

EXPLANATORY MEMORANDUM TO
THE PHARMACY (PREMISES STANDARDS, INFORMATION OBLIGATIONS,
ETC.) ORDER 2016

2016 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This Order makes changes to the Medicines Act 1968, the Pharmacy Order 2010 and the Pharmacy (Northern Ireland) Order 1976.

2.2 It is being made in particular to:

- remove the requirement for the General Pharmaceutical Council's (GPhC) standards for registered pharmacy premises to be set in rules;
- expressly enable the Pharmaceutical Society of Northern Ireland (PSNI) to set standards for registered pharmacy premises;
- apply the standards to associated premises that are integral to the delivery of pharmacy services as well as to pharmacies;
- revise the sanctions which the GPhC and PSNI may use where pharmacy owners breach the standards;
- introduce the use of interim suspension orders by the GPhC and PSNI against pharmacy owners when that is in the public interest;
- make changes to the GPhC's powers to gather information from pharmacy owners;
- clarify what information the GPhC may publish in its reports of pharmacy inspections; and
- make a correction to the GPhC's procedure on the notification of the death of a pharmacist.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Other matters of interest to the House of Commons

3.2 The territorial application of this instrument includes Scotland and Northern Ireland and it is not a financial instrument that relates exclusively to England, Wales and Northern Ireland.

4. Legislative Context

4.1 The GPhC and the PSNI are the regulators of the pharmacy professions. They are unusual among professional regulators in that, alongside their role as the regulator of pharmacists, and pharmacy technicians for GPhC, they also provide varying degrees

of system regulation through their role under Part 4 of the Medicines Act 1968 in registering and monitoring retail pharmacy premises. The GPhC is the regulator for pharmacy in Great Britain and the PSNI for Northern Ireland.

- 4.2 The GPhC is obliged under the Pharmacy Order 2010, which is the framework legislation governing most of its activities, to promote safe and effective practice at registered pharmacies and to achieve this it has specific obligations to set standards for registered pharmacies. 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.
- 4.3 The GPhC has developed and piloted, in consultation with key stakeholders and with the support of English, Welsh and Scottish Health Ministers, 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. The intention is to avoid a regulatory model which leads pharmacies towards a compliance-driven or checklist approach in meeting its standards. Instead the intention is to provide a clear framework through which owners of pharmacies are required to consider how best to meet GPhC standards, focusing on the needs of patients.
- 4.4 This type of framework builds on the best practice of others, including the work of the Cabinet Office, the Better Regulation Executive's principles of good regulation, the Hampton principles for inspection and enforcement, and the Professional Standards Authority's view on "right touch regulation". The proposal that the standards should not be placed in legislative rules follows as a consequence of this approach and will enable the GPhC to respond quickly when reviewing and updating the standards to keep pace with the increasingly rapid changes in pharmacy service provision.
- 4.5 The proposals on premises standards to a large extent accord with those proposed by the Law Commission in their report: "Regulation of Health Care Professionals: Regulation of Social Care Professionals in England" (Cm 8839: SG/2014/26), published in April 2014.
- 4.6 It is also 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 be done by amendment of the Pharmacy (Northern Ireland) Order 1976, which is the framework legislation governing most of its activities. It will enable the PSNI to put their premises standards, which are currently set in guidance, on a statutory footing so that in future they can be set in statutory codes of practice. It is proposed that the PSNI, like the GPhC, will be enabled to take an outcomes based approach to registered pharmacy standards, but reflecting its own particular approach and circumstances.

5. Extent and Territorial Application

- 5.1 This instrument extends to England and Wales, Scotland and Northern Ireland, except that where amendments are made to other legislation of more limited extent, those amendments have the same extent as the legislation being amended.
- 5.2 The territorial application of the instrument is set in Section 3 under "Other matters of interest to the House of Commons".

6. European Convention on Human Rights

6.1 The Minister of State for Community and Social Care, the Rt. Honourable Alistair Burt MP, has made the following statement regarding Human Rights:

In my view the provisions of the Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 are compatible with the Convention rights.

7. Policy background

What is being done and why

The policy objectives

7.1 The key aim of this legislation, changing the way in which the standards for registered pharmacy premises are set and administered by the pharmacy regulators, the GPhC and the PSNI, is to achieve a better balance between:

- criminal law and professional regulation so that matters which should be within the ambit of the pharmacy regulators are dealt with by them, by registration sanctions, rather than by the criminal courts;
- what is set and/or approved by Ministers and what is simply set by the pharmacy regulators; and
- legislation and standards, so that less is set in legislation, which by its nature is binding and takes time to change, and more is set in standards that are generally set in codes of practice. Developing and using standards will provide a better basis to achieve important goals, such as promotion of safe and effective practice at registered pharmacies, while also encouraging innovation in pharmacy practice.

The GPhC's standards for registered pharmacy premises

7.2 As just mentioned, the key change, and one of the Law Commission's recommendations, is that the GPhC will no longer be required to set standards for registered pharmacies in rules. Instead these will be aligned with other regulatory standards and be non-binding, code of practice style obligations, enforced via disciplinary procedures.

7.3 There are four refinements to the current legislation in the Pharmacy Order 2010, which will support the GPhC's approach to modernising pharmacy regulation:

- a) Article 19 of this Order (with consequential amendments elsewhere) sets out that rather than the standards for registered pharmacy premises being drafted as inflexible rules, they will be code of practice style obligations, focussed on outcomes and consistent with other forms of regulatory standards or codes.
- b) Article 19 of this Order also changes the current list of what the standards may relate to, to support this more flexible approach, covering broader areas or domains such as "governance arrangements", "working environments", and "the patient and public experience", with less emphasis on specific activities like "record keeping", "standard operating procedures" and "incident reporting mechanisms", which characterise this current list within the Pharmacy Order 2010.

- c) the updated list now also makes reference to setting standards in respect of associated premises, i.e. premises at which activities are carried on which are integral to the provision of pharmacy services “at or from” registered pharmacies. The GPhC’s ability to set standards in respect of these premises is qualified by the fact that they are only permitted to do so to the extent appropriate for ensuring the safe and effective provision of pharmacy services at or from a registered pharmacy. This reference to “associated premises”, which was also part of the Law Commission proposals, reflects the fact that in some respects the traditional model of pharmacy premises being entirely self-contained operations at which all aspects of the retail pharmacy business are carried on is, for some businesses, outdated. Integral parts of the businesses operation – for example electronic data storage – may be elsewhere.
- d) The current arrangements for pharmacy standards allow them to be set in such a way that they impose obligations not just on pharmacy owners but also on superintendent pharmacists, all of whom have to be individual registered pharmacists. This is being clarified so that the standards for registered pharmacies just relate to the obligations on pharmacy owners.

7.4 As a consequence of moving the standards out of rules, they will no longer be included in a statutory instrument that is subject to Privy Council approval, which has to be laid before both the United Kingdom and Scottish Parliaments. This will bring them into line with standards for individual registrants which are not subject to such procedures. Further increasing the autonomy of the GPhC in this way is in line with government policy (also a “deregulatory” gain, decreasing the amount of government control) and creates space for others to modernise and innovate where this is appropriate. However, Article 18 of this Order introduces an explicit requirement for the GPhC to consult Scottish Ministers, Welsh Ministers and the Secretary of State for Health on changes to all of its standards, not just its premises standards.

The PSNI’s standards for registered pharmacy premises

7.5 Article 13 of this Order places a statutory duty on the pharmacy regulator in Northern Ireland, the PSNI, to set standards for registered pharmacies and clarify what those standards may cover. This will enable the PSNI to put their premises standards, which are currently set in guidance, on a statutory footing so that in future they can be set in statutory codes of practice. The same wording is being used 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.

7.6 Additionally there is a further change, through amendment of the provisions of the Pharmacy (NI) Order 1976 to require PSNI to publish their registered pharmacy standards.

7.7 Article 4 of this Order establishes that the provisions for Northern Ireland will only be commenced when PSNI is in a position to introduce their new standards. The commencement order will 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.

The GPhC’s and PSNI’s enforcement powers in respect to registered pharmacies

- 7.8 Some of the enforcement powers of the GPhC and the PSNI are common to both bodies but others are different. Where there is already a common approach the changes being made apply equally to both regulators. 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.
- 7.9 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) are changed by Article 9 of this Order. They will now apply to retail pharmacy businesses owned by a pharmacist or a partnership, as well as to bodies corporate. Also clarified is that the test to apply sanctions, where premises standards are not met. The key test is whether or not the pharmacy owner is unfit to carry on the retail pharmacy business safely and effectively.
- 7.10 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 rather than its registration procedures or criminal sanctions.
- 7.11 To achieve this focus, amendments are also being made to the GPhC's sanctions provisions in the Pharmacy Order 2010 relating to breaches of improvement notices (through the provisions on Article 23 of this Order). Firstly, prosecutions will no longer be brought in cases of breaches of premises standards, the matter will 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.
- 7.12 The disciplinary procedures of the GPhC and the PSNI, where action is taken against individual registrants, both provide for possible interim suspension orders either while cases are ongoing or pending the outcome of an appeal. Use of these powers is subject to procedural safeguards to ensure that they are only used where the public interest calls for it, such as where suspension is necessary for the protection of the public.
- 7.13 Article 25 makes changes to the Pharmacy Order 2010 and Article 15 to the Pharmacy (Northern Ireland) Order 1976 which enable the GPhC and the PSNI to make interim suspension orders, pending a full hearing of the case, against the owners of pharmacy premises. This is achieved through a modification of the current powers to make interim suspension orders in relation to individual registrants, and reflects the move to better align the disciplinary provisions for pharmacy owners in respect to breaches of pharmacy premises standards with those for individual registrants.
- 7.14 Consequential changes are also made to the pharmacy regulators' regulation and rule making powers, which will include enabling them to be able to treat suspended entries in the premises registers as still on the register. This could be used to ensure premises registration fees could be collected even when premises are suspended during disciplinary proceedings against a pharmacy owner, or after an adverse finding but

pending an appeal. It is also proposed to provide for interim suspensions from the register, prior to a disqualification decision or removal decision taking effect – as the decision will only take effect after the time for bringing an appeal has elapsed or, if an appeal is brought, until the appeal is disposed of by the court of first instance.

- 7.15 As with the regulators' current powers, these new powers are only be exercisable for the protection of members of the public or where otherwise in the public interest. The disciplinary procedures for pharmacy owners are currently out of step with the disciplinary procedures of the regulatory bodies for health care professions generally in not allowing for interim suspensions, which means a potential gap in public protection.

Other changes for the GPhC

- 7.16 Article 21 of this Order amends Article 9 of the Pharmacy Order 2010 to provide for publication of the GPhC's reports and outcomes from pharmacy premises inspections. The 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.
- 7.17 The opportunity is being taken to correct an error in the Pharmacy Order 2010 to require notification of the death of a registered pharmacist or registered pharmacy technician by a registrar of births and death, or in Scotland a district registrar, rather than by the Registrar General, which is what the legislation states now. This is achieved by an amendment brought in by Article 24 of this Order.
- 7.18 Article 7 of the Pharmacy Order 2010 currently requires the making of rules by the GPhC not just in relation to premises standards but also in relation to the information obligations. Article 19 of this Order amends the information provisions so that they are permissive, such that the GPhC "may", rather than "must", make rules in respect to obtaining information from pharmacy owners.
- 7.19 Also clarified by Article 19 of this Order is 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.
- 7.20 The Pharmacy Order 2010 makes no provision, currently, about how these information gathering rules are to be enforced, and this gap is being filled. The most pragmatic solution is to make use of the existing enforcement regime, thus Article 22 of this Order provides for breaches of the Regulations to be enforced via the GPhC's improvement notice system.
- 7.21 However, this means 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 in the Scottish and United Kingdom Parliaments, which provide for the possibility of legislation being voted down.

Consolidation

7.22 There are no plans to consolidate the legislation amended by this Order.

8. Consultation outcome

8.1 The consultation, which ran from 12 February until 14 May 2015 drew 159 responses from a variety of respondents including from pharmacy professionals, patients and the public, representative groups and organisations.

8.2 The overwhelming majority of respondents supported the proposals with many welcoming the proposals. However, the need for guidance was raised in response to a number of the proposals, whether from regulatory, professional bodies or others, to help understanding the proposed changes and their impact in practice.

8.3 Overall, the responses provided constructive and useful views as well as support for moving to the next part of the process.

8.4 67% of responses were in favour of the GPhC's standards for registered pharmacies not being placed in legislative rules. Comments in support included observations that the standards should be focused on outcomes for patients to encourage improvement in the quality of services provided and that changes should require consultation with all stakeholders. Guidance was suggested to clarify certain matters, such as what were considered "associated premises". 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 pharmacy owners choose to meet the standards.

8.5 There were 21 responses to the proposals to place a statutory duty on the PSNI to set standards for registered pharmacies, clarify what those standards can cover and to require PSNI to publish their registered pharmacy standards. All of the responses were positive. Respondents who expressed an opinion were of the view that there should be parity of pharmacy standards across the UK.

8.6 94% of those who answered this question supported the approach to be taken by the regulators to breaches of standards by pharmacy owners. 3 respondents were concerned about how suspension orders would be enforced and the possibility that if action was taken that resulted in a suspension, it could jeopardise patients' access to medicines, if the pharmacy in question was the only one in the area. There was also a request for further clarity on how the approach would operate in a situation where failure to comply with premises standards concerned a breach in, for example, just one premises of a multiple pharmacy company. 3 of the 8 respondents who did not support the proposal 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 third suggested that owners should be more accountable but superintendents should not be held less accountable as a result.

8.7 91% of those who answered the question supported the proposal for the publication of GPhC reports and outcomes of pharmacy inspections. Those who responded positively remarked upon the approach being in line with that adopted by other system regulators, such as CQC and that it supported transparency. However, it was vital that the inspection, rating and reporting system is fair and fit-for-purpose. An accompanying explanation of the regulations and standards, to aid understanding by members of the public, was suggested. Concerns expressed by those who did not agree with the proposal and some who did, were that further engagement with

stakeholders is needed; the system for 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.

- 8.8 95% of those who answered this question supported the proposed changes to the GPhC's powers to obtain information from pharmacy owners. Of those who provided comments, while responding positively, there was concern that appropriate information governance and safeguards should be put in place to ensure that the rules do not impose disproportionate burdens. 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. 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.
- 8.9 To supplement the consultation and 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. At these events 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.
- 8.10 Participants at the events gave unanimous support to the proposals for an outcomes based approach to standards for registered pharmacy premises. It was suggested that this approach was even more relevant the greater the range of services available at a pharmacy. The emphasis on patient safety was welcomed and it was recommended that pharmacy users should have a voice in whether good outcomes for patients are being achieved by the pharmacy. Publication of inspection reports, in Great Britain, was also welcomed.
- 8.11 A series of presentations was also 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.

9. Guidance

- 9.1 The GPhC's standards for registered pharmacy premises will be supported by guidance on specific issues, where this is necessary.
- 9.2 Guidance in relation to standards for registered pharmacy premises in Northern Ireland will be a matter for consideration by the PSNI as the standards are developed.

10. Impact

- 10.1 The net cost to business has been assessed as £0m (EANCB on 2009 prices). No measurable impact on charities or voluntary bodies was identified.
- 10.2 There is no measurable impact on the public sector. It is anticipated that the pharmacy regulators will absorb the new work as part of their on-going responsibilities to promote the safe and effective practice of pharmacy.

10.3 An Impact Assessment is submitted with this memorandum and is published alongside the Explanatory Memorandum on the legislation.gov.uk website.

11. Regulating small business

11.1 The legislation applies to activities that are undertaken by small businesses.

11.2 The changes which this Order brings to the regulatory and inspection regimes for registered pharmacy premises are designed to enable small businesses to work within a framework that fits their business model while patients and the public continue to receive safe and effective services from the pharmacy.

12. Monitoring & review

12.1 The Department has committed itself to undertaking a review of the measures brought in by this Order within five years of it being made and a report of the review will be published.

13. Contact

13.1 Theresa Prendergast at the Department of Health Telephone: 020 7972 1118 or email: Theresa.prendergast@dh.gsi.gov.uk can answer any queries regarding the instrument.