Will Serious Shortage Protocols help ease drug shortages?

ANGELA DOWDEN

Historically, pharmacists have had very limited options when faced with drugs that are out of stock, but recently introduced Serious Shortage Protocols could theoretically help mitigate shortages by giving them the power to dispense something different. But what do pharmacists and prescribers make of these new protocols, and what are the implications for patients?

SPL

"Desperate times call for desperate measures," as the saying goes. When the desperate time is the unavailability of a specific drug, the desperate measure is a Serious Shortage Protocol, or SSP.

In the past, pharmacists have had very limited options when faced with out of stock medicines – essentially just helping the patient identify another pharmacy with stock, referring the patient back to the prescriber, or contacting the prescriber themselves to request a different prescription. However, an SSP enables community pharmacists, under specific circumstances, to supply a medicine different from the one written on the prescription, without needing to seek authorisation from the prescriber.

The Human Medicines Regulations 2012 were altered to introduce SSPs in February 2019, while further changes came into force in July 2019 as part of the NHS (Amendments Relating to Serious Shortage Protocols) Regulations 2019.[1] Previously, pharmacists were only able to use their judgement to amend a prescription when the prescriber had simply omitted to write the presentation (*eg* tablet, capsule, liquid) or if the quantity or strength was missing.

But these new measures don't help when bearing the brunt of a patient's upset and frustration if a drug is not in stock.

Why now?

SSPs were brought in as part of planning for a potential no-deal Brexit on 29 March 2019. But the law change is permanent, and SSPs are here to stay as a means to help deal with drug shortages currently happening on an unprecedented scale.

In a survey by *Chemist+Druggist* in September 2019,[2] 402 community pharmacy professionals reported experiencing shortages in each of the 36 categories of medicines listed, over the previous six months. The same survey found that two in five pharmacies spend more than an hour a day on shortages. And with an already stressed health service, it's

unlikely to get better any time soon.

The reason for specific drug shortages are complex and hard to tease out, but the Pharmaceutical Services Negotiating Committee (PSNC) list the following as contributing factors:

- Manufacturing issues or disruption
- Capacity issues
- Commercial withdrawal
- Intervention in market mechanisms relating to the pricing of medicines and drug reimbursement
- Drug recalls and quality issues
- Availability of raw ingredients, including active pharmaceutical ingredient shortages
- Increased demand
- Distribution and logistical problems
- Excessive parallel exporting
- Unexpected national demand
- Stockpiling and panic buying
- Supply quotas.

A new contributory factor is that some GP practices have begun issuing three-monthly prescriptions during the COVID-19 crisis.

"The explanation given by surgeries is that they wish to protect their staff and reduce the clerical workload," explains Cheshire-based pharmacist Fionnuala Keen, who has witnessed the practice. "These are legitimate reasons in themselves, but the unintended consequence is marketplace shortages."

How the new protocols work

SSPs are issued by the Department of Health and Social Care (DHSC) when a shortage is considered significant enough by government ministers under guidance from clinicians.

SSPs require community pharmacists to supply a specified medicine or device in accordance with the protocol rather than a prescription. The SSP may specify one or more of the following actions:

1. Issuing a reduced quantity of a drug
2. Giving an alternative strength
3. Giving an alternative dosage form
4. Dispensing a generic equivalent
5. Dispensing a therapeutic alternative.

Each protocol precisely sets out which actions pharmacists should take, under what circumstances and for how long.

The Serious Shortage Protocol (SSP) operational guidance acknowledges that therapeutic or generic equivalents are not suitable for some patients or medicines – specifically treatments for epilepsy.

The guidance says that "in these cases, patients would always be referred back to the prescriber for any decision about their treatment before any therapeutic or generic alternative is supplied".

This caveat was included in response to concerns raised by epilepsy groups. It means that should any SSPs for drugs used in epilepsy be issued in the future, epilepsy patients can be sure they won't have their medicines switched without proper consultation.

"For some epilepsy medicines, it is not appropriate for people to switch between different brands or to generic versions of the same drug. There is the potential for any such changes to affect a person's seizure control, potentially leading to breakthrough seizures for some," says Epilepsy Action Deputy Chief Executive Simon Wigglesworth.

"This is recognised by the Medicines and Healthcare products Regulatory Agency (MHRA), which has produced guidance on switching between different manufacturers' products."

Different excipients in theoretically identical drugs can also affect patients, while generic drugs that are a different colour or size to branded ones may cause anxiety or compliance issues in older patients, or in patients with memory problems or confusion.

"We're glad the government has followed the MHRA advice and taken our concerns on board, but we will continue to monitor this area closely," says Wigglesworth.

Box 1. Generics *versus* brands: spotlight on epilepsy

Pharmacy contractors are notified by NHSmail of any new SSP going live or when amendments to existing SSPs are published. The website of the NHS Business Services Authority (NHSBSA) also carries details of all SSPs (www.nhsbsa.nhs.uk).

SSP operational guidance notes[3] issued by the NHSBSA cover all the practicalities that pharmacists need for dealing with the protocols, including endorsement and payment, record keeping, and how and when to notify other health professionals.

As of April 2020, just five SSPs have been issued, covering only two drugs: haloperidol and fluoxetine. All five have related to adjustment of dosage form or strength only. In the case of a short supply of fluoxetine 10mg tablets, for example, the SSP instructs pharmacists to supply 10mg capsules.

So far, so uncontroversial, but giving a patient one month's supply of a drug instead of three, or issuing a different strength or form of a drug (steps 1, 2 and 3 above) is quite different from a pharmacist dispensing a generic equivalent or even a sister drug (steps 4 or 5 above).

Prescriber concerns

In response to stakeholder concerns,[4] the DHSC has said that protocols enabling pharmacists to issue a therapeutic or generic equivalent would only be used in "very exceptional circumstances". Such circumstances haven't occurred yet, but the provision in the legislation has caused doctor's groups to express alarm. The BMA says it doesn't agree with dispensing a therapeutic equivalent as a blanket approach. "Patients have idiosyncratic responses to drugs within the same class, and the pharmacist will not know what has already been used," it explains.

While the Academy of Medical Royal Colleges have said they have no problem with generic equivalents when there are no significant differences in drug release, they noted in their consultation response[5] that "making significant changes to prescriptions without reference back to the originating clinician… could pose unnecessary risks for the patient – and the dispensing pharmacist".

For some stakeholders, it was the haste with which SSPs were introduced that raised the most suspicion and concern. The Good Law Project claimed that the govern-

ment's initial consultation on SSPs – which lasted only one week in December 2018 – was "insufficient and unlawful". However, in hearings in the High Court (March 2019) and Court of Appeal (May 2019), the courts sided with the government.

Pharmacist support

On the other hand, the pharmacy sector is broadly in support of SSPs – in principle at least. "We community pharmacists are at the frontline… and we need to be better empowered to act in the event of medicines shortages," says Sibby Buckle, Vice Chair of the Royal Pharmaceutical Society English Pharmacy Board.

The PSNC says it supports SSPs, which it considers "seek to safeguard the supply of essential medicines to patients in the event of serious shortages of medicines". However, the Pharmacists' Defence Association, in its consultation response,[6] expressed concern that SSPs might open the door to governmental interference in medicines supply "in the absence of the usual parliamentary involvement and oversight".

Some pharmacists have also expressed that they wouldn't be comfortable assigning a generic or therapeutic equivalent without back up from the GP or other prescriber.

"Changing over to generics often does not go down well with the patient," explains Keen. "If the buck ends up stopping with pharmacists on this, it's going to be another thing they haven't the time or resources to deal with."

Fit for purpose?

The overwhelming sentiment from the frontline of dispensing is that SSPs are good enough in theory, but not working effectively enough in practice to ease shortage misery.

"What would help is a lot more SSPs to come on stream quickly, particularly those allowing pharmacists to deliver a smaller quantity of a drug while there's such an acute hiatus in supply," suggests Keen. "This would immediately reduce the time spent calling round suppliers, the number of times we have to send away patients with owings on prescriptions, and how many times we have to contact GPs."

Pharmacist and prescriber Sultan Dajani, from Wainwrights Chemist in Hampshire, agrees: "If we get a drug shortage tomorrow we have to wait a long time for an SSP, if it happens at all. We've had shortages of common antidepressants, painkillers, HRT and more, but no SSP has kicked in for those. It seems to me like one of those good ideas turned bad at the implementation stage. An overhaul is possible, but it needs a lot more input from pharmacists on the frontline."

Meanwhile, inadequacies in how day-to-day drug shortages are communicated is adding to the problem. "We're expected to report [to the PSNC] on shortages, but we don't have anything electronically to feed that information in or make it easy, so it gets neglected as we have so many other priorities," Dajani explains.

Going forward

Is it likely that SSPs will become better fit for purpose in time? There's theoretical potential for tweaks and changes in July 2020, which is when a review is due (one year after the first protocol was introduced). And as *Prescriber* went to press there was a potentially interesting development with the drafting of new emergency legislation by the Home Office to ease the supply of controlled drugs during the coronavirus pandemic. The new legislation provides for an extension of SSPs to potentially include Schedule 2, 3 and 4 (Part I) controlled drugs.

Pharmacists like Dajani believe a much more root-and-branch reform of SSPs is needed – and there are signs that GPs are beginning to push back against the reticence of their own professional bodies and call for the same. In November 2019, a motion by Shropshire and Telford local medical committee (LMC), debated at the English LMC conference, voted to extend SSPs and asked the BMA's General Practitioners Committee to urgently enter into discussions to give pharmacists more control in prescribing safe and considered alternatives.

As one West Midlands GP told *Prescriber*: "We are overwhelmed with patients returning to us because the medicine we've prescribed isn't available. It's time we trusted pharmacists to be the professionals they are and provide what they have on their shelves."

In summary, views on how to tackle drug shortages vary a lot, but there is a broad consensus that pharmacists must have flexibility to mitigate shortages, with relevant controls in place. SSPs are the vehicle that has been created for this, but the consensus is that they need more scope to deliver better.

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Declaration of interests

None to declare.

Angela Dowden is a freelance journalist and registered nutritionist