Rebalancing Medicines Legislation and Pharmacy Regulation

Report on responses to the public consultation on the Pharmacy (Premises Standards, Information Obligations etc.) Order 2016
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Prepared by

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Innovation Growth and Technology Directorate
Department of Health
Executive summary

1. On 12 February 2015, the Department of Health, on behalf of the four UK Health Departments, published a consultation seeking views on a series of proposals in two draft Orders:

   - The Pharmacy (Preparation and Dispensing Errors) Order
   - The Pharmacy (Premises Standards, Information Obligations, etc.) Order

   The closing date for responses was 14 May 2015.

   This report provides details of responses received to the consultation questions on the Pharmacy (Premises Standards, Information Obligations, etc.) Order. It summarises what we heard and our response, having considered all responses and feedback from engagement events, held during the consultation period. Note that the questions in this report retain their original numbering from the consultation document.

   A separate report will be published on the responses to the consultation questions on the Pharmacy (Preparation and Dispensing Errors) Order.

2. The draft Order takes forward proposals on one element of the Rebalancing Medicines Legislation and Pharmacy Regulation work programme. Views will be sought in turn, by public consultation, on proposals in respect of other elements of the programme.

   - The Pharmacy (Premises Standards, Information Obligations, etc.) Order, in summary:
     - amends the provisions of the Pharmacy Order 2010 in respect of the General Pharmaceutical Council (GPhC) setting standards for registered pharmacy premises, so that these will no longer be in rules. The Order also makes provision for the Pharmaceutical Society of Northern Ireland (PSNI) to set standards for registered pharmacy premises;
     - provides that breach of premises standards will be referred to the Fitness to Practise Committee of the GPhC rather than, as at present, through enforcement notices, breach of which could lead to criminal proceedings or disqualification proceedings;
     - makes provisions on interim orders, and publication of inspection reports; and
     - corrects a provision in the Pharmacy Order 2010 relating to notification of the death of a registered pharmacist or registered pharmacy technician.
Overview of the consultation responses

Background

3. The UK wide consultation, was issued on the 12th February 2015, on behalf of the four UK Health Departments, seeking views on a series of proposals in two draft Orders:
   - The Pharmacy (Preparation and Dispensing Errors) Order
   - The Pharmacy (Premises Standards, Information Obligations, etc.) Order

4. For the Pharmacy (Premises Standards, Information Obligations, etc.) Order responses were invited to 9 questions in total, made up of:
   - 5 questions in respect of pharmacy standards and regulation, one of which was for Northern Ireland only
   - 3 questions in respect of the Impact Assessment published in relation to the draft Order, and
   - A question on the Equality Assessment published as part of the consultation.

   The closing date for responses was 14 May 2015.

Overview of responses

5. We are grateful to everyone who took time to respond to this consultation. We received many very useful comments and suggestions both at stakeholder events and in the written responses. We have given careful consideration to all views expressed in developing this report.

6. In total the consultation drew 159 responses from a variety of respondents and in a number of formats.

7. 128 were received through Citizen Space (cloud based software which provides an easily-to-use method of responding to government consultations).

8. 30 were received though a web based mailbox and 1 was received in hard copy.

9. Responses were received from pharmacy professionals, patients and the public, representative groups and organisations. A breakdown of respondents is attached at Annex B and a list of organisations/businesses responding can be found at Annex C.

General Comments

10. The overwhelming majority of respondents supported the proposals.

11. Overall, the responses provided constructive and useful views as well as support for moving to the next part of the process.
Patients’ and public engagement

12. To support patient and public engagement a number of events were arranged to inform participants about the proposed legislative changes and to elicit their views. They were held in Cardiff, London, Edinburgh and Belfast. The Leeds event was cancelled as no pharmacy users signed up to the event. At these events members of the Department of Health team, supported by devolved administration colleagues, as appropriate, provided a presentation on the proposals, facilitated a discussion and elicited views. Although attendance at the events was low (26 pharmacy users across the UK), the presentations gave rise to some lively debate and some in-depth questioning of the policy intentions. There was also positive feedback on the arrangements and content of the events, which enabled patient and public representatives to engage with the issues and express their views.

13. There was unanimous agreement with the proposals for an outcome based approach to pharmacy premises standards. It was suggested that this approach was even more relevant given the greater the range of services available at a pharmacy.

14. Publication of pharmacy premises inspection reports, in Great Britain, was also welcomed.

Events organised by others

15. A series of presentations was organised by the professional bodies (Royal Pharmaceutical Society, Pharmaceutical Society of Northern Ireland – Pharmacy Forum and the Association of Pharmacy Technicians United Kingdom) for their members across the UK. These informed the responses of those organisations to the consultation as well as supporting and encouraging others to respond separately. In addition, members of the programme board and other pharmacy organisations helped promote understanding and awareness of the proposals as well as encouraging responses to the consultation.

Responses submitted to the consultation

General responses

16. Responses of a general nature were received from 9 organisations. In each case, a view was given on an area of interest or on specific points. These responses are taken into account for consideration at the appropriate point.
Removing the obligation to set pharmacy premises standards in rules

Consultation Question 10:

Do you agree that in relation to GPhC, the obligation to set standards in rules should be removed?

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<tr>
<th>Responses</th>
<th>Agree</th>
<th>Disagree</th>
<th>Not Answered</th>
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<tr>
<td>Number</td>
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<td>32</td>
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<td>%</td>
<td>67%</td>
<td>13%</td>
<td>20%</td>
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What we proposed

17. The GPhC and the PSNI are unusual among professional regulators in that, alongside their role as the regulator of pharmacists, and pharmacy technicians in the GPhC, they also provide varying degrees of system regulation through their role in registering and monitoring pharmacy premises.

18. In connection with this latter role, the GPhC, set up under the Pharmacy Order 2010 as the independent regulator for registered pharmacy professionals in Great Britain, is obliged to promote safe and effective practice at registered pharmacies, and to achieve that end, it has specific obligations to set standards for registered pharmacies, which pharmacy owners and superintendent pharmacists are accountable for meeting. As the law currently stands, those pharmacy standards have to be set in rules and failure to meet GPhC rules relating to pharmacy standards could result in improvement notices, which if breached could lead either to criminal proceedings or suspension or removal of the premises from the premises register.

19. The GPhC has developed and approved, in consultation with key stakeholders, standards for registered pharmacies. The standards are outcome-based, focusing on the achievement of results for patients and moving away from prescriptive requirements. These outcomes-based standards will be supported by guidance on specific issues, where this is necessary.

20. The intention is to avoid a regulatory model which leads pharmacies towards a compliance-driven or checklist approach in meeting its standards.

21. The key change, and one of the Law Commission’s recommendations, is that the GPhC should no longer be required to set standards for registered pharmacies in rules. Instead these should be aligned with other regulatory standards and be “code of practice” style obligations which are outcomes-based, focusing on the achievement of results for patients. Such outcomes-based standards are then supported by guidance on specific issues,
What we heard

22. Out of 159 respondents, 129 answered this question. Of these 84% agreed that, in relation to the GPhC, the obligation to set standards in rules should be removed.

23. Comments in support also included observations that the standards should be focussed on outcomes for patients to encourage improvement in the quality of services provided and that changes should require consultation with all stakeholders, not just Ministers.

24. While supporting the proposal, guidance was suggested to clarify whether “associated premises” included prescription collection points.

25. Those not supporting the proposal were concerned that removing the “black and white” rules could lead to unhelpful variation for employee pharmacists in the way pharmacies choose to meet the standards.

26. Two respondents commented on the way in which the GPhC is proposing to grade pharmacies in its inspection reports and also on the need to consult registrants, patients and the public on proposed changes to its standards.

Quotes:

“We believe that an outcomes-based system will allow for the variability in registered premises, and promote innovative ways to meet the required standards. The system should be transparent and easy to understand so that it is clear whether standards are being met.”

“This will allow the GPhC to react to changes in pharmacy practice in a more timely manner”.

“Unless GPhC is unable to set detailed standards, the obligation to set standards in rules should remain as they are the pharmacy regulatory body”.

Our response

27. The proposal as outlined will be taken forward.

PSNI premises standards for registered pharmacies - this question was specific to Northern Ireland

Consultation Question 11:

Are you content to place a statutory duty on PSNI to set standards for registered pharmacies?

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<th>Responses</th>
<th>Agree</th>
<th>Disagree</th>
<th>Not Answered</th>
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<tr>
<td>Number</td>
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<td>138</td>
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<tr>
<td>%</td>
<td>13%</td>
<td>0%</td>
<td>87%</td>
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What we proposed

28. It is proposed to place a statutory duty on the pharmacy regulator in Northern Ireland (the PSNI) to set standards for registered pharmacies and clarify what those standards can cover. This will enable the PSNI to put their premises standards, currently set in guidance, on a statutory footing so that in future they can be set in statutory codes of practice. It is proposed to use the same wording as for the GPhC for the list of what the standards may contain, so the PSNI could also take an outcomes based approach to registered pharmacy standards, albeit reflecting its own particular approach and circumstances. The discussion under the previous heading is therefore also relevant to the proposed arrangements for Northern Ireland.

29. Additionally, having regard to the different nature of the legislative scheme in Northern Ireland, it is also proposed to make a further change, through amendment of the provisions of the Pharmacy (NI) Order 1976 to require the PSNI to publish their registered pharmacy standards.

30. The provisions for Northern Ireland would only be commenced when PSNI is in a position to introduce their new standards. The commencement order would require the agreement of the Northern Ireland Minister for Health Social Services and Public Safety (HSSPS), so effectively the implementation timetable would be subject to agreement with the Minister’s Department.

What we heard

31. The question was about arrangements for regulatory standards in Northern Ireland. There were 21 responses, all of which were positive.

32. Of the respondents:-
   a) 10 were from individual pharmacists or organisations in Northern Ireland;
   b) 9 were from UK wide organisations;
   c) 2 were from individual pharmacists who were not based in Northern Ireland.

33. Respondents who expressed an opinion were of the view that there should be parity of pharmacy standards across the UK.

Our response

34. We propose to work with colleagues in the Department of Health, Social Services and Public Safety on this aspect of the consultation and with the regulator and professional body in Northern Ireland to take forward the proposal, recognising the commencement of any legislation is for Northern Ireland I to determine.

Quote:

“We agree that the standard the PSNI sets for pharmacy premises should be outcome focused and in the form of a statutory code rather than in their current guidance format”.

Breaches of premises standards

Consultation Question 12:

Do you agree with the approach we are taking to breaches of premises standards by pharmacy owners?

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<tr>
<th>Responses</th>
<th>Agree</th>
<th>Disagree</th>
<th>Not Answered</th>
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<tbody>
<tr>
<td>Number</td>
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<td>8</td>
<td>33</td>
</tr>
<tr>
<td>%</td>
<td>74%</td>
<td>5%</td>
<td>21%</td>
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What we proposed

35. Some of the enforcement powers of the GPhC and PSNI are common to both bodies but others are different. Essentially, where a common approach has already been adopted, the proposals make changes that apply equally to the GPhC and PSNI, but some additional proposals are also made which relate solely to the GPhC’s statutory improvement notice procedure, for which there is no PSNI direct equivalent.

36. It is proposed to amend the GPhC’s and PSNI’s disqualification procedures for pharmacy owners, and the procedures for removing premises from the premises register (section 80 of the Medicines Act 1968), firstly, so they apply to retail pharmacy businesses owned by a pharmacist or a partnership, as well as bodies corporate, and, secondly, to clarify that the test to apply sanctions, where premises standards are not met, is whether or not the pharmacy owner is unfit to carry on the retail pharmacy business safely and effectively.

37. In Great Britain, this will replace, in part, the powers under article 14 of the Pharmacy Order 2010, which allowed the Registrar of the GPhC to suspend or remove entries from its register where a pharmacy owner failed to comply with an improvement notice that related to breaches of premises standards in the GPhC’s rules. Those powers could be used against pharmacy owners that were individual pharmacists or partnerships, as well as bodies corporate. For Great Britain, the changes are intended to facilitate more proportionate sanctions by the pharmacy regulator where there are breaches of premises standards, and focus enforcement action on the GPhC’s disciplinary procedures.

38. With similar intentions in mind, it is proposed to make two additional amendments to the sanctions provisions in the Pharmacy Order 2010 relating to breaches of improvement notices. Firstly it is proposed that prosecutions should no longer be brought in cases of breaches of premises standards and the matter must instead be dealt with as a disciplinary matter, by the Fitness to Practise Committee. Secondly, the option is removed of the breach being dealt with as a registration matter by the Registrar and potentially, on appeal, by the GPhC’s Registration Appeals Committee. This streamlining means that all breaches of premises standards will be dealt with as disciplinary matters.
What we heard

39. Out of 159 respondents, 126 answered this question. Of these 94% supported the approach to be taken by the regulators to breaches of pharmacy premises standards by pharmacy owners.

40. 3 respondents indicated a concern about how suspension orders would be enforced and the possibility that if action was taken that resulted in a suspension, it could jeopardise access to medicines if the pharmacy in question was the only pharmacy in the area.

41. There was also a request for further clarity on how the approach would operate in a situation where failure to comply with pharmacy premises standards concerns a breach in, for example, just one premises of a multiple pharmacy company.

42. Of the 8 respondents that did not support the proposal, only 3 provided comments. One expressed the view that the legal redress should remain, another suggested that further legal change might be needed to ensure that the “owner” was accountable and took their accountability seriously. The other comment suggested that owners should be more accountable but superintendents should not be held less accountable as a result.

Quotes:

“This will ensure patient safety is made the first priority”.

“We believe that the public should be protected and appropriate action should be taken by the GPhC where there is a gap in public protection”.

“We believe that it is appropriate for the GPhC to deal with breaches of improvement notices via the disciplinary process rather than as a matter for prosecution and that it is appropriate to include all retail pharmacy businesses”.

“We welcome moves away from legislative sanctions to the use of regulation. The use of interim suspensions may be challenging as a suspension order could deprive a community of a pharmacy service. We would expect the core value of acting in the public interest would ensure services to a population are maintained during any investigation”.

“For public confidence in the profession it is important that the disciplinary procedures for pharmacy owners are brought into line with those of other regulatory bodies. Interim suspensions provide a consistent approach to public protection. Ensuring breaches are dealt with as disciplinary matters by the Fitness to Practise Committee will potentially be more efficient and effective in terms of public protection”.

Our response

43. The proposal as outlined will be taken forward. The sale or supply of a medicine from a pharmacy operating a prescription collection point, which was arranged such that the sale or supply was a lawful transaction, could be regulated by the pharmacy regulators as part of the registration of premises.
Publication of GPhC reports and outcomes from pharmacy premises inspections

Consultation Question 13:

Do you agree with the changes to provide for publication of GPhC reports and outcomes from pharmacy inspections?

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<th>Responses</th>
<th>Agree</th>
<th>Disagree</th>
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<tbody>
<tr>
<td>Number</td>
<td>113</td>
<td>11</td>
<td>35</td>
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<td>%</td>
<td>71%</td>
<td>7%</td>
<td>22%</td>
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What we proposed

44. It is proposed to amend Article 9 of the Pharmacy Order 2010 to provide for publication of GPhC reports and outcomes from pharmacy premises inspections. Those changes will make clear that if such a report includes personal data it is assumed under data protection requirements that such information can be published as a result of the GPhC’s pharmacy regulatory function.

What we heard

45. Out of 159 respondents, 124 answered this question. Of these 91% supported the proposal for the publication of GPhC reports and outcomes of pharmacy inspections.

46. Those who responded positively remarked upon the approach being in line with that adopted by other system regulators, such as the Care Quality Commission and that it supported transparency. However, it was vital that the inspection, rating and reporting system is fair and fit-for-purpose.

47. It was suggested that the reports should be accompanied by an appropriate explanation to aid understanding, by members of the public, of the regulations and standards.

48. The concerns expressed by those who did not agree with the proposal and some who did, included that further engagement with stakeholders is needed; inspection grading needs to be addressed; that an appeals process should be available before the publication of the report; and that piloting of the new arrangements should be considered.

Quotes:

“The more information re Pharmacy inspections and reports is made public the better. The information should be made available via the NHS Choices website”

“This change would be in line with the approach operated by other system regulators such as the CQC”

“Promotes openness and transparency and accountability”.

“We also agree that where relevant personal data needs to be included in reports that this will be in accordance with data protection requirements. Consistency in reporting the outcomes of pharmacy inspections will be even more important when reports are published. GPhC may consider a pilot approach to assess the impact of this change”.

13
Our response

49. The proposal as outlined will be taken forward. The GPhC are also running a new inspection prototype but will not be publishing inspection reports during the prototype phase. The reports will remain confidential between the GPhC and the owner/superintendent of individual pharmacies. When the GPhC have completed the prototype phase and refined the new model they will consider publishing inspection reports.

Changes to the GPhC’s powers to obtain information from pharmacy owners

Consultation Question 14:

Do you agree with the changes to the GPhC powers to obtain information from pharmacy owners?

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<th>Responses</th>
<th>Agree</th>
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<tr>
<td>Number</td>
<td>119</td>
<td>6</td>
<td>34</td>
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<td>%</td>
<td>75%</td>
<td>4%</td>
<td>21%</td>
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What we proposed

50. Article 7 of the Pharmacy Order 2010 currently requires the making of rules by GPhC not just in relation to pharmacy premises standards but also in relation to the information obligations. It is proposed to amend the information provisions so they are permissive, such that the GPhC “may”, rather than “must”, make rules in respect to obtaining information from pharmacy owners.

51. It is also proposed to clarify when the GPhC can require pharmacy owners to provide such information through its rules. The information obligations cover such matters as the details of the key people responsible for the business (e.g. directors and superintendent pharmacists of bodies corporate, and partners in partnerships), information about investigations of and offences committed by those key people (and in some cases by the business itself), business addresses, and details of the type or types of activities undertaken at registered pharmacy premises.

52. The Pharmacy Order 2010 makes no provision, currently, for enforcement arrangements relating to the rule-making powers for the supply of information by pharmacy owners, which compromises the proper functioning of these rules. The most pragmatic solution is to make use of the existing enforcement regime and to make breach of information obligations, set out in rules in the Pharmacy (Premises Standards, Information Obligations etc.) Order, subject to the improvement notice procedure outlined in the Pharmacy Order 2010, which is why the relevant Health Ministers are proposing that breaches of the Regulations should be enforced via the GPhC’s improvement notice system.

53. However, this would mean that breaches of the rules could potentially lead to fines in the lower courts. This being so, it is recognised that it is important that there are safeguards to ensure that the rules do not impose disproportionate burdens. First and foremost
among these are GPhC’s own procedures, but there are backstop safeguards in that the rules will require approval by Order of the Privy Council and will be subject to Parliamentary ‘negative resolution’ procedures, which provide for the possibility of legislation being voted down.

What we heard

54. Out of 159 respondents, 125 answered this question. Of these 95% supported the proposed changes to the GPhC’s powers to obtain information from pharmacy owners.

55. Of those who provided comments, while positive, there was concern that appropriate information governance and safeguards should be put in place to ensure that the rules do not impose disproportionate burdens.

56. A number of respondents commented that further details were required before a full response could be made to the question, with one respondent also querying whether enforcement notices were the best way to deal with non-compliance.

57. It was felt that the regulators needed to work closely with all stakeholders on rules requiring information provision for pharmacy owners to ensure that the frequency and nature of information requests or requirements to maintain data were reasonable and proportionate.

58. No comments were provided by those not supporting the proposal, apart from one respondent who made the point that clarity was needed on both the powers and the reach of information requests.

Quotes:

“Any information necessary should be made available to the GPhC and a lot more information should be made available to the public”.

“Rules would need to ensure that the nature of the information that could be collected in this way was limited to that which was deemed to be necessary to collect in the public interest”.

“We believe that the information that may be collected will be helpful to the GPhC with respect to regulating the profession, and note the safeguards to ensure that the rules do not impose disproportionate burdens”.

Our response

59. The proposal as outlined will be taken forward. Furthermore there will be a correction made to article 29 of the Pharmacy Order 2010 which erroneously provided for the Registrar General to notify the Registrar of the GPhC of the death of a registered pharmacist or pharmacy technician in Great Britain. The requisite notification should be made by a registrar of births and deaths.
Impact Assessments

60. Questions 20 to 22 relate to the material presented in the consultation Impact Assessment, published alongside the draft Order in respect of pharmacy premises standards.

Consultation Question 20:

We have prepared an IA covering costs and benefits of the pharmacy premises standards proposals. Do you agree with our assessment?

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<td>%</td>
<td>50%</td>
<td>3%</td>
<td>47%</td>
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What we heard

61. Out of 159 respondents, 85 answered this question. Of these 94% agreed the assessment of costs and benefits of the pharmacy premises standards proposals. One respondent commented that if the two regulators did not agree a common set of standards, different costs were likely to arise and this had not been taken into account.

62. The small number of those who disagreed either did not offer further comment or, in one case, said that they were unable to base a judgement on the data provided.

Consultation Question 21:

Our initial analysis of the proposed changes to pharmacy premises standards suggest that our preferred option, Option 2, has no significant transition or on-going costs relative to the current framework. This is based on our assumptions in Annex A of the IA. Are our assumptions valid?

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<thead>
<tr>
<th>Responses</th>
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<th>No</th>
<th>Not Answered</th>
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<tr>
<td>Number</td>
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<td>76</td>
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<td>%</td>
<td>50%</td>
<td>2%</td>
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What we heard

63. Out of 159 respondents, 83 answered this question. Of these 96% agreed that our assessments were valid. Four respondents disagreed, two of whom offered the comment that costs associated with attending briefings and presentations to understand the new process must be factored into the IA as this has a particular impact on small independents.
Consultation Question 22:

We do not consider there will be any specific adverse impacts from this proposal on small or micro businesses. Do you agree?

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<th>Responses</th>
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<th>Disagree</th>
<th>Not Answered</th>
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<tr>
<td>Number</td>
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<td>52%</td>
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<td>47%</td>
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What we heard

64. Out of 159 respondents, 85 answered this question. Of these 98% agreed with our assessments. Two disagreed but offered no comment.

Overview of responses to questions on the Impact Assessment (IA)

65. A final IA will be prepared taking account of the results of the consultation and other material obtained since the consultation commenced.

66. In addition to the questions highlighted in the consultation, DH undertook further work with pharmacy interests, drawing on their experience and obtaining additional material of relevance, to ensure that the next version of the IA would be as robust as possible.

67. Overall, responses to the questions relating to the IA showed that a big majority of the respondents support the results of the analysis described in the IA.

Costs:

- "Standards of premises in non-registered premises should reach a minimum, and this combined with the registration of all pharmacies,"

Our Response

68. The IA has been reviewed in light of the views from the consultation. Further consideration has been given to the following points:

a) Revisit the Small and Micro Businesses section for the premises standards IA in light of consultation responses and other evidence to address factors highlighted by Regulatory Policy Committee.

b) Review the approach to the premises standard IA to include a more quantitative approach in certain aspects, based on material provided following further discussions with regulators and pharmacy representative organisations.
Equality Assessment

69. An initial assessment of the impact of the proposals on equality, was published alongside the consultation document and responses were invited, including any additional information, in relation to how the proposals on which we are consulting might impact on equality, both in relation to patients and the public who use the services available through pharmacies and the pharmacy teams within pharmacies.

Consultation Question 23:

Do you have any additional evidence which we should consider in developing the assessment on equality?

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<tr>
<th>Responses</th>
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<th>No</th>
<th>Not Answered</th>
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<td>48</td>
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<td>%</td>
<td>6%</td>
<td>64%</td>
<td>30%</td>
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What we heard

70. Out of 159 respondents, 111 answered this question. Of these 92% offered no additional evidence. (The 8% who indicated yes did so in response to The Pharmacy (Preparation and Dispensing Errors) Order).

Next steps

71. The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 together with this report on the consultation will be laid before the Scottish Parliament and the UK Parliament for at least 28 days before it comes into force in accordance with affirmative resolution procedures.
Summary of consultation questions

Question 10: Do you agree that in relation to GPhC, the obligation to set standards in rules should be removed?

Question 11: (for respondents in Northern Ireland): Are you content to place a statutory duty on PSNI to set standards for registered pharmacies?

Question 12: Do you agree with the approach we are taking to breaches of premises standards by pharmacy owners?

Question 13: Do you agree with the changes to provide for publication of GPhC reports and outcomes from pharmacy inspections?

Question 14: Do you agree with the changes to the GPhC powers to obtain information from pharmacy owners?

Question 20: We have prepared an IA covering costs and benefits of the premises standards proposals. Do you agree our assessment? If not, please provide additional information (with estimates) regarding other costs or benefits that you think have not been considered in the IA.

Question 21: Our initial analysis of the proposed changes to pharmacy premises standards suggests that our preferred option, Option 2, has no significant transition or ongoing costs relative to the current framework. This is based on assumptions in Annex A of the IA. Are our assumptions valid? If not, please identify what other costs and assumptions have not been identified and provide examples and estimates that will help us quantify and monetise the costs.

Question 22: We do not consider there will be any specific adverse impacts from this proposal on small or micro businesses. Do you agree? If not, please identify what these impacts are and their likely costs and explain why they are specific to small and micro businesses. Also, please provide evidence on how small and micro businesses would be affected by an alternative prescriptive rules-based approach compared to an outcome-based system. Please say (i) what assumptions we should use (ii) identify the impacts and (iii) estimate their likely costs and explain why they are relevant to small and micro businesses.
Question 23: Do you have any additional evidence which we should consider in developing the assessment of the impact on equality?
## Respondents (by category, as self-recorded on the consultation responses)

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<tr>
<td>3</td>
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<td>69</td>
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<tr>
<td>4</td>
<td>A pharmacy technician</td>
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</tr>
<tr>
<td>5</td>
<td>A pharmacy owner</td>
<td>2</td>
</tr>
<tr>
<td>6</td>
<td>Other</td>
<td>9</td>
</tr>
<tr>
<td>7</td>
<td>A pharmacist on behalf of a healthcare organisation</td>
<td>20</td>
</tr>
<tr>
<td>8</td>
<td>A pharmacist on behalf of another organisation</td>
<td>4</td>
</tr>
<tr>
<td>9</td>
<td>A pharmacy technician on behalf of a healthcare organisation</td>
<td>1</td>
</tr>
<tr>
<td>10</td>
<td>A member of the pharmacy team on behalf of a healthcare organisation</td>
<td>1</td>
</tr>
<tr>
<td>11</td>
<td>A healthcare organisation</td>
<td>15</td>
</tr>
<tr>
<td>12</td>
<td>Other organisation</td>
<td>26</td>
</tr>
</tbody>
</table>
Responses to the consultation

Organisations:
Abertawe Bro Morgannwg University Hospital
Action Against Medical Accidents
All Party Pharmacy Group
Association of Pharmacy Technicians UK
Attorney General for Northern Ireland
Bart’s Health, NHS Trust
Belfast Health and Social Care Trust
Bradford College
Cheshire and Wirral Local Pharmaceutical Committee
Colchester Hospital University NHS Foundation Trust
Community Pharmacy
Community Pharmacy NI
Community Pharmacy Scotland
Community Pharmacy Wales
Crown Prosecution Service
Derby Teaching Hospitals NHS FT
Dispensing Doctors Association
East & South East Specialist Pharmacy Services
General Pharmaceutical Council
Great Western Hospital NHS Foundation Trust
Guild of Healthcare Pharmacists
Health and Social Care Board, Northern Ireland
Health Education England
Health Education Kent, Surrey and Sussex
Health Education Thames Valley
Health Foundation
Healthcare Improvement Scotland
HMP Swansea Pharmacy
Hywel Dda University Local Health Board
ICHT
Integritas Registered Charity
Kettering general hospital
King's College Hospital NHS Foundation Trust
Law Society of Scotland
Leeds Teaching Hospitals NHS Trust
LETB Pharmacy Leads Group (Health Education England)
MEHT
Mid Essex Healthcare Services Trust
Mid Essex Hospital Services NHS Trust
Morgannwg Local Practice Forum Steering Group of the RPS
National Pharmacy Association
NHS Ayrshire and Arran
NHS Borders
NHS England
NHS Greater Glasgow and Clyde
NHS Lanarkshire
NHS Lothian
NHS Orkney/Shetland
NHS Pharmacy Education and Development Committee
NHS Scotland Directors of Pharmacy
NHS Sheffield CCG
NHS Shetland
NHS Wales
NICE
North East Senior Pharmacy Managers Group - Workforce Training and Development Group.
North of Tyne Local Pharmaceutical Committee
Northern Health and Social Care Trust
Northumbria Healthcare NHS Foundation Trust
Oxford University Hospitals NHS Trust
Papworth Hospital NHS Foundation Trust
Parkinson’s UK
Patients First
Pharmaceutical Services Negotiating Committee
Pharmaceutical Society of Northern Ireland
Pharmacists Defence Association
Pharmacy and Prescribing Support Unit, NHS Greater Glasgow and Clyde
Pharmacy Forum NI
Pharmacy Schools Council
Pharmacy Voice
Professional Standards Authority for Health and Social Care
Royal Pharmaceutical Society
Royal Wolverhampton NHS Trust
Sandwell and West Birmingham NHS Trust
Scottish Prescribing Advisers Association
Sheffield Teaching Hospitals NHS Foundation Trust
South Eastern Health and Social Care Trust
South Staffordshire Local Pharmaceutical Committee
South Warwickshire NHS Foundation Trust
Suffolk LPC
Sussex Community NHS Trust
Thames Valley and Wessex Chief Pharmacists Group
The Luton & Dunstable University Hospital
University Hospital of South Manchester
University Hospital Southampton NHS Foundation Trust
University Hospitals Bristol NHS Foundation Trust
University of Wolverhampton
Wales Centre for Pharmacy Professional Education
Walsall Healthcare NHS Trust
Western Health & Social Care Trust
Wexham Park Hospital
Wye Valley NHS Trust

Business:
Asda Pharmacy
B K Kandola Ltd
Bannside Pharmacy Ltd
BLM
Boots Pharmacists Association
Boots UK & Manchester Pharmacy School
Boots UK / Walgreens Boots Alliance
Charles Russell Speechlys LLP
Intrahealth
L. Rowland and Co. (Retail) Ltd. t/a Rowlands Pharmacy
Medicare
Mounts health centre pharmacy
Nuffield Health
Numark
PCT Healthcare
SKF Lo (Chemists) Ltd
The Co-operative Pharmacy
Weldricks
Well - Bestway Group
Well Pharmacy
WR Evans (Chemist) Ltd