SOP Promoting Our Products

KEY PRINCIPLES

- **We make sure our statements about our products are accurate, complete, and supported by scientific evidence.**
- **We only promote products for their approved uses.**
- **Our materials and activities are approved through local procedures before we use them.**
- **We do not give medical advice.**

WHY IT MATTERS

We understand that real patients use our products to help treat, cure, or prevent disease. Because we take patient health seriously, we want healthcare professionals (HCPs) to have the information they need to make the best treatment decisions.

When we talk about our products, we provide accurate information that presents a complete picture of their benefits and risks, based on scientific evidence.

This SOP and the process, along with our values and behaviours and your own good judgment, will help you make the right decisions when promoting our products.

WHAT YOU NEED TO KNOW

Our Patients. Patients are at the heart of what we do. If a patient asks for medical advice, we direct them to their HCP.

Our Materials and Activities. We use promotional materials and activities after they have been reviewed and approved by Nominated Signatory. We use them with the intended audience in the way they are approved to be used.

Internal Collaboration. We recognise that whether an activity is seen as promotional depends on the purpose, content, and context, not necessarily the job title of the messenger. When Commercial employees work with Medical or Reimbursement employees (for example, to develop promotional materials), we respect the difference and separation between these groups and do not direct each other's work.

PROMOTIONAL ACTIVITIES AND MATERIALS

What are they?

Promotional activities and materials are tools we use to encourage someone to choose our products. "Choose" could mean prescribe, administer, recommend, purchase, supply, use, or pay or reimburse for, our products. Activities and materials which *appear* to encourage a product choice are also promotional.

Why and How We Do It

AstraZeneca's long-term future depends on selling and marketing our products the right way. We follow local process for approval of promotional activities and materials to make sure HCPs get the most accurate information to use in deciding how to treat their patients and to protect our ability to keep delivering life-changing medicines.

We promote our products only after they have been approved. We promote them for their approved uses, consistent with product labelling, to HCPs in appropriate medical specialties.

We do not promote our products for unapproved uses.

Refer to Promotional and Non promotional materials approval process and material withdrawal for further details:

- The word “new” must not be used to describe any drug which has been generally available, or therapeutic indication which has been generally promoted, in India for more than 12 months.
- Brand names of products of other companies must not be used in comparison unless the prior consent of the companies concerned has been obtained.
- When communicating with patients, AZ must not give medical advice, but must instead refer the patients to their HCPs for further information.
- Scientifically-trained employees and Commercial employees may collaborate or coordinate in appropriate circumstances to develop and deliver promotional and non-promotional activities and supporting materials, but they must not direct each other’s activities.
- AZ employees in customer-facing roles must be appropriately trained on AZ products and uses and related information, using only approved training materials.
- Promotion to the public/patients (i.e. “direct to consumer” advertising) is not allowed in India. However, non promotional activities to public/patients for awareness is allowed and has to follow the principles for non promotional activities.
- Only Nominated Signatories have the authority for final approval and sign- off of promotional materials.
- Where the purpose of promotional material is to provide persons qualified to prescribe or supply with sufficient information upon which to reach a decision for prescribing or for use, then the following minimum information, must be given clearly and legibly and must be an integral part of the promotional material:
- The relevant drug, the name and address of the holder of the authorisation or the business name and address of the part of the business responsible for placing the drug on the market;
- The name of the drug, and a list of the active ingredients, using the generic name, placed immediately adjacent to the most prominent display of the name of the drug;
- Recommended dosage, method of use and, where not obvious, method of administration;
- Adverse reactions, warnings and precautions for use and relevant contraindications of the product;
- A statement that additional information is available on request;
- The date on which the above particulars were generated or last updated.
- Promotional material such as mailings and journal advertisements must not be designed to disguise their real nature. Where the company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble editorial matter.
- All promotional materials appearing in journals, the publication of which is paid or secured or arranged by the company and referring by brand name to any product, must comply with above clause of this SOP as appropriate, irrespective of the editorial control of the material published.
- Promotional material must confirm, both in text and illustration, to canons of good taste and must be expressed so as to recognize the professional standing of the recipients and not be likely to cause offence.
- The names or photographs of healthcare professionals must not be used in promotional material.
- Promotional material must not imitate the devices, copy slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.
- Where appropriate (for example, in technical and other informative material), the date of printing or of the last review of promotional material must be stated.
- Postcards, other exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising to the lay public or which could be considered unsuitable for public view.

- Audio-visual material must be accompanied by all appropriate printed material so that all relevant requirements of the Code are complied with.

Revision History

Version number	Valid from	Modified sections
As assigned by ECMS	1st June 2024	• To update SOP in ECMS system
9.0	1st May 2023	• Page 1 – Removed reference “We promote directly to patients only where the law allows” to avoid confusion.
8.0	15th June 2021	• Revision History column added at the end for ease of reference • No further changes to Promoting our Products SOP Version 7. Approval sought to comply with re-approval timelines and avoid expiry of the SOP
7.0	July 2019	• Aligned to Global Standards. • Added Local UCPMP requirements. • Added only reference to Promotional materials and withdrawal SOP removing the embedded document.
6.1	March 2018	• Reapproved without any changes. Approval sought to comply with re-approval timelines and avoid expiry.

Document Approvals

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