

1.0 Purpose

The purpose of this Policy is to ensure that all Product marketing, advertising, promotional, scientific, and sales (“MAPSS”) materials used in conjunction with activities conducted by or on behalf of Danaher’s operating companies comply with all applicable Product marketing, advertising and promotion laws and regulations in the countries in which Danaher operating companies do business.

Danaher and its operating companies are committed to disseminating accurate and substantiated information about its Products and, where appropriate, competitive products. All MAPSS materials that are disseminated by or on behalf of Danaher companies must contain accurate, appropriately supported, balanced, up to date information that is truthful and not false, deceptive or misleading.

2.0 Scope

This Policy applies worldwide to all Danaher’s Diagnostics, Life Science associates and Hach’s medical business associates, Products and Services. Additionally, the requirements outlined in this Policy must be communicated to and followed by those associates acting on behalf of Danaher’s Diagnostics, Life Science and Hach’s medical business whose responsibilities include creating, reviewing, approving or disseminating MAPSS materials as well as Product or Service related sales or marketing communications, education and training for internal or external recipients.

This Policy is global in scope and is supplemented by each operating company through specific corporate, operating company and business unit procedures and guidance to reflect applicable national or regional legislation and regulations. To the extent that there is a difference between the standards set forth in this Policy and the national law or regulation, the national and regional laws and regulations shall take precedence.

3.0 Definitions

MAPSS: May include the following:

(1) Advertising (e.g. television, radio, print, web (internet), social media); (2) press releases; (3) links to branded and corporate websites; (4) Booklets/pamphlets/posters/brochures and holders; (5) Patient, Healthcare provider or Consumer promotional programs; (6) endorsements and testimonials; (7) Convention booths/kiosks and Materials utilized at such booths; (8) Direct mail pieces, including professional mailings or scientific publications disseminated for educational or promotional purposes; (9) Internet activity (e.g., “adword” buys, hosted web sites, “likes or automated tools for sharing or forwarding social media content); (10) Invitations to events; (11) Material accompanying product samples or product demonstrations; (12) In-office educational programs or presentations; (13) Product related press releases; and (14) Video news releases that contain product claims.

Off-Label Use: An intended use, indication for use or other use of a medical Product that is not (1) cleared, approved or otherwise authorized by a relevant health authority, or (2) included in the Product's labelling, Instructions For Use, marketing application or license authorized by a relevant health authority within the respective country.

Product: Any medical product, In Vitro Diagnostic (IVD), Analyte Specific Reagent (ASR), General Purpose Reagent (GPR), Investigational Use Only (IOU), Research Use Only (RUO), Pharmaceutical, and Biologic that are regulated by FDA or equivalent global Health Authorities. This includes software, service and accessories.

Repurposed Content: Product marketing, advertising, promotional, sales, scientific, educational or training material content used and adjusted to fit different communication channels.

Substantiation: Tests or studies, including clinical studies, bench studies, peer-reviewed scientific literature, proprietary research, authoritative sources, performance tests, objectively conducted or obtained by qualified professionals using procedures or techniques accepted as accurate and reliable that prove or support all material facts and messages that can be reasonably inferred from a claim or promotional message.

Unsolicited Request: Request for off-label information initiated by persons or entities that are completely independent of Danaher's operating company, i.e., health care professionals, health care organizations or patients and that has not been prompted by any Danaher or operating company associate.

4.0 Policy Statement

4.1 General

This Policy sets forth minimum standards that apply to all Product and/or Service related MAPSS materials regardless of the communication medium. This Policy also applies to all Product and/or Service oriented sales training material.

4.2 Guiding Principles

The procedures and processes for creating, reviewing, approving, using and disseminating MAPSS materials must provide the level of oversight that is appropriate based on applicable laws and regulations, and the content, purpose and medium. Danaher operating companies must adhere to the guiding principles described below for the creation, review, approval, use and dissemination of MAPSS materials and execution of MAPSS activities.

Any Product MAPSS or education and training materials, whether the purpose is for customer-facing use or internal use, involving existing or proposed Products or Services must:

1. Be reviewed and approved in advance in accordance with this policy, applicable procedures and applicable laws and regulations;
2. Promote only the intended use(s), claims, and performance of the Product as legally authorized, cleared or approved by appropriate regulatory authority, except where expressly permitted by applicable operating company procedure;
3. Not contain Off-label claims that are PROHIBITED for the specific Product or Product related use identified, whether these claims are made through marketing, advertising, promotional or training material or verbally, except where expressly permitted by applicable operating company procedure;
4. Comply with all applicable laws, regulations, directives, and standards promulgated by national, regional and local legislative and/or regulatory bodies of the countries in which the communication is to occur;
5. Contain reference, or otherwise be supported by appropriate substantiation and up to date information that is truthful, accurate and not false, deceptive, misleading or contradicted by the weight of accepted scientific evidence;
6. Accurately reflect the nature, performance and characteristics of the product, service or offering it identifies, describes or represents and, where comparing a Product with one or more competitive products, accurately reflect the nature, performance and characteristics of and not omit material information about the competitive product(s);
7. Not directly or indirectly overstate the benefits or positive attributes of the product or omit any material information regarding the product's risks or limitations for use;

4.3 Procedures

All Danaher's operating companies within scope of this policy must establish advertising and promotional procedure(s) which must conform to the following minimum requirements:

1. Define types of marketing collateral that are subject to this policy including medium such as company website and social media sites, trade shows, webinars, hands-on training, etc.
2. Define requirements for the MAPSS review and approval process, including

roles and responsibilities. This should include requirements for review and approval process for Repurposed Content, single Product versus multiple Product communication materials, as well as single versus multiple businesses multiple Product communication materials.

3. Define that approved MAPSS materials may not be modified or may only be modified in clearly delineated ways.
4. Define how to respond to unsolicited requests for off-label information.
5. Define where applicable, requirements for review and dissemination of scientific literature on off-label use.
6. Define requirements for life cycle management of content management systems.
7. Define distribution channels and access rights for MAPSS or educational and training material, both external as well as for internal use.
8. Define requirements for determining when and how MAPSS and other Product and/or Service related sales or educational materials and will be obsoleted and removed from use.
9. Define procedures for auditing of MAPSS or educational and training material, both external as well as for internal use.
10. Define requirements for periodic internal audits of the procedures and processes for creating, reviewing, approving, using and disseminating MAPSS materials.

4.4 Training

All Danaher's Diagnostics, Life Science and Hach's medical business units' customer-facing associates and associates that are involved in the MAPSS process must be periodically trained on the operating company's advertising and promotional procedures and the applicable laws, regulations and guidelines, including off-label promotion as it relates to company Products.

5.0 Consequences of Non-Compliance

Failure to comply with this policy and/or applicable laws and regulations may result in disciplinary action up to and including termination of employment.

Failure to adhere to applicable laws and regulations concerning medical Product marketing, advertising and promotional activities may also result in severe financial penalties for the company and could result in personal liability.

6.0 Reporting Violations

Associates are expected to report any actual or potential violations of this Policy. Reports should be made to a supervisor, the Office of Compliance, Human Resource, the Operating Company and/or Danaher Legal departments, or through the Danaher Integrity & Compliance Hotline. Danaher will not tolerate any form of retaliation against an associate who makes a report in good faith.