



INTERACTIONS WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANIZATIONS GLOBAL POLICY

TITLE: Interactions with Healthcare Professionals and Healthcare Organizations Global Policy	
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1. PURPOSE

Angelini Pharma is committed to acting with the highest standards of honesty, transparency and correctness when interacting with the scientific community.

Ethical relationship with Healthcare Professionals and Healthcare Organizations (hereafter HCP and HCO) is a critical part of developing and marketing healthcare products. Physicians need to learn how to use new products. Angelini Pharma representatives have the important role to teach them how to use these products. To help ensure the integrity of the relationship between our representatives and doctors Angelini Pharma base standards and requirements on Company codes of conduct as well as legal, regulatory and professional requirements of the countries of where business is done.

2. SCOPE

All Angelini Pharma Employees (hereafter “Employees”) are responsible for adhering to the principles of this policy.

This policy applies to all Countries involved in Angelini Pharma business, taking into account local requirements. In case of conflict between the Local Regulation and the policy the stricter of the two shall be applied.

Third parties involved in conducting activities covered by this policy and on behalf of Angelini Pharma are expected to comply with this policy.

The following principles must be followed when dealing with any healthcare professionals, healthcare organizations and systems.

3. GENERAL RULES

Angelini Pharma regularly conducts internal audits to assess any violation respect to this policy.

Contact the Compliance or Legal representative if you have a question or are uncertain about the scope or application of the Global Policy Interactions with HCP and HCO.

Breaching this policy means also breaking the law with consequences such as disciplinary actions in accordance with the applicable Law.

4. MEDICAL INFORMATION COMMUNICATIONS

Angelini provides reply to medical enquiries from HCPs and others about the use of our products. In providing this information about our products, Angelini Pharma strives to ensure that such communications are accurate, substantiated, scientifically rigorous and consistent with applicable legal and regulatory standards.

5. INTERACTIONS WITH THE SCIENTIFIC COMMUNITY

5.1. PROMOTIONAL ACTIVITIES

Angelini Pharma may interact with HCPs and HCOs, either directly or via a third party, to promote products. All interactions must have clear intent, transparent objectives, and must not interfere with the independence of the HCPs and HCOs.

Angelini Pharma may produce and disseminate content (printed, electronically, and orally) to inform, educate, or promote its products. All content must be accurate, fair, balanced, truthful and not misleading, based on adequate substantiation and consistent with the scope of the relevant product’s marketing authorization.

Angelini Pharma Employees working with HCP and HCO, and other third parties working on Angelini Pharma’s behalf must take care to avoid promoting, directly or indirectly, any product use that Angelini Pharma has not being permitted to promote based on applicable local laws and regulations or agreements with Regulatory Authorities.

5.2. EVENTS

Angelini Pharma may organize, or fund events organized by third parties with the objective to provide scientific information or education or disease areas of interest.

Events must have clear purpose and be transparently conducted.

If the purpose of the event is non-promotional, materials with brand colors and logos or any promotional content cannot be used, and any perceptions of disguised promotion must be avoided.

- THIRD PARTY MEDICAL MEETINGS AND CONFERENCES: Angelini Pharma provides funding to third party organizations to support medical education and medical conferences. The main purpose of medical congresses, conferences, symposia and similar programs supported by Angelini Pharma must be scientific exchange and/or medical education.
- ANGELINI HOSTED EDUCATIONAL AND/OR PROMOTIONAL MEETINGS: are designed to educate healthcare professionals about our products. Such meetings must be focused on education.

COMMON RULES:

- Hospitality offered in connection with meetings must be appropriate and compliant to applicable laws, regulations and industry codes.
- Hospitality will not include Angelini-sponsored entertainment e.g. sporting or leisure events.
- Meetings are to be held in appropriate venues conducive to the main purpose of the meetings and, where practical, near where the majority of the attendees live or work.
- Angelini Pharma will not provide financial support for attendance by spouses or guests (unless qualified in their own right to attend).

5.3. CONSULTANT MEETINGS AND USE OF HEALTHCARE PROFESSIONAL CONSULTANTS

Angelini Pharma may engage with HCPs and HCOs for professional services, either directly or via a third party. Such services may include the engagement of HCPs as speakers for promotional speaking programs, scientific standalones, or other events, consulting engagements, advisory boards and/or market research, participating in clinical trials or other research, speaking at presentations or conferences or training Angelini Pharma employees. Irrespective of direct engagement or via a third party, Angelini Pharma is responsible for engaging appropriately and without the intent, perception or consequence of inappropriately influencing HCPs or HCOs to prescribe, purchase, recommend, sell, or improve access for any of Angelini products.

ENGAGEMENT OF HCP/HCO RULES:

- Engagements of HCP/HCO must be based on a legitimate business need for the service;
- HCPs or HCOs engaged must have the necessary experience and/or capabilities to provide the specific service;
- The engagement must be confirmed in a written agreement signed by both parties before commencing any services;
- Conflicts of interest must be identified before engaging the selected HCP/HCO, to be avoided;
- Compensation for services must be reasonable and at fair market value in relation to the services rendered;
- Only modest, reasonable meals and hospitality must be provided;
- All interactions and transfer of value must be properly tracked, documented, reported, and accounted for, in accordance with local laws, regulations and industry codes;
- Evidence of the service provided by the HCP/HCO should be collected and filed.

5.4. EXTERNAL FUNDING

Angelini Pharma may provide funding or other support to external organizations. This includes grants, donations, funding for medical education such as preceptorship programs, and sponsorships according to local laws, regulations, and industry codes.

EXTERNAL FUNDING OR SUPPORT MUST:

- Only be given to legitimate organizations, never to individuals;
- Be aimed at supporting healthcare, scientific research or education and not used to influence HCPs or HCOs to prescribe, purchase, recommend, sell, or improve access for any of Angelini products.
- Have a clear and defined purpose;
- Be reasonable and legitimate in light of the activity being funded;
- Be properly tracked, documented, reported, and accounted for, in accordance with local laws, regulations and industry codes.

5.5. PRODUCT SAMPLES

Where permitted by local laws, regulations, and industry codes, free samples of Angelini Pharma products may be provided to HCPs authorized to prescribe that product in order to enhance patient care or provide experience with the product. Pharmaceutical samples must be permanently labeled as samples and managed with systems of control and accountability. They must never be resold or otherwise misused.

Over the counter (OTC) product samples may be distributed directly to customers where permitted by local laws, regulations, and industry codes.

Samples may not be used as gifts and may not be sold, purchased, traded or offered for sale, purchase or trade.

5.6. DISCLOSURE OF CLINICAL TRIAL INFORMATION

All sponsored clinical trials must be ethical in their design and implementation. It is required that Angelini Pharma sponsored clinical trial conform to well-accepted international standards, such as the Good Clinical Practice (GCP), guidelines of the International Conference of Harmonization and the Nuremburg Code. All clinical trial protocols must comply with Angelini Pharma Standard Operating Procedures for clinical research.

Angelini Pharma supports the publication of study results in a timely manner and must not withhold or suppress data. Confidential and/or patentable information, and personal information are protected. Where required by local laws, regulations and/or industry codes, Angelini Pharma must disclose and report any payments or transfer of value made to HCPs and/or their institutions for research studies and third-party medical writing support for publications.

6. TRANSPARENCY

Angelini Pharma recognizes that interactions with HCPs and HCOs can give rise to apparent or actual conflicts of interest.

Angelini Pharma supports the disclosure of financial and other interests and relationships that may create apparent or perceived conflicts of interest in research, education or clinical practice.

In dealing with HCPs and HCOs care will be taken to ensure that such dealings comply with all applicable laws, regulations, professional requirements and industry codes.

7. BOOKS AND RECORDS

Angelini Pharma must prepare and maintain records that accurately and reasonably detail and document all the activities in every phase carried out with HCP/HCO. The retention and archive of Angelini Pharma must be consistent with Angelini Pharma's standards and tax and other applicable laws, regulations and industry codes.

8. REPORTING SUSPECTED OR ACTUAL VIOLATIONS

Any Employee with knowledge of suspected misconduct must report his/her suspicion promptly.

Employees who report potential misconduct in good faith or who provide information or otherwise assist in any inquiry or investigation of potential misconduct will be protected against retaliation.

9. DEFINITIONS

CLINICAL TRIAL: Clinical trial is a research study that explores whether a medical treatment or device is safe and effective for humans. It plays a critical role in the process of bringing new therapies to patients.

DONATION: providing funds, assets or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.

EVENTS: All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) (each, an "Event") organized or sponsored by or on behalf of a company.

FAIR MARKET VALUE: The value should consider the nature of the services provided (specific duties and responsibilities, specific objectives and deliverables, and the expected or required allocation of time (hours) for each duty and/or responsibility), the qualifications (current and prior positions, educational credentials and specialized training, professional certifications, academic appointments, research experience and funding history, invited presentations, publication history, other professional leadership activities, and recognition in the healthcare community or other field in which the HCP/HCO operates), the geographic location, the nature of the market for the services to be provided by the HCP/HCO, and the prevailing rates for similar services.

FUNDING: Providing financial resources to finance a need, program, or project.

HEALTHCARE ORGANIZATION (HCO): Any legal person (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations within the scope of the EFPIA PO Code) or (ii) through which one or more HCPs provide services.

HEALTHCARE PROFESSIONAL (HCP): Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.

MARKET RESEARCH: The process of gathering, analyzing and interpreting information about a market, about a product or service to be offered for sale in that market, and about the past, present and potential customers for the product or service; research into the characteristics, spending habits, location and needs of your business's target market, the industry as a whole, and the particular competitors to face.

OVER THE COUNTER (OTC) PRODUCT: A product marketed for use by consumer without the intervention of an HCP in order to obtain the product.



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THIRD PARTY REPRESENTATIVE: Refers to those who are authorized to act for or on behalf of Angelini Pharma, and may include distributors, subcontractors, regulatory agents, advisors, consultants, clinical research organizations, market research firms, meeting planners, agents, custom brokers and contract manufacturing organizations.

10. DOCUMENT HISTORY

Effective Date	Version	Change Reason and Description
Refer to flag page	1.0	New document