

## **Explanatory Memorandum to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) (Amendment) (EU Exit) Regulations 2020**

This Explanatory Memorandum has been prepared by Health and Social Services Group and is laid before Senedd Cymru in conjunction with the above subordinate legislation and 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 (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) (Amendment) (EU Exit) Regulations 2020.

I have made the statements required by the European Union (Withdrawal) Act 2018. The statements can be found in Part 2 of the annex to this memorandum.

Vaughan Gething AS/MS

**Minister for Health and Social Services**

2 December 2020

## **PART 1**

### **1. Description**

These Regulations amend the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004 (SI 2004/1022 (W)119) (the Principal Regulations).

The Principal Regulations make provision as to the drugs, medicines or other substances that may be ordered for patients in the provision of medical services under a general medical services contract within the meaning of section 42 of the National Health Service (Wales) Act 2006.

These Regulations are being made in consequence of the UK's withdrawal from the European Union (EU). Amendments to the Principal Regulations are required to correct EU references to ensure the SI remains operable at the end of the transition period following the UK's exit from the EU.

### **2. Matters of special interest to the Legislation, Justice and Constitution Committee**

This instrument is being made using the powers conferred by paragraph 1(1) of Schedule 2 to the European Union (Withdrawal) Act 2018 ("the 2018 Act").

As set out in the Ministerial statement in Part 2 of this Explanatory Memorandum, it is proposed that this instrument be subject to negative resolution procedure. This instrument makes minor and technical amendments and therefore should be subject to annulment.

The instrument has been subject to scrutiny by the Legislation, Justice and Constitution Committee (LJCC). Sifting took place on 16 November 2020, whereby the LJCC agreed the appropriate procedure for the instrument is the negative resolution procedure. The report laid by the LJCC can be found at: <https://senedd.wales/laid%20documents/cr-ld13815/cr-ld13815-e.pdf>

### **3. Legislative background**

The Regulations are made in exercise of the powers in paragraph 1(1) of Schedule 2 and paragraph 21 of Schedule 7 to the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union.

### **4. Purpose and intended effect of the legislation**

The Regulations make amendments to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) Regulations 2004. In line with the Withdrawal Agreement, the amendments change references from "Exit Day" to "IP Completion Day" with regard to the right of specified patients from EU/EEA States and Switzerland, who were receiving

specified prescriptions for erectile dysfunction since 14th September 1998, to continue to receive those prescriptions post IP Completion Day.

## **5. Consultation**

As there is no policy change, no public consultation was undertaken. The purpose of the instrument is to enable the current legislative and policy approach to remain unchanged by the withdrawal of the UK from the EU.

As required by paragraph 4(a) of Schedule 2 to the European Union (Withdrawal) Act 2018, the Secretary of State has been consulted during the preparation of these Regulations. No comments or objections were received from the Secretary of State for Health.

No amendments to this Instrument were made as a consequence of the consultation.

## **6. Regulatory Impact Assessment**

The Welsh Ministers' Regulatory Impact Assessment Code for Subordinate Legislation ("the Code") was considered in relation to these Regulations.

The Regulations make minor technical amendments in line with the Withdrawal Agreement. The amendments have no, or no significant, impact on business, charities or voluntary bodies, and have no significant impact on the public sector.

They are of a technical nature to ensure an updated and functioning statute book and do not introduce new novel or contentious policy.

In accordance with Section 4.2 of the Code, it was therefore not considered necessary to carry out a regulatory impact assessment as to the likely costs and benefits of complying with these Regulations.

# Annex 1

## Statements under the European Union (Withdrawal) Act 2018

### Part 1

#### Table of Statements under the 2018 Act

This table sets out the statements that may be required of the Welsh Ministers under the 2018 Act. The table also sets out those statements that may be required of Ministers of the Crown under the 2018 Act, which the Welsh Ministers have committed to also provide when required. The required statements can be found in Part 2 of this annex.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(7) and 4(3), Schedule 7  <i>Paragraph 3(7) (anticipated to be a requirement on Welsh Ministers in Standing Orders)</i>	The Welsh Ministers exercising powers in Part 1 of Schedule 2 to make a Negative SI  Paragraph 3(7) applies to Ministers of the Crown, but Welsh Ministers have committed to make the same statement	A statement to explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation of the LJC Committee (as sifting committee)
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2. Welsh Ministers have committed to make the same statement when exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2. Welsh Ministers have	A statement to explain the good reasons for making the instrument and that what is being done is a reasonable course of action.

		committed to make the same statement when exercising powers in Schedule 2	
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2. Welsh Ministers have committed to make the same statement when exercising powers in Schedule 2	<p>A statement to explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them.</p> <p>A statement that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.</p>
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2. Welsh Ministers have committed to make the same statement when exercising powers in Schedule 2	A statement to explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g. whether minor or technical changes only are intended to the EU retained law.
Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2. Welsh Ministers have committed to make the same statement when exercising powers in Schedule 2	A statement setting out the 'good reasons' for creating a criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and paragraph 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority.	A statement to explain why it is appropriate to create such a sub-delegated power.

		Welsh Ministers have committed to make the same statement when exercising powers in Schedule 2 or paragraph 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority	
Urgency	Sub-paragraph (2) and (8) of paragraph 7, Schedule 7	Welsh Ministers exercising powers in Part 1 of Schedule 2 but using the urgent procedure in paragraph 7 of Schedule 7	A statement that the Welsh Ministers are of the opinion that it is necessary to make the SI using the urgent procedure and the reasons for that opinion.

## Part 2

### Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

#### 1. Sifting statement

The Minister for Health and Social Services, Vaughan Gething has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In my view the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) (Amendment) (EU Exit) Regulations 2020 should be subject to annulment in pursuance of a resolution of Senedd Cymru (i.e. the negative procedure)”. This is the case because the changes being made are minor and technical in nature. There is no change to policy.

#### 2. Appropriateness statement

The Minister for Health and Social Services, Vaughan Gething has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In my view the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) (Amendment) (EU Exit) Regulations 2020 does no more than is appropriate”. This is the case because the changes being made are solely in order to address inoperabilities arising from EU exit. There is no change to policy.

#### 3. Good reasons

The Minister for Health and Social Services, Vaughan Gething, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action”. These are that it ensure that the law is operable and clear following implementation completion day.

#### 4. Equalities

The Minister for Health and Social Services, Vaughan Gething has made the following statement(s) “The draft instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts”.

The Minister for Health and Social Services, Vaughan Gething has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In relation to the instrument, I, Vaughan Gething have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010.”

## **5. Explanations**

The explanations statement has been made in paragraph 4 (Purpose & intended effect of the legislation) of the main body of this explanatory memorandum.

## **6. Criminal offences**

Not applicable/required.

## **7. Legislative sub-delegation**

Not applicable/required.

## **8. Urgency**

Not applicable/required.