

Appendix 6: Accessing medicines over the internet

PHILIPLEE

DUBLIN | BRUSSELS | SAN FRANCISCO

ADVICE

To: Dr. Fiona Lyons, Clinical Lead in Sexual Health, HSE Sexual Health and Crisis Pregnancy Programme

From: Anne Bateman and Jacinta Conway

Date: 13 July 2016

PrEP: Accessing medicines over the internet and related issues

Dear Fiona

Further to your email dated 21 June, this is our advice in relation to the questions you raised in that email and in your subsequent email dated 1 July. Our answers are set out under each question below.

1. Is there a legal impediment to an individual accessing medication over the internet with a prescription?

There is no law in Ireland prohibiting an individual patient from accessing medicine via the internet with a prescription. (It is a criminal offence to obtain prescription medicine without a prescription. Further, it is a criminal offence to supply medicines by mail order, which would cover sending medicines purportedly obtained/ordered over the internet to a patient, even if that patient had a valid prescription in respect of those medicines). The primary legalisation relating to this area is the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) (“the **Prescription Regulations**”). The Prescription Regulations apply only to the supplier and/or prescriber of medicines and not to an individual patient who might use the prescription to access medicines. The most relevant regulations are Regulation 7(1) which provides the requirements for a prescription to be valid (see as discussed below under question 3), and Regulation 19(1) which specifically prohibits the supply of medicines by mail order¹.

1 Supply by mail order is defined as “any supply made after solicitation of custom by the supplier

whether inside or outside of the state, without the supplier and customer being simultaneously present and using a means of communication at a distance whether written or electronic to convey the custom solicitation and the order for supply.” There is no definition of “solicitation of custom” in the Prescription Regulations, however it is possible that it could be deemed to include advertising on a website and/or making medicines available for purchase on a website.

2. Is there a legal impediment to a physician providing information about PrEP resources (for example www.iwantprepnnow.co.uk) as part of an overall discussion about HIV prevention where the resources may include how to access medication over the internet?

Currently, there is no law restricting the specific information that a physician can and cannot provide to their patient. The issue is dealt with under Section 44.1 of the Irish Medical Council’s Guide to Professional Conduct and Ethics for Registered Medical Practitioners 2016 (“The Professional Code”). Section 44.1 covers provision of information to the public and states:-

“Information about medical services published in the media, internet or other means is generally in the public interest provided the information is factually accurate, evidence based and not misleading”

Therefore, a physician may provide information about PrEP resources as part of an overall discussion about HIV prevention where the physician believes the resources to be factually correct, evidence-based, not misleading and believes it to be in the best interests of the patient to be informed of such resources.

It falls to the Medical Council to regulate this duty on the part of the physician, and any perceived misconduct in this regard is a disciplinary matter to be addressed by the Medical Council. Should the Medical Council decide such actions require discipline, Section 57 of the Medical Practitioners Act 2007 (the “MPA 2007”) entitles the Medical Council to make a complaint to the Preliminary Proceedings Committee (the “PPC”) on grounds of misconduct by the physician. The PPC will in turn investigate the matter, and if it deems necessary, refer the matter to the Fitness to Practice Committee. The Fitness to Practice Committee will provide a report of their findings. Should a physician be found guilty of misconduct by the PPC and/or the Fitness to Practice Committee, Section 70 of the MPA 2007 entitles the Medical Council to impose sanctions ranging from a censure in writing, to a fine of €5,000, to cancellation of the physician’s certificate to practice medicine.

3. Is there a legal impediment to a physician providing an individual with a prescription where the prescription will be used to source medication over the internet?

Regulation 7(1) of the Prescription Regulations states that for a prescription to be valid it must:-

“(a) be in ink or other permanent and unalterable electronic form and be signed and dated by the person issuing the prescription with his or her or her usual signature, either in handwriting or by electronic signature;

(b) clearly indicate the full name, including the full first name of the person issuing the prescription and specify his or her professional qualification;

(c) specify the work address, the including the name of the EEA state of the person issuing the prescription;

(d) specify the email address, telephone number or fax number(with the appropriate international prefix) of the person issuing the prescription;

(e)specify the full name, including the full first name and date of birth of the person for whose

treatment the prescription is issued; and

(e) specify the following details, where applicable of the product to be supplied on foot of the prescription;

(i) The common name of the medicinal product;

(ii) The brand of the medicinal product if – the medicinal product prescribed is a biological medicinal product or the person issuing the prescription has deemed it medically necessary to include the brand name on the prescription and has stated on the prescription the reasons justifying the use of the brand name;

(iii) The quantity;

(iv) The strength of the medicinal product; and

(v) The dosage regime

A physician is not under a legal obligation when providing a prescription to either state where the medicine is to be sourced, or to satisfy himself/herself that a patient is not sourcing the medicine online. Further, the Professional Code does not require a physician to satisfy himself/herself that prescribed medicines will not be sourced over the internet. There are however, general duties contained within the Professional Code that a physician that may be relevant: specifically, the physician should take reasonable steps to ensure a patient is not inappropriately obtaining drugs from multiple sources (Section 42.7 of the Professional Code); and the physician must comply with the Misuse of Drugs legislation (Section 42.3 of the Professional Code). However, none of the relevant legislation (including the Prescription Regulations) prohibits the use by the patient of a prescription to purportedly source the prescribed medicine online.

4. Is there a legal impediment to an NGO/advocacy group providing information about PrEP resources (for example www.iwantprepnw.co.uk) as part of an overall discussion about HIV prevention where the resources may include how to access medication over the internet?

Irish legislation does not deal with the provision of medical information by NGOs as such.

The World Association of Non-Government Organisations (WANGO) has published a code of Ethics and Conducts for NGOs worldwide, however this does not contain specific obligations in relation to the provision information to the public, only a general duty on the NGO to ensure that the information is accurate and that it is adhering to the law of the nation in which it is organised. Therefore, subject to the below, an NGO in Ireland should not face a legal impediment to providing information about PrEP resources to patients.

An individual NGO may have its own code of conduct and ethics (which may contain specific information in relation to the provision of medical information). Each member of an NGO should be advised to establish if their NGO has a particular code and, if so, satisfy themselves that they are adhering to any such code before providing information on PrEP resources.

In relation to individual members of NGOs, you might note that Section 41 of the MPA 2007 provides that it is an offence for a person to falsely represent themselves to a registered medical practitioner, with the penalty for such an offence being a fine up to €5,000 or imprisonment up to 6 months or both. Further, Section 44 of the Nurses and Midwives Act 2011 provides for the same offence (in relation to representing oneself as a registered nurse), not do carrying the same penalties. Therefore, any member of an NGO who is not a registered medical practitioner or registered nurse, but who find themselves providing medical information to individuals should be careful not to do so in a context in which they represent themselves to be a registered medical practitioner or nurse and/or in which the patient might be led to believe from the context (including from the giving of information on PrEP resources and/or sourcing medication) that the person providing this information had such a qualification.

On a general note, complementary therapists are subject to consumer protection legislation when treating/advising patients, and in particular are subject to the Consumer Protection Act 2007 (the “CPA 2007”). Section 42 of the CPA 2007 prohibits misleading commercial practices. Further, Section 43 prohibits the provision of false or misleading information. Therefore, there is a duty on such therapists to ensure that information provided to patients is accurate and fair and would not cause the patient to make a decision in terms of purchasing medicines that it would not otherwise make. It is unclear whether these provisions would apply to NGOs and/or individuals belonging to NGOs. It is unlikely that these provisions would apply to NGOs/individuals belonging to NGOs as they are, by their nature, non-profit seeking and do not charge a fee for providing medical treatment/advices. They would not therefore come under the definition of a “trader” for the purposes of consumer protection legislation.

We hope that the above answers your questions, but please let us know if you have any queries or require further clarification.

This advice is given solely in connection with the instructions of the HSE and is given for the benefit of, and may be relied upon by, the HSE only (and specifically by the HSE personnel to whom it is addressed). It is for the confidential use of the HSE and may not be relied upon by any other person or for any other purpose. Philip Lee neither owes or accepts any duty to any other third party in connection with this advice and shall not be liable for any loss, damage or expense of whatsoever nature which is caused by their unauthorised reliance on the advice/information provided.

Philip Lee Solicitors
13 July 2016