

# **Explanatory Memorandum to the National Health Service (Amendments Relating to Serious Shortage Protocols) (Wales) Regulations 2019**

This Explanatory Memorandum has been prepared by the Primary Care Division of the Health and Social Services Group, and is laid before the National Assembly for Wales in conjunction with the above related subordinate legislation in accordance with Standing Order 27.1.

## **Minister's Declaration**

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the National Health Service (Amendments Relating to Serious Shortage Protocols) (Wales) Regulations 2019. I am satisfied that the benefits outweigh any costs.

Vaughan Gething AM  
**Minister for Health and Social Services**  
10 October 2019

## **1. Description**

1.1 The Human Medicines (Amendment) Regulations 2019 (“the amendment Regulations”) were made on 14 January and came into force on 9 February 2019. These amend the Regulations to provide for the sale or supply of prescription only medicines by a pharmacist under an SSP issued by the Secretary of State for Health and Social Services and the Ministers of Northern Ireland (medicines regulation being a devolved matter in Northern Ireland) and either of them acting alone or both of them acting jointly.

1.2 The amendment regulations give the Secretary of State for Health and Social Services and NI Ministers powers to issue SSPs where, in their opinion, the United Kingdom or part of the United Kingdom is experiencing, or may experience, a severe shortage of particular prescription only medicines. The SSPs will allow for substitution, by pharmacists and, only in restricted circumstances, of a different form, quantity, or strength of a prescription only medicine, or a different prescription only medicine, to that ordered by the prescriber.

1.3 The National Health Service (Amendments Relating to Serious Shortage Protocols) (Wales) Regulations 2019 will amend the terms of service for NHS pharmacists in Wales to facilitate compliance with SSPs issued under the Human Medicines Regulations 2012.

1.4 These regulations will also extend the definition and scope of a SSP to include a written protocol issued by Welsh Ministers, in circumstances where Wales, or any part of it is, in the opinion of the Welsh Ministers, experiencing or may experience a shortage of a specified drug (other than one which is a prescription only medicine) or appliance or a drug (other than one which is a prescription only medicine) or appliance of a specified description.

1.5 SSPs will improve the means by which the Welsh Government can manage critical shortages of medicines.

## **2. Matters of Special Interest to the Constitutional and Legislative Affairs Committee**

2.1 Not applicable.

## **3. Legislative Background**

3. Sections 80(2) and 83(6) of the National Health Service (Wales) Act 2006 (“the 2006 Act”) give the Welsh Ministers the power to make regulations for the purpose of arrangements for the provision (by Local Health Boards) of proper and sufficient drugs and medicines and listed appliances which are ordered for those persons by a medical (or dental) practitioner in pursuance of his functions in the health service, and to include provision relating to the conditions a Local Health Board may prescribe for providers of pharmaceutical services.

3.2 Schedule 4 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 sets out the terms of service for pharmacists and Schedule 5 sets out the terms of service for NHS appliance contractors.

3.3 This instrument will follow the negative resolution procedure. This means that it will be made and laid before the Assembly but will not be brought into force until at least 21 (calendar) days from the date of laying. In addition, there is a 40 (calendar) day period which also commences from the date of laying whereby a Member may table a motion seeking the annulment of the instrument. Unless an annulment motion is tabled, there shall be no debate of this instrument in Plenary.

#### **4. Purpose & Intended Effect of the Legislation**

4.1 These regulations amend the terms of service for NHS pharmacists in Wales to facilitate compliance with SSPs issued under the Human Medicines Regulations 2012.

4.2 These regulations also extend the definition and scope of a SSP to include a written protocol issued by Welsh Ministers, in circumstances where Wales, or any part of it is, in the opinion of the Welsh Ministers, experiencing or may experience a shortage of a specified drug or appliance or a drug or appliance of a specified description, where the specified drug or the drug of a specified description is not a prescription only medicine.

4.3 A SSP issued by Welsh Ministers under these regulations will provide alternative arrangements for the supply of health care products (drugs and appliances) that are not prescription only medicines, by an NHS pharmacist or an NHS appliance contractor providing pharmaceutical services within the NHS in Wales, where that health care product is ordered on a prescription form and there is, or may in the future be, a serious shortage of the product. A SSP will allow an NHS pharmacist or an NHS appliance contractor to supply a different product, or a different quantity of the product ordered to that ordered on the prescription form, in the circumstances and subject to the conditions set out in the SSP.

4.4 Schedules 4 and 5 of the 2013 Pharmaceutical Services Regulations, which contain the terms of service for NHS pharmacists and NHS appliance contractors in Wales are amended to make the following provision in respect of SSPs:

- Consideration must be given to supplying in accordance with a SSP rather than fulfilling an NHS prescription for that product, where a SSP is in place.
- Where an NHS pharmacist or NHS appliance contractor does supply in accordance with the SSP, the original NHS prescription must be endorsed accordingly, and a notification that the supply is in accordance with the SSP must be included in the dispensing label on the packaging of the product supplied or, in the case of a supply by a NHS appliance contractor, in a separate note for the patient. The original NHS prescription can no longer be fulfilled, and the original prescription form, in its endorsed form, is repurposed as the record of the SSP supply for payment purposes.
- If a product supplied by (or under the supervision of) an NHS pharmacist in accordance with a SSP is a prescription only medicine that is different to but has a similar therapeutic effect to the product originally ordered, the NHS pharmacist must notify the patient's NHS GP practice of the substitution (if the patient has one). An NHS pharmacist or NHS appliance contractor must also notify a patient's NHS GP practice in other cases of a supply in accordance with a SSP, if a requirement to notify has been issued.
- If an NHS pharmacist or NHS appliance contractor does not think it reasonable or appropriate to supply in accordance with a SSP, but is unable to fulfil the original prescription

with reasonable promptness, they will not breach the NHS terms of service if the original prescription is nevertheless fulfilled within a reasonable timescale.

- Where an NHS pharmacist or NHS appliance contractor does not think it reasonable or appropriate to supply in accordance with a SSP but cannot fulfil the original prescription within a reasonable timescale, they may refuse to dispense the product in question. If they do refuse to do so, they must provide the patient or the patient's representative with appropriate advice, as necessary, about reverting to the prescriber for the prescriber to review the patient's treatment.

## **5. Consultation**

5.1 Officials have discussed these proposals with Community Pharmacy Wales, which represents community pharmacy contractors in Wales.

## **PART 2 – REGULATORY IMPACT ASSESSMENT**

### **Regulatory Impact Assessment relating to the National Health Service (Amendments Relating to Serious Shortage Protocols) (Wales) Regulations 2019**

#### **INTRODUCTION**

1. This Regulatory Impact Assessment (RIA) has been developed to consider the implications of introducing Regulations under Sections 80(2) and 83(6) of the National Health Service (Wales) Act 2006 (“the 2006 Act”). The National Health Service (Amendments Relating to Serious Shortage Protocols) (Wales) Regulations 2019 (“the regulations”) amend the terms of service for NHS pharmacists in Wales to facilitate compliance with Serious Shortage Protocols issued under the Human Medicines Regulations 2012, relating to prescription only medicines (POMs). Where a Serious Shortage Protocol (SSP) is not in place, it is a criminal offence to supply a POM other than as ordered by the prescriber.

2. The regulations also extend the definition and scope of a SSP to include a written protocol issued by Welsh Ministers, in circumstances where Wales, or any part of it is, in the opinion of the Welsh Ministers, experiencing or may experience a shortage of a specified drug or appliance or a drug or appliance of a specified description (non-prescription only medicines), and make further provision in relation to SSPs within the terms of service of NHS pharmacists and NHS appliance contractors.

3. A SSP issued by Welsh Ministers under the regulations will provide alternative arrangements for the supply of health care products (drugs and appliances) that are not prescription only medicines, by an NHS pharmacist or an NHS appliance contractor providing pharmaceutical services within the NHS in Wales, where that health care product is ordered on a prescription form and there is, or may in the future be, a serious shortage of the product. A SSP will allow an NHS pharmacist or an NHS appliance contractor to supply a different product, or a different quantity of the product ordered to that ordered on the prescription form, in the circumstances and subject to the conditions set out in the protocol.

4. There has been no consultation with stakeholders because these are technical changes to the NHS (Pharmaceutical Services) (Wales) Regulations 2013 (“the 2013 Regulations”).

#### **CURRENT POSITION**

5. The current terms of service for NHS pharmacists, contained within the 2013 Pharmaceutical Regulations, require NHS pharmacists to provide the drugs so ordered on a prescription form. This means that whilst the Human Medicines Regulations 2012 provide for a

pharmacist to deviate from a prescription where a Serious Shortage Protocol is in place, doing so will result in a pharmacist being in breach of their terms of service.

There is currently no provision for Welsh Ministers to issue SSPs for non-POMs in Wales.

6. Furthermore, there are no procedures in place with regard to compliance with SSPs, for example, regarding the provision of information to patients and/or primary care providers in relation to the dispensing of medicine(s) pursuant to a SSP.

## **PURPOSE AND EFFECTS OF THE DRAFT REGULATIONS**

7. Normally if a pharmacist or a dispensing appliance contractor (DAC) is unable to dispense what is on a NHS prescription, they will either send the patient back to the prescriber or, if there is an urgent need, contact the prescriber, discuss an alternative medicine and then get the prescription changed by the prescriber.

8. The Department of Health and Social Care (DHSC) manages the UK medicines supply chain and has well established governance processes for managing shortages in collaboration with manufacturers, wholesale suppliers, clinicians, the NHS and the Medicines and Healthcare Products Regulatory Agency (MHRA).

9. The changes introduced by the regulations will facilitate compliance with Serious Shortage Protocols and provide a useful tool in managing medicines shortages that affect the UK. They will allow for substitution, by pharmacists, of a different form, quantity, or strength of a prescription only medicine, or a different prescription only medicine (POM), to that ordered by the prescriber, in the circumstances and subject to the conditions specified within the SSP.

10. A protocol would only be introduced in the exceptional case of a serious shortage, if it would help manage the supply situation after discussion with the manufacturer and/or marketing authorisation holder. The power to issue SSPs is a reserve power that would only be used in exceptional circumstances.

11. Given non-prescription only medicines (non-POMs) are also liable to shortages and the increased risk associated with EU exit, it is considered reasonable to extend the provision to non-POMs in Wales to NHS pharmacists and dispensing appliance contractors. The changes introduced by the regulations will widen the cover to non-POMs prescribed on a prescription form and dispensed by pharmacists or NHS appliance contractors, i.e. pharmacy medicines, medicines on general sale, other products treated as “drugs” on NHS prescriptions (such as medical foods) and appliances. As with SSPs for POMs, for these non – POM protocols there must be a serious shortage, and the protocol will need to be approved by Ministers in the same way as for an SSP for a POM – and go through a process of clinical design and approval.

12. The Regulations seek to improve the means by which the Welsh Government can manage critical shortages of medicines.

## **COST AND BENEFITS CONSIDERATIONS**

### **Options**

13. This RIA considers two options:

- **Option One** – Do nothing
- (i) **Option Two (the preferred option)** – Use the powers within sections 80(2) and 83(6) the 2006 Act (Section 83 (2)) to make regulations to introduce a power for Welsh Ministers to issue Serious Shortage Protocols (SSPs), which will provide alternative arrangements for the supply of health care products (drugs and appliances) that are not prescription only medicines, by an NHS pharmacist or an NHS appliance contractor providing pharmaceutical services within the NHS in Wales, where that health care product is ordered on a prescription form and there is, or may in the future be, a serious shortage of the product. A SSP would allow an NHS pharmacist or an NHS appliance contractor to supply a different product, or a different quantity of the product ordered, in the circumstances and subject to the conditions set out in the SSP, without having to revert back to the prescriber; and
- (ii) Make consequential changes to the terms of service for NHS pharmacists and NHS appliance contractors, to make provision for SSPs, and to facilitate compliance by pharmacists with SSPs for prescription only medicines, which may be issued by the Secretary of State and/or the Minister for Health, Social Services and Public Safety in Northern Ireland, under the Human Medicines Regulations 2012.

### **Option One – Do Nothing**

#### **Description**

14. There would be no change to the current legislation under this option. This would mean that NHS pharmacists would be in breach of their terms of service should they dispense medicines pursuant to a SSP. As a consequence the governments' ability to manage medicines shortages would not be improved nor would a patients access to alternative medicines to those in critical shortage.

#### **Costs**

15. As this option proposes no change, there would be no additional costs to the Welsh Government, to NHS Wales or dispensing practitioners as a result of doing nothing.

#### **Benefits**

16. There are no additional benefits from this option.

#### **Conclusion**

17. The option to do nothing is not considered sufficient or appropriate as it does not improve the ability of government and health board's to manage a medicine shortage. If not adopted, and pharmacists were to dispense under the terms of a SSP then they would be in breach of their terms of service.

## **Option Two – Use the powers within the 2006 Act (Sections 80 (2) and 83(6)) to introduce regulations to prescribe changes to the Terms of Service for pharmacists and dispensing appliance contractors**

### **Description**

18. This option will facilitate compliance with Serious Shortage Protocols for prescription only medicines by pharmacists and put in place provisions which will allow Welsh Ministers to issue Serious Shortage protocols to put in place alternative supply arrangements in Wales for non-prescription only medicines dispensed by NHS pharmacists and appliance contractors. As a consequence the governments' ability to manage medicines shortages would be improved as would a patient's access to alternative medicines to those in critical shortage.

### **Costs**

#### **Welsh Government**

19. The costs to the Welsh Government to announce the coming into force of the changes is negligible. Contractors will be made aware of the changes by a Welsh Health Circular – Chief Pharmaceutical Officer letter. Drafting this letter will cost: Officials wage rate Band 2 £98.00 / day @ 2day = £196.00

20. There are no costs attributed to Welsh Government in regard of developing or issuing a SSP; these costs being born by DHSC at the UK level.

#### **Health boards**

21. There may be a variation in costs to health boards prescribing budgets, dependant on the detailed action of a SSP; however it is expected these costs will be negligible and managed by health boards within their existing prescribing budgets.

#### **Dispensing Practitioners**

22. Any cost to dispensing contractors in terms of time of having to consider a change to the quantity, strength or form (e.g. tablets rather than capsules) will be offset against the time otherwise having been spent in sourcing an alternative medicine to that prescribed and having to make arrangements for a new prescription form to be written. Costs are therefore considered to be neutral.

## **BENEFITS**

23. The introduction of the change to the Terms of Service for dispensing contractors and, as a consequence, the ability to utilise a SSP in Wales will improve the Welsh Government's and health boards' ability to support the management of medicines shortages in the UK. Depending on the severity of specific medicines shortages and available mitigating action making use of a SSP will improve a patient's access to medicines where the supply is disrupted.



## **SUMMARY AND PREFERRED OPTION**

24. **Option One** is not considered sufficient or appropriate and would mean that NHS pharmacists would be in breach of their terms of service should they dispense medicines pursuant to a SSP. This option does not contribute to improved management of medicines shortages.

25. **Option Two** is the preferred option and through the introduction of the National Health Service (Amendments Relating to Serious Shortage Protocols) (Wales) Regulations 2019 it would contribute to improved management of medicines shortages.