

Guidelines Regulating Advertising and Promotion of Non-prescription Medicines in Egypt

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➤ Introduction:

Pharmaceutical promotion influences how doctors and pharmacists choose: to prescribe and dispense medicines. These decisions may, however, lead to sub-optimal treatment choice to damage public health and escalate health care costs. Irrational use of medicines resulted due to inappropriate treatment, waste of resources and increased drug resistance. Many countries either depend on the pharmaceutical industry to self-regulate promotional activities through voluntary control practice or have introduced a legislative framework. Regulating marketing and promotional materials related to drug advertising is not only an ethical obligation. It is of serious health concern essential to support, encourage and promote rational drug use.

The phenomenon of unethical drug promotion practices is common worldwide; its severity is more deep rooted in developing countries. Pharmaceutical industry spends a substantial portion of its budget on market research, but do not carry out adequate research on unethical promotion practices.

Egypt relatively has a large number of registered pharmaceuticals on the market, ultimately leading to one of the highest worldwide pharmaceuticals expenditures per total health expenditures. To face this challenge, Egyptian drug authority has also directed its attention to marketing promotional materials distributed by pharmaceutical companies, with particular attention paid to health claims so as not to mislead healthcare practitioners. It is of a pressing need indeed because the issue of recertification (whether for physicians or pharmacists) is not widely encountered by respective syndicates. With day-to-day new drug discoveries and warnings, it is imperative to regulate drug promotion. All this is in compliance with WHO recommendations and guidelines of the field.

Our Ultimate goal is to allow pharmaceutical companies to practice fair and transparent promotion, deliver accurate and updated health claims with adequate warnings to health practitioners. This requires a strong and cohesive effort and collaboration between, pharmaceutical companies, drug regulatory authority and healthcare practitioners. Improving patients' health, wellbeing and therapy outcomes is our focal point and our joint ethical, professional and responsibility.

➤ Definitions:

1. Advertisement & Promotion:

The two terms are used interchangeably and include any activity undertaken, organized or sponsored by a member company which is directed at healthcare professionals or public to promote the prescription, recommendation, supply, administration or consumption of its products through all media.

2. Healthcare Professional:

Any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product.

3. Nonprescription products:

Nonprescription drugs are defined as drugs that are generally safe and effective when used in appropriate doses for use by general public and they can be available to consumers without a prescription from a physician, however, people are encouraged to consult pharmacist prior to use.

➤ Types of Materials (Scope):

1. Printed promotional material to be distributed E.g. Newspapers, Magazines, Booklets, Flyers and Consumer leaflets.
2. Printed promotional material for display purposes only E.g. Banners, Panels, Posters, Stands and Posts, outdoor advertising including billboards.
3. Audiovisual media. E.g. cinema, television or radio commercial, audiotapes, videotapes.
4. Electronic media advertising, such as websites, press releases intended for internet publication, and other on-line advertisements and social media.
5. Others. For examples: promotional scripts for use by telephone help lines, promotional text messages, aerial promotions such as hot air balloons, advertisements on wall fences and motor vehicles, sports, art and other sponsorships, promotional sponsorships for radio and TV programs and so on.

➤ Advertising Guidelines

➤ General Rules:

- Products subjected to these guidelines are the products classified as Non- Prescription Medicines in Egypt classification of medicines.
- Non- Prescription Medicines are defined as:
- Non- Prescription Medicines list may include products defined in the pharmacy law act no. 127/1955 article 58 or other products regulated and controlled by the Central Administration of Pharmaceutical Affairs.

➤ Prohibition on advertising unlicensed medicines

Non- Prescription Medicines which do not have a valid marketing authorization license (registration license). It may not be advertised for medicinal purposes. It is in breach of the regulations to issue any promotional material for a licensable medicine until the license has been granted

○ Quality standards

An advertisement must:

1. Comply with the particulars listed in the approved insert leaflet (if it can be assessed).
2. Encourage the rational use of the product by presenting it objectively and without exaggerating its qualities and,
3. Not be misleading.

Box 1:

(1) Compliance with the approved insert leaflet:

An advertisement must not promote a medicine outside the therapeutic indications listed in the approved insert leaflet for that medicine. This means an advertisement cannot promote a medicine for use in treating or preventing conditions or illness for which it has not been licensed. Nor can an advertisement promote a medicine for use by a patient group not indicated. For example, an advertisement with a baby where the NPM was not indicated below the age of 2 years would violate this provision.

An advertisement may include statements not included in the approved insert leaflet provided that these can be substantiated and are not inconsistent with the approved insert leaflet information. A claim that went beyond specific information included in the approved insert leaflet would be likely to breach this provision.

(2) Encouraging rational use

An advertisement must encourage the correct and proper use of medicine, this is appositive obligation. This might include; when a medicine should be taken, how much should be taken, the route of administration, by whom it should be taken and special precautions.

An advertisement must present information which is factually correct and those facts should not be

Exaggerated in any way by the presentation of the advertisement. For example: An advertisement for a product offering symptomatic relief should not imply that it cures the Underlying condition.

An advertisement would not be objective if it failed to refer to any significant limitations that were relevant to the claims made for the product. Similarly an advertisement that includes data, trials or studies that are not presented accurately or in context would be considered as exaggerating the properties of a product. Where a relative change is quoted, the absolute values should also be given to enable the reader to fully assess the magnitude of the claimed benefit.

(3) Not misleading:

Advertisement must not lead to an incorrect belief of any nature about the medicine.

Unrealistic or inappropriate images can give rise to misleading expectations about the product or the indicated patient population. An example could be the use of a driving image in an advertisement for a medicine where caution is required over impairment of driving ability.

- Who is responsible?

The primary responsibility of the content and dissemination of all advertising and promotion of a medicine lie with the license holder, who is also responsible for the training and conduct medical representatives.

- Keeping records

- A license holder also has a duty under the regulations to keep samples of advertising materials available.

- The MOH has power to require copies of any published advertising from any person appearing to be involved in its publication.

- To comply with these legal requirements, the MOH considers that the minimum time that materials should be kept for by license holders and/or other parties is a period of 3 years after either the date of approval.

- The MOH maintains records of complaint cases for a period of 5 years from completion of any action.

- Prohibition of direct consumer advertisement of prescription medicines

The regulations prohibit the issue of any advertisement wholly or mainly directed to the general public which is likely to lead to the use of a prescription only medicine(POM).

Government controlled vaccination campaigns that have been approved by health ministers are exempt from this prohibition.

- Advertising should not give the impression that a medical consultation or surgical operation is unnecessary, for example by offering a diagnosis or suggesting treatment by post, electronic communication or telephone.

- An advertisement for medicine must not: be likely to lead to consumer self diagnosing or inappropriately treating potentially serious diseases.

- There should be a clear and legible invitation to read carefully the instructions on the leaflet contained within the package or on the label as the case may be. A reference to the label alone should be made only where no leaflet is provided or where the label carries a clear and specific instructions to refer to the enclosed leaflet.

- Promotional material should indicate the target audience (HCPs or public) and include references in support of claims in the promotional material.

- Print media advertisement must include the approval number which is to stand alone be prominently displayed and located in the bottom right hand corner of the advertisement.

➤ References:

- For a certain piece of information that is mentioned in the approved insert leaflet, no contradicting or different data from any reference are to be mentioned in an advertisement.
- Only full published articles are to be submitted, no abstracts are to be accepted as references.
- Data from different references is to be clearly separated, and no framing in this case is allowed.
- References are to be written in this form: the name of the author, the title of the reference in details, the name of the journal, the year of the publishing.
- Data from studies made on a particular brand are only to be used for the generics using the active ingredient name.
- Claims form clinical studies are only to be coming from conclusions complying with the predetermined primary or secondary endpoints, without omitting of phrases that may change the meaning or leading to ambiguity.
- Exaggerated or non- scientific claims or slogans are not to be approved, will be subject to committee decision.
- Minimal information on a presented clinical study should at least be mentioned in the promotional material to determine the quality of the study and the value of its result, this includes:
 - A. Study methodology & objective.
 - B. Dosage.
 - C. Treatment duration and follow up.
 - D. Number of patients involved for each arm of the study if possible.
 - E. Statistical significance.
 - F. Specifications (if any) on race, age of subjects
- Non-clinical studies (ex: in-vitro, ex-vivo, preclinical evidences) are not to be considered except for affinity, selectivity data & claims that can't be supported by clinical evidence.

➤ Product Characteristics

➤ Product Representation

- The advertisement must include the product's therapeutic indication. In addition, non-therapeutic and/or cosmetic claims may be presented, providing these do not obscure the therapeutic indication or suggest a therapeutic benefit. The emphasis should always be on the therapeutic effect.

Application

The advertised product must not be represented as food or cosmetic

Example:

Calcium supplement (chocolate chew format)

- Acceptable claim: "Try product X calcium supplement, it is a delicious way to get extra calcium"
- Unacceptable claim: "Try product X for a tasty chocolate treat"

Application

Example:

Anti-dandruff shampoo; indication: controls flaking, scaling and itching associated with dandruff.

- Acceptable claim: "Product X shampoo controls dandruff flakes and it has a moisture rich formula for shiny hair".
- Unacceptable claim: "Use product X shampoo because it has a moisture rich formula" (with emphasis on the cosmetic attributes and no reference to the therapeutic claim).

➤ Indication / Recommendation Use – single Medicinal Ingredient:

- The advertisement must clearly communicate the intended therapeutic use for the product as per its insert
- Advertisement must include at least one indication for use of the product. All advertising must reflect the approved indication accurately and in its entirety.
- For treatment of the specified condition where the condition includes a reference to its severity e.g. mild or moderate, this should be included. Words or illustrations should not suggest that a more serious degree of the condition can be treated.

Application

For single Medicinal Ingredient / single indication products the product's sole indication must be presented in the advertisement

Example:

Cough syrup, indication: for relief of dry coughs

- Acceptable Claim: "Product X relieves dry coughs so that you can get on with your day"
- Unacceptable Claim: "Product X lets you can get on with your day" (without reference to the therapeutic indication)

Application

For single Medicinal Ingredient / multiple indication products: at least one indication must be presented in the advertisement

➤ Indication / Recommendation Use – Multiple Medicinal Ingredients:

The advertisement must clearly communicate the symptoms that the product is intended to treat/relieve or the intended therapeutic use as per product TMA.

Application

For multiple medicinal ingredients / multiple indication products: at least one symptom per medicinal ingredient must be presented in the advertisement (it is acceptable to give prominence to one symptom)

Notes:

- This does not apply in cases where multiple ingredients relieve/treat a single symptom/condition.
- For multi-vitamin/multi-mineral supplements, it is sufficient to include the therapeutic indication of “vitamin supplement”/ “mineral supplement”.

Example:

Cough/Cold Preparation with 3 medicinal ingredients (guaifenesin, dextromethorphan, chlorpheniramine). Indication: Relieves chest congestion, dry cough and runny nose

- Acceptable Claim: “Got a miserable cold? Product X relieves your hacking cough, plus chest congestion and runny nose”
- Unacceptable Claim: “Got a miserable cough? Try product X to relieve it”

Application

For Advertisement solely promoting a family of products including both single and multiple ingredient formulations, it is sufficient to include a general “symptom relief” statement.

Example

Brand X Family of Cough and Cold Products. A product line of single and multi-ingredient cough and cold liquids and capsules containing one or a combination of the following active ingredients:

Acetaminophen

Dextromethorphan

Guaifenesin

Chlorpheniramine

- Acceptable Claim: Visuals: beauty shot of various Brand X cough and cold products “For your cough and cold symptoms, there’s a Brand X product for you”
- Unacceptable Claim: Visuals: beauty shot of various Brand X cough and cold products “For your cough there’s a Brand X product for you”

➤ Direction for use/ dosage and administration:

- An advertisement must not be misleading as to the Direction for use/ dosage and administration.
- An advertisement must encourage the correct and proper use of a medicine, this is a positive obligation. This might include when a medicine should be taken, the route of administration, by whom it should be taken and special precautions.

Application

When described or depicted, Direction for use/ dosage and administration must be consistent with the products approved insert leaflet

Example:

Wart remover .direction for use: apply every 2 days for 12 weeks until wart is gone.

- Acceptable Claim: “Remove warts. Use as directed”
- Unacceptable Claim: “Remove warts in one easy step”

Application

Depictions of ingestion must be consistent with the products approved insert leaflet

Example:

Cough syrup .direction for use two teaspoons every 4 hours.

- Acceptable depiction: Women swallowing a teaspoon of syrup
- Unacceptable depiction: Women drinking directly from the bottle

➤ Duration of Action:

- An advertisement must not be misleading as to the duration of action of the advertised product.
- Claims for fast action should be related to a condition where speed of onset is relevant and may not be appropriate for chronic conditions or those not requiring immediate relief.
- The time scale for which “fast” claims are appropriate will depend on the clinical indication and the speed of action of other products in the category. It is unlikely that a time to onset of relief of more than 30 minutes would be considered to be “fast” for a product for relief of an acute condition.
- For a 24-hour relief claim, data must show clinical effect over the 24-hour period. The product should be for once daily dosing but a once daily dosing interval alone is insufficient to support a 24-hour claim.

Application

When described or depicted, the duration of action must be consistent with the products approved leaflet insert.

Example:

Analgesic: Indication / Use: relieves headache for up to 8 hours.

- Acceptable Claim: “Product X relieves headache for up to 8 hours”
- Unacceptable Claim: “Product X relieves headache all day long”

Application

Duration of pharmacological action must not be equated by duration of relief unless supported by the products approved leaflet insert. Dosing interval must not be equated with duration of action or duration of relief unless supported by the products approved insert leaflet

Example:

H2-antagonist: Indication / Use: Controls acid for up to 12 hours; relieves heartburn.

- Acceptable Claim: “Product X controls acid for up to 12 hours and relieves heartburn”
- Unacceptable Claim: “Product X relieves heartburn for up to 12 hours”

➤ Duration of Use:

- An advertisement must not be misleading as to the recommended duration of use of the advertised product.

Application

When described or depicted, the duration of use must be consistent with the product's approved leaflet insert. When a product must be used for a specific period of time to obtain the desired effect, this information must be included in the advertisement.

Example:

product X Glucosamine: Indication / Use: effective in reducing joint pain. Use for minimum of 2 months to see beneficial effect

- Acceptable Claim: "Product X Glucosamine reduces joint pain when used for at least 2 months"
- Unacceptable Claim: "Product X Glucosamine reduces joint pain quickly"

Application

Products intended for short term/occasional use must not be represented for long term/chronic use.

Example:

Antacid: Indication / Use: For the relief of occasional heartburn

- Acceptable Claim: "When heartburn strikes, try Product X for relief"
- Unacceptable Claim: "When living with daily heartburn, use Product X for relief"

➤ Efficacy:

- An advertisement must not be misleading by directly or indirectly exaggerating the degree of relief/benefit to be obtained from use of the advertised product.
- Efficacy claims are to be specific.
- Efficacy claims are to be from clinical studies and not from ex-vivo, in-vitro, or any preclinical evidences (ex: on affinity, selectivity or the pharmacological profile).
- High adverse events rate or incidence (if any) accompanying high efficacy in a clinical study are to be clearly mentioned as the efficacy claims obtained from the clinical study.
- Superiority /More efficacy claims are to be from clinically &statistically significant results of at least one comparative head-to-head clinical study

Application

When described or depicted, efficacy claims must be consistent with the product's approved leaflet insert.

Example:

Acne medicine: Indication / Use: helps treat and keep skin clear of new acne pimples.

- Acceptable Claim: "Product X helps treat and keep skin clear of new acne pimples"
- Unacceptable Claim: "Product X cure acne"

➤ Medicinal Vs. Non-medicinal Ingredients:

- Product benefits must not be presented in a manner that misleads the consumers, as to the nature of either the medicinal (therapeutic) or non-medicinal (non-therapeutic) ingredients

Application

No medicinal (therapeutic) benefit can be directly or indirectly attributed to a non-medicinal (non-therapeutic) ingredient.

Example:

Product X Cough Syrup (honey flavored): Indication / Use: For relief of dry coughs (as per the product's approved leaflet insert, honey is a non-medicinal [nontherapeutic] ingredient)

- Acceptable Claim: "Product X cough syrup relieves your dry cough and the honey coats your throat to provide a soothing sensation"
- Unacceptable Claim: "Try Product X cough syrup – soothing honey relieves your dry cough"

➤ Onset of Action:

- An advertisement must not be misleading as to the time to onset of action of the advertised product.

Application

- When depicted or described, the onset of action must be consistent with the product's approved leaflet insert, i.e., claims for action within a specific time period are only permitted if contained in the product's approved leaflet insert.

Example:

Antacid: Indication / Use: Relieves heartburn in 30 minutes

- Acceptable Claim: "Product X relieves heartburn in 30 minutes"
- Unacceptable Claim: "Product X Relieves heartburn in minutes"

Application

Time to onset of action must not be equated with time to onset of relief, unless clearly specified in the product's approved leaflet insert.

Example:

Analgesic: Indication / Use: Relieves headache in 45 minutes (the approved leaflet insert states tablet dissolution of 10 minutes)

- Acceptable Claim: "Product X dissolve in 10 minutes and provides headache relief in 45 minutes"
- Unacceptable Claim: "Product X dissolve in 10 minutes to provide fast relief"

➤ Claims and representation

The examples provided are for guidance only. The ultimate acceptability of any claim must be evaluated within the overall context of the advertisement.

➤ Absence of Ingredient Statements:

- An advertisement must not include an absence of ingredient claim in a manner that creates an erroneous impression about the advertised product or competitor product(s).

Application'

Absence of ingredient statements for medicinal and non-medicinal ingredients are acceptable under the following conditions:

Medicinal:

- The statement provides useful and easily identifiable information to the consumers that reinforces existing labeling and aids consumer medication selection.
- The statement to the effect that an ingredient has been removed from a product due to a regulatory amendment should only be used for a limited time (i.e. one year assuming continuous marketing or longer depending on circumstances e.g. one season where products are only marketed seasonally) from the time of the application of the amendment.
- For single ingredient products, the absent ingredient is of the same product class or has the same therapeutic effect as the actual medicinal ingredient.
- For multiple ingredient products, the absent ingredient would likely be found in a combination product of that type.
- There is no misleading representation as to the safety and merit of the absent ingredient.

Example:

Product which does not contain phenolphthalein

- Acceptable Claim: "Reformulated. Now phenolphthalein-free"
- Unacceptable Claim: "Reformulated. Now safer since phenolphthalein-free"

Non-Medicinal:

- The statement provides useful and easily identifiable information to the consumer to aid in product selection for secondary non-therapeutic attributes such as taste, odor, caloric content, allergic potential or other meaningful attribute.
- The statement to the effect that an ingredient has been removed from a product due to a regulatory amendment should only be used for a limited time(i.e one year assuming continuous marketing or longer depending on circumstances e.g. one season where products are only marketed seasonally) from the time of the application of the amendment.
- The statement is accurate.
- There is no direct or indirect implication that the absent ingredient is medicinal.

Example:

Product which does not contain gelatine

- Acceptable Claim: “Gelatine-free”
- Unacceptable Claim: “More effective since gelatine-free”

Application

Sweetening Agents:

- A product can be described as “sugar free” if it contains none of the chemical classes of sugar, including sugar alcohols.

Example:

Product X cough syrup (sweetened with aspartame – artificial sweetener)

- Acceptable Claim: “Product X cough syrup is sugar-free”

Example:

Product X cough syrup (sweetened with mannitol – sugar alcohol)

- Unacceptable Claim: “Product X cough syrup is sugar-free”

➤ Absence of Side Effect Statements:

- An advertisement must not include a claim for an absence of side effect in a manner that creates an erroneous impression about the advertised product or competitive product(s).
- Absence of side effect statements are acceptable under the following conditions:
 - The weight of scientific evidence exists to support the statement, e.g., incidence of side effect is compared to placebo and is consistent with the product's term of market authorization.
 - The side effect is associated with comparable components of that class.
 - No unnecessary emphasis on statement.
 - The statement provides practical information (i.e., the side effect or benefit can be readily identified by the recipients).

Example:

Cold Medicine Indication / Use: Relieves cough and nasal congestion

- Acceptable Claim: "Product X relieves your cough and stuffy nose and it won't make you sleepy"
- Unacceptable Claim: "Get cough and nasal congestion relief, plus an energy boost"

➤ Children:

- Advertising should not be directed to children.
- An advertisement must not be misleading by suggesting that a child is capable of making a rational decision regarding the use of the advertised product.
- Advertising materials aimed at parents and carers should not be included in non-promotional materials aimed at children.
- Special care should be taken in advertisements depicting children and young people.

Application

- Drug advertising must be directed to adults
- An advertisement must not depict or encourage unsupervised use of drugs by children or suggest that a child can self-diagnose or self-medicate
- Advertisement must not depict product storage in locations accessible to children.

Example:

Cough Syrup:

- Acceptable Depiction:
Child and father depicted with father holding product bottle and spoon.
- Unacceptable Depiction:
Child: "Daddy always gives me this syrup when I cough, so I'm going to take it now"
Child depicted self-administering product.

➤ Clinically Tested / Proven:

- An advertisement must not be misleading with respect to use of the statement “clinically tested/proven”.

Application

- Claims for “clinically tested/proven” with respect to the product’s therapeutic attributes, are limited to those included in the product’s approved leaflet insert. Results from clinical studies that would expand the scope of permissible advertising claims cannot be used in advertising until such claim(s) are authorized by MOH.

Example:

Analgesic: Indication / Use: Relieves arthritis pain

- Acceptable Claim: “Clinically proven to relieve arthritis pain for up to 8 hours” (where clinical data is available to support duration of action)
- Unacceptable Claim: “Clinically proven to relieve arthritis pain for up to 8 hours” (where clinical data does not support “8 hours” claim)

➤ Comparative Claims – Therapeutic/ Non-therapeutic Comparisons:

- Advertising to the general public should not suggest that one product is better than (or equivalent to) another treatment or product.

➤ Endorsements / Seals:

Recommendations and endorsement

- An advertisement to the general public should not contain materials which refer to recommendations by scientists or health care professionals or which refer to recommendations by celebrities who because of their celebrity could encourage consumption of products.
- Advertisers should not suggest that their product is “special” or different from or better than other products only because it has been granted a marketing authorization or registration.
-
- Endorsements by or seals of recognized medical or educational entities are acceptable, providing the terms of the recognition are consistent with the product’s approved leaflet insert.
- Note. The advertiser should provide written material from the endorsing agency describe the nature and scope of the endorsing agency and the nature and scope of the product recognition
-
- Combination recommendations or first-line treatment recommendation or any type of recommendations are to be coming from updated international guidelines and these claims must clearly state that they are: “according to name of the guideline/the year”.

Example:

- Acceptable Endorsement: “Product X, in our opinion, is effective in
- Unacceptable Claim: “All doctors recommend using product X”

➤ Product Merits:

- An advertisement must not mislead consumers by exaggerating product merit.
Advertisement should not mislead or contain any exaggerate claims either direct or implied.
- An advertisement must avoid, overstatements and exaggeration i.e., the sole, the unique, best product, be aware of imitation... etc.
- It is not appropriate to refer to any medicine as “essential” in advertising. Medicines are indicated for people suffering from a specific condition rather than the general population, and they may not be suitable for everyone.

Application

It is unacceptable to exaggerate the severity of the condition that can be relieved with the advertised product.

Example:

Analgesic Indication / Use: For the relief of mild to moderate migraine pain

- Acceptable Claim: “Product X provides migraine pain relief”
- Unacceptable Claim: “Product X relieves severe migraine pain” (in words or depiction)

Application

It is unacceptable to use superlative terminology to exaggerate therapeutic property of a product unless supported by its insert.

Example:

Antacid:

- Acceptable Claim: “Effective formula/relief”
- Unacceptable Claim: “Amazing formula/relief”

Application

It is unacceptable to suggest that use of the promoted product is a substitute for good health practices and a healthy lifestyle.

Example:

Antacid:

- Acceptable Claim: “Use Product X for the relief of occasional heartburn”
- Unacceptable Claim: “since I discovered product X I can eat whatever I want”

➤ Extra Strength / Maximum Strength:

- An advertisement must not be misleading by suggesting that an “extra” strength product provides a greater benefit than a “regular” strength product in cases where both are indicated for the same condition.

Application

It is not acceptable to suggest that there is a correlation between the amount of medicinal ingredient and degree of efficacy unless this is part of the product’s patient insert leaflet.

Example:

Antacid

- Acceptable Claim: “use product X for the relief of occasional heartburn”
- Unacceptable Claim: ““since I discovered product X I can eat whatever I want”

Example:

Antacid tablets: 200 mg Regular Strength - 300 mg Extra Strength - 400 mg Ultra Strength

Indication / Use (all strengths): For relief of occasional heartburn

- Acceptable Claim: “When you’ve got occasional heartburn, choose Product X antacid. Available in 3 strengths”
- Unacceptable Claim: “When you’ve got occasional heartburn, choose Regular Strength Product X antacid. When you’ve REALLY overdone it and you’ve got bad heartburn, choose Ultra Strength Product X for relief of extreme heartburn”

➤ Ministry of health Approved:

- Advertisers should not suggest that their product is “special” or different from or better than other medicines because it has been granted marketing authorization or registration.

➤ Graphics / Schematics / Statistics / Terminology:

- Graphics, language, schematics, statistics, and terminology used to present product features or characteristics must not do so in a manner that will mislead the consumer as to the therapeutic merits of the product.
- Graphs and charts are to be clearly indicate the source(s) of it and be faithfully reproduced
- Data represented in graphs and charts are to represent the result of the objective of the clinical study.

Application

- Risk information authorized for the consumer labeling including labels and consumer information documents should be presented to the consumer in absolute rather than relative terms.
- Scientific or technical information should be presented in terminology suitable for the target audience
- Advertisement must be simple & easy to understand. Confusing medical terms must be avoided.

Example:

Product X Authorized Risk Information: Incidence of side effect Y is reduced from 1 in 100,000 to 1 in 200,000

- Acceptable Claim: “Product X reduces the risk of side-effect Y from 1 in 100,000 to 1 in 200,000”
- Unacceptable Claim: “Product X reduces the risk of side-effect Y by 50%”

➤ Health / Healthy / Healthful:

- An advertisement must not be misleading by suggesting that a product may restore, maintain or promote health, unless such claims are included in the product's insert.
- The public promotion of a pharmaceutical product for human use shall not contain any material which:
 - Suggests that the health of the subject can be enhanced by taking the medicine.
 - Suggests that the health of the subject could be affected by not taking the medicine.

This prohibition shall not apply to the vaccination campaigns.

- Advertisers shall not give the impression that the normal lifestyle requires the use or consumption of a specific medical product.
- Advertisers must not claim that a certain medical product is essential for living within modern life pressures.
- An advertisement must not suggest that a certain medical product will enhance sportive or educational performance.

Application

It is unacceptable to make claims regarding health or promotion of health unless such claims are included in the product's insert.

Example:

Vitamin B1: Indication / Use: A factor in the maintenance of good health

- Acceptable Claim: "Product X Vitamin B1 helps maintain good health"
- Unacceptable Claim: "Product X Vitamin B1 makes you healthy"

➤ Implied / Indirect Claims:

- Implied or indirect claims must be consistent with the product's approved insert.
Application
- All elements of an advertisement will be considered when assessing conformity to the product's insert 1, (e.g., audio, visuals, placement of text, context, graphics, special effects).
- Photos and pictures are evaluated as claims and must be proved and be relevant without exaggerations.

Example:

Analgesic: Indication / Use: For arthritis pain relief

- Acceptable Claim: "Analgesic X relieves arthritis pain"
Visuals: Woman's gardening has been interrupted by her arthritis pain acting up.
Later on we see her resume her gardening since her arthritis pain has been relieved.
- Unacceptable Claim: "Analgesic X relieves arthritis pain"
Visuals: Woman's gardening has been interrupted by her arthritis pain acting up.
Later on we see her doing cartwheels in her backyard.

➤ Natural:

- An advertisement must not mislead a consumer to believe that a non-prescription drug or a natural health product is “natural” or “natural source (d)” if it is synthetically derived.

Application

- Natural: An ingredient can be described as “natural” if it is obtained from a natural source material, is in a form found in nature, and has undergone only the most minimal processing (e.g., drying, grinding, powdering, chopping, encapsulating). Example: encapsulated powdered garlic.
- Natural source: An ingredient can be described as “natural source” if it is obtained via extraction, isolation and/or processing of plant, algal, fungal, bacterial, or animal material or minerals. Processing can include such steps as boiling and steaming. The ingredient must have the same chemical identity as that in the source material. Ingredients found in nature that undergo chemical modification such as derivatives and salts are considered synthetic and not natural source.

Examples:

Vitamin E (d-alpha-tocopherol) isolated from soybean is natural source. The derivative, d-alpha-tocopheryl acetate, produced via chemical modification of vitamin E from soybean, is not natural source, nor is the totally synthetic dl-alpha-tocopheryl acetate.

- Multi-ingredient products:
 - Claims that one or several ingredients in a multi-ingredient product are natural/natural source are permissible.
 - Claims about a product, as a whole, being natural/natural source are permissible if this statement is true for all ingredients (medicinal and nonmedicinal).
 - Claims can also be made to the effect that a “product contains X% natural/natural source ‘Y’ ” where X is the actual percentage of ingredient Y in the product that is natural/natural source.
 - Advertising should not suggest a product does not have any side-effects or that its safety or efficacy is due to the fact that it is natural.

Example:

Product Y that contains 40% synthetic and 60% natural source vitamin C (ascorbic acid)

- Acceptable Claims: “Product Y is a source of vitamin C for the maintenance of good health. Product Y contains 60% natural source vitamin C for the maintenance of good health”
- Unacceptable Claim: “Product Y is a natural source of vitamin C for the maintenance of good health”

➤ Natural Action / Naturally:

- An advertisement must not be misleading by claiming that a product acts “naturally since all non-prescription drugs, including natural health products, modify the body’s physiological processes.
- A product’s therapeutic effect cannot be described as “natural” or “natural action/acting naturally”.

Example:

- Acceptable Claim: “Product X relieves symptom X by (authorized mechanism of action)”
- Unacceptable Claim: “Product X acts naturally to relieve ...”

➤ Need:

- An advertisement must not mislead consumers by suggesting that the advertised product is needed.
- It is not acceptable for an advertisement to claim that a consumer “needs” a specific product or ingredient. However, it is acceptable to suggest that an individual “needs relief” or treatment in cases where the condition will not resolve on its own.

Example:

Cough Syrup:

- Acceptable Claim: “Need relief of stubborn cough? Try Product X Cough Syrup”
- Unacceptable Claim: “For cough relief, you need Product X Cough Syrup”

Example:

vaginal antifungal product X:

- Acceptable Claim: “Need treatment for your yeast infection? Look to Product X”
- Unacceptable Claim: “got a yeast infection, you need Product X”

➤ New / Improved:

- The terms “new” and “improved” may be used only for a period of one year from the date of marketing a new formulation.
- The product attribute that is “new” or “improved” must be clearly specified, e.g., “improved taste”, “improved format”.

Example:

- Acceptable Claim: “new and improved tablet coating”
- Unacceptable Claim: “new and improved tablet ” (unqualified)

➤ Potent / Potency (See also: Power / Strength):

- An advertisement must not be misleading by referring to a non-prescription drug as being “potent” or having a “potent” formulation.

Application

- All non-prescription medicines contain sufficient medicinal ingredients to be effective as per their authorized therapeutic indications. Therefore, the relief to be derived from such products is an indicator of their effectiveness and not their “potency”.

Example:

Non-prescription Medicine”

- Acceptable Claim: “Effective formulation
- Unacceptable Claim: “Potent Formulation”

➤ Power / Strength:

- An advertisement must not be misleading by suggesting that a particular product contains more than sufficient medicinal ingredient to relieve/treat/prevent a particular condition or symptom.
- An advertisement must not be misleading by suggesting that there is a correlation between the amount of medicinal ingredient and degree of efficacy unless this is part of the insert.

Application

All drugs are formulated (i.e., contain sufficient medicinal ingredient) to be effective for the condition/symptoms they are designed to relieve/treat/prevent.

It is thus appropriate to claim that a product is “effective”, “strong enough”, or “tough enough”, for the condition or symptoms it is designed to relieve/treat/prevent. It is unacceptable to suggest that the product, in and of itself, is “strong” or “powerful”.

Example:

- Acceptable Claim: “Product X has the power to relieve condition Y”
- Unacceptable Claim: “Product X is powerful”

➤ Risk/Safety Information Communication:

- In order to make informed decision, consumers should be provided with fair and balanced information about the benefits and the risks associated with the use of the advertised product.
- Particulars in relation to side-effects, warnings and precautions and contra-indications, dosage and method of use and warnings should be clearly printed, legible and be placed in such a position in the advertisement to allow the reader to associate the various benefits and risks of using the product without difficulty.
- With regards to side-effects, those listed in the insert for certain products may be quite extensive. As a minimum, the information should indicate all the common-side and also those which are rarer but may be serious together with an indication that other uncommon side-effects are listed in the approved insert leaflet; it is also recommended that advertisements should include a reminder giving information on reporting suspected adverse events.
- Where an advertisement is directed at treatment of particular group of patients, companies should ensure that the information includes all the relevant insert particulars, for example where a product is being promoted for use in children, the particulars should convey all the information in the approved insert leaflet relevant to that group. This would probably dictate greater detail than would be required in an advertisement for the same product targeting a more general patient population

Application

Consumer should always

- Be advisable to read the label and follow direction for use for the advertised product
- Where there are known risks be provided with a general risks/cautnary statements that the advertise product may pose risks and may not be suitable for every one(or similar words)

○ Technical requirements:

- Visual disclosures (supers) in broadcast advertisements shall always be of a size, shade and duration sufficient for an average person to read and comprehend it.
- The general risk/cautionary statement should be verbally communicated in television and radio messages in a clear and understandable manner.
- Disclosures in print advertisements shall always be in a type size and location sufficiently noticeable for an average person to read and comprehend it.

Example:

Cold product X

- Acceptable Claim: “Product X is suitable for adults over 18 years of age looking for relief cough, cold and flu symptoms”. Product X may pose risk and may not be suitable for everyone. Read the label and follow directions for use. Additional balanced information may be obtained by calling xxx-xxxxx or by consulting the website xxxx
- Unacceptable Claim: “Product X is suitable for adults over 18 years of age looking for relief cough, cold and flu symptoms””

➤ Risk Reduction Claims:

- An advertisement must not mislead consumers through inappropriate use of a risk reduction claim.
- Definition – Risk Reduction: describes the relationship between using a medicinal ingredient and reducing risk of developing a specific disease or abnormal physiological state, by significantly altering a major risk factor or factors recognized to be involved in the development of the chronic disease or abnormal physiological state.

Application

It is unacceptable to make a risk reduction claim that is inconsistent with a product's insert and/or that involves a condition that:

- Is not appropriate for self-diagnosis
- Requires monitoring by a health care provider.

Example:

Calcium supplement indication / use: help prevent osteoporosis

- Acceptable Claim: "Product X calcium supplement may reduce the risk of developing osteoporosis"
- Unacceptable Claim: "Product X calcium supplement may reduce the risk of developing bone cancer"

➤ Safe / Side Effect Free:

- Claims stating “safe”, “side effect free” and “no known side effects” are unacceptable.
- Safety data are only be from clinical trials on a sufficiently large number of subjects.
- Data from safety studies claiming low incidence of a certain adverse event is to be accompanied by warnings (if any) regarding this certain adverse event.
- Claims that a medicine is generally well tolerated and claims relating to the overall incidence of side effects versus placebo in clinical trials may be acceptable if supported by evidence, provided that a misleading impression is not given.
- Claims that a product has a well-established safety profile are only possible once there has been extensive post marketing experience, 'Well established' should not be confused with 'good'.

Application

It is misleading to suggest that a product is "safe" “side effect free” and “no known side effects” since all products carry some degree of risk and no medicine is completely risk free as individual patients respond differently to treatment.

It is misleading to suggest that a product is "safe" or that it can be used without harm or without side effects because it is derived from nature.

Example:

- Acceptable Claim: “Suitable for children over 12 years of age”
- Unacceptable Claim: “Safe because it is natural source”

➤ Sampling:

- Advertising for drug sampling is unacceptable as distribution of drugs as samples to the general public is prohibited.

Application

Advertisement must not include offers for samples to the general public

Example:

Unacceptable Claim: “for a sample call 1-800-123-4567”

➤ Scare advertising:

- An advertisement must not create an erroneous impression regarding the merit of a product through use of fear-inducing copy or visuals.
- Advertising should not cause consumers unwarranted anxiety that they are suffering from any ailment. Nor should it imply that suffering may arise if a consumer fails to respond to the advertisement claim.

Application

An advertisement must not:

- Suggest that the health of a consumer will suffer, or that full health cannot be attained without using the promoted product.
- Exaggerate the possible consequences of not treating a condition or disorder.
- Describe more serious diseases or effects that may result from the original condition if left untreated.

Example:

Hand Germicidal Cleanser

- Acceptable Claim: “Product X kills germs”
- Unacceptable Claim: “germs are everywhere! Don’t be at risk. Use Product X to prevent SARS”

➤ Storage Conditions:

- An advertisement must not mislead consumers regarding the safe and appropriate storage conditions of a product.

Application

When depicted or described, the storage conditions must be consistent with the product's insert.

Example:

Authorized Storage Conditions: "Store between 15-30 degrees Celsius"

- Acceptable Depiction: "Product stored in medicine cabinet"
- Unacceptable Depiction: "Product depicted as being stored in glove box of car during a snow storm"

➤ Structure Function Claims:

- An advertisement must not mislead consumers through inappropriate use of a structure function claim.
- Definition – Structure Function: describes the effect of a medicinal ingredient on a structure or physiological function in the human body, or a medicinal ingredient's support of an anatomical, physiological, or mental function.

Application

It is unacceptable to make a structure function claim that is inconsistent with a product's insert and/or that involves a condition that:

- Is not appropriate for self-diagnosis
- Requires monitoring by a health care provider.

Example:

Product X Glucosamine: Indication / Use: A factor in the building of healthy cartilage

- Acceptable Claim: "Product X Glucosamine is a factor in building healthy cartilage"
- Unacceptable Claim: "Product X Glucosamine will treat your arthritis"

➤ Superscripts / Footnotes or “Supers”:

- Superscripts or footnotes may be used to provide clarification or additional information about a product.
- Superscripts/Footnotes shall appear clear, legible and be understood by the consumer
- If a super is necessary for the ad to be considered acceptable, this super should stay on screen for a sufficient length of time to be read by the average person.

Example:

Insert : Provides 8 hours of relief

- Acceptable Claim: Audio: “Relief all work day” - Super: “Provides 8 hours of relief”
- Unacceptable Claim: Audio: “Around the clock relief” - Super: “Provides 8 hours of relief”

➤ Testimonials / Quotations:

- An advertisement must not be misleading by using a testimonial or quotation to state or imply a benefit that exceeds a product’s insert.

Application

Testimonials are acceptable provided the claim do not exceed the product’s insert

Example:

Product Y Echinacea: Indication / Use: traditionally used for the relief of sore throat due to colds

- Acceptable Claim: “Product Y Echinacea is traditionally used to relieve sore throats due to colds. Product Y contains echinacea. It worked for me!”
- Unacceptable Claim: “I tried Product Y Echinacea and I just couldn’t believe the results. It was amazing! It’s made my immune system stronger than ever”

➤ Therapeutic Guarantees / Absolute Claims:

- Some individuals may respond to a particular medication and others may not, part of the inherent variability of drug action in a population. Therefore, an advertisement must not be misleading as to the merits of a product by directly or indirectly suggesting that it will be effective for all individuals, or that it will be effective every single time it is used.
- It should be free from any claim statement or suggestion that it is surely successful credible magic & miraculous or it offers granted treatment.

Application

When depicted or described, an advertisement must realistically present the product's efficacy.

Note. Guarantees of purity, quality or physical characteristics are acceptable (i.e., guarantees about nontherapeutic attributes) if true and supportable

Example:

- Acceptable Claim: "Product X provides effective relief"
- Unacceptable Claim: "Product X is proven 100% effective for everyone, 100% of the time"

➤ Unique:

- An advertisement must not be misleading by describing the therapeutic aspects of a product as unique if the product does not provide a unique therapeutic benefit/effect.

Application

It is unacceptable to claim that a product has a unique therapeutic formulation or provides a unique therapeutic benefit unless the product is unique in both therapeutic formulation and effect.

Examples:

Unique (Therapeutic):

- Acceptable Claim: “Our antiperspirant is unique because it provides 48 hours of continual wetness protection” (acceptable if the only antiperspirant approved for a 48 hrs. duration of action).
- Unacceptable Claim: “Our antiperspirant is unique because it provides long lasting protection” (unacceptable since most antiperspirants provide long lasting protection)

Application

- The term unique is acceptable when used to accurately describe non-therapeutic/cosmetic product features, e.g., unique fragrance.

Unique (Non-therapeutic):

- Acceptable Claim: “Shampoo X fights dandruff and has a unique shine enhancing ingredient” (Advertiser would have to provide attestation that no other shampoo contains this shine ingredient)

➤ Withdrawal of term of market authorization:

- Advertising is not permitted for products for which the approved insert leaflet has been withdrawn by MOH for health and safety reasons, or for products that have voluntarily been withdrawn or discontinued by the manufacturer.

Application

In the case of a product for which the approved insert leaflet has been withdrawn, or products voluntarily discontinued by the manufacturer, the preclearance agency will immediately revoke any previously assigned approval numbers.

➤ Disclaimer:

- An advertisement for non-prescription medicine shall contain: a list of ingredients or the following statement prominently displayed or communicated, i.e., standing out so as to be easily read from a normal viewing distance, and /or heard and understood:
“ALWAYS READ THE LABEL”

Except:

In the case of direct marketing and internet marketing, which must contain:

- a) Full list of active ingredients (where the product name is also the single active ingredient, the pack shot displaying the product name will be sufficient to meet this requirement); and
- b) The mandatory warning statements prominently displayed on each page of the catalogue or internet that features therapeutic goods; and
- c) Any mandatory advisory statements required to be included on the product label, prominently displayed on each page that features the relevant medicine/s; and
- d) If the medicine, when used according to the directions:
 - Has known serious adverse effects (in terms of severity and clinical importance); or
 - Is contraindicated for a known group of people because it could cause serious adverse effects which are reflected in the regulatory requirements on the label or in the consumer medicine information (CMI) an appropriate warning of those effects must be given, prominently displayed on each page that features the relevant medicine/s; and
- e) Radio commercials which are 15 seconds or less.

“USE ONLY AS DIRECTED”

“IF SYMPTOMS PERSIST SEE YOUR DOCTOR /HEALTHCARE PROFESSIONAL”

“YOUR [APPROPRIATE HEALTHCARE PROFESSIONAL] WILL ADVISE YOU WHETHER THIS PREPARATION [PRODUCT NAME] IS SUITABLE FOR YOU/YOUR CONDITION”

Must be in all advertisements other than radio commercials that are 15 seconds or less, for claims relating to symptoms of disease conditions.

➤ Analgesics:

- An advertisement for analgesics (other than product labels and radio advertisements which are 15 sec or less) must contain the following statement, prominently displayed or communicated i.e., standing out so as to be easily read from a normal viewing distance, and/or heard and understood:

“Use only as directed. Incorrect use could be harmful. Consult your healthcare professional if symptoms persist”

“Always read the label. Use only as directed by a healthcare professional”

- An advertisement for analgesics must not imply that:
 - Analgesics consumption is safe.
 - Analgesics will relax, relieve tension, sedate or stimulate.

➤ Weight management:

- Advertisements for therapeutic goods containing claims for weight management, meaning weight loss, measurement reduction, clothing size loss and weight control/maintenance, must have an appropriate balance between the claims and references to healthy energy-controlled diet and physical activity.

GUIDELINES FOR EDUCATIONAL MATERIAL

➤ Educational Information to the General Public:

1. Disease education activities may provide information, promote awareness and educate the public about health, disease and their management.
2. The following criteria should be satisfied:
3. The educational material must be current, accurate and balanced;
4. The educational material should not focus on a particular product,
5. Educational material may take reference to the availability of different treatment options (which may include a range of prescription products/classes and/or alternative treatments such as surgery or over the counter products) but this should not be of such a nature that an individual would be encouraged to seek a prescription for a prescription only product.
6. The educational material must include the name of the pharmaceutical company must be identified on any disease education activity but should be given prominence.
7. The educational material must include a statement directing the patient to seek further information about the condition or treatment from his/her doctor.
8. The emphasis of the disease education activity should be on the condition and its recognition rather than on the treatment options.
9. The language used should be designed to convey key messages clearly, supported by appropriate design and formatting appropriate for the intended audience.

Examples of patient educational material which could be used include:

1. Patient information about a medical condition which may discuss all medically important treatment methods but only in very broad terms (no emphasis on any one product) this type of material could be distributed directly to the general public as a community service.
2. Patient information about a medical condition or specific treatment (not brand name) which is prepared in conjunction with the relevant professional society and is endorsed by that society. This type of material may be distributed to the general public, as a community service.

Particulars to be included in advertisements to the public:

1. The name of the medicinal product.
2. If the product contains only one active ingredient, the common name of the medicinal product.
3. One or more indications.
4. The information necessary for correct use of the medicinal product.
5. An express and legible invitation to read carefully the instructions in the leaflet or on the label.
6. Warnings, precautions, contra-indications, common side effects.

➤ Advertising to the pregnancy:

- The following guidance is provided for the advertising of any licensed medicine which is promoted for use during pregnancy:
 - Advertisements to the general public mentioning the use of the product during pregnancy are only acceptable for medicines where the Summary of Product Characteristics (SPC) supports the use of the product in pregnancy- providing the other principles/guidance are followed. This does not preclude the general advertising of other products for common conditions, even where the advertising may be seen by pregnant women, provided that the advertisement does not promote, in words or images or context, the use of the product in pregnancy.
 - Advertisements should not convey the message that it is usual for pregnant women to take medicines. Advertisers are encouraged to include advice on non-pharmacological measures where appropriate.
 - Advertisements should not state or imply that the advertised product, or any other medicine, cannot harm the developing fetus and ultrasound scans or images of a fetus should not be used in promotion of a medicine.
 - Advertising should reflect any warning statements on the license concerning use at particular times during pregnancy (for example, a product which should not be used close to the expected date of delivery).
 - Advertisements should actively encourage seeking advice from a doctor, pharmacist or other healthcare professional concerning use of the product at any time during pregnancy.
 - All advertisements for medicines promoting use in pregnancy directly to pregnant women should include a general warning message appropriate to the medium being used (e.g., print, television, radio). An example of appropriate wording is given below. We would also encourage the inclusion of such a warning in any general advertising for a systemic medicine where the target audience is mainly pregnant women (e.g., in a pregnancy magazine).

"Medicines can affect the unborn baby. Always talk to your doctor or pharmacist before taking any medicine in pregnancy"

➤ Reminder advertisement:

- Advertisements relating to products which act as a reminder and which consist solely of the name of the product are exempt from the need to include other essential information.
- A "promotional aid" is a form of reminder advertisement. It is a non-monetary gift made for a promotional purpose by a commercially interested party (e.g. the supply of an item such as a pen, notepad or). The cost of such items to the donor should be valued 20 LE or less.

Examples of unacceptable brand name reminder items include mugs, clocks, etc.

- An individual brand name reminder should be of token value, should not bring discredit to the industry and should be chosen on the basis that the item is clearly a brand name reminder and not any other promotional material, such as printed promotional material.

Brand name reminders must include the following information:

- a) The brand name of the product;
- b) The approved Name(s) of the active ingredient(s) placed adjacent to the most prominent presentation of the brand name; and
- c) Where applicable, the notation 'See Warning', drawing attention to the warning in the Product Information.

Brand name reminders may also include:

- d) A non-promotional logo or image; or
- e) A company name or logo.

Brand name reminders must not include:

- f) Indications or therapeutic category;
- g) Promotional claims including promotional tag lines and/or statements.

➤ Trade advertisements:

- The regulations provide that “reference material and announcements of a factual and informative nature, including ... price lists “shall not be taken to be an advertisement, provided that no product claim is made. Materials relating to medicines issued in trade publications in the form of an informative announcement. Such an advertisement should not contain any recommendation relating to the use of the medicinal product other than as a part of the name of the medicinal product. A true representation of the approved pack may be included.

➤ Non-prescription for HCP:

1. This chapter provides guidance on advertising of non-prescription products, targeting healthcare professionals who are “persons qualified to prescribe or supply “(PQPS) medicines as defined in the regulations.
2. Essential information compatible with the approved insert leaflet of the product(s)
3. It is not acceptable for the information to be presented on such a way that a reader has to turn the material a round to read the text, for example, diagonally or a round the borders of the page.
4. This information is intended as a reference for healthcare professionals; it is not a substitute for reading the approved insert leaflet but should convey all the key information from the approved insert leaflet to be considered before prescribing or supplying the medicine.
5. Regulations require one or more of the licensed indications to be provided as well as a succinct summary of the entries in the approved insert leaflet for the dosage and method of use. A succinct summary of the approved insert leaflet information relating to side effects, precautions and contra-indications is also needed and the route of administration should be shown when not obvious. The information must also include the actual product name, active ingredients, license number, legal status and the name and address of the license holder. In addition, the cost is required, except for audio-visual advertisements and;
6. With regard to side-effects, as a minimum, the information should indicate all the common side effects likely to be encountered in clinical practice and also those which are rarer but may be serious, together with an indication that other uncommon effects are listed in the SPC.