



Northern Ireland
Assembly

Committee for Health

OFFICIAL REPORT (Hansard)

SL1 Human Medicines (Provisions relating to Registered Dental Hygienists, Registered Dental Therapists and Registered Pharmacy Technicians) (Amendment) Regulations 2024 and SL1 Human Medicines (Amendment Relating to Original Pack Dispensing) (Northern Ireland) 2024: Department of Health

2 May 2024

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SL1 Human Medicines (Provisions relating to Registered Dental Hygienists, Registered Dental Therapists and Registered Pharmacy Technicians) (Amendment) Regulations 2024 and SL1 Human Medicines (Amendment Relating to Original Pack Dispensing) (Northern Ireland) 2024: Department of Health

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Members present for all or part of the proceedings:

Ms Liz Kimmins (Chairperson)
Mr Danny Donnelly (Deputy Chairperson)
Mrs Linda Dillon
Mrs Diane Dodds
Miss Órlaithí Flynn
Mr Colin McGrath
Mr Alan Robinson

Witnesses:

Mr Chris Garland	Department of Health
Ms Fiona Kirkpatrick	Department of Health
Ms Caroline Lappin	Department of Health
Ms Karen Simpson	Department of Health

The Chairperson (Ms Kimmins): Thank you for coming to the Committee today. In attendance from the Department of Health we have Caroline Lappin, the Chief Dental Officer (CDO); Chris Garland, senior principal pharmaceutical officer; Fiona Kirkpatrick, senior principal pharmaceutical officer; and Karen Simpson, head of the medicines legislation unit. You are all very welcome. We have about 20 minutes for the session. I therefore invite you to make your opening remarks.

Ms Karen Simpson (Department of Health): You have two SL1s in front of you. I will take them together, if that is OK.

The Chairperson (Ms Kimmins): That is perfect.

Ms Simpson: Thank you for the opportunity to brief the Health Committee today on two SL1s that make amendments to the Human Medicines Regulations 2012, or, as abbreviated, the HMRs. The HMRs govern the arrangements for the licensing, manufacturing, wholesale dealing and sale or supply of medicines for human use. My colleagues, as professional leads, can assist in further clarifying the proposals.

The first SL1, the Human Medicines (Provisions relating to Registered Dental Hygienists, Registered Dental Therapists and Registered Pharmacy Technicians) (Amendment) Regulations 2024, proposes to allow dental hygienists and dental therapists to supply and administer specified prescription-only

medicines, as well as pharmacy or general sales list medicines in the practitioner's scope of practice, under exemption, without the use of a patient-specific direction (PSD) or a patient group direction (PGD) or without obtaining a prescription. Only dental hygienists and dental therapists who have successfully completed their education in the use of exemptions will be able to supply and administer medicines to their patients.

Dental hygienists and dental therapists using exemptions must be able to show their employer and the General Dental Council (GDC) that they are up to date by undertaking appropriate continuing professional development (CPD) and by demonstrating that they continue to practise safely and effectively. The use of exemptions will support dental hygienists and dental therapists in providing the right care to patients without unnecessary delays, as well as adding capacity to dental care teams.

The second proposal in the first SL1 will enable registered pharmacy technicians across England, Wales and Scotland to supply and administer medicines using patient group directions in any setting, including the health service and the independent and voluntary sectors. A patient group direction is a written instruction that allows healthcare professionals specified in the HMRs to supply and/or administer medicine directly to a group of patients with an identified clinical condition. The proposal will enable registered pharmacy technicians to administer specified medicines under an appropriate PGD without requiring the intervention of trained prescribers. The PGD itself provides a clear scope of practice, with specific education and governance requirements, as defined by appropriate clinical governance assurance processes. The proposals, in their entirety, share the same aim, which is for patients to receive the treatment that they need faster than they would should they need to wait for another appointment with an additional healthcare professional. Ultimately, that gives patients access to a wider range of services delivered by healthcare professionals, with the right level of skills, at the right time, thus supporting better patient healthcare outcomes and reducing the need for appointments in other parts of the healthcare system.

The proposed amendment to the HMRs for pharmacy technicians will not apply immediately in Northern Ireland, as pharmacy technicians are not currently a regulated profession here. When the role of a pharmacy technician becomes a registered healthcare profession in Northern Ireland, a further amendment to the HMRs may be made so that they can use PGDs. Work is ongoing in the Department to progress the registration and regulation of pharmacy technicians. It will require necessary amendments to primary legislation, namely the Pharmacy (Northern Ireland) Order 1976. A project management structure has been put in place to take forward that work, including the establishment of a pharmacy technician regulation and development oversight board to develop policy and take forward the necessary legislative changes.

I turn now to the second SL1 on the Committee's agenda, which is the Human Medicines (Amendment Relating to Original Pack Dispensing) Regulations (Northern Ireland) 2024. The statutory rule (SR) creates a specific requirement for medicines containing all forms of valproate always to be dispensed in their original manufacturer's packaging to ensure that girls and women receive warnings about the risk of taking such medicines when pregnant. The manufacturer's original packaging includes specific warnings and pictograms on the labelling, which is unique, including a patient card, along with a statutory patient information leaflet and an additional patient booklet that highlight the risks of taking the medicine while pregnant. Valproate-containing medicines are used to treat epilepsy and bipolar disorder. There are known risks associated with valproate-containing medicines, including significant risks to children of mothers who took valproate-containing medicine during pregnancy. Exposure of an unborn baby to valproate during pregnancy is associated with a high risk of congenital malformations and neurodevelopmental disorders, which may lead to permanent disability.

The aim of amendments to require manufacturers' original full-pack dispensing of valproate-containing medicines is to decrease further the number of babies who are exposed to valproate in pregnancy. Pharmacists, however, will be able to make an exception for whole-pack dispensing of medicines containing valproate on an individual patient basis where a risk assessment is in place that refers to the need for different packaging and where processes are in place to ensure the supply of patient information leaflets.

The SR will introduce original pack dispensing to allow pharmacists in Northern Ireland the flexibility to dispense up to 10% more or 10% less of a medicine than the quantity prescribed if it means that pharmacists can dispense the medicine in its original manufacturer's packaging. That will support increased patient safety by improving patient access to safety information that is included in a medicine's original packaging. The provisions will also help community pharmacies streamline how they manage workload by enabling greater use of automation within the dispensing process and will

release capacity in pharmacy teams to undertake patient-centred services that meet population health needs and support Health and Social Care (HSC) transformation.

Regarding Assembly procedures, the HMRs are made under powers in the Medicines and Medical Devices Act 2021. In the Act, the Department of Health in Northern Ireland is named as the "appropriate authority", in recognition of the fact that the regulation of medicines is a matter devolved to Northern Ireland. Both sets of regulations will be subject to the draft affirmative resolution procedure and will be laid in, and approved by a resolution of, the Assembly. An Assembly debate on each of the two sets of regulations will therefore be required.

The Human Medicines (Provisions relating to Registered Dental Hygienists, Registered Dental Therapists and Registered Pharmacy Technicians) (Amendment) Regulations 2024 is a joint statutory instrument (SI) with the Department of Health and Social Care (DHSC) in England, and it was laid for debate and approval in Parliament on 29 April.

The Human Medicines (Amendment Relating to Original Pack Dispensing) Regulations (Northern Ireland) 2024 is a Northern Ireland statutory rule, as those amendments have already been made by Parliament and came into force in GB only on 11 October 2023, given that there was no sitting Northern Ireland Assembly at the time.

If, following consideration of the SL1s on the policy intent of the amendments, the Health Committee is content, the Department will seek to lay the legislation next week — the week commencing 6 May — and provisionally schedule the necessary Assembly debates for 3 June 2024 in order to allow the Committee the opportunity for further consideration of the legislation alongside the views of the Examiner of Statutory Rules (ESR).

I am happy to take questions.

The Chairperson (Ms Kimmins): Thank you, Karen. My questions are mainly on the first SL1. The number of people who responded who agreed with it is high. Do we have any understanding of why those who disagreed with it did so? Moreover, what medications will dental hygienists and pharmacy technicians be allowed to administer?

Ms Simpson: The reason that people disagreed with the SL1 in the consultation responses was mainly to do with its making sure that proper training was in place and that governance arrangements were assured. For dental hygienists, there were mentions of annotation on the register. The feedback received was that the General Dental Council, as the regulator, would provide that regulation and assurance and ensure that dental hygienists had completed their professional training. Caroline, do you want to answer the question on medicines?

Ms Caroline Lappin (Department of Health): Yes. Northern Ireland was involved, along with the rest of the UK, in determining the list of medicines that would be administered. There is a specific list of medicines that are administered and then supplied. The supply list is really only a list of things that patients will take at home, such as a high-dose fluoride toothpaste, which is already prescribable, and a medication called nystatin.

The administering list is for things that are already used every day in the work of a dental hygienist or dental therapist in the practice. That list has been consulted on around the UK and kept very tight so that it is specific to the work that falls within the scope of a dental hygienist or a dental therapist in the practice.

The Chairperson (Ms Kimmins): OK. Thank you. That is very helpful. Danny, did you want to come in?

Mr Donnelly: Did you say "nystatin"? Nystatin is used to treat angina.

Ms Lappin: Nystatin suspension is used for the treatment of fungal conditions of the mouth.

Mr Donnelly: OK.

Ms Lappin: *[Inaudible.]*

Mr Donnelly: Very good.

Mrs Dodds: When we are talking about those who work in pharmacies, the fact is that many of them are not registered and would therefore need to receive significant training. I spent this morning talking to people from pharmacies. Pharmacies are experiencing significant financial difficulties at the moment. Would any such training be provided by the Department of Health, or would pharmacies have to organise that training? How does that work? Is it right that that would then mean that some pharmacies would have that facility and some would not?

Ms Simpson: We do not have registered pharmacy technicians in Northern Ireland at the moment. If they were in community pharmacies, they would go through a qualification process. Do you want to say something about that, Fiona?

Ms Fiona Kirkpatrick (Department of Health): Yes. First, this is enabling legislation for PGDs, so it will be useful and can be applied where there is clear patient benefit, depending on the circumstance. When pharmacy technicians become a registered workforce in Northern Ireland, as part of the pharmacy technician regulation and development group, which we are undertaking to establish at the moment, they will have to meet certain training needs in order to be on the register and will have to do continuing professional development. We have to work through the detail of that, but that training will take place. There may then be specific training requirements for that particular PGD, and governance around that will be put in place. Given that we do not have registered pharmacy technicians in Northern Ireland, we will be able to learn from our counterparts across the UK as this moves forward, but the legislation is certainly enabling where it is safe and appropriate to do so.

Mrs Dodds: It is therefore some way off.

Ms Kirkpatrick: The current timetable for the introduction of enabling legislation for pharmacy technicians is the end of December 2025. We are working to progress that, and three subgroups are working on the legislation as well as on workforce development and the education needs of the workforce. All of that is therefore being considered through the oversight board. We are meeting monthly and have a busy schedule in order to meet the December 2025 deadline.

Ms Simpson: Community Pharmacy Northern Ireland sits on the oversight board, so it is involved as well.

The Chairperson (Ms Kimmins): OK. Are members happy enough? No one else has indicated to ask a question. Thank you, all. That was very helpful.

Members, we will take both SL1s at the same time, if you are happy enough. Are members content with the merits of the policy and that the Department should make the statutory rules for both SL1s that we have discussed today?

Members indicated assent.