Department of Health

The Scottish Government
Riaghaltas na h-Alba

Northern Ireland Assembly

Llywodraeth Cymru
Welsh Government

Rebalancing Medicines Legislation and Pharmacy Regulation: draft Orders under section 60 of the Health Act 1999

Response form

February 2015

Instructions for responding to the consultation

The Government wants your views on the proposals set out in the two pharmacy related draft Orders. These relate to:

- the introduction of a defence to prosecution for pharmacy professionals where an inadvertent error is made in dispensing or compounding a medicine, and setting out the conditions which need to be met for the defence to apply, and
- removal of the requirement for the General Pharmaceutical Council (GPhC) to set standards for registered pharmacy premises in rules, requiring the Pharmaceutical Society of Northern Ireland (PSNI)to set statutory pharmacy standards, revision the GPhC's enforcement powers in respect of registered pharmacies and making the same changes for PSNI, where appropriate, and certain other changes.

The response form below can be used to help you do that.

You can find out more and respond to this consultation at:
http://consultations.dh.gov.uk

The closing date for responses is 14 May 2015.

Responses received after this date may not be read. Consultation responses should be returned to: mailto:MB-Rebalancing >21@dh.gsi.gov.uk

Or if you would prefer to send your response by post:

The Pharmacy Team
Medicines, Pharmacy and Industry Division
Department of Health
Ground Floor North
Wellington House
133 – 155 Waterloo Road
London
SE1 8UG

What we will do next

We will read and consider all responses and publish a response to the consultation. The Government response will set out how comments and views shaped the final decisions taken in respect of the two areas, the subject of this consultation.

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We would appreciate it if you will indicate whether you are

A patient or carer	**( )**
A member of the public	**( )**
A pharmacist	**( )**
A pharmacy technician	**( )**
A member of the pharmacy team	**( )**
A pharmacy owner	**( )**
Another healthcare professional	**( )**
Please give details……	
Other	**(X)**

Please give details: The Professional Standards Authority for Health and Social Care promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and voluntary registration of people working in health and care. We are an independent body, accountable to the UK Parliament. As part of our work we oversee nine health and care professional regulators – including the General Pharmaceutical Council (GPhC) and the Pharmaceutical Society of Northern Ireland (PSNI) - and report annually to Parliament on their performance. More information about our work and the approach we take is available at www.professionalstandards.org.uk.

If you are responding on behalf of an organisation please indicate if it is

A healthcare organisation	**( )**
Other organisation	**(X)**

Please also indicate if your response relates to

England	**(X)**
Northern Ireland	**(X)**
Scotland	**(X)**
Wales	**(X)**

Consultation questions

Dispensing errors

Question 1: Do you agree with our overall approach, i.e. to retain the criminal offence in section 64 and to provide a new defence for pharmacy professionals against prosecution for inadvertent dispensing errors, subject to certain conditions?

Yes (X) **No ( )**

Comments

We are aware from our recent work on the professional duty of candour that the current threat of a criminal prosecution for the strict liability offence under section 64 of the Medicines Act 1968 is one of the factors that inhibits pharmacy professionals from protecting patients by disclosing and learning from dispensing errors. We therefore agree that it is necessary to decriminalise *inadvertent* dispensing errors and leave such matters to be dealt with under the GPhC/PSNI fitness to practise procedures.

We understand from the consultation paper that the section 64 offence relates to selling or supplying a medicine that is not of the nature or quality demanded/prescribed. Further we note from paragraphs 34 - 36 of the consultation paper that because the offence applies to everyone it is considered inappropriate to alter the offence itself and that the best way to decriminalise inadvertent dispensing errors would be to introduce a defence specifically for such errors.

The conditions within the proposed defence appear necessary to ensure prosecutions can still be pursued for dispensing errors or deliberate acts that are such that the pharmacy professionals responsible for them cannot properly be said to have been acting professionally. We hope that the conditions prove to be workable and that their complexity does not defeat the defence's objective of reassuring pharmacy professionals that they will not be prosecuted for inadvertent dispensing errors.

We hope that the Rebalancing Board succeeds with its plans to develop an equivalent defence for pharmacy professionals who work in hospital pharmacies. We are unsure whether medicines supplied from a doctors dispensing practice would fall within the ambit of section 64. If they are, thought should also be given to whether an equivalent defence needs to be introduced for people in that setting.

Given the complex nature of the proposed defence it seems to us that until some investigation has taken place it is unlikely to be clear whether or not the proposed defence would apply. We therefore hope that appropriate steps are taken to ensure that the introduction of the proposed defence will not reduce the capacity or willingness of the police and other relevant law enforcement agencies to investigate dispensing errors. In the interests of patient safety, the investigatory burden should not rest entirely with the lesser investigatory resources and powers of the GPhC/PSNI.

The GPhC/PSNI will need to be prepared to manage the potential challenges of pursuing fitness to practise proceedings in circumstances where the proposed defence has been raised successfully in the course of a criminal investigation or prosecution.

Question 2: Do you agree that, once a defendant has done enough to show that the relevant pharmacy professional might have been acting in the course of his or her profession, the prosecution should have to show, beyond a reasonable doubt, that the pharmacy professional was not "acting in the course of his or her profession" in order to secure a conviction?

Yes (X) **No ( )**

Comments

Question 3: Do you agree the two proposed illustrative grounds that the prosecution could rely on to establish that the pharmacy professional was not acting in the course of their profession, if they were proven beyond reasonable doubt?

Yes ( ) **No ( )**

Comments

Unsure. We do not consider we have the necessary expertise in criminal proceedings to offer a view on this matter.

Question 4: Do you agree that where a pharmacy professional does not follow procedures established for the pharmacy and an error takes place, this should not, on its own, constitute grounds for a decision in criminal proceedings that the pharmacy professional is not acting in the course of their profession?

Yes ( ) **No ( )**

Comments

Unsure. It depends on the nature of the breach of procedure and the relevant professional judgment exercised.

Question 5: Do you agree that for the defence to apply, the sale or supply of the medicine must have been in pursuance of either a prescription or (in the case of sales) directions from an appropriate prescriber?

Yes ( ) **No ( )**

Comments

Unsure. We do not have the sufficient knowledge of medicines law and pharmacy practice to offer a view on whether this condition needs to be narrower or wider.

Question 6: In your view, should it be part of a defence where someone is charged with a dispensing error that if an appropriate person at the pharmacy knew about the problem before the defendant was charged, all reasonable attempts were made to contact the patient unless it was reasonably decided not to do so?

Yes (X) **No ( )**

Comments

We agree that this would help incentivise pharmacies and pharmacy professionals to fulfil their respective candour obligations. Decisions about whether and whom should inform the patient should be taken in accordance with the principles of the statutory and professional duties of candour.

Question 7: Do you agree that the unregistered staff involved in the sale or supply of a medicine (including, for example pharmacy assistants who hand over medicines that have been dispensed or van drivers who deliver medicines to patients) or the owner of the pharmacy where a dispensing error occurs should potentially be able to benefit from the new defences?

Yes (X) **No ( )**

Comments

We consider that this is sensible to encourage unregistered staff to disclose errors so that they can be corrected and prevented in the future.

It will be important for the GPhC/PSNI to ensure ultimate professional responsibility for the sale and supply of medicines is clear, given the availability of the defence. When an unregistered staff member makes an

error, the GPhC/PSNI will need to consider whether the responsible pharmacist, superintendent pharmacist, pharmacy owner and/or the pharmacy premises had complied with its standards for mitigating the risk of such incidents and, if appropriate take regulatory action. We would expect the GPhC/PSNI to encourage law enforcement agencies and others to notify them if they are aware of such incidents.

It would be helpful to know if any thought has or will be given to introducing an equivalent defence for unregistered staff who work in a doctor's dispensing practice or a hospital pharmacy.

Question 8: Do you agree that the defence should not apply in cases where unregistered staff involved in sale or supply of medicine deliberately interfere with the medicine being sold or supplied at or from the pharmacy?

Yes (X) No ( )

Comments

As stated above, when such incidents occur the GPhC/PSNI will need to consider whether it needs to take any regulatory action against the responsible pharmacist, superintendent pharmacist, pharmacy owner and/or the pharmacy premises. We would expect the GPhC/PSNI to encourage law enforcement agencies and others to notify them if they are aware of such incidents.

Question 9: Do you agree with the overall approach to the new defence in section 67B in relation to the offence in section 63, i.e. to retain the criminal offence and provide a new defence subject to essentially the same conditions as will apply in relation to section 64?

Yes (X) No ( )

If you think different, additional or fewer conditions should apply, could you explain what, if any, conditions you think should apply.

We understand that section 63 relates to the offence of adding or removing something from a medicine in a way that is likely to cause harm to anyone who uses it.

For the same reasons given above in our response to question 1 we agree a defence should be introduced for inadvertent errors pharmacy professionals

make while preparing (compounding) medicines.

We hope that the Rebalancing Board will also find an appropriate way to extend this defence to pharmacy professionals who work in hospital pharmacies that have not elected to be registered with the GPhC/PSNI.

Pharmacy standards and related matters

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

Yes **(X)** **No** **( )**

Comments

We welcome the reference to our paper *Right-touch Regulation* in paragraph 104 of the consultation paper. In line with the agility and proportionality principles of right-touch regulation we agree that the GPhC's standards for pharmacy premises should be in a Code rather than Rules.

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

Yes **(X)** **No** **( )**

Comments

We agree that the standards 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.

We note that this and the other provisions for the PSNI would only be commenced when the PSNI is in a position to introduce their new premises standards. Given our role in overseeing the PSNI the Minister may wish to seek our advice in this regard.

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

Yes **(X)** **No** **( )**

Comments

The changes described in paragraphs 117 – 123 of the consultation paper seem likely to help the GPhC and PSNI regulate pharmacy premises and owners effectively.

The changes in this section include a proposal to extend the GPhC's and PSNI's disqualification procedures (under section 80 of the Medicines Act 1968) so that they apply to pharmacy businesses owned by a pharmacist or a partnership, as well as bodies corporate. This expansion will bring about a commensurate increase in the decisions within the jurisdiction of our power to refer GPhC and PSNI decisions to the courts (under section 29 of the National Health Service Reform and Health Care Professions Act 2002). We would therefore expect to be consulted about the timetable for commencing this aspect of the draft Order.

Please refer to our answer to question 20 for information about the cost consequences of this for the Professional Standards Authority.

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

Yes **( )** **No** **( )**

Comments

Agree in part.

We agree the GPhC should have a power to the publish reports of its inspections of registered pharmacies. Publishing inspection reports can encourage improvement and learning.

However, we are concerned that it is also proposed that if an inspection report includes personal data it is to be assumed for the purposes of the Data Protection Act that the disclosure is required. In the interests of patient privacy and public confidence in the GPhC we do not consider personal data about a patient should be included unless they consent.

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

Yes **( )** **No** **( )**

Comments

Agree in part.

It seems appropriate to change the requirement for the GPhC to make rules about obtaining information from pharmacy owners to a power to make such rules. It also seems sensible to introduce a means to enforce these rules and to do this via the GPhC's existing improvement notice system.

We do not feel able to offer a view on the changes referred to in paragraph 127 of the consultation paper because we are unclear how the draft Order will change the list of matters the GPhC can require pharmacy owners to provide. It would have been helpful if the consultation paper provided more detail about these changes.

Business and equality impacts

Dispensing Errors Impact Assessment

Question 15: An IA has been prepared covering the costs and benefits of the dispensing error proposals. Do you agree with our assessment?

Yes **( )** **No** **( )**

If not, please provide details and estimates of any impacts and costs that you consider are not relevant or, alternatively, have not been taken into account.

We have no view on this.

Question 16: Do you consider there are any additional significant impacts or benefits on any sector involved that we have not yet identified?

Yes **( )** **No** **( )**

If "yes" please provide details and estimates.

We have no view on this.

Question 17: As part of preparing this IA we have asked business representatives whether, if the new defences were introduced, they would have a downward impact on employee cost pressures (for instance, any reduction in the risk of being prosecuted could slightly reduce legal or insurance costs). No significant cost impacts have so far been identified. Are there specific impacts on small and micro businesses that we need to take into account?

Yes ( ) No ( )

If "yes" please explain any specific impacts on small or micro businesses**.**

We have no view on this.

Question 18: At this stage, we do not consider it is feasible to estimate a "typical" cost of prosecutions for dispensing errors on individual professionals or pharmacy businesses because of the small numbers involved over the last decade. Do you agree with this?

Yes ( ) No ( )

If not, do you have any relevant information which we can consider?

We have no view on this.

Question 19: We have provided an estimate of the magnitude of the cost and benefits that may arise from the potential implementation of the introduction of the change in approach to dispensing errors. These estimates rely on a number of general assumptions – summarised in Annex B of the IA. These include the length of time it takes a pharmacist to deal with different types of dispensing errors. In addition, we have also made assumptions regarding the potential benefits from learning and from a lower risk of prosecution. Do you think the assumptions we have made are proportionate and realistic?

Yes ( ) No ( )

If not what assumptions should we use? Please provide an estimate of the cost of such assumption.

We have no view on this.

Pharmacy Standards Impact Assessment

Question 20: We have prepared an IA covering costs and benefits of the premises standards proposals. Do you agree with our assessment?

Yes ( ) **No ( )**

If not, please provide additional information (with estimates) regarding other costs or benefits that you think have not been considered in the IA.

As mentioned in our answer to question 12, the proposed expansion of section 80 of the Medicines Act 1968 could increase the number decisions within the jurisdiction of our power to refer (appeal) decisions to the courts (under section 29 of the National Health Service Reform and Health Care Professions Act 2002). We would need to review these extra decisions and if necessary refer them to the courts. Page 20 of the IA considers this particular proposal but does not assess how many decisions are likely. In the absence of this information we are unable to estimate the potential cost implications for the Professional Standards Authority.

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 our assumptions in Annex A of the IA. Are our assumptions valid?

Yes ( ) **No ( )**

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.

We have no view on this.

Question 22: We do not consider there will be any specific adverse impacts from this proposal on small or micro businesses. Do you agree?

Yes ( ) No ( )

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**.**

We have no view on this.

Equality Assessment

Question 23: Do you have any additional evidence which we should consider in developing the assessment of the impact on equality?

Yes ( ) No (X)

If “yes” please provide the additional evidence of the impact on equality.

Confidentiality of information

If you would like any part of the content of your response (as distinct from your identity) to be kept confidential, you may say so in a covering letter. We would ask you to indicate clearly which part(s) of your response are to be kept confidential. We will endeavour to give effect to your request but as a public body subject to the provisions of the Freedom of Information legislation, we cannot guarantee confidentiality.

We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter. Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and, in most circumstances this will mean that your personal data will not be disclosed to third parties.