Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Information and Standards

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

June 2018

Safer Better Care

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high-quality and safe care for people using our health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered. HIQA's ultimate aim is to safeguard people using services and improve the safety and quality of health and social care services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

- **Setting Standards for Health and Social Services** — Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.
- **Regulation** — Registering and inspecting designated centres.
- **Monitoring Children's Services** — Monitoring and inspecting children's social services.
- **Monitoring Healthcare Safety and Quality** — Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health Technology Assessment** — Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.
- **Health Information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

Overview of the health information function of HIQA

Healthcare is information-intensive, generating huge volumes of data every day. Health and social care workers spend a significant amount of their time handling information, collecting it, looking for it and storing it. It is therefore imperative that information is managed in the most effective way possible in order to ensure a high-quality, safe service.

Safe, reliable healthcare depends on access to, and the use of, information that is accurate, valid, reliable, timely, relevant, legible and complete. For example, when giving a patient a drug, a nurse needs to be sure that they are administering the appropriate dose of the correct drug to the right patient and that the patient is not allergic to it. Similarly, lack of up-to-date information can lead to the unnecessary duplication of tests — if critical diagnostic results are missing or overlooked, tests have to be repeated unnecessarily and, at best, appropriate treatment is delayed or at worst not given.

In addition, health information has a key role to play in healthcare planning decisions — where to locate a new service, whether or not to introduce a new national screening programme and decisions on best value for money in health and social care provision.

Under section 8(1)(j), HIQA is charged with evaluating the quality of the information available on health and social care and making recommendations in relation to improving the quality and filling in gaps where information is needed but is not currently available.

Information and communications technology (ICT) has a critical role to play in ensuring that information to drive quality and safety in health and social care settings is available when and where it is required. For example, it can generate alerts in the event that a patient is prescribed medication to which they are allergic. Further to this, it can support a much faster, more reliable and safer referral system between the patient's GP and hospitals.

Although there are a number of examples of good practice, the current ICT infrastructure in Ireland's health and social care sector is highly fragmented with major gaps and silos of

information which prevents the safe, effective, transfer of information. This results in people using the service being asked to provide the same information on multiple occasions.

In Ireland, information can be lost, documentation is poor, and there is over-reliance on memory. Equally, those responsible for planning our services experience great difficulty in bringing together information in order to make informed decisions. Variability in practice leads to variability in outcomes and cost of care. Furthermore, we are all being encouraged to take more responsibility for our own health and wellbeing, yet it can be very difficult to find consistent, understandable and trustworthy information on which to base our decisions.

As a result of these deficiencies, there is a clear and pressing need to develop a coherent and integrated approach to health information, based on standards and international best practice. A robust health information environment will allow all stakeholders, the general public, patients and service users, health professionals and policy makers to make choices or decisions based on the best available information. This is a fundamental requirement for a high reliability healthcare system.

Through its health information function, HIQA is addressing these issues and working to ensure that high quality health and social care information is available to support the delivery, planning and monitoring of services.

One of the areas currently being addressed through this work programme is the need to develop recommendations to support electronic prescribing (ePrescribing) across organisational boundaries. In 2013, HIQA completed an international review on ePrescribing to inform the adoption of appropriate standards in Ireland. This review was revised in 2018 and is available on www.hiqa.ie. Both reviews focused on the prescribing and dispensing of medication in the community rather than in the hospital settings. Countries researched in the international review initially focused on the electronic sharing of prescriptions in community setting and, following successful implementation, built upon this by implementing ePrescribing in other setting such as within hospitals outpatient departments, emergency departments and inpatient settings. This is explained as a consequence of both GPs and pharmacists having similar processes with their peers and hence being able to support computerisation of the process. By contrast, hospital medication management processes are typically more complex, incorporate multiple processes, including medication reconciliation on admission, ward based dispensing, recording administration of medication

to patients and discharge planning making standardisation and computerization more complicated.

Based on the findings of the 2018 review, this document contains draft recommendations for consultation on the national, community-based ePrescribing programme in Ireland.

Contents

Executive Summary **8**
Methodology **18**
Chapter 1 Background **21**
1.1 Introduction to ePrescribing 21
1.2 Benefits of ePrescribing 23
1.3 ePrescribing in Ireland 27
Chapter 2 Recommendations **29**
2.1 Scope 29
2.2 Governance 31
2.3 Data privacy 34
2.4 Stakeholder engagement 36
2.5 Standards-based approach 38
2.6 Implementation 42
Chapter 3 Conclusion **45**
Appendix A Advisory Group membership **46**
Appendix B Draft Consultations Questions **47**

Executive Summary

This document contains draft recommendations for consultation in respect of the national, community-based ePrescribing programme in Ireland. The draft recommendations for consultation are based on factors that have been found to support the success of national, community-based ePrescribing programmes internationally. HIQA's *ePrescribing: an International Review* is published as a companion to this Draft for Consultation document and is available at www.hiqa.ie.

ePrescribing is used to describe all aspects of the generation and transfer of prescriptions electronically using a dedicated system, whether in paper or electronic form, rather than faxing or emailing the prescription.(1) International sources consistently identify ePrescribing as taking place in primary care. Thus, ePrescribing involves the generation of the prescription by GPs, the transmission of prescriptions electronically from GP to pharmacy over national networks and a pharmacist dispensing the prescription:

- **Step 1**. **ePrescribing**, where the prescriber generates the prescription electronically — for example, when the GP generates a paper script with a barcode using the GP management software.
- **Step 2**. **Electronic transfer of prescription**, where the prescription is transmitted electronically to the dispenser. The prescription information is usually sent as a message to a central message repository where it can be retrieved.
- **Step 3. eDispensing**, where the dispenser retrieves the prescription (and optionally reports on the medicines given to the patients) — for example, when the patient presents the paper prescription, the pharmacist scans a barcode to identify then retrieve the prescription information from the central message repository.

Thus, the term ePrescribing encompasses both the entire process and the three separate steps that comprise it. In 2013, HIQA completed an international review on ePrescribing to inform the adoption of appropriate standards in Ireland. In 2018, HIQA published a revised version of the international review, outlining lessons learnt from ePrescribing initiatives internationally, to inform the adoption of appropriate standards in Ireland. Both reviews focused on the prescribing and dispensing of medication in the community setting, rather

than in the hospital setting, in each country examined. Countries researched in the international review initially focused on the electronic sharing of prescriptions in community setting and, following successful implementation, built upon this by implementing ePrescribing in other setting such as within hospitals outpatient departments, emergency departments and inpatient settings.

Countries initially focus on ePrescribing in a community setting as both GPs and pharmacists have similar processes to their peers, which helps support computerisation of the process. By contrast, hospital medication management processes are typically more complex, incorporate multiple processes, including medication reconciliation on admission, ward-based dispensing, recording administration of medication to patients and discharge planning, making standardisation and computerisation more complicated. However, solutions developed to support the successful implementation of community-based ePrescribing can be reused in hospital settings.

A national, community-based ePrescribing programme can deliver significant benefits for patients, prescribers, pharmacists and others involved in the process.[1] In particular, ePrescribing can improve patient safety considerably by reducing errors of mistaken identity, incorrect dosage, incorrect medication, adverse drug interactions, and so on. It can also resolve challenges concerning overlapping medications and improve medication practices. It can also reduce the number of pharmacist interventions significantly. Furthermore, ePrescribing can cost far less and take less time than processing the same prescriptions manually.

The vision for the Irish national, community-based ePrescribing programme is set out in the Department of Health's eHealth strategy.[2] The goal of ePrescribing strategy in Ireland is to reduce medication errors, thereby reducing the associated costs and speeding up patient access to medication.[3] The eHealth Ireland organization is responsible for realizing this vision and, in June 2015, announced the National ePharmacy Programme, which included ePrescribing in primary care and the National Medicinal Product Catalogue among its projects. eHealth Ireland's ePrescribing in Primary Care initiative has published a high-level plan for a phased, standards-based implementation. The programme's phased approach included the development of the initial building blocks (phase 1), leading to an 'ePrescription' phase (phase 2), followed by the roll out of ePrescribing in primary care (phase 3). Currently the initiative is in the process of gaining approval for its business case.

A phased, standards-based implementation is in line with international best practice in implementation, as identified by HIQA's international review of ePrescribing from 2018. For completeness, this document takes account of best practice in key areas identified in that review and makes a recommendation in each following areas:

- scope and legislative requirements
- governance
- data privacy
- stakeholder engagement and communication strategy
- standards-based approach
- implementation.

Recommendation 1 — Scope and legislative requirements

The national, community-based ePrescribing programme should be defined with input from key stakeholder, and an ongoing collaborative approach between stakeholder organisations should be established. A roadmap should be agreed by organizations and agencies involved in the programme, who should prioritise supporting programme elements and the rollout of the programme. The roadmap should clearly articulate that community-based ePrescribing is scope of the project. It should outline a clear vision, including an effective governance structure, support for data privacy, the need for a detailed stakeholder mapping and engagement plan, a standards-based approach and a phased implementation plan incorporating lessons learned from pilot projects previously undertaken. Once the scope is defined, the legal requirements to implement the programme must be reviewed and clearly set out. The roadmap should outline the benefits expected for stakeholders and organisations and identify any risks to the overall programme. Finally, the roadmap should show how the national, community-based ePrescribing programme will integrate with existing and planned eHealth services, including future hospital-based medication management capabilities.

HIQA recommends:

- The programme should be undertaken as a collaborative approach between the major stakeholders.
- The legal requirements should be outlined and supporting policy and legislative changes should be developed.
- A roadmap should be developed for the programme.
- A detailed business case, including the benefits and costs, should be developed for the programme.
- The programme should be prioritized by the organisations involved to support successful implementation.
- Benefits should be identified and articulated at an early stage, including the benefits to be realized for patients, for prescribers, for pharmacists and for broader stakeholders.
- The two existing pilots should be formally reviewed and the lessons learned should be published.

Recommendation 2 — Governance

A formal board of governance, with representatives from all stakeholder organizations and groups should be established to provide leadership for the national, community-based ePrescribing program. The board of governance needs to consider how it will balance a clear national vision, articulated in the ePrescribing roadmap, with a real understanding of local needs. The programme governance remit shall include engaging stakeholders, ensuring a standards-based approach is adopted and monitoring risk, implementation and deployment. The programme governance remit shall include engaging stakeholders, ensuring a standards-based approach is adopted and monitoring risk, implementation and deployment among other ePrescribing activities.

HIQA recommends:

- A programme board should be established to advice and support the project team.
- The programme board should be representative of all stakeholder organisations and groups, which should be reflected in the makeup of the governance structure.
- Clinical leadership should be embedded within the programme with responsibility for the case for change, to the specification of requirements, through to the delivery phases of the programme.
- A detailed project plan should be agreed and progress against timelines should be reported at key intervals.
- Risks, together with controls and mitigating actions, should be documented and managed appropriately.

Recommendation 3 — Data privacy

Ensure that the collection and processing of patient data meets the requirements of data protections legislation, including the General Data Protection Regulation. To this end, it is recommended that an end-to-end privacy assessment of the entire ePrescribing lifecycle should be undertaken and the findings published. The assessment should include the patient's consent to use of their data at each stage of the lifecycle. Data generated within the systems will provide benefits including clinical audit and clinical improvement but primary and secondary use of information within the system must be within agreed limits and legislation.

HIQA recommends:

- The project should be undertaken in line with all data protection legislation. A thorough privacy impact assessment should be undertaken and made publicly available.
- Consent to collect information and subsequent access to and sharing of the information collected should be monitored. Information should be retained only for the purpose(s) for which it was collected.
- Primary and secondary use of information within the system must be within agreed limits and legislation.
- Access to the information should be undertaken using robust authentication services, which should also be monitored and audited.

Recommendation 4 — Stakeholder engagement and communication strategy

Those responsible for programme governance need to work closely with all stakeholder groups and organisations as equal stakeholders, including but not limited to patients, prescribers, pharmacists, vendors, and funding and reimbursement services, in order to understand their needs fully and to gain consensus on the solution to be implemented. A national, community-based ePrescribing solution needs to be well-designed for the business process of stakeholders, including GPs and community pharmacists. They also need to educate stakeholders about the benefits to them, which should spur adoption of ePrescribing in the community.[4,5,6] The communication strategy should include continued communications with all stakeholders, including the public, throughout implementation.

HIQA recommends:

- The programme should be inclusive of all stakeholders, and stakeholder engagement should be central to all stages in the programme.
- As part of engagement, stakeholders' requirements, business processes and benefits should be elicited and documented and then used to inform the development of relevant standards and implementation solutions.
- Requirements should be gathered through multiple methods, including stakeholder interviews, focus groups, advisory groups and public consultation.
- Software vendors who will develop solutions to support the programme should be engaged in an open and transparent way.
- Communication plans should be developed and awareness sessions with stakeholders should be undertaken throughout the lifecycle of the programme. The communication strategy should include continued communications with all stakeholders, including the public, throughout implementation.
- Materials such as supporting documentation for programme implementation and meeting minutes should be published in a timely manner.

Recommendation 5 — Standards-based approach

A standards-based approach to community-based ePrescribing should be undertaken. Informed by stakeholder requirements, international standards should be localised to support Irish needs. Based on international evidence, a phased message brokering solution supporting the transfer of electronic prescriptions from prescribers to pharmacists should be implemented, building on the infrastructure of the national messaging broker (Healthlink). A diverse range of standards are required, including but not limited to information models, identification services, authentication services, security standards, messaging standards and reference models. Continuous review of the implementation of the ePrescribing solution should be undertaken by the board to ensure a robust standards-based approach is being implemented.

HIQA recommends:

- Business requirements and process flow should be specified and documented.
- Information requirements should be specified and documented and a data model developed.
- A diverse range of standards are required, including but not limited to standards for identity management, authentication and security. Standards-based services should be implemented and utilised in the ePrescribing programme.
- Messaging specification should be developed based on Health Level 7 (HL7) standards. The version of HL7 currently in use in Ireland is v2.4, which was approved in 2000. Subsequent revisions of the standard incorporated specific enhancements related to ePrescribing and should be considered. HL7's Fast Healthcare Interoperability Standard, in development since 2012 and close to normative status, should also be considered as a candidate for implementation.
- An up-to-date and regularly maintained national medicinal products reference catalogue describing all prescribable and dispensable items should be developed and integrated into the ePrescribing solution.
- Relevant clinical terminologies and classification systems such as SNOMED CT, LOINC ATC codes should be integrated with information models, messaging specifications and other products such as the national medicinal products reference catalogue required to support the ePrescribing solution.
- Data quality should be to the forefront of the programme and standards. Data quality should be integrated into the process. A data quality framework should be developed and

implemented so as to ensure the highest possible quality data is shared in the implemented ePrescribing solution.

Recommendation 6 —Implementation

Programme governance should also include clear agreement on a pilot-based, phased implementation approach. Effective piloting can help to identify potential issues and proactively resolve them ahead of wider implementation. Using a phased approach allows these issues to be identified then resolved iteratively, which can help to improve performance and stakeholders' experience of the system. A phased approach also facilitates early input from stakeholders, which can help to build momentum for later stages. An ePrescription service should also be implemented as part of a 'family' of eHealth services, without which it may be far less effective.

HIQA recommends:

- A phased model of implementation informed be research and international best practice localised to support Irish needs should be undertaken.
- A further pilot is undertaken to ensure that the implementation approach is fit for practice and scalable. The pilot should be based on the standards agreed in Recommendation 5. The pilot should be used to inform the decision as to whether the ePrescribing solution should be based on a version of the Health level 7 version 2.x standard or whether now is the appropriate time to adopt the HL7 Fast Healthcare Interoperability Standard.
- In order to support rollout of the solution communication and training, programmes for all relevant individuals should be required.
- Services such as identity and authentications service used in the implementation of the program should be scalable to support other eHealth initiatives and lesson learnt from their use in the programme should be used incorporated into their design.
- A benefits realisation review should be incorporated undertaken at relevant times during the implementation of the project and reported on.

Methodology

The draft recommendations for consultation in this document were developed as per HIQA's legislative remit under the Health Act 2007 and subsequent amendments to the Act. Under the Health Act 2007, HIQA has a statutory remit to develop standards, evaluate information and make recommendations about deficiencies in health information. The responsibilities of HIQA in this regard are outlined in the following sections of the Act:

- Section 8(1)(i): to evaluate available information respecting the service and the health and welfare of the population
- Section 8(1)(j): to provide advice and make recommendations to the Minister for Health and the HSE about deficiencies identified by HIQA in respect of the information referred to in paragraph (i).

Under Section 8(1)(j) of the Health Act 2007, HIQA is charged with providing advice and making recommendations to the Minister for Health and the Health Service Executive (HSE) about deficiencies identified by HIQA respecting the service and the health and welfare of the population.

In 2012, HIQA carried out its first review of international experience of electronic prescribing (ePrescribing) and the electronic transfer of prescriptions. In 2018, HIQA completed a follow-up review, which examined changes in international practices and adoption in the six countries identified in the original review as well as best practices in several other countries that were identified as having made significant progress in the interim.

For the international review, a desktop investigation of ePrescribing-related materials was undertaken. The investigation identified reports, articles and other materials from countries that had achieved or had made significant progress towards full national adoption of ePrescribing. It also included materials from countries where full adoption at regional level had not led to full adoption at national level. Both international reviews concentrated on ePrescribing in primary care, that is, ePrescribing as it occurs typically between GPs and community pharmacists. ePrescribing (and dispensing) can take also take place in secondary or tertiary care — such as hospitals — where it is often known as medication management.

However, secondary or tertiary care presents a different set of challenges and is, therefore, largely outside the scope of the review and these recommendations.

While every effort was made to review all pertinent materials and include all relevant facts, each review was limited by the availability of English-language materials and by widely varying availability of information on each aspect of national, community-based ePrescribing programmes. They were also limited by the paucity of research on national, community-based ePrescribing programmes outside Europe compared with the significant body of available research on national, community-based ePrescribing programmes in Europe.

At the time of the original review, national, community-based ePrescribing programs were well underway in many countries.[7] These programs prompted much subsequent research on the factors that led to, or hindered, the successful adoption of ePrescribing.[1,4,5,8,9,10,11] Thus the follow-up review drew on a wealth of findings, together with materials from each national, community-based ePrescribing programme, to identify factors that contributed to the success of national, community-based ePrescribing programmes. This research found that other aspects, including governance, strategy and stakeholder engagement, of a national ePrescribing program were equally important to successful adoption and, if neglected, could derail the programme.[4] The follow-up review also captured the EU standards that have been adopted, which are directly relevant to the Irish context. Following the completion of the international review, HIQA has undertaken to develop a set of recommendations to the Minister for Health, based on the findings of the review.

Advisory Group

As part of the development process, and in line with its legal remit, HIQA has set up an ePrescribing Recommendations Advisory Group consisting of representatives from a range of stakeholder organizations. These organizations are listed in Appendix A.

The Advisory Group was asked to consider both the evidence in *ePrescribing: An International Review* and the first draft of the Draft Recommendations for Consultation (this document), which was developed based on the findings of the 2018 review. The Advisory Group has made submissions in respect of the recommendations, which HIQA has taken under advisement and appropriate changes have been made.

Next steps

The Draft Recommendations for Consultation will be made available for public consultation on Friday 22 June 2018. The public consultation will run for six weeks, closing on Friday 3 August 2018. Appendix B documents the consultation questions and provides information on how to make submissions to the consultation.

Once the public consultation is complete, the Draft Recommendations for Consultation document will be updated with all accepted changes and then circulated to the Advisory Group for final review at the meeting on 14 August 2018.

The final Draft Recommendations will then be approved by each level of the HIQA organization — Directorate, Executive Management Team, and Board — before being submitted to the Minister for Health and being published on the HIQA Website.

Chapter 1 Background

This document contains draft recommendations for consultation in respect of the national, community-based ePrescribing programme in Ireland. The recommendations are based on factors that have been found to support the success of national, community-based ePrescribing programmes. HIQA's *ePrescribing: an International Review* is published as a companion to this Draft for Consultation document and available at www.hiqa.ie.

1.1 Introduction to ePrescribing

The United States Centers for Medicare and Medicaid Services state that 'ePrescribing is a prescriber's ability to electronically send an accurate, error-free and understandable prescription directly to a pharmacy from the point-of-care, an important element in improving the quality of patient care.'[12] This definition captures the generation of the prescription, the transmission of the prescription from prescriber to pharmacy and the pharmacy's dispensing of the prescription.

In a similar manner, the original Fifth Community Agreement between the Australian Department of Health and the Pharmacy Guild of Australia includes the following concepts: the prescriber's ability to generate an accurate prescription electronically, the electronic transfer of the prescription to the dispenser and the dispenser's ability to receive and dispense the prescription. It also states explicitly that the prescription must be signed digitally, transmitted securely and integrate with the pharmacy billing system.[13]

The European Patient Smart Open Services (epSOS) initiative, which sought to develop an eHealth infrastructure that would enable seamless and secure access to patient health information across borders for European citizens, defined the ePrescribing process as having two parts:

- **ePrescribing** is defined as a prescriber's ability to electronically send an accurate, error-free and understandable prescription directly to a pharmacy from the point of care.[14,15]
- **eDispensing** is defined as the act of electronically retrieving a prescription and reporting on giving the medicine to the patient as indicated in the corresponding ePrescription.[15]

These international programmes reflect the general understanding that the term ePrescribing is used to describe all aspects of the generation and transfer of prescriptions electronically using a dedicated system, whether in paper or electronic from, rather than faxing or emailing the prescription.[1] The same sources consistently identify ePrescribing as taking place in primary care, which involves the generation of the prescription by GPs, the transmission of prescriptions electronically from GP to pharmacy over national networks and the pharmacy dispensing the prescription.

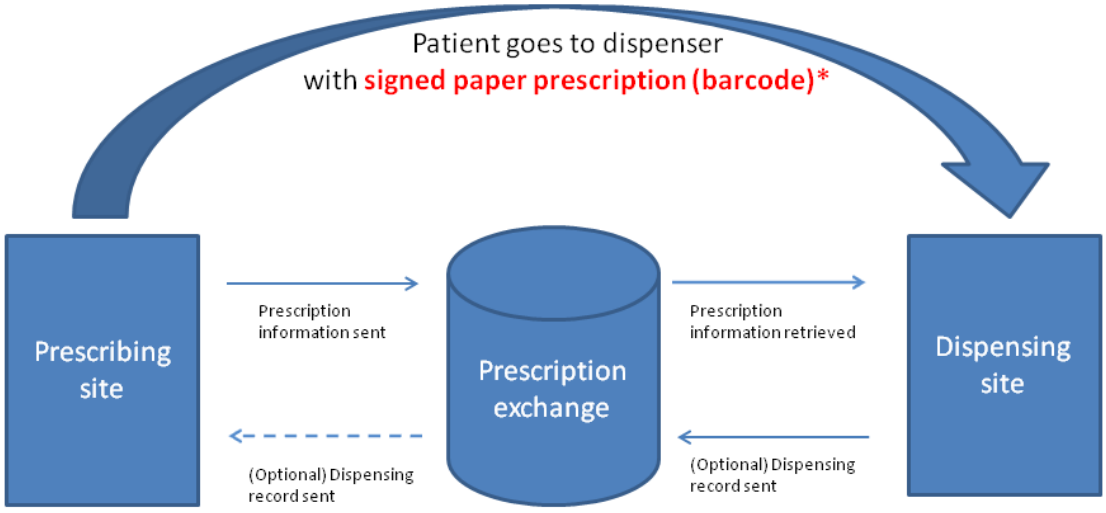

Figure 1. ePrescribing with signed paper prescription as legal document

In this scenario, ePrescribing mimics the paper-script-based business practice and the paper prescription remains the legal document, indicated in red with an asterisk (*):

1. **ePrescribing:** The prescriber generates a paper prescription with a barcode, which the prescriber signs. The barcode can contain either a unique identifier or all the prescription information.

2. **Electronic transfer of the prescription:** The electronic prescription is sent to the prescription exchange, where it is stored until it is downloaded and dispensed.
3. **eDispensing:** The dispenser scans the barcode on the paper prescription, which contains either all of the prescription information or a unique identifier to retrieve the prescription information.

The dispenser can optionally send an acknowledgement that the prescription items have been dispensed.

International programmes usually take a phased approach to implementation. A two-phased approach was adopted in England. During the first phase, a signed, barcoded paper prescription continues to be the legal document, with prescription information transferred electronically in parallel. This approach allows time for stakeholders to build skills and experience the benefits of ePrescribing as well as for the requisite legislative changes to be introduced. This provides a solid foundation for the second phase, when the digitally signed, electronic prescription is the legal document.

A two-phased approach was also adopted in Australia, with two similar levels of implementation levels supported — first, with the paper prescription as the legal document, and, second, with the electronic prescription as the legal and definitive document. Both levels assumed that prescription information was transferred electronically through a message broker. However, the Australian implementation approach supported direct transfer from GP practice to pharmacy as a temporary and interim measure.

These implementations, and ten others, are described in detail in the accompanying document, *ePrescribing: An International Review*. ePrescribing has been introduced, or is on the roadmap for introduction, in many more countries worldwide. ePrescribing has been shown to deliver significant benefits for patients and stakeholders alike.

1.2 Benefits of ePrescribing

A national, community-based ePrescribing programme can deliver significant benefits for patients, prescribers, pharmacists and others involved in the process.[1] In particular, ePrescribing can improve patient safety considerably, for example, by reducing errors of mistaken identity, incorrect dosage, incorrect medication and adverse drug interactions. It

can resolve challenges concerning overlapping medications and improve medication practices. It can also reduce the number of pharmacist interventions significantly. ePrescribing can cost far less and takes less time than processing the same prescriptions manually, saving time and money.

1.2.1 Time savings and efficiency gains

Swedish physicians estimated that electronic prescribing saved them about 30 minutes daily.[4,7] Estonian physicians estimated that repeat electronic prescriptions took about 10–15 seconds, with new prescriptions taking about 30–60 seconds.[4,9] The manual processes had not been timed and so no comparison was possible, making these perceived rather than measured time savings.[9] UK physicians saw repeat prescriptions as one of the top advantages of ePrescriptions.[16] UK physicians' estimates of time saved differed, and while most GPs found it faster to generate prescriptions electronically, others found signed paper-based prescriptions faster.[17]

ePrescribing also resulted in efficiency gains for pharmacists, included better stock management and less paperwork at the end of the month.[18] In research from 2016, 55% of Swedish pharmacists felt that they saved time using electronic retrieval and dispensing.[18] However, UK pharmacists could wait up to 30 seconds for a prescription to be downloaded from the prescription exchange.[18] Evidence is mixed on whether ePrescribing reduced callbacks between prescribers and pharmacists: early UK studies showed a drop from 6% to 1%.[19] However, a review of more than 30,000 Swedish prescriptions showed that 2% of electronic prescriptions required a callback compared to 1.2% of paper prescriptions.[20]

NHS Digital estimated that, over the three years from 2013 to 2016, the 'transformative' electronic prescription service (EPS) saved the NHS £130 million.[21] Prescribers saved £327 million, while pharmacists saved nearly £60 million over the same period.[21] NHS Digital also reported significant time savings for prescribers, for pharmacists and for patients.[21] For example, pharmacists reported saving on average 54 minutes per day through faster dispensing and 43 minutes per day through fewer trips to GP practices to collect paper prescription forms.

1.2.2 Health and social benefits

Health benefits from ePrescribing included reduced medication errors, with approximately half of the 17% of patient hospitalizations through error being considered avoidable.[4] The Estonian Health Information Fund estimated that 80,000 (6%) of patients would benefit from the error reduction aspect of ePrescribing, while prescription errors were reduced by 15% in Sweden.[4] ePrescribing can make time-critical medications more readily available, for example, Estonian data indicates that increased availability of emergency contraceptives was correlated with use of ePrescribing.[4] ePrescribing can also provide useful data on patients' adherence (or otherwise) to prescribed medications, which can prompt policy measures to encourage adherence.[4] In the United States, Surescripts reported that electronic prescribing drove a 10% increase in patient first-fill medication adherence,* which reduces hospital readmissions and improves patient care.[22,23]

Research also looked at the social benefits of ePrescribing.[4] In 2016, the percentage of patients who were satisfied with the ePrescribing service was high in Estonia (92%) and Nordic countries such as Sweden (85%).[18,24] However, patient satisfaction is often based on the improvement that patients experience, for example, before the introduction of ePrescribing, UK pharmacists often collected patients' prescriptions from the GP, so patients experienced no change in service.[4,25] Patient satisfaction may also be affected by the implementation, for example, in the second phase of the UK implementation some patients felt constrained by having the option to nominate a pharmacy, rather than being able to drop in wherever they wished.[4] ePrescribing may also reduce patients' involvement, for example, the patient may need a doctor or pharmacist to tell them where in the process their ePrescription is.[4] Finally, ePrescribing may provide financial savings for countries and improve social care for the elderly.[4]

1.2.3 Cost benefits

While Estonia saw the reduction of a small incidence of fraud thanks to ePrescribing, the benefits it realized in direct economic costs were far greater.[4,9] Printing costs for paper prescriptions dropped from €63,668 in 2009 to around €1,000 in 2010.[4] This meant that

* Medication adherence indicates whether the patient has followed the course of treatment. First fill adherence means whether the patient fills a new prescription for the course of treatment, a prerequisite for medication adherence. Factors that influence a patient's medication adherence are of significant interest, as medication adherence has a huge impact on the success of the course of treatment.

the country's investment in the ePrescribing system was almost completely offset by the savings on the printing and secure storage of the forms.[4] However, in the UK, the second phase of their solution potentially increased paper usage because GP printed prescriptions for patients who request them while pharmacists often print them to check.[25]

Any economic gains need to be offset against the implementation costs.[4] In Estonia, direct total implementation costs were estimated at €500,000 by 2016.[9] That figure includes once-off system implementation costs and annual maintenance costs but excludes large scale costs of project management, system integration and other operating expenditures.[4] However, Swedish numbers showed that these costs need to be viewed over several years.[26] By 2008, the cumulative investment costs over the eight years since nationwide implementation were estimated at €155 million, while the estimated cumulative benefits were estimated to be €330 million.[26]

However, ePrescribing does not always results in cost reductions. In spite of the combined effort of the Australian Commonwealth, the Australian Pharmacy Guild, and the two Australian prescription exchange operators, eRX and MediSecure, electronic prescribing remains a high cost for the Australian state. Under the Sixth Community Pharmacist Act (FCPA), Australian pharmacists continue to be paid 15 cents for each electronic prescription dispensed to offset the 15 cents that eRX and MediSecure charge for each digital prescription processed.[27] However, eRX reported dispensing 753,000 electronic prescriptions at a cost of AU$112,950 per day.

1.2.4 Transparency and fraud detection

When researchers investigated whether ePrescribing improved transparency, they found that prescribers were more accountable for what they prescribed in terms of adhering to clinical guidelines, while pharmacists' practices around the medications they dispense and how quickly they dispense were more transparent.[4] The Estonian system displayed the active ingredient rather than the brand name to GPs, who must justify adding a brand name.[4] Prescriptions by active ingredient, rather than brand name, went from 50% to 90% of all prescriptions, which reduced patients' costs by about 25%, though the Estonian Health Insurance Fund's pharmaceutical costs were not reduced overall.[4]

ePrescribing can also counteract fraud, creating audit trails that make it more difficult to obtain or redeem multiple prescriptions, with faster detection of abuse and fraud.[28] Fraud reduction was the main driver behind the introduction of ePrescribing in Northern Ireland, where losses had been estimated as being more than £7 million.[4,29] In Estonia, ePrescribing revealed a small group of single doctors misusing their entitlements to obtain psychotropic drugs in collaboration with criminal groups.[4]

1.3 ePrescribing in Ireland

The vision for the Irish national, community-based ePrescribing programme is set out in the Department of Health's eHealth strategy. The goal of ePrescribing strategy in Ireland is to reduce medication errors, thereby reducing the associated costs and speeding up patient access to medication.[3] The eHealth Ireland organization is responsible for realizing this vision and, in June 2015, announced the National ePrescribing Programme, which included ePrescribing in primary care and the National Medicinal Product Catalogue among its projects.

The national, community-based ePrescribing programme also published its plan for a phased, standards-based implementation. The programme's phased approach included the development of the initial building blocks (phase 1), leading to an 'ePrescription' phase (phase 2), followed by the roll out of ePrescribing in primary care (phase 3). The adoption of a phased, pilot-based approach is in line with recommendations and best practices.

Research also indicated the importance of an interoperability framework for secure information exchange with other services, such as an electronic medical record system. A

system to uniquely identify citizens was also a crucial component, with the system required to uniquely identify healthcare professionals such as GPs and pharmacists.[1]

As part of phase 1, eHealth Ireland worked with a number of organizations to develop a relevant interoperability framework based on national and international standards. HIQA, whose statutory remit includes developing national technical standards for health information, has defined and agreed the related standards for messaging and datasets, including:

- *ePrescription dataset and clinical document architecture standard* (March 2015)[30]
- *Data model for an electronic medicinal product reference catalogue – a National Standard* (March 2015)
- *National Standard for a Dispensing Note including a Clinical Document Architecture specification* (January 2017).[31]

In November 2016, the Irish Department of Health acquired a national licence for SNOMED when it became the 29th member of SNOMED International. Moreover, national health identifier legislation has been passed, permitting the creation and use of the Individual Health Identifier. As discussed, all successful national, community-based ePrescribing programmes used a national patient health identifier, which now has the legislative basis for use in Ireland.

Two ePrescribing pilot projects have also been undertaken. The first pilot, which transferred prescription information directly from GP to pharmacy, indicated that using a transaction broker was preferred. In the second pilot project, GPs sent the prescription information to the cloud and generated the legal paper script, which included a barcode. Pharmacists then scanned the barcode, ensuring the correct prescription information was downloaded.

Chapter 2 Recommendations

The following recommendations are intended to support the successful adoption and implementation of a national, community-based ePrescribing programme in Ireland.

2.1 Scope

International evidence shows that successful national, community-based ePrescribing programmes typically had a clearly defined business case and roadmap.[1,4,5,17] The business case showed the benefits that the national, community-based ePrescribing programme was expected to realize as well as metrics to evaluate the success of the programme, such as user satisfaction surveys of patients, GPs, and community pharmacists. The business case also identified overall projected budgets, resourcing and timelines for the programme.

Evidence from successful national programs showed that each roadmap was agreed by all organizations and agencies involved and each demonstrated how the different elements of the programme would combine to realize the expected benefits. Programme roadmaps also showed an understanding of the larger context of the programme, indicating how the ePrescribing solution would integrate with existing and planned eHealth services and programmes, for example, several national ePrescribing systems relied on their national medicinal product catalogue being updated automatically fortnightly or monthly.

As part of roadmap development, successful countries typically carried out a detailed stakeholder analysis, which identified each of the stakeholder groups that would either play a part in or be affected by the programme. Stakeholder groups included patients, general practitioners (GPs), community pharmacists, GP practice management software vendors, and pharmacy management software vendors among others. The expected programme benefits were then reviewed and analyzed for each major stakeholder group, as well as each group's broad requirements. The roadmap also detailed the need for piloting of standards to support stakeholder requirements.

Finally, the evidence showed that the business case and roadmap were usually formally agreed by all organizations and agencies involved in the programme, who supported the

prioritization of programme elements and the rollout of the programme and committed the necessary finances and resourcing to the project.

Recommendation 1 — Scope and legislative requirements

The national, community-based ePrescribing programme should be defined with input from key stakeholder, and an ongoing collaborative approach between stakeholder organisations should be established. A roadmap should be agreed by organizations and agencies involved in the programme, who should prioritise supporting programme elements and the rollout of the programme. The roadmap should clearly articulate that community-based ePrescribing is scope of the project. It should outline a clear vision, including an effective governance structure, support for data privacy, the need for a detailed stakeholder mapping and engagement plan, a standards-based approach and a phased implementation plan incorporating lessons learned from pilot projects previously undertaken. Once the scope is defined, the legal requirements to implement the programme must be reviewed and clearly set out. The roadmap should outline the benefits expected for stakeholders and organisations and identify any risks to the overall programme. Finally, the roadmap should show how the national, community-based ePrescribing programme will integrate with existing and planned eHealth services, including future hospital-based medication management capabilities.

HIQA recommends:

- The programme should be undertaken as a collaborative approach between the major stakeholders.
- The legal requirements should be outlined and supporting policy and legislative changes should be developed.
- A roadmap should be developed for the programme.
- A detailed business case, including the benefits and costs, should be developed for the programme.
- The programme should be prioritized by the organisations involved to support successful implementation.
- Benefits should be identified and articulated at an early stage, including the benefits to be realized for patients, for prescribers, for pharmacists and for broader stakeholders.
- The two existing pilots should be formally reviewed and the lessons learned should be published.

2.2 Governance

Successful national programmes typically had a clear governance structure for ePrescribing, together with a clear and specific ePrescribing strategy.[1] The board of governance, or similar body, is usually responsible for governance of ePrescribing standards and infrastructure, for example, overseeing the development of national standards, engaging stakeholders and national messaging and broker services among other ePrescribing activities.[1] Thus, a crucial requirement is a clear vision defined in the ePrescribing roadmap, developed and supported by a board of governance with the ability to agree appropriate standards and other factors.

In Norway, the Norwegian Directorate of eHealth coordinates the development and delivery of eHealth services, including ePrescribing. The directorate works closely with key stakeholders and developed the Norwegian health network with special focus on these stakeholders' needs. Similar, NHS Digital regulates all architecture and standards for the transfer of health information in England, including the ePrescribing service. Furthermore, although healthcare is organized at regional level in Sweden, the Swedish eHealth Authority retains organizational responsibility for ePrescription.

The Danish eHealth authority, Medcom, was established in 1994 as a publicly-funded, non-profit cooperative body to develop standards and profiles for the exchange of healthcare-related data in the Danish healthcare sector. All ePrescribing and eHealth-related programmes in Denmark are coordinated by MedCom. From its inception, Medcom focussed on strategic areas in turn, first developing messaging standards and infrastructure, then moving on to develop the web portal and other areas. Medcom also takes a proactive approach, training software suppliers in the software specifications it develops, and it is considered to be one of the most important factors in the success of Danish eHealth programmes.

In contrast, the Dutch situation is less centralized and more complex. Work on ePrescribing systems began in the 1990s. However, following a decision by both houses of parliament in 2011, healthcare infrastructure was transferred from public to private ownership and healthcare providers were allowed to connect to any infrastructure of their choosing. This

decision resulted in the development of a number of regional infrastructures in parallel, which have yet to achieve full interoperability.

Research has found a correlation between the national health system within a country and the successful adoption, or otherwise, of ePrescribing.[14] First, the research categorized the health systems used in Europe using commonly agreed criteria:

- National Health Service Model or Beveridge model: healthcare is largely provided by a single, state authority, which may also be able to set standards and incentivize (or enforce) compliance.
- Social Insurance Service Model or Bismarck model: healthcare is supplied by a combination of public and private providers, typically funded from an insurance system that employers and employees deduct from payroll.
- Transition countries: healthcare systems are in transition, as these are largely former Eastern Bloc countries.[14]

Then the researchers reviewed ePrescribing adoption in EU countries and found that countries with a Beveridge model were most likely to have adopted ePrescribing.[14] Countries with a Bismark model typically had a lower rate of adoption than Beveridge model countries, which may be a result of the decentralized nature of the governance structure.[14] Finally, transition countries were found to be the least likely to have adopted ePrescribing.[14]

However, Estonia was found to be a exception, being a transition country that is considered one of the most digitally advanced nations in the world. One factor in this success may be that, similar to the Beveridge model, Estonia has a single public payer. This payer, the Estonian Health Insurance Fund, not only developed the ePrescribing service independently of the other eHealth services — usually developed by another dedicated standards institution — but could incentivize use, which spurred adoption of the ePrescribing service.

This reflected another implication of the same findings. Where a country did not have a centralized health system, a single national governance body that articulated and implemented a clear vision for ePrescribing could create the conditions that would ensure the success of the national, community-based ePrescribing programme.

Recommendation 2 — Governance

A formal board of governance, with representatives from all stakeholder organizations and groups should be established to provide leadership for the national, community-based ePrescribing program. The board of governance needs to consider how it will balance a clear national vision, articulated in the ePrescribing roadmap, with a real understanding of local needs. The programme governance remit shall include engaging stakeholders, ensuring a standards-based approach is adopted and monitoring risk, implementation and deployment among other ePrescribing activities.(1)

HIQA recommends:

- A programme board should be established to advice and support the project team.
- The programme board should be representative of all stakeholder organisations and groups, which should be reflected in the makeup of the governance structure.
- Clinical leadership should be embedded within the programme with responsibility for the case for change, to the specification of requirements, through to the delivery phases of the programme.
- A detailed project plan should be agreed and progress against timelines should be reported at key intervals.
- Risks, together with controls and mitigating actions, should be documented and managed appropriately.

2.3 Data privacy

The General Data Protection Regulation emphasizes the need for transparency, security, and accountability when collecting and processing EU citizens' data and supports EU citizens' rights to data privacy. The Irish Data Protection Commission outlines the eight responsibilities of data controllers and processors in this respect:

- obtain and process information fairly
- keep it only for one or more specified, explicit and lawful purposes
- use and disclose it only in ways compatible with these purposes
- keep it safe and secure
- keep it accurate, complete and up-to-date
- ensure that it is adequate, relevant and not excessive
- retain it for no longer than is necessary for the purpose or purposes
- give a copy of his/her personal data to an individual, on request.

Data must also be stored securely, and access should be granted only to the correctly authorized personnel, with the citizen's consent. Note that information collected for one purpose is still subject to those regulations when shared with another system, for example, in Norway, the ePrescription infrastructure and the Summary Care Record infrastructure are under different governance rules. The ePrescription infrastructure is only allowed to store prescriptions while they are valid, while the Summary Care Record infrastructure can store them for up to three years.

An end-to-end privacy impact assessment would ensure compliance with the General Data Protection Regulation and identify any lacunae, such as the need for legislation recognizing digital signatures or requirements for audit trails using robust authentication services. It would also clarify how best to inform the citizen/patient regarding the proposed use of their data and to obtain their consent, in the context of the overall ePrescribing service.

Legislative and policy changes will required for an electronic prescription to be recognized as a legal prescription in Ireland. These changes include legislation for digital signatures and other measures.

Recommendation 3 — Data privacy

Ensure that the collection and processing of patient data meets the requirements of data protections legislation, including the General Data Protection Regulation. To this end, it is recommended that an end-to-end privacy assessment of the entire ePrescribing lifecycle should be undertaken and the findings published. The assessment should include the patient's consent to use of their data at each stage of the lifecycle. Data generated within the systems will provide benefits including clinical audit and clinical improvement but primary and secondary use of information within the system must be within agreed limits and legislation.

HIQA recommends:

- The project should be undertaken in line with all data protection legislation. A thorough privacy impact assessment should be undertaken and made publicly available.
- Consent to collect information and subsequent access to and sharing of the information collected should be monitored. Information should be retained only for the purpose(s) for which it was collected.
- Primary and secondary use of information within the system must be within agreed limits and legislation.
- Access to the information should be undertaken using robust authentication services, which should also be monitored and audited.

2.4 Stakeholder engagement

Researchers noted countries with successful national, community-based ePrescribing programmes balanced a compelling vision with strong local engagement, combining both 'bottom up' and 'top down' approaches.[1,4,5,6] Effective national community-based ePrescribing systems take account of end-users' requirements, that is, the needs of patients, GPs, community pharmacists and others, and ensured that stakeholders were committed to the programme.[1,4,5,6] For example, the Danish programme leadership preferred to introduce the national, community-based ePrescribing programme on a voluntary basis, and when stakeholders had experienced the benefits, made the system mandatory.[4] MedCom, the Danish publicly-funded, non-profit cooperative body worked closely with key stakeholders to gain consensus on the standards to be implemented and provided training that enabled stakeholders to understand the benefits of the system.

The leaders of the Swedish national, community-based ePrescribing programme also gained and retained the cooperation of all stakeholders, which was considered a key factor in successful adoption.[4] The Estonian Health Insurance Fund took a more centralized, but nonetheless successful, approach by mandating use of the ePrescribing service they had developed first for reimbursement and gradually for the whole ePrescribing process.

A national, community-based ePrescribing solution needs to be well-designed for the business process of stakeholders including GPs and community pharmacists.[4,5,6] Where the ePrescribing solution improves this business process, and where stakeholders are aware of this improvement, stakeholders are much more likely to adopt the system.[4] In Denmark, GPs adopted the electronic medication record because it provided an integrated and complete list of medication, with contraindications and up-to-date prices, which was far faster than the paper-based process.[4] In contrast, UK interviewees told researchers that the ePrescribing systems needed to be optimized, for example, owing to the number of alerts they generated.[4] These shortcomings were attributed, at least in part, to vendors having little incentive to support interoperability or to innovate.[4]

Recommendation 4 — Stakeholder engagement and communication strategy

Those responsible for programme governance need to work closely with all stakeholder groups and organisations as equal stakeholders, including but not limited to patients, prescribers, pharmacists, vendors, and funding and reimbursement services, in order to understand their needs fully and to gain consensus on the solution to be implemented. A national, community-based ePrescribing solution needs to be well-designed for the business process of stakeholders, including GPs and community pharmacists. They also need to educate stakeholders about the benefits to their groups, which should spur adoption of ePrescribing in the community.[4,5,6] The communication strategy should include continued communications with all stakeholders, including the public, throughout implementation.

HIQA recommends:

- The programme should be inclusive of all stakeholders, and stakeholder engagement should be central to all stages in the programme.
- As part of engagement, stakeholders' requirements, business processes and benefits should be elicited and documented and then used to inform the development of relevant standards and implementation solutions.
- Requirements should be gathered through multiple methods, including stakeholder interviews, focus groups, advisory groups and public consultation.
- Software vendors who will develop solutions to support the programme should be engaged in an open and transparent way.
- Communication plans should be developed and awareness sessions with stakeholders should be undertaken throughout the lifecycle of the programme. The communication strategy should include continued communications with all stakeholders, including the public, throughout implementation.
- Materials such as supporting documentation for programme implementation and meeting minutes should be published in a timely manner.

2.5 Standards-based approach

An effective vision includes clear agreement on technical aspects of strategy, such as implementation approach and common standards.[1,4,5,6] Research again indicated the importance of an interoperability framework for secure information exchange between prescribers and pharmacists and a data model and minimum dataset, including reference catalogues.[1,4] Countries with a successful national, community-based ePrescribing programme tended to have established a national infrastructure that spans eHealth services, which avoids the situation of developing similar services — such as for user identification and authentication — for each individual eHealth service.[4]

For example, the Danish eHealth agency, MedCom, defined national standards and tested and approved systems, which avoided the establishment of isolated islands who could communicate only with local partners.[4] From the beginning, prescriptions could be sent to any pharmacy in the country.[4] This common framework can allow for a certain amount of customization to local needs.[4] As noted earlier, part of NHS Digital's remit is setting all national standards for interoperability in England. NHS Wales used their ePrescribing service as a proof of concept for their Minimum System Specification—a mechanism for setting national standards for interoperability, now in widespread use.

In Sweden, INERA AB, the Swedish Association of Local Authorities and Regions' company developed six architecture principles that supported the decentralized development of a health ecosystem. In Norway, regional networks were consolidated into a dedicated secure network, which GPs, hospitals and nursing homes can access. Furthermore, the Estonian ePrescribing service uses only HL7-based messages in its message broker model.

In contrast, the Dutch Government decided in 2010 to remove itself from decisions around healthcare standards and implementations. While the Dutch eHealth organization, NICTIZ retains its brief to coordinate the implementation of health IT projects and to provide governance for eHealth projects, the healthcare infrastructure was transferred from public to private ownership. In effect, any group of GPs or other stakeholders were allowed to adopt any common infrastructure that they wished to adopt. As a result, while regional networks were set up and are well used, the Netherlands still does not have a national ePrescribing system.

An effective set of national standards is considered to include a unique patient identifier.[4] Experts from Denmark and Estonia, two of the most digitally advanced nations, emphasise the widespread use of this patient identifier in everyday life.[4] In Denmark, unique health identifiers for patients have existed since 1966. A suitable legal framework is also necessary to protect citizens' data.[4]

Several researchers noted that ePrescribing is usually part of a wider strategic program of eHealth services, which is indicative of a certain maturity in the digitization process.[4,8,10] An ePrescription service is seen as part of a 'family' of eHealth services, without which it may be far less effective, for example, if health records are kept on paper, there is much more work involved in providing an ePrescription service.[4] Four countries surveyed in the research (Denmark, Estonia, Sweden and the United Kingdom) introduced electronic medical records and ePrescribing concurrently.[4] In contrast, piecemeal introduction of eHealth services, including ePrescribing, can have adverse consequences in terms of service interoperability and results in fewer benefits.[4]

Recommendation 5 — Standards-based approach

A standards-based approach to community-based ePrescribing should be undertaken. Informed by stakeholder requirements, international standards should be localised to support Irish needs. Based on international evidence, a phased message brokering solution supporting the transfer of electronic prescriptions from prescribers to pharmacists should be implemented, building on the infrastructure of the national messaging broker (Healthlink). A diverse range of standards are required, including but not limited to information models, identification services, authentication services, security standards, messaging standards and reference models. Continuous review of the implementation of the ePrescribing solution should be undertaken by the board to ensure a robust standards-based approach is being implemented.

HIQA recommends:

- Business requirements and process flow should be specified and documented.
- Information requirements should be specified and documented and a data model developed.
- A diverse range of standards are required, including but not limited to standards for identity management, authentication and security. Standards-based services should be implemented and utilised in the ePrescribing programme.
- Messaging specification should be developed based on Health Level 7 (HL7) standards. The version of HL7 currently in use in Ireland is v2.4, which was approved in 2000. Subsequent revisions of the standard incorporated specific enhancements related to ePrescribing and should be considered. HL7's Fast Healthcare Interoperability Standard, in development since 2012 and close to normative status, should also be considered as a candidate for implementation.
- An up-to-date and regularly maintained national medicinal products reference catalogue describing all prescribable and dispensable items should be developed and integrated into the ePrescribing solution.
- Relevant clinical terminologies and classification systems such as SNOMED CT, LOINC ATC codes should be integrated with information models, messaging specifications and other products such as the national medicinal products reference catalogue required to support the ePrescribing solution.
- Data quality should be to the forefront of the programme and standards. Data quality should be integrated into the process. A data quality framework should be developed and

implemented so as to ensure the highest possible quality data is shared in the implemented ePrescribing solution.

2.6 Implementation

A coordinated, phased rollout was also considered crucial to the success of an national, community-based ePrescribing programme.[4] As a small country, Estonia used a 'big bang' implementation approach, with the ePrescribing system implemented simultaneously throughout the country.[4,9] However, shortcomings in the piloting process meant that only when the system was implemented was it discovered that it could not tolerate the load. GPs were instructed to use paper prescriptions for six months while the issues were resolved.[4,9] Thus, managing expectations is now considered to be vital — it is important that the benefits of ePrescribing are not over stated and to indicate that there will always be some issues to resolve.[4]

Effective piloting was also identified as crucial. Some UK implementations, which involved multiple systems, experienced similar technical problems that were subsequently compared and resolved.[4] The structured and highly successful Swedish implementation strategy started with a central pilot in Stockholm, followed by competition driven rollouts in each locality.[4] Each locality planned their own training and operational startup and conducted evaluation meetings for three to six months after operations began.[4]

For larger countries, such as the UK, a phased approach was necessary to cope with the size and resulting complexity.[4] A phased approach also meant that early successes built momentum for later phases in the implementation cycle.[4] Stakeholder support could also be built gradually, with research indicating that early engagement of programme champions and management of strong dissenters contributing to success.[4]

Researchers note that the installed base, that is, the technologies, systems, and business processes already in use, has been shown to have a huge impact on eHealth services, including an ePrescribing service, that a national programme seeks to implement.[5] The pre-existing built environment, the standards already adopted and the existing and planned services need to be considered when deciding the technical architecture, standards and other aspects of the final ePrescribing solution.[5] All of Europe's ePrescribing leaders have some work remaining, for example, some systems use databases with unstructured information that require coding and possibly translation into English before the data can be usefully integrated with the ePrescribing service and other eHealth services.

In Norway, vendors originally started to develop ePrescribing functionality as part of GP practice management software. However, when the GP software vendor with 75% market share struggled to develop the ePrescribing functionality in its main product, the future of the entire national, community-based ePrescribing programme looked uncertain. The Norwegian Minister for Health indicated that she could not accept this uncertainty and the vendor decided to develop the ePrescribing module as a separate product. This separate ePrescribing product — and the Norwegian programme —were ultimately successful but the episode shows the complications that arose.

Additionally, where stakeholders are already using other eHealth services, the adoption of ePrescribing processes is less disruptive and can take advantage of investments already made, for example, where GPs were already receiving laboratory test results and hospital discharge summaries electronically, they had already invested in the necessary software and understood the benefits of electronic exchange of clinical documents.[4]

ePrescriptions may raise questions of privacy, which rest on public trust in the institutional handling of sensitive data.[4] Prior to the introduction of the ePrescribing service, Estonia had built trust by gradually introducing useful eHealth services, without any failures and with effective penalties for small data breaches.[4] In Denmark and Sweden, decades of research and investment in ePrescribing have also built public trust gradually.[4] In Denmark, Estonia and Sweden, citizens are also used to using eServices to file taxes, to vote and to sign documents electronically.[4] In contrast, UK NHS data breaches are more commonly reported and willingness to disclose personal information for eServices is lower.[4]

Recommendation 6 —Implementation

Programme governance should also include clear agreement on a pilot-based, phased implementation approach. Effective piloting can help to identify potential issues and proactively resolve them ahead of wider implementation. Using a phased approach allows these issues to be identified then resolved iteratively, which can help to improve performance and stakeholders' experience of the system. A phased approach also facilitates early input from stakeholders, which can help to build momentum for later stages. An ePrescription service should also be implemented as part of a 'family' of eHealth services, without which it may be far less effective.

HIQA recommends:

- A phased model of implementation informed be research and international best practice localised to support Irish needs should be undertaken.
- A further pilot is undertaken to ensure that the implementation approach is fit for practice and scalable. The pilot should be based on the standards agreed in Recommendation 5. The pilot should be used to inform the decision as to whether the ePrescribing solution should be based on a version of the Health level 7 version 2.x standard or whether now is the appropriate time to adopt the HL7 Fast Healthcare Interoperability Standard.
- In order to support rollout of the solution communication and training, programmes for all relevant individuals should be required.
- Services such as identity and authentications service used in the implementation of the program should be scalable to support other eHealth initiatives and lesson learnt from their use in the programme should be used incorporated into their design.
- A benefits realisation review should be incorporated undertaken at relevant times during the implementation of the project and reported on.

Chapter 3 Conclusion

International evidence showed that successful ePrescribing programmes have both a very clear scope and a detailed business case that outlined both expected benefits and costs. The governance structure of each programme was defined from the outset, as was the programme's business owner or sponsor. Data privacy was also a high priority, with robust guidelines developed, for example, for data collection and access and for consent such as in cases where psychiatric medication had been prescribed. Stakeholder groups, including the public, were identified and engaged early in the programme and regular communication continued throughout the lifetime of the programme. Effective programmes also sought and reached clear agreement on common standards that should be adopted and on the implementation approach.

These programmes typically implemented their national, community-based ePrescribing programmes first. The community-based implementation facilitated the piloting of standards, such as for robust authentication services, and the lessons learned were used to inform the later, more complex implementation of medication management in secondary settings. Stakeholders from secondary care were usually engaged from the beginning of the programme in order to highlight the future implications of ePrescribing for secondary care and to ensure that future requirements for medication management were understood.

These Draft Recommendations are based on this international evidence and have been further developed in collaboration with the groups and organizations listed in Appendix A. The Recommendations will be made available for a six-week public consultation, running from Friday 22 June to Friday 3 August 2018. Appendix B documents the consultation questions and provides information on how to make submissions to the consultation.

Once the Public Consultation is complete, the Draft Recommendations for Consultation document will be updated with all accepted changes, then circulated to the Advisory Group for final review at the meeting on 14 August 2018. The final Draft Recommendations will then be approved by each level of the HIQA organization — Directorate, Executive Management Team, and Board — before being submitted to the Minister for Health and being published on the HIQA website.

Appendix A Advisory Group membership

The following groups and organizations participated in the Advisory Group:

- Irish Pharmacy Union
- Access to Information Programme (HSE)
- Council of Clinical Information Officers (HSE)
- Department of Health
- ePharmacy (HSE)
- General Practice IT Group
- Health Products Regulatory Authority
- Hospital Pharmacists Association of Ireland
- Irish College of General Practitioners
- Irish Hospital Consultants Association of Ireland
- Irish Platform for Patient Organizations, Science, and Industry
- National Medicinal Catalogue Programme (HSE)
- Office of the Chief Information Officer (HSE)
- Pharmaceutical Society of Ireland
- Primary Care Reimbursement Service (HSE)
- School of Pharmacy and Pharmaceutical Sciences, TCD.

Appendix B Draft Consultations Questions

The key issue for Ireland is to determine what recommendations can support the success of the national, community-based ePrescribing programme in Ireland. This document is available for public consultation for a six-week period. In this way, the public, service users and service providers will have the opportunity to provide feedback and participate in the development process. We invite all interested parties to submit their views on this document.

Question 1:

Do you wish to add anything to support **Recommendation 1: Scope**?

Question 2:

Do you wish to add anything to support **Recommendation 2: Governance**?

Question 3:

Do you wish to add anything to support **Recommendation 3: Data Privacy**?

Question 4:

Do you wish to add anything to support **Recommendation 4: Stakeholder Engagement?**

Question 5:

Do you wish to add anything to support **Recommendation 5: Standards-based Approach?**

Question 6:

Do you wish to add anything to support **Recommendation 6: Implementation?**

Question 7:

Do you wish to add any other **Recommendation** to these Draft Recommendations?

How to submit feedback

There are several ways to tell us what you think.

Your comments can be submitted by downloading and completing the consultation feedback form available from www.hiqa.ie and e-mailing your completed forms to technicalstandards@hiqa.ie.

You can also print off a copy of the feedback form from our website and post it to us at:

Health Information and Quality Authority
Draft Recommendations for Consultation (ePrescribing)
George's Court
George's Lane
Smithfield
Dublin 7.

For further information or if you have any questions, you can talk to the consultation team by calling (01) 8147683. The closing date for receipt of comments is 5pm on Friday 3rd August 2018.

How we will use your comments

Following the consultation, all submissions will be considered and used as appropriate to inform the work of the Authority and of the eSAG in the development of national standards for eHealth interoperability. The Authority will work with the eHealth Standards Advisory Group to prioritise areas of work where standards should be developed in line with our guiding principles. We would like to thank you for taking the time to submit your comments.

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Health Information and Standards Directorate
Health Information and Quality Authority
Unit 1301, City Gate,
Mahon,
Cork
T12 Y2XT