



AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

PSI Public Consultation Report on the Pharmacy Assessment System

December 2016

1. Introduction

As part of its function as the pharmacy regulator, the PSI is empowered under the Pharmacy Act 2007 to conduct inspections of registered pharmacies (community/retail and hospital) for the purposes of assessing their compliance with pharmacy and medicines legislation, PSI guidance and good pharmacy practice. In May 2015, the Council of the PSI agreed to update the policy approach for routine pharmacy inspections, to include a self-audit or self-assessment for pharmacies (now referred to as the Pharmacy Assessment System).

The Pharmacy Assessment System has been developed by the PSI, following engagement with pharmacists, pharmacy owners and other key stakeholders. It is intended to be a practical tool to facilitate the supervising pharmacist, superintendent pharmacist and pharmacy owner, in conjunction with the pharmacy team, to critically review and reflect on their pharmacy's practice and identify areas where improvements are required.

1.1 About the Consultation

A public consultation on the Pharmacy Assessment System and the Guide to completing the Assessment was held from 22 March 2016 to 15 April 2016. Both documents were available to view on the PSI website together with a link to a short online survey for respondents to provide their comments. The option of sending comments in writing, via letter or email, was also provided.

Invitation to take part in the consultation was made by way of email to all registrants (with the exception of those already signed up to take part in the Pilot of the Pharmacy Assessment System), and a list of stakeholders, including other regulators and patient representative groups. A reminder email was sent to the same parties on 8 April 2016. Issue 2, April 2016 of the PSI Newsletter also invited comments to this consultation.

1.2 Response to the Consultation

A total of 79 responses were submitted to the consultation. 76 respondents accessed the online survey and 3 responses were received by email.

Of the 76 responses received through the online survey it was noted that 2 responses were duplicates submitted by the same individual and so these were removed from the analysis, leaving a total of 74 survey responses. 54 respondents answered all questions in the survey, while the remaining 20 provided partial responses.

1.3 About this Report

This report summarises the responses and comments received from the online survey questions and the email submissions. A majority of responses from the online survey have been presented in table/graph format throughout. However, as questions 10, 13 and 15 of the survey invited respondents to provide their comments, a summary of these responses received has been included.

2. Results

2.1 Respondents' Profile

This section of the report details the profile of 79 respondents gathered from questions 1-5. It includes information gathered through the online survey and profile information indicated in email submissions.

Respondents who provided their full name/organisation name are listed in Appendix 1.

Respondents' Profession		
Answer Provided ¹	No. of Respondents	Percentage of Total Respondents
Pharmacist	58	75.0%
Pharmacy owner	20	25.9%
Pharmaceutical assistant	4	5.2%
Pharmacy employee	5	6.5%
Other healthcare professional	0	0.0%
Member of the public	2	2.6%
Other (please specify)	9	11.7%

'Other' respondents' profession listed were: 1) Regulator, 2) Supervising Pharmacist, 3) Pharmacy Technician, and 4) Pharmacy Student / OTC Assistant.

Pharmacist Role		
Answer Provided ¹	No. of Respondents	Percentage of Total Respondents
Supervising Pharmacist	32	55.1%
Superintendent Pharmacist	24	41.4%
Employee Pharmacist	19	32.8%
Other (please specify)	5	8.6%

'Other' pharmacist roles listed were: 1) Support Pharmacist, 2) Locum, 3) Inspector, and 4) Representative body.

Pharmacists' Main Area of Employment		
Answer Provided	No. of Respondents	Percentage of Total Respondents
Community	46	79.3%
Hospital	9	15.5%
Academia	0	0.0%
Industry	0	0.0%
Other (please specify)	3	5.2%

'Other' pharmacists' main area of employment listed were: 1) Hospital and other, 2) State Institute for Drug Control and 3) Government.

¹ Respondents were permitted to select more than one option.

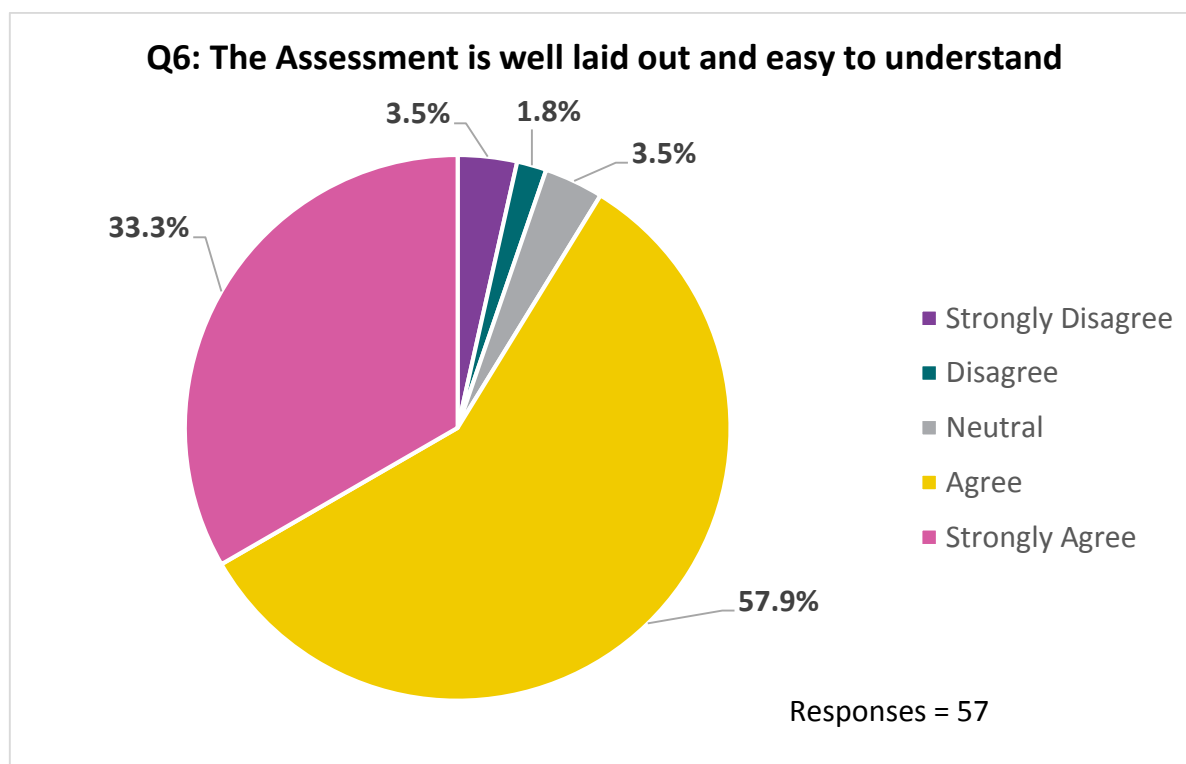
Respondents Response Capacity (I am responding...)		
Answer provided	No. of Respondents	Percentage of Total Respondents
In a personal capacity	62	80.5%
On behalf of an organisation or group	15	19.5%

2.2 Summary of the Response to the Online Survey Questions and Email Submissions

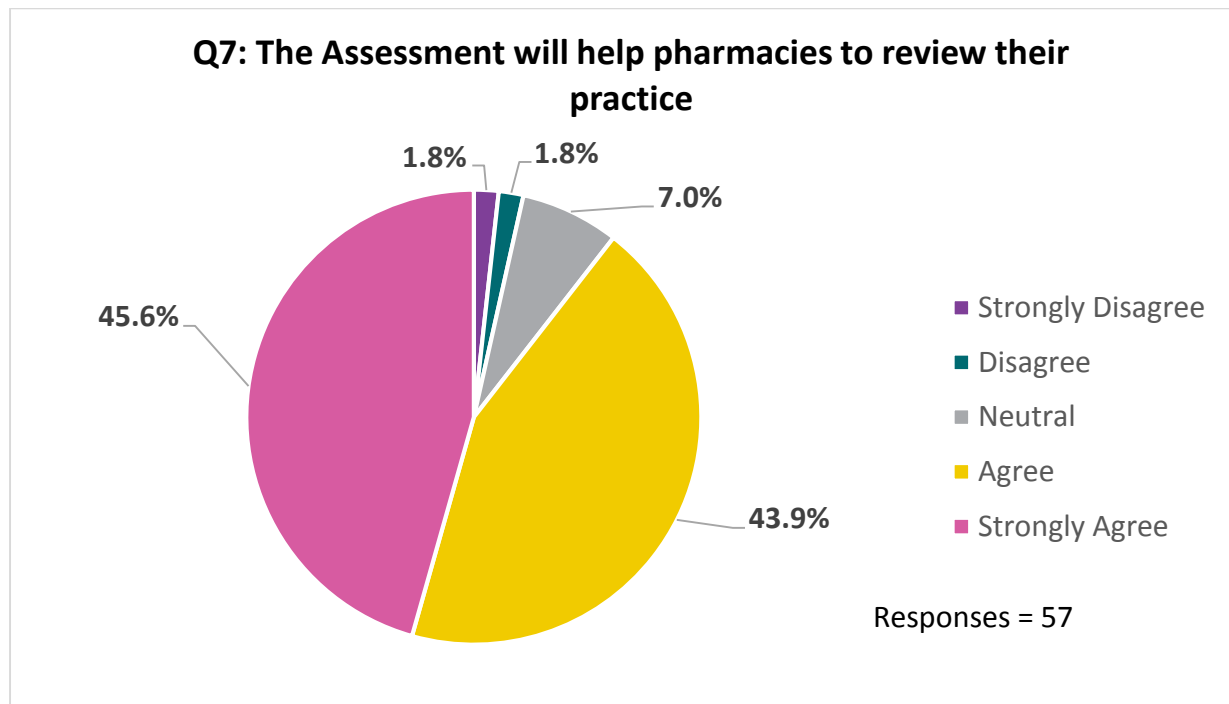
2.2.1 The Pharmacy Assessment System

This section of the report includes the information gathered from questions 6-10, which focused on the Pharmacy Assessment System.

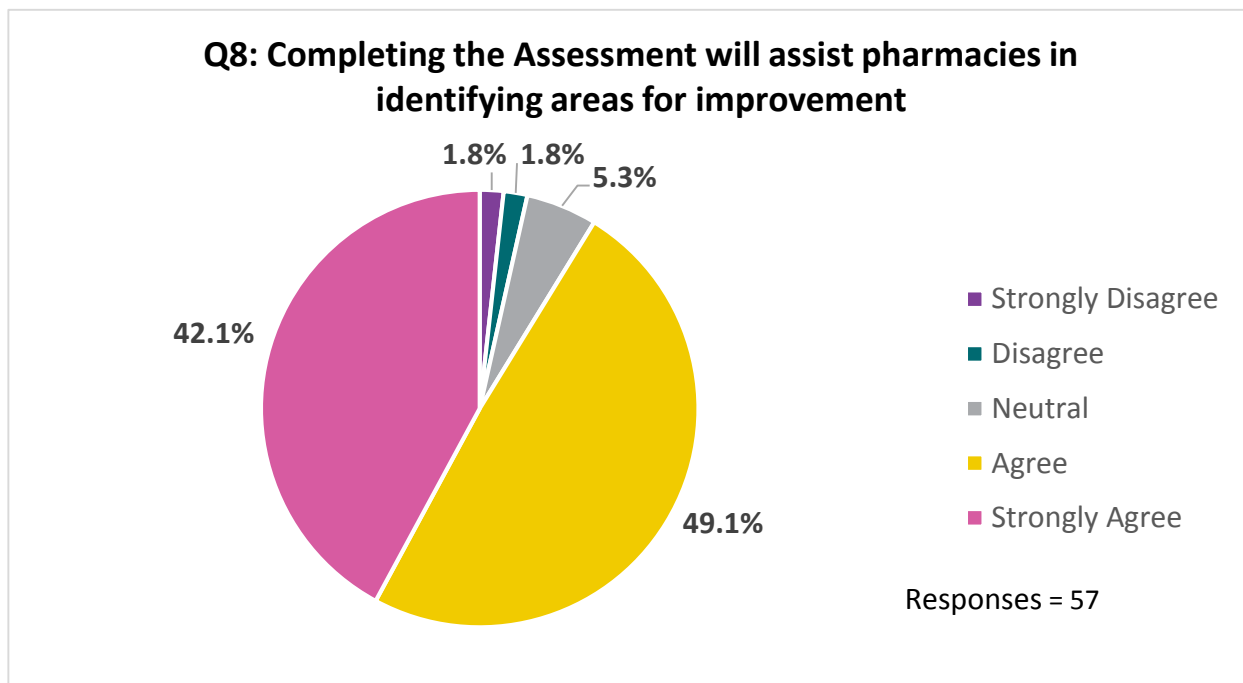
Question 6:



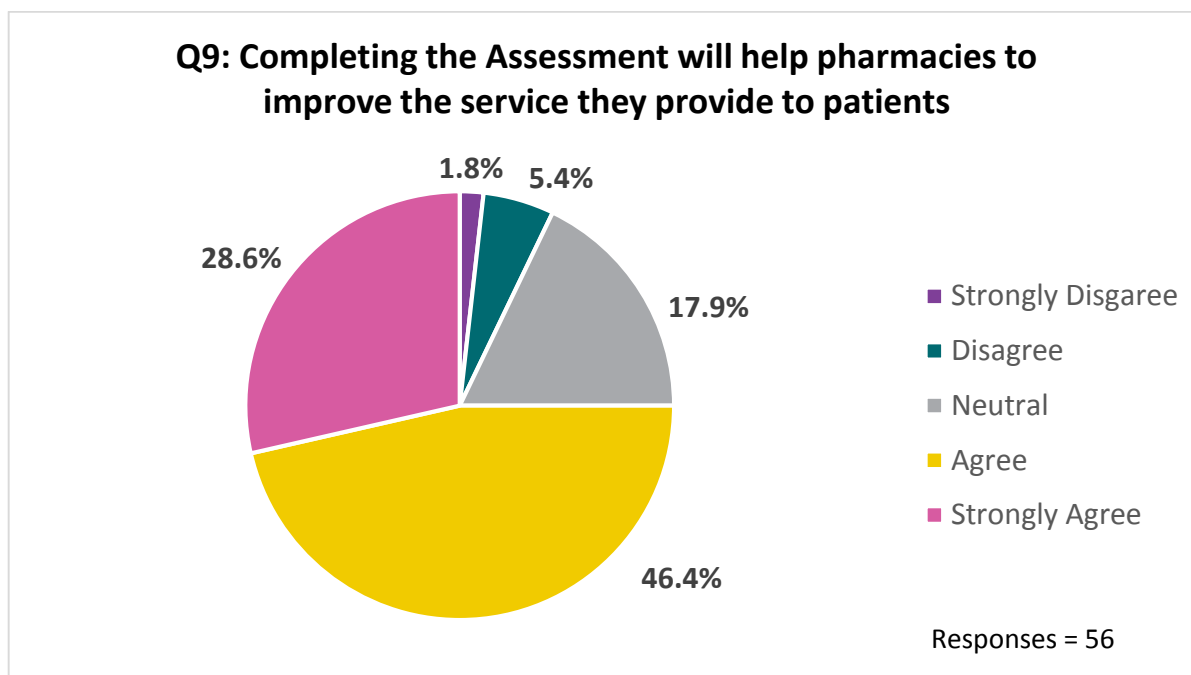
Question 7:



Question 8:



Question 9:



Question 10:

Respondents were invited to provide any additional comments they had on the Pharmacy Assessment System. Thirty-one responses were received in response to this question through the online survey together with email submissions. A summary of the comments is outlined below:

- The Assessment was well laid out, easy to follow and will help pharmacies to identify and implement improvement. It was also felt that it would be beneficial for new pharmacists to be part of a self-auditing process.
- The Assessment will help in assuring a continuous quality improvement cycle in a pharmacy. It was also suggested that resources and training should be provided to pharmacists to help them implement quality assurance processes in pharmacies. In addition, it was felt that the roll out of the Assessment may be premature without proper training.
- Some suggestions for improvement were also made such as making the assessment shorter or less time consuming for pharmacists, completion online, additional sections and changes or clarifications to Part 2, the Compliance Assessment. One respondent suggested that Part 2 should be removed from each section of the Assessment.
- It was felt that not all sections of the Assessment were relevant to hospital pharmacy practice. Other respondents felt that the Assessment should be amended depending on the size and structure of the pharmacy.

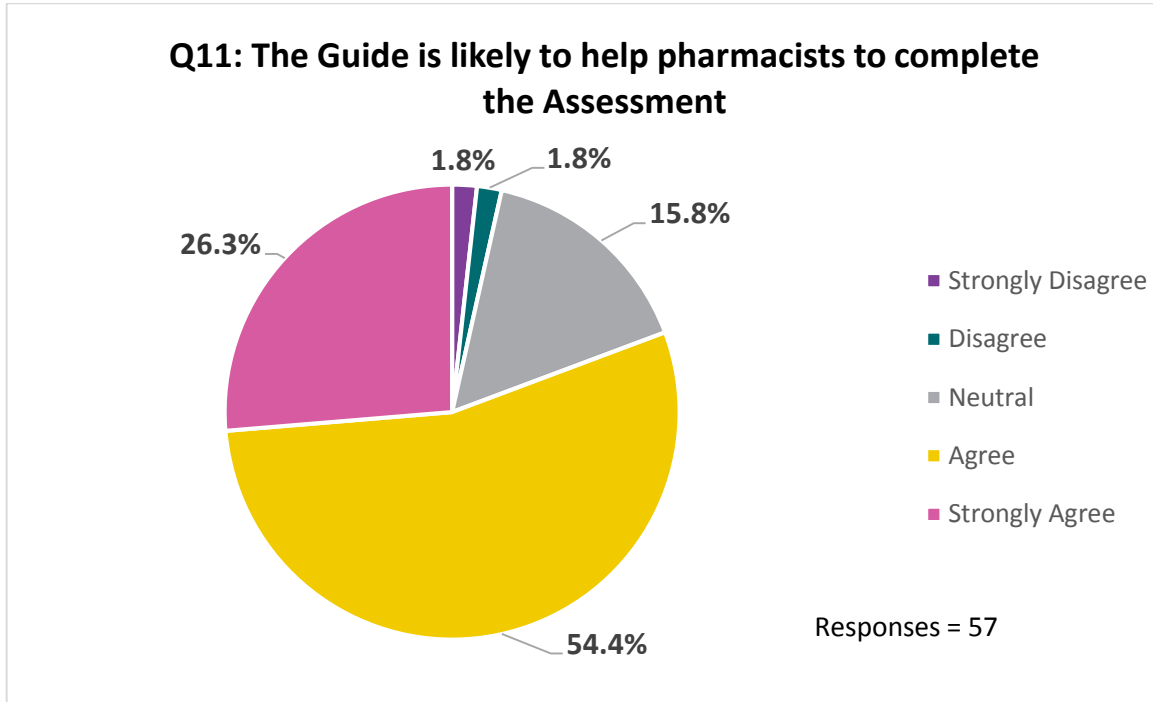
- It was suggested that an on-line version of the Assessment should be provided, though it was acknowledged that a paper version was useful. It was also suggested that an on-line system could automatically create an action plan for discussion.
- It was suggested that completing the Assessment once every 12 months would be adequate as opposed to every six months, which was suggested as being 'over burdening', provided the previous assessment had not identified issues.
- It was indicated that it would take at least two months to complete the Assessment properly.
- It was suggested that the time taken to complete "additional paperwork" could be put to better use, and that it would be beneficial to read the guidelines as a reminder of good practice.
- It was suggested that sections be weighted in terms of priority and perceived potential for adverse harm.
- It was felt that it was useful for pharmacy owners to sign off on actions required in the pharmacy to highlight the responsibilities of pharmacy owners and to support employee supervising and superintendent pharmacists. Although one respondent felt that some questions in the assessment were beyond the control of supervising pharmacists, for example staff and premises.
- A list of SOPs could be provided and to clarify the equipment requirements in pharmacies.
- The use of the Assessment as part of the inspection process was queried and it was felt that making its use compulsory would make it a "box ticking exercise".
- Additional space for completing action plans should be provided.
- The cost / benefit implications of the Assessment for pharmacies was queried

Other comments made on topics, outside of the scope of the Pharmacy Assessment System were received, but are not listed above.

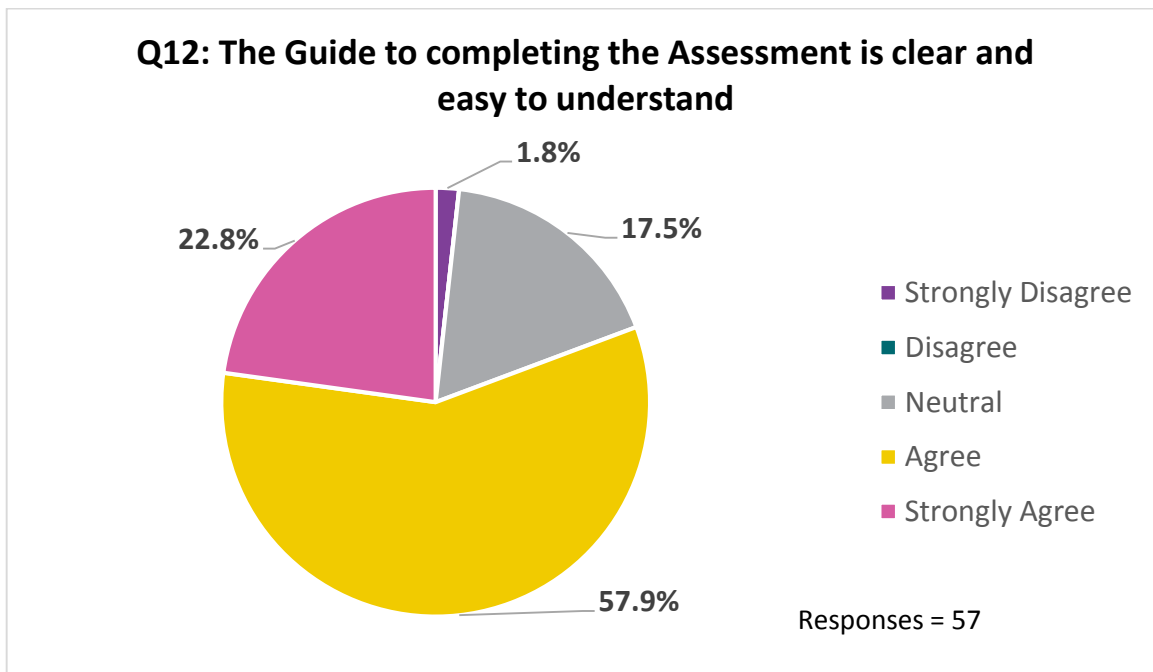
2.2.2 The Guide to completing Pharmacy Assessment System

This section of the report includes the information gathered from questions 11-13, through the online survey, which focused on the accompanying Guide.

Question 11:



Question 12:



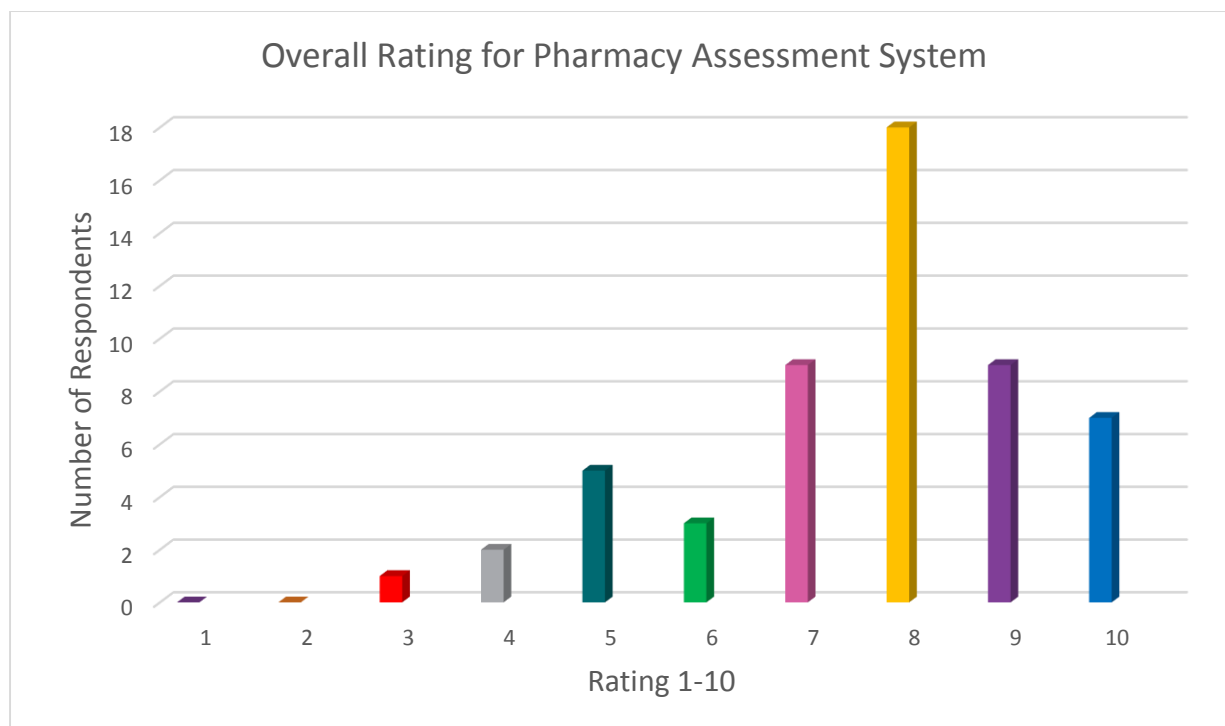
Question 13:

Respondents were invited to provide any additional comments they had on the Guide to Completing the Pharmacy Assessment System. Seven comments were received in response to this question through the online survey. A summary of the comments is outlined below.

- The majority of comments were positive and supportive of the Guide. It was felt that 'it gave very clear direction', although one respondent indicated that the Guide was too long and wordy.
- The usefulness of the completed sample sections was mentioned and it was suggested that these should be expanded.
- A recommendation that key regulations should be identified and prioritised within the Guide.
- It was suggested that the Guide should be signed by all parties prior to completing the evaluation.

Question 14:

Respondents were asked to give their overall rating for the assessment on a scale of 1 to 10, with 1 being very poor and 10 being excellent. 54 responses were provided through the online survey, and the average overall rating was **7.6**.



Question 15:

Respondents were asked to provide any final suggestions for improvements to the Pharmacy Assessment System. Seventeen suggestions were received in response to this question through the online survey. A summary of the comments and feedback received is outlined below.

- It was indicated that the assessment in its current presentation was good, easy to use and would help identify areas for improvement, with one respondent outlining that 'I would urge all pharmacies to audit their practice against the tool'.
- It was suggested that the assessment could include additional sections, in time, for example flu vaccination or emergency hormonal contraception, and that it could cover additional areas, for example the counselling process and a template for clinical review.
- It was also suggested that some sections were time consuming, for example review of the prescription register and that an annual completion of the assessment may be sufficient. In addition, that it should be a tick box review.
- It was suggested that a separate assessment system is needed for hospital pharmacies, as some sections were not relevant to the hospital setting.
- Suggestions were made to develop an online system, instead of a 'pdf' version. It was also suggested that an online version could allow for action plans to be automatically populated when the assessment is completed.
- Suggestions were made to review and make changes to the compliance ratings in Part 2.
- The level of detail required to be recorded in the staff roles, responsibilities and training section was queried, in cases whereby staff work solely in retail or administration roles.
- It was proposed that pharmacy owners, superintendent and supervising pharmacists should log onto the PSI website on a six month to a yearly basis to indicate that they have read the PSI website and legal guidance.

3. Conclusion

The PSI welcomed the submissions to this important consultation and would like to thank all contributors for the information provided. The comments received proved invaluable and were considered, together with the results of the Pilot of the Pharmacy Assessment System, in finalising these documents.

The final version of the Pharmacy Assessment System together with the accompanying Guide was launched in October 2016. The Pharmacy Assessment System is to be completed once every six months, with the first cycle commencing in all pharmacies in January 2017.

Appendix 1 – Respondents

Respondent Name		Organisation / Group (if applicable)
Joan	Peppard	
Cathriona	Gavin	
Marie	Richardson	Stacks Pharmacy Skerries
Tanya	Smith	Anna Kelly Pharmacy
Vera	Myslivcova	Apolena Jonasova, State Institut for Drug Control, Czech Republic
Aidan	Cunningham	
Eva	Brennan	St. Stephen's Hospital, Glanmire, Cork
Pauline	Kavanagh	
Maura	Keady	
Anne	Ryan	Green Cross Pharmacy
Anne-Marie	O'Sullivan	
Therese	Byrne	
Deirdre	O'Mahony	
Anne	O'Neill	
Aine	O'Connor	
David	Jordan	
Mike	Corcoran	Tusla Child & Family Agency, Children's Regulation Unit
Mary	Rennick	
Emma	Vaughan	
Mary Teresa	Spillane	
Emmeline	Landers	Corr's Life Pharmacy Group
Joan	Bourke	
Maureen	Linehan	
Niamh	Morgan	
Fionnuala	Kennedy	
Colm	Kennelly	
Sinead	Mahony	
Marie	McConn	
Angela	Barrett	Newpark Pharmacy
Eoin	Reen	
Claire	Murphy	Allcare Pharmacy
Trang	Truong	
Mary	Marnane	
Shane	Lonergan	Lonergans Pharmacy Ltd
Maria	Creed	Pharmacy Dept., MMUH
Fergal	Leahy	
Mohammad	Mortazavi	
Mrs Eadaoin	Purcell	
Michael	Tierney	
Nuala	Hart	
Marie Therese	Early	Natural Options (TotalHealth) Pharmacy
Marianne	Fitzgibbon	
Igusti Ayu	Sumiartini	
Noor	Bajalan	

Clodagh	Loughlin	
Geraldine	Fitzgerald	
Ronan	Whelan	
Mark	Davis	
Victoria	Jones	
Eilish	Costello	
Crona	O'Reilly	
Nicholas	Scullion	
Pamela	Logan	Irish Pharmacy Union (2,200 pharmacists)
Keith	McConville	
John	Madden	
Hazel	Greville	
Bridget	Cullen	
Mags	Cullen	
Carol	Johansson	
Dan	Scott	
Mark	O'Connell	
Peter	Twomey	
Richard	Woods	
Eileen	Doran	
O'Keeffe's	Dingle	O'Keeffe's Pharmacy Ltd
Noel	Conroy	
Rachel	Gubbins	Castletroy Pharmacy
Caitriona	Fisher	Health Product Regulatory Authority