

Serious Shortages Protocols Review Royal Pharmaceutical Society response

Q1: Have you had, or been made aware of by colleagues or stakeholders, any concerns about the impact of the Serious Shortage Protocols (SSPs) issued over the past year on the prescription only medicines market?

Whilst we have no concerns over the impact of the SSPs on the prescription only medicines market, our members have expressed concerns about the use of these protocols.

Pharmacists have a professional responsibility to support patients with their medicines, including when there is a national shortage. They are the trained experts in medicines and their use. However, their experience and concerns with SSPs include:

- Perception that SSPs have been rarely used
- When SSPs are used feedback is that they are bureaucratic and professionally frustrating
- There is a lack of consistency in the way pharmacists are empowered to deal with medicines shortages across GB. England and Wales have SSPs whereas in Scotland community pharmacists are empowered to support patients through changes in formulation, quantity, strength and use of generic equivalent medicines (<https://www.cps.scot/media/2915/copy-of-medicines-shortages-guidance-1.pdf>)
- The SSP system is inflexible, and scalability is a practical issue

Q2: Have you had, or been made aware of by colleagues or stakeholders, any concerns about the impact of the Serious Shortage Protocols issued over the past year on patient safety?

Very few SSPs have been implemented and we are not aware of any concerns about the impact on patient safety.

However, we have engaged extensively with patient groups, GP representative bodies and other key stakeholders to develop a more pragmatic approach. Together we have come to an agreed proposal to changes in medicines legislation that would negate the need for SSPs, apart from situations where a therapeutic substitution is required. This solution would reduce bureaucracy, be enabling and speed up access to appropriate treatment for patients in a safe and effective manner. This unified approach across all sectors and all three countries in Great Britain would streamline systems and processes for the benefit of patients. This approach also enables pharmacists to use their professional judgement.

Pharmacists and GPs are having to spend more time dealing with medicines shortages, with community pharmacists legally obliged to contact prescribers or refer people back to prescribers to amend original prescriptions, even for minor adjustments. This is frustrating for the patient, pharmacist and prescriber. The process can cause delays in access to medicines and takes up health professionals' time, which could be used elsewhere to support patient care.

We believe that legislation should be amended to allow pharmacists to make minor amendments to a prescription, without a protocol, when a medicine is out of stock. Amendments would include changes such as a different quantity, strength, formulation or generic version of the same

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medicine (generic substitution) in discussion with the patient. Such substitutions are routine for pharmacists in both secondary care and general practice. Rules that enable minor substitutions by community pharmacists are used in Scotland for medicines on a recognised shortages list. In Wales, the All Wales Pharmacist Enabling and Therapeutic Switch Policy enables pharmacists to make certain changes in secondary care without contacting the prescriber.

We recognise there are particular considerations for certain medicines, such as treatments for epilepsy or organ transplants where the product has a narrow therapeutic index and substitution could be harmful. This change in policy should be supported with guidance on when substitutions may or may not be suitable. All of this should be underpinned by person centred care, clear communication, between clinicians involved in prescribing decisions (e.g. specialists in secondary care) and decisions taken in discussion with patients. We would expect the patient voice to continue to help shape future policy development.

The RPS believes there is a better solution which uses the clinical expertise and professionalism of pharmacists to help manage the continuity of care for people prescribed medicines that are in short supply. We have set out our proposal in our [medicines shortages policy](#).



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