Annex B
CONSULTATION QUESTIONNAIRE

Question 1 :
Do you agree that the arrangements that should be in place to support an organisational duty of candour should be outlined in legislation ?

Yes √☐ No ☐

Comments

The National Pharmacy Association is the not for profit trade body which represents the vast majority of independent community pharmacy owners (including independent multiples) in Scotland and across the UK. The Association provides its members and the staff that work in the member pharmacies with professional and commercial support, professional indemnity insurance as well as representing the interests of community pharmacy.
The NPA is pleased to have the opportunity to respond to this consultation and limits its response to those areas which are more directly relevant to the independent community pharmacy network. The NPA is available for further discussion on this consultation.
General Comments

The NPA agrees with the principle of candour within the NHS. We believe that there is a culture of honesty and openness in independent community pharmacy but agree that in some cases more strict measures may ensure evidence of this is available.

We wish to remind the Scottish Government that pharmacists can be prosecuted for making a dispensing error. The Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board is reviewing the sanctions associated with dispensing errors. The recent work of the Board has shown how criminal sanctions associated with dispensing errors can act as a barrier to openness and transparency. This is about a climate of fear in which a health care professional may feel unable to admit when they have made a mistake. This is likely to prevent opportunities for learning and therefore lead to more serious incidents and greater patient harm. The work of the Board is progressing and subject to the necessary legislative processes we understand that the Department of Health will be consulting on proposed changes in 2015.

Community pharmacy is a highly regulated healthcare sector with requirements which place a duty of care upon pharmacists operating within this environment. This duty of care encompasses openness with patients when, on rare occasions, things go awry. The healthcare regulator for pharmacy, the General Pharmaceutical Council (GPhC), has a duty to protect patients and within this ensures that community pharmacy reports errors and rectifies any causative factors.

We support the GPhC signing a joint statement with other health regulators on *openness and honesty - the professional duty of candour*. We agree that pharmacists and pharmacy technicians have a professional duty to be open and transparent at all times.

Community pharmacists are highly skilled experts in medicines. They dispense 90 million prescriptions a year in Scotland and provide national and local enhanced health services including prescribing for minor ailments and clinical pharmaceutical care with the Chronic Medication Service.

In our experience as the main indemnity insurer for community pharmacy we believe medication dispensing errors including those which may potentially cause harm are fairly easy to identify. In instances of such errors, patients often realise they have an incorrect medicine and don't take it. The number of errors which arise in community pharmacy are very low compared to the number of complaints from other parts of the NHS.

Appropriate handling of the situation when an error and potential harm has been made, including an apology, helps facilitate any further complaint management. The NPA supports its members and provides guidance on handling complaints and claims of injury are generally settled swiftly. The NPAI has its own, experienced, team of legal pharmacy expert advisors who support NPA members in notifying, apologising and informing patients in the instance of errors.

The Patients Rights Act Scotland implemented in 2012 introduced requirement from pharmacists to report complaints to the NHS. The NHS Board Accountable Officer/CD team must be notified of all significant events, near misses, incidents and concerns involving CDs that occur within the pharmacy. These reporting mechanisms enable learnings to be disseminated to a wider audience. The NPA believes additional burdens placed on community pharmacy contractors which only serve to duplicate existing requirements and do not in any way enhance patient care or safety should be avoided. We would therefore, urge Scottish Government to avoid bringing in unnecessary regulation. Additionally, we would encourage Scottish Government to develop requirements which do not result in simple box-ticking on an annual basis. We would urge the Scottish Government to develop specific requirements for primary care settings. Such specific requirements should be appropriate for community pharmacy contractors and not just an add on to existing clinical governance requirements.

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Answers to specific questions as relating to community pharmacy
Question 1: Do you agree that the arrangements that should be in place to support an organisational duty of candour should be specified in detail?

The requirements should be proportionate to the risk and the context. As stated above community pharmacy is highly regulated. Consideration should

be given to existing regulation and the potential harm to patients before increasing regulation. Any increase in bureaucratic burden which takes pharmacists away from delivering patient facing care which can improve patient's health and safety is to be deplored.
We would not wish to see requirements for candour based on secondary care being applied to primary care and would urge the Scottish Government to develop specific requirements for primary care settings. Such specific requirements would be more appropriate for community pharmacy contractors.

Question 2: Should the organisational duty of candour encompass the requirement that adequate provision be in place to ensure that staff have the support, knowledge and skill required?

We support this in principle however we are concerned as to how this will work in practice for community pharmacy. What may be feasible for large health and social care institutions may be unfeasible for primary care organisations unless they receive appropriate support.

Question 3a: Do you agree with the requirement for organisations to publically report on disclosures that have taken place?

Again we support this in principle however unless patients and the public are able to understand how the steps taken by the pharmacy will make their practice safer we are concerned that this could have a negative impact on the reputation of the profession in general and the individual pharmacist. The number of dispensing incidents relative to the number of prescriptions dispensed is very low and we wouldn't want the confidence of the public in pharmacy to be negatively affected.

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Question 3b: Do you agree with the proposed requirements to ensure that people harmed are informed ?

Yes √☐ No ☐

Comments

As we said earlier, under the current legislation a pharmacist can face criminal prosecution for a simple dispensing error. Whilst the government has issued guidance not to prosecute in cases of a simple dispensing error, pharmacists may well be reluctant to put in writing anything which could be misconstrued, especially in more complex cases, and used against them in a court of law. Experience tells us that the current system of a verbal acknowledgement of the error and apology works well.

Question 3c: Do you agree with the proposed requirements to ensure that people are appropriately supported ?

Yes √☐ No ☐

Comments

Yes. However we are concerned if this support is over and above what is normally provided by a community pharmacy. Pharmacy businesses are unlikely to be able to resource complex support

Question 4:
What do you think is an appropriate frequency for such reporting ?

Quarterly ☐ Bi-Annually ☐ Annually √☐ Other ☐ (outline below)

Comments

No more frequently than quarterly and preferably annually incorporating information already supplied to the NHS.

Question 5:
What staffing and resources that would be required to support effective arrangements for the disclose of instances of harm ?

Comments

Question 6a:
Do you agree with the disclosable events that are proposed ?

Yes √☐ No ☐

Comments

Question 6b: Will the disclosable events that are proposed be clearly applicable and identifiable in all care settings ?

Yes ☐ No ☐

Comments

Question 6c:
What definition should be used for ‘disclosable events’ in the context of children’s social care?

Comments

Question 7
What are the main issues that need to be addressed to support effective mechanisms to determine if an instance of disclosable harm has occurred ?

Comments

Question 8:
How do you think the organisational duty of candour should be monitored ?

Comments
The Regulator of the profession concerned should monitor organisational duty of candour.

Question 9:
What should the consequences be if it is discovered that a disclosable event has not been disclosed to the relevant person ?

Comments
The Regulator of the profession should take scrutinise any such event against the professional standards and take appropriate action.

End of Questionnaire