



PSNC's response to the Department of Health and Social Care's 12-month review of Serious Shortage Protocols

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Introduction

1. The Pharmaceutical Services Negotiating Committee (PSNC) promotes and supports the interests of all NHS community pharmacies in England. We are recognised by the Secretary of State for Health as the body that represents NHS pharmacy contractors.
2. We work closely with Local Pharmaceutical Committees (LPCs) to support their role as the local NHS representative organisations.
3. Our goal is to develop the NHS community pharmacy service, and to enable community pharmacies to offer an increased range of high quality and fully funded services; services that meet the needs of local communities, provide good value for the NHS and deliver excellent health outcomes for patients.
4. We welcome the opportunity to be able to provide comments on this 12-month review of the Serious Shortage Protocol policy.

Consultation Questions

5. The Department of Health and Social Care (DHSC) seeks input to the review and in particular, responses to the following questions:
 - 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 the prescription only medicines market?
 - 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?

Response

6. The PSNC supported the introduction of Serious Shortage Protocols (SSPs) and supports their continued use.
7. The reasons for the introduction of the policy remain relevant, particularly as we approach the end of the Transition Period on 31 December 2020.
8. In December 2018, in response to the DHSC consultation on SSPs, we stated:

We have been asked to respond to the consultation ... [on SSPs] ... and have discussed the issues with representatives of the Department of Health and Social Care (DHSC). We and other community pharmacy, pharmacy and dispensing contractor organisations have also discussed the proposals with DHSC at a meeting of the Community Pharmacy Brexit Forum.

PSNC is broadly supportive of the proposed legislative changes, which we consider will seek to safeguard the supply of essential medicines to patients in the event of serious shortages of medicines, including any serious shortages following a no-deal Brexit. The Government's revised planning assumptions suggest that there could be serious shortages of patients' essential medicines following a no-deal Brexit.

PSNC's comments and observations on this consultation are set in relation patients' needs, professional issues and practical and financial issues; followed by responses to the specific questions raised by DHSC.

<https://psnc.org.uk/contract-it/brexit-and-community-pharmacy/serious-shortage-protocols-ssps/>

9. In addition to the UK leaving the EU, the ongoing coronavirus outbreak has the potential to cause medicine shortages. There are also medicine shortages associated with other factors, such as manufacturing problems, and while the goodwill of the pharmacy sector has been relied on in the past to manage and regulate supply to patients, statutory provision for this, in the form of serious shortage protocols, is important.
10. While the number of SSPs issued has been relatively low, they are one of the valuable options available to manage the medicines supply chain and one of the few statutory options to manage supply of medicines from community pharmacies to patients.
11. SSPs require additional professional consideration, over and above prescriptions, and there is, accordingly, additional financial support for their use by community pharmacies. The process of reimbursement and remuneration for SSPs is cumbersome (there are understandable reasons for this) and PSNC is keen to see this claims process made simpler (as we understand DHSC is as well).
12. PSNC supports the Royal Pharmaceutical Society's arguments for a more flexible system to manage shortages but recognises that some control or guidance is required to ensure that the volumes of certain medicines in the market are considered. Otherwise, a low volume medicine may be chosen as an alternative to a drug in serious shortage and become seriously short itself. Solving one problem would simply create another.
13. SSPs allow supplies of recommended alternatives to patients, without requiring them to be referred back to their prescriber. While the serious shortage of a medicine itself may prompt a temporary change in prescribing practice, SSPs provide an option for those patients whose prescriptions remain unchanged. There are many safeguards in place for SSPs, for example, they are used only when considered appropriate by DHSC and its clinical advisors, and if the supervising pharmacist considers the application of the SSP to that patient is appropriate. In addition, generally they are 'voluntary' in the sense that they may be used in practice only if the patient accepts their use.

14. Given the broad range of possible SSPs – on quantity, strength, formulation, generic equivalent and therapeutic equivalent – views of SSPs sometimes vary according to the type of SSP under discussion.
15. Broadly, PSNC considers that the impact of SSPs has been positive, as one part of a range of measures to mitigate potential medicine supply issues and shortages, for the benefit of patients and to ensure essential medicines are dispensed to patients in a timely manner.
16. Answering the specific questions asked:

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 the prescription only medicines market?

17. As far as we are aware, there has been no significant impact on the prescription only medicines market following the introduction of any SSPs. During the period individual SSPs have been active, it is possible that there were slightly higher than usual demand of the recommended alternatives at wholesaler level, but not sufficient to trigger a shortage of the recommended alternatives.
18. On a couple of occasions, price concessions were granted for recommended alternatives for two SSPs as their reported purchase prices were higher than Drug Tariff prices (see table below).

SSP	Price concession drug and price	Price concession month	Other affected lines and price
SSP05 Fluoxetine 10mg tablets	Fluoxetine 10mg capsules - £46.70 (DT £30.85)	March 2020	Fluoxetine 60mg capsules - £6.99 (March 2020) (DT £5.31)
			Fluoxetine 60mg capsules - £6.99 (April 2020) (DT £4.98)
SSP08 Salazopyrin® EN-Tabs 500mg	Sulfasalazine 500mg gastro-resistant tablets - £10.72 (DT 10.06)	October 2020	N/A

19. Other antidepressants were also granted concessionary prices during the period Fluoxetine 10mg tablet SSPs were in operation, but we have made no direct association between the SSP and price concession. For example, ongoing supply and pricing issues for other antidepressants such as venlafaxine and mirtazapine may have existed for other reasons.

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?

20. PSNC is not aware of any patient safety issues arising from the use of SSPs but is not directly involved in this work.