An Roinn Sláinte
DEPARTMENT OF HEALTH

Professor Sean Tierney
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Royal College of Surgeons in Ireland
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02nd September, 2014

Re: Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2014

Dear Professor Tierney

I am writing to inform you that the Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2014 ('Regulations') which will introduce a number of significant changes to the requirements for prescriptions in Ireland and associated record keeping are expected to be signed into law within the coming weeks.

Background

The purpose of these Regulations is to transpose and give effect in Irish law to:

1. ***Obligations set out in Directive 2012/52/EU on cross border prescriptions***[19] to facilitate the writing of prescriptions in Ireland for dispensing in another EEA[20] state (**'outgoing EEA prescriptions'**) and the recognition in Ireland of prescriptions written in another EEA state (**'incoming EEA prescriptions'**). This Directive sets out the minimum information which must be contained in cross-border prescriptions in order to facilitate the recognition of prescriptions issued in another EEA state.

2. The Government's commitment to the Troika to introduce ***compulsory use of INNs***[21] (i.e. name of the active pharmaceutical ingredient) on prescriptions written in Ireland for dispensing in Ireland (**'national prescriptions'**).

Summary of Changes

The Medicinal Products (Prescription & Control of Supply) Regulations 2003 as amended (S.I. No. 540 of 2003) set out the requirements relating to the prescribing, supply and

[19] Commission Implementing Directive of 20 Dec 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State. OJ L. 356. 22.12.2012, p. 68-70
[20] European Economic Area (EEA) comprises all EU member states and Iceland, Liechtenstein and Norway.
[21] Commitment No. 45 in the Memorandum of Understanding with the Troika on Specific Economic Policy Conditionality June 2013: *"The authorities will set high level annual targets for increasing the share of generic drug usage in the medium-term. Enabling measures – such as compulsory prescription by International non-propriety name (INN) by end-October 2013, where appropriate – required for the achievement of these targets will be put in place and kept under further review."*

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dispensing of prescription-only medicines in Ireland. The new Regulations will amend the 2003 Regulations and the key changes being introduced are as follows:

1. Prescription requirements

(a) Incoming EEA prescriptions – the Regulations will specify the requirements that must be satisfied in order to dispense a prescription written in another EEA state, including who may write such prescriptions and the minimum information that the prescription must include. The dispensing of incoming prescriptions for controlled drugs that are subject to additional prescription rules in the Misuse of Drugs Regulations, 1988 as amended, i.e. Schedule 1, 2 and 3 controlled drugs, will be prohibited.

Directive 2012/52/EU on cross border prescriptions allows for the recognition of EU cross-border prescriptions which are digitally signed. Consequently, these Regulations will permit the dispensing of incoming EEA prescriptions received electronically. Electronic prescribing is not being introduced at this point for national prescriptions or outgoing EEA prescriptions.

(b) Outgoing EEA prescriptions – the Regulations will specify what minimum information must be included on a prescription issued in Ireland to a patient who has indicated that he/she intends to have it dispensed in another EEA state. The issuing of outgoing EEA prescriptions for Schedule 1, 2 and 3 controlled drugs will not be permitted.

(c) National prescriptions – the requirements for prescriptions issued in Ireland for dispensing in Ireland will be brought generally in line with what will apply to incoming and out-going EEA prescriptions in order to promote consistency, where appropriate, between national and cross-border prescriptions. As a result of this, a number of new pieces of information will be required to appear on national prescriptions, including:

- Name of the medicine prescribed to include the common (INN) name
  This fulfils the Government's commitment to the Troika in respect of compulsory use of INNs.

- Date of birth for all patients
  Currently age must be specified for under 12s only.

- Email and telephone or fax of prescriber
  The prescriber's address will continue to be required in addition to this new information. This new information will not be required on health (GMS) prescriptions.

- Doctor's registration number
  The Department notes that Medical Council guidance has required the inclusion of this on prescriptions for some time. The purpose of this amendment is to ensure consistency in the legislation governing prescription-writing.

- Dosage regimen.

2. **Pharmacy Record-keeping**

Pharmacy record-keeping requirements for dispensed medicines will be updated to take account of the additional information that will now appear on prescriptions.

3. **Updating of Terms**

Certain terminology relating to nurse prescribers and pharmacies will be updated to take account of changes arising from legislation enacted since the Medicinal Products (Prescription and Control of Supply) Regulations 2003 came into force.

Once finalised, the Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2014 will be published on the Department's website www.health.gov.ie and on www.irishstatutebook.ie. Reference should be had to the final signed version of the Regulations for the detailed requirements that will apply.

Timeline for Implementation

The Department is aware that these Regulations will significantly change the current requirements for national prescriptions in Ireland. In this context, it is proposed that new prescription requirements for national prescriptions will come into operation **six months** following the entry into force of the Regulations. The exact dates will be specified in the final Regulations.

All other provisions, including the statutory requirements with respect to outgoing and incoming cross border prescriptions and dispensing records, will apply **immediately** following the Regulations coming into force, expected to be in mid-late September.

I will forward a copy of the Regulations to you once finalised.

The Department would appreciate your cooperation in making your registrants / members aware of these new Regulations and their implications for prescribing and dispensing.

Yours sincerely

Pamela Carter

Pamela Carter
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