

Legal, IP & Compliance

Corporate Ethics & Compliance

Corporate Policy on Interaction with HCP, HCO, PO and Consumers



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01. PURPOSE

This Policy establishes the principles that should apply to the Interactions with Healthcare Professionals, Healthcare Organisations and Patients Organisations and Consumers.

Ferrer's Interactions will always be based on the principles of Lawfulness, Independence, Trust, Transparency, Integrity and Respect in accordance with the Ferrer Ethical Code and applicable regulations.



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02. Scope of application

This Policy applies directly to all Ferrer people, regardless of their hierarchical, functional, or geographic position.

If there is a regulatory requirement in a country that is stricter than the one established in this Policy, the more restrictive one will apply.

It also applies to distributors, agents and partners in a broad sense in any geographic area where Ferrer has signed trade agreements for the sale and/or promotion of its own or third-party products, on contractually agreed terms.



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03. Interactions with HCP, HCO, PO and Consumers

Collaborations with HCPs, HOs, POs and patients must meet a legitimate need. Procedures are in place detailing additional local requirements and approval workflows prior to the execution of such interactions.

3.1. Interactions with Patient Organisations

Ferrer can have Interactions with patients, caregivers or consumers in a manner that is always ethical, with mutual respect, transparency and guaranteeing independence.

The objectives and scope of any partnership must be transparent and free of any conflict of interest that could occur, so that any financial or other type of support provided by Ferrer will always be clearly acknowledged.

Ferrer will refrain from applying to be an exclusive collaborator/sponsor of a PO or any of its main activities.

It is not allowed to influence PO in the benefit of Ferrer interests and any interaction with promotional purposes should be avoided, and cross-promotion of medicines or medical devices must not be encouraged.

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Prescription medicines and other product categories can only be directly promoted to consumers in countries where this is legally permitted.

The collaborations with PO or patients will correspond to a legitimate need for the service and will be set forth in an agreement/contract signed by both parties before the service provision begins. Compensation for services will be reasonable in relation to the service provided.

Ferrer can carry out Patient Support Programmes (PSP), which will require prior approval from PA&PA, Corporate Medical Department and E&C . To this end, the interested area (applicant) must provide the following documentation:

- a)** Report on the PSP (purpose of the PSP),
- b)** informative document to health authorities and hospitals; and
- c)** an informed consent with the minimum information on the PSP so that the patient can understand the purpose and scope.

If a PO seeks Ferrer's support to sponsor or attend a scientific activity or fees are paid for services provision, the provisions of this Policy in relation to scientific events and fees should be followed.

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3.2. Training and educational tools and materials

Ferrer does not allow HCP to be directly or indirectly offered or given any type of incentive, bonus or gift (in cash or kind) .

The following are not considered incentives and their provision is therefore allowed: scientific material, promotional material, tools for professional use in medical or pharmaceutical practice, training or informational material that meets the following conditions: a) is of inexpensive value¹ , b) is directly related to the exercise of medicine or pharmacy and c) is of benefit to patient care.

Material is considered to be of inexpensive value when its market price, including taxes, does not exceed 70 € or its perceived local equivalent, unless the local legislation establishes a more restrictive value.

Within the framework of scientific and professional meetings organized by Ferrer related to prescription medicines, only pens and pads may be offered or provided, provided that they only incorporate the Ferrer logo, and their Market Price does not exceed 10 € (including taxes) or its local equivalent, unless the local legislation establishes a more restrictive value.

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Informational and educational tools, materials and elements of medical purpose related with prescription medicines can only include the Ferrer name and must not feature the product brand or active ingredients, unless the name of the medicine is essential for correct use of the material or element by the patient.

Materials and items required for the routine work of the HCP must not be offered since they will be provided by the employer. Courtesy and cultural gifts are also banned.

With regards the promotion of products other than prescription medicines, Ferrer allows the gifting of materials of professional use in medical or pharmaceutical practice and stationery items, as long as the market price does not exceed 10 € or its perceived local equivalent unless the local legislation establishes a more restrictive value.

Local procedures establish the approval of these elements prior to their purchase and supply to HCP, along with maximum permitted values for the definition of the “inexpensive value” concept.

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3.3. Samples

Ferrer people may freely supply prescribing HCP with a reasonable amount of medicine and device samples as required to familiarise themselves with the product, get experience in its safe and effective use, all this so long as it responds to a previous request by said professionals and in accordance with local procedures. Samples must never be an incentive for the HCP.

OTC product samples can be directly supplied to consumers to facilitate their knowledge around the product and its functions when regulations allow this.

All samples must be labelled “*Free sample. Not for sale*” and comply with additional labelling and approval requirements as established by law.

Local procedures must cover at least the following: (1) the definition of reasonable quantities; (2) control, evidence and reporting to ensure exclusive delivery to HCP and respecting limits; and (3) processes to collect expired samples for destruction; and (4) must be well preserved to ensure quality standards and traceability during all stages up to the delivery of the sample to the PS.

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3.4. Scientific-Technical events and meetings and associated hospitality

Ferrer can organise, partner on or sponsor meetings of an exclusively scientific and professional nature. It cannot organise or engage in meetings that contain entertainment elements or activities or which are of a recreational nature. Excluded from this ban are the welcoming cocktail events, work lunches and closing dinners commonplace in official programmes of congresses and scientific meetings, so long as they are reasonable and moderate, do not include additional elements (cultural, leisure, entertainment, etc.) and do not exceed the limits established in this Policy. The same principles apply to in-person and virtual meetings alike.

Ferrer can neither organise nor sponsor meetings intended for recipients other than HCP, except for congresses and activities for patients.

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3.4. Scientific-Technical events and meetings and associated hospitality

Third-party meetings sponsored by Ferrer must have a website accessible to the target audience through the official digital channel of the organisation and/or the technical secretary. The detailed scientific programme, venue and dates of the event, as well as the organizing HCO or PO must be present on the website. Ferrer can never sponsor an event organised by an HCP on an individual basis.

Meetings sponsored by Ferrer must state as such on all related documents and also in any work, speech or document published in relation to it. Information on the event must comply with the standards established in this Policy regarding promotional and informational content.

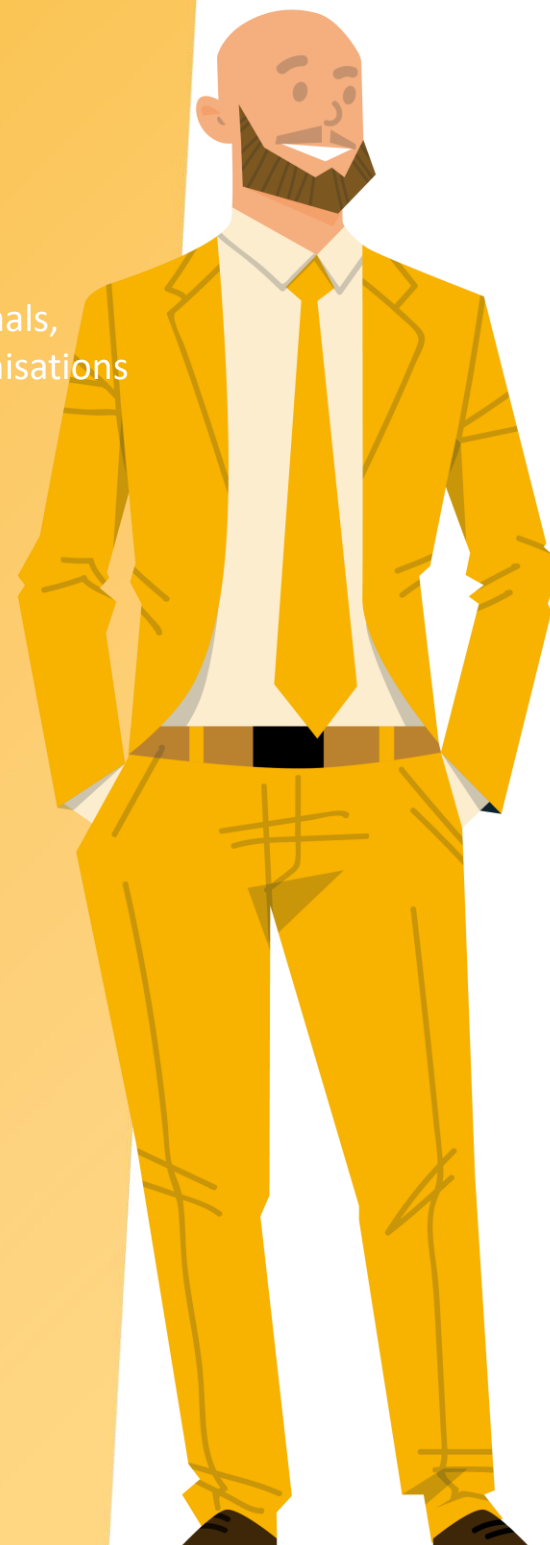
3.4.1 Promotional content distributed or displayed at scientific events:

Any promotional content distributed or displayed at meetings must have obtained prior internal authorisation and must follow the regulations of the country where the event is held. In the case of virtual meetings and given the potential attendance of people of different nationalities at the event, legends must be incorporated in the material specifying possible sales differences of promoted products, type of indication or any other condition required to comply with local regulations.

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3.4.2 Approval and communication of meetings and events:

For scientific and promotional meetings and/or events organised or sponsored by Ferrer, prior approval must be sought through the established channels before they are held. E&C department will approve/monitor and verify that all elements of event organisation comply with the obligations established in this Policy and in other internal regulations and will handle reporting this to the authorities or third parties when mandatory.



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3.4.3. Venue:

Chosen venues must be suitable and offer a reasonable level of hospitality. The venue cannot be an incentive and it must convey a suitable image. Venues will be selected considering the ease of travel for participants, cost, and suitability and appearance of the site. The use of clinical, health, educational environments and business hotels and conference centers is considered appropriate.

Ferrer may not organise or sponsor scientific meetings in hotels distinguished by their leisure offering.

In the selection of the location, preference should be given to well-connected business cities.

As far as possible, scientific meetings will not be held in tourist areas and/or seasons, nor coinciding with major sports or recreational events or other large shows.

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Local/national meetings will be prioritised over international ones unless it makes more sense logistically for either of the following reasons: :

- I) Most of the invited participants are from abroad, or
- II) An important resource or expertise which is the core purpose of the event is located abroad.

If organising or sponsoring international meetings, the country where most attendees come from should be selected. Spain's Code of Good Practices will be respected at these international meetings, along with that of the event's host country and the codes of the countries of residence of the attending HCP.

The platforms where virtual meetings are held must be provided with mechanisms to verify that only HCP have access to the content.

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3.4.4. Hospitality (food, travel, registration and accommodation):

The hospitality concept includes the real costs of food, travel, registration and accommodation. Hospitality must always be secondary to the scientific purpose of the meeting and limited to including logistics means as strictly necessary, reasonable and moderate and that enable HCP to attend the event. Hospitality can never be used to make up for the time HCP spend attending the event and it will be adjusted to the duration of the event.

Hospitality never will be reimbursed directly to HCP, except in the case of minor costs for travel (taxi, mileage, etc.) with appropriate justification of said expenses.

In any case, hospitality (including meals) cannot be extended to other than HCP attending the event.

Maximum costs per person (including taxes, beverages and tips) will be established in the different local procedures.

The offering of alcoholic beverages and any other expenses other than those described in this section is prohibited.

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No type of hospitality will be permitted in virtual meetings, except for registration.

If attendees must travel in a public transport, it will preferably be in economy class, except for long-haul flights, in accordance with the expenses policy in force at all times.

Maximum costs per attendee (taxes, drinks and tips included) will be established in line with the different local procedures.

Costs arising from registration, travel or accommodation at scientific meetings will be documented and published in accordance with the law or Code of Good Practices.



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3.4.5. Fees and sponsorship at scientific meetings:

Ferrer can pay fees for professional service provisions within the framework of scientific activities. Payment will be calculated according to the fees table Ferrer has for this purpose. The table considers market prices and work hours, or service effectively rendered.

Ferrer does not permit payment to HCP to make up for time spent attending the event.

3.5. Service provided by HCP, HCO and PO

Ferrer permits the hiring of HCP, HCO and PO individually or in a group for the provision of consulting services which involve the payment of remuneration either directly or through a third party.

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The following requirements must apply to the services provision:

- They must respond to a legitimate need and the purpose of collaborating with healthcare, research, teaching/training or the organisation of scientific or professional meetings.
- They must not seek to unduly influence prescribing.
- They must be free of conflict of interest.
- The criteria for selecting consultants should be based on legitimate need, and the person responsible for the selection should have the necessary expertise to assess whether the HCP meets these criteria.
- Payment must be monetary and adjusted to the internally defined FMV.
- The number of recruited HCP must not exceed the number reasonably required to deliver on the planned purpose.
- A service provision contract/agreement should be in place in advance, detailing: the provision of services, the fees to be charged, as well as any other necessary additional clauses.

Ferrer will include a clause in these contracts/agreements by which the HCP undertakes to state they are providing these advisory services each time they write or publicly speak out regarding any matter covered by or related to their agreement with Ferrer.

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When an HCP provides services in the framework of a scientific event, the provisions of this Policy in relation to scientific events should be followed.

Ferrer must maintain documentary support of the services provided by the HCP and use these services for their intended purpose.

The services will be published in accordance with the provisions of point 4 of this policy.



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3.6. Donations or Sponsorships

Donations will be regulated by the provisions of Ferrer's Corporate Donations Policy.

This support cannot be provided directly to individuals on a personal basis (patients or HCP) unless it is to attend a scientific meeting.

In sponsorship contracts/agreements must clearly state the service or benefit obtained by Ferrer, the form of publication and the disclosure of Ferrer's sponsorship in a transparent manner so it is clearly recognised and obvious.

If the sponsorship is related to a scientific activity, it must comply with what is specified in the section on scientific and technical events or meetings.

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3.7. Clinical Trials

Ferrer will only sponsor or engage in Clinical Trials intended to meet medical needs and/or provide data that help delivering a better understanding of the disease and/or improve decision making in the treatment of patients; discover or check clinical, pharmacological or other pharmacodynamic effects and/or identify any adverse reaction of a medicine or any of its products; or to study the absorption, distribution, metabolism and excretion of a medicine in order to determine its safety and/or efficacy.

These studies should not be undertaken under any circumstances as a procedure to promote a product or for the purpose of inducing prescription.

In the event that meetings are held, it must comply with what is specified in the section on scientific and technical events or meetings.

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3.8. Market Studies

Market Studies must comply with the laws in force and follow the ethical action framework of the Code of Conduct of the European Pharmaceutical Market Research Association (EphMRA).

They will be conducted through a third party and comply with the following requirements, considering the particularities of local legislation:

- I) Blinding of the identity of study participants.
- II) Anonymous nature of the information collected, so that Ferrer has no possibility of associating the data or opinions obtained with each specific study participant.
- III) Aggregated treatment of responses or data obtained.
- IV) Proportionality between universe and sample.
- V) The participant does not know the link between Ferrer or its products and the study (the Ferrer sales network must therefore play no role in study development or execution).
- VI) Obtained study results and data must not be published or used in promotional material.

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Market studies must not be an incentive for the recommendation, prescription, purchase, supply or administration of medicines or medical devices. Internal procedures will cover at least the following principles:

- A written protocol clearly establishing the purpose, methodology, expected results and use.
- Contracts/agreements to be signed off on with professionals and/or organisations engaging in the studies, specifying the nature of the service provisions, participation conditions and remuneration of professionals, etc.
- The remuneration of HCP must be in the form of cash, must meet market criteria and must be in keeping with the time spent, work done, and responsibilities assumed.
- Internal approval must be obtained from the E&C department before studies are conducted.

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04. Transparency

Ferrer will comply with the regulations and commitments reached with Code of Practice for the Pharmaceutical Industry, Local Codes and any other regulation applicable regarding transparency. Information will be published on the Ferrer website and/or the platforms each country determines.

In the case of Interactions with HCP, Ferrer will inform all HCP that their data will be published in accordance with the regulations in force. Interactions with HCP resident in the European Union will be published individually and preferentially for residents in other countries as well.

Ferrer must adapt the corporate website to impede subsequent processing of data related to this publication which could deviate from the pursued purpose. The publication will have a methodological note enclosed with it enabling correct data interpretation.

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05. Roles and responsibilities

5.1 E&C (Corporate & Local)

- Advise the business areas on all matters related to the content of this Policy and on risk management, monitor and review the different controls provided for the established procedures on a regular basis.
- Promote audits, if considered necessary, at company, subsidiary, distributor or partner level and in external enterprises to verify compliance.

5.2 Business Units (Marketing, Sales, Market Access, Business Intelligence) and Communication Department

- As risk managers they must comply with the obligations arising from this policy and its implementing procedures, as well as with applicable sector codes and laws.
- Foster application of and compliance with applicable regulations and procedures.
- Participate in training activities.

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05. Roles and responsibilities

5.3 Scientific Departments (Medical Area, R&D Area)

- As risk managers they must comply with the obligations arising from this policy and its implementing procedures, as well as with applicable sector codes and laws .
- Foster application of and compliance with applicable regulations and procedures.
- Participate in training activities.

5.4 Back Office Departments (IT, Finance, Procurement, Business Support, Travel, People and other)

- Support all the areas involved in this policy.
- Manage activities related to the promotion of our products or Interactions with HCP, HCO or PO in which they intervene, complying with the spirit of this Policy and current procedures.

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05. Roles and responsibilities

5.5 Legal Department

- Participate in the revision of contracts/agreements related to commercial activity and the drafting of clauses and legal texts to adapt them to the regulations in force and Ferrer's interests.
- Ensure and guarantee that the documents they check comply with the laws in force on Compliance matters.

5.6. Internal Auditing

- Internal Auditing will audit compliance of Policies and their implementing SOPs. If nonconformities or areas of improvement are detected, it will establish remedial actions and verify their timely implementation.
- It will inform E&C of audit results and its remedial plan.

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06. Document custody and filing

The documentation will be kept by the Departments involved in the information systems only for the period required by current legislation and Ferrer's document conservation policies.



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07. Approval, review and distribution

This Policy will be the object of review and ongoing improvements, especially when business circumstances so require. In any event, this Policy will ordinarily be reviewed and updated once a year, where applicable, or sooner if required by internal or external circumstances. Failure to comply with this Policy may lead to disciplinary measures.

This Policy will come into force from the 28th June 2024 and will be available to all Ferrer Group people through the usual internal channels.

Board of Directors

Corporate Ethics & Compliance

Control of versions

Version	Changes	Effective date
1.0	First version	11/01/2021
2.0	Second version	07/07/2022
3.0	Third version	11/01/2023
4.0	Fourth version	28/06/2024

Departments / governing bodies involved

	Department / GB	Entity	Date
Prepared by	Corporate E&C	Grupo Ferrer Internacional, S.A.	26/06/2024
Approved by	Board of Directors	Grupo Ferrer Internacional, S.A.	28/06/2024

Relevant information

Scope of application (global / local)	Global
Related regulations	Ferrer Group Ethical Code Corporate Ethics & Compliance Policy Corporate ABAC Policy Corporate Data Privacy Policy Corporate Donations Policy
Main Body Responsible for Enforcement	Ethics & Compliance Department

Corporate Ethics & Compliance

Annex 1

Definitions

Healthcare Organisation (HCO):

All legal person and entity

- I) That are a medical, pharmaceutical or scientific association, health institution (regardless of its legal or organisational form) such as hospitals, clinics, foundations, universities and other academic entities, scientific societies, or
- II) Through which one or more Healthcare Professionals provide services.

Healthcare Professional (HCP):

Any members of the medical, dentistry, pharmaceutical, nursing or podiatry professions or any other person legally considered as such or who, in the exercise of their profession, could directly or indirectly perform or condition the activities of prescribing, buying, supplying, dispensing or administering human medicines or medical devices. This definition includes any official or employee of a public administration or organisation (public or private), as well as wholesalers and distributors who can perform the described activities.

Interactions:

Activities carried out, organised or sponsored by Ferrer or under its control (foundations, associations, institutes, agencies, suppliers, etc.) from which partnerships, support and/or considerations or any type in favour of a third party could directly or indirectly arise.

Market Study:

Is understood as any social and/or opinion consisting of systematically gathering and interpreting information on people or organisations, with statistical and analytical methods, to obtain new insights or to contribute decision-making support elements.

Market price:

Amount an individual generally pays, including taxes, to acquire one unit of a good (product, material, item or similar) or service on a reference market.



Corporate Ethics & Compliance

Annex 1

Research and development:

Activities associated with the design or implementation of

- I) Preclinical studies (defined by the OECD in “Principles of Good Laboratory Practice”),
- II) Clinical trials (defined in Regulation (EU) No. 536/2014, Spanish Royal Decree 1090/2015 and provided for in point 6.7 of this Policy) and
- III) Post-authorisation safety studies (according to Spanish Royal Decree 957/2020).

Patient Organisation (PO):

A non-profit organisation, including the organisations or groups that belong to it, comprising mainly patients and/or their caregivers, who represent and/or support the needs of patients and/or their caregivers.

Sponsorship:

Any funding or support activity, regardless of who the organiser is, of an event, meeting, scientific study, scientific activity, etc., where Ferrer receives a consideration in exchange for financial collaboration.

Value transfers:

Any direct or indirect payment or compensation in cash or kind, regardless of the purpose. Value transfers that are part of business operations between laboratories and distributors, pharmacy offices and Healthcare Organisations are excluded from this concept. A value transfer is direct when performed directly by Ferrer and indirect when performed by a third party (suppliers, agents, partners or associates, or foundations) acting on Ferrer’s behalf.

E&C:

Ethical & Compliance Department

Legal, IP & Compliance

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