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 ☒

Pharmacists already have a professional duty of candour as healthcare professionals and are bound by this in all aspects of their daily practice.

We refer you to the recent joint statement from the Chief Executives of the statutory regulators of healthcare professionals which is now very explicit in the requirements to tell, apologise, support , remedy if possible and explain short and long term effects when something goes wrong with their treatment which causes ,or has potential to cause harm or distress.

In addition to the regulatory standards, our own professional standards advocate honesty and openness. We promote a culture of learning from errors with staff empowered to raise concerns in the workplace, and to be supported when they do.

As healthcare professionals we fully support the principles of honesty and openness when things go wrong. However, for the pharmacy profession there is a singular problem of concern which has not yet been resolved, where a genuine dispensing error can result in a criminal prosecution due to the wording of the Medicines Act 1968.
Pharmacists, uniquely among health professionals could be liable for criminal prosecution when declaring a dispensing error in the normal course of their duties, even when no harm resulted. A change in the legislation is required to align pharmacy with all other healthcare professionals.

We are aware that there is work progressing, albeit slowly, through Westminster and the Independent Rebalancing Board chaired by Ken Jerrold to address this but until resolved, regrettably therefore, we propose that at the present time a statutory duty of candour must not be introduced for pharmacists.

Dispensing errors in pharmacy occur very seldom and as stated above, professional practice ensures that when they do they are dealt with openly , honestly and swiftly to minimise any potential patient harm. However , it might be useful to note that until the Medicines Act anomaly is remedied and, while pharmacists are placing themselves at risk of criminal proceedings by reporting dispensing errors , participation in investigations relating to incidents covered by a statutory 'duty of candour 'might impact on their rights under article 6 of the European Convention on Human Rights. This would be particularly with regard to the right to silence and a privilege

against self-incrimination, in any subsequent criminal proceedings.
We support the principles of a duty of candour and would like to have the current situation remedied as quickly as possible and seek to discuss this with Scottish Government at the earliest opportunity, before any legislation is drafted.

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 ☐

We agree that organisations have a duty to ensure all staff are fully appraised of the need for openness and transparency and training and support must be provided by the organisation.
This must be combined with a just culture of learning from mistakes to encourage reporting of errors.

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

Yes ☐ No ☐

While we agree in principle with the requirement for openness and transparency more clarity is required around the extent of the detail which would be made public. We would not like to see individuals publicly named as incidents resulting in harm are often the result of a combination of events. Pharmacists working in the NHS already report incidents through the Datix database which is in the public domain and in community the regulator intends to publish inspection reports on community pharmacies but we are not yet sure what level of detail this will provide .

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

Yes ☒ No ☐

As answered above, our professional duty of candour requires that pharmacists must tell patients or their carers when anything has gone wrong, and to explain any possible repercussions.

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

Yes ☒ No ☐

We agree that staff should be trained to deal with any incidents resulting in harm and supported through this process so that patients and their families can then receive adequate emotional and practical support from the organisation. The national guidance proposed will be necessary to provide a consistent approach and eliminate the variation which has been of concern.

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

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

We suggest that any reporting is integrated into current reporting procedures and timescales as far as possible to minimise extra bureaucratic burden. This might be variable across different organisations.

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

Since error reporting is already part of professional practice and the numbers of errors in pharmacy are very small, with an even smaller number resulting in harm, we would not envisage reporting to require additional resource. If however disclosures were to result in an additional layer of investigation beyond that which is currently carried out to analyse root causes of errors and improve processes, this would result in a requirement for additional resource.

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

Yes ☐ No ☒

We have concerns as to how the events would be defined. For medicines, a person can suffer harm as a result of an allergy or unforeseeable adverse reaction which could result in a hospital visit. Great care needs to be taken to ensure that healthcare professionals are not at extra risk in the normal course of their professional practice due to events outside their control.

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

Yes ☒ No ☐

We believe that when harm has occurred this will clearly identifiable.

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

As the professional body for pharmacists it is not within our remit to comment on children's social care

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?

For healthcare professionals their professional judgement, the complaints procedures, and reporting to immediate line managers should initiate any required disclosures.

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

We agree that monitoring should be embedding into existing requirements as far as possible. The General Pharmaceutical Council is the pharmacy regulator and inspects all registered pharmacies and regulates individual pharmacists, investigating any complaints. The usual fitness to practice governance would cover duty of candour. In addition, other agencies such as Health Improvement Scotland already have a scrutiny role.

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

For pharmacists this would be for the regulator to decide under their fitness to practice procedures with consequences decided based on the circumstances of individual cases.

End of Questionnaire