New offence of ill-treatment or wilful neglect – Response from the General Pharmaceutical Council

Executive summary

1. The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and registered pharmacies in Great Britain. It is our role to protect, promote and maintain the health, safety and wellbeing of patients and the public who use pharmacy services in England, Scotland and Wales. Our principal functions include:
    - Approving qualifications for pharmacists and pharmacy technicians and accrediting education and training providers;
    - Maintaining a register of pharmacists, pharmacy technicians and pharmacy premises;
    - Setting standards for conduct, ethics, proficiency, education and training, and continuing professional development (CPD);
    - Establishing and promoting standards for the safe and effective practice of pharmacy at registered pharmacies;
    - Establishing fitness to practise requirements, monitoring pharmacy professionals' fitness to practise and dealing fairly and proportionately with complaints and concerns.

2. We welcome the opportunity to respond to this consultation and our response is in two parts. We set out some broad points about the creation and necessity of the legislation below in the context of pharmacy and have addressed those questions most relevant to our field in the subsequent section. We believe that:
    - It is important to consider the links between the proposed offence and the work being undertaken in pharmacy to review dispensing errors legislation, under the auspices of the Rebalancing Programme Board;
    - The potential for unintended consequences needs to be thoroughly explored so that risks can be identified and managed. For example, these could include the possibility of the new offence (and the behaviour of investigation and prosecution authorities in relation to it) driving defensive practice, particularly when it comes to candour in healthcare settings;
    - Any new offence, given the context in which it will be committed and the recipients of such treatment, should be included as an 'autobar' offence for the purposes of Disclosure & Barring Service referrals in England and Wales and Disclosure Scotland;
    - The new law cannot just apply to the NHS but must apply across different healthcare settings.

Overview

3. Although our role is only a small part of the wider health and care sector, and we regulate a very small proportion of the 1.3 million NHS workforce, we see recent reports such as Francis and Berwick having lessons for us all.

4. We believe that healthcare professionals and organisations that intentionally harm patients to whom they have a duty of care, whether through ill-treatment or wilful neglect, should face the consequences of their actions or omission. We are aware that legislation already exists to prosecute individuals for offences against the person and the appropriate regulator can issue sanctions against registrants that intentionally harm patients to protect the public. However, we acknowledge this new offence will close a specific gap, particularly with respect to organisations.

5. The pharmacy profession has been arguing for changes to the offences around dispensing errors. In introducing a new offence in this area the risk of mixed messages for pharmacy professionals is apparent and will no doubt need to be considered. The purpose of the review of dispensing error legislation is to improve public protection by encouraging the recording, reporting and learning from dispensing errors to improve patient safety. Therefore, the impact of the introduction of a new offence would need to consider the ongoing work in this area to ensure there is no duplication and confusion for pharmacy professionals.

6. There is a balance to be struck around confidently reporting mistakes and issues without the risk of inappropriate prosecution. The recent work of the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board has shown how criminal sanctions associated with errors can act as a barrier to open and transparent reporting and learning, which leads to an improved quality of service for patients. The strategy evident in that work is to reform the criminal law to ensure it is appropriately targeted, to facilitate a more open culture, to ensure that regulation is ready and able to respond to poor practice, and to encourage the sector to raise its game in terms of reporting and learning.

7. As well as looking at the actions of an individual healthcare professional focus needs to be on the whole system that surrounds a failure in healthcare failing when issues arise. Therefore, we believe it is essential that the scope of any new offence should include organisations in order to avoid organisations apportioning liability and responsibility to individuals alone. Limiting the scope would eliminate opportunities for authorities to address wider system failures such as those that occurred at the Mid Staffordshire NHS Trust.

8. The inclusion of recklessness within the ambit of the offence could have unintended consequences. The possibility of criminal investigations being required in all cases where there is no hint of intent or deliberate neglect but a fault somewhere on the spectrum of carelessness could have significant ramifications which will need to be carefully considered by policy-makers and Parliament.

9. The content of associated guidance for those investigating cases and the Crown Prosecution Service will be relevant as to how this potential new law will be applied, implemented and considered alongside legislation relating to dispensing errors.

Consultation questions

We have made some broad comments above about the necessity of the legislation, particularly in the context of pharmacy. Notwithstanding these comments, we have answered the questions below on the basis, or assumption, that the new offence will be introduced.

A. Scope of the offence	
i) NHS or wider ● We propose that the new offence should apply in all formal adult health and social care settings, in both the public and private sectors. Do you agree with this approach?	Rather than trying to define the scope of the legislation through means of NHS or private care, formal or informal, it may be possible to extend the scope to those 'in receipt of health and social care' as this covers most, if not all, relevant settings as well as adults and children.
ii) Children ● Should the new offence apply in all formal health settings in both the public and private sector used by children (including services used by both children and adults)? ● Should the new offence apply in any other settings used by children (including services used by both children and adults)? Please explain your view and what sorts of services you believe should or should not be included.	Yes. We have no comment to make on this question.
iii) Formal service provision ● We propose that only formal health and social care arrangements should be within scope of this offence. Do you agree with this approach?	Yes.
B. Elements of the offence	
i) Conduct or outcomes ● We propose that the new criminal offence should focus entirely on the conduct of the provider/practitioner,	Yes. Criminally culpable neglect is rightly considered blameworthy; the fact that a patient may have fortuitously escaped harm

rather than any consideration of the harm caused to the victim of the offence. Do you agree with this approach?	should not give rise to a defence.
C. Describing the offence for organisations	
● Do you agree than an approach based on the way in which an organisation managed or organised its activities is the best, most appropriate way to establish the offence in respect of organisations?	The proposal is clear and holds those responsible accountable. We would also support the inclusion of some element of action taken on reported complaints or the use of complaints data. This is consistent with the outcomes of Francis and Berwick reports.
D. Other issues	
i) Penalties ● We propose that penalties for individuals convicted of this offence should mirror those set out in section 44 of the Mental Capacity Act 2005. Do you agree? ● Do you agree with our proposals in relation to penalties in respect of organisations? Do you think there are other penalties which would be appropriate?	As the existing and proposed offences attempt to address a similar issue it seems logical to have similar penalties available rather than establish differing penalties for similar offences with similar thresholds. The definition of 'leaders', in this context, may possibly be problematic in understanding what roles are covered by the scope of the offence and whether it is limited to board and/or senior executive staff when there may also be culpability at (senior) managerial level. In a pharmacy context it is clear who is responsible i.e. the Responsible Pharmacist to the Superintendent and the body corporate.
ii) Matters for prosecutorial discretion ● We propose adopting the same approach to referral of private prosecutions to the Director of Public Prosecutions as is available in respect of the section 44 offence in the Mental Capacity Act 2005. Do you agree? Are there other ways to address this issue?	Similar to that set out above, this is logical for the purposes of clarity and consistency.