

Dear Superintendent /Supervising Pharmacist

**Re: Supply of medicinal products containing paracetamol**

I wish to draw to your attention a report recently published in the Irish Journal of Medical Science, (DOI 10.1007/s11845-008-0270-8) entitled “Paracetamol availability in pharmacy and non-pharmacy outlets in Dublin, Ireland”. The contents of this report are of particular interest to superintendent and supervising pharmacists with reference to their accountabilities under the new regulatory system established under the Pharmacy Act 2007.

As you are aware the sale and supply of medicinal products containing paracetamol in this country is governed by provisions of the Medicinal Products (Prescription and Control of Supply) Regulations, 2003 to 2008 and also by the Regulation of Retail Pharmacy Businesses Regulations 2008. I enclose for your attention a copy of the Practice Notice issued by the PSI Standards and Practice Unit which was updated to reflect legislative changes that came into effect on 1<sup>st</sup> December 2008 and your attention, in particular, is drawn to the following;

- The supply of any medicinal product containing paracetamol, from a pharmacy, must always occur **by or under the personal supervision** of a pharmacist, irrespective of the pack size or formulation provided.
- The supply of a greater quantity in any one transaction of the relevant tabulated amounts must occur **by a pharmacist** and must comply with the requirements that -
  - a pharmacist **personally interviews** the individual requesting such supply and be satisfied that it is safe in the circumstances to facilitate such supply, and
  - the total quantity supplied does not exceed fifty (50) dosage units, or in the case of a product not in tablet, capsule or similar form, two packs.

Article 10 of the Regulation of Retail Pharmacy Businesses Regulations, 2008, sets out the professional role of the pharmacist in the partnership management and facilitation of self care by the patient. This provides that legislative accountability lies with the owner, the superintendent and the supervising pharmacist to ensure that in the course of a sale or supply of a medicinal product, other than supply on foot of a prescription, and prior to such sale or supply, to ensure that a pharmacist is satisfied that the purchaser/recipient of the product is

- aware of the appropriate use of the medicinal product,
- that it is being sought for that use, and
- in so far as the pharmacist, is aware, the product is not intended for abuse and/or misuse.

It is therefore necessary that appropriate governance systems are in place in each individual pharmacy, and, for that purpose, superintendent pharmacists must ensure that operational policies and procedures relating to the supply and the counselling to be provided are in place in each pharmacy and that such criteria are complied with by all pharmacy staff in their supply of medicinal products.

The PSI is, in the interest of the health, safety and welfare of patients, charged with the regulation of the practice of the profession of pharmacy and is accountable for fulfilling this role. The commencement of Part 7 of the Pharmacy Act 2007 on the 29<sup>th</sup> November 2008 is relevant to this responsibility, and in the pursuance of this the Inspection and Enforcement Unit intends to conduct a number of monitoring inspections shortly which will include assessment of the adherence to the provisions governing the sale and supply of such medicinal products, including, in particular, those containing paracetamol .

Yours sincerely

Damhnait Gaughan  
Head of Standards and Practice

## PRACTICE NOTICE

### Supply of Products containing Paracetamol

The supply of medicinal products containing Paracetamol, in both pharmacy and non-pharmacy outlets, is governed by specific provisions detailed in the Medicinal Products (Prescription and Control of Supply) Regulations, 2003-2008. The supply of a product containing Paracetamol, from a pharmacy, must always occur by or under the personal supervision of a pharmacist, irrespective of the pack size or formulation provided.

The regulations provide that, except in accordance with a prescription, products containing paracetamol may only be supplied in the following specified circumstances.

Dosage strength and form	Pharmacy only	Non-pharmacy outlet
Dosage unit containing more than 120mg but not more than 500mg of Paracetamol.	Pack size of 24 units or less	Pack size of 12 units or less
Dosage unit containing more than 500mg but not more than 600mg of Paracetamol.	Pack size of 20 units or less	Pack size of 10 units or less
Dosage unit containing more than 600mg but not more than 1000mg of Paracetamol.	Pack size of 12 units or less	Pack size of 6 units or less
Dosage unit containing not more than 120mg of Paracetamol intended for use in children under 6 years of age	Pack size of 24 units or less	Pack size of 12 units or less
Liquid formulation containing not more than 120mg of Paracetamol per 5mls intended for use in children under 6 years of age	Pack size of 140mls or less	Pack size of 60mls or less
Liquid formulation containing not more than 250mg of Paracetamol per 5mls intended for use in children over 6 years and under 12 years of age other than a product intended for use in children under 6 years of age.	Pack size of 140mls or less	N/A
Liquid formulation containing not more than 250mgs of Paracetamol per 5mls other than a product intended for use in children under 6 years of age		Pack size of 60mls or less
Liquid formulation containing not more than 250mgs of Paracetamol per 5mls, other than a product intended for use in children under 6 years of age or a product intended for use in children between the ages of 6 and 12years.	Pack size of 240mls or less.	N/A

The supply of a product containing Paracetamol by or under the personal supervision of a pharmacist in a pharmacy, or from a non-pharmacy outlet, is restricted to the quantities as specified in the above table, in any one transaction.

In certain circumstances, however, and only in a pharmacy a greater amount may be supplied. This supply is predicated on the requirement that the pharmacist personally interviews the patient requesting the product, and that he or she is satisfied that it is safe, in the circumstances, to supply the product.

For products where the dosage unit is in the form of a tablet or capsule, or other similar pharmaceutical form, the total quantity supplied may be up to fifty dosage units. For a product which is formulated in any other manner two packs only may be supplied.

It is also a requirement that for over-the counter supply of medicinal products containing Paracetamol, which are formulated in a solid unit dosage form, must be supplied in blister packing, or an equivalent as determined under its product authorisation.

The regulations also provide for particular statements that shall appear on the outer packaging of a medicinal product, or on its immediate packaging if there is no outer packaging, , and also for statements that shall appear on the package leaflet.

Practitioners are reminded of these controls to ensure the safe and appropriate management of the supply of Paracetamol containing products in the interest of the health, safety and welfare of patients.

The full text of the amendment Regulations may be accessed at  
[http://www.dohc.ie/legislation/statutory\\_instruments/pdf/si20080512.pdf](http://www.dohc.ie/legislation/statutory_instruments/pdf/si20080512.pdf)