Prescription Medicine Promotion guidelines

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1.Introduction

The main objective of this guideline is to support and encourage
The improvement of health care through the rational use of medicinal drugs

2. Definitions

Awareness material:

Awareness materials provide information, promote awareness and educate about particular condition or disease

Claim:

It says something about the promoted drug or what it does. Claims can be made directly by stating, for example, "Brand X treats heartburn." Claims also can be made indirectly by the use of pictures or other graphics. For example: a picture of a playground full of children suggests a claim that the promoted drug treats children.

Educational Material:

Means any representation which is intended to provide information about a medical condition or therapy which does not contain specific promotional claims.

Healthcare Professional:

Any member of the medical, dental, pharmaceutical or nursing professions.

Prescription Products:

A prescription product requires doctor authorization to purchase

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Promotion:

Any activity undertaken, organized or sponsored by a MAH (marketing authorization holder) which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its products through all media.

Promotional Claim:

Any statement made by a MAH or MAH's representative, whether verbal or written, which conveys the positive attributes of a product which extends beyond a simple non-qualitative or quantitative description of the therapeutic category or ***approved indication*** for the purpose of encouraging the usage of that product. It includes statements concerning efficacy, rate of adverse reactions or other cautionary aspects of the product and comparative information.

Reminder

- Brand Name Reminders are those which call attention to the name of the product but don't include Indications or dosage recommendations for use of the product.

Risk Reduction:

Describes the relationship between using a medicinal ingredient and reducing risk of developing a specific disease or abnormal physiological state.

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.

3-Scope

The scope of these guidelines shall cover:

1-All printed and electronic promotional materials (directed to health care professionals only) undertaken by MAH operating in Egypt for a POM (prescription only medicine) that

*intended for human use.

*have been officially registered.

A- Printed promotional materials.**E.g.**
- Journal advertisements directed at healthcare professionals.
- Printed promotional materials provided to or used for discussion with healthcare professionals: E.g. Detail Aids, Booklets, Block Notes, Drop Cards, Flyers, Brochures, and non-leaf behind Materials.
- Printed promotional materials for display purposes only in scientific communities like Conferences and pharmacies. E.g. posters and stands.
- Other printed promotional materials.

B- Electronic promotional materials E.g.:
- Soft promotional materials on I-Pad, Mobile Applications for Health Care Professionals Websites, e-mail, video,.
- Power point presentations for health care professionals that prepared by the company.

NOTE:
Power point presentations of the external lecturers (in the scientific events that sponsored by the company) will not require previous approval but the company is responsible for their content.0=

2- All printed and electronic Educational (non promotional) materials (directed to health care professionals or distributed to patients through healthcare proffessionals)

- Product educational materials .
  Which are not included in the risk management plan of the product .

- Awareness material about a particular condition or disease.

3- Reminders.

Don't require previous approval but must follow this guidelines and will be subjected to post auditing.

4. General Rules for Promotional ,Educational and Awareness Materials

4.1 Products subjected to these guidelines are prescription only medicines .

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4.2 Any Approved Material must include the approval number which is to stand alone be prominently displayed and located on the first page of the material.

4.3 All materials must comply with the locally accepted traditions and religious directions.

4.4 All materials should indicate the target audience in the first page.

4.5 Ethical promotion criteria are to be complied with, without any direct or indirect offence to Competitors or the pharmaceutical industry or medical field in general.

4.6 No new data are to be added or modifications of any kind are to be made after Submitting the material for review and before approval except upon request of the reviewer Pharmacist otherwise it is considered another file.

4.7 The printed or published materials must be identical to the approved &stamped ones.

4.8 responsiblity

The primary responsibility for the content and dissemination of all promotional and educational Materials of a PM lie with the MAH, who is also responsible for The awareness materials & the training and conduct of medical representatives.

4.9 Prohibition of Promotion on unlicensed product

POM which do not have a valid Registration license must not be promoted for medicinal purposes.

4.10 health authority approval claims

Claims that the product is **FDA** (food & drug administration) **, EMA**(European medicine agency) **or any health authority approved**

- must be supported by evidence (link)
- Is trade name specific and can't be generalized to other products containing the same active substance or combination of active substances.

4.11 Content

Printed And electronic promotional materials that are directed to Health Care Professionals must contain:

1-Trade Name

2-The Active Ingredients INN or Generic Names

(*Placed immediately adjacent to the most prominent display of the name of the product, in the first Appearance of the product name*

3-Content of active ingredients per dosage form
(If single placed immediately adjacent to the most prominent display of the name of the product, in the first Appearance of the product name)

4-Name of other ingredients known to cause problems

5-Approved therapeutic uses (at least one use)

6-Dosage form and regimen

7-Side-effects and major adverse reactions (incidence>1%)

8-Precautions, Contra indications, warnings, pregnancy, lactation and fertility

9-Interactions

10-Name and Address of manufacturer or distributer

11-References to scientific literature

12-MM(Marketing Material) approval NO. &invalidation date of the promotional material
(the approval extend for 1 year from the date of the approval)

13-The following sentences.

1-Always read the full prescribing information.*(if not already present in the promotional material)*
2- Other less common side effects are listed in full prescribing information. .*(if not already present in the promotional material)*
3- Healthcare professionals are asked to report any suspected adverse reactions.

- The safety data must be stated using a type size not less than 1.5 mm based on the lower case 'e' for printed materials.
- 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 product.

- Where a promotional material is concerning treatment of a particular group of patients, MAH 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 a promotional material for the same product for treating a more general patient population.

5.Promotional Material Guidelines

5.1 Quality standards *(see box1)*

A promotional material must:

(1) Comply with the particulars listed in the approved insert leaflet.

(2) Encourage the rational use of the product by presenting it objectively and without exaggerating its Qualities.

(3) Not be misleading.

(4) Represent a "fair balance" between efficacy and safety so that, health-care professionals can get Complete and accurate information on the product.

(5) Not be vague (ambiguous) and incomplete***.(Especially regarding indications, adverse effects and precautions)***

(6) Use updated references.(the most recent in the field)

Box 1:

(1) Compliance with the approved insert leaflet
This means a promotional material cannot promote a p product for use in treating or preventing conditions or illness for which it has not been licensed. Nor can promote a product for use by a patient group not indicated. ***For example***, a promotional material with an infant where the product was not indicated below the age of 2 years would violate this provision.

(2) Encouraging rational use
-This might include when a product should be taken, how much should be taken, the route of administration, by whom it should be taken and special precautions.
See section (5.3.4)
-*A* promotional material for a product offering symptomatic relief should not imply that it cures the underlying condition. **(If not present in the approved insert leaflet)**
-A promotional material would not be objective if it failed to refer to any significant limitations that were relevant to the claims made for the 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. **(When applicable)**

(3) Not be misleading
A promotional material must not lead to an incorrect belief of any nature about the product. 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 promotional material for a product where caution is required over impairment of driving ability. *See section (5.3.17)*

5.2 References

5.2.1 For a certain piece of information that is mentioned in the approved insert leaflet, no **contradicting from any reference are to be mentioned in the promotional material.**

5.2.2 Only full articles are to be submitted, no abstracts are to be accepted as references.

5.2.3 Data from different references are to be clearly separated, and no framing in this case is allowed.

5.2.4 The reference must be stated using a type size not less than 1.5 mm based on the lower case 'e' for printed materials.

5.2.5 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, and the year of publishing.

5.2.6 Data from studies made on a particular brand are to be used for the generics (using the active ingredient name only) if of same concentration, same dosage form & same indication.

5.2.7 Non-clinical studies (ex: in-vitro, ex-vivo, preclinical evidences) are not to be considered except for affinity, selectivity data & claims that can't supported by clinical evidence.

NOTE.

- They are not suitable for indications or adverse effects.
- They are suitable for mechanism of action of approved drugs , teratogenicity and other toxicities.

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5.3 Claims

5.3.1General

5.3.1.1 All information, claims and graphical representations provided to healthcare Professionals must be current, accurate, balanced and must not mislead either directly, by Implication, or by omission.

5.3.1.2 All claims must be referenced.

5.3.1.3 Claims must not imply that a product or an active ingredient has some special merit, quality or property unless this can be substantiated by sufficient evidence.

5.3.1.4 Claims from clinical studies must be complying with the predetermined primary or secondary end points, ***without omitting of phrases that may change the meaning or leading to ambiguity.***

5.3.1.5 Exaggerated or non-scientific ambiguous claims, slogans or pictures are prohibited.

(See section 5.3.12)

5.3.1.6 Photos and pictures are evaluated as claims and must be proved and relevant without exaggerations. *(See section 5.3.17)*

Note. They must confirm with approved indications and limited to the allowed populations.

The following are examples of situations where material may breach the guidelines:

A) Information or conclusions from a study that is clearly inadequate in design and scope.

b) Citation of data previously valid but made obsolete or false by the evaluation of new data.

c) Suggestions or representations of uses, dosages, indications or any other aspect of the Product Information not approved by the MOH.

d) Shortening an approved indication so as to remove a qualification or limitation to the indication.

e) Hiding severe or important adverse drug reactions, warnings, age group limitation or pregnancy limitation.

f) Statements made about a competitor product, particularly negative statements, not balanced with corresponding information about the product being promoted.

f) Shortening the title of graphical representations reproduced from literature in a manner that alters the original author's meaning.

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g) Literal or implied claims that a parameter, contraindication, cautionary statement, adverse reaction or limitation on a claim in the Product Information leaflet, is not cause for concern.

h) Lack of substantiation of claims not of a medical or scientific nature. It includes information or claims relating to marketing factors such as pricing and market share.

5.3.2 Product Characteristics

5.3.2.1 The promoted product must not be represented as a food or cosmetic.

5.3.2.2 `Absence of Ingredient Statements

- A promotional material must not include *an absence of ingredient* claim in a manner that creates an incorrect impression about the promoted product or competitor product(s).

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

- **Medicinal**

  - The statement provides useful and easily identifiable information to the HCPs that reinforces existing labeling and aids HCPs medication selection.
  - 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.

- **Non-Medicinal**

  - The statement provides useful and easily identifiable information to the HCPs to aid in product selection for secondary non-therapeutic attributes such as taste, odour, caloric content, allergic potential or other meaningful attribute.
  - The statement is accurate.
  - There is no direct or indirect implication that the absent ingredient is medicinal.

  Ex: A product can be described as "sugar free" if it contains none of the chemical classes of sugar, including sugar alcohols.

5.3.3 Indication / Recommended Use

The promotional material must clearly communicate the intended therapeutic use of the product as per its approved insert leaflet.

- 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.

- The promotional material must include at least one indication for use of the product
  - For single medicinal ingredient / single indication products: The product's sole indication must be presented in the Promotional Material.
  - For single medicinal ingredient / multiple indication products: At least one indication must be presented in the Promotional Material.
  - For multiple medicinal ingredients / multiple indication products: At least one symptom per medicinal ingredient must be presented in the promotional material (it is acceptable to give prominence to one symptom).

Note: This does not apply in cases where multiple ingredients relieve/treat a single symptom/condition.

5.3.4 Direction for Use/Dosage and Administration

- A promotional material must not be misleading as to the Directions for Use/Dosage and Administration.
- A promotional material must encourage the correct and proper use of a product; this is a positive obligation.
- When described or depicted, directions for use/dosage and administration must be consistent with the product's approved insert leaflet.

5.3.5 Efficacy

- A promotional material must not be misleading by directly or indirectly exaggerating the degree of relief/benefit to be obtained from use of the promoted product.
- Efficacy claims are to be specific.
- High adverse events rate or incidence (if any) accompanying high efficacy in a clinical study are to be clearly mentioned accompanying efficacy claims from this clinical study.
- Superiority of certain effect/More efficacy claims are to be from clinically and/or statistically remove significant results of at least one comparative head-to-head clinical study.
- When depicted or described, efficacy claims must be consistent with the product's approved insert leaflet

5.3.6 Medicinal vs. Non-medicinal Ingredients

- Product benefits must not be presented in a manner that is misleading, as to the nature of either the medicinal (therapeutic) or non-medicinal (non-therapeutic) ingredients.
- No medicinal (therapeutic) benefit can be directly or indirectly attributed to a non-medicinal (non-therapeutic) ingredient.

5.3.7 Onset of Action

- A promotional material must not be misleading as to the time to onset of action of the promoted 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.
- When depicted or described, the onset of action must be consistent with the product's approved insert leaflet, i.e. claims for action within a specific time period are only permitted if contained in the product's approved insert leaflet.
- Time to onset of action must not be equated with time to onset of relief, unless clearly specified in the product's approved insert leaflet.

5.3.8 Duration of Action

- A promotional material must not be misleading as to the duration of action of the promoted product.

- 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.

- When described or depicted, the duration of action must be consistent with the product's approved insert leaflet.
- Dosing interval must not be equated with duration of action or duration of relief unless supported by the product's approved insert leaflet.
- Duration of pharmacological action must not be equated with duration of relief unless supported by the product's approved insert leaflet.

5.3.9 Duration of Use

- A promotional material must not be misleading as to the recommended duration of use of the promoted product.
- When described or depicted, the duration of use must be consistent with the product's approved insert leaflet. When a product must be used for a specific period of time to obtain the desired effect, this information must be included in the promotion material.
- Products intended for short term/occasional use must not be represented for long term/chronic use.

5.3.10 Clinically Proven

- A promotional material must not be misleading with respect to use of the statement "Clinically proven".

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

5.3.11 Comparative statements

- In presenting a comparison, care must be taken to ensure that it properly reflects The body of evidence and does not mislead by distortion, by undue emphasis or in any other Way.

- Comparison of ingredients must be factual, fair and capable of substantiation and referenced to its Source; and must not be disparaging.

- 'Hanging' comparatives - those that merely claim that a product is better, stronger or more

widely prescribed etc. must not be used.

- Where a claim of comparative efficacy or safety is made, it must not be based on a comparison of Product Information documents that does not reflect the general Literature, as those documents are based on different databases and are not directly comparable.
  (It must be based on at least 1 head to head clinical trial)

- The accepted level of statistical significance is $p < 0.05$. If comparative data that are not statistically significant are used, such data must comply with the following Conditions:

1- The lack of significance must be stated explicitly; it is insufficient to state the p -`Value.
2- The data must not be used to generalize or to indicate superiority or inferiority.

- The claim and its presentation should:

(i) Identify the compared entities5(to be mentioned in the same page).
(ii) Not obscure the therapeutic use of the promoted Ingredient.
(iii) Not attack the compared drug ingredient(s) in an Unreasonable manner.
(iv) Be expressed in terms, language and graphics that can be understood by the intended audience.

5.3.12 Expressions

- Exaggerated or all-embracing claims must not be used.
- Claims should not imply that the product or an active ingredient has some special merit, quality or property.
- It is unacceptable to claim that the product has a unique therapeutic / non-therapeutic formulation or provides a unique therapeutic/ non-therapeutic benefit unless the product is unique in therapeutic or non-therapeutic formulation and effect.
  It must be supported by evidence of adequate quality.

- Expressions and statements not allowed in Promotional and educational materials Includes all stated below and all other similar meanings

1- Incomparable ,powerful, very limited quantity, seize the opportunity, amazing guaranteed, pain free, safe, has no side effects, has no toxic hazards or risks of addiction.,100%, veracious, magic, miraculous, assured success, credible, best product, beware of imitations, ideal, famous, granted treatment ,trust.
Note: Guarantees of purity, quality or physical characteristics are acceptable (i.e., guarantees about non therapeutic attributes) if true and supportable.

2- Absolute statement like cures completely certain illness or disease should be replaced by helps to… can't live without and all alike expressions.

3- Expressions that mean stability or permanent effect like "Permanent, Eternal, get rid completely".

4-"Fight old age", but the expression "helps to fight old age signs" could be used.

5-Unique, Pioneer, Original, First, immediate results, *(unless its relevance to a clinical outcome can*

Be substantiated with evidence of adequate quality).

6- (Statement proceeded by without …) *(unless its relevance to a clinical outcome can be Substantiated with evidence of adequate quality).*

7-Brand names of products of other companies.

8-The: Use of the definite article to imply a special merit, quality or property for a product is unacceptable if it cannot be substantiated. For example, a claim that a product is 'The analgesic' implies that it is in effect the best, and might not be acceptable.

9-New: The word 'new' must not be used to describe any product, presentation, or therapeutic indication that has been available for more than 12months in Egypt.

5.3.13 Imitation

Promotional information should not imitate the devices, copy slogans or general layout adopted by other MAH in a way that is likely to mislead or confuse.

5.3.14 Safety

Safety messages given in promotion

- Safety messages given in promotion must comply with the approved insert leaflet.
- Promotional material which states or implies that a product is "safe" is unacceptable.
- All products have the potential for side-effects and no product is completely risk-free as individual patients respond differently to treatment.

For example the term "placebo-like" in relation to safety or side-effects is considered to be misleading as it implies that there are no associated side-effects. By implication the product could be assumed to be 100% safe, when no product is completely risk-free.

- Claims that a product is generally well tolerated, including claims relating to the overall incidence of side effects versus placebo in clinical trials, may be acceptable if supported by evidence, provided a misleading impression is not given.
  (At least 1 clinical trial that aims to assess safety)

- Claims that a product has a well-established safety profile must be supported by evidence, 'Well established' should not be confused with 'good'.*(it must be mentioned exactly as reference)*

- 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.

- Promotional material must include a reminder giving information on reporting of suspected adverse reactions. *(see 4.12 section)*

5.3.15 Absence of Side Effect Statements

- A promotional material must not include a claim for an absence of side effect in a manner that creates an incorrect impression about the promoted product or competitive product(s).
- **Absence of side effect statements** is acceptable under the following conditions:
  - Scientific evidence exists to support the statement; e.g. incidence of side effect is compared to placebo and is **consistent with the product's Insert Leaflet.**
  - The side effect is associated with comparable components of that class.

Note: promotional material should not suggest that a product does not have any side-effect or that its safety or efficacy is due to the fact that it is natural.

5.3.16 Risk Reduction Claims

- A promotional material must not mislead HCPs through inappropriate use of a risk reduction claim.
- Risk Reduction Claims must be supported by a suitable reference
- It is only appropriate to extrapolate from surrogate endpoints where a link between the surrogate endpoint and the clinical outcome is supported by the evidence and consistent with the product approved insert leaflet.

5.3.17 Pictures

- Photos and pictures are evaluated as claims and must be proved and be relevant without exaggeration.
- Pictures included should be related to the promoted product, to serve its purpose only& consistent with the product approved insert leaflet.
- Pictures that breach the Egyptian culture and Islamic teachings are not allowed.
- Pictures should not contradict Egyptian common interest and policies.
- Pictures that show intimacy or sex appeal are not allowed.
- MAH should sign a declaration taking the responsibility of photos of individuals in the design.
- Pictures that breach the medical ethics are not allowed.
- Pictures that encourage unhealthy, risky behaviors and habits are not allowed.

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5.3.18 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 HCPs as to the therapeutic merits of the product.

- Graphs and charts are to clearly indicate the source(s) of it and be faithfully reproduced.
- Data represented in graphs and charts are to represent the results of the objective of the clinical study.
- Minimal information on a presented chart 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 design & objective.
  B. Dosage.
  C. Treatment duration and follow up.
  D. Number of subjects involved for each arm of the study.
  E. Statistical significance.
  F. Specifications (if any) on race, age of subjects

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5.3.19 Endorsements / Recommendations /Seals

- A promotional material should not contain recommendations by scientists or healthcare professionals.
- Companies should not suggest that their product is "special" or different from or better than other products because it has been granted a marketing authorization or registration."
- Endorsements by, or seals of well recognized groups are acceptable, providing the terms of the endorsement/recognition are consistent with the product's approved insert leaflet.
- Combination recommendations, 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".

5.3.20 Product merit:

- It is unacceptable to exaggerate the severity of the condition that can be relieved with the promoted product.
- It is unacceptable to suggest that use of the promoted product is a substitute for good health practices and healthy lifestyle.
- A promotional materials for vitamins should not imply that vitamin supplements:

  (a) Are a substitute for good nutrition or a balanced diet.

  (b) Are in any way superior to or more beneficial than dietary nutrients or that normal Health may be affected by not taking vitamin supplements.

5.3.21 Extra Strength / Maximum Strength

- A promotional material 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.
- 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.

5.3.22 Health / Healthy / Healthful

- A promotional material must not be misleading by suggesting that a product may restore, maintain or promote health, unless such claims are included in the Product's approved insert leaflet. *This prohibition shall not apply to the vaccination campaigns*
- A promotional material shall not give the impression that the normal lifestyle requires the use or consumption of a specific product.
- A promotional material must not claim that the use of a certain product is essential for living within modern life pressures.
- A promotional material should not suggest that a certain products use will enhance sportive or educational performance.
- **Weight management: A** promotional material 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.

5.3.23 Natural

- A promotional material must not mislead HCPs to believe that a product is "natural" or "natural source" if it is synthetically derived.
- **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 and 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 d-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 non-medicinal).
  - 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.
  - A product with ingredient(s) of natural source must not be claimed to be

superior (efficacy/safety)because of being natural.

5.3.24 Natural Action / Naturally

- A promotional material must not be misleading by claiming that a product acts "naturally" as products, including natural health products, modify the body's Physiological processes.

5.3.25 Need

- A promotional material must not mislead HCPs by suggesting that the promoted product is needed.
- It is not acceptable for a promotional material to claim that a patient "needs" a specific product or ingredient. However, it is acceptable to suggest that an individual "needs relief" or treatment.

5.3.26 Potent / Potency

- A promotional material must not be misleading by referring to a product as being "potent" or having a "potent" formulation. *Unless supported by suitable reference and mentioning exactly as reference*

All products contain sufficient medicinal ingredients to be effective as per their approved therapeutic indications. Therefore, the relief to be derived from such products is an indicator of their effectiveness and not their "potency".

5.3.27 Power / Strength

- A promotional material 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.
- A promotional material 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 approved insert leaflet.
- All products 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 "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** "

See section (5.3.12)

5.3.28 Structure Function Claims

- A promotional material must not mislead HCPs through inappropriate use of a structure function claim.
- It is unacceptable to make a structure function claim that is inconsistent with a product's approved insert leaflet.

5.3.29 Withdrawal of Terms of Market Authorization

- Promotion is not permitted for:

  1- Products that have voluntarily been withdrawn or discontinued by the manufacturer.

  2- Products that have been withdrawn by MOH.

6. Promotion of products which are promoted for use during pregnancy:

The following guidance is provided for the promotion of any product which is promoted for use during pregnancy:

- All the information contained in the pregnancy and lactation section of the insert should be conveyed in the prescribing information in the promotional material.
- Promotional material should never state or imply that the promoted product or any product can't harm the developing fetus.
- The use of ultrasound scans or images of a fetus is inappropriate in the promotion of products for use in pregnant women.
- Promotion should reflect any warning statements on the approved insert leaflet concerning use at particular times during pregnancy (for example, product which should not be used close to the expected date of delivery).

(a) Where there is a specific approved indication for use in pregnancy, product may be promoted for use in pregnancy.

(b) Where there is not a specific indication for use in pregnancy Textual information may be included in the promoted material (additional to the prescribing information) regarding the use of the product during pregnancy, reflecting section (pregnancy and lactation) of the approved insert leaflet, however a separate pregnancy directed material is not acceptable.

-It will be submitted for committee to review case by case.

-The use of images of pregnant women is not appropriate in this situation.

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7. Educational non promotional material (directed to health care professionals or distributed to patients through healthcare professionals)

Product Educational Materials

Information to support patients who have been prescribed a particular product which is prescribed by their doctors. The purpose of such information should be educational, provide a demonstrable benefit to the patient and should encourage patients to seek further information or explanation from

the appropriate healthcare professional.

It must:

1- Be provided to health care professionals to be given to their patients.

2-The content of such material must be designed to assist the patient compliance by providing information which clarifies method of administration, precautions , special instructions and similar information.

3- Not include promotional statements or claims.

4- Not include comparisons with other products.

5- Not include quotes from experts, opinion leaders or patients.

6-be simple and easy to understand. Confusing medical terms must be avoided

E.g. Dosage wheel, alert cards for patients to carry, or additional advice on how to take the product.

N.B: product educational non promotional material directed to health care professionals will follow the same rules as those directed to patient .If, it contains any promotional claim it will be subjected to the same evaluation of promotional materials.

2. Awareness material

- Awareness materials provide information, promote awareness and educate about health & disease, It should:

- Discuss a medical condition or disease state.
- Include MAH name.
- Not include product trade name.

The following criteria should be satisfied:

- The awareness material must be current, accurate and balanced.
- The awareness material may make reference to the availability of different treatment but this should not be of such a nature that an individual would be encouraged to seek a prescription for a prescription only product.
- The awareness material must include the name of the MAH but should not be given prominence.
- The awareness material must include a statement directing the patient to seek further information about the condition or treatment from his/her doctor.
- The emphasis of the disease education activity should be on the condition and its recognition rather than on the treatment options.
- The language used should be simple and easy to understand& designed to convey key messages clearly, supported by design and formatting appropriate for the intended audience.

- Examples :

Patient information about a medical condition which may discuss all medically important treatment methods but only in very broad terms.

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8-Reminder

- Reminder calls attention to the name of the product but don't include indications or recommendations for use of the product.
- Individual brand name reminder should be of token value, should not bring discredit to the industry.
- Reminder is not allowed for products whose labeling has a "**boxed warning**" about certain very serious product risk.
- Reminder Don't require previous approval but must follow this guidelines and will be subjected to post auditing.

Brand name reminders must include the following information:

1) The trade name of the product

And/or

2) MAH name or logo.

Brand name reminders must not include:

1) Indications or therapeutic category.

2) Promotional claims including promotional tag lines and/or statements (slogan).

Brand name reminders may include the following information:

1) A non-promotional logo or image. (Written, printed, or graphic matter containing no representation or suggestion relating to the promoted product).

3) Information relating to quantitative or qualitative ingredient statements.

4) Dosage form.

5) Quantity of package contents.

6) Price.

9. The Role of Marketing Material &Media Monitoring Department

1. Monitoring of promotional &educational materials for products.
2. Monitoring awareness materials.
3. Handling of complaints.
4. Education of ethical promotion & rational use of medicines.

10. Regulation

Promotion of pharmaceutical products is regulated by the following:

1- Egyptian constitution 2014 article 18.

2- Pharmacy law act No. 127\1955 articles 63.

3-Law No. 48 of 1941 Combating Fraud and Deception amended by law No. 281 of 1994

4- Ministerial decree No. 76 of 2000.

5- Ministerial decree No. 429 of 1976.

6 - Decision of the technical Committee 20/11/2008.

11. Sanction

Penalties are regulated by:

1-Law No. 48 of 1941 Combating Fraud and Deception amended by law No. 281 of 1994

2- The ministerial decree no. 76\2000 that includes cancelling or suspending the marketing authorization license of the product in case of publishing without the authority approval.

3- The Ministerial Decree No. 429 of 1976 that includes scientific office license withdrawal in case of Violation of laws and regulations

12. Complaints

Scope: same as regular scope.

1. Complaints files are received composed of:

- A cover letter (the form can be found online). http://www.eda.mohealth.gov.eg
- A copy of the promotional material.

2. The MAH will be notified there is a complaint against it (The complainant name will never be reveled), in order to submit all the documents and references required to defend the claims in the promotional material.

3. The promotional material will be reviewed thoroughly.

4. The promotional material will be submitted for committee review.

5. A decision regarding the promotional material is taken, according to the severity of the violation and could get to cancel the registration license of the product and prevent re-registration for a year.

6. The complaining party will be notified of the final action.

13. Abbreviations

WHO: World Health Organization

MOH: Ministry Of Health

POM: Prescription Only Medicine

MAH: Marketing Authorization Holder

FDA: Food and Drug Administration

EMA: European Medicine Agency

CAPA: Central Administration of Pharmaceutical Affairs

INN: International Nonproprietary Name

HCPs: Health Care Professionals

14. References

1. Ethical criteria for medicinal drug promotion .**WHO**
2. .The blue guide: advertising and promotion of medicines in UK *Third Edition. August 2012*
3. Australian code of conduct *edition 16* **.** *2010*
4. Emirates: http://www.moh.gov.ae/en/Services/Pages/ServiceDescription.aspx?PID=9.
5. FDA code of federal regulation title 21 part 202 prescription drug advertisement.