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RPS response to: Urgent Consultation on changes to the Human Medicines Regulations 2012 in relation to the supply and the UK's exit from the EU

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Thank you for inviting the Royal Pharmaceutical Society to respond to the consultation on changes to the Human Medicines Regulations 2012 in relation to the supply of medicines, including the scenario for supply should the UK exit from the EU without agreement.

We agree in principle that a "serious shortage protocol" (SSP) should be in place across the UK should a serious national shortage of medicines occur and we welcome the proposal to enable pharmacists to substitute and dispense medicines in line with a clinical protocol. This will mean pharmacists can act in the patient's best interests and patients will have the opportunity to access safe and effective pharmaceutical care from a pharmacist in a timely fashion, whilst ensuring a safe supply framework through:

1) the "serious shortage protocol" (SSP) developed with clinicians, and
2) the professional skill and judgement of pharmacists in using the protocol, referring to the GP or other prescribers when use isn't appropriate

Local medicines policies which enable generic and therapeutic substitution according to locally developed clinical formularies do already exist across the country and there will be lessons from how these are developed which can help inform how a national SSP should be implemented. We believe it is important that we are involved in developing the SSP together with other professional bodies and Royal Colleges. The

detail within the SSP will be critical to local implementation and pharmacists working closely with GPs and other prescribers.

There is precedent for preparing enabling legislation to manage medicines issues with the pandemic preparations in 2009.

We also support the proposals to introduce a mechanism to amend the Human Medicines Regulations 2012 in the event of the United Kingdom leaving the European Union and unable to make changes under the European Communities Act. This is necessary, to manage a serious shortage of medicines and may also be needed for other unforeseen scenarios following a UK exit from the EU without agreement.

We believe the impact of the proposed changes will be positive for patients, ensuring pharmaceutical care can be provided safely and efficiently for as many people as possible. The proposals should also mean a reduction in bureaucracy between the pharmacy and GPS or other prescribers, whilst continuing to allow good communications between pharmacists and GP or other prescriber for situations falling outside of the protocol. It is important good lines of communication remain open, particularly during a national shortage which will increase the need for healthcare professionals to work collaboratively to deliver agreed treatment outcomes.

Our suggestions for the draft provisions include

1) An amendment to Regulation 226A (4)(a) enables a "dosage" change in addition to quantity and dosage form changes where this is not already enabled by schedules 25 and 26. This could be necessary for example if a modified release form of a medicine were substituted for a standard release medicine or vice-versa which would require a dosage change in addition to quantity and dosage form change.

2) To consider an amendment to Regulation 334B (1) to widen the scope of when Ministers may modify the Human Medicines Regulations to be wider than serious shortage of medicinal products in the event of the UK leaving the EU without an agreement.

3) To consider an amendment to Regulation 226A (5)(a). We have a possible concern that the need for an SSP to be issued on behalf of Ministers may restrict opportunity for the healthcare system to respond locally to serious shortages.

Ends

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