Corporate Policy 5
On-Label Product Promotion

Purpose

The promotion of medical products is regulated by the United States Food and Drug Administration ("FDA") and regulatory bodies in other countries in which Stryker conducts business ("other authority"). The applicable laws and regulations are designed to make certain that the information that manufacturers provide to health care professionals and patients about the uses, benefits, and risks of medical products is truthful, not misleading, and based on robust scientific information and sound clinical evidence. Among other things, these laws and regulations generally limit the promotion of medical products to the cleared or approved uses of those products, or uses which are otherwise consistent with the labeling of those products. As part of Stryker's commitment to operating ethically and lawfully, Stryker and its agents must only promote Stryker products for uses that are consistent with the labeling for those products. Executing on this commitment is consistent with Stryker's business goals, as it supports the company's reputation for professionalism and our credibility among health care professionals and patients.

Stryker's Code of Conduct provides that the company "will represent its products and services accurately and will comply with applicable regulatory and legal requirements governing the marketing and sale of its products and services." The purpose of this On-Label Promotion Policy is to provide further guidance and direction on the company's commitment to promoting its products and services in compliance with applicable regulatory and legal requirements by making it clear that Stryker employees, contractors, consultants, and other third parties acting on Stryker's behalf may only promote Stryker products for on-label uses.

Scope

This Policy applies to all employees, officers, and directors of Stryker and its domestic and foreign subsidiaries. In addition, where noted, this Policy also applies to contractors, consultants and other third parties acting on Stryker's behalf when those persons engage in educating on or promoting Stryker products (e.g., distributors and educational speakers).

Basic policies

1. **Definitions for purposes of this Policy**

   1.1. The term 'health care professional" ("HCP") means those individuals or entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe products sold, leased, or distributed by Stryker.

   1.2. The term "on-label use" means any use that (i) the FDA or other authority has cleared or approved for a product, (ii) is consistent with then current FDA or other comparable authority guidance, or (iii) is within the scope of an applicable 510(k) exemption or a similar exemption under applicable laws or regulations outside the United States.

   1.3. The term "off-label use" means any use that (i) the FDA or other authority has not cleared or approved for a product, (ii) is not consistent with then current FDA or other comparable authority guidance, or (iii) is not within the scope of an applicable 510(k) exemption or a similar exemption under applicable laws or regulations outside the United States.

   1.4. The term "promotion" (or "promoting") means any activity undertaken, organized, or sponsored by Stryker that may encourage the prescription, purchase, lease, recommendation to use, or use of Stryker products. Some examples of promotion include, but are not limited to:

   - Activities of sales representatives, including the presentation of detail aids or other printed materials to HCPs, emails from sales representatives to HCPs recommending the use of a Stryker product, and conversations between sales representatives and HCPs when the sales representative recommends the use of a Stryker product.
   - Advertisements of Stryker products in medical journals.
   - Information about Stryker products presented to the general public in the form of television or print advertisements, direct mail pieces, or internet websites or other electronic media.
   - Any activity undertaken, organized, or sponsored by Stryker, the purpose of which is to provide information on the safe and effective use of Stryker products. Examples of such activities include product trainings and presentations and trainings on Stryker products given by Stryker employees or HCPs to other HCPs or to patients, including when the presenting HCPs are paid by Stryker or are acting on behalf of Stryker.

2. **Standards for promotion:** All promotion of Stryker products must be truthful, non-misleading, accurate, objective,

balanced, scientifically sound, and consistent with the on-label use of the product. Such promotion of Stryker products must not be misleading by omission, exaggeration, undue emphasis, or in any other way. These principles apply to contractors, consultants and other third parties engaged by Stryker for the purpose of promoting Stryker products.

3. **Prohibition of off-label promotion**

   3.1. Promotion of a Stryker product for an off-label use is prohibited. Promotion of an off-label use is not acceptable even when the off-label use is an accepted medical practice or standard of care. These principles apply to contractors, consultants and other third parties engaged by Stryker for the purpose of educating on or promoting of Stryker products on behalf of Stryker.

   3.2. Examples of prohibited off-label promotion may include, but are not limited to:
   - Promoting a Stryker product for an unapproved or uncleared use when no Premarket Approval Application ("PMA"), 510(k) or applicable exemption applies (e.g., promoting an implant for use in a part of the body or in a manner that is not within its approved or cleared use).
   - Promoting a Stryker product for a specific use within a general on-label use (e.g., promoting a laser for use in a stented coronary artery when the laser is only cleared for use in coronary arteries).
   - Promoting two separately approved or cleared products for combined use when those products are not approved or cleared for use together (e.g., promoting a cleared Stryker product for use as an attachment to another cleared Stryker product, when the combination of the two products has not been approved or cleared by the FDA or other authority).
   - Promoting an unapproved or uncleared method of implantation, deployment, placement, insertion, removal, or other surgical technique for a Stryker product (e.g., promoting insertion of an implant from a posterior approach when the regulatory approval of the implant only covers insertion from an anterior approach).
   - Promoting a Stryker product for a specific patient population that is not covered by the approval or clearance (e.g., promoting a fixation device for use in pediatric patients when the device is not specifically approved or cleared for pediatric use).
   - Calling on physicians whose specialties are such that the Stryker product in question could only be reasonably expected to be used off-label by that physician (e.g., calling on a pediatric surgeon when the product is contraindicated for use in pediatrics).
   - Soliciting physician participation in a clinical study of an off-label use of a product, where the investigation is not properly authorized under applicable law (e.g., in the US, funding a clinical study on an unapproved indication for use that is set to be initiated without an approved Investigational Device Exemption (IDE)).

4. **Approval of promotional materials:** Only materials that have been approved pursuant to the applicable Stryker procedures may be used in connection with the promotion of Stryker products. Both the alteration of Stryker-approved promotional materials and the use of home-made promotional materials that have not been reviewed and approved by Stryker are prohibited.

5. **Obligations of sales and marketing personnel:** All sales and marketing personnel must be familiar with and understand the on-label uses of products for which they are responsible. They must also ensure that any third parties that they engage to educate on Stryker products (e.g., educational speakers) are familiar with and understand the on-label uses of any relevant products.

6. **Unsolicited questions from HCPs concerning off-label uses of Stryker products:** Field representatives shall not directly respond to unsolicited questions from HCPs concerning unapproved or uncleared uses of Stryker products.

   6.1. All unsolicited requests by HCPs for the provision of information about the off-label use of Stryker products shall be directed to the Clinical Affairs or Medical Affairs employees and/or department, or applicable Medical Consultant ("CA") and follow established procedures.

   6.2. Company responses will be prepared and disseminated by CA in accordance with then current guidance from the FDA or other applicable health authority(ies).

   6.3. If an HCP initiates a discussion regarding the functionality (e.g., manner of use, product characteristics, or operating parameters) of a Stryker product for an off-label use in an immediate patient care setting (including immediately prior to a surgical procedure), the field representative may describe the functionality of the Stryker product for that use after notifying the HCP that the proposed use is off-label. The field representative may only describe information on product functionality on which the representative has been trained or which information has been provided to the field representative pursuant to Stryker policy by the company. Anecdotal information shall not be described by the field representative.

   6.4. If an HCP initiates such a discussion other than in an immediate patient care setting, the field representative shall offer to direct the inquiry to CA.

   6.5. Under no circumstances shall a field representative participate in discussion about potential clinical outcomes of an off-label use or make reference to other information where the outcomes of such off-label use may be discussed.

Compliance

All employees and directors of Stryker Corporation are responsible for complying with this On-Label Promotion Policy, and the president or executive in charge of each division, subsidiary or operating unit is responsible for ensuring that his or her employees know and comply with this Policy. Violations of this Policy will result in disciplinary action, up to and including dismissal. If you have questions about this Policy, please contact your legal, compliance or RAQA business partner, or Stryker's chief compliance officer, Chief Legal Officer/General Counsel or Vice President of Corporate RAQAC.