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IMPORTANT INFORMATION – Serious Shortages Protocol, NHS Contract Amendment (England)

Dear Superintendent,

I would like to bring to your attention that [The National Health Service \(Amendments relating to Serious Shortages Protocols\) Regulations 2019](#) (the NHS SSP 2019) were laid before Parliament on Friday 7 June 2019 and will come into force from **Monday 1 July 2019**.

These regulations amend aspects of the NHS Terms of Service of NHS community pharmacists, NHS dispensing appliance contractors, dispensing doctors and mandatory terms for Local Pharmaceutical Services schemes, in relation to SSPs. They also amend the [NHS \(Charges for Drugs and Appliances\) Regulations 2015](#) (known as “the charges regulations”).

SSPs allow for alternative arrangements to be put into place for supply of a drug or appliance ordered on a prescription where there is, or may be, a serious shortage of that drug or appliance. Legislation governing SSPs was introduced in early 2019 as part of no-deal Brexit planning, but it is **not** dependent on it.

[The Human Medicines Regulations 2012](#) (known as “the 2012 regulations”) have already been amended under [The Human Medicines \(Amendment\) Regulations 2019](#) to allow pharmacists from a retail pharmacy business to supply a different Prescription-Only Medicine (POM). The NHS SSP 2019 regulations laid before parliament now extend the scope of SSPs to all drugs and appliances that may be dispensed as part of providing pharmaceutical services in England, not just POMs.

From a community pharmacy perspective specifically, a number of key changes are introduced under the NHS SSP 2019 regulations. I have summarised these below. Please note that these changes relate specifically to the **provision of NHS services and dispensing of NHS prescriptions in England only**.

Key changes:

* NHS pharmacists “**must consider whether it is reasonable and appropriate to supply in accordance with the SSP instead of in accordance with the prescription form or repeatable prescription.**” A different product or quantity or both may be provided if in the professional judgement of the pharmacist it is appropriate and reasonable to do so with reasonable promptness and in accordance with the SSP

* Pharmacists **must** notify the patient’s GP if the product provided in accordance with the SSP is a POM that is different to but has a similar therapeutic effect to the product originally prescribed. Furthermore, in other cases of supplies made under SSPs, the patient’s NHS GP practice must also be notified if such a requirement is implemented for clinical reasons (further clarification will be provided on this in due course)

* When a SSP is in effect for a drug or appliance prescribed on a prescription form, but in the opinion of the registered pharmacist, supplying a different product or quantity would be inappropriate or unreasonable, the pharmacist is able to supply the product ordered on the original prescription — even if the pharmacist is able to supply this within a reasonable timescale, but not with reasonable promptness; their terms of service will not be breached by doing so. These amendments have removed the need for supply to be made with reasonable promptness

where an SSP is in place; instead, the supply should be made within a reasonable timescale (this has not been defined in measurable terms)

* Furthermore, where the requested drug or appliance is covered under a SSP, but in the pharmacist's professional judgement it is not appropriate or reasonable to provide an alternative product or quantity to that ordered, and the pharmacist is unable to provide the product ordered on the original prescription within a reasonable timescale — the pharmacist may simply refuse to provide the drug or appliance ordered. In such cases, the NHS pharmacist **must** provide the patient (or representative) with appropriate advice about returning to the prescriber to review the patient's treatment

* When a product is supplied under the SSP, a notification to this effect **must** be included in the dispensing label on the packaging of the product supplied, including identification of the particular SSP

* Where a different drug or appliance has been provided under the SSP covering the drug or appliance requested on the original prescription form, the NHS pharmacist cannot make the supply under the original prescription form in addition to that made under the SSP

* In parallel to the NHS SSP 2019 regulations, amendments are made to the Charges Regulations when a product is supplied in accordance with a SSP. The original prescription form, when endorsed, will be repurposed for recording the SSP supply for prescription charge exemption and remission of charges. Furthermore, for patients who would normally pay a prescription charge, no prescription charge will be payable when a supply is made in accordance with a SSP for a smaller quantity of a drug or fewer appliances supplied

* Under transitional arrangements, a separate token ("a dispensing token") is to be used to record supplies made under SSP. This is for the purposes of prescription charge exemptions, remission of charges and reimbursement . Further guidance on this will be available in due course

Further guidance and clarification on a number of operational and legislative aspects of the NHS SSP 2019 regulations and SSPs will be available in due course. In the meantime, I would advise you to ensure that your teams, including any locums you engage, are aware of the changes I have highlighted in this update. My team are currently working on a template SOP which will be available shortly to support you and your team in ensuring that the new requirements relating to the supply of medicines/appliances under SSPs are met.

From an indemnity perspective, NPA professional indemnity insurance will cover NPA members, customers (and the pharmacists they employ/engage) when supplying medicines/appliances under the relevant enabling legislation and the Serious Shortages Protocols (SSPs) which apply. It is acknowledged pharmacists will be expected to exercise professional judgement to determine the appropriateness of making each supply.

For further information please contact the NPA Pharmacy Services team on 01727 891800 or email at: pharmacyservices@npa.co.uk,

Kind regards,



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