WHITNEYMOORE

THE PHARMACY REGULATOR'S GUIDANCE ON THE SALE OF CODEINE MEDICINES – A LEGAL PERSPECTIVE

Pharmacists will be all too aware of the Pharmacy Regulator's recent Guidance on the safe supply of non-prescription medicines containing codeine, which took effect on 1 August 2010.

The Guidance contains two requirements which, from a legal perspective, raise serious doubts regarding their validity and enforceability. The first of these is the requirement to store codeine medicines "out of the sight of the public". The second is the requirement that the sale of these products be conducted only by the pharmacist.

By all accounts, the implementation of the Guidance in pharmacies throughout the country is having a serious impact on pharmacy businesses. The fact that these products may not be displayed has resulted in a sharp fall in sales. Some pharmacies are reporting a drop of up to 50%. The requirement that the sale of these products be made only by pharmacists is increasing their workload and causing delays for patients. There have also been many accounts of patients who have felt humiliated in a very public way by a refusal to supply, which does nothing to create goodwill with patients.

I will leave it to others to argue the merits of whether the safety issues surrounding these products justify the requirements contained in the Guidance (which the Regulator has said will be strictly enforced against non-compliant pharmacists) and will consider the legal status of the Guidance itself. Suffice to say, however, that the safety of medicines is a matter for the Irish Medicines Board, and not for the Pharmacy Regulator, and it is also worth pointing out that the medicines the subject of the Guidance have been classified by the IMB by reference to their quality, safety and efficacy as available over-the counter, without prescription for at least 30 years.

It is important to note that the Pharmaceutical Society of Ireland not only has the power to draw up codes of conduct and guidance for pharmacists but the Pharmacy Act of 2007 which established the Society imposes a duty on it to do so. So also the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), which regulate how pharmacy businesses are to operate, provides that *"[t]he Council of the Society may, with the prior approval of the Minister, publish detailed guidelines for the purpose of facilitating compliance with these Regulations."*

However, it is equally important to stress that such codes of conduct, guidelines and other "soft law" documents of this nature have a limited and defined legal status and the courts have made it very clear that no such document can alter or displace established law, as this is a function which under the Constitution is vested in the Oireachtas. Any such guidance can only be with respect to how to proceed in a particular legal context.

The legal context in this case is provided by the 2008 Regulations referred to above. They set out the law relating both to the storage of codeine medicines and to the manner in which the sale and supply of medicinal products is to be conducted. As regards storage, the Regulations require the pharmacy owner and the superintendent pharmacist to ensure that medicines containing codeine "are not accessible to the public for self-selection." The question therefore arises as to what is the correct interpretation of the phrase "accessible to the public for self-selection". A product that is *visible* but which cannot be picked off the shelf by members of the public – as has

traditionally been the case where these products have been displayed on shelves behind the counter – is not accessible for self-selection in that the sale and supply of the product requires the intervention of the pharmacy staff prior to the actual purchase.

This interpretation is supported by the general presumption against unclear changes in the law. The courts have held that, particularly where fundamental rights are at issue, clear statutory language is necessary. If the Minister had intended when making the 2008 Regulations to require that these products be hidden from view, the Regulations should have said so in clear and unambiguous language. An example of this is the legislation relating to the sale of tobacco products which obliges retailers to keep them "*in a closed container or dispenser that is not visible or accessible to any person other than the [retailer] or a person employed by him or her.*"

As far as the sale of medicinal products is concerned, the 2008 Regulations state that this must be carried out "*by or under the personal supervision of a registered pharmacist.*" This does not mean that only the pharmacist can carry out the sale of such products; what is required is that this happens under the general supervision of the pharmacist. Nor, it must be said, do the 2008 Regulations make any distinction in this regard between medicines containing codeine and other medicinal products.

In our view, the Regulator's Guidance mis-states the law on these two issues and the requirements in the Guidance go further than what the law requires. For this reason, the Guidance cannot be said to facilitate compliance with the legal requirements but to create additional obligations. To that extent, we believe the Regulator has exceeded its powers and there would be no basis in law for the Regulator to prosecute pharmacists who did not comply with these requirements.

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