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

Consultation on HIQA Draft recommendations for the national, community-based ePrescribing programme in Ireland

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The Pharmaceutical Society of Ireland (PSI) is the statutory regulator for pharmacists and pharmacies in Ireland under the Pharmacy Act 2007. In addition to ensuring compliance with the Pharmacy Act, the PSI is also responsible for ensuring compliance with the medicinal products legislation including the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended.

The PSI welcomes the opportunity to be part of the advisory group for the recommendations and to comment on the draft recommendations as part of this public consultation.

In addition to specific comments on the draft recommendations which are outlined below in this submission, the PSI has the following more general comments which we believe it is important to place on the record:

1. The PSI welcomes the development of ePrescribing in Ireland and appreciates the many patient safety benefits and efficiencies that can be realised from the implementation of such a system.

2. The PSI is concerned, however, 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 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 for the development of an ePrescribing system are under consideration, 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 as drafted to date.

3. The PSI is also of the view that the status and development stage of the national ePrescribing programme is unclear. For example, in parallel to this consultation, which appears designed to make recommendations about setting up a national ePrescribing programme, the PSI has also been invited by HIQA to participate in a consultation on the development of standards on technical information requirements for community based ePrescribing – a project which appears to be at an advanced stage. Any lack of clarity as to the overall design and direction of the e-Prescribing programme is not desirable. Hence, the PSI would strongly suggest that HIQA make it clear in the preamble to these recommendations precisely how they fit with the overall e-Prescribing programme and where that programme stands at the time the recommendations are being made.

We hope the above comments are of assistance in the finalising of the recommendations and we remain available to discuss any aspect of this further.

Specific comments in relation to the draft recommendations are outlined below.

Background

It is clear that HIQA has undertaken to develop a set of recommendations to the Minister for Health based on the findings of HIQA's follow-up international review of ePrescribing, *ePrescribing: An International Review* (May 2018). The PSI strongly suggests however that further clarification be given on the relationship between these recommendations and the HSE's eHealth and ePrescribing / ePharmacy programme. Section *1.3 ePrescribing in Ireland* provides information on eHealth Ireland's ePrescribing in Primary Care initiative and an update on work to date on this initiative including its plan for a phased, standards-based implementation, development of an interoperability framework, development of national technical standards, introduction of national health identifier legislation and the operation of two ePrescribing pilot projects. Clarity must be provided on how the recommendations for the Minister for Health are aligned to the work carried out to date under eHealth Ireland's and the HSE's ePrescribing programme.

Use of the term 'Dispenser'

In section *1.1 Introduction to ePrescribing* 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 prescription are pharmacists. This should be reflected in the recommendations.

Recommendation 1 – Scope and legislative requirements

The PSI suggests that in addition to identifying the benefits expected for stakeholders, the challenges anticipated for stakeholders should also be outlined.

The PSI notes that HIQA recommends that the legal requirements to implement the programme should be outlined and supporting policy and legislative changes should be developed. The PSI believes that substantial consideration of how an ePrescribing system would be implemented in the current legislative and regulatory environment is essential, in order to allow such a system to be meaningful and effective. Consideration must be given to the legislative and regulatory framework currently in place around the prescribing and supply of medicines, in particular the relevant pharmacy and medicines legislation including the Pharmacy Act 2007, the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) and the Misuse of Drugs Regulations 2017 (as amended).

Therefore, in addition to identifying the legal requirements for implementation of an ePrescribing Programme, the legislative changes required around the prescribing and supply of medicines must also be identified. Also, for any developments in ePrescribing it is important that the public is protected and the current safeguards that exist in legislation are replicated or enhanced in any new systems that are implemented, to ensure the continued safe and rational use of medicines. This includes the use of electronic signatures- please see comments below under Recommendation 3 - Data Privacy. The prescribing and supply of a medicine are elements of the regulated supply chain of that medicine from the manufacturer to the patient. The ePrescribing system proposed under the scope of this project must operate in compliance with the legislative requirements in place at the time of implementation, and with any future changes to legislation.

Recommendation 2 – Governance

The PSI has concerns that the governance structure as outlined in the recommendations is unclear and potentially weak as regards assigning clear responsibility for leadership and direction. We would suggest that further detail be provided on the governance structure and on the board of governance, including who will be responsible for directing and overseeing the delivery of a national ePrescribing program.

The PSI notes from the international review that where a country did not have a centralised health system, the establishment of a single, national governance body that articulates and implements a clear vision for ePrescribing could create the conditions that would ensure the success of a national, community-based ePrescribing programme. The PSI would suggest that the recommendation '*A programme board should be established to advise and support the project team*' is amended to '*A single, national programme board should be established to direct, advise and support the project team*'.

Recommendation 3 – Data Privacy

Digital Signatures

In section *2.3 Data Privacy*, the term 'digital signatures' is referred to. Under the Medicinal Products (Prescription and Control of Supply) Regulations 2003 and the Misuse of Drugs Regulations 2017 (as amended), prescriptions are legal documents which for their validity are required to be signed and dated by the person issuing them, with their usual signature. Checking the validity and authenticity of prescriptions is an important function discharged by pharmacists in the course of dispensing. The requirement for a signature enables the pharmacist to do this. For any developments in ePrescribing it is important that the public is protected and the current safeguards that exist in legislation are replicated or enhanced in any new systems that are implemented, to ensure the continued safe and rational use of medicines.

Regulation (EU) no 910/2014 of the European Parliament and of the Council, of 23 July 2014, on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC refers to and defines three types of electronic signature:

(a) Electronic signatures ('electronic signature' means data in electronic form which is attached to or logically associated with other data in electronic form and which is used by the signatory to sign)
(b) Advanced electronic signatures ('advanced electronic signature' means an electronic signature which meets the requirements set out in Article 26)
(c) Qualified electronic signatures ('qualified electronic signature' means an advanced electronic signature that is created by a qualified electronic signature creation device, and which is based on a qualified certificate for electronic signatures)

It is the PSI's view that substantial consideration on the choice of electronic signature employed is essential if ePrescriptions are to be provided for in the legislation relating to medicines. The current safeguards in place for paper prescriptions (signed by prescriber with their usual signature) must be replicated, if not enhanced, for ePrescriptions. The electronic signature employed must guarantee the integrity of the text as well as provide authentication, i.e., give added assurance that the individual signing the prescription is really the person that he or she claims to be, and that the content has not been altered. This is most essential where medical prescriptions are concerned to ensure the safe and rational use of medicines, and to safeguard the integrity of the medicine supply chain from manufacturer to patient.

The PSI believes that consideration should also be given to linking the prescriber's electronic signature to the prescriber's health services provider identifier and their regulatory body's registration system, to enable further verification of the prescriber's electronic signature.

Data Protection (including Data Privacy and Patient Consent)

Data protection, including data privacy and patient consent, will be fundamental to the success of a community-based ePrescribing programme in Ireland. The PSI suggests that further analysis of all aspects of data protection is carried out, and that the Data Protection Commissioner be included as a key stakeholder to advise on data protection matters including data privacy and patient consent.

The recommendation states that '*Consent to collect information and subsequent access to and sharing of the information collected should be monitored.'* In addition to this the PSI strongly suggests that consideration be given to how patient consent could present as a potential challenge to the success of the programme and how this potential challenge could be addressed in an appropriate manner, bearing in mind the rights of all involved.

Recommendation 4 – Stakeholder Engagement

The PSI supports HIQA's view that stakeholder engagement and communication strategy will be fundamental to the success of a community-based ePrescribing programme in Ireland.

The PSI considers it important to be cognisant of how the healthcare system must function as a whole and not to focus solely on the primary healthcare system when developing an ePrescribing programme.

The PSI suggests that the relevant regulatory bodies also be included as key stakeholders.

The PSI suggests that the Data Protection Commissioner be included as a key stakeholder to advise on data protection matters including data privacy and patient consent. (See Recommendation 3 above)

Recommendation 5 – Standards-based Approach

The recommendation states that a standards-based approach to community-based ePrescribing should be undertaken. It was the PSI's understanding that a standards-based approach had been agreed on and that standards have in fact already been developed. Section 6.2 of the international review of ePrescribing states that the National ePrescribing Programme has published its plan for a phased, standards-based implementation, and that as part of phase 1, eHealth Ireland worked with a number of organisations to develop a relevant interoperability framework based on national and international standards. HIQA defined and agreed the related standards for messaging and datasets.

The PSI notes that reference is made in section *2.5 Standards-based approach* to ePrescribing being part of a wider strategic program of eHealth services. There is no reference made to this in the recommendation, however it is mentioned under Recommendation 6 – Implementation. The PSI would suggest therefore that the last paragraph in section 2.5 be relocated to section *2.6 Implementation*.

The PSI suggests that specific reference be made in this recommendation to the use of unique identifiers (i.e. Individual Health Identifiers, Identifiers for Health Professionals, and Identifiers for Locations) which have been identified as a fundamental building block in the roll out of a national, community-based ePrescribing programme.

Recommendation 6 – Implementation

With regard to the pilot based approach, the PSI suggests clarifying that the implementation and pilot phase will be a national, non-proprietary based pilot.

It is recommended that an ePrescription service be implemented as part of a 'family' of eHealth services. The PSI suggests that consideration be given to the implementation of the electronic health record (EHR) in conjunction with the ePrescribing programme. If this is not possible, consideration of future interoperability between these two systems must be a priority.

Final Comment

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 recommendations in general as they relate to pharmacies and pharmacists, and those availing of pharmacy services.

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