



PDA's Response to the DHSC's '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)'

December 2018

About the Pharmacists' Defence Association

The Pharmacists' Defence Association (PDA) is a not-for-profit organisation which aims to act upon and support the needs of individual pharmacists and, when necessary, defend their reputation. It currently has more than 28,000 members. The PDA Union was inaugurated in May 2008 and achieved independent certification in 2011.

The PDA is the largest pharmacist membership organisation and the PDA Union is the only independent Trade Union exclusively for Pharmacists, in the UK.

The primary aims of the PDA are to:

- Support pharmacists in their legal, practice and employment needs
- Represent the individual or collective concerns of pharmacists in the most appropriate manner
- Proactively seek to influence the professional, practice and employment agenda to support members
- Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practices, so improving patient care
- Work with like-minded organisations to further improve the membership benefits to individual pharmacists
- Arrange insurance cover for individual pharmacists to safeguard and defend their reputation.

The consultation ran for one week, from the 5th to the 12th of December 2018.

Excerpts from the consultation document

Introduction

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). Measure include a request to 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.

In addition, the Government has 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.

The government is seeking views on two proposed changes to the Human Medicines Regulations 2012 to facilitate management of drug supply should the UK leave the EU without an agreement (no deal Brexit).

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

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 lay in Parliament in January 2019.

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 Regulations are made under the European Communities Act. If the UK leaves the EU without a deal the Government can no longer make regulations under the European Communities Act which means that it cannot amend the Human Medicines Regulations in the way that it has done to date. The Government is 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 Ministers 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 changes to the legislation to support the supply chain in a 'no deal' scenario are required, this amendment will facilitate 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.

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.

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.

PDA Response

Section 226A – Sale etc by a pharmacist in accordance with a serious shortage protocol

The PDA understands the need to introduce provisions to enable supply by a pharmacist in accordance with an SSP, in the event of a no-deal Brexit, and broadly agrees with the provisions in that regard set out in the draft legislation introducing section 226A of the Human Medicines Regulations 2012. The PDA understands that the proposed section 226A would apply irrespective of whether or not the UK leaves the EU (and if it does, regardless of the circumstances).

The four reasons for which a medicine substitution may be required under an SSP are:

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

The government appears to have overlooked the fact that other areas of legislation would also need to be amended in order to make it lawful for a pharmacist to substitute a medicine. These include at least:

- The Human Medicines Regulations section 17 (assembling not in accordance with a prescription)
- The Medicines Act 1968 Section 64 (supply of a medicine not of the nature or quality demanded)

Section 344B – Modifications to deal with serious shortages

We are concerned about the regulation-making power proposed to be entered as paragraph 344B. As currently drafted, it would allow amendments to be made to nine of the seventeen parts of the Human Medicines Regulations 2012 by Ministers, including but not limited to the "*sale by a pharmacist in accordance with an SSP*" provisions (the proposed Section 226A). This amendment would transfer a significant amount of power from parliament to Government Ministers, which would have significant constitutional implications in relation to medicines. It has not been made clear what safeguards would be in place to ensure appropriate use of these executive powers. No definition of "serious shortage" has been provided which would indicate how this is to be determined by the government.

The consultation document states that the introduction of section 344B would only come into force in a 'no deal' Brexit scenario. However, on reading the actual statute, these powers would be in effect in the event of any Brexit at all. That arises because the wording of 344B (4) includes the words "*where one but not the only significant factor contributing to the shortage is the withdrawal of the United Kingdom from the European Union*" – since it does not make any reference to a "no deal" scenario.

In other words, the statute would allow Ministers to amend significant sections of the Human Medicines Regulations including rules relating to the sale and supply of medicinal products (over and above allowing pharmacists to supply under an SSP), due to matters affecting supply which may be broadly unrelated to a 'no-deal' Brexit and could even be implemented with an EU withdrawal agreement in place, since the statute makes no mention of 'no deal' withdrawal.

These powers could make it possible to sanction medicines supply to patients in non-pharmacy locations in the absence of any pharmacist input or usual safeguards, for reasons which are not even predominantly related to withdrawal from the EU. We are concerned that this could pose a

risk to patient safety and would open the door to governmental interference in medicines supply in the absence of the usual parliamentary involvement and oversight.

Our view is that the proposed legislation should be amended to ensure:

- The "modifications to deal with serious shortages" provisions must only be exercisable in the event of a "no-deal" Brexit, not any Brexit at all (as is currently proposed). That is to say, these powers should only come in to play at a time when the UK does not have a trade deal with the EU. It might be that the UK leaves the EU without a deal, then subsequently negotiates one afterwards; these powers must not be in effect in that event.
- The "modifications to deal with serious shortages" must only be in effect until those shortages have resolved.
- The withdrawal from the EU must have been the only cause of the shortage, rather than having merely made a "significant" contribution.
- If the latter point above is not accepted, the withdrawal from the EU should have been the *principal* cause, not just a "significant" one.

Finally, we would urge the Government to consider what additional support is provided to front line staff, since implementation of SSPs will require time for staff to liaise with patients and explain the changes to their medication. Thought must also be given to the time required to ensure that any changes to patient medication can be fed back to general practice and recorded in patient clinical records in a timely and straightforward manner. This is likely to negate the comments the government made in the consultation document that *"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"*; our view is that the government's assertion is wrong and overlooks the fact that such liaison will be necessary to ensure continuity of care.

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 – but subject to our recommendations

Recommendation

The Government must ensure that safeguards are in place to prevent inappropriate use of Serious Shortage Protocols for factors unrelated to EU withdrawal.

Recommendation

In order to allow pharmacists to lawfully make supplies under a Serious Shortage Protocol, the government must amend other areas of law to make it lawful. This includes at least section 17 of the Human Medicines Regulations 2012 and Section 64 of the Medicines Act 1968.

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 – but subject to our recommendations

Recommendation

The regulation-making powers to make ‘modifications for serious shortages’ must only be exercisable in the event of a "no-deal" Brexit, not any Brexit at all (as is currently proposed) and then only whilst the UK does not have a trade deal with the EU (since it may acquire one post-Brexit).

Recommendation

The “modifications to deal with serious shortages” must only be in effect until those shortages have resolved.

Recommendation

The ‘no-deal’ withdrawal from the EU must have been the only cause of the shortage, rather than having merely made a "significant" contribution.

If this is not acceptable, then a no deal withdrawal must be the principal cause of the shortage, not one of a number of ‘significant’ causes.

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

We take the view that there may be an unwarranted degree of optimism about the ability of these provisions to enable 'quick access' to treatment. We would suggest that those patients who are frail, vulnerable or who suffer from cognitive impairment may suffer a negative impact as a result of changes to their therapy which they may find hard to understand and which hard-pressed pharmacy staff will need to counsel them about in potentially busy and stressful situations.

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

Yes – the draft 344B provisions do not clearly set out the criteria required for use of the amended regulatory powers as described in the consultation information. That is:

- Medicines shortages as a result of a **'No deal' Brexit**

Please see our comments above for further information.