

# HEALTH ACT 2006

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## EXPLANATORY NOTES

### COMMENTARY ON SECTIONS

#### Part 3 Chapter 2

#### Medicines and Pharmacies

125. Chapter 2 of Part 3 of the Act provides for the amendment of provisions of the Medicines Act 1968 (the “Medicines Act”), and also a provision of the Health Act 1999, relating to pharmacies, pharmacists and the sale and supply of medicines.
126. Part 4 of the Medicines Act (sections 69 to 84) contains provisions relating to the registration of retail pharmacies, the lawful conduct of retail pharmacy businesses and prohibitions on the use of certain titles, emblems etc. relating to pharmacy. Under the existing provisions, a person, whether a corporate body or an individual, is only lawfully conducting a retail pharmacy business if at each pharmacy premises from which they conduct their business, the retail supply of medicines, or the supply of medicines in circumstances corresponding to retail sale (e.g. the dispensing of medicines in accordance with NHS prescriptions) is under the “personal control” of a pharmacist. The provisions of this Chapter of the Act change these arrangements, by removing the requirement for personal control and substituting new requirements under which there must be a “responsible pharmacist”, responsible for the safe and effective running of the pharmacy business.
127. Other provisions of the Medicines Act require that certain activities relating to medicines may be conducted only by or under the supervision of a pharmacist. The provisions of the Act amend the Medicines Act in order to enable Ministers to prescribe conditions which must be complied with if that activity is to be considered as done under the supervision of a pharmacist. The intention is to clarify the pharmacist’s obligations to supervise.
128. In addition to the provisions of the Act, the Government propose to make orders under the existing powers of the Medicines Act, so as to enable registered and suitably trained staff working in a pharmacy to supervise the preparation, dispensing, sale and supply of medicines, without direct supervision by a pharmacist. The intention is that the pharmacist can use his clinical skills and training to offer a wider range of services, including away from the pharmacy (for example, in health centres and clinics).
129. These provisions extend to the entire United Kingdom.

#### *Section 26: Requirements about supervision*

130. [Section 26](#) relates to the requirements in the Medicines Act relating to the supervision of certain activities by pharmacists.
131. [Section 26\(1\)](#) amends section 10 of the Medicines Act. Under the Medicines Act a licence is required to manufacture or supply medicinal products; section 10 of the Medicines Act provides for various exemptions from the licensing requirements of the Medicines Act where, in certain circumstances, a pharmacist, or a person acting

under the supervision of a pharmacist, prepares, assembles, dispenses or supplies a medicine. Section 26(1) inserts new subsections in section 10. These confer on the “Health Ministers” (i.e. the Secretary of State for Health and the Northern Ireland Department for Health, Social Services and Public Safety) a power to make regulations prescribing conditions which must be complied with if that activity is to be considered as done under the supervision of a pharmacist. If any of the prescribed conditions apply to that activity and are met, that will be sufficient for the activity in question to be considered as done under supervision. In addition, the new powers will extend to prescribing conditions in relation to “remote supervision” – i.e. where the pharmacist supervises an activity without being present at the pharmacy (e.g. by using a video link). If no such conditions are prescribed, the pharmacist cannot supervise remotely. The intention is that the regulations will clarify the pharmacist’s obligations to supervise.

132. **Section 26(2)** amends section 52 of the Medicines Act. Section 52 of the Medicines Act imposes conditions on the sale or supply of any medicine which is not a “general sale list” medicine; in particular that any transaction for the sale or supply of a medicine to a customer must be carried out by, or under the supervision of, a pharmacist. A general sale list medicine is one which may be sold in retail premises which can be secured so as to exclude the public, but which are not a pharmacy (e.g. a supermarket or newsagent shop). Section 26(2) makes amendments to section 52 of the Medicines Act, identical to those for section 10; i.e. enabling the Health Ministers to make regulations relating to the requirements for supervision by a pharmacist.

### ***Sections 27 to 30: Pharmacy premises***

133. Under section 75 of the Medicines Act, a retail pharmacy must be registered. The register is administered by a registrar appointed by the Royal Pharmaceutical Society of Great Britain (or, in Northern Ireland, the Pharmaceutical Society of Northern Ireland). The applicant for registration must be a person “lawfully conducting a retail pharmacy business”. In addition, section 52 of the Medicines Act requires that a medicine, other than a general sale list medicine, must be sold or supplied by such a person. Sections 69 to 72 of the Medicines Act specify the conditions which must be complied with if a person is to be considered to be lawfully conducting the business. Section 70 specifies conditions for individual pharmacists or partners. Section 71 specifies those for corporate bodies. Section 72 specifies conditions that apply where a pharmacist carrying on a retail pharmacy business dies or is otherwise prevented from carrying on his business (e.g. if he is adjudged bankrupt) and a representative carries on his business.
134. Under the existing provisions, at each pharmacy premises the business of retail sale of medicines (whether general sale list medicines or not) or the supply of such medicines in circumstances corresponding to retail sale (e.g. the supply of medicines in response to NHS prescriptions) must at all times be under the personal control of a pharmacist.
135. **Sections 27 to 30** amend these provisions; in particular, to remove the requirement for personal control and replace this with a requirement that for each pharmacy premises, there must be a “responsible pharmacist” in charge of the business of retail sale or supply of medicines.

### ***Section 27: Control of pharmacy premises: individuals and partnerships***

136. **Section 27(1)** substitutes a new section 70 of the Medicines Act, which relates to the requirements for retail pharmacy businesses carried on by individuals or partnerships. The effect of the substitution is to replace the requirement for each pharmacy to be under the personal control of a pharmacist with a requirement that for each pharmacy premises, there should be a responsible pharmacist. The responsible pharmacist must be in charge of the pharmacy business, in so far as it relates to the retail sale of medicines, or the supply of medicines in circumstances corresponding to retail sale (e.g. the supply of the medicines in accordance with NHS prescriptions).

137. The new section 70(3) replaces the existing requirement in section 70 for the pharmacist in personal control of the pharmacy to exhibit conspicuously in the pharmacy his registration certificate. In practice, where there is more than one pharmacist working in a pharmacy, each will display his or her registration certificate. To avoid doubt as to the responsible pharmacist in charge of the pharmacy, section 70(3) requires the responsible pharmacist to display conspicuously in the pharmacy a notice stating that he is the pharmacist in charge at that time, and which includes details of his registration number.
138. New section 70(4) provides that where the pharmacy business is carried on by an individual, the responsible pharmacist must be that person or another pharmacist. Where a pharmacy business is carried on by a partnership, the responsible pharmacist must be one of the partners (in Scotland, one of the partners who is a pharmacist) or another pharmacist.
139. New section 70(5) sets out a requirement that where pharmacy premises in Great Britain have been registered for less than three years, the responsible pharmacist may not be a pharmacist who is a pharmacist by virtue of section 4A of the Pharmacy Act 1954 (i.e. a pharmacist who is qualified in another EU state whose qualification is recognised in the UK). Article 2(1) of Directive 85/433/EEC provides for Member States to recognise specified diplomas etc awarded by other Member States. Article 2(2) of the Directive, however provides for a derogation under which member States need not give effect to the diplomas with respect to pharmacies open to the public, which have been in operation for less than 3 years. Section 70(5) exercises that derogation in relation to Great Britain.
140. [Section 27\(2\)](#) makes a consequential amendment to section 78 of the Medicines Act (which relates to the prohibition on the use of certain titles, emblems etc relating to pharmacy), replacing references to “personal control” with references to the pharmacist in charge of the pharmacy business at the premises.

### ***Section 28: Control of pharmacy premises: bodies corporate***

141. [Section 28](#) substitutes section 71 of the Medicines Act, which relates to the requirements for a retail pharmacy business carried on by a body corporate. The requirement in section 71 for a body corporate conducting a pharmacy business to have a superintendent pharmacist remains. Section 71 is however altered so as to remove the existing requirement that at pharmacy premises where the business is carried on, the retail sale or supply of medicines must be under the personal control of a pharmacist. This requirement is replaced by a requirement to have a responsible pharmacist, subject to the same conditions as apply under the new section 70 of the Medicines Act substituted by section 27. [Section 28\(2\)](#) makes a consequential amendment to section 124(2)(b) of the Medicines Act, which concerns offences by bodies corporate.

### ***Section 29: Control of pharmacy premises: representative of pharmacist in case of death or disability***

142. [Section 29](#) amends section 72 of the Medicines Act, which specifies the conditions that apply where a pharmacist carrying on a retail pharmacy business dies or is otherwise prevented from carrying on his business (e.g. if he is adjudged bankrupt) and a representative carries on his business. Section 29 amends the provisions so as to remove the requirement that at each premises the retail pharmacy business is under the personal control of a pharmacist, replacing it with a requirement for there to be a responsible pharmacist, as in the amended sections 70 and 71.

### ***Section 30: The responsible pharmacist***

143. [Section 30](#) inserts two new sections 72A and 72B of the Medicines Act, to make provision in relation to the “responsible pharmacist” mentioned in sections 70, 71 and 72 of the Medicines Act (as amended by this Act).

144. Section 72A(1) places a duty on the responsible pharmacist to secure the safe and effective running of the pharmacy business in question, insofar as this concerns the retail sale of medicines, or the supply of medicines in circumstances corresponding to retail sale (e.g. the supply of medicines in accordance with NHS prescriptions). Section 72A(2) states that a pharmacist may not be in charge of more than one set of pharmacy premises except in circumstances specified in regulations made by the Health Ministers (i.e. the Secretary of State for Health and the Northern Ireland Department for Health, Social Services and Public Safety), and then only if such conditions as may be specified are complied with. Section 72A(3) to (5) impose requirements relating to the procedures which must be established and maintained by the responsible pharmacist and as to record keeping.
145. Section 72A(6) provides for the Health Ministers to make further provision in regulations in relation to the responsible pharmacist. Section 72A(7) provides that those regulations may in particular make provision about the matters referred to in section 72A(1) to (4); i.e. the duties of the responsible pharmacist, the circumstances in which a person may be a responsible pharmacist in respect of more than one set of premises at a time, the duty to establish and maintain procedures and the duty to keep records. Furthermore, section 72A(7) provides that the regulations may make provision for a variety of related matters including: the qualifications and experience that a pharmacist must have to be a responsible pharmacist; the responsible pharmacist's absence from the pharmacy (for example, to impose conditions as to how long a responsible pharmacist may be absent); his supervision of the preparation, assembly, dispensing and supply of medicines at the pharmacy when he is not present; the circumstances in which he may supervise such activities at a pharmacy when he is not the responsible pharmacist for that pharmacy; the format and content of procedures to secure the safe and effective running of the business; and the form and content of the records which must be made by the responsible pharmacist.
146. New section 72B(1) provides that where a person fails to comply with any requirements of new section 72A of the Medicines Act, or of regulations made under that section, this may constitute misconduct for the purposes of section 80 of the Medicines Act, section 8 of the Pharmacy Act 1954 and Article 20 of the Pharmacy (Northern Ireland) Order 1976; and the Statutory Committee of the Royal Pharmaceutical Society of Great Britain or the Pharmaceutical Society of Northern Ireland may deal with such a failure accordingly. Section 72B(2) provides that if a pharmacist does not have the qualifications and experience specified in the regulations, he cannot act as a responsible pharmacist. If such a person is in charge of the retail sale/supply of medicines at a pharmacy, the person carrying on the retail pharmacy business in question will not be lawfully conducting that business.
147. Under section 72B(3) and (4), if a pharmacist is absent from the pharmacy for a period longer than that permitted in the regulations, or is named as responsible pharmacist for more than one pharmacy without satisfying the requirements in the regulations which govern such matters, they cannot be considered for the purposes of these provisions as being in charge of the business at the pharmacy. Unless another responsible pharmacist is appointed for the pharmacy, the person carrying on the retail pharmacy business in question will not be lawfully conducting that business.
148. [Section 30\(2\)](#) makes a consequential amendment to section 77 of the Medicines Act, which deals with the annual return, which every person carrying on a retail pharmacy business must make to the registrar responsible for keeping the register of retail pharmacies under the Medicines Act. The amendment removes the requirement to send to the registrar the name of the pharmacist in personal control of the retail pharmacy business.
149. [Section 30\(3\)](#) amends section 84 of the Medicines Act, which relates to criminal offences under Part 4 of the Medicines Act. The new provision makes it a criminal offence for a person to fail to comply with the record keeping requirements imposed

under the new section 72A. Any person guilty of the offence would be liable on conviction in the magistrates' court to a fine not exceeding level 3 on the standard scale, currently up to £1,000.

### ***Section 31: Enforcement***

150. **Section 31** makes consequential amendments to sections 108, 109 and 110 of the Medicines Act, which relate to enforcement. New sections 108(6A) and 110(3A) ensure that, as with the enforcement of other provisions of the Medicines Act relating to the retail sale and supply of medicines, arrangements may be made for the enforcement of the provisions of section 72A relating to record keeping by the Pharmaceutical Societies of Great Britain and Northern Ireland. Also, new sections 108(6B) and 110(3B) place a specific duty on both the Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland to enforce those elements of section 72A which are not subject to an offence, as a matter of professional misconduct, for example, the content of the standard operating procedures that must be maintained in each pharmacy. This duty applies wherever the registered pharmacy is located, in a hospital or in the community.
151. New sections 108(6C) and 110(3C) clarify that the appropriate Minister does not have a duty to enforce those provisions which are not subject to offences, as the appropriate Minister has no means under the Medicines Act to do so. However, sections 108(6D) and 110(3D) do give the appropriate Minister a right of entry to inspect and investigate in relation to the other provisions in section 72A which are not subject to an offence, reflecting the arrangements in Northern Ireland where the Health Department Inspectorate inspect and investigate matters in pharmacies, rather than the Pharmaceutical Society of Northern Ireland. Similar provisions have been made for England, Scotland and Wales to maintain consistency in the legislation.
152. However, the provision in section 108(10) which provides that the Secretary of State may prosecute in respect of the offences in section 72A if satisfied that the Royal Pharmaceutical Society has failed to do so is not replicated for Northern Ireland. This is to reflect the fact that in Northern Ireland it is the policy intention that the Health Department Inspectorate (not the Pharmaceutical Society) will have primary responsibility for prosecuting in respect of those criminal offences, and would therefore not be appropriate to include this qualification for Northern Ireland.

### ***Section 32: Order-making powers***

153. **Section 32** amends section 129(5) of the Medicines Act, which provides that regulations under the Medicines Act may make different provision for different areas or in relation to different cases or different circumstances. The amendment extends this power to orders made under the Medicines Act. This means that if, as is proposed, the Health Ministers make further orders under the Medicines Act to enable acts to be carried out by registered and suitably trained pharmacy staff, rather than by or under the supervision of a pharmacist, those orders may make different provision for different parts of the United Kingdom.

### ***Section 33: Orders under section 60 of the Health Act 1999***

154. **Section 33** amends Schedule 3 to the Health Act 1999, which makes provision about Orders in Council under section 60 of the Act. Orders under that section may make provision in relation to the regulation of health care professions. Section 33 omits paragraph 2(2) of Schedule 3, so as to remove the limitation that orders under section 60 may not make amendments to the Medicines Act except in relation to a profession regulated by the Pharmacy Act 1954.