

Dear Colleague

**SERIOUS SHORTAGE PROTOCOL:
JEXT® 300 MICROGRAMS/0.3ML (1 IN 100) SOLUTION
FOR INJECTION AUTO-INJECTOR PEN**

Purpose

1. To advise of a Serious Shortage Protocol (SSP) in place for Jext® 300 micrograms/0.3mL (1 in 1000) solution for injection auto-injector pen, from 21 August 2023 to 15 September 2023.

Background

2. Changes made to the Human Medicines Regulations 2012 and the NHS (Pharmaceutical Services) (Scotland) Regulations 2009, the latter of which became effective from 31 October 2019, allow the use of Serious Shortage Protocols (SSPs).
3. An SSP is an additional tool to manage and mitigate medication shortages and may be used when other measures have been exhausted or are likely to be ineffective. There are two types of SSP; one that covers prescription only medicines and another that covers pharmacy and general sales list medicines and appliances.
4. Each SSP is individually developed and authorised clinically, to enable community pharmacists and dispensing doctors to dispense a different strength or formulation or alternative medicine or appliances in accordance with the protocol, rather than having to refer prescribing decisions back to the original prescriber. These protocols are time limited.
5. Community pharmacists are expected to use their professional skill and judgement to decide whether it is reasonable and appropriate to substitute a person's prescribed medicine using the SSP. The person will also have to agree to the alternative supply.

25 August 2023

Addresses

For action

Chief Executives, NHS Boards
Director Practitioner Services,
NHS NSS

For information

Directors of Pharmacy
NHS Medical Directors

Enquiries to:

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St Andrew's House
EDINBURGH
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Email:

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6. Certain classes of medicines, for example cytotoxic medicines, biologics, anti-epileptic medicines and certain antipsychotic medicines, are not considered to be suitable for SSPs due to concerns about ensuring bioequivalence. In these cases, people should be referred back to the prescriber for any decision about their treatment before any therapeutic or generic alternative is supplied.
7. The addition of new SSPs and any amendments or extensions to existing SSPs are documented on the NHS Business Services Authority website using the following link: [Serious shortage protocols \(SSPs\) | NHSBSA](#).

Medicine supply situation requiring the use of an SSP

8. A supply issue with Jext[®] 300 micrograms/0.3mL (1 in 1000) solution for injection auto-injector pen has been identified. In order to manage stock supplies fairly and effectively, there is a UK-wide SSP in place, which allows community pharmacists to substitute a prescription of the noted product with the same quantity of EpiPen[®] 300 micrograms/0.3mL (1 in 1000) solution for injection auto-injector pens. This SSP can be accessed using the following link: [SSP058 Jext 300mcg autoinjector.pdf \(nhsbsa.nhs.uk\)](#)

Operational overview

9. Between 21 August 2023 and 15 September 2023, for patients presenting with an NHS or private prescription for a supply of Jext[®] 300 micrograms/0.3mL (1 in 1000) solution for injection auto-injector pen, community pharmacists may substitute this product with the **same quantity** of EpiPen[®] 300 micrograms/0.3mL (1 in 1000) solution for injection auto-injector pens, for eligible patients, in accordance with this SSP.
10. Total quantity supplied in accordance with this protocol is to be equivalent to the number of days treatment prescribed on the original prescription.
11. Community pharmacists are asked to review and familiarise themselves with the scope and the clinical situation to which this SSP applies, as outlined in the guidance provided within [SSP 058](#).
12. **When a substitution is made, pharmacists need to ensure that the patient's prescriber and/or GP practice is notified in accordance with this SSP.**
13. Community pharmacists are asked to ensure that the patient and their carer/guardian, when applicable, understands how to administer an EpiPen[®] 300 micrograms/0.3mL (1 in 1000) solution for injection auto-injector pens. Further information and guidance of how to use an EpiPen[®] can be found in the links below:
 - <https://www.gov.uk/drug-safety-update/adrenalineauto-injectors-aais-new-guidance-and-resources-for-safe-use>
 - <https://www.epipen.co.uk/en-gb/hcp/patientsupport/epipen-trainer-pen>
 - <https://www.epipen.co.uk/en-gb/hcp/epipen-explained>
14. If a patient or their carer/guardian declines to receive the medicine under this SSP, the pharmacist should use their professional judgement to determine if other courses of action are appropriate whilst taking into consideration wider supply issues. If this does not address their concerns, the patient should be referred back to their prescriber.

15. Similarly, if a patient does not meet the inclusion criteria for this SSP then they should be referred back to their prescriber promptly.
16. This SSP 058 only applies to prescriptions for Jext[®] 300 micrograms/0.3mL (1 in 1000) solution for injection auto-injector pen. Supply in accordance with this SSP only allows supply of a specific substitution up to the duration of treatment prescribed. However, if the pharmacist thinks that an alternative product, would be suitable for the patient they should either contact the prescriber to discuss this (with the patient's consent) or direct the patient back to the prescriber.

Additional information

17. Jext[®] 300 micrograms/0.3mL (1 in 1000) solution for injection auto-injector pens are licensed for patients weighing 30 kilograms or above. EpiPen[®] 300 microgram auto-injectors are licensed for patients weighing 26 kilograms or above, a weight that most children will have reached by the age of 9.
18. Supplying to patients weighing below 26kg would represent an off-licence use of the medicine. However, if the patient weighs less than 26kg, the prescriber will have prescribed Jext[®] 300 micrograms/0.3mL (1 in 1000) solution for injection auto-injector pen as an off licensed use as its licensed use is for patients weighing 30 kilograms or above and therefore the pharmacist may consider it appropriate to supply the medicine off licence. Please see the BNF guidance: <https://bnf.nice.org.uk/drugs/adrenaline-epinephrine/>
19. This SSP is not suitable for patients with known previous hypersensitivity or severe adverse reaction to EpiPen[®] 300 micrograms/0.3mL (1 in 1000) solution for injection auto-injector pen or its excipients, patients in this group should be referred back to their prescriber promptly.
20. If the pharmacist, using their professional judgement, considers that supplying the patient in accordance with the SSP would not be appropriate, the patient should be referred back to their prescriber promptly.

Supporting information on notifying other healthcare professionals

21. Any items supplied in accordance with an SSP in response to an NHS prescription also needs to be supplied in accordance with NHS Pharmaceutical and Local Pharmaceutical Services Regulations.
22. Those Regulations provide that where a therapeutic equivalent is supplied, a pharmacist will need to inform a patient's GP practice. This would generally be expected within the next working day, but further guidance would be given in any case where this applied.
23. Where a different quantity, an alternative pharmaceutical form, an alternative strength or a generic equivalent is provided, it may not always be necessary that the patient's prescriber is informed, as the existence of the SSP may be enough for the prescriber to be aware that these changes in dispensing may take place, unless national arrangements agreed with the relevant representative bodies state otherwise. However, guidance may be issued on particular SSPs to indicate that prescribers should be informed of any patients that receive supply under it.

24. In the absence of any preferred local alternate communication channels, all feedback to prescribers should be sent by NHSmail. The NHS Service Finder is a way for pharmacies to look up the email address of the patient's GP.

Fees and Endorsements

25. When an SSP is introduced, the pharmacist should use the Other endorsement function quoting SSP and the relevant reference number – in this case add SSP 058. A community pharmacy contractor will receive a multiplier per item of 5 (x5), via the dispensing pool, for any necessary supply in accordance with SSPs. Endorsements must be made in line with the SSP to be eligible for payment.

26. The paper form should be endorsed PMR with details added of what was supplied as well as 'SSP 058' annotated. This is to ensure accurate reimbursement for non-barcoded forms or where an electronic claim message is unavailable.

Enquiries

27. For any queries on the detail of this SSP, please contact the Scottish Government Pharmacy Team at PharmacyTeam@gov.scot.

Action

28. Health Boards are asked to note the contents of this Circular and to bring it to the attention of community pharmacy contractors on their Pharmaceutical Lists and Area Pharmaceutical Committees. This Circular should also be brought to the attention of General Practices.

Yours sincerely



Alison Strath
Chief Pharmaceutical Officer