Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

ePrescription Dataset and Clinical Document Architecture specification (for trial use) - Draft for consultation

Consultation Feedback Form

November 2014

Your views are very important to us. We would like to hear what you think about the draft ePrescription dataset and CDA specification.

Your comments will be considered and will inform the development of the ePrescription dataset and CDA specification. When commenting on a specific aspect of the draft dataset and specification, it would help us if you tell us which element you are commenting on or the table number that you are commenting on.

The closing date for consultation is 5pm on Friday 19 December 2014

You can email your completed form to lmcquaid@hiqa.ie.

About you

Name	Irish Medical Organisation
Address	10 Fitzwilliam Place Dublin 2
Contact details	Ms Vanessa Hetherington vhetherington@imo.ie 01 676 7273
Organisation* ***Please indicate if you are making your submission in a personal capacity only or on behalf of your organisation**	Irish Medical Organisation
Date	5th January 2015

General feedback questions

You may provide us with feedback on the specific questions asked within the consultation document and repeat here (see questions that follow), or alternatively you can provide us with general comments.

Consultation Question 1

Question 1: Are there benefits in having a standardised ePrescription Dataset and Clinical Document Architecture specification and, if so, what are the main benefits?

Please comment
The Irish Medical Organisation (IMO) welcomes the opportunity to comment on *a standardised ePrescription Dataset and Clinical Document Architecture* specification to facilitate electronic prescribing between General Practice and Community Pharmacy in Ireland.

Electronic prescribing can improve patient safety and efficiency by reducing prescription and transcription error and delays in verification. Electronic prescribing is also more secure particularly in relation to the prescribing of controlled drugs where a patient may try to alter their prescription. ePrescribing is a priority programme in the Government's eHealth strategy however the strategy document gives no detail on how ePrescribing is to be developed in Ireland. In a recent submission to the Department of Health on the Draft Misuse of Drugs (Amendment) Regulations 2013, the IMO called on the Department of Health, in the interest of security and efficiency, to consider investing in the development of a package for electronic prescribing similar to the electronic Acute Medication Service (eAMS) which prevails in the NHS in Scotland.

The IMO has received two documents for consultation in relation to ePrescribing – the *standardised ePrescription Dataset and Clinical Document Architecture* and the *standardised data model for a national electronic medicinal product reference catalogue*. Both documents pre-suppose a significant level of IT knowledge and as such it is difficult to assess how user friendly it will be in practice. A practical demonstration of its functionality would allow the IMO to provide a better assessment of its use. The IMO requests that a pilot study is carried out, with the participation of the IMO, in a number of practices, with operatives of variable IT skills, to assure that both the *standardised ePrescription Dataset and Clinical Document Architecture* and the *standardised data model for a national electronic medicinal product reference catalogue* are user-friendly, fit for purpose, does not increase workload for GPs and allows the benefits of ePrescribing to be maximised.

Practice software systems such as CompleteGP, Health One, Helix Practice Manager, Socrates, medtech32 already allow GPs to issue electronic prescriptions the IMO are not aware of any electronic transfer of prescriptions between General Practice and Community Pharmacy. The IMO would request that, when piloting the, HIQA also consult with GP software producers to ensure that the standardised ePrescription Dataset and Clinical Document Architecture can be easily embedded within existing software packages and at minimal cost. The pilot study must also ensure that prescription data can be safely and securely transferred between GP and pharmacy settings.

Ensuring the effective and secure transfer of prescriptions between General Practice and Community Pharmacy has the potential to increase workload for medical practitioners and will require significant resources. The IMO recommends that HIQA carry out an economic impact analysis that compares the cost and benefit of investing in a national package for electronic prescribing (such as the eAEMS) vs the cost and benefit of standardising and maintaining existing Practice and pharmacy systems. The economic impact analysis must include an assessment of medical practitioner workload. A national ePrescribing system could also include a comprehensive medicines formulary that could support doctors in clinical decision making and include those data items that have been excluded from the model such as the adverse effects, drug/allergy, drug/drug and drug/food interactions.

HIQA should ensure that *standardised ePrescription Dataset and Clinical Document Architecture* and the *standardised data model for a national electronic medicinal product reference catalogue* takes into account

the recommendations in the *Guidelines on ePrescriptions Dataset for Electronic Exchange under Cross-Border Directive 2011/24/EU published in* November 2014 by the eHealth Network, (A network of national eHealth authorities from all 28 EU countries and chaired by the European Commission).

For example there is an issue with multiplicity of coding systems for the identification of medicinal products across Europe as highlighted by the EMA (European Medicines Agency) and the CPME (The Standing Committee of European Doctors of which the IMO is a member). The European Medicines Agency is currently compiling a database of all medicines authorised for human use in the EU and EEA established under the legal obligations laid down in Article 57 (2) of Regulation (EU) No 1235/2010.
The Article 57 database provides a European-wide reference and terminology for medicinal product(s) (including information about therapeutic indications, strength, pharmaceutical form and route of administration) that may support the identification and exchange of such information for cross-border ePrescriptions. The guidelines state that Member States will work with the EMA and the European Commission to explore this issue.

Consultation Question 2

Question 2: Have the appropriate classes been included in the ePrescription data model?

Please comment

Consultation Question 3

Question 3: Have all of the appropriate data items been included in the ePrescription dataset? Would you leave out any of the data items listed? Would you suggest additional data items?

Please comment
The IMO would like to make comments on the following data items:

1.6 Gender - gender identity should be as stated by the patient
1.7 Health Identifier – this should be the number or code assigned to an individual under the Health Identifiers Act 2014

2.8 Health Identifier – this should be the number or code assigned to a healthcare practitioner under the Health Identifiers Act 2014
4.6 Medicinal Product Package and 4.7 Number of Packages– it is unclear as to why the size/type of package and the number of packages should be included – the number of doses should be sufficient. Physicians may not be aware of the number of doses contained in a package and may vary depending on the manufacturer.
4.12 Frequency – the frequency a medication is to be administered should be mandatory
4.16 Substitution – There may often be clinical reasons why a prescribed medication should not be substituted for a generic alternative and it is vital that practitioners have the option to include a code for Do Not Substitute rather than resorting to hand writing as per the legislation.
4.17 Indications – The clinical indication is sensitive information and this data item should not be included
5.9 Confidentiality Code – Coding information as R-Restricted or V-Very Restricted is open to variable interpretation. This data item should either be coded as N-Normal or R-restricted.

Table 2 -A data item is also required for the electronic signature of the prescribing physician to ensure that ePrescriptions comply with legislation.

Consultation Question 4

Question 4: Do the explanations provided in Tables 1 – 7 of the consultation document adequately explain each of the data items? If not, please suggest improvements?

Please comment

Consultation Question 5

Question 5: Are there any alterations needed for the clinical document architecture specification? If so, please suggest improvements?

Please comment

As per question 1 above the clinical document architecture pre-supposes a significant level of IT knowledge and as such it is difficult to assess how user friendly it will be in practice. A practical demonstration of its functionality would allow for a better assessment of its use. The IMO recommend that a pilot study is carried out in a number of practices, with operatives of variable IT skills, to assure that the standardised ePrescription Dataset and Clinical Document Architecture is user-friendly, fit for purpose, does not increase the workload for GPs and allows the benefits of ePrescribing to be realised.

3.7 Custodian – The custodian is the organisation that must securely maintain the document. There is no reference to security required.

General Comments

Please provide any general feedback you wish to give below.

Please comment

Thank you for taking the time to give us your views.

Please return your form to us either by email or post:

lmcquaid@hiqa.ie

Health Information and Quality Authority
ePrescription Dataset and Clinical Document Architecture specification (for trial use) - Draft for consultation
George's Court
George's Lane
Smithfield, Dublin 7

If you have any questions on the draft data set, you can contact the consultation team by calling (01) 8147685.

Please return your comments to us either by email or post before 5pm on December 19th 2014.

Please note that the Authority is subject to the Freedom of Information Acts and the statutory Code of Practice regarding FOI.

For that reason, it would be helpful if you could explain to us if you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances.