



Serious Shortage Protocols

What are SSPs?

In early 2019, following consultation, changes to the Human Medicines Regulations were made to allow the introduction of Serious Shortage Protocols (SSPs) in the event of a serious shortage of medicines. The necessary changes to the Northern Ireland Pharmaceutical Regulations are well advanced, but no date has been set for their coming into operation. Community pharmacists will be informed in advance of the introduction date.

The detail of how SSPs would be implemented is still being finalised and further guidance will be issued from the Department of Health (DoH) and other professional and representative bodies including CPNI.

The intention is that an SSP will be issued only if a medicine has been judged by Ministers to be in serious short supply. The SSP will set out a clear protocol for community pharmacists to follow if they are unable to source that medicine for patients who have been prescribed it. The protocol will say what other prescription medicines could be dispensed, without the pharmacist needing to go back to the prescriber.

For example, pharmacists might be able to supply:

- a) a different quantity of the medicine;
- b) a different formulation of the medicine;
- c) a generic version, alternative branded version of the medicine;
- d) a different quantity, formulation or strength of biological medicinal product;
- e) a medicine with a similar therapeutic effect.

The SSP will specify exactly what alternative quantity, or pharmaceutical form, or strength, or therapeutic equivalent or generic equivalent could be supplied by the pharmacist and under what circumstances. SSPs are more likely to be issued to allow for alternative quantity, strength or pharmaceutical forms to be given, than for generic or therapeutic substitution.

Why are SSPs being introduced?

SSPs are being introduced as an additional tool to help community pharmacies to manage any potential serious shortages of prescription medicines. In recent years we have seen an increase in shortage problems for a combination of reasons; factors such as Brexit planning and associated contingencies may be adding to the ongoing issues.

Community pharmacies already work hard to manage supply issues when problems do occur to ensure that patients can get the medicines they need, when they need them. They may, for example, give 'staged' dispensing or 'owings'; liaise with GPs to find alternative medicines that may be suitable; or contact suppliers to try to source the medicine. SSPs will help community pharmacists to continue to supply patients with appropriate medication where a serious shortage of any specific medicine should occur.

It is important to understand that an SSP will only be introduced for a medicine if there is judged to be a **serious shortage** of that medicine. The SSP will only apply to that specific medicine and it will set out clearly what alternatives, for example a different formulation (e.g. capsules rather than tablets), pharmacists can dispense. GPs will be notified when an SSP has been issued so that prescribers will know what adjustments may be being made to their patients' medicines.

What are the benefits of SSPs?

The DoH has indicated that the main benefit of an SSP is that it should enable patients to continue to have access to treatment without undue delays. SSPs may also reduce pressure on GPs because when a serious shortage occurs, GPs will not have to see all patients who have been prescribed the affected medicine to

Please note: The detail of SSPs and how they would be implemented is still being developed and as such, this summary may be subject to amendments in the future.

issue a new prescription. In a situation with multiple shortages, SSPs could have an important role in reducing delays in getting patients their medicines.

When will an SSP be introduced?

Ministers will decide whether a medicine shortage is serious enough for an SSP to be required. The pharmaceutical industry provides regular reports on issues which may potentially interrupt the supply of medicines and affect patients. In each case, the risk to patients is assessed and tools to mitigate the impact on patients are decided. In future, this could include SSPs.

An SSP would only be used when other measures to mitigate the impact of the shortages on patients have been exhausted or are likely to be ineffective. An SSP will also only be issued if clinicians advise that it is appropriate and after discussion with the manufacturer and/or marketing authorisation holder.

How will an SSP be introduced?

When a serious shortage of a medicine prompts consideration of issuing an SSP, work will be undertaken by DoH in collaboration with the Department of Health and Social Care (Lon) and other health bodies. If an SSP is to be issued, a panel of clinicians will decide on what is needed for each medicine, including naming specific medicines that are suitable alternatives. Any SSP would be time limited and the protocol would indicate the period during which it has effect.

A standard template is being developed to create an SSP. The authorised SSP will be published and various communications channels will be used to alert pharmacies. Prescribers will also be alerted and CPNI will post communications on our website.

More information and FAQs can be found on CPNI website

<https://www.communitypharmacyni.co.uk/>