Dear Dr Wilson and Professor Barber

Response to the Review of NHS Pharmaceutical Care of Patients in the Community in Scotland Evidence Gathering Exercise.

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 your evidence gathering exercise for the review of NHS Pharmaceutical Care of Patients in the Community in Scotland.

Whilst the review as a whole is of interest to us, we have limited our response to comments where we feel our work is directly relevant to the proposals. We are happy to continue to contribute to future work in this area.

The GPhC recognises that the way in which pharmacy care and services are organised is changing and that pharmacy has the potential to make an even greater contribution to the health and well being of the public than it has so far. Protection of the public must be paramount, but we believe that it is incumbent on us to ensure that our regulation does not hinder developments or innovations in practice which have the potential to bring significant benefits to patients. We want to ensure we regulate in a way that takes account of developments in pharmaceutical care in Scotland following this review.

As an organisation, the GPhC is committed to regulating in a fair and proportionate manner that is in line with the level of risk posed to the health, safety and wellbeing of patients and the public. We are conscious of the importance of avoiding duplication of regulation. We are working with other regulatory bodies and organisations to reduce or eliminate regulatory overlap and identify any regulatory gaps and would wish to work with the Scottish Government and other relevant stakeholders to identify any regulatory overlap or gaps that may arise as a result of this review.

The GPhC sets the standards for education and training, conduct, ethics and performance and continuing professional development for the pharmacy professions. We are also in the process of developing new standards...
for registered pharmacies. Our standards are intended to provide a workable framework for pharmacy professionals to practise safely and effectively. We believe that our standards are fully compatible with the ambitions of the Healthcare Quality Strategy for Scotland which this review is based around. Our standards can be found at http://www.pharmacyregulation.org/standards.

Our policy direction when developing standards is to focus on the outcomes for patients and the public. This approach recognises the professional skills in pharmacy and enables individuals to use their knowledge, skills and judgement to decide how best to meet the outcomes we have described. The standards we develop are designed to take account of the different models of delivering pharmacy services across Great Britain and to support innovations and developments in practice.

Our approach to standards development is demonstrated in our current consultation on draft standards for registered pharmacies. The purpose of these standards is to ensure the right environment, both organisational and physical for the safe and effective practice of pharmacy at registered pharmacies. The standards will apply to all registered pharmacies in Great Britain. Full details of the draft standards and our proposed approach to regulating pharmacy premises can be found at www.registeredpharmacies.org.

As part of the consultation, we have set out which premises we believe must be registered with us and adhere to our standards. This is based on our interpretation of the legal requirements set out in the Medicines Act 1968 and the Pharmacy Order 2010. We intend to use a two stage approach in deciding whether to register a premises as a pharmacy. Stage 1 is an eligibility test and stage 2 is a compliance test. The eligibility test is based on the legal definition of a retail pharmacy business and the legal definition for the sale and supply of pharmacy and prescription only medicines. To decide if a premises is eligible to register as a pharmacy we will ask whether the pharmacy services will include the sale of pharmacy medicines for human use and/or the supply of prescription only medicines for human use against a prescription. If the answer is no, we will not register the premises as a registered pharmacy. The compliance test is based on our standards for registered pharmacies being met.

While our decision on whether to register a premises as a pharmacy will be based on medicines legislation requirements for the sale and supply of medicines, we recognise that the role of pharmacy extends far beyond dispensing medicines on prescription and believe that the public expect us, as the pharmacy regulator, to ensure the wide range of pharmacy services provided by registered pharmacies are safe. As a result we use the term ‘pharmacy-services’ throughout the draft standards. This term is intended to apply to all pharmacy related services provided by a registered pharmacy at the registered premises, or any associate premises and would, for example, include the supply of medicines, advice and smoking cessation services, as well as services the registered pharmacy may provide at other locations such as care homes.

The standards we are consulting on apply only to registered pharmacies and the services provided by registered pharmacies. However, when practising in other settings, pharmacists and pharmacy technicians remain accountable to us through our standards of conduct, ethics and performance.

The GPhC believes that patients and the public rightly expect consistent standards to apply regardless of where they receive their pharmaceutical service. If the model for delivering NHS pharmaceutical care services in Scotland changes, we would wish to work with the organisations that may be responsible for regulating the other environments from which pharmaceutical care services could be provided in the future. As your work progresses you may wish to consider whether the GPhC’s current registration jurisdiction in relation to premises (linked as it is to supply of medicines, as explained above) is likely to be adequate when it comes to ensuring patient safety in the context of pharmaceutical care provided outwith a traditional medicines-oriented pharmacy location.

In developing our new standards for registered pharmacies, we recognise that our current inspection model will need to change. We are continuing to explore and seek views on how best to inspect registered pharmacies in a
way that is proportionate and risk based. We are proposing to move away from a ‘one size fits all’ approach to inspection where all registered pharmacies are inspected approximately every three years, to a model where we prioritise inspections for those pharmacies where we believe that there is a higher risk to the public either because of the nature of services they provide, or because we have concerns. We will give careful consideration to the recommendations of this review and to the potential changes to pharmaceutical care services in Scotland when developing our new inspection model.

With regard to education and training, we define the education and training requirements for pharmacists and pharmacy technicians, as well as setting education standards for pharmacy support staff. Our education and training standards focus on the outcomes we wish to achieve to ensure newly registered pharmacists and pharmacy technicians are competent to practise safely and effectively.

We have not been prescriptive about the delivery structures for the education and training of the pharmacy profession. Our standards are intended to be flexible enough to respond to the changes and developments within professional practice and to support multidisciplinary learning. Our standards have also been written in such a way that they could accommodate potential changes to the model for delivering initial education and training. The new qualifications for pharmacy technicians have just been introduced, with the first cohort of students qualifying next year. We suggest that the appropriateness and effectiveness of these new qualifications are reviewed once they have been delivered in their entirety.

We would welcome the opportunity continue to contribute to this review and look forward to reading your recommendations. 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.

Yours sincerely

Lynsey Cleland
Director for Scotland
General Pharmaceutical Council
DD: 020 3365 3426
Email: lynsey.cleland@pharmacyregulation.org