



Department  
of Health &  
Social Care

## Consultation response

Consultation with stakeholder representative bodies on changes to the Human Medicines Regulation 2012 (HMR2012) to ensure the continuity of supply of medicines (including in a 'no deal' EU exit)

14 January 2019

## Consultation

1. The Department consulted with the relevant stakeholder representative bodies on two proposals:
  - 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. Whilst this proposal was prompted by the EU exit work it was not linked to a 'no deal' EU exit.
  - 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 replace the regulation making power in the European Communities Act (ECA) for certain limited purposes and would ensure we continue to have 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 ECA to make regulations (because we will no longer be in the EU and therefore the ECA will no longer apply).
2. We engaged with a range of stakeholder representative bodies about the proposals. As part of that engagement we also conducted a written consultation between 5 and 12 December 2018. In response to the written consultation we received 47 responses from across the NHS, industry, pharmacists', doctors' and patient representative bodies.
3. We engaged with stakeholder representative bodies before, during and after the written consultation. In addition to and separate from the consultation we received correspondence from some patient groups on the serious shortage protocol.

## Serious shortage protocols

4. Currently, if a pharmacy cannot dispense what is on a prescription, it will either send the patient back to the prescriber or if there is an urgent need, contact the prescriber, discuss an alternative and then get the prescription changed by the prescriber.
5. A serious shortage protocol enables retail pharmacists, in the event of a serious shortage of a prescription only medicine that affects or may affect the whole or any part of the United Kingdom, to dispense in line with the protocol rather than against a prescription, without going back to the prescriber. The protocol may prescribe one of the following options: an alternative quantity, an alternative pharmaceutical form, an alternative strength, a therapeutic equivalent or a generic equivalent.

6. Any protocol would be developed with input from clinicians. Only if the protocol allows it, retail pharmacists can supply either an alternative quantity, strength, pharmaceutical form or medicine as prescribed in the protocol. Each protocol would clearly set out what action can be taken by the retail pharmacy, under what circumstances, for which patients and during which period.
7. The power to issue protocols is a reserve power that the Department anticipates would only be used in exceptional circumstances. Protocols for either an alternative quantity, strength or pharmaceutical form are likely to be more common than protocols for a therapeutic or generic equivalent, which would only be used in very exceptional circumstances, where appropriate.
8. Protocols for therapeutic or generic equivalents will not be suitable for all medicines and patients. For example, those protocols would not be suitable for treatments for epilepsy or treatments requiring biosimilar products where the medicines that are prescribed need to be prescribed by brand for clinical reasons. In these cases, patients would always be referred to the prescriber for any decision about their treatment before any therapeutic or generic alternative is supplied.
9. A protocol is only one of the tools that can be used to manage shortages. The Department has well-established governance processes for managing shortages in collaboration with manufacturers and suppliers, clinicians, the NHS and the Medicines and Healthcare Products Regulatory Agency. A protocol would only be introduced in case of a serious shortage, if it would help manage the supply situation and if clinicians think it is appropriate, after discussion with the manufacturer and/or marketing authorisation holder.
10. Separately, the Department will work with the Pharmaceutical Services Negotiating Committee to consider the implications for community pharmacies' terms of service as set out in the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

### **What did respondents to the consultation say?**

11. Consultation responses were broadly supportive of the proposal. However, patient groups and doctors' representative bodies raised concern about automatic therapeutic or generic substitution of medicines for high-risk patients, for example patients with epilepsy or transplant patients, without consulting the prescriber. Separate from the consultation, correspondence was received from further patient representative groups raising identical concerns.
12. Similar concerns were raised more generally about therapeutic or generic substitution where the MHRA requires prescribing by brand, including anti-epilepsy medicines or biological products.
13. Industry representative bodies queried the role of the manufacturer or supplier and expressed concern about the need for the provisions and the protocols to be time limited or linked to a 'no deal' exit from the EU. They also asked for a serious shortage to be defined.

14. Some respondents expressed concern about the short period of time that was given to respond to the consultation.
15. A range of operational issues were raised, including for example informing the prescriber when a pharmacist dispenses against the protocol, communication with patients, communication about the protocols to retail pharmacies. Those issues will be picked up as part of operationalising the serious shortage protocol.
16. Pharmacy representative bodies expressed a concern that supply against a serious shortage protocol would be a breach of section 64 of the Medicines Act 1968. However, NHS supply will be under the protocol and no longer in pursuance of a prescription and therefore sections 64 is not engaged.

### **What did we do?**

17. The proposal for the serious shortage provisions was prompted by the preparations for a 'no deal exit' from the EU. The provisions have however not been linked to a 'no deal' EU exit and have not been time limited (although any protocol itself would be time limited). Regardless of whether a shortage of a medicine is caused by a 'no deal' EU exit or something else, a serious shortage protocol can be a useful tool for managing any shortage and mitigating any impact on patients.
18. To address concerns about the lack of public consultation and the provisions not being time-limited we have amended the regulation post-consultation to include a review clause. The Department will be required by law to review the serious shortage protocol provision as soon as is reasonably practical after the end of one year after the first protocol starts to have effect. The review will look at, specifically, any adverse consequences for either the market in prescription only medicines or patient safety.
19. A stakeholder consultation will be conducted as part of the review. This has been clarified in the Explanatory Memorandum accompanying the Statutory Instrument.
20. To meet concerns about the definition of serious shortage we have clarified in the regulation that a serious shortage is a serious shortage in the opinion of Ministers. A protocol would only be introduced by Ministers in case of a serious shortage, if it would help manage the supply situation and if clinicians think it is appropriate, after discussion with the manufacturer and/or marketing authorisation holder.
21. In response to the consultation responses, further amendments to the regulation were made. An amendment was made to make it explicit that any protocol can cover a medicine of a different strength. Several drafting changes were also made.
22. To address several concerns but in particular the suitability of a protocol for high-risk patients or certain specific medicines that are prescribed by brand, the Explanatory Memorandum provides further clarification on how a serious shortage protocol would work in line with paragraphs 4 to 9 of this document.
23. In particular, it is worth noting any protocol will be developed with input from clinicians and only if they deem it appropriate will Ministers publish a protocol

allowing either an alternative quantity, strength, pharmaceutical form or medicine to be dispensed in line with the protocol. Protocols for therapeutic or generic equivalents will not be suitable for all medicines and patients. For example, they will not be suitable for treatments for epilepsy or treatments requiring biological products where the medicines that are prescribed need to be prescribed by brand for clinical reasons. In these cases, patients would always be referred to the prescriber for any decision about their treatment before any therapeutic or generic equivalent is supplied.

## Power to modify the HMR2012 in case of 'no deal' exit only

24. The HMR2012 are made under the European Communities Act (ECA). In case of a 'no deal' EU exit, the Department can no longer make regulations under the ECA and therefore the HMR2012 can no longer be amended. The proposed regulation would enable the Department to make temporary changes to the HMR2012 to deal with serious shortages caused by the UK's exit from the EU but only in a no deal scenario. If the UK exits the EU with a deal then we can continue to make regulations under the ECA and this regulation does not enter into force

### **What did respondents to the consultation say?**

25. Respondents were broadly supportive of this proposal. Some respondents however thought the power to modify the HMR2012 was too broad and would transfer power from Parliament to Government. However, any regulations would be temporary, to deal only with serious shortages caused by a no deal exit and would be subject to annulment by resolution of either House of Parliament. There was some misunderstanding as some respondents said they wanted these provisions linked to a 'no deal' exit only. The proposed provisions were linked to a 'no deal' exit and will only enter into force in case of a 'no deal' exit.
26. Some respondents linked this proposal to the proposal for serious shortage protocols which it is not. They provided similar comments which were not of relevance to this proposal.
27. As for the serious shortage protocol, some respondents asked for a serious shortage to be defined.

### **What did we do?**

28. To meet concerns about the definition of serious shortage we have clarified in the regulation that a serious shortage is a serious shortage in the opinion of Ministers. Several drafting changes were also made.