

HealthandSport@scottish.parliament.uk

23 July 2015

Dear Sir/Madam

Call for Views on the Health (Tobacco, Nicotine etc. and Care) Scotland Bill

We are writing in response to the call for views on the above Bill.

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.

Whilst the Bill 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.

Nicotine Vapour Products

One of the ways in which we protect the public is by setting standards for registered pharmacies (<http://www.pharmacyregulation.org/standards/standards-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. We have a team of inspectors who routinely visit registered pharmacies to assess how well our standards are being met and have been undertaking a program of work to modernise our inspection approach in order to ensure it continues to reflect and respond to developments in pharmacy practice (<http://www.pharmacyregulation.org/pharmacystandardsguide>).

Our standards make clear that the health, safety and wellbeing of patients must be the first concern for pharmacy owners when deciding what products and services to supply in a pharmacy, and for pharmacists and pharmacy technicians when giving advice and information to patients.

Other organisations are better placed, both in terms of legal vices and expertise, to make decisions about the efficacy and safety of NVPs such as e-cigarettes. However we do recognise the importance of ensuring that patients and the public, particularly those who wish to stop smoking, are appropriately encouraged and supported to do so and are therefore supportive of the range of ongoing initiatives across Great Britain to increase the evidence base, ensure the public are informed and make sure that appropriate controls are in place.

When deciding whether a NVP such as an e-cigarette should be sold from a registered pharmacy, we would expect the pharmacy owner to consider relevant guidance from appropriate bodies such as the MHRA and Royal Pharmaceutical Society. Pharmacy owners must also ensure that their staff are empowered to exercise their professional judgement in the interests of patients and the public.

When an individual enters a pharmacy seeking advice on giving up smoking, pharmacists and pharmacy technicians have an important role in explaining the options available, including the risks and benefits of different products to help them make an informed choice. This would include impartial and up-to-date information about the availability and benefits of nicotine replacement therapies for which there is evidence about safety, quality and efficacy.

The proposals set out in the Bill would require registered pharmacies who sell e-cigarettes or other NVPs to be on a Register of tobacco and NVP retailers and to comply with various controls relating to the sale of NVPs that will be enforced by local authorities.

As one part of a complex system for overseeing and improving the quality of pharmacy care and services, the GPhC is conscious of the importance of avoiding duplication of regulation. We understand that effective joint working with partner organisations is essential and already work with a range of regulatory bodies and enforcement organisations across Great Britain to reduce or eliminate regulatory overlap and identify any regulatory gaps. We would therefore wish to work with the Scottish Government, local authorities and other relevant stakeholders to identify any regulatory overlap or gaps that may arise as a result of the proposals for NVP retailers. We would also wish to ensure that we are appropriately informed of any concerns, offences or banning orders in relation to NVPs that involve a registered pharmacy of pharmacy professional so that we can give due consideration of this in the context of our regulatory work.

Duty of Candour

We support the Scottish Government's aim of making sure that health and social care providers are open and honest when individuals have been harmed as a result of the care or treatment they have received and are working to strengthen existing requirements for pharmacy professionals.

In October 2014 we signed a joint statement on the professional duty of candour with other regulators of healthcare professionals (http://www.pharmacyregulation.org/sites/default/files/joint_statement_on_the_professional_duty_of_candour.pdf) and are considering how we can be more explicit about this professional duty as part of the current review of our Standards of Conduct, Ethics and Performance. The duty of candour is also being considered as part of the work we are taking forward to review our Initial Education and Training Standards for the pharmacy team.

The seriousness of failing to be open and honest with patients is something we have reflected as part of new guidance to help our Fitness to Practise Committee decide what sanction is appropriate in particular cases (http://pharmacyregulation.org/sites/default/files/good_decision_making_-_fitness_to_practise_hearings_and_sanctions_guidance_june_2015.pdf). The guidance advises the Committee to consider sanctions at the upper end of the scale when cases involve a failure to raise concerns or when a pharmacy professional takes deliberate steps to avoid being candid, or to prevent someone else from being candid.

In addition to ensuring that the pharmacy professionals we regulate understand the fundamental duty they have to be open and honest with patients when things go wrong, the GPhC also recognises the need for a culture of openness, honesty and learning within the environments in

which pharmacy services are provided. It is essential that any concerns about the safety of service provision can be raised without fear and that these concerns are effectively dealt with and learnt from. These important themes are prominent in our standards for registered pharmacies and our new inspection model will provide a more robust process for checking whether concerns are indeed raised and acted on within registered pharmacies.

As we work to strengthen our standards in relation to openness, transparency and candour we would wish to continue to collaborate with the organisations that may be responsible for monitoring the proposed duty of candour.

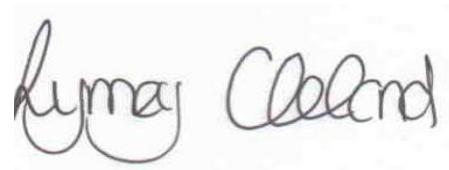
Wilful Neglect

Although instances of deliberate neglect or mistreatment may be uncommon, we believe that health and social care professionals and organisations that intentionally harm people they have been trusted to care for should face the consequences of their actions or omissions.

We do however think that it is extremely important that any offence of wilful neglect or ill-treatment does not cover instances of genuine error or accident. The recent work of the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board has shown how criminal sanctions associated with dispensing errors can act as a barrier to open and transparent error reporting and can hinder learning that would help improve the quality of service for patients. We therefore believe that it is essential to make a clear distinction between a genuine error or accident and the deliberate neglect or mistreatment of patients.

I hope the above information is of assistance. If you would like further information or clarification about any aspects of the GPhC's work please do not hesitate to contact me on the details provided below.

Yours sincerely

A handwritten signature in black ink that reads "Lynsey Cleland". The signature is written in a cursive style with a large initial 'L'.

Lynsey Cleland

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