

Distribution of Professional Use Only Products

Professional use products are not intended to be available for direct sale to the public due to special considerations such as:

- potency,
- route of administration,
- indications unsuitable for direct consumer use,
- the necessity of professional guidance,
- package size as related to safety
- other special considerations

These include products such as dental use drugs, surgical use antiseptics and other products that are not considered to be prescription drugs but are used or dispensed directly in the health care practice by the professional. Distribution of these products is most often directly to the practitioner or institution such as a hospital, so that distribution in retail outlets is not frequent. The labeling of these products usually indicates that they are for professional use only and is often distinct so that they cannot be mistaken for consumer products.

Further, this is to clarify the issue of selling ASA 80mg in containers exceeding 1.92 grams (i.e. more than 24 tablets of 80mg per tablet) and labeled “For Professional Use Only”.

- Section C.01.037 of the Food and Drugs Regulations states in part:

*“(1) No person shall sell to the general public a drug that is recommended solely for children if the package in which the drug is sold contains (a) more than 1.92 gram of salicylamide or salicylic acid or the equivalent quantity of a salt of salicylic acid.
(2) Subsection (1) does not apply to a drug dispensed pursuant to a prescription.”*

- It is mandatory for the manufacturer to package ASA 80 mg in a child resistant package,
- Because analgesia and antipyresis in children are the only approved indications for 80 mg ASA, pharmacists are prohibited from selling packages of ASA exceeding 1.92 gram (i.e. more than 24 x 80 mg tablets) for both children and adults, **UNLESS** the product is being dispensed pursuant to a prescription, and the contents are labeled accordingly,
- Pharmacists may purchase packages of 80 mg ASA exceeding 1.92 grams. Such packages must be broken down so as not to exceed 1.92 grams (24 0x 80 mg) prior to nonprescription sale,
- When dispensing packages of ASA 80 mg in package labeled “For Professional Use Only”, the product should be repackaged, rather than over-labeling the manufacturer’s original package with the prescription label,
- ASA, intended for use in children, is a Schedule II drug. Sales can only be made by a pharmacist, or intern under the immediate supervision of a pharmacist, and must be sold from an area of the pharmacy to which there is no public access and no opportunity for self-selection.