

**THE PHARMACEUTICAL SOCIETY OF IRELAND**



**Guidance on Data Protection for Pharmacists**

**Consultation Report September 2014**

## **PSI response to the public consultation on draft Guidance on Data Protection for Pharmacists**

### **Introduction**

The Pharmaceutical Society of Ireland produces guidance to support the profession in discharging their legal and professional duties. The PSI has prepared Guidance on Data Protection in order to help pharmacists understand and meet the requirements of Data Protection Legislation which apply to their daily practice. Pharmacists handle personal data every day when dispensing prescriptions, providing pharmacy services and interacting with patients and other healthcare professionals.

This guidance has been prepared alongside the Office of the Data Protection Commissioner, the body responsible for enforcing Data Protection legislation.

### **About the consultation**

A public consultation on the draft Guidance on Data Protection for Pharmacists was held from Monday 23<sup>rd</sup> of June 2014 until Friday 18<sup>th</sup> July 2014. The draft guidance was available to view on the PSI website along with a link to a short online questionnaire to be completed with comments. The option of sending comments in writing, via letter or email, was also provided. Submissions were invited from all pharmacists via the PSI eNewsletter Issue 5, 2014.

A total of 14 submissions were received to the consultation. Of the submissions, 8 individuals completed their details in the online questionnaire but did not respond to any questions on the guidance. These individuals are not included in this report; the other 6 responses are included. Respondents who provided their names or PSI registration numbers are listed in Appendix A.

### **About this report**

This report provides details of the comments received and the PSI response to the issues raised. The guidance has been revised and amended in light of submissions received. This report and the revised guidance will now be submitted to the Pharmacy Practice Development Committee and PSI Council for approval before a finalised version is published on the PSI website.

The PSI would like to thank all who took the time to provide submissions to the consultation.

## Results from the Consultation

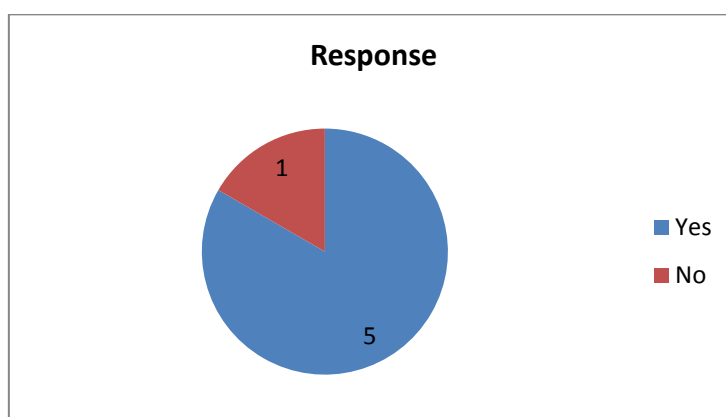
### Respondents Profile

<b>Respondents</b>	
Pharmacists	4
Irish Pharmacy Union	1
Other (pharmacy student)	1

<b>Area of Practice</b>	
Community	3
Representative Body	1
Regulator	1
Pharmacy student	1

### Response to the Consultation Questions

Figure 1. Consultation question: Is the guidance clear and easy to read?

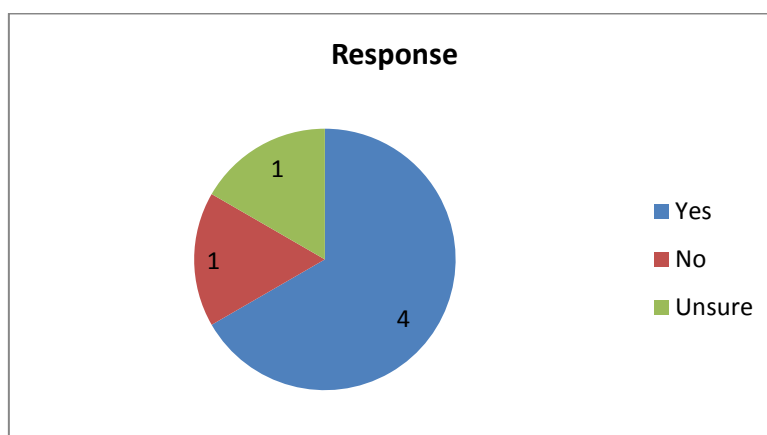


Consultation question: If not, please explain which part and why.

<b>Submission</b>	<b>PSI Response</b>
The guidance is a general overview of data protection. It is too theoretical and does not address the specific issues that a typical pharmacist has to deal with in the course of their work.	This guidance is intended to assist pharmacists in meeting their obligations under data protection legislation and to help them understand how it applies to their daily practice when making professional judgements, writing standard operating procedures and training other staff members. It is not intended to address every scenario that a pharmacist may encounter. It is at the discretion of the pharmacist to decide how to apply this guidance to a situation that they are faced with, taking into account other relevant legislation and their obligations under the Code of Conduct.

<p>I am not clear as to who the data controller 'is' or, perhaps more importantly, ought to be, in a retail pharmacy business. (While the guidelines identify the SIP as responsible, they would probably need to also be the SVP in order to be effective data controllers.) Clarity also required in situations where data is being collated for research purposes etc.</p>	<p>'Data Controller' is defined in the Data Protection Act 1988 and this definition is included in the 'Glossary of terms used' section of the guidance. It is the responsibility of the pharmacy owner/superintendent pharmacist to decide who the Data Controller is within their organisation.</p> <p>With regards to patient information being used for research purposes, the Data Protection Commissioner has produced a document entitled <i>Data Protection Guidelines on research in the Health Sector</i> which is available to view on their website <a href="http://www.dataprotection.ie">www.dataprotection.ie</a>. A reference to this document has been added to the PSI guidance to direct pharmacists who require more information in this area.</p>
<p>It is very long.</p>	<p>Noted.</p>

Figure 2. Consultation question: Is it clear how the 'Eight Principles of Data Protection' relate to the handling of personal data by pharmacists?

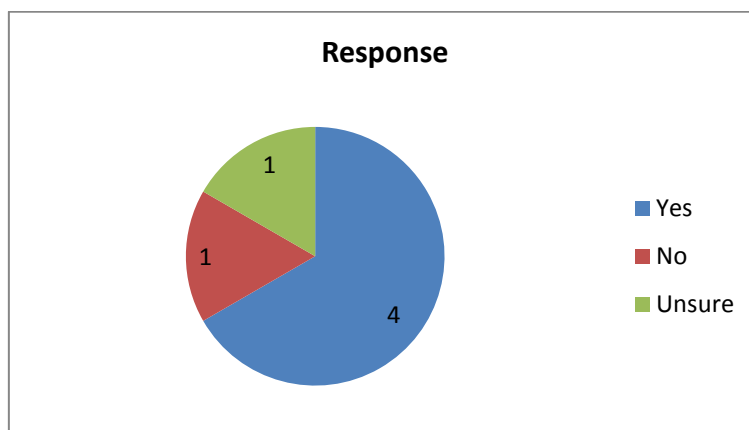


Consultation question: If not, please explain which of the principles are unclear

Submission	PSI Response
<p>It would be better if the guidance was more specific as to what pharmacists can and cannot do.</p>	<p>The aim of this guidance is to assist pharmacists to meet their obligations under Data Protection legislation. Every situation that a pharmacist will encounter will vary and the pharmacist must use their professional judgement to decide how to apply this guidance taking into account other relevant legislation and their obligations under the Code of Conduct.</p>

<p>Principle 5: It is very difficult to honour when the community pharmacist does not receive sufficient information regarding e.g. diagnosis and background to prescribing to claim to have an 'accurate, complete and up-to-date' record.</p> <p>Principle 7: There is much confusion as to the length of time for which e.g. prescriptions should be kept (perception of regulatory requirement (2.5 years), VAT period (6 years), age of consent (21 years)) and specific guidance would be helpful.</p>	<p>This requirement would apply to the information that the pharmacist is provided with by the patient or information that they ought to reasonably be aware of.</p> <p>Specific requirements for the length of time for retention of prescriptions and other records made in the pharmacy falls under pharmacy, medicines and Misuse of Drugs legislation and not Data Protection legislation, therefore this is not addressed in this guidance document. The PSI guidance has been amended to make the distinction between these requirements more clear.</p>
<p>Yes, but I have some back ground to them. The possible use of a short example / case stories for each of the principles may help if there ever was any uncertainty.</p>	<p>The PSI acknowledge the suggestion of using case studies to help with understanding how to apply the Eight Principles of Data Protection to everyday practice. The PSI would like to highlight that if a pharmacist or pharmacy owner is unsure of how to apply these principles they should contact the Data Protection Commissioner in the first instance for further assistance.</p>

Figure 4. Consultation question: Is it clear when patient consent is needed to disclose personal data and the limited circumstances when information can be disclosed without patient consent?

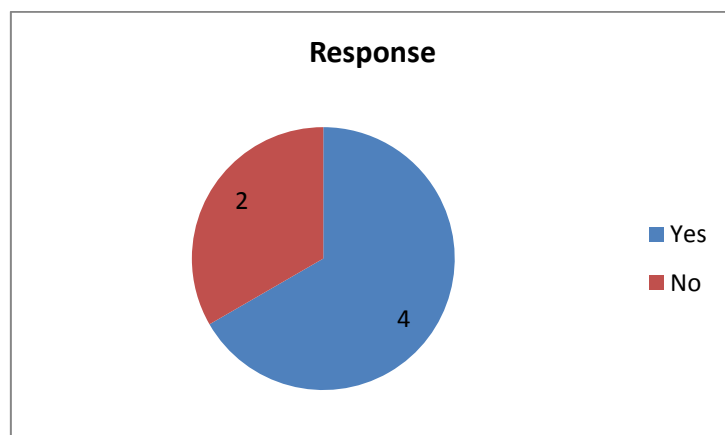


Consultation question: If not, please explain what is unclear

Submission	PSI Response
<p>When a patient presents a prescription to a pharmacist for dispensing, it has always been taken that this implies consent for the pharmacist to keep a record of the details of the prescription.</p>	<p>Noted.</p>
<p>While I accept that the Duty of Care principle</p>	<p>Pharmacists should use this guidance to assist</p>

<p>'trumps' all others, over-emphasis on not sharing information has the potential to deter pharmacists from engaging when they are faced with (professional) dilemma scenarios.... I have two examples I use in teaching e.g. a) A lady purchasing folic acid is partner to a patient for whom prescriptions have been dispensed for a serious STD/other? b) A young 'person' at the counter telling the assistants that he has just purchased his first car ... and you know he is 'non-compliant' with his anti-epileptics etc? ... does either situation represent an 'urgent risk' to life or health? (The link with the data controller adds to my concern here ... are we indicating that it could only be the data controller that would breach confidentiality?) The guidelines, page 8, might be interpreted as confining the pharmacist to a subordinate role i.e. to a request from another HCP, rather than proactively seeking to 'disclose' in order to address a situation of concern (as above).</p>	<p>them in making professional judgements in the situation with which they are faced. If in doubt the pharmacist should contact the Data Protection Commissioner or their legal advisor for further guidance.</p>
<p>Point per point yes, but with the volume of various situations you feel like following more of a gut inclination rather than a memorized statement pertaining to the answer</p>	<p>Agreed. As stated above this guidance is intended to assist pharmacists to meet their obligations under Data Protection legislation; it is the responsibility of the pharmacist as to how they apply it to individual situations that they are faced with.</p>

Figure 4.1. Consultation question: Does the guidance document improve your understanding of data protection legislation?



Consultation question: Please provide your further comment

Submission	PSI Response
I don't think it is clear enough to assist	Comments have been noted.

pharmacists in their roles as data processors.	
Particularly the section of the document highlighting requests by specific individuals for personal data, eg gardai.	Comments have been noted.

Consultation question: Have you further queries on data protection legislation that you would like the guidance document to address?

Submission	PSI Response
I would also emphasise the importance of recording templates (e.g. for services) as an essential support to claiming to assure accuracy of data recorded.	Agreed, but this is outside the remit of this guidance.
Cloud storage: Is it not enough to use a reputable cloud storage provide e.g. dropbox / one drive by microsoft than having to enter into written records with them.	The Data Protection Commissioner has produced guidance on 'Cloud' storage which states that data protection law requires there be a written contract with the cloud provider and any sub-processors to underpin its obligations. This is referenced in the current guidance.

Consultation question: Do you have any further comments about the contents of this guidance?

It's a welcome addition to the toolkit. Is there enough of a link to advise to not store CD registers on top of or beside the safe? (i.e. in the event of a break in/hold up, the 'criminal' would then have the addresses of patients to whom CDs were recently dispensed etc. (If not considered suitable for this subject matter, then perhaps this could be reinforced elsewhere?)	Comments have been noted with thanks.
In the first page, there is reference made to a number of pieces of legislation which require pharmacists to hold data but I noticed that the Medicinal Products (Prescription and Control of Supply) Acts were omitted. In regards to communication technology, I am always wary of giving out information over the telephone even if I can satisfy myself of the identity of the caller. I often find it better to ring the caller back such as through the main switchboard of the hospital or their number on the PSI website to ensure that they are who they claim to be. Would this be worth suggesting? I would also like to see that any requests for patient information from	Comments have been noted with thanks.

<p>other healthcare professionals to only be answered by the pharmacist on duty. When I worked as a clinical pharmacist, I would ring numerous pharmacies on a daily basis and it was usually a non-pharmacist member of staff giving me the information. I do not feel this was appropriate in light of the data protection legislation.</p>	
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Appendix A: List of respondents

Pamela Logan (MPSI: 5944) (Irish Pharmacy Union)

Cicely Roche (MPSI: 4906)

Louisa Power (MPSI: 9409)

MPSI: 10674

Peter O'Donnell