
EXPLANATORY NOTE

(This note is not part of the Order)

This Order principally makes provision relating to the position and responsibilities of a superintendent of a body corporate that is carrying on a retail pharmacy business, and in relation to the responsibilities of the responsible pharmacist who is in day to day charge of particular retail pharmacy premises.

Part 1 contains general provisions, including powers to make commencement and transitional provisions orders and the procedural requirements relating to them.

Part 2 contains amendments to the Medicines Act 1968 (“the 1968 Act”) relating to responsible pharmacists and superintendent pharmacists.

It is a requirement of section 72A of the 1968 Act, in terms, that whenever retail pharmacy premises are open for business, there must be a responsible pharmacist in respect of the premises. An amendment is made to section 72A to clarify when premises are to be considered open for business for these purposes. The responsibility of responsible pharmacists to establish, maintain and keep under review operating procedures is removed, as is their duty to make certain records. At the same time, the duty of pharmacy owners to ensure that those records are properly maintained, and are kept for a prescribed period, are also removed – as are the provisions making breaches of the record keeping requirements offences (article 5(1) to (4) and paragraphs 3 and 4 of Schedule 1).

The powers of the responsible Ministers under section 72A of the 1968 Act to make regulations in respect of responsible pharmacists are replaced by powers of the General Pharmaceutical Council (GPhC) as regards Great Britain and the Council of the Pharmaceutical Society of Northern Ireland (PSNI) as regards Northern Ireland to make rules or regulations under that section. These powers are qualified by a new duty to have regard to the principle that the burdens imposed on businesses by rules or regulations are the minimum necessary to secure the benefits expected to result from them – and by new consultation obligations. The existing Regulations are revoked but transitionally saved, pending the first rules by the GPhC as respects Great Britain and the first regulations of the Council of the PSNI as respects Northern Ireland (article 5(5) and (6) and 8 and paragraphs 5 and 9 of Schedule 1).

By virtue of section 71 of the 1968 Act, in order to carry on a retail pharmacy business, a body corporate must have a superintendent. A new requirement is introduced which means that the superintendent has to be a senior manager who has authority to take decisions about certain matters relating to retail sale of medicinal products and the supply of medicinal products in circumstances corresponding to retail sale. A restriction preventing superintendents from being the superintendent of more than one pharmacy business is removed, as is the requirement for businesses proposing to use the title of “chemist”, or related expressions, to have a superintendent as a member of their board (article 6(1) and (3)).

A new duty for superintendents is set out in section 72AA of the 1968 Act which relates to securing the safe and effective running of the pharmacy business so far as concerns the retail sale of medicinal products and the supply of medicinal products in circumstances corresponding to retail sale (article 6(2)). The GPhC and the Council of the PSNI are also given additional powers to include a description of the professional responsibilities of superintendents and responsible pharmacists as part of the standards they set in their codes of practice relating to conduct and performance (article 7).

There are also some further consequential amendments to the Medicines Act 1968, the Health Act 2006 and the Pharmacy Order 2010 (paragraphs 6 to 8, 10 and 11 of Schedule 1). These

include changes to the enforcement arrangements to take account of both the new duty for superintendent pharmacists and the new arrangements for subordinate legislation in respect of responsible pharmacists.

There are also some minor changes clarifying that medicines may be supplied from as well as at pharmacy premises, and that retail pharmacy businesses may be carried on from as well as at pharmacy premises (Schedule 2). It is also made clear that the PSNI may appoint a deputy registrar who may be authorised to act for the registrar in any matter (article 10).

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