

Matthew Tester
Healthcare Quality Division
Health and Social Services Group
Welsh Government
Cathays Park
Cardiff
CF10 3NQ

Email to: HQDMailbox@wales.gsi.gov.uk

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Dear Matthew,

**General Pharmaceutical Council Response to Welsh Government Green Paper
- Our Health, Our Health Service**

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 patients and the public who use pharmaceutical services in England, Scotland and Wales.

We welcome the opportunity to respond to the consultation on the quality of health services and the governance and functions of the NHS in Wales. Whilst the proposals as a whole are of interest to us, we have limited our response to comments on the chapters and sections where we feel our work is directly relevant. We are happy to continue to contribute to future discussions on how we can all play our part in improving the health and wellbeing of patients and the public.

We are responsible for defining the education and training requirements for pharmacists and pharmacy technicians. We also set standards for pharmacy support staff, including dispensing assistants and medicines counter assistants.

Our statutory role as set out in the Pharmacy Order 2010 is:

‘To protect, promote and maintain the health, safety and well-being of members of the public and in particular of those members of the public who use or need the services of registrants, or the services provided at a registered pharmacy, by ensuring that registrants, and those persons carrying on a retail pharmacy business at a registered pharmacy, adhere to such standards as the Council considers necessary for the safe and effective practice of pharmacy.’

Consistent with other health professional regulators, our legislation makes explicit that our purpose is that of patient protection. We are unique amongst the UK health professional regulators as we have a statutory role in relation to ‘system’ regulation (i.e. regulating the provision of services by registered pharmacies) as well as the regulation of individual pharmacists and pharmacy technicians.

Our main work includes;

- setting standards for the education and training of pharmacists, pharmacy technicians and pharmacy support staff, and approving and accrediting their qualifications and training
- maintaining a register of pharmacists, pharmacy technicians and pharmacies
- setting the standards of conduct and performance that pharmacy professionals have to meet throughout their careers
- setting the standards of continuing professional development that pharmacy professionals have to achieve 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

Our Standards for Registered Pharmacies and all other standards relating to the behaviours of registrants and pharmacy staff can be found on our website.

In the next section of this response we have made comments on a chapter by chapter basis.

Part 1 Quality First and Foremost

Chapter 1. We have no comments.

Chapter 2. Enabling quality

The GPhC sets out the standards of conduct, ethics and performance that all pharmacy professionals must follow. Pharmacy professionals are pharmacists and pharmacy technicians who are registered with us. It is important that they meet our standards and practise safely and effectively. Their conduct will be assessed against the standards and failure to comply could put their registration at risk.

If concerns are raised about our registrants we will consider these standards when deciding if we need to take any action. Other professional regulators also set standards for their registrants working in Wales.

Quality and co-operation: The GPhC has a Memorandum of Understanding with Healthcare Inspectorate Wales to support the sharing of and to maintain patient safety and confidence in pharmacy services.

In our standard of conduct, ethics and performance we require our registrants to “Develop your professional knowledge and competence” and to “Maintain and improve the quality of your practice by keeping your knowledge and skills up to date and relevant to your role and responsibilities.” This duty placed on our registrants is in-line with Welsh Government’s aim of placing similar duties on organisations.

Integrated planning: We have no comments.

Chapter 3. Quality in Practice

Meeting Common Standards: All GPhC registrants that work within NHS Wales, or in other sectors, are required to meet professional standards set out in our Standards of conduct, ethics and performance.

Clinical supervision: We believe continuous lifelong learning is a vital part of career development and improved outcomes for service users. We will be introducing new arrangements in 2018 to show the public that pharmacy professionals continue to meet the standards for safe and effective practice throughout the course of their careers.

The GPhC’s Council found the arguments for the introduction of the continuing fitness to practise framework compelling to maintain public confidence in the pharmacy professions.

- Opinion polling has repeatedly shown that the public believe health professionals are already subject to regular reviews or assessments of fitness to practice.
- Evidence from the Bristol Inquiry Report showed that competence did not always grow with experience and could diminish over time, and that there was no system in place to spot waning competence, to support those professionals or to protect patients.
- As the independent pharmacy regulator, the GPhC has a duty to assure fitness to practise of registrants from the point they come onto the register. The Bristol Inquiry underlined that waiting for things to go wrong did not protect patients adequately, and that there was evidence of suboptimal performance within the medical profession.
- Despite seeking a more flexible and tailored approach to meet a common standard, the Westminster government still expects the health professional regulators to provide evidence on this subject and a clear direction of travel.

The GPhC Council have agreed some draft principles, subject to review due to ongoing work, in relation to the continuing assurance of fitness to practise of pharmacists and pharmacy technicians:

- The focus should be assurance of continuing fitness to practise and not a fixed point assessment.
- The model should be consistent with the generic principles agreed by the Non Medical Revalidation Working Group
- The model will need to consider more than one source of information
- Some form of assessment will be required and will need to be made against a standard
- That standard should be based on the standards of conduct, ethics and performance which apply to all registrants
- The model must take full account of the structure of the pharmacy workforce
- Any model would need to be appropriately costed and subject to testing, including piloting

The GPhC expects our registrants to undertake continuing professional development (CPD) as an important assurance to patients and the public that pharmacy professionals are keeping their knowledge and skills up to date and reflecting on their practice. CPD will be an important element of the new framework alongside peer discussion and evidence drawn from professional practice.

Chapter 4. Openness and honesty in all we do

Along with other 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.

This duty for pharmacy professionals to be candid with patients and others is already reflected in our regulatory framework; both in our standards and in our guidance. However, this joint statement was a further step forward in promoting a wider culture in healthcare where openness and transparency is the norm.

The statement also supports our ongoing work around strengthening the current requirements for openness and transparency for pharmacy professionals. For example, our review of the Standards for conduct, ethics and performance will reflect on how we can be more explicit about the need to be candid. It will also be considered as part of the work we are taking forward around our new Initial Education and Training standards.

The proposal to introduce a statutory duty of candour is in-line with our position.

Making it easier to raise concerns in an integrated system.

As mentioned earlier in this response the GPhC has a Memorandum of Understanding with Healthcare Inspectorate Wales setting out how we will share information and investigate together where appropriate.

There is no mention in this section of the role of the professional regulators in addressing concerns relating to the performance or behaviour of registered professionals inside or outside the NHS. The GPhC Standards of conduct, ethics and performance place obligations on our registrants in Standard 7 to:

- Make sure that there is an effective complaints procedure where you work and follow it at all times
- Make the relevant authority aware of any policies, systems, working conditions, or the actions, professional performance or health of others if they may affect patient care or public safety.
- If something goes wrong or if someone reports a concern to you, make sure that you deal with it appropriately
- Co-operate with any investigations into your or another healthcare professional's fitness to practise and keep to undertakings you give or any restrictions placed on your practice because of an investigation.

This obligation placed on GPhC registrants and similar obligations placed on other registered health professionals are vital if any changes to systems regulation are to work effectively.

Chapter 5: Better Information, Safely Shared

The GPhC places responsibilities on registrants relating to the safe sharing of information in its Standards of conduct, ethics and performance in Standards 3.5, 3.7 and 3.8 and gives further information in our Guidance on patient confidentiality which is set out below.

“We believe that giving patients the choice to allow pharmacy professionals to access their records can help them to receive better care. The pharmacy professionals supporting them will have access to important information about their medical history and their medicines and will be able to work more effectively with other health professionals involved in their care.”

Pharmacy professionals in some settings, including hospitals and GP surgeries, are already accessing records and using this information and their expertise to improve the health and well-being of their patients. As the pharmacy regulator, we can assure patients that pharmacy professionals and community pharmacies have to

meet our standards when accessing patient records. These standards make clear the responsibilities of pharmacy professionals and pharmacy owners, including in relation to holding patients' information securely, obtaining patients' consent before accessing their information and respecting their privacy."

Chapter 6: Checks and Balances

Whilst this chapter mentions regulation and inspection it mainly looks at inspections and the role of HiW and CSSIW. All of the establishments inspected and overseen by HiW and CSSIW have registered health and care professionals working within them who have professional responsibilities and who are accountable to their own regulator. There is no mention of the role of the professional regulators nor any mention of an obligation of the inspecting bodies to work with them.

The GPhC has a memorandum of understanding with HiW and has regular meetings to share information as appropriate. It would seem sensible to put in place regulations to ensure that all systems regulators and inspecting bodies share information and work together where appropriate to do so.

There is no mention of the Wales Concordat Cymru which exists to:

- Provide a forum to share high level information, new approaches and ideas about improving the impact and effectiveness of regulation, inspection, audit, scrutiny and service improvement.
- Identify trends in regulation, inspection, audit and scrutiny and broader service improvement policy and practice.
- Share good practice and influence policy makers collectively, when appropriate.
- Share experiences and identify opportunities for collaboration.
- Further develop and refine the systems and for sharing more detailed information between relevant bodies; through bilateral agreements and protocols when appropriate.
- Foster a collaborative ethos that encourages both proportionality and effective risk assessment and management.

Members of this forum individually and collectively make a contribution to quality, safety and improvement in healthcare and their roles should be considered in the development of any new legislation.

Representing patients and the public: The GPhC engages with the CHCs at a board and local level and very much values their contribution and input to our work in Wales and more widely. We consider patient and public input into policy development and their role in raising concerns vital for us if we are to regulate effectively.

Part 2: Strong Organisation and strong governance

Advisory Structure: The GPhC is a member of the Welsh Pharmaceutical Committee and we are therefore interested in this area of the paper. We feel that this committee provides a valuable forum for informing the Chief Pharmacist and other government officials of key issues and concerns within all sectors of pharmacy across Wales.

We welcome the opportunity to continue to work in collaboration. If you would like further information on the points raised in this response, or any other aspects of the GPhC's work please do not hesitate to contact me on the details provided below.

Darren Hughes
Director for Wales

General Pharmaceutical Council
DD: 01656 864895
Email: darren.hughes@pharmacyregulation.org