

From the Acting Chief Pharmaceutical Officer
Cathy Harrison



Department of
Health

An Roinn Sláinte

Mánnystrie O Poustie

www.health-ni.gov.uk

FOR ACTION

Chief Executives, Health and Social Care
Board/Business Services Organisation/
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onward transmission to relevant staff*)

Assistant Director of Integrated Care, Head of
Pharmacy and Medicines Management, HSCB
(*for onward distribution to Community
Pharmacies*).

Head of General Medical Services, HSCB (*for
onward distribution to GP Practices*)
GP Medical Advisers, Health and Social Care
Board.

RQIA (*for onward transmission to all
independent providers including
independent hospitals and travel clinics*)

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Dear Colleagues,

SERIOUS SHORTAGE PROTOCOL – INFORMATION FOR HEALTH PROFESSIONALS

I am writing to provide you with further information and guidance about the use of Serious Shortage Protocols (SSP) in Northern Ireland.

The global production of medicines and medical supplies is complex and highly regulated, and materials and processes must meet rigorous safety and quality standards. Supply problems can arise for various reasons such as manufacturing issues, problems with raw ingredients and batch failures. There are already well established procedures in place to deal with shortages and ensure that any risks to the public are minimised.

An SSP is an extra tool to manage and mitigate the impact of medication shortages and enables community pharmacy contractors to supply against the protocol rather than a prescription. It is anticipated that SSPs will only be used when a medicine prescribed is in short supply or unavailable and when other measures have been exhausted or are likely to be ineffective.

An SSP will allow for substitution, in restricted circumstances, of a different strength, quantity or pharmaceutical form of a medicine, or a different medicine/device to that ordered by the prescriber, without the need to seek authorisation from the prescriber. This means patients do not need to go back to the prescriber before receiving an alternative quantity, brand, formulation or medicine.

The Human Medicines (Amendment) Regulations 2019 which came into operation on 9 February 2019 are UK-wide in their extent and provide for a “serious shortage protocol” (SSP) to be issued where there is or may be a serious shortage of a specified medicine.

Amendments have also been made to the Pharmaceutical Regulations (Northern Ireland) 1997 through the Pharmaceutical Services (Amendments Relating to Serious Shortage Protocols) Regulations (NI) 2019¹. These regulations come into operation today (31 October 2019) and ensure that any supply under a SSP by a community pharmacy contractor is in line with their Terms of Service.

Notification of SSPs, guidance and other information.

When a decision has been taken to issue an SSP, the Department of Health will notify the relevant HSC organisations who will advise General Practitioners, GP Locums and community pharmacy contractors. The Business Services Organisation (BSO) will also publish information about each SSP on a dedicated page on its website - www.hscbusiness.hscni.net/services/3063.htm

A copy of the operational guidance for SSPs is attached at **Annex 1**. A copy of FAQs and a patient information leaflet will also be made available on the BSO website.

Yours sincerely,



Cathy Harrison
Acting Chief Pharmaceutical Officer

¹ <http://www.legislation.gov.uk/nisr/2019/186/contents/made>