

# Consultation on changes to HMR2012 in relation to supply and the UK's exit from the EU

## A response from the Academy of Medical Royal Colleges

December 2018

### Development of a Serious Shortage Protocol

The Academy of Medical Royal Colleges (the Academy) is the coordinating body for the UK and Ireland's 24 Medical Royal Colleges and Faculties. We ensure that patients are safely and properly cared for by setting standards in clinical practice and the way doctors are educated, trained and monitored throughout their careers.

The Academy is keen to take the opportunity to respond to the consultation on changes to the HMR2012 in relation to supply and the UK's exit from the EU. This response has been agreed by Academy's members.

Whilst we recognise that the necessity for a short consultation period we were concerned at what appears to have been a very limited initial consultation with no general notification and no information on the DHSC consultations website. It does seem inexplicable and unacceptable that an issue of this importance is not the subject of wide consultation and that medical royal colleges as doctors' professional bodies were not specifically engaged in the process.

#### Question 1: Do you agree with the introduction of the provision for a 'serious shortage protocol' to deal with serious national shortages of medicines?

Serious shortages of drugs would cause significant risks to patients. The Academy therefore recognises that planning for managing a serious drug shortage, whatever the cause, is sensible. As such the Academy welcomes any proposals to support timely decision-making and delivery of drugs to patients in the event of serious shortages.

#### Question 2: Do you agree with the introduction of a regulation making power in relation to serious shortages in case of a 'no deal' Brexit?

As above.

#### Question 3: Do you have views on the principles outlined above, which are informing our assessment of impacts?

The options of,

- Dispensing a reduced quantity
- Dispensing an alternative dosage form
- Dispensing a therapeutic equivalent
- Dispensing a generic equivalent,

have the potential for significant impact for a patient particularly for those with multi-morbidities on a range of drugs.



Dispensing reduced quantities will simply increase frequency of prescribing but could be a very short-term solution. Generic equivalents are a valid alternative when there are no significant differences in drug release. Dispensing an alternative dosage or a therapeutic equivalent are more likely to affect patients.

Pharmacists are skilled clinical staff with expert knowledge of drugs and their effects. However, they may not necessarily know the clinical history of the individual patient in the way that the GP or specialist who has originated the original prescription will do.

Making significant changes to prescriptions without reference back to the originating clinician, whether GP or hospital specialist, could pose unnecessary risks for the patient – and indeed the dispensing pharmacist.

Patients must be at the centre of this process and agree with any proposed changes to their medication. This means there must be a clear discussion with patients about changes to their medication and the rationale for it, should this be required.

### *Developing a protocol*

Any protocol must avoid the risks of either being so high level and generic it is of limited practical use or having to be at an immensely and impossibly detailed level to capture individual circumstances and eventualities.

We would therefore caution against rushing the development of such a protocol, and would expect that clinician expertise is at the centre of any such developments, and that pharmacist training in use of such protocols is factored in. The Academy would expect that Medical Royal Colleges and other professional bodies are closely involved in the development of any protocol.

In developing a protocol, we would expect that, unless the specific circumstances are set out in the protocol, that as a principle, significant changes should not be made without reference back to the originating prescribing clinician and the involving the patient.

In any detailed work it would be necessary to highlight that some groups are potentially particularly vulnerable when substitutions or generic equivalents are used – e.g. HIV and drug interactions and immunosuppressed patients where the narrow therapeutic window can mean that pharmacokinetic differences between preparations can become important.

It will also be to ensure there is a clear written record included in the patient record of any alterations to the expected medication whether taken by the pharmacist alone or following discussion with the originating prescriber.

A protocol must also define what is meant by a serious shortage and the timescale for which interim arrangements will be expected to last.

### *Population wide decisions*

These regulations consider arrangements for the dispensing of drugs to patients on an individual and specific basis. Serious shortages may necessitate interruption of some medications and that prioritisation must come centrally as it otherwise places patients, doctors and pharmacists in conflict. There will need to a population-based approach to issues of distribution of available drugs and prioritisation of patient groups.

### *Question 4. Do you have comments on the draft provisions?*

Section 3, 334B 1 Part 2 of the amendment gives ministers powers to modify the application of the Regulations in the event of serious shortage. We would expect that any substantive change in the Regulations are the subject of proper consultation with all interested parties. From the perspective of the Academy that means Medical Royal Colleges representing clinicians.