

Global Pharma Policy

Interactions with Healthcare Professionals and Healthcare Organizations

Approval Flow for this Global Pharma Policy

	Function
Prepared	Global Compliance
Checked	Global Medical, Global Legal, Global HR & Organization, Global Finance & Administration
Approved	CEO

Information about this version of the Global Pharma Policy

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1. Purpose and principles

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

This Document aims to ensure that the representatives, officials and all those who, for various reasons, collaborate with the Company follow, in the performance of their activities, lawful, correct and transparent conduct in line with the Company's guiding values in pursue its corporate purpose, so as to prevent the risk of commission of crimes and behavior that is in any case unlawful or improper.

2. Implementation of Global Pharma Policy by Angelini Pharma Group companies

All Group companies comply with the requirements of this Policy.


It is the responsibility of the directors and managers of the Group companies to always set an example and guide employees so that they fully understand the scope of the Policy and of the internal control systems adopted.

3. Regulatory references

- Legislative Decree No. 219 of 24 April 2006 as subsequently amended;
- Legislative Decree No. 231 of 8 June 2001 as subsequently amended;
- Legislative Decree No. 24 of 10 March 2023;
- Legislative Decree No. 196 of 30 June 2003 as subsequently amended;
- Regulation (EU) No. 2016/679;
- Legislative Decree No. 101 of 10 August 2018;
- IFPMA Code of Practice;
- EFPIA Code of Practice;
- Farmindustria Code of Practice;
- Confindustria Medical Devices Code of Ethics;
- National and local regulations applicable to the cases described in this Group Policy.

4. Internal references

- Code of Ethics of the Angelini Industries Group;
- Organisation, management and control models adopted pursuant to Legislative Decree No. 231 of 8 June 2001 by Angelini Pharma S.p.A.;
- Internal regulatory documents adopted by the Group's overseas companies in compliance with the applicable local legislation;
- Global Compliance Guidelines;
- "Anti-corruption and Relations with Public Officials" Group Policy;
- "Management of Conflict of Interest" Group Policy;
- Whistleblowing Global Policy;

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- Transparency Global Policy.

5. Scope of application

This Policy regulates the interactions with any Healthcare Professionals and Healthcare Organizations.

In case of conflict between the Local Regulation and the Policy the stricter of the two shall be applied.

If you have any questions or want information on this Policy, each Recipient may request the necessary clarification from the Global Compliance function.

6. Recipients

This Policy applies **to all Group companies**.

It is adhered to by all **representatives, officials** and **employees** involved in the process, including **Third Parties**.

7. Definitions, abbreviations and acronyms

Term	Definition
Decree 231/2001	Legislative Decree No. 231 of 8 June 2001, (<i>"Regulations governing the administrative liability of legal entities, companies and associations, including those without legal personality, pursuant to article 11 of Law No. 300 of 29 September 2000"</i>).
Compliance Laws	The laws, legislative acts and regulations - however named - on anti-corruption and prevention of offences in force in the countries where business activities are carried out/envisaged by the Group Companies (including: the U.S. Foreign Corrupt Practices Act; the UK Bribery Act; the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions; etc.).
Group Code of Ethics	A company document that, in the context of business organisational matters, defines the ethical-social responsibilities and principles of conduct to be followed by all participants in the activities of the Angelini Industries Group Companies, including stakeholders.
231 Model	The Organisation, Management and Control Models adopted by the Group's Italian company pursuant to the Decree, setting out the principles and rules of conduct aimed at preventing the

Term	Definition
	commission of offences constituting the entities' administrative liability for crime.
Compliance Model	The internal compliance regulations adopted by the foreign Group Companies in accordance with the respectively applicable Compliance Laws.
Clinical Trial	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) or (ii) through which one or more HCPs provide services.
Healthcare Professional (HCP)	Any person who carries out their activity in the medical sector, dentistry, public, private or hospital pharmacies, any nurses, Administrators or staff of Local Health Authorities, any technical or administrative personnel of public or private healthcare structures and any other person within the scope of their

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Term	Definition
	professional activity can prescribe, dispense, purchase or administer a medicinal specialty. Intermediary pharmaceutical distributors are however excluded.
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.
Third Parties	Those who are authorized to act for or on behalf of Angelini Pharma, and may include suppliers, agents, consultants, vendors, partner in general.

8. Interactions with the Scientific Community

8.1. Activities

Angelini Pharma may interact with HCPs and HCOs, either directly or via third party. 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 HCPs and HCOs, 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 been permitted to promote based on applicable laws and regulations.

8.2. Medical information communication

Angelini Pharma 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.


8.3. Events

Angelini Pharma may organize, or fund - also through Third Parties - events with the objective to provide scientific information or education on disease areas of interest.

Events must have clear purpose and be transparently conducted.

Hospitality extended in connection with events must be appropriate, limited to travel, meals, accommodation and genuine registration fees and in compliance with applicable laws, regulations and industry codes.

Angelini Pharma may offer meals (food and beverages) to HCPs or HCOs' members according to the

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monetary threshold set by the relevant regulation following the “Host Country Principle”.

Angelini Pharma will not provide hospitality and financial support for attendance by spouses or guests unless qualified in their own right to attend.

All forms of hospitality offered to HCPs or HCOs’ members must be reasonable in level and strictly limited to the main purpose of the event.

Hospitality will not include sponsoring or organizing entertainment events e.g. sporting or leisure.

8.4. Contracted services and scientific consultancies

Angelini Pharma, based on a legitimate need, may engage HCPs and HCOs for professional services, either directly or via Third Party. Such services may include i. the engagement of HCPs or HCOs as speakers for promotional speaking programs, scientific standalone events, ii. consulting engagements, advisory boards and/or market research, iii. participating in clinical trials or other research, iv. speaking at presentations or conferences or v. training to Angelini Pharma employees.

Irrespective of direct engagement or via Third Party, Angelini Pharma is responsible for engaging appropriately and without the perception of inappropriately influencing HCPs or HCOs to prescribe, purchase, recommend, sell any of Angelini Pharma products.

Rules to engage HCPs and HCOs

- Engagements of HCP/HCO must be based on a legitimate need;
- The criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants must have the expertise necessary to evaluate whether the particular consultant meets those criteria;
- The number of consultants retained and the extent of the service are not greater than reasonably necessary to achieve the identified need;
- Conflicts of interest must be identified before engaging the selected HCP/HCO;
- A written contract is agreed in advance of the commencement of the services;
- Compensation for services must be reasonable and reflects the fair market value in relation to the services provided;
- Only modest, reasonable meals and hospitality must be provided;
- All interactions and transfers 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;
- Rotation mechanisms must be defined to prevent the same consultant from being engaged more than one assignment during predefined periods of time.

8.5. 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 organizations, to individuals are not permitted;
- Be aimed at supporting healthcare, scientific research or education and not used to influence HCPs or HCOs to prescribe, purchase, recommend, sell any of Angelini Pharma 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;
- Not include as recipients political or union trade organizations.

8.6. 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.

Samples may not be used as gifts and may not be provided to HCPs for their personal use or for any purpose other than free distribution to patients for their use; samples may not be sold, purchased, traded or offered for sale, purchase or trade.

8.7. 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 Practices GxP. 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.

9. Transparency

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

Angelini Pharma supports the disclosure of transfers of value, 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 interactions comply with all applicable laws, regulations and industry codes.

10. Traceability and archiving

Angelini Pharma must document adequately and accurately all activities – in each phase – with HCPs and HCOs.

The retention and archive of documents by Angelini Pharma must be consistent with the company's standards and tax and other applicable laws, regulations and industry codes.

11. Information and training

All Functions, bodies and individuals involved in the process regulated by this Global Policy must comply with it and make others comply with it.

Angelini Pharma promotes awareness of this Global Policy among Employees and Third Parties through publication on the company Intranet portal and on the company website in addition to other means of dissemination. Angelini Pharma plans and runs training activities on the subject.

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

12. Reporting violations and Whistleblowing

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.

13. Applicable penalties

Angelini Pharma has an effective, proportionate and dissuasive sanctioning regime that establishes sanctions for employees and third parties in the event of violations of this Policy and of corporate ethical principles.

14. Privacy

The processing of personal data shall be carried out in accordance privacy regulations, e.g. Regulation (EU) no. 2016/679 and Legislative Decree no. 196 of 30 June 2003, referring to the procedures adopted in this matter by the Company.

15. Version history of this Global Policy

Version history	Version	Issue	Description
	1.0	1 July 2020	First issue
	2.0	20 June 2024	General revision, updating of references and template, express prohibition of funding political or trade union organisations.