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## EXPLANATORY NOTE

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

This Order sets out the arrangements for the professional regulation of pharmacists in Great Britain and pharmacy technicians in England and Wales. The arrangements for pharmacists replace those set out in the Pharmacy Act 1954, which is repealed.

This Order contains the necessary legislative framework for the implementation, in Great Britain, of Council Directive [85/432/EEC](#) concerning the co-ordination of provisions laid down by law, regulation or administrative action in respect of certain activities in the field of pharmacy<sup>(1)</sup>, as amended<sup>(2)</sup>, and Council Directive [85/433/EEC](#) concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy<sup>(3)</sup>, as amended<sup>(4)</sup>. The implementing measures in respect of these directives were previously set out in the Pharmacy Act 1954. It also contains measures relating to the implementation in England and Wales, as regards pharmacy technicians, of Council Directive [92/51/EEC](#) on a second general system for the recognition of professional education and training<sup>(5)</sup>, as amended<sup>(6)</sup>.

Part 1 contains preliminary matters. These include the commencement arrangements and the interpretation provisions (articles 1 and 3). Parts 1, 2 and 7 of the Order extend to Great Britain, but Part 3, which relates to the registration of pharmacy technicians, only extends to England and Wales – and Parts 4 to 6, in so far as they relate to registered pharmacy technicians or applicants for restoration to their register, also only extend to England and Wales. In addition, where other legislation is amended, the amendments have the same territorial extent as the provisions being amended (article 2).

Article 4 contains general duties of the Royal Pharmaceutical Society of Great Britain (“the Society”). These include the main purpose of the Society, when exercising functions that affect the health and safety of the public, which is to protect, promote and maintain the health and safety of the public. There are also duties to have proper regard to specified interests, and in respect of co-operation with specified bodies (article 4).

There are new powers in respect of the composition, membership and functions of the Council of the Society (“the Council”), and the Council is given various duties in respect of publications, including publication of annual accounts and an annual report (articles 5 and 6).

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(1) OJNo. L 253, 24.9.1985, p.34.

(2) Council Directive [85/432/EEC](#) has been amended by Directive [2001/19/EC](#) (OJ No. L 206, 31.7.2001, p.1) and is repealed by Directive [2005/36/EC](#) (OJ No. L 255, 30.9.2005, p.22).

(3) OJ No. L 253, 24.9.1985, p.37.

(4) Council Directive [85/433/EEC](#) has been amended by: Council Directive [85/584/EEC](#) (OJ No. L 372, 31.12.1985, p.42); Council Directive [90/658/EEC](#) (OJ No. L 353, 17.12.1990, p.73); the Act of Accession of Austria, Sweden and Finland (OJ No. L 1, 1.1.1995, p.1); Directive [2001/19/EC](#) (OJ No. L 206, 31.7.2001, p.1); and the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded (OJ No. L 236, 23.9.2003, p.33). Directive [85/433/EEC](#) is also repealed by Directive [2005/36/EC](#).

(5) OJ No. L 209, 24.7.1992, p.25.

(6) Council Directive [92/51/EEC](#) has been amended by: Commission Directive [94/38/EC](#) (OJ No. L 217, 23.8.1994, p.8); the Act of Accession of Austria, Sweden and Finland (OJ No. L 1, 1.1.1995, p.1); Commission Directive [95/43/EC](#) (OJ No. L 184, 3.8.1995); Commission Directive [97/38/EC](#) (OJ No. L 184, 12.7.1997, p.31); Commission Directive [2000/5/EC](#) (OJ No. L 54, 26.2.2000, p.42); Directive [2001/19/EC](#) (OJ No. L 206, 31.7.2001, p.1); the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded (OJ No. L 236, 23.9.2003, p.33); Regulation (EC) No. [1882/2003](#) (OJ No. L 284, 31.10.2003, p.1); and Commission Decision [2004/108/EC](#) (OJ No. L 32, 5.2.2004, p.15). Directive [92/51/EEC](#) is also repealed by Directive [2005/36/EC](#).

The Society is to have six statutory committees, and provision is made for the Council to make rules in connection with such matters as their size, composition, membership, procedures and functions (article 7). There is also provision for the Council to determine remuneration and allowances for its own members, members of the statutory committees, and for specialist advisers (article 8). The Council of the Society is to keep appointed a Registrar and may also appoint a Deputy Registrar (article 9).

Part 2 contains provisions relating to registration of pharmacists in Great Britain. The Registrar is to continue to maintain the Society's existing register of pharmacists, which is to be divided into two parts: a practising part and a non-practising part (article 10). There are provisions relating to entitlement to registration: registrants must be appropriately qualified, be fit to practise, and where appropriate have met additional requirements as to education, training, experience and continuing professional development (article 11). There is also provision in respect of the recognition of qualifications and of additional education, training and experience (article 12). There are also a range of functions relating to the education and training of pharmacists and those wanting to join this profession, including the approval of qualifications, premises and providers of education and training (articles 13 to 15). There are also supplemental provisions, including a rule making power in respect of the process underpinning the carrying out of the Society's various functions under articles 14 and 15 (article 16).

There are rule making powers in respect of applications for registration, or retention in the registers, and provision in respect of notification of decisions and the time limits within which certain applications by pharmacists need to be processed (articles 17 and 18). There are a number of restrictions relating to registration and the unlawful use of certificates of registration, and these include restricting the professional title "registered pharmacist" to registrants (article 20).

Part 3 contains parallel provisions relating to the registration of pharmacy technicians in England and Wales. The Registrar is to establish and maintain a new statutory register of pharmacy technicians, which is to be in two parts, a practising and a non-practising part, and which is to replace the existing voluntary register (article 21). There are transitional arrangements allowing for the transfer of certain pharmacy technicians from the existing voluntary register to the new statutory register, and for allowing persons who have been practising as pharmacy technicians onto the statutory register, even if they do not have the approved qualifications, provided they satisfy certain other criteria (Part 2 of Schedule 2). There are provisions relating to entitlement to registration: registrants must be appropriately qualified, be fit to practise, and where appropriate have met additional requirements as to education, training, experience and continuing professional development (article 22). There is also provision in respect of the recognition of qualifications and of additional education, training and experience (article 23), and a range of functions relating to the education and training of pharmacy technicians and those wanting to join this profession, including the approval of qualifications, premises and providers of education and training (articles 24 to 26). Again, as in Part 2, there are also supplemental provisions (article 27).

There are rule making powers in respect of applications for registration, or retention in the registers (article 28), and a number of restrictions relating to registration and the unlawful use of certificates of registration. These include restricting the professional titles "pharmacy technician" and "registered pharmacy technician" to registrants, although under the transitional arrangements, unregistered technicians may continue to use these titles for two years, or for longer if they have applied for registration within the two year period and their application has not been disposed of (article 29).

Part 4 contains provisions relating to matters common to both registers. The Council is to make rules relating to the form and keeping of the registers, and the Registrar is to publish lists of pharmacists and pharmacy technicians containing information derived from the entries in the registers (article 30). There is also provision in respect of the making of annotations in the registers to denote specialisations (article 31), and in respect of certificates of registration (article 32). Registrants also have continuing obligations with regard to their registration entries (article 33). The Registrar has obligations to keep the registers correct, and has powers to deal with fraudulent and incorrect entries

(article 34). Provision is made to enable the Registrar to take action where he finds out, after a person is registered, about a fitness to practise matter arising before that person was registered, including powers to remove such a person from the registers. Rules may provide him with information gathering powers to assist him in finding out about such matters (article 35). Provision is also made for rules to deal with moving between the practising and non-practising parts of the registers, and for voluntary removal from the registers (articles 36 and 37).

All registrants in the practising parts of the registers are required to have adequate and appropriate professional indemnity cover, and again there are information gathering powers in respect of this requirement (article 38). All registrants in the practising parts of the registers must also undertake continuing professional development, and rules will provide for sanctions where continuing professional development obligations are not met (article 39). Provision is also made for the Council to make rules which will allow them to charge fees in connection with registration functions, and non-payment of fees may lead to applications being refused or removal from the register (article 40). There is provision for the restoration of registrants to the registers where they have been removed under Parts 2 to 4 (article 41), and for appeals to the Registration Appeals Committee against appealable registration decisions. These decisions are thereafter appealable through the courts (articles 42 to 44). There are also transitional arrangements for dealing with outstanding registration applications, including those which are under appeal (Part 3 of Schedule 2).

Part 5 contains measures relating to the fitness to practise of registrants. The Council is to publish guidance on the professional standards expected of registrants (article 45), and the Society is given powers to obtain information from third parties about a particular registrant (article 46). They may also publish any information about the fitness to practise of registrants where it is in the public interest to do so (article 47).

Provision is made about what it means for fitness to practise to be impaired (article 48) – and the framework within which allegations of impairment are to be considered is set out. Usually, cases will be considered first by the Registrar, who will then refer them on to the Investigating Committee. The Investigating Committee has power to deal with the case itself by way of warnings or advice, or may refer the matter on to the Health Committee or the Disciplinary Committee. As well as giving advice and warnings, these Committees may suspend registrants or attach conditions to their registration – and in the case of the Disciplinary Committee, may direct that the registrant be removed from the registers. There is also provision for the review of earlier decisions to suspend or impose conditions (articles 49 to 52).

The Council may also establish a scheme of professional performance assessments to assist the Registrar and the fitness to practise committees (article 53). Provision is also made for interim orders suspending registration or attaching temporary conditions to registration while an investigation is ongoing (article 54).

If a registrant has been removed from the registers for fitness to practise reasons, there are arrangements for allowing him to be restored to the registers in defined circumstances (article 55). Provision is also made for appeals to the courts against appealable fitness to practise decisions (article 56), 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 57 and 58). There are also arrangements for dealing with outstanding disciplinary proceedings under the Pharmacy Act 1954 in respect of criminal convictions or misconduct, including cases which are under appeal (Part 4 of Schedule 2).

Part 6 contains provisions relating to proceedings before a fitness to practise committee or the Registration Appeals Committee. Essentially, these matters are to be covered in rules, but 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 59 to 62).

Part 7 contains miscellaneous measures. The Society is given a general power to charge fees, but this must not be used in areas where there are specific charging arrangements under the Order (article 63). There is provision for the Society to enter into arrangements to approve qualifications, premises and providers of education and training for pharmacists, pharmacy technicians and those wanting to join these professions outside the United Kingdom (article 64). The time limits for bringing prosecutions are extended (article 65), and provision is made in respect of the procedural aspects of rules and orders under the Order (article 66 and 69).

Consequential amendments, revocations and repeals are made in respect of other legislation, and the amendments to the Poisons Act 1972 also remove the responsibilities of the Privy Council in respect of the appointment of the Society's inspectors (article 67 and Schedule 1). Provision is also made for further transitional provisions to supplement the provisions in Schedule 2 (article 68). As well as the transitional provisions noted above, Schedule 2 also provides for certain outstanding business and premises cases to be dealt with by the Statutory Committee, established under the Pharmacy Act 1954, instead of the Disciplinary Committee (Part 5 of Schedule 2), and for the Council to deal with consequential modification of the Society's byelaws (paragraph 4 of Schedule 2).