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 ☒

Along with other UK regulators of healthcare professionals, the General Pharmaceutical Council (GPhC) has signed a joint statement on openness and honesty - the professional duty of candour. The statement reflects the GPhC’s requirement that pharmacists and pharmacy technicians need to be open and transparent at all times, and serves as a reminder that candour is an essential duty for all professionals. The implications of need for this should be understood by all of our members and should be reflected in current practices. Community Pharmacy Scotland fully understands the need for a duty of candour following recommendations of the Berwick and Francis reports however we feel it is not necessary to underpin this through legislation. Current arrangements with the Regulator and Health Boards (through the 2009 General Pharmaceutical Regulations in Scotland, Patient Rights Act 2011) should be enough to ensure that duty of candour takes place in a professional way ensuring improvement in practice and appropriate disclosure with patients. There are fundamental advantages of regulation over legislation. While they should have the same effect, regulation is far easier to modify and should therefore cost less in both time and money. There are also other areas of practice improvement where community pharmacy teams are being brought into to help engender a culture where staff are supported to be candid e.g. Scottish Patient Safety Programme (SPSP). The focus to primary care for the SPSP includes community pharmacies.

Question 2:
Do you agree that 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?

Yes ☒ No ☐

An organisational duty of candour should be in place whether a statutory or professional duty of candour operates. Staff should be supported by organisations to understand the requirements around duty of candour, so that the principles are understood by the whole team. Indeed the General Pharmaceutical Council (GPhC) gleam evidence from the whole team around learning environment, culture and procedures, so duty of candour could form part of that. Fortunately in Scotland our community pharmacy network is extremely safe with little evidence of systemic flaws affecting
patient care. However there are occasions when healthcare professionals, including pharmacists, are called upon to disclose and discuss incidents where harm has occurred from services they provide. We would expect that support to be delivered to staff to ensure the ‘planned, co-ordinated and consistent approach’ advocated for respectful disclosure of episodes of harm is understood by our members.

Currently one perceived barrier to disclosure of harm via pharmacists is the spectre of criminalisation from a single dispensing error when no harm was intended. This reserved legislation is being looked at under wider rebalancing of the laws around pharmacy regulation and practice.

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

Yes ☒ No ☐

The General Pharmaceutical Council (GPhC) is currently working through a new inspection regimen for community pharmacies which includes guidance and specific standards on professional duty of candour. Once the inspection regime is out of the prototype (pilot) phase it is the intention of the pharmacy regulatory body to publish inspection reports publically. These reports will include the individual pharmacy approach to disclosure of harm to patients. Community Pharmacy Scotland feels this is sufficient alongside other measures of reporting such as disclosure through Health Board systems.

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

Yes ☒ No ☐

This duty for pharmacy professionals to be candid with patients and others is already reflected in the General Pharmaceutical Council (GPhC) regulatory framework; both in their standards and in their guidance. Community Pharmacy Scotland would therefore already expect our members to be informing patients and others, when appropriate, as part of their current practice.

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

Yes ☒ No ☐

See answer 2
Question 4: What do you think is an appropriate frequency for such reporting?

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

Community Pharmacy Scotland feels that, where possible, reporting should coincide with other areas where reporting is necessary. A quarterly submission is required under the Patient Rights Act 2011 for complaints so it may be appropriate to consider this timeframe for submission alongside this similar area of legislation.

The important factor here is to minimise or reduce the amount of red tape which is experienced by community pharmacy teams.

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

Community Pharmacy Scotland feels unable to comment on this on behalf of our members. Our members make individual judgements on staffing levels taking factors such as effective delivery of service and patient safety into account, but as independent contractors this is up to them to operate as they see fit.

Other agencies such as Health Boards would also have to be adequately supported to ensure effective arrangements are put in place and maintained so that they are in a position to support individuals with the legislative requirements.

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

Yes ☒  No ☐

Medicines are where most of the incidents will be drawn from pharmacy. It can be taken from the general description for disclosable events that incidents involving medicines would fit. Community Pharmacy believes that our members would recognise the need to disclose events of harm involving medicines with patients as part of our professional duty of care to them.

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

Yes ☒  No ☐

Community Pharmacy Scotland is clear what the definitions indicate in our healthcare sphere and would hope this would mean that other health and social care partners can identify within their own area of expertise what this would look like.
There would always be instances however where this may not always be obvious.

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

Community Pharmacy Scotland feels that this definition should be dealt with by experts in this field.

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?

The majority of events will probably be obvious in their nature and be disclosed and reported appropriately. It may be required that every HSCP or Health Board (in the instances involving healthcare professionals) have a designated ‘Disclosable Harm Officer’ so that instances and processes can be identified and discussed with a specific individual(s), who could provide consistency on a local level according to national guidance. These ‘officers’ could also form a network to support a consistent approach and ensure that best practice can be shared. Bearing Health and Social Care Integration in mind these ‘officers’ should work across the fields if possible.

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

Community Pharmacy Scotland would stress that any system should be as free from bureaucracy for our members as possible. We do not want any system to divert resource away from frontline patient care. We do recognise though that in any organisational system it is better to reflect and review the effectiveness of the system to ensure it delivers what is intended. The ‘Disclosable Harm Officers’ within Health Boards could facilitate this monitoring as per the regulations in place governing pharmaceutical service provision. Community Pharmacy Scotland believes that learnings from other stakeholders such as the General Pharmaceutical Council (GPhC) should be considered. We already are aware that the GPhC has recently formed a memorandum of understanding with the various Health Boards in Scotland and sharing of appropriate information is important to facilitate the culture and safe practice all practitioners will want to deliver for patients.

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

Community Pharmacy Scotland believes that this should be for Health
Boards (with whom pharmacies are contracted to deliver services under the 2009 regulations) and the regulator (General Pharmaceutical Council, GPhC) to look into the circumstances surrounding any such event. This can then be dealt with under recognised procedures.

End of Questionnaire