PSI
CUMANN CÓGAISEOIRÍ NA hÉIREANN
The Pharmaceutical Society of Ireland
AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

Submission to the Draft Standard for Consultation: Information Requirements for Community-based ePrescribing

September 2018

Pharmaceutical Society of Ireland
PSI House, 15-19 Fenian Street
Dublin 2, D02 TD72
01 218 4000
www.psi.ie

The Pharmaceutical Society of Ireland (PSI) is an independent statutory body, established under the Pharmacy Act 2007 ('the Act'). It is charged with, and is accountable for, the effective regulation of pharmacy services in Ireland, including responsibility for supervising compliance with the Act. The PSI is also charged with ensuring compliance with certain medicines and controlled drugs legislation. It works for the public interest to protect the health and safety of the public by regulating the pharmacy profession and pharmacies.

The PSI welcomes this opportunity to make a submission to HIQA's public consultation on the Draft Standard: Information requirements for community-based ePrescribing.

This submission is presented in three parts:

1. Existing legal and regulatory frameworks in Ireland (which will impact community-based ePrescribing)
2. Specific Commentary on the draft information requirements
3. Final comments

Existing legal and regulatory frameworks in Ireland

As stated in a previous submission to HIQA (*Consultation on the draft recommendations for the national, community-based ePrescribing programme in Ireland, submitted by PSI on 3 August 2018*) the PSI is concerned that the important provisions on the control of medicines supply that are enshrined in Irish legislation for the protection of public health and safety do not appear to be receiving adequate consideration as part of the overall national ePrescribing programme. It is fundamental to the development of any ePrescribing system, that the prescription is seen as a legal document which plays a critical part in the wider regime of strict control over the supply and possession of medicinal products. In order to be considered valid, a prescription must comply with the requirements of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended), and, for controlled drugs, the Misuse of Drugs Regulations 2017 (as amended). This legislation will require amendment to allow for ePrescribing, and any future ePrescribing system must preserve, or indeed, enhance the safeguards already in place under this legislation. Therefore, while the technical standards information requirements for the development of an ePrescribing system are under consideration in this consultation, the legal and public health safeguards for the proper control of medicines must also be considered as part of the development of any national ePrescribing system. The PSI does not consider this central requirement to be adequately reflected in the recommendations and requirements as drafted to date.

Specific commentary on the draft information requirements

Figure 1: the term 'dispenser' is used. This term is not defined in the document nor is it a legally recognised person in Ireland. The healthcare practitioners authorised in Irish medicines legislation to supply medicines to patients on foot of a prescription are 'pharmacists'. This should be reflected in all infographics used. The term 'dispenser' is also used in Figure 3, Appendix 7.

Use cases 7 and 8: the PSI suggests removing the word 'modified', and replace this with 'substituted'. This is the terminology used most in pharmacy practice, to describe when a pharmacist, upon contacting the prescriber, makes a change to the medication/therapy prescribed.

Table 1: the PSI suggests further consideration is given to the 'optionality' of data item 1.7 'Health Identifier of the Patient'. Additionally, we would suggest mandating the inclusion of a method to capture a health identifier relating to the pharmacist and pharmacy, as well as the prescriber and prescribing practice in tables 2 and 3 where appropriate. This would enable the relevant individual or organisation to be identified easily and accurately. This would also be in line with the Health Identifiers Act 2014, which provided for the establishment and maintenance of national registers for Individual Health Identifiers and Health Service Provider Identifiers (Practitioners and Organisations). The PSI suggests consulting with the HSE's Health Identifiers (HIDs) Programme on this matter.

Table 2: this table outlines the prescribing information requirements, therefore this list must mirror the prescription requirements set out in legislation for a legally valid prescription; Regulation 7 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended. The PSI suggests that the name, address, phone number and registration number of the prescriber is included. Furthermore, the Misuse of Drugs Regulations 2017, as amended, sets out the details needed to be written on a prescription for controlled drugs. The PSI strongly suggests that the prescription requirements for controlled drugs are also considered when drafting the information requirements for prescribing/dispensing. Regarding the use of 'should' and 'shall', it is suggested that HIQA consult relevant medicines legislation. Examples include:

- Regulation 7 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended.
- Regulation 15 of the Misuse of Drugs Regulations 2017, as amended
- Regulation 7(1A) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended (note, this regulation refers to prescriptions issued in an EEA state other than Ireland including ePrescriptions).

Table 2: data item 2.15 relates to 'Advice to Patient'. The PSI suggests also including such a data item in table 3, as a 'should', so that pharmacists are provided with the technical functionality to record the advice given to each patient.

Table 3: the PSI suggests that HIQA refer to Regulation 10 (Pharmacy Records) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended. Regulation 10 sets down what information is legally required to be held in each pharmacy's dispensing record (or prescription register). Therefore the PSI suggests that HIQA consider including those requirements necessary under Regulation 10 for a prescription register held in a pharmacy to be accurate.

Table 3: data Item 3.9 sets out the proposed label instructions. When supplying medicines from a pharmacy, they need to be labelled as per the requirements of Regulation 9 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended. The PSI suggests that HIQA note these requirements when considering data item 3.9.

Figure 3 Appendix F: reference is made to a 'Repository' in the figure. It is unclear from the document what the 'repository' refers to. We suggest clearly defining 'repository', including what this is used for, when will this exist and who will have access to this. There also appears to be inconsistency with the terminology used in the document, with the 'message exchange' referring to a 'prescription exchange' in some instances – perhaps this needs further consideration.

Emergency Supply: currently, pharmacists can provide patients with an 'emergency supply' of medicines (see Regulation 8 of Medicinal Products (Prescription and Control of Supply) Regulations, as amended), either at the request of the patient, or at the request of a prescriber. It is suggested that tables 2 and 3 are amended to provide for this area of prescribing/dispensing practice.

Pharmacy services: pharmacy practice has evolved in recent years, with legislation providing for the supply administration of certain vaccines directly by pharmacists, supply of emergency hormonal contraception (i.e. the morning after pill) to patients without a prescription by pharmacists and also the supply and administration directly by pharmacists of certain prescription-only medicines for use in an emergency situation (e.g. adrenaline in cases of anaphylaxis). It is suggested that the information requirements be amended in light of these changes to pharmacy practice.

Final comments

The PSI is of the view that the status and development stage of the national ePrescribing programme is unclear. In the preceding two months, a number of consultations have been released by HIQA, pertaining to projects associated with the broader eHealth agenda. The work and dedication to the programme as a whole is to be commended, however any lack of clarity as to the overall design and direction of the ePrescribing programme is not desirable. It is therefore suggested that HIQA make it clear in the preamble to these draft requirements precisely how the requirements fit within the overall plan for the national ePrescribing programme upon the publication of any future draft recommendations/requirements.

The PSI, as the pharmacy regulator, is available to provide any further information, clarification or assistance that you require in relation to any matters outlined above or on the draft information requirements in general as they relate to pharmacies and pharmacists, and those availing of pharmacy services.

PSI – The Pharmacy Regulator, PSI House, Fenian St, Dublin 2, D02TD72

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