

Inquiry into complaints and raising concerns in health and care providers – written evidence submitted by 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. Although our role is only a small part of the wider health and care sector, and we regulate a very small proportion of the 1.3million NHS workforce, we see recent events such as Mid Staffs, where concerns and complaints were not handled appropriately as providing a sober lesson for us all. And while there are no direct references in the report's recommendations to pharmacy professionals or the GPhC we accept that a number of the recommendations apply to all healthcare professionals and systems regulators.
3. We are one small part of a wider system which is there to protect the public. It has been a long running challenge about how to ensure it is easy for patients to raise concerns with the right individual and organisation at the right time for it to be handled appropriately. The system should work for the patient; not the patient having to navigate around a complex system.
4. As a regulator with responsibility for both professional and systems regulation - through our professional *Standards of Conduct, ethics and performance* and new approach to inspecting registered pharmacies and *our Standards for Registered Pharmacies* - we detail evidence across both professional and systems regulation and how we commit to meeting particular objectives in this area as set out in our recently published Strategic Plan 2014-17.
5. Given our role that cuts across the profession and systems aspects of pharmacy the GPhC recognises the importance of an environment and culture in pharmacy where healthcare professionals need to be open and honest with patients and the public and feel able to raise

concerns with employers. These important themes are prominent in our new standards for registered pharmacies and the new prototype inspection model will provide a more robust process for checking whether concerns are indeed raised and acted upon.

6. The development of the new inspection model and improvements to fitness to practise will increasingly allow us to analyse data to consider what, if any, trends emerge as well as specific issues for concern either about a registrant or a premises. We recognise that we have much to do to improve our learning from data and information that we hold, including increasing the sophistication of our analysis of the source and nature of concerns and complaints raised with us. The capability to cross-reference and compare data between functions, using this data efficiently to identify issues proactively, is seen as a priority.
7. This submission sets out evidence across each of the terms of reference of the inquiry and seeks to outline our commitment in meeting the relevant recommendations from the Francis Report and other subsequent reports. The following is a summary of the main points from our submission. The main body of our submission then follows:
 - The GPhC has identified the main issues for pharmacy regulation emerging from the Francis Report and agreed the actions that the organisation needs to consider in response, in order to further safeguard patients and the public. These include the role of patient experience and patient voice, transparency, candour, whistleblowing, professionalism and partnership working all of which have been incorporated into the organisation's wider strategy through our Strategic Plan 2014-17.
 - Our new inspection model is designed to encourage reporting and learning from errors.
 - At the core of our published standards is the requirement to ensure the appropriate environment and processes are in place so that complaints are forthcoming and are dealt with.
 - The GPhC is a prescribed body under the Public Interest Disclosure Act 1998 (PIDA) and our *Guidance on Raising Concerns* contains information relevant to pharmacy professionals about PIDA.
 - We are strengthening our work in developing and improving collaboration with other health and social care professional and systems regulators. In particular, we are in the process of developing Memoranda of Understanding with key regulatory partners. This should reinforce our ability to demonstrate that information is shared, and that action is taken be it signposting or joint action, rather than simply having an agreement in place.

1 Handling of concerns raised by staff about care given in the health and care sectors

- 1.1 Our aim as a regulator is to create an environment in which pharmacy professionals have confidence – and are empowered – to raise issues and concerns appropriately. Our *Guidance on Raising Concerns* contains information for pharmacy professionals that raise concerns and information for employers about how to manage concerns.
- 1.2 We have established fitness to practise procedures through which all complaints and concerns about registrants are rigorously assessed and dealt with fairly and proportionately. This is done through our decision making mechanisms, including the threshold criteria and independent investigating and fitness to practise committees. We also deal with complaints involving registered pharmacy premises where there are concerns from a ‘systems’ perspective.
- 1.3 We are awaiting the publication of proposals from the Law Commission on the reform of the legislative framework underpinning our work and that of the other health professional regulators. We see this as critical in making a major step forward in developing a modern and effective professional regulatory framework. In particular patients and the public wish to see their concerns handled quickly and appropriately.

2 The extent to which the findings of recent inquiries have been incorporated into the complaints process

- 2.1 The GPhC set out its position on the Francis report earlier this year and identified the relevant themes emerging from the report for pharmacy and pharmacy regulation, including the role of patient experience and patient voice, transparency, candour, whistleblowing, professionalism and partnership working.
- 2.2 The GPhC Strategic Plan 2014-17 has been drafted to reflect these themes as part of the organisation’s wider strategy. We already have a significant programme of work underway to improve the regulation of pharmacies and pharmacy professionals which is consistent with many of the issues and recommendations within the Francis Report.
- 2.3 We are strengthening the work we are doing in developing and improving collaboration with other health and social care professional and systems regulators and some immediate changes have been made. We are making it easier for people to raise concerns by improving the content of our website, creating online concerns forms and improving our online guidance around raising concerns. Some of this work has been initiated; other elements are linked to the introduction of new IT systems and applications software.
- 2.4 A GPhC Decisions Circular has been produced; giving details of the outcomes of Fitness to Practise hearings where a decision has been made that affects the registrant’s registration status. The first circular was issued on 20 September 2013 to a list of organisations, including all the NHS Health Teams and regulators in other European countries. The circular is updated and issued on a monthly basis.

2.5 Our approach to the outcomes and recommendations of the Berwick review into patient safety will be to build them into the strategic and corporate planning processes as appropriate. We are considering the Berwick report alongside the Francis, Cavendish, Clwyd & Hart and Keogh reports. Our approach also needs to be considered in the context of the work of the Rebalancing Medicines Legislation and Pharmacy Regulation initiative and the outcome of the Law Commission's review of professional regulation as referenced above.

3 Support for staff who wish to make complaints or raise concerns

3.1 Our *Guidance on Raising Concerns* contains details of organisations that may be able to support professionals in raising concerns. The guidance is available on our website and is sent to all registrants.

3.2 At the core of our *Standards for registered pharmacies* is a requirement for there to be systems in place for feedback and concerns about the pharmacy, services or the staff that work in it to be raised, and for action to be taken where appropriate. Staff must also be empowered to provide feedback and raise concerns about meeting the standards and other aspects of pharmacy services.

4 The consequences of complaints for care providers and of raising concerns for the employment prospects of staff

4.1 Our *Standards for registered pharmacies* set out a clear requirement that pharmacy owners and superintendents must ensure there are suitable mechanisms in place to enable members of the public, patients and staff to raise concerns. Concerns handled effectively by providers of services at a local level, as set out in the Francis Report, often provide the most effective resolution. A key element of the new inspection model is to examine and review how concerns are dealt with by registered pharmacies.

4.2 Our *Standards for registered pharmacies* highlight this as an issue and our new inspection model is designed to encourage reporting and learning from errors.

5 Openness about complaints and concerns, and accessibility of information

5.1 Our website contains extensive information about raising concerns and making complaints. Our *Publication & Disclosure* policy¹ sets out what we will routinely publish and disclose at various stages of the fitness to practise process.

5.2 We continue to report regularly to Council on Fitness to Practise performance, including both quantitative and qualitative information, as follows:

- Total case loads and number/percentage closed
- Age profile of overall case load

¹<http://pharmacyregulation.org/sites/default/files/Publication%20and%20Disclosure%20Policy%20Dec%202013.pdf>

- Performance against target to conclude 95% of cases within 12 months
- Age profile of cases over 15 months
- Professional Standards Authority fitness to practise activity datasets
- Interim Orders
- Statutory appeals
- DBS/Disclosure Scotland referrals

5.3 In February 2014 the Council received a report that provides statistical information around the equality and diversity characteristics of those pharmacists and pharmacy technicians within the fitness to practise process. Issues in relation to medicines management at ward level are principally a matter for NHS hospitals and their regulator, the Care Quality Commission (and equivalent bodies in Scotland, Wales and Northern Ireland). However, we do recognise that much more needs to be done to encourage intelligence gathering about medication errors – both prescribing and dispensing – in pharmacy.

5.4 We also recognise that have we much to do to improve our learning from data and information that we hold, including increasing the sophistication of our analysis of the source and nature of concerns and complaints raised with us. Improvements are being made to the way we categorise concerns at source with allegations tracked through to decision making to enable better analysis and insight and inform policy development.

5.5 It is our intention in future to publish inspection reports and through publication of these reports we will provide information for patients on the standards they should expect to receive from a pharmacy. Clear labelling of how well the pharmacy has met our standards will aid their understanding of standards and provide them with a clear picture of a pharmacy's performance.

5.6 Short term improvements to our IT system will provide the infrastructure for collecting evidence from inspections of registered pharmacy premises to inform future policy development and learning. We are also examining the ways in which we can analyse data gathered across all of our functions including inspections, fitness to practise, standards and education.

5.7 The need to identify opportunities to share information, both in terms of formal data, and local informal intelligence, is highlighted in the Francis Report. We have been working with key partners to build this in to our IT systems and process modelling as we review our systems. We have established regular update meetings with the Care Quality Commission and processes for information sharing; this is being developed into a formal Memorandum of Understanding. We also meet regularly to discuss complex policy and legal issues where there is a need for joint assessment of organisations or providers registered with us both. Similar arrangements have been established with the MHRA.

6 The role of commissioners, system regulators and professional regulators with regard to complaints and concerns

- 6.1 The GPhC has a unique role as a professional and systems regulator and handling concerns across both fields is extremely important in upholding trust in the profession and public confidence in the regulator. We set out standards in *Conduct, Ethics and Performance* that all pharmacy professionals must apply. We also set *Standards for registered pharmacies*. The purpose of these standards is to create and maintain the right environment, both organisational and physical, for the safe and effective practice of pharmacy. Our core standards documents, including the student code of conduct and the standards for the initial education and training of pharmacists place patient safety at their centre. This includes the importance of raising concerns.
- 6.2 Every pharmacy professional has a duty to raise any concerns about individuals, actions or circumstances that may be unacceptable and that could result in risks to patient and public safety. This is a strong theme throughout our published standards and associated guidance.
- 6.3 Our *Standards of conduct, ethics and performance* state that pharmacy professionals must take action to protect the well-being of patients and the public. In particular, standard 6.8 sets out that pharmacy professionals must act with honesty and integrity to maintain public trust and confidence in their profession.
- 6.4 Pharmacy professionals must make sure that there is an effective complaints procedure in place where they work and that it is being followed at all times. Relevant authorities must be made aware of any policies, systems, working conditions, or actions, professional performance or health of others if these may affect patient care or public safety. If something goes wrong or if someone reports a concern to them, they must make sure that it is dealt with appropriately.
- 6.5 Our new inspection model reflects our desire, and the sentiments expressed in Francis, to move away from a regulatory model where checking compliance is the sole purpose. The standards include a requirement for patients to be able to provide feedback and for that to be taken into account and action taken as appropriate. Evidence of pharmacies acting on patient views will be sought as part of the inspection process and we will continue to review how we can learn from the new model and enhance it during the prototype phase.
- 6.6 Our *Standards for registered pharmacies* state that the risks associated with providing pharmacy services must be identified and managed. The standards set out a clear requirement that pharmacy owners and superintendents must ensure there are suitable mechanisms in place to enable members of the public, patients and staff to raise concerns. A key element of the GPhC's new inspection model is to examine and review how concerns are dealt with by registered pharmacies. Staff must be empowered to provide feedback and raise concerns about meeting the standards and other aspects of pharmacy services. Concerns must be raised when it is suspected that medicines or medical devices are not fit for purpose.
- 6.7 We are required to lay our strategic plan in Parliament. Included amongst our strategic objectives is a commitment to putting people at the heart of everything we do as a regulator, as well as using the knowledge gained from our regulatory services and from our work with others in order to promote improvement in the quality of pharmacy care and services. This reflects the

commitment of the GPhC to be a proactive learning organisation (including with regard to complaints) and to use them as a trigger for improvement.

- 6.8 It also links to our ongoing work of developing Memoranda of Understanding with key regulatory partners. This should reinforce our ability to demonstrate that information is shared, and that action is taken rather than simply having an agreement in place. The memoranda will enable us to share intelligence with other system regulators and to grasp issues more effectively. Our timetable of memoranda development and implementation will not only eliminate duplication but will also help identify gaps and enable us to share learning even more widely.
- 6.9 The student code of conduct and the standards for the initial education and training of pharmacists also place patient safety at their centre. This includes the importance of raising concerns, an issue considered within the latest review of the education outcome standards, where a new strengthened outcome has been proposed for consideration. We are seeking to learn more from data and information emerging from accreditation of pharmacy and pharmacy technician education, as well as pre-registration education and training.

7 The operation of the Public Interest Disclosure Act 1998 in relation to health and social care

- 7.1 As mentioned above, our aim as a regulator is to create an environment in which pharmacy professionals have confidence to disclose issues and concerns appropriately. The GPhC is a prescribed body under PIDA and our *Guidance on Raising Concerns* contains information about Public Interest Disclosure Act 1998 (PIDA) relevant to pharmacy professionals.
- 7.2 We also brought this issue to the attention of all registrants through an edition of our registrants' bulletin, which was published at the end of May last year. It included a piece reminding registrants of their right to speak out in the public interest and making them aware that in such cases PIDA will provide them with legal protection.

8 Future plans for improvements in this area

- 8.1 Our Strategic Plan 2014-17 sets out the importance we place on managing information and seeing concerns and complaints as a source of feedback, to be considered both individually, on their merit, and also as a source of intelligence to be analysed and, where appropriate, acted upon.
- 8.2 We recognise that we need to make better links between quality-assured information from different sources so that our regulatory interventions can be more effectively targeted and stand up to challenge. We will be analysing data from our regulatory functions and critically scrutinising intelligence about pharmacy issues and risks. This will help inform targeted regulatory interventions across all our areas of responsibility and will subsequently help us evaluate their impact.
- 8.3 The recently introduced Decisions Circular will improve openness about complaints handling and outcomes. We will be keeping this under review and will be seeking feedback on its

usefulness and any further refinements required. We will be seeking formal feedback from stakeholders in Spring 2014.

- 8.4 The development of the new inspection model and improvements to fitness to practise will increasingly allow us to analyse data to consider what, if any, trends emerge as well as specific issues for concern either about a registrant or a premises. We are strengthening the work we are doing in developing and improving collaboration with other health and social care professional and systems regulators.

9 Conclusion

- 9.1 We must all learn the lessons from the Francis Report and, for pharmacy in particular, take clear action to help to encourage professionalism and improve the safety and quality of pharmacy services. We are committed to working constructively with the professional bodies, fellow health regulators and others to take forward relevant recommendations identified in the Francis Report itself and the Government's initial response, including considering what more can be done to encourage and support health professionals to be open and honest with patients.
- 9.2 We also need to make sure we have the systems in place to take quick and appropriate action when a pharmacy professional or pharmacy is failing to meet our standards and all complaints, whether professional or systems related, are treated fairly and efficiently. We believe this can be achieved through our commitment to:
- Promoting a culture of openness in pharmacy, by setting clear standards and introducing a more robust process for checking whether concerns are raised and acted upon through the new approach to inspections,
 - Improving the way we use information from different sources so that our regulatory interventions can be more effectively targeted. We will be analysing data from our own regulatory functions and from other organisations, in order to target our regulatory interventions effectively based on risk to patients,
 - Providing clear information for patients and the public on the standards they should expect from their pharmacies, including through the publication of inspection reports in time, and making it easier for people to raise concerns when these standards are not met.