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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations are made in exercise of the powers in the European Union (Withdrawal) Act 2018 (c.16) in order to address failures of domestic legislation to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union.

These Regulations amend legislation concerned with the regulation of pharmacy professionals in Northern Ireland.

They amend the Health and Personal Social Services (Northern Ireland) Order 1972 (S.I. 1972/1265), the Pharmacy (Northern Ireland) Order 1976 (S.R. 1976/1213 (N.I. 22)), the Pharmaceutical Services Regulations (Northern Ireland) 1997 (S.R. 1997/381) and the Council of Pharmaceutical Society of Northern Ireland (Continuing Professional Development) Regulations 2012/312. They revoke the European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192) and the Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (Northern Ireland) 2008 (S.R. 2008/193).

Regulation 3 requires the Secretary of State to perform a review of provisions dealing with recognition of European Union qualifications within the Regulations. The Secretary of State is also required to produce and publish the conclusions of the review.

Part 1 of the Schedule removes rights and obligations under Directive 2005/36/EC (“the Directive”). The Directive is concerned with the recognition of professional qualifications across the European Union, including the recognition of pharmacists.

Part 1 of the Schedule removes provisions currently dealing with registration of and registers for “visiting” practitioners from relevant European States. “Visiting” practitioners provide services on a temporary and occasional basis, rather than becoming established in their profession in the UK. Part 3 of the Schedule saves certain provisions relating to “visiting” practitioners so that those who are entitled and have provided all documentation required to acquire that entitlement, before exit day, or have a pending application as at exit day, are dealt with under the current legislation. The savings provisions do not permit renewals of registrations under the “visiting” system.

Part 1 of the Schedule omits the definitions for and removes references to “exempt person” and “General Systems Regulations”. An “exempt person” is a person with certain rights under European Union legislation. These rights will no longer be available in the UK after exit day. The “General Systems Regulations” currently provide a domestic legislative basis for recognition of certain European qualifications. They also provide for regulators to require individuals to undertake compensatory measures and/or adaption periods where European qualifications fall short of the standards required by the Pharmaceutical Society of Northern Ireland (“the PSNI”). After exit day PSNI will not refer to the amended “General Systems Regulations” for new registrations.

Part 1 of the Schedule provides that qualifications and diplomas issued by relevant European States and currently recognised as giving automatic recognition in other relevant European States, will be qualifications enabling registration as a pharmaceutical chemist, unless a particular qualification or diploma has been designated by the registrar. Amendments provide that such designation will be subject to approval by the Department.

Part 1 of the Schedule removes or amends provisions giving those with rights under European legislation special treatment in relation to fees for registration, indemnity provisions and language testing requirements.

*Status: This is the original version (as it was originally made).*

Part 1 of the Schedule omits references to “Directive 2002/58/EC” Directive 2002/58/EC is concerned with privacy and electronic communications. In the same part of these Schedules references to “the Directive” have been omitted or amended where required. The UK will no longer be subject to obligations imposed by Directives after exit day.

Part 1 of the Schedule also removes or amends (where required) references to “competent authority”. A competent authority is an authority or body within a relevant European State that has obligations or rights under the Directive to receive or issue evidence and information connected to qualifications, and to receive applications and take decisions under the Directive. In NI the Pharmaceutical Society for Northern Ireland holds this status. Competent authorities in the UK will no longer have rights and obligations under “the Directive” after exit day.

Part 1 of the Schedule removes references to the “European professional card” or “EPC”; “IMI”, and “IMI file”. The EPC is a system of professional qualification validation operated by the European Commission. The IMI is the Internal Market Information system and is the digital system used to process and communicate EPC information and other information about health and social care professionals (e.g. fitness to practice decisions), and an IMI file is a file held on that system. The UK will no longer have access to IMI after exit day, so it will no longer be able to offer or recognise new EPCs or pass on or accept other information via the IMI system.

Part 1 of the Schedule removes references to “national”. Post-exit eligibility for registration will depend on where the qualification is from as opposed to the nationality of the professional.

Part 2 amends and revokes legislation concerned with the regulation of pharmacy professionals in Northern Ireland.

Part 3 of the Schedule saves pending applications in relation to registration made before exit day. Various savings are also made to provide that pre-exit day legislation continues to apply so far as is practically possible after exit day for those who were registered before exit day, or whose applications were pending on exit day.

Part 3 of the Schedule deals with transitional and saving provisions to allow for continued appeals against EPC decisions. The provisions allow individuals to appeal, after exit day against EPC decisions made before exit day and that are within pre-exit day appeal periods, to the PSNI against the effect of the EPC decisions. The PSNI is also obliged to give effect to the decision as far as practically possible without access to IMI. Part 3 of the Schedule does not preserve EPC appeal rights as this is dealt within the Part 1 provisions of the Schedule.

Part 3 of the Schedule contains provisions to allow appeals against “IMI alerts”. An IMI alert is an alert issued through the IMI system about the fitness to practice of a health or social care professional, to relevant European States. Although the United Kingdom’s access to IMI will cease after exit day the regulator will be obliged to notify the European Commission by other means of the outcome of the appeal. Any individual who has an alert issued against them that is still within pre-exit day appeal periods after exit day will be permitted to appeal to the relevant Registering body in the UK against the effect of the alert.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.