

## **Guidance on proposed changes to the Human Medicines Regulation 2012 to ensure the continuity of supply of medicines (including in a 'no deal' EU exit)**

### **Background**

The Department of Health and Social Care recently consulted on two proposals affecting the supply of drugs in the UK:

#### **Proposal 1**

a) Changes to the Human Medicines Regulations 2012 (HMR2012) to enable Ministers to publish serious shortage protocols in relation to prescription only medicines, allowing pharmacists in retail pharmacies, for a specific medicine in shortage, to dispense a different quantity/dosage form or substitute a prescribed medicine with either a generic/therapeutic equivalent as prescribed in the protocol.

Four scenarios are envisaged/possible; dispensers can:

1. Dispense a smaller quantity
2. Dispense a different formulation (e.g. naproxen for naproxen etc.)
3. Dispense a different strength (e.g. 250mg 2 bd for 500mg 1 bd)
4. Dispense a substitute, either a generic or a different drug with similar therapeutic properties (e.g. omeprazole for lansoprazole)

These changes cannot be made on an ad-hoc basis in response to local difficulties, each formulation subject to shortage would require a specific central direction.

It is not anticipated that dispensing a substitute would be used other than in exceptional circumstances and that it would be drawn up with expert clinical advice. The sign off process would be by ministers on approval by the Chief Pharmacist and at a local level.

Pharmacies would not have to contact the prescriber for any of the first three options, but where a therapeutic equivalent is dispensed the prescriber will need to be notified. Prescribers will need to decide on clinical grounds what action is required on receipt.

#### **GPC UK response**

GPC UK raised concerns about allowing pharmacists and other dispensers to dispense a therapeutic alternative, but supported the other provisions. We have been assured that this would only very rarely be used, and that appropriate advice would be taken by the responsible minister

The changes will ensure that pharmacists will not be at risk of breaching the law if they have to change their processes. It will apply to specific medicines only and be time limited.



**Proposal 2**

b) Changes to the Human Medicines Regulation that, only in case of a 'no deal' EU exit, would enable regulations to be made to modify the application of the HMR2012 to deal with serious shortages of medicinal products. This would ensure the UK government would retain the power to make temporary changes to the HMR2012 to deal with shortages in a 'no deal' scenario when we can no longer rely on the European Communities Act to make regulations.

**GPC UK response**

In terms of the proposed regulation to deal with serious shortages of medicinal products, GPC UK accepted that as it is needed to support the supply chain in the event we leave the EU without a deal, we would not raise any fundamental objections to its introduction.

**Other issues***Indemnity*

It should be noted that any issues around indemnity resulting from these changes will be covered by the introduction of the state backed scheme from April 2019 insofar that the work comes within its eligibility criteria.

*Patients*

Patients will need to agree to any substitution and if not will be referred back to their GP practice. It is therefore essential that community pharmacists explain to patients what is happening in a bid to reduce the impact on the relationship between the patient and their GP/pharmacist

*Practices*

It remains unclear when a GP or other practice prescriber will need to be told of a substitution/reduced quantity etc. It has been suggested they will only require the information if they need to know from a clinical perspective. The expectation is that they will only be told in the scenario where a substitute, either a generic or a different drug with similar therapeutic properties, is dispensed.

Protocols would only be issued when there is a serious national shortage. It is not designed to change current 'owing' mechanisms used by pharmacies.