General guidelines on the promotion of pharmaceutical products:

1. CAPA regulates all promotional materials for health care professionals and public.
2. Promotional materials of (drugs, Biologicals, food supplements, cosmetics or medical devices) are not to be distributed prior to getting approved and printing the CAPA approval code.
3. Promotional materials are only allowed for currently registered products.
4. Promotional materials must comply with the locally accepted traditions and religious directions.
5. Ethical promotion criteria are to be complied with, without any direct or indirect offence to competitors or the pharmaceutical industry in general.
6. Clear statement of the direction of the promotional material on the front page in the same language of the promotional material.

7- The promotional material must

- **Comply with the particulars listed in the product insert leaflet; any promotional material must not promote a medicine outside the therapeutic indications listed in the insert.**
- **Encourage the rational use of the product by presenting it objectively and without exaggerating its qualities; this is a positive 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.**
- **Not be misleading; Unrealistic or inappropriate images can give rise to misleading expectations about the product or the indicated patient.**

8-promotional materials directed to physicians & health-care professionals must include:-

- The active ingredient(s) name(s).
- The trade name.
- Content of active ingredient per dosage form or regimen.
- Name of other ingredients known to cause problems.
- Approved therapeutic uses. (at least 1 indication).
- Dosage form and regimen.
- Side effects and major adverse reaction (incidence > 1%) .
- Precautions, contraindications and warnings.
- Major interactions.
- Name and address of manufacturer or distributor.
- References to scientific literature as appropriate.
- CAPA approval code & invalidation date of the promotional material.

9-promotional materials directed to the public must include:-

The active ingredient(s) name(s).

The trade name.

Major indications for use. (At least 1 indication).

Major precautions, contra indications &warnings, side effects.

Name and address of manufacturer or distributor.

Price information must be honest and accurate.

References to scientific literature as appropriate.

CAPA approval code & Invalidation Date of the promotional material.

10- Materials directed to the public are to discourage both self-diagnosis and medication and must encourage seeking professional medical help.

11- Promotional materials directed to the public are not to be on addict-able or narcotic drugs.

12- Promotional material directed to the patients or the public are only to be distributed in the clinics.

13- REMINDER advertisement consists of: trade name of the product, active ingredient, name of manufacturer &conc.

14- Submitted promotional materials for review are to be identical with the intended to finally print materials in the number of pages (no two pages in one) and submit an identical copy with dimensions.

15- Promotional materials must represent a “fair balance” between efficacy and safety so that, health-care professionals and consumers can get complete and accurate information on the product.

AFTER APPROVAL

1- Any adjustment or change on the promotional material content or design cannot be done without informing the premarket, audit and media monitoring administration and it is considered another promotional material to be approved on.

2- After printing the approved promotional materials, they are to be officially released by the administration of the audit on scientific offices.

3- After printing the approved promotional material, a copy is to be submitted to the administration.

4- Approval on any promotional material expires after one year or less until the registration license expires in case not under re-registration.

5- The company must hold or suspend the distribution of the promotional material if there are any insufficiencies or new risk information emerging by using the product till the decision of the administration in coordination with the pharmacovigilance Centre.