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## EXPLANATORY NOTE

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

This Order makes provision for the establishment of the General Pharmaceutical Council (“the Council”) and sets out the arrangements for the regulation by the Council of the professions of pharmacist and pharmacy technician in Great Britain. It also amends and supplements various provisions in Part 4 of the Medicines Act 1968 (c.67), and in section 9 of the Poisons Act 1972 (c.66) in respect of the regulation and inspection of registered pharmacies in Great Britain. The regulation of the professions of pharmacist and pharmacy technician and the regulation and inspection of registered pharmacies was, prior to the commencement of this Order, undertaken by the Royal Pharmaceutical Society of Great Britain (“the Society”) in pursuance of arrangements set out in the Pharmacists and Pharmacy Technicians Order 2007 (“the 2007 Order”) (as amended), which is now revoked.

This Order implements in part Council Directive 2005/36/EC(1) (“the Directive”) on the recognition of professional qualifications. It replaces the necessary legislative framework for the implementation, in Great Britain, of the Directive which was previously set out in the 2007 Order.

Part 1 contains preliminary matters. These include commencement arrangements and the interpretation provisions (articles 1 and 3). This Order extends to Great Britain. Where other legislation is amended, the amendments have the same territorial extent as the provisions being amended (article 2).

Part 2 (articles 4 and 6) and Schedule 1 make provision for the establishment of the Council and of its statutory committees. The Council is to be constituted as provided for by an order of the Privy Council under article 4 and is required to make provision, in rules, in respect of the size, composition and procedures of each of its statutory committees. Part 2 also sets out the Council’s principal functions and general duties which are linked to the safe and effective practice of pharmacy. These include the Council’s main purpose which is to protect, promote and maintain the health, safety and well-being of the public when exercising functions that affect the public. It is also under a duty to prescribe requirements as to the evidence of health and good character that are to be met in order to satisfy the Council that a person is capable of the safe and effective practice of pharmacy (article 4). The Council is also under a duty to have proper regard to specified interests and in respect of co-operation with specified bodies (article 6).

Part 3 contains rule making powers for the purpose of implementing the Council’s function of establishing and promoting standards for the safe and effective practice of pharmacy at registered pharmacies. These standards are intended to supplement existing provision in Part 4 of the Medicines Act 1968 (Part 3 of the Medicines Act 1968 (section 66) also makes provision in respect of the standards to be met by registered pharmacies). Part 3 also makes provision for the inspection of registered pharmacies by inspectors appointed by the Council (under article 8) for the purpose of enforcing compliance by persons carrying on a retail pharmacy business at a registered pharmacy with such standards as are set in rules by the Council (under article 7). The inspectors are given various powers to enter, search and remove items from premises (articles 10 and 11) and any person who intentionally obstructs an inspector exercising these functions commits an offence (article 12). Provision is also made for the service of improvement notices on a person carrying on a retail pharmacy business at a registered pharmacy (article 13), in respect of a failure to comply with

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(1) OJNo. L 255, 30.09.2005, p.22, as amended by Council Directive 2006/100/EC of 20 November 2006, OJ No. L 363 of 20.12.2006, p.141.

standards, for non compliance with the terms of an improvement notice to be an offence (article 14), and for a right of appeal to the Court of Appeal against an improvement notice (articles 16 and 17).

Part 4 contains provisions for the registration of pharmacists and pharmacy technicians in Great Britain. It also contains supplementary provision in respect of the registration of registered pharmacies in Great Britain to that which is contained in Part 4 of the Medicines Act 1968. Part 4 of this Order provides for the appointment of a Registrar (article 18) who is to establish and maintain a register of pharmacists, pharmacy technicians and premises at which the business of a retail pharmacy is lawfully conducted (“the Register”) and to perform the functions of Registrar conferred by this Order (article 19) and by any other enactment (pharmacists and pharmacy technicians who have been entered in the Register by the Registrar are defined in the Order as “registrants”). There are provisions in Part 4 relating to entitlement to entry in the Register, the procedure for dealing with applications for entry and for the renewal of an entry in the Register and for annotating the Register to denote specialisations. Provision is also made in Part 4 for the notification of decisions and the time limits within which certain applications need to be processed, for the form and keeping of the Register and for public access to certain information contained in lists derived from the Register. Prospective registrants must be appropriately qualified, fit to practise and, where appropriate, have met additional requirements as to education, training, experience and continuing professional development (article 20). There is also provision in Part 4 for the recognition of qualifications and of additional education, training and experience (articles 21 and 22). All registrants are also required to have in place adequate and appropriate professional indemnity arrangements (article 32). In addition to provision for the Registrar to enter in the Register visiting pharmacists and pharmacy technicians from relevant European States (article 33 and Schedule 2). Part 4 contains provision for the Registrar to temporarily enter in the Register a pharmacist or pharmacy technician, or a group of pharmacists or pharmacy technicians, when advised by the Secretary of State of the existence of emergency circumstances involving loss of life or human illness etc (article 34). Part 4 also contains offences relating to entries in the Register and the unlawful use of notices or certificates of registration and also restricts the use of the professional title “pharmacist” and “pharmacy technician” to registrants (article 38). There are provisions in respect of appealable decisions (articles 39 and 40) including provision for appealing from the Appeals Committee against such decisions to a court of law (article 41).

Part 5 makes provision in respect of the education, training and continuing professional development of registrants and prospective registrants. The Council is under a duty to publish and promote the standards of proficiency that it must set for the safe and effective practice of pharmacy which it is necessary for a person to achieve in order to be entered in the Register. The Council is also under a duty to establish and promote the standards of pre-registration education and training necessary to achieve those standards of proficiency. In this regard, the Council has a number of specific obligations relating to pre-registration education and training of prospective registrants. Part 5 includes other provision relating to the pre-registration education and training of prospective registrants including the approval of qualifications, courses and providers of education and training (including institutions and tutors). Similar provision is made in respect of the Council’s duty to establish and promote the standards of proficiency that it is necessary for registrants to maintain in order to be retained in the Register (article 42). The Council is under a duty to establish and promote the standards of continuing professional development necessary for a registrant to achieve and maintain those standards of proficiency, to adopt a framework setting out the requirements and conditions in respect of a registrant’s continuing professional development and to make rules in respect of persons who fail to comply with the requirements or conditions of the framework (article 43).

Part 6 makes provision relating to the fitness to practise of registrants. The Council is to establish the professional standards expected of registrants (article 48) and the Council has powers to obtain information from third parties about a particular registrant (article 49). The Council may also publish any information about the fitness to practise of registrants where it is in the public interest to do so (article 50). Provision is included in Part 6 about what it means for fitness to practise to be impaired

(article 51) and a framework is set out within which allegations of impairment are to be considered. Usually, cases will firstly be considered by the Registrar who will then refer them to the Investigating Committee. The Investigating Committee has power to deal with the case by way of issuing warnings or giving advice. In addition, the Fitness to Practise Committee may suspend registrants or attach conditions to their entry in the Register and may also direct that the registrant be removed from the Register (article 54). Provision also exists in Part 6 for the review of earlier decisions to suspend a registrant or to impose conditions on a registrant's entry in the Register. The Council may also establish a scheme of professional performance assessments to assist the Registrar, the Investigating Committee and the Fitness to Practise Committee (article 55). Provision is also made for interim orders suspending a registrant's entry in the Register or attaching temporary conditions to an entry in the Register while an investigation is ongoing (article 56). If a registrant has been removed from the Register for fitness to practise reasons, there are arrangements for allowing that registrant to be restored to the Register in defined circumstances (article 57). Provision is also made for appeals to the courts against appealable fitness to practise decisions (article 58) and in respect of when fitness to practise decisions are to take effect – including provision for temporary measures pending the outcome of an appeal, if a decision is being appealed (articles 59 and 60).

Part 7 contains provisions relating to proceedings before the Investigating Committee, the Fitness to Practise Committee or the Appeals Committee. Essentially, these matters are to be provided for in rules. However, there are particular provisions relating to the use of legal, clinical and other specialist advisers. There are also provisions for dealing with witness summonses and orders for the production of documents which may be enforced through the courts (articles 61 to 64).

Part 8 makes miscellaneous provision which includes giving the Council a general power to charge fees which must not be used in relation to areas where there are specific charging arrangements under the Order (article 65). Provision is also made about the making of rules by the Council under this Order (article 66), the designation of the Council as the competent authority in Great Britain for the purposes of certain provisions of the Directive (article 67), for the amendments, repeals, revocations and transitional provisions and savings that are set out in Schedules 4, 5 and 6 (articles 68 and 69) and for the Privy Council procedures which are to apply in respect of the making of rules under this Order (article 70).

Consequential amendments, revocations and repeals (including the revocation of the 2007 Order) are made in respect of other legislation (Schedule 4) which are mostly minor in nature and are required to reflect the establishment of the Council and the creation of the Register. However, significant amendments have been made to sections 71 to 80 of Part 4 of the Medicines Act 1968 in order to reflect the new criteria and procedures for registration which are to apply in respect of premises at which a retail pharmacy business is conducted. In addition, twelve new sections have been inserted into the Part 4 of that Act (new sections 74A to L) which provide for the registration of premises in Great Britain and make supplemental provision in respect of that registration. These new provisions also enable the voluntary removal of registered pharmacies from the Register, the temporary registration of pharmacies in emergency circumstances and for temporary annotations to the Register to be made in respect of registered pharmacies entered in the Register under the new emergency registration provision. Significant amendments have also been made to section 9 of the Poisons Act 1972 the effect of which are to remove the function of inspecting registered pharmacies, previously undertaken by the Society, from that legislation and to confer that function on the Council.

Schedule 5 makes provision relating to the transition from the Society to the Council. In particular, it ensures that there is continuity of membership of the committees (paragraph 2), that outstanding applications for registration in the registers held by the Society are dealt with by the Council, that entries in the old registers are transferred over to the new Register established and maintained by the Council under this Order (paragraphs 3 and 4). Provision is also made for appeals in respect of appealable registration decisions that are pending before the Society immediately before the establishment of the Council to be dealt with by the Council (paragraph 5) and for appeals in respect of appealable registration decisions in relation to which the time limit for bringing an appeal has not

expired before the establishment of the Council to be dealt with by the Council (paragraph 6). In addition, it allows pharmacy technicians, in certain cases, to be registered up to July 2011 even if they are not appropriately qualified (paragraph 7) and to be exempt from committing certain offences (paragraph 8). It preserves the validity of education, training and experience being undertaken at the point of change (paragraph 9). It provides for certain provisions of the Medicines Act 1968 as amended by Schedule 4 to this Order to have effect in relation to premises entered in the Register pursuant to paragraph 3(4) of Schedule 5 (paragraph 10). It allows outstanding fees to be collected by the Council (paragraph 11), for the Council to deal with outstanding fitness to practise proceedings or proceedings in respect of premises in accordance with the rules previously applying or in such other manner as it thinks fit (paragraphs 12 to 14, and requires the Society to supply necessary information to the Council (paragraph 15). It treats the transfer from the Society to the Council as a relevant transfer for the purpose of the Transfer of Undertakings (Protection of Employment) Regulations 2006 ([S.I.2006/246](#)) (paragraph 16) and allows for an order to be made in respect of the transfer of property, rights and liabilities from the Society to the Council (paragraph 17) and any necessary grants or loans necessary as a result of the transfer (paragraph 18). Finally, further transitional measures are made in respect of the cancellation of elections to the Council of the Society and the appointment of members of the Council of the Society as members of the Council (paragraph 19).

Schedule 6 makes savings to preserve the effect of amendments that were made to certain provisions of primary and secondary legislation by the 2007 Order which is now revoked.