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PSNC Interim Briefing: An Introduction to Serious Shortage Protocols

In early 2019, changes to legislation were started to permit the Government to use Serious Shortage Protocols (SSPs) in the event of a serious shortage of a medicine. The final legislative changes have yet to be passed.

PSNC supports the use of this legislation as part of the measures that will help to manage any serious shortages of medicines, such as those which may occur if the UK exits the EU without an agreement (a no-deal Brexit). This PSNC Interim Briefing describes how we expect that SSPs might operate.

Please note: The detail of SSPs and how they would be implemented is still being worked out by the Department of Health and Social Care (DHSC) and as such, this briefing may be subject to amendments in the future.

SSPs: Introduction and Benefits

What are SSPs?

Legislation is being passed that will allow for an emergency measure called the Serious Shortage Protocol (SSP) to be put in place to help manage supply if there is a serious shortage of one or more medicines.

The intention is that an SSP will be issued only if a medicine has been judged by the Minister 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:

- Dispense a reduced quantity of medicine;
- Dispense an alternative dosage form;
- Dispense a therapeutic equivalent; or
- Dispense a generic equivalent.

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.

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 (eg capsules rather than tablets,) pharmacists can dispense. GPs will be notified when an SSP has been put in place so that prescribers will know what adjustments may be being made to their patients' medicines.

The introduction of SSPs **does not mean** that pharmacists will be empowered to make changes to patients prescribed medicines more widely. Each SSP will apply to a specific medicine, with specific alternatives allowed to be dispensed within a specific time period.

Why are SSPs being introduced?

Serious Shortage Protocols (SSPs) are being introduced as an additional tool to help community pharmacies to manage any potential serious shortages of prescription medicines. Problems with the supply of medicines are not a new phenomenon and can occur for a number of reasons, for example where manufacturers have problems making or transporting medicines; or where more people are suddenly prescribed a medicine, which uses up supply. In recent years we have seen an increase in shortage problems for a combination of these reasons, and pharmacies are already having to spend a lot of time trying to source medicines for their patients. Factors such as Brexit planning and contingency 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 (this is where the pharmacy gives patients some of their medicines and will ask them to come back to collect the rest of the prescription later); liaise with GPs to find alternative medicines that may be suitable; or make many phone calls to different suppliers to try to find the medicine.

SSPs will help community pharmacists to continue to supply patients with appropriate medication where a **serious shortage** of any particular medicine should occur, for instance following a no-deal Brexit. More broadly, the community pharmacy sector is working with Government and others on plans to ensure that the supply of medicines and medical devices is maintained after the UK exits the EU, including in a no-deal scenario. The legislation allowing SSPs to be introduced is being brought in alongside this but is separate from those wider Brexit preparations.

What are the benefits of SSPs?

The Government says that the main benefit of a Serious Shortage Protocol (SSP) is that it should enable patients to continue to have access to treatment without undue delays. SSPs may also reduce pressure on general practitioners because when a serious shortage occurs, GPs will not have to see all patients who have been prescribed the affected medicine to issue a new prescription. In a situation with multiple shortages, SSPs could have an important role in reducing delays in getting patients their medicines and freeing up GPs' time.

SSPs: Considerations and Working in Practice

What will pharmacists be able to do under an SSP?

As explained above, a Serious Shortage Protocol (SSP) will only be issued for a particular medicine where the Minister judges there to be a serious shortage. The SSP could specify several potential actions which community pharmacists should consider for patients with prescriptions for the affected medicine. Pharmacists could be instructed that they could consider supplying:

- a) a **different quantity** of the medicine specified within the original prescription;
- b) a **different formulation** of the medicine specified within the original prescription;
- c) a **generic version, alternative branded version or the separate constituent parts** of the named medicine specified within the original prescription;
- d) a **different quantity, formulation or strength of biological medicinal product to that specified** within the original prescription; or
- e) a **medicine with a similar therapeutic effect** to that specified within the original prescription.

For each of these scenarios, specific guidance will be provided on the alternative quantity, formulation, strength, name of generic or alternative branded version of the medicine which is authorised to be supplied under the SSP. 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.

When will an SSP be introduced?

The Government will decide whether a medicine shortage is serious enough for a Serious Shortage Protocol (SSP) to be required. The Department of Health and Social Care (DHSC) receives regular reports from the pharmaceutical industry about issues which may potentially interrupt the supply of medicines and affect UK patients. In each case, DHSC assesses the risk to patients and decides what tools to use to mitigate the impact on patients. In future, this could include SSPs.

The triggers for considering an SSP and the protocol itself will depend on the medicine and the supply situation, including whether alternative medicines are available. Ministers have confirmed that 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 Government to consider issuing an SSP, work will be undertaken by DHSC in collaboration with other health bodies, including the Devolved Administrations and NHS England.

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. If and when the SSP is introduced, pharmacists will be given a set of clear instructions to follow when prescriptions for the affected medicine are presented to them.

A standard template is being developed to create an SSP. The authorised SSP will be published by PSNC and NHS England who will use their various communications channels to alert pharmacies to its publication. NHS England will also alert prescribers. PSNC is developing a page on its website so that pharmacies can easily access all the latest information and communications on SSPs: psnc.org.uk/SSPs

SSPs: Frequently Asked Questions

Is it safe for community pharmacists to make changes to prescribed medicines?

A Serious Shortage Protocol (SSP) will only ever be introduced if clinicians think it is appropriate to do so. Any SSP will be developed with and signed off by clinicians and it will give pharmacists, who are experts in medicines and their use, clear instructions to follow, as outlined above in this briefing. Each protocol will clearly set out what alternative can be dispensed by a pharmacy, under what circumstances, including for which patients and during which period. Pharmacists still have to use their professional discretion as to whether supplying against the protocol rather than the prescription is appropriate, or whether the patient needs to be referred back to their prescriber.

The Department of Health and Social Care (DHSC) are working on operationalising the serious shortage legislation, including the governance processes and the creation of a national, clinically-chaired group advising Ministers, as well as national oversight at senior doctor level. Ministers have confirmed that operation of the SSP legislation will be reviewed one year after the first protocol has been issued.

What information will be given to patients about medicines shortages and SSPs?

Every shortage is different, and at a national level decisions about whether and how to communicate about them to patients will depend on a number of factors, the DHSC has said. DHSC will work closely with all stakeholders to consider how best to communicate a supply problem to those affected, including, where necessary, engaging with relevant patient groups regarding specific medicine shortages. Any patient can of course always talk to their local community pharmacy about the supplies of their medicine.

Will GPs be told when pharmacists have changed a patients' medication?

GPs and pharmacies will be informed via national communications of any SSPs that are issued, so prescribers should have clarity about what will happen in the event that a prescription only medicine is not available. Each individual SSP will include details of when the prescriber does or does not need to be informed of a supply against the SSP and any timescales for notification, where this is required.

What if there is no alternative for a medicine that could be supplied under an SSP?

The Government has acknowledged that protocols for therapeutic or generic equivalents will not be suitable for all medicines and patients. For example, such protocols would not be suitable for medicines that need to be prescribed by brand for clinical reasons, such as biological medicines. In these cases, patients would always be referred to the prescriber for any decision about their treatment.

What impact will SSPs have on community pharmacies?

Community pharmacists are experts in medicines and are very used to sourcing medicines and to having conversations with patients about their prescribed medicines. As such, the introduction of SSPs will build on the work that pharmacists already do in this area. However, the introduction of SSPs does require some logistical planning, and in particular PSNC is working with the Government and DHSC to clarify matters such as how pharmacies will be alerted when SSPs are issued; how pharmacies will claim any reimbursement, if appropriate, for any medicines they have supplied under an SSP; any records that pharmacies may be required to keep; and any increases in workload and costs that the SSPs may bring for community pharmacies.

How was the SSP legislation consulted on?

PSNC welcomes the speed with which DHSC has sought to bring forward this legislation, which we support. DHSC consulted stakeholder bodies representing pharmacists, doctors, patient groups and the pharmaceutical industry and asked those bodies to share the consultation as they saw fit. PSNC responded to the consultation and DHSC has reported that a total of 47 responses were received and that these were broadly supportive of the proposals.