



MEMORANDUM OF ADVICE

**to Superintendent Pharmacists,
and other pharmacists
who may contemplate becoming owners
of Retail Pharmacy Businesses,
from the
PHARMACEUTICAL SOCIETY OF IRELAND
on possible public health risks
arising from certain commercial practices.**

INTRODUCTION

- 1.1 The Pharmaceutical Society of Ireland ["PSI"] was established under the Pharmacy Act (Ireland) 1875. The PSI was reconstituted by the Pharmacy Act 2007 [the "Act"], the preamble of which declares its intention to be

"an Act to make new provision for the regulation of pharmacy...for a new system of registration of qualified pharmacists... and of pharmacies... and for the setting up of new procedures to ensure that pharmacists are and continue to be fit to practise and to prevent pharmacists, pharmacy owners and medical practitioners from entering into certain inappropriate relationships".

The Oireachtas has entrusted significant duties and powers to the PSI in the area of the sale and supply of medicinal products and the governance of the profession of pharmacy. Section 7(1)(a) of the Act defines the principle function of the PSI as being

"To regulate the profession of pharmacy in the State having regard to the need to protect, maintain and promote the health and safety of the public".

- 1.2 The purpose of this Memorandum is to alert the members of the profession of concerns which the PSI has, arising out of certain emerging commercial practices in the establishment and development of retail pharmacy businesses. This is particularly the case in the light of the recently and radically deteriorated economic climate and the steps which the Government is taking to address it.

Decisions and business strategies adopted by members of the profession in recent years when the economy was in good order, whilst sustainable then may not be sustainable in the short to medium-term future. It would not be proper for the PSI to become involved in the commercial market-place of retail pharmacy businesses nor is it the PSI's function or desire so to do.

Having said that, it is the function of the PSI, when it apprehends that commercial developments and practices are emerging and growing which may adversely affect public health, to advise members of the profession of their concerns and, if necessary, should considered warnings not be heeded, to take steps to protect the welfare of patients.

These steps may be taken under Part 4 of the Act which deals with the registration of pharmacists and retail pharmacy businesses. They may also be taken under Part 6 – Complaints, Enquiries and Discipline and (hopefully rarely) under Part 5 – Criminal Offences. In cases where circumstances warrant, the PSI will not hesitate to use the wide powers of investigation conferred on it by Part 7 of the Act.

BACKGROUND

- 2.1 There has been, and there continues to exist, a certain (and in most cases, a healthy) tension within the profession of pharmacy between the provision of professional healthcare in the area of the sale and supply of medicines and the pursuit of commercial profit. For the great majority of pharmacists and the proprietors of retail pharmacy businesses this does not pose a problem.

- 2.2 In the case of the proprietors of retail pharmacy businesses, such proprietors are bound by the provisions of the Act and in particular Section 17 thereof and by the Regulation of Retail Pharmacy Businesses Regulations 2008 (SI No. 488 of 2008) made by the Minister pursuant to Section 18 of the Act. Superintendent pharmacists have particular obligations under the Act and in particular they must fulfil the duties imposed on them by Sections 27(b), 28(a) and 29(b).
- 2.3 Registered pharmacists (in particular superintendent and supervising pharmacists) and registered retail pharmacy businesses are subject to the provisions of Parts 4 and 6 of the Act, which deal respectively with registration and with complaints, inquiries and discipline. They must conduct themselves and their businesses in a manner which is directed towards the protection of patients' health. For the very great majority of pharmacists who are proprietors of retail pharmacy businesses, and for superintendent pharmacists, there is no difficulty in abiding with both the letter and the spirit of the Code of Conduct for Pharmacists and the legislation. There is regrettably a very small minority of people involved in the profession who in some cases, and sometimes for reasons of commercial naivety, find themselves in difficult waters. Their continued registration under Part 4 may be at risk. They may also find themselves subject to investigations under Part 7 of the Act and possible fitness to practise inquiry under Part 6.
- 2.4 The PSI wishes to assist this minority group in raising the standard of their professional practices and conduct to a level which has already been attained by the great majority of the profession. The PSI wishes to create an environment in Ireland for the practice of pharmacy which in all respects is orientated towards public health preservation and gain, and where commercial profit, although essential, is always subordinate to patient health.
- 2.5 There are a number of key agencies, some regulatory, some commercial and some peer healthcare practitioners who wittingly or unwittingly can become drivers, catalysts (and sometimes unwitting facilitators) of adverse behaviour on the part of pharmacists or proprietors of retail pharmacy businesses. Pharmacists need to be sensitive to any improper demands and pressures, however inviting these may appear to be at a superficial level. The PSI, through the office of the Registrar, is committed to providing any further information or assistance which any member of the profession may require arising out of this memo. The Registrar and his staff are also available for consultation and advice for any pharmacist or proprietor of a retail pharmacy business requiring guidance in relation to the matters raised.
- 2.6 The PSI has, pursuant to Section 7(2)(a)(iii) of the Act, drawn up a Code of Conduct for Pharmacists (a copy of the code is attached to this memorandum). Registered pharmacists are reminded of the requirement to comply with this code at all times.

PLANNING ISSUES

3.1 Historically in the profession of pharmacy there was a proliferation of different categories of people who could and did practise what is now called pharmacy. They included Licentiates of Apothecaries Hall, chemists and druggists and registered druggists. In tandem with such classes of persons, there emerged a nomenclature for the premises in which pharmacy services were provided and which included:

- Chemist
- Medical hall
- Medical supply store
- Drug hall
- Drug store
- Medical store
- Chemist shop
- Dispensing pharmacy
- Pharmacy

3.2 The 2007 Act has moved away from these old concepts and establishments and has replaced them with an entity known as "a retail pharmacy business". A retail pharmacy business is defined in Section 2(1) of the Act as meaning

"a business (not being a professional practice carried on by a registered medical practitioner or a registered dentist) which consists of or includes the sale or supply of medicinal products other than medicinal products on a general sales list (whether or not such products on such a list are also sold or supplied in the course of the business)".

3.3 Pharmacists, the proprietors of retail pharmacy businesses and their professional advisors should be clear and aware as to the nature of the new entity which has been created by the 2007 Act. A failure to distinguish the new concept from the older concepts which were in circulation can cause problems.

3.4 One example where such problems may arise is when applying to the PSI for registration, as a retail pharmacy business, in respect of a premises which does not have the relevant planning permission. The PSI is aware of a case in which planning permission was granted for what was termed a "dispensary". This is an historical entity which differs substantially in its function from a modern retail pharmacy business referred to in the Pharmacy Act 2007.

The granting of a planning permission for an entity other than a retail pharmacy business may cause problems for an applicant at the time of registration of that business with PSI. Pharmacists and their advisors need to ensure that that for which they seek planning permission from a planning authority is in fact an entity and a premises which is capable of registration under the 2007 Act. In this regard they should also be aware that under Section 17(1)(f) of the Act they must satisfy the PSI that the retail pharmacy business and premises will also conform to and be conducted in accordance with the Act and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), made under it.

- 3.5 As a matter of policy the PSI favours an even and rational distribution of retail pharmacy businesses such that all patient catchment areas (including less populated small towns and rural areas) are uniformly served. The PSI wishes to see that there is convenience of access for patients. In this regard it must be noted that there are many patients who do not have their own transport and accordingly locating a retail pharmacy business in an area which is not easily accessible either on foot or via public transport is undesirable. The PSI believes further that it is very important for patients to enjoy a freedom of choice in relation to the pharmacist with whom they deal.

For this reason the location of pharmacy services (particularly in rural areas) in places which are some distance away from centres of general economic activity such as a town or village does not best facilitate patient or consumer choice. A town or village, where the single retail pharmacy business is located on its outskirts or some distance away is, from a patient convenience and choice perspective, far less desirable than in a town whose centre is served by a number of competing pharmacies and other diverse businesses and services. Such developments will also adversely impact on the viability of the towns that are targeted for these developments. The planning authorities, therefore, should be vigilant in respect of the implications of these developments and ensure that the interests and convenience of patients, and the public at large, are also taken fully into account in making decisions on all such developments.

FINANCE AND INVESTMENTS

- 4.1 Traditionally Ireland has been a profitable market within which retail pharmacy businesses could operate. The factors which created such a market include the fact that the State is the largest purchaser (through the GMS and other schemes) of medicinal products. Price cuts and other changes in reimbursement, greater competition, more vigilant patient purchasers, the availability of generic medicines and public sentiment based on international price comparisons will all impact on the market. In short, the profitability of retail pharmacy businesses may not continue to be as strong as was formerly the case. The PSI has no interest in levels of profitability per se. However, the PSI is concerned that commercial pressures created by reduced profitability may drive the proprietors of retail pharmacy businesses and pharmacists who are employed therein (particularly superintendent and supervising pharmacists) into work practices or conduct which could adversely impact on patient welfare and public health. Some examples of this might include:
- Not having sufficient professional staff (and support staff) to appropriately discharge their professional and statutory duties and responsibilities.
 - Failure to support and carry out appropriate and necessary reviews of medicines therapy prior to the dispensing of prescriptions.
 - Following review, failure to provide necessary advice on their proper use and storage of medicines.
 - Failing to provide adequate counselling on the rational use of medicines.
 - Working longer than permitted hours or failing to take rest breaks as outlined in the Organisation of Working Time Act 1997. In this regard the practice of pharmacy requires a high level of concentration and attention. Fatigue and overwork can lead to error which may cause patient injury or death.

- Selling healthcare products which have questionable therapeutic effect, value or patient benefit.
- Cross-selling a variety of medicines when a single medicine would be adequate.
- Requiring or permitting unqualified staff to do work which should more properly be done by a pharmacist or a pharmaceutical assistant. (This may be an offence contrary to Section 31 of the Act.)
- Supplying the most profitable medicines.
- “Link” selling and use of software to promote same.
- Over-reliance on unqualified staff.
- Failure to create adequate time for engagement with other healthcare professionals.

These work practices are not conducive to patient health and will not be tolerated by the PSI. Pharmacy proprietors, superintendent pharmacists and supervising pharmacists should be particularly sensitive to their obligations in regard to these matters.

- 4.2 The PSI is also concerned that the Government strategy for primary care as set out in “*Primary Care – A New Direction*” (2001), which supports the development and roll out of Primary Care Teams that are ideally located on the same site (page 28), may have been partly corrupted by some of the “half way house” developments currently being established in this area. The 2001 document states, at page 20, under the heading “Model of Primary Care”:

“Primary care will be centred on the needs of individuals and groups of people and will match their needs with the competencies required to meet them. Some of the essential competencies will include assessment, diagnosis, therapy, nursing, midwifery, prevention, health education, counselling, administration, management, social services, referral and rehabilitation. A group of primary care providers will come together to form an interdisciplinary team known as the Primary Care Team. These teams will serve small population groups of approximately 3,000 to 7,000 depending on whether a region is rural or urban. Among other factors the number and ratio of team members will depend on needs assessment, location and population size”.

“*Primary Care – A New Direction*” sees the community pharmacist as one of seven members of a primary care network which in turn supports the primary care team comprising of ten other professions or occupations, including GPs, nurses, midwives, physiotherapists, occupational therapists and social workers.

- 4.3 The PSI is concerned that the co-location of a number of medical general practices with a retail pharmacy business in a single location may mistakenly be viewed as constituting a primary care unit as envisaged by Government policy. They are not. Financial models for the development of these hybrid co-location enterprises sometimes reveal that the retail pharmacy business becomes a significant (and sometimes key) financial driver for the success of the enterprise.

The disproportionate contribution which a retail pharmacy business is sometimes called upon to make in terms of the price paid for a shop premises or the rent offered therefore is an unhealthy one insofar as patient safety is concerned. The PSI is aware of circumstances where the agreed price or rent to be paid for a premises can exceed local price and rental comparisons by a factor of three. The proprietors of a retail pharmacy business may take an understandable commercial view that the proximity of a retail pharmacy business to a number of medical practices will result for reasons of consumer convenience in increased footfall, higher turnover and enhanced profit.

In any given situation this may or may not turn out to be the case and from one perspective it is of no concern to the PSI. What does concern the PSI, however, is the emergence of a financial model which is so skewed that it has the potential to put the proprietors of retail pharmacy businesses under undue financial pressure and may lead to the adoption of unprofessional work practices (see paragraph 4.1 supra) and, in extreme cases, may even force them to wind down or close.

The emergence of such a hybrid model also thwarts the development of primary care units as envisaged by the Government and supported by the PSI and the profession of pharmacy generally. What appears to be emerging at a macro level is a hybrid version of a Primary Care Centre which is constituted by the ad hoc co-location of medical practices, retail pharmacy business and some other healthcare professionals. This does not accord with the primary care model intended by Government and is not in the best interest of public health or necessarily the convenience of the public.

- 4.4 The wind down or closure of a retail pharmacy business in any circumstances may have significant adverse impact on patients. Quite apart from the immediate interruption in the supply of medicines, a patient is faced with the prospect of finding a new pharmacist with whom they can develop what is often a very personal patient-pharmacist relationship. A process of transfer of records then has to take place with consequent disruption for the patient. The absence of a patient history or record may also result in danger to the patient.

Therefore, when considering the financial commitments associated with opening or taking over a retail pharmacy business, pharmacists need to exercise prudent judgement, taking into account all healthcare implications for patients, before committing to a commercial arrangement which may place such pharmacists under unfair financial pressure. The personal financial necessity of a pharmacist can never be placed before the therapeutic needs of a patient and a sensible pharmacist should strive to ensure that such a conflict will not take place. In addition to the effect on patient wellbeing, the closure of a pharmacy also impacts on pharmacist employees and other employees of the business. There may also be consequent reputational damage for the profession.

- 4.5 Great care needs to be taken by persons who are considering embarking upon or investing or participating in a hybrid co-location enterprise of the type described above to ensure that the pharmacy is viable, that the financial commitments made are sustainable and that the arrangements do not give rise to any possible breaches of section 63 of the Pharmacy Act 2007, which prohibits certain economic arrangements between pharmacists or pharmacies and doctors (see also paras 6.1 – 6.7 below).

VALUATION OF A RETAIL PHARMACY BUSINESS

- 5.1 The PSI wishes to ensure that pharmacists and the professionals working in this area clearly understand the relatively new concept of a retail pharmacy business as outlined in paragraph 3.2 above. The newly created concept of a retail pharmacy business and the regulations under which it must operate may have a significant impact on what might colloquially be termed as “valuing a chemist shop”. The PSI is aware of the reliance which is placed upon the opinions of valuers, auctioneers and estate agents by their clients, who include proprietors of business, banks, financial institutions and other investors. The PSI wishes to ensure that no pharmacist or proprietor of a retail pharmacy business is, by reason of any inadequate or artificial valuation of a retail pharmacy business, encouraged to take unwarranted commercial risks, such that they may impact on the provision of pharmacy services in the pharmacy in question, in a manner that threatens the health and safety of patients or the professional integrity of the pharmacist proprietors or pharmacist employees or the profession generally. Pharmacists need to be very realistic and critical when approaching the question of the value of a retail pharmacy business. Failure to do so may only create future problems.

SECTIONS 63 AND 64 OF THE PHARMACY ACT 2007

- 6.1 The PSI believes it is again timely to remind the profession, and the wider community with whom the profession enjoys various relationships, of the provisions of Sections 63 and 64 of the Act.
- 6.2 Sections 63 and 64 of the Act deal with the difficult issue of improper economic relationships between doctors and pharmacists. They are designed to prohibit the creation of those improper relationships between pharmacists and doctors and between retail pharmacy businesses and medical practices. From a common-sense standpoint it is clear that the two healthcare professionals, doctor and pharmacist, should be independent of each other in the treatment of patients. The pharmacist as a healthcare professional, in his or her own right, has a duty to be more than a mere conduit for medicinal products. He or she must always bring their professional knowledge and skills in the area of medicines to bear in the best interests of the patient.
- 6.3 If a pharmacist has concerns in relation to what a doctor has prescribed or what non-prescription medicine a patient may be taking or seeking, then they have a professional duty to raise them and if necessary act upon those concerns. If a pharmacist were, by virtue of some economic relationship, beholden to a doctor then his or her independence might be compromised. It is for this reason, principally, that Sections 63 and 64 seek to separate and prohibit any improper commercial relationship between pharmacists and doctors.

A doctor or other healthcare professional ought not have any “interest” in the commercial success of a retail pharmacy business and vice versa. If such interests were permitted then the temptation for abuse and risk to patient safety and exploitation would almost certainly increase. Such a situation would result in loss of patient trust in their healthcare professionals with consequent fundamental damage to the reputation of the respective professions. Once again, the tension between unbiased and independent patient healthcare and commercial self interest must be maintained and as necessary kept in check.

- 6.4 Section 63 declares that it is professional misconduct by a registered pharmacist or a registered medical practitioner if he or she has a beneficial interest in the medical practice or registered retail pharmacy business of the other. Beneficial interest is defined in Section 63(5) as including the interest of a director or a shareholder in a company or the interest of a member in a corporate body which is not a company. An “interest” also includes the interest of the landlord in the rent (or other consideration) of a leased premises in circumstances where the rental value and/or the consideration is not an open market one or where the rent or consideration is ascertained by reference to the receipts or profits of the pharmacy business or medical practice as the case might be.
- 6.5 Section 64 provides that a registered retail pharmacy business and a medical practice shall not be carried on in the same premises as each other or in separate premises which are so organised that public access to the one is only available through the other and there is an arrangement between them which:
- “provides for, acknowledges or regulates a financial benefit to any of them arising from or facilitated by the co-location or juxtaposition described in that subsection.”* (Subsection 1 of section 64)
- 6.6 Section 64 also prohibits the improper recommendation of patients between medical practitioners and registered pharmacists or pharmacy owners and prohibits the payment of “commissions” by pharmacists to doctors or vice versa. Section 64(6) imposes a duty on a registered pharmacist or pharmacy owner to report a contravention of Section 64 to the PSI.
- 6.7 In light of the above, particular care needs to be taken by pharmacists or proprietors of retail pharmacy businesses (and their professional advisers) so as to ensure that any financial or trading model which they may establish complies fully with provision of these sections of the Act. The PSI believes most firmly that the independence and autonomy of the pharmacy profession must be preserved and will take a most serious view of any attempt to undermine it.

SUPERINTENDENT AND SUPERVISING PHARMACISTS

- 7.1 Superintendent pharmacists and supervising pharmacists are entrusted with particular and important duties under the Act and the Regulations. It is the function of a superintendent pharmacist personally to control the management and administration of the sale and supply of medicinal products.

It is the function of a supervising pharmacist to take whole-time charge of the carrying on of a retail pharmacy business in the premises where that business is conducted. The creation of the roles of superintendent pharmacist and supervising pharmacist was designed to ensure that there would always be an appropriately qualified and experienced registered pharmacist (as opposed to a non-pharmacist) ultimately in charge of and accountable for the activities of a retail pharmacy business, the proprietors of which may be persons other than registered pharmacists.

- 7.2 Having regard to the special position and responsibilities entrusted to them under the Act, it is essential that all registered pharmacists (and in particular superintendent and supervising pharmacists) ensure that, regardless of the commercial or other pressures which may be brought to bear in the conduct of a retail pharmacy business, that patient health and wellbeing is always paramount, that the requirements of the Act and any Regulations and Rules made thereunder are complied with and that, as healthcare professionals, the registered pharmacists concerned abide by their own code of conduct.

Professional misconduct or poor professional performance (as defined by the Act) cannot, and will not, be excused on the grounds that the pharmacist in question was only following orders or instructions or company policy or procedure. It is the pharmacist as a healthcare professional who must ultimately answer for his or her own conduct in any given situation and, in line with the case of a superintendent pharmacist, for the conduct of the company where the sale and supply of medicinal products are concerned.

CONCLUSION

- 8.1 The PSI hopes that this memorandum will be of use to members of the profession in identifying certain aspects of commercial relationships or practices which the PSI apprehends may adversely impact on patient health and safety. Whilst the PSI has no remit (and nor does it desire to have any remit) in the commercial market-place for the sale and supply of medicinal products, nonetheless in circumstances where agreements, practices or business models emerge which in the opinion of PSI constitute a threat to patient health and safety then the PSI will, in fulfilment of its principal statutory duty, take whatever steps may be necessary to protect and preserve patient safety and health.
- 8.2 As previously indicated, the Registrar and his staff are available to offer advice and guidance in relation to any aspect of this memo.

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Dr. Ambrose McLoughlin
Registrar