme are procured on a UK-wide basis that is led by our colleagues in the Department of Health and Social Care. They speak to

suppliers all the time. We expect that there will be advances in formulations as we progress and that we will move more towards that business-as-usual-type approach that we hope to see. We hope that that time-bound extension will allow us to continue to deliver COVID vaccination programmes as they currently are while we work on a longer-term solution.

Mr Martin Coleman (Department of Health): Your last question was about the longer-term future for COVID vaccinations. We are guided by the Joint Committee on Vaccination and Immunisation (JCVI), which guides all four UK Departments on vaccination strategy, including on who should be vaccinated and when. As things stand, there will be a spring booster for certain categories. Those are people aged 75 and over, care home residents and the immunosuppressed. It is likely that there will be a programme again in the autumn at the same time as the flu programme in 2024. Beyond that, it is impossible to say. More than likely, there will be a programme in the future. We cannot say at this stage that there will definitely be a programme in 2025 and 2026, but the likelihood is that there will be some sort of COVID programme. It may be more targeted in that it may be directed more at the over-75s or whatever, but it probably will continue for the foreseeable future.

The Chairperson (Ms Kimmins): Thank you. That was very helpful. Thanks for your time.