EXPLANATORY MEMORANDUM TO

THE EUROPEAN QUALIFICATIONS (PHARMACISTS) (AMENDMENT ETC.) (EU EXIT) REGULATIONS (NORTHERN IRELAND) 2018

2018 No. 585

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health (Northern Ireland) and is laid before Parliament by Act.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 The European Qualifications (Pharmacists) (Amendment etc.) (EU Exit) Regulations (Northern Ireland) 2018 amends the Pharmacy Order 1976 (the 1976 Order) and makes transitional and savings provisions, in reliance on the powers conferred by section 8(1) and paragraph 21 of schedule 7 of the European Union (Withdrawal) Act 2018.

2.2 These changes are being made to address deficiencies arising as a consequence of the United Kingdom's (UK) withdrawal from the European Union (EU).

Explanations

2.3 The European Union Directive 2005/36/EC on the recognition of profession qualifications ("the Directive") sets out a reciprocal framework of rules for the recognition of professional qualifications. This enables European Economic Area and Swiss nationals to have their professional qualifications recognised and gain access to the regulated profession in which they are qualified in another EEA State in order to work on a permanent or temporary basis.

2.4 There are two different systems for recognising qualifications:

- the automatic system – in healthcare this applies to doctors, dentists, general care nurses, midwives and pharmacists (the "sectoral professions"). These professions have harmonised training standards across the EEA. Qualifications listed in Annex V of the Directive meet these harmonised standards, and competent authorities of EU member states are obliged to recognise these qualifications on an automatic basis with no further checks on the competence of the holder of the qualification.
- the general system – qualifications not listed in Annex V, including those in non-sectoral professions, are covered by the general system. Applications from holders of such qualifications are considered on a case by case basis. In some cases, a member of a sectoral profession will have a qualification recognised under the general system where that qualification is not included in Annex V of the Directive.

Why is it being changed?

2.5 Following the UK's exit from the EU, the Directive and Treaty rights (Treaty on the Functioning of the European Union) will no longer apply to the UK. Therefore,

domestic legislation implementing the Directive, including the 1976 Order, will not operate effectively after exit day. Some areas of the legislation will be inoperable as a consequence of exiting the EU and it will no longer be appropriate to retain other areas given that they are based on a reciprocal relationship with the EU.

2.6 The Government wishes to retain some of the framework for the recognition of professional qualifications to enable EEA qualified professionals to continue to practise in the UK.

2.7 This instrument amends the 1976 Order to ensure that a system of recognition of professional qualifications continues and that individuals with EEA qualifications will have a means to seek recognition of their qualifications after exit day.

What will it do now?

2.8 The amended 1976 Order will provide alternative arrangements for the registration of pharmacists from EEA States who wish to register in Northern Ireland after exit day. The amendments will address issues of legal inoperability and protect citizens' rights.

2.9 Qualifications included in Annex V of the Directive will be acceptable unless the Pharmaceutical Society of Northern Ireland (PSNI) designate them not to be. PSNI will designate qualifications where they consider that the qualification is not equivalent to UK qualification standards. Such designation of a qualification will require the consent of the Department of Health NI. Holding an Annex V qualification will oblige the PSNI to recognise the qualification without further competency testing of the applicant.

2.10 A review of the continued recognition of Annex V qualifications will be conducted two years after these regulations come into force.

2.11 The amended 1976 Order will no longer include obligations on PSNI to abide by the Directive training standards when setting standards for UK qualifications, although the PSNI may use future Directives as a guide when setting standards in NI.

2.12 The amended 1976 Order will contain transitional and savings provisions which; protect recognition decisions already made, allow applications which have been made before exit day to be concluded under the same pre-exit legislation and allow individuals practising under temporary and occasional status or under the European Professional Card to continue to do so until such entitlement expires.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument is laid using the powers of the European Union (Withdrawal) Act 2018. They are being made using the affirmative process as provisions concerned with the power to charge fees are being amended in this instrument.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 In the view of the Department, for the purposes of Standing Order No. 83P of the Standing Orders of the House of Commons relating to Public Business, the subject-matter of this entire instrument would be within the devolved legislative competence of the Northern Ireland Assembly if equivalent provision in relation to Northern

Ireland were included in an Act of the Northern Ireland Assembly as a transferred matter.

3.3 The Department has reached this view because the instrument would be within the legislative competence of the Northern Ireland Assembly.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is Northern Ireland.

4.2 The territorial application of this instrument is Northern Ireland

4.3 The territorial application of this instrument is set out in Section 3 under "Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)".

5. European Convention on Human Rights

5.1 The Minister of State for Health at the Department of Health and Social Care, Stephen Hammond, has made the following statement regarding Human Rights:

"In my view the provisions of the European Qualifications (Pharmacists) (Amendment ETC.) (EU Exit) Regulations (Northern Ireland) 2018 are compatible with the Convention rights."

6. Legislative Context

6.1 The Directive facilitates the free movement of professionals across the EEA by establishing rules for the recognition of professional qualifications which enable EEA nationals to have their professional qualifications recognised in another EEA state. This allows professionals to practise in other EEA states on an established or temporary basis while simplifying administrative procedures and providing efficient safeguards to patient and public safety.

6.2 This instrument amends the 1976 Order to ensure the Regulations can operate effectively post exit and to correct deficiencies which have arisen as a consequence of the UK leaving the EU.

7. Policy background

What is being done and why?

7.1 When the UK exits the EU, the UK will no longer be a signatory to the Directive. This will cause inoperability in domestic legislation, including the 1976 Order, if amendments are not made. As a result, these Regulations must be amended to correct deficiencies and ensure a system is in place at the time of exit that is effective and proportionate.

7.2 As set out in para. 2.4 the Directive provides the framework for two systems for the recognition of professional qualifications, these are the automatic and general systems. These systems allow for EEA nationals to have their professional qualifications recognised for the purposes of established or temporary and occasional services with minimal barriers. It also facilitates the movement of some professions via the European Professional Card, which is an electronic certificate used in recognition procedures under both the automatic and general systems.

7.3 Parts of the Directive are implemented in NI by the 1976 Order. They implement; the automatic system, minimum length of basic training for pharmacists in Northern Ireland and the EPC.

What will change

Scope

7.4 The provisions of the 1976 Order apply to EEA nationals or any persons with a right to be treated as such. Under the current system eligibility is primarily based on an applicant's nationality rather than where a qualification was gained. Once the UK leaves the EU it will no longer be lawful to retain preferential treatment for EEA nationals and therefore eligibility will be based solely on whether an individual holds a relevant EEA qualification.

7.5 Third country qualifications held by EEA nationals will no longer be in scope of the amended 1976 Order.

The automatic system

7.6 The automatic system obliges the PSNI to recognise pharmacy qualifications listed in Annex V of the Directive. Applicants possessing a listed qualification will be able to access and pursue professional activities in the same manner as a national of the territory in which they apply.

7.7 The amended 1976 Order will retain arrangements for recognising pharmacist qualifications listed in Annex V at exit day by obliging the PSNI to recognise such qualifications as being sufficient for practising in the UK. The recognition of the qualification will no longer be dependent on certification from an EU competent authority. These recognition procedures will be handled by the PSNI and the qualifications listed in Annex V will be deemed acceptable overseas qualifications. The PSNI will be able to designate qualifications as no longer being acceptable with the approval of the Department of Health NI.

7.8 The continued recognition of Annex V qualifications will be subject to a review by the Secretary of State of Department and Health and Social Care two years after these Regulations come into force.

The general system

7.9 If an EEA qualification is not listed in Annex V then it falls within scope of the general system. The general system currently requires UK regulatory bodies to compare the level of qualification to the relevant UK qualification standards. In instances where a qualification is comparable, then the holder of the qualification must be registered and allowed access to the profession. UK regulatory bodies may offer compensatory measures to applicants in the form of adaption periods, aptitude tests, partial access or professional experience where a qualification is different to UK standards. If compensatory measures are not feasible a UK regulatory body can refuse to recognise the qualification. The current general system is implemented by the General System Regulations 2015.

7.10 The PSNI does not have a system for the recognition of international qualifications, apart from those listed in annex V of the Directive. Applications under the general system are considered by the General Pharmaceutical Council (GPhC), which regulates the pharmacy profession in England, Scotland and Wales. Registration with the GPhC allows a pharmacist to practise in Northern Ireland via an existing

Memorandum of Understanding (MoU) between the two regulatory bodies. Applications for recognition of qualifications under the general system will be considered by GPhC rather than PSNI.

European Professional Card

7.11 The European Professional Card (EPC) is an electronic certificate that facilitates recognition procedures for some professions. In the context of health and care professionals it currently applies to nurses, pharmacists, and physiotherapists. In a no deal exit the UK will lose access to the online "Internal Market Information" (IMI) system which facilitates the EPC, and will no longer be able to process EPC applications. This instrument therefore revokes provisions relating to EPC procedures.

7.12 Professionals who are currently in scope of the EPC will have their qualifications recognised through the routes set out above.

Provision of services on a temporary and occasional basis

7.13 The Directive sets out rules which facilitate the temporary and occasional provision of services. This allows EEA professionals to practise across the EEA without the need for full registration with the relevant regulator. Providing temporary and occasional service allows the professional to remain established in their home state while practising in another state. Regulators can require professionals to issue a declaration in advance of their temporary and occasional service. If an applicant is a sectoral profession then any temporary and occasional registration requirements must be automatic, and fees cannot be charged.

7.14 This instrument revokes the provisions for temporary and occasional service provision since they rely on reciprocal arrangements with the EEA designed to facilitate free movement of persons and services and allow a high level of market access with limited regulatory oversight, which is no longer appropriate once the UK leave the EU. Accordingly, there will no longer be an obligation on regulators to facilitate temporary and occasional registration.

IMI and Alert mechanism

7.15 The Internal Market Information system (IMI) is an online tool used by regulators to share information. IMI allows competent authorities to share details of applicants and qualifications. It also provides an Alert Mechanism which makes EEA regulators aware of a professionals' compromised fitness to practise or restrictions on their practise. The 1976 Order requires regulators to process applications and exchange information via IMI. The UK will no longer have access to the IMI when it leaves the EU. This instrument therefore revokes provisions which require UK regulatory bodies to use IMI as part of recognition procedures.

Transitional and Saving provisions

7.16 The instrument contains transitional and saving provisions which provide for; the protection of recognition decisions awarded prior to exit day; applications in progress at the time of exit to conclude, as far as possible, under the same rules that applied when they were started; the continued registration of professionals practising under EPC and temporary and occasional registration until such registration expires.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument is being made using the power in section 8 of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018 in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union. In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 This instrument does not make any consolidation of other documents.

10. Consultation outcome

10.1 Consultation between UK regulatory bodies, Devolved Administration officials and Government officials, supported by Government Legal Advisors, took the form of regular meetings and engagement specific to the amendments made by this instrument, beginning in August 2017. This has centred around technical discussions concerning the proposed amendments to the provisions of the Regulations and how proposed amendments could impact the provision of health and care services in devolved regions.

10.2 Policy responsibility for the regulation of the Pharmacy profession is fully devolved in Northern Ireland. Northern Ireland officials have agreed that they are content for Department of Health and Social Care to lay this instrument. This approach follows the decision by UK Government Ministers that, in the interest of securing legal certainty in Northern Ireland, the UK Government will take through the necessary secondary legislation at Westminster for Northern Ireland in close consultation with Northern Ireland Civil Service officials.

11. Guidance

11.1 In 2015, the Government published guidance for regulatory bodies of regulated professions. It set out general guidance on the obligations placed upon regulatory bodies by the Directive.

11.2 This guidance will be updated to reflect the changes that are made to the 1976 Order by this instrument.

12. Impact

12.1 There is no significant impact on business, charities or voluntary bodies. This instrument ensures that a system of recognition of professional qualifications continues and that individuals with EEA qualifications will have a means to seek recognition of their qualifications after exit day.

12.2 There is no, or no significant, impact on the public sector.

12.3 An Impact Assessment has not been prepared for this instrument because the equivalent annual net direct cost to business falls below the £5m threshold as detailed in the Business Impact Target.

12.4 No significant impacts on business, or no significant direct impacts, have been identified as a result of these legislative amendments, since they allow for the continued registration of EEA qualified pharmacy professionals in Northern Ireland.

12.5 Changes to the procedure for recognising qualifications could make access to the pharmacy profession more difficult. This would impact on the availability of pharmacy professionals, which would have an impact on public services. However, any such change is at the discretion of the regulator. There is an expectation that such a change would only be made if there was a perceived benefit to doing so.

13. Regulating small business

13.1 The legislation does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

14.1 As this instrument is made under the EU Withdrawal Act 2018, no review clause is required.

15. Contact

15.1 Mark Bennett at the Department of Health and Social Care Telephone: 01132546501or email: Mark.Bennett@dhsc.gov.uk can be contacted with any queries regarding the instrument.

15.2 Claire Armstrong, Deputy Director for Professional Regulation, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Stephen Hammond at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

Annex

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 under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly 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	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	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	Ministers of the Crown exercising sections 8(1), 9, and	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising sections 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

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

1. Appropriateness statement

1.1 The Minister of State for Health at the Department of Health and Social Care, Stephen Hammond has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the European Qualifications (Pharmacists) (Amendment etc.) (EU Exit) Regulations (Northern Ireland) 2018 does no more than is appropriate".

1.2 This is the case because the instrument only makes changes required to correct the deficiencies arising from the United Kingdom's withdrawal from the European Union without an agreement.

2. Good reasons

2.1 The Minister of State for Health at the Department of Health and Social Care, Stephen Hammond 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".

2.2 The instrument makes amendments to United Kingdom's domestic legislation which establishes the framework for the recognition of professional qualifications. These amendments correct deficiencies arising the United Kingdom's withdrawal from the European Union without a withdrawal agreement and ensures an operable system for recognition at exit.

3. Equalities

3.1 The Minister of State for Health at the Department of Health and Social Care, Stephen Hammond has made the following statement(s):

"The European Qualifications (Pharmacists) (Amendment etc.) (EU Exit) Regulations (Northern Ireland) 2018 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.

3.2 The Minister of State for Health at the Department of Health and Social Care, Stephen Hammond has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the European Qualifications (Pharmacists) (Amendment etc.) (EU Exit) Regulations (Northern Ireland) 2018 instrument, I, Stephen Hammond, 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."

4. Explanations

4.1 The explanations statement has been made in section 2 of the main body of this explanatory memorandum.