Williams Review into Gross Negligence Manslaughter (GNM) in healthcare

Briefing from the General Pharmaceutical Council

About us

1. The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in Great Britain. It is our job to protect, promote and maintain the health, safety and wellbeing of members of the public by upholding standards and public trust in pharmacy. Our main work includes:
   - setting standards for the education and training of pharmacists, pharmacy technicians, and approving and accrediting their qualifications and training
   - maintaining a register of pharmacists, pharmacy technicians and pharmacies
   - setting the standards that pharmacy professionals have to meet throughout their careers
   - investigating concerns that pharmacy professionals are not meeting our standards, and taking action to restrict their ability to practise when this is necessary to protect patients and the public
   - setting standards for registered pharmacies which require them to provide a safe and effective service to patients
   - inspecting registered pharmacies to check if they are meeting our standards

Gross negligence manslaughter: the legal framework

2. The review seeks to cover a number of areas about the relevant legal framework, including how healthcare professionals are adequately informed about where the line is drawn between gross negligence manslaughter (GNM) and negligence, and what processes are gone through before initiating a prosecution for GNM. It is important for us to clarify the following points:
   - As the regulator, it is not our role to interpret the law on gross negligence manslaughter and the equivalent offence of culpable homicide in Scotland, or to make charging decisions.
   - It is the role of the Police to decide whether to investigate cases involving the death of a patient, where there may have been errors or negligence by health professionals, and for the prosecuting authorities to decide which cases should be pursued through the Criminal Courts.
   - If a pharmacy professional is convicted of a criminal offence, we have a role in determining whether their fitness to practise is impaired by reason of the conviction.
   - However, we have a different role to that of the Criminal Courts. Our role is to protect, promote and maintain the health, safety and wellbeing of members of the public by upholding standards and public trust in pharmacy. One of the ways that we do this is by ensuring that those on our register are fit to practise, and where necessary, issuing sanctions that are sufficient for the protection of the public and for upholding public confidence in pharmacy. Whilst the effect some sanctions have, for example a suspension or removal, could be punitive, a sanction must not be imposed to punish a registrant.
• We consider all cases involving convictions in line with our fitness to practise procedures. A conviction for gross negligence manslaughter will be taken seriously and investigated through our usual processes. However, this does not mean that a pharmacy professional will automatically be erased from our Register, and we will consider each case on its own facts and merits.

• If there is a prosecution then any further regulatory action will normally be put on hold until any police investigation, and subsequent court proceedings, have concluded. Once they have concluded then we will follow our fitness to practise procedure as set out in the Pharmacy Order 2010, and associated guidance. Even where there is no criminal conviction, we will investigate all information that might call into question whether a pharmacy professional’s fitness to practise is impaired.

• If the Committee considers it is necessary for the protection of the public, in the public interest, or in the interests of the pharmacy professional concerned, they may make an interim order to suspend the pharmacy professional from the Register, or impose conditions on the pharmacy professional’s registration.

Our approach to managing concerns

3. We are committed to protecting, promoting and improving the health and safety of people who use pharmacy services in Great Britain.

• We have a range of policies, formal criteria and operational procedures which are used to guide the way in which we investigate concerns.

• We investigate concerns about pharmacy professionals that could suggest there is a risk to patient safety or could affect the public’s confidence in pharmacy.

• A pharmacy professional’s fitness to practise can be impaired for a number of reasons, and these are set out in the legislation. The reasons include misconduct, deficient professional performance, not having the necessary knowledge of English, ill-health and a conviction for a criminal offence.

The decision-making process

4. Decision-making guidance is used at each stage to help us decide what action to take. The guidance is based on the law and established procedures, and takes account of the principles of good regulation. We publish the following decision-making guidance:

• *Good decision making: Investigations and threshold criteria guidance* - this guidance is used to decide whether to refer a concern to the Investigating Committee (IC).
• **Good decision making: Investigating committee meeting and outcomes guidance** – this covers IC meetings, the decision-making process and the outcomes of IC meetings.

• **Good decision making: Fitness to practise hearings and sanctions guidance** – this covers fitness to practise hearings and the decisions made by an FtPC during a hearing.

5. There are a number of considerations taken into account at the different stages of the process, including; the circumstances of the allegations and whether there is an ongoing risk to members of the public, aggravating or mitigating factors, the registrant’s behaviour, attitude and actions, relevant information and evidence, and public interest considerations.

**Concerns involving dispensing errors**

6. The majority of cases that we deal with involving the harm or death of a patient relate to dispensing errors. A small number of these cases have led to prosecutions. However, it is important to note that these prosecutions have primarily related to offences under the Medicines Act; not gross negligence manslaughter.

• We look into errors reported to us so that we can assure ourselves that there are no fitness to practise issues, and to ensure any underlying systemic issues are addressed to prevent similar errors occurring in future.

• However, we have consistently been clear that single dispensing errors do not in our view constitute a fitness to practise concern, if there are no significant aggravating factors.

• The majority of single dispensing errors are dealt with by the GPhC inspectors (who are pharmacy professionals) by way of guidance. If our investigation provides assurance that there are no aggravating features giving rise to fitness to practise concerns we can conclude the case by issuing guidance.

• We will also consider the specific facts and circumstances of each case, for example, whether the pharmacy professional has acted with candour and honesty, whether they followed standard operating procedures and how they have responded to the error.

**Decriminalisation of dispensing errors**

7. Unlike other health professionals, pharmacists and pharmacy technicians are currently at risk of criminal prosecution for a strict liability offence when inadvertent human error happens in the course of their professional practise. Changes to the law in this area are being introduced by Ministers:

• **The Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018** has now been laid before Parliament. The Order introduces defences to the criminal offences relating to inadvertent preparation or dispensing errors by registered pharmacy professionals (registered pharmacists and registered pharmacy technicians) acting in the course of their profession in registered pharmacies - predominantly community pharmacies.

• We are supportive of these changes, which are intended to encourage increased reporting of errors, without the fear of prosecution, and allows for individual and shared learning from those mistakes, leading to improved patient safety.
• It is important to recognise that pharmacy professionals may still be subject to prosecution under the Medicines Act where the conditions of the defence are not met, for example a deliberate disregard for patient safety would not benefit from the defence, as such a person would not be “acting in the course of his or her profession”. In addition, under general criminal law, where patient harm occurs or where there is pre-meditated criminal intent, pharmacy professionals may be prosecuted on the same basis as any other person.

• Notwithstanding the future changes to the law, we will continue to be able to use ‘fitness to practise’ procedures to determine what, if any, action is to be taken in cases involving dispensing errors.

• The Order applies only to pharmacy professionals making inadvertent preparation and dispensing errors in registered pharmacies. Hospital pharmacies are generally not registered and do not have the same governance arrangements. A separate order providing defences to section 63 and section 64 of the Medicines Act 1968, in the case of an error made by a pharmacy professional in a hospital or other care setting (e.g. pharmacy services for care homes and prisons), is being developed separately by the Department of Health and Social Care.

The use of expert witnesses in fitness to practise proceedings

8. We do not often need to instruct external expert witnesses for our fitness to practise cases. Where we need to obtain expert opinion evidence as part of our investigation, we are able to call on our inspectors, who are usually able to offer an informed, expert opinion about the relevant aspect of pharmacy practice.

9. Where the fitness to practise concern relates to a registrant’s health, we regularly instruct medical experts to examine the registrant, and to offer an opinion about the registrant’s fitness to practise.

Regulators’ right of appeal

10. The GPhC does not have an equivalent power to that of the GMC, to appeal fitness to practise decisions. However, the Professional Standards Authority (PSA) has the discretion to refer to the High Court any final fitness to practise panel decision made by the GPhC if that decision is insufficient for public protection. The PSA has to date only appealed one of the GPhC’s final fitness to practise decisions. Information about this case can be found [here](#).

Reflective learning

11. Reflective learning, openness and transparency plays a vital role in ensuring mistakes are learned from and not covered up. It is essential that we have a learning culture across healthcare and we are committed to ensuring we play our part in achieving this.

• We make clear in our standards for pharmacy professionals that pharmacy professionals must speak up when things go wrong. Our standards for registered pharmacies set out that pharmacy owners have an obligation to support pharmacy professionals to do this and promote a culture of openness, honesty and learning.
• Our guidance on raising concerns provides pharmacy professionals and employers with important information on when and how to raise concerns. We are currently working to improve this document and provide pharmacy professionals with web-based tools to ensure they are equipped to decide on the best organisation to raise a concern with.

• At the end of this month, we are beginning the introduction of revalidation for pharmacy professionals. This has been designed to support and encourage reflection.

• We will continue our work to promote a culture of openness, honesty and learning across pharmacy, and we will be urging everyone who employs pharmacy professionals or works within pharmacy to do the same.

12. We also recognise that the case of Dr Bawa-Garba has caused concern among health professionals, including pharmacy professionals. In February, we issued a statement, which included the following extract:

“*We understand that pharmacy professionals may be worried about reporting errors and taking part in processes to learn from errors. But it is vital for patient safety that errors are reported and discussed. For this reason, our revalidation proposals seek to encourage and support pharmacy professionals to reflect on where their practice could be improved during their peer discussion. We recognise there may be concern over how these reflections could be used, and so we want to be clear that we will not ask pharmacy professionals or peers to record what was discussed. Instead they will be asked to record how the process of having a peer discussion has benefited their practice. Records should not contain any details which could identify a patient. We will be producing further information to help pharmacy professionals understand what they are expected to do.*”

**Further information**

13. You can find out more information about us on our website on [www.pharmacyregulation.org](http://www.pharmacyregulation.org).