



## Briefing: Medicines and Medical Devices Bill

### Role of the General Pharmaceutical Council

The General Pharmaceutical Council (GPhC) regulates pharmacists, pharmacy technicians and registered pharmacies in Great Britain. There are:

- **57,629 pharmacists**
- **23,647 pharmacy technicians**
- **14,181 pharmacies on our register (as at 29/02/20).**

Our role is to protect the public and give them assurance that they will receive safe and effective care when using pharmacy services. We set standards for pharmacy professionals and pharmacies to enter and remain on our register, and seek assurance these standards are met, including by inspecting pharmacies. We also act to protect the public and to uphold public confidence in pharmacy if there are concerns about a pharmacy professional or pharmacy on our register.

### Background briefing on key topics relating to the Bill:

#### Independent pharmacist prescribers

- Registered pharmacists can become independent prescribers after completing a course accredited by the GPhC. A pharmacist independent prescriber may prescribe autonomously for any condition within their clinical competence.
- There are currently **8,563 independent pharmacist prescribers** on our register. There are also a further **297 supplementary pharmacist prescribers**, who can prescribe a number of different medicines within the framework of a patient-specific clinical management plan, which has been agreed by a doctor.

#### Pharmacy inspections and enforcement powers

- We inspect registered pharmacies across Great Britain. During an inspection, our inspectors look for evidence that the pharmacy is meeting our **standards for registered pharmacies**.
- We have begun **publishing pharmacy inspection reports on a new website**, after getting the legal powers to do so and consulting on plans for publishing reports with patients and the public and the pharmacy sector.
- We also have **powers to take enforcement action against pharmacies** not meeting our standards, including imposing improvement notices and conditions.

#### Regulation of online pharmacies

- We regulate and inspect all online pharmacies operating from premises in Great Britain.

- In April 2019 we published **updated guidance for pharmacies providing services at a distance including on the internet**. This introduced new safeguards to protect patients going online for medicines.
- We have taken **regulatory and enforcement action against online pharmacies** after identifying significant patient safety concerns in relation to supply of high-risk medicines online through our inspections.
- We are also continuing to work closely with other regulators involved in regulating online primary care services, governments and other stakeholders across Great Britain to improve the safety and quality of care for patients online.
- This includes working with other health regulators across Great Britain to develop a guide for patients and the public to help them keep safe when going online for medicines.
- We have also publicly supported calls from the Care Quality Commission for changes to legislation to enable them to regulate online prescribing services in England that employ pharmacist prescribers only (currently they only have powers to regulate services which employ employee medical prescribers or nurse prescribers). Healthcare Improvement Scotland is introducing this change for pharmacist prescribing services in Scotland.
- We have also expressed the view that after the end of the transition period, prescriptions from the EEA should not continue to be recognised in the UK. Continuing the recognition of electronic EEA prescriptions when the cross-border healthcare directive no longer applies fails to ensure patient safety in the digital healthcare environment and poses significant risks to patient safety.

### Current logo schemes for online pharmacies and online suppliers of medicines

- We operate a voluntary logo scheme for online pharmacies. There are currently 321 pharmacies with our voluntary logo. Members of the public can click on the logo on an online pharmacy's website and be taken through to the pharmacy's entry on our register.
- Anyone selling medicines to the public via a website, including all online pharmacies, must be registered with the MHRA and display the Distance Selling logo on every page of the website offering medicines for sale (even if they are not a registered pharmacy and only sell medicines you can buy off the shelf).
- We will carefully consider the outcomes of the bill in relation to our voluntary logo scheme for online pharmacies, and will continue our close working relationship with the MHRA in this area.

### Our legal and regulatory position in relation to falsified medicines

- We make clear in our standards that pharmacy owners and pharmacy professionals have an important responsibility to only supply legitimate medicines obtained from a reputable source.
- We have worked closely with the MHRA to help make sure the requirements brought in by the Falsified Medicines Directive are being met by registered pharmacies or that they are working towards this, and **issued this joint statement setting out our roles**.
- We have used our existing inspection processes to assess whether pharmacies are meeting the new requirements and can take action if we find pharmacies are not taking appropriate steps.

### Hub and spoke pharmacies

- We already regulate and inspect 'hub' and 'spoke' pharmacies operating in Great Britain, where the hub and spokes are owned by the same legal entity.

- Both the hub and spoke pharmacies are required to meet our standards, and we will consider the context in which they operate during inspections.
- We acknowledge that a move to enable a 'hub' and a related 'spoke' to be operated by different companies will raise significant issues of responsibility, accountability and liability.
- We await the outcome of this bill and will need to consider the detail of any changes carefully.

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