Submission to the Department of Health and Children

Consultation on Draft Regulations under Section 18 of the Pharmacy Act

S/08/04

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The Competition Authority
An tÚdarás Iomaíochta

RETAIL PHARMACY BUSINESSES REGULATIONS 2008

Draft Regulation 5

1.1 Draft Regulation 5(1)(a) provides that the pharmacy owner and the superintending pharmacist must ensure that the management and administration of the sale and supply of medicines is "*under his or her personal control*".

a) However, if the pharmacy owner is a corporate body, such management and administration could not, by definition, be under "*personal* control".

b) Even if management etc. could be under the "personal control" of a corporate owner, such personal control could not be exercised simultaneously by two entities – if it could, it would not be "personal".

1.2 The same issues seem to arise throughout the various other provisions of Draft Regulation 5.

Draft Regulation 8(2)

1.3 There appears to be something missing in the introduction to this sub-Article ("*Paragraph (1)(a) shall not apply to until the 30 April 2011*").

Draft Regulation 14 – Offences

1.4 This provides that six specified provisions of the Regulations are "*relevant provisions*" under section 18(3) of the Pharmacy Act 2007 ("the 2007 Act"). This means that breach of any of these provisions would be subject to significant penalties under section 72 of the Act (including up to 10 years imprisonment for conviction on indictment of a second offence).

1.5 While most of the offences provided for appear to be clear, that proposed under draft Regulation appears to be too vague. The Regulation should specify how the products concerned are to be disposed of, as otherwise a person cannot know whether or not they have complied with it. One person's standard of safety may not be another's.

1.6 More importantly, however, it appears that no offence is being created for breaches of any of the <u>other</u> provisions of the draft Regulations (i.e. other than the breaches specified in draft Regulation 14). The reason for such large-scale omission is not apparent – there seems little point in creating significant statutory duties on retail pharmacy businesses, if (a) no offence is proposed to be created for any breach of such duty, or (b) no penalty is provided for. If some residual sanction is in fact intended for breach of the bulk of duties created by the draft Regulations – for example, exposure to investigation, reprimand, censure etc. by the Pharmaceutical Society of Ireland – this should be made clear in the Regulations.

Prices of medicinal products

1.7 These Regulations apply generally sensible requirements to retail pharmacy businesses, for the purpose of protecting and enhancing the health and safety of consumers. However, the preamble to section 18(1) of the 2007 Act also refers to regulations being made for the convenience of the public.

1.8 The Competition Authority considers that it would be a great convenience for the public to be given more price information about medicinal products, ideally before they purchase such products. It would also assist price competition between retail pharmacies, particularly where the consumer was paying the full price of the product without assistance from the State.

1.9 The display of retail prices is compulsory in certain other areas, e.g. petrol, alcohol sales. If the 2007 Act allows for such a requirement in the case of medicines (perhaps via section 18(1)(i) or through some other mechanism), this should be provided for. Such provision would require retail pharmacists to

a) advise individual consumers, in advance of filling drug prescriptions, of the price(s) they propose to charge, broken down between product price and dispensing fee (if any)

b) display on all prescription labels the final price of all dispensed items,

c) have available, and allow customers to access, price databases for prescribed medicines before purchase (e.g. by touch screen or similar technology.