

The APEC Mexico City Principles

Section Two: Promotional Information and Activities

What the APEC Principles say:

- A. No medicines shall be promoted for use in a specific economy until the requisite approval for marketing for such use has been given in that economy. Promotion should be consistent with locally approved product information.
 1. It is understood that national laws and regulations usually dictate the format and content of the product information communicated on labelling, packaging, leaflets, data sheets and in all promotional material.
 2. Companies commit that pertinent and appropriate information will be made available to all healthcare professionals in all economies, as permitted by applicable laws and regulations.
- B. Promotional information should be clear, legible, accurate, balanced, fair, objective and sufficiently complete to enable healthcare professionals to form his or her opinion of the therapeutic value of the medicines concerned.
 1. Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It should not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.
 2. Promotional information should be capable of substantiation either by reference to the approved labelling or by scientific evidence. Such evidence should be made available on request to healthcare professionals. Companies should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.
 3. Companies are responsible for compliance with applicable laws and regulations, including intellectual property laws, and local, national, and regional industry codes of ethics.
 4. Clinical assessments, post-marketing surveillance and experience programmes and post-authorization studies must not be disguised promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose.
 5. Materials sponsored by a Company relating to medicines and their uses, whether promotional in nature or not, should clearly indicate by whom they have been sponsored.

What this means:

For Companies: Companies are responsible for all promotional information and materials they distribute;

For Industry Associations: Codes should advise that members' promotional materials align with local regulations.

For Healthcare Professionals: Expect that enterprise representatives have knowledge about their medicines. Healthcare professionals should seek further information from enterprise representatives to support information provided in promotional materials.

In practice, this means:

- Ensure that there are appropriate procedures in place for the enterprise to approve all promotional materials that will be used by company representatives when interacting with healthcare professionals. Enterprise representatives should not use any materials that have not been approved by their company.
- It is critical that pharmaceutical promotion is balanced and not misleading. Healthcare professionals will place much greater value on promotional information that:
 - is up to date, balanced and not misleading;
 - includes claims that are substantiated by the approved labeling or other relevant scientific evidence;
 - gives a fair representation of the therapeutic value of the medicine; and
 - expands their knowledge of the medicine to assist in patient care.