



Response to the 'Informal consultation on urgent changes to the Human Medicines Regulations 2012 to ensure the continuity of supply of medicines (including in a 'no deal' Brexit)'

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Introduction

PSNC promotes and supports the interests of all NHS community pharmacies in England and is recognised by the Secretary of State for Health and Social Care as the body that represents NHS pharmacy contractors.

We have been asked to respond to the consultation set out in Annex A to this document and have discussed a number of the issues with representatives of the Department of Health and Social Care (DHSC). We and other community pharmacy, pharmacy and dispensing contractor organisations have also discussed the proposals with DHSC at a meeting of the Community Pharmacy Brexit Forum.

PSNC is supportive of the proposed legislative changes, which we consider will seek to safeguard the supply of essential medicines to patients in the event of serious shortages of medicines, including any serious shortages following a no-deal Brexit. The Government's revised planning assumptions – that delays/reduced flow of goods at relevant border ports could last for 6 months – suggest that there could be serious shortages of patients' essential medicines following a no-deal Brexit.

Our comments on the proposed legislation are set out, as well as our general observations on any implementation of the proposals in the event of serious shortages of medicines.

PSNC's comments and observations on this consultation are set in relation patients' needs, professional issues and practical and financial issues; followed by responses to the specific questions raised by DHSC.

Comments and Observations

Amendment 1: provision for a 'serious shortage protocol' for serious national shortages of medicines

Patients' needs

The proposed legislation introduces Serious Shortage Protocols (SSPs) as an exception to Regulation 214 (1) of the Human Medicine Regulations 2012 - as an exception to the sale or supply of a prescription only medicine in accordance with a prescription given by an appropriate practitioner - where there **is**, or **may be**, a serious shortage of a prescription only medicine in the UK or any part of the UK. Supply under an SSP is subject to the conditions of the SSP **and** the pharmacist under whose supervision the sale or supply is made must exercise his or her professional 'skill and judgment ...'.

Comments on the draft legislation

Any appropriate substitution of a medicine – generic or brand – should be available – we are not convinced that the current drafting permits the substitution of one branded or proprietary medicine for another, which may be vital.

It is also important that SSPs can be drafted to permit the substitution of a generic medicine against any branded medicine of the same active ingredient(s) – to ensure any local reliance on non-originator brands of medicines does not complicate the substitution of medicines/introduction of SSPs.

Any appropriate substitution of a - biological medicinal product or biosimilar medicine - with a similar medicinal product should be available – this is arguably within the current drafting.

An SSP may be issued if the UK or any part of the UK is 'experiencing or may experience a serious shortage' so there is some flexibility to allow its introduction before there is a serious shortage. However, it is suggested DHSC should have even greater flexibility over the introduction of SSPs - to allow the introduction of an SSP in the expectation, or if there is a possibility, of a serious shortage of a medicine; or if there is a serious shortage of another relevant medicine. This would give the option of issuing SSPs well before a serious shortage, could avoid the need to rush the introduction of an SSP and could better help to avoid a serious shortage in the first place.

The proposed legislation should permit an SSP to change the supply of a medicine in relation to its quantity, strength (e.g. 10mg or 20mg strength) or pharmaceutical form (e.g. tablets or capsules). It is suggested that the term 'dosage form' should be avoided as it is undefined.

Any relevant associated changes to the prescription, for example, to the directions for use, should be permitted by an SSP, subject to the specific content of the SSP. This would ensure that appropriate professional judgement could be applied by the supervising pharmacist.

It may be helpful to be clear about when an SSP must end or clarify that an SSP may continue for a period of time after a serious shortage of a medicine has ended, to ensure there is no dispute about this subsequently.

It may also be helpful to be clear about the status of the prescription after supply of a medicine against an SSP, to ensure the prescription can be retained by community pharmacy for the purposes of payment for supply against the SSP.

General observations

Efforts should be made to minimise any confusion or concern of patients and carers, with clear written information for patients provided with any SSP, including in some cases, the nature of the substitution.

Local liaison between GP surgeries and community pharmacies is likely to be necessary to ensure that GP surgeries are informed of any supplies in accordance with an SSP, as opposed to the patient's prescription – for example, changes to the quantity of medicine or if a different medicine is supplied as a result of an SSP.

Clear communication channels from DHSC to all prescribers and pharmacists and others in the medicines supply chain will be necessary to ensure that healthcare professionals are fully informed of SSPs and can give appropriate advice to their patients; and others in the supply chain are also fully informed and, for example, any relevant community pharmacy quotas for substitute medicines can be revised.

SSPs should be sufficiently flexible, to ensure that person-centered decisions can be made pharmacists.

In the event of a no-deal Brexit, there could be serious shortages of many medicines. DHSC may need to consider its capacity to draft and issue numerous SSPs with appropriate guidance and communications to all relevant parties. Community pharmacy has indicated that, in principle, the sector would be willing to make pharmacists available to DHSC to ensure the continuity of supply of essential medicines to patients.

Once an SSP has expired/ the serious shortage has been resolved, there will need to be a mechanism or procedure to return a patient to their previous treatment (if clinically appropriate).

Professional Issues

The proposed SSPs will allow pharmacists in community pharmacies to ensure a patient receives an appropriate medicine if the UK is experiencing or may experience a serious shortage of the medicine. This raises a number of professional issues for community pharmacy.

Comments on the draft legislation

The supervising pharmacist exercises his or her skill and judgement in relation to (we suggest) - quantity or strength or pharmaceutical form - in relation to what is 'reasonable and appropriate'. With therapeutic substitution, skill and judgement is applied as follows - the supply of an alternative medicine must be 'reasonable' - and the directions for use 'appropriate'. The reason for this difference of approach is not clear.

With regard to any change in the strength of a medicine, this could have the effect of changing the directions for use.

It may be necessary to use SSPs before 29 March 2019 or the exit day and, therefore, the legislation should be in place as soon as practicable.

General observations

Pharmacists may have considerable workload explaining to patients and/or carers the changes to medicine supplies and minimising the risk of administration errors (e.g. double doses being taken if a patient has stock at home of the previous drug or another pharmaceutical form).

Pharmacists may also have considerable workload once the SSP expires, if the patient returns to the original prescription.

An IT platform to record pharmacists' actions implementing SSPs may be helpful, to assist otherwise onerous workload ensuring appropriate records are provided to GP practices. There are likely to be reciprocal workload issues for GP practices unless the process is automated through an IT solution.

If appropriate training is available to community pharmacy, this may help certain pharmacists in relation to the nature of SSPs generally, as well as complex clinical issues with certain SSPs.

It may be helpful to have a national advisory group to assist DHSC with the identification of current or future serious shortages of medicines and/or the drafting, authorising, issuing and implementing of SSPs.

Community pharmacy has access to a patient's summary care record but not the full clinical record which could assist a supervising pharmacist as he or she applies his or her skill and judgement to the supply of medicine against an SSP.

Assurances are sought that the defences available to pharmacists against offences under Section 64 of the Medicines Act 1968 will apply to medicines supplied in accordance with an SSP.

Practical and financial issues

In the event of serious shortages and the introduction of SSPs, the workload and, therefore, the cost of the provision of medicines to NHS patients is likely to increase dramatically, due to the additional responsibilities in relation to patients and other healthcare professionals, and additional professional and NHS responsibilities; for example, additional advice and information to patients, as well as additional recording, reporting and claiming duties. Practical issues will need to be discussed with DHSC and NHS England prior to the implementation of SSPs.

Comments of the draft legislation

There are no comments on the draft legislation relating to practical and financial issues.

General Observations

The impact assessment should note the operational impact and costs for community pharmacy associated with SSPs.

The impact assessment should note the **increased stress** for the pharmacy teams – concern about obtaining essential supplies of medicines for patients and concern about any breach of the community pharmacy’s statutory terms of service with the NHS to supply with reasonable promptness (unless this is changed) – and **increased work** - trying to source a patient’s medicine prior to the serious shortage - from one of the main wholesalers, one of many short-line wholesalers as well as importers and other smaller wholesalers, or even sometimes other local pharmacies or the local hospital and the **increased work** associated with the SSP, due to the additional responsibilities in relation to patients and other healthcare professionals, and additional professional and NHS responsibilities; for example, additional advice and information to patients, as well as additional recording, reporting and claiming duties.

The medicines supply chain is complex, and community pharmacies already spend a lot of time sourcing medicines for their patients and managing medicines shortages when they occur. In the event of a no deal Brexit, the pressure on community pharmacy from a practical and financial aspect is likely to be very significant; and at a time when community pharmacy is already subject to funding cuts and Margin clawback.

The overall workload and remuneration of community pharmacy may require consideration in the event of a no-deal Brexit, with relevant issues including, for example: whether an additional fee for dispensing against an SSP is appropriate; any additional remuneration for increased dispensing; other associated work and costs sourcing medicines in short supply; general community pharmacy assistance with a serious shortage of medicines in the UK or part of the UK; the capacity and availability of community pharmacy; and, the need to maintain the viability of community pharmacy during a period of serious shortages of medicines and the use of SSPs. If there are a significant number of serious shortages in the event of a no-deal Brexit, it is likely that measures will be necessary to provide stability to the community pharmacy network of independent businesses. If the medicines supply system becomes very erratic, general payments to contractors based on average volumes may be appropriate.

Consideration should be given to the current Drug Tariff concession pricing system, in particular:

- Ensuring that overall funding for the community pharmacy sector, including Margin, is delivered reasonably evenly throughout the year (not simply calculated at the end of the year) and any recovery of Margin made from previous years is suspended; and,

- Ensuring there is equitable reimbursement for individual contractors providing medicines to patients where the concession price imposed by DHSC is significantly lower than the market price of the medicine.

Relevant reimbursement issues need to be considered. Currently the reimbursement system is largely “paid as prescribed” but against an SSP it may need to be “paid as dispensed/endorsed”. This may increase costs for community pharmacy and be a practical and financial issue for NHSBSA, which processes community pharmacy payments for NHS England.

Consideration should also be given to reducing non-essential work associated with the Community Pharmacy Contractual Framework during any period of serious shortages of medicines and/or issuing of SSPs; to reduce the workload of community pharmacy and make resources available to help manage SSPs.

Ensuring there is equal access to Margin for community pharmacy contractors is important at any time, as part of the incentives to ensure competitive purchasing. The use of non-originator branded medicines prescribed in place of generic medicines produces inequitable variations in the distribution of Margin, adversely affecting the supply of medicines under Part 7 of the NHS Act 2006.

There should be consideration of additional issues relating to the Patient Medication Record computer systems used by community pharmacy, in particular, the possible warnings from the system, payment claims through the system and associated additional workload; electronic prescriptions may not match the substitutions or quantities dispensed etc. Consideration should also be given to claims for payment via the Electronic Prescription Service and any potential issues for systems also assisting compliance with the Falsified Medicines Directive (FMD).

Consideration should be given to potential intellectual property issues that may arise, particularly in circumstances where there may be a serious shortage of the medicine.

An SSP may affect professional indemnity and increase the costs borne by community pharmacy as part of the provision of NHS pharmaceutical services.

Amendment 2: provision for a regulation making power in relation to serious shortages in case of a 'no deal' Brexit

This is a sensible and pragmatic proposal, including the 2-year period before any further legislative provision is necessary.

Consultation Questions

Question 1: Do you agree with the introduction of the provision for a 'serious shortage protocol' to deal with serious national shortages of medicines?

Yes, subject to the above comments and observations.

Question 2: Do you agree with the introduction of a regulation making power in relation to serious shortages in case of a 'no deal' Brexit?

Yes, this is a sensible and pragmatic proposal.

Question 3: Do you have views on the principles outlined above, which are informing our assessment of impacts?

Yes, as stated above.

Question 4: Do you have comments on the draft provisions?

Yes, as stated above.

Conclusion

PSNC supports the proposals, subject to our comments on the draft legislation.

About PSNC

PSNC promotes and supports the interests of all NHS community pharmacies in England. We are recognised by the Secretary of State for Health and Social Care as the body that represents NHS pharmacy contractors. We work closely with Local Pharmaceutical Committees to support their role as the local NHS representative organisations.

Our goal is to develop the NHS community pharmacy service, and to enable community pharmacies to offer an increased range of high quality and fully funded services; services that meet the needs of local communities, provide good value for the NHS and deliver excellent health outcomes for patients.

Annex A

Dear all,

Informal consultation on urgent changes to the Human Medicines Regulation 2012 to ensure the continuity of supply of medicines (including in a ‘no deal’ Brexit)

Prompted by the preparations for the UK’s exit from the EU, the Department of Health and Social Care is proposing some changes to the Human Medicines Regulations 2012 to ensure the continuity of supply of medicines when the UK leaves the EU, including in a ‘no deal’ scenario. We have spoken to a number of representative bodies about the changes and would be happy to speak to others as well.

Normally, we would consult publicly for 12 weeks before making any changes to the Human Medicines Regulations 2012. However, you will understand that any legislative changes in relation to the UK’s exit from the EU need to be progressed quickly so that they are in force before the day that the UK leaves the EU. Therefore, we are seeking views of the relevant stakeholder representative bodies on the proposed changes **by close on 12 December 2018**.

Background

The Government is preparing for the UK’s exit from the EU, including for a scenario in which the UK leaves the EU without agreement (a ‘no deal’ scenario). We have asked pharmaceutical companies that supply the UK with medicines from, or via, the EEA, to ensure they have a minimum of six weeks’ additional supply in the UK. And in light of this, we have advised healthcare providers (hospitals, pharmacies etc.) and prescribers that they do not need to take any steps to stockpile additional medicines or write longer prescriptions.

In addition, we have now also undertaken an exercise to identify any further actions that could support the continuity of supply of medicines in a ‘no deal’ scenario. The actions range from trying to increase the manufacture or packaging of products in the UK to controlling distribution and dispensing flexibilities and stopping exports. We believe that most of the actions identified can be taken within the existing legislative framework, the Human Medicines Regulations 2012, but may require, for example, the Medicines and Healthcare products Regulatory Agency (MHRA) to fast track applications or the Department to make changes to the Drug Tariff.

There are however two areas that require changes to the legislation. We are seeking your views on the proposed changes to the Human Medicines Regulations 2012 in these areas.

Amendment 1: provision for a ‘serious shortage protocol’ for serious national shortages of medicines

This amendment introduces a new regulation into the Human Medicines Regulation 2012 enabling Ministers to issue a ‘serious shortage protocol’. Such a protocol could be issued in case of a serious national shortage and would enable community pharmacists and other dispensers, to dispense in accordance with the protocol rather than the prescription without contacting the GP. The pharmacist would still use their professional judgment to decide on what medicine to dispense. The protocol would be developed with clinicians and would clearly indicate what alternative can be dispensed and to which patients it applies. The protocol covers four possibilities:

- Dispensing a reduced quantity
- Dispensing an alternative dosage form
- Dispensing a therapeutic equivalent
- Dispensing a generic equivalent

A ‘. In particular in a scenario with multiple large shortages, protocols will support pharmacists and GPs by reducing the time needed for pharmacists and GPs to liaise with each other and with patients. It has been drafted as a reserve power that would allow Ministers to issue serious shortage protocols during any serious national shortage, not just for potential supply shortages in a ‘no deal’ scenario.

This amendment will be progressed as part of the ‘Human Medicines (FMD) (Amendment) Regulations 2019’ which we expect to be laid in Parliament in January 2019.

Question 1: Do you agree with the introduction of the provision for a ‘serious shortage protocol’ to deal with serious national shortages of medicines?

Amendment 2: provision for a regulation making power in relation to serious shortages in case of a ‘no deal’ Brexit

This amendment introduces a new regulation into the Human Medicines Regulation 2012 enabling Ministers to continue to make changes to the Human Medicines Regulation 2012 in relation to serious shortages caused by the UK's exit from the EU.

The Human Medicines Regulation are made under the European Communities Act. If the UK leaves the EU without a deal we can no longer make regulations under the European Communities Act which mean that we cannot amend the Human Medicines Regulations in the way that we have to date. We are therefore proposing a new regulation making power in the Human Medicines Regulations themselves, using powers under the EU Withdrawal Act 2018. That power will enable us to continue to amend the Human Medicines Regulations but only in relation to serious shortages as a consequence of Brexit and can be considered a safety valve. If we have to make changes to the legislation to support the supply chain in a 'no deal' scenario then we can do that.

This amendment will be progressed as part of the 'no deal' legislation which we expect to lay in Parliament in January 2019. Unlike the amendment to introduce the 'serious shortage protocol', this amendment will only be progressed in case the UK leaves the EU without a deal.

Question 2: Do you agree with the introduction of a regulation making power in relation to serious shortages in case of a 'no deal' Brexit?

Impact assessment

We expect that a 'serious shortage protocol' would have an impact on pharmacists and GP and on patients:

- There will be a positive impact on pharmacists and GPs who will save time and resource by not having to liaise with each other for each individual patient that has been prescribed a medicine for which a protocol is available.
- There will be a positive impact on patients who continue to have (quick) access to treatment.

We have not yet quantified the impact.

Equality impact assessment

We expect that both proposals will help secure the continuity of supply of medicines and allow patients, including those with protected characteristics, continued access to medicines.

Question 3: Do you have views on the principles outlined above, which are informing our assessment of impacts?

Draft regulations

The draft regulations have been attached to this email. New regulation 226A covers the ‘national shortage protocol’ and new regulation 344B covers the regulation making power in a ‘no deal’ situation.

Please note that whilst the two amendments have been included in the same draft Statutory Instrument, they will be taken forward in separate Statutory Instruments. New Regulation 344B will only be progressed in case of a ‘no deal’ whereas regulation 226A will be progressed anyway.

Question 4: Do you have comments on the draft provisions?

Please send your responses to the questions or any other comments to me **by close on 12 December 2018.**

If you have any questions, please do not hesitate to contact me.

STATUTORY INSTRUMENTS

2019 No. 000

MEDICINES

The Human Medicines (Amendment) Regulations 2019

<i>Made</i>	- - - -	2019
<i>Laid before Parliament</i>		2019
<i>Coming into force</i>	- -	March 2019

The Secretary of State and the Minister of Health, Social Services and Public Safety, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972⁽¹⁾, and the Secretary of State, in exercise of the powers conferred by section 8 of the European Union (Withdrawal) Act 2018⁽²⁾, make the following Regulations.

The Secretary of State and the Minister of Health, Social Services and Public Safety, have been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to medicinal products⁽³⁾.

(1) 1972 c. 68. Section 2(2)...
(2) 2018 c. 16.
(3) S.I. 1972/1811.

Citation, commencement and interpretation

1. These Regulations may be cited as the Human Medicines (Amendment) Regulations 2019 and come into force on [March 2019].

Amendment of the Human Medicines Regulations 2012

2.—(1) The Human Medicines Regulations 2012⁽⁴⁾ are amended as follows.

(2) After regulation 226 (emergency sale etc by pharmacists: pandemic disease), insert—

“Sale etc by a pharmacist in accordance with a serious shortage protocol

226A.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business if conditions A, B and C are met.

(2) Condition A is that the prescription only medicine is sold or supplied for the purpose of being administered to a person in accordance with a serious shortage protocol (SSP).

(3) Condition B is that the requirements of the SSP in respect of to whom the prescription only medicine may be sold or supplied for the purpose of being administered, and subject to what conditions, are satisfied.

(4) Condition C is that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied is of the opinion, in the exercise of his or her professional skill and judgment, that—

- (a) in a case to which paragraph (5)(b)(i) applies, selling or supplying a different quantity or dosage form of the prescription only medicine to the quantity or dosage form of the prescription only medicine ordered by the prescriber is reasonable and appropriate; or
- (b) in a case to which paragraph (5)(b)(ii) applies—
 - (i) selling or supplying a prescription only medicine other than the prescription only medicine ordered by the prescriber is reasonable, and
 - (ii) sale or supply of the substituted prescription only medicine, in accordance with the directions for use that he or she specifies, is appropriate.

(5) For the purposes of this regulation, a SSP is a written protocol that—

- (a) is issued on behalf of the Ministers (either of them acting alone or both of them acting jointly) in circumstances where the United Kingdom or any part of the United Kingdom is experiencing or may experience a serious shortage of a prescription only medicine or prescription only medicines of a specified description;
- (b) provides for the sale or supply by or under the supervision of a pharmacist and subject to such conditions as may be specified in the SSP—
 - (i) of a different quantity or dosage form of the prescription only medicine to the quantity or dosage form ordered by the prescriber, or
 - (ii) of a prescription only medicine other than the prescription only medicine ordered by the prescriber;
- (c) provides, in a case to which sub-paragraph (b)(ii) applies, that the other prescription only medicine is to be—
 - (i) a generic version of the prescription only medicine being substituted, or that both products are generic versions of another prescription only medicine,
 - (ii) in the case of a biological medicinal product, a similar medicinal product to the prescription only medicine being substituted, or that both products are similar medicinal products to another biological medicinal product, or
 - (iii) a prescription only medicine that has a similar therapeutic effect to the prescription only medicine being substituted; and

(4) S.I. 2012/1916.

- (d) specifies the period for which, and the parts of the United Kingdom (which may be all of the United Kingdom) in which, the protocol is to have effect.”.

(3) After regulation 344A, insert—

“Modifications to deal with serious shortages

344B.—(1) The Ministers may by regulations modify the application of any of the specified provisions in circumstances where the United Kingdom, or any part of the United Kingdom, is experiencing or may experience a serious shortage of medicinal products, or of medicinal products of a specified description, arising from the withdrawal of the United Kingdom from the European Union.

(2) Regulations may only be made under paragraph (1) for the purposes of preventing, remedying or mitigating the serious shortage that is being or may be experienced.

(3) For the purposes of paragraph (1), the “specified provisions” are the provisions of Parts 1, 3 to 5, 10 to 13 and 16, and of the associated Schedules.

(4) The reference in paragraph (1) to a serious shortage arising from the withdrawal of the United Kingdom from the European Union includes reference to a serious shortage where one but not the only significant factor contributing to the shortage is the withdrawal of the United Kingdom from the European Union.

(5) No regulations may be made under paragraph (1) after the end of, or that have effect after the end of, the period of two years beginning with exit day.

(6) The power to make regulations under paragraph (1) is exercisable by statutory instrument.

(7) Regulations made under paragraph (1) are subject to annulment by resolution of either House of Parliament.”.

Signed by authority of the Secretary of State for Health

Date

Name
Parliamentary Under Secretary of State
Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations...