

ORPHALAN CODE OF BUSINESS CONDUCT – COMMUNICATION TO DISTRIBUTORS AND SUPPLIERS

Orphalan is an international pharmaceutical company. As such it is committed to conduct its business in accordance with high ethical standards through its employees and all its business partners.

Some regulations govern healthcare companies, and in particular their interactions with healthcare professionals (HCPs). This is the case of relevant sections of the French Public Healthcare Code for example and the guidelines set forth by industry associations in many countries.

Other regulations govern companies because of the geographical location of their operations, globally, irrespective of their industry field. This is the case of the 1077 US Foreign Corrupt Practices Act, the UK Bribery Act 2010 or the Brazil Clean Companies Act.

In particular, Orphalan abides by all global anti-bribery laws, including the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions (OECD), the UN Convention against Corruption (UNCAC), and other applicable anti-bribery laws (such as French Sapin 2 Law, UK Bribery Act 2010, US Foreign Corrupt Practices Act).

Therefore, we expect and trust that interactions of Orphalan's suppliers ("Suppliers") and distributors ("Distributors") with other third parties, and in particular government officials and healthcare professionals, will be in line with and will not contradict our standards and rules of honest and ethical business conduct. To this end, please find below a summary of Orphalan Code of Business Conduct that is designed to provide all employees and those with whom Orphalan does business (including its distributors), with a formal statement of Orphalan's business conduct principles and policies.

I. DEFINITIONS

"Government Official" includes employees of government-owned or -controlled companies or facilities. This includes healthcare professionals employed by such entities. It also includes all employees of any government agency or department, political party officials, candidates for political office, and officers and employees of public international organizations.

"Corruption" is the fact for a person to solicit or accept a donation or any advantage in order to perform, or refrain from performing an action within the scope of his/her duties. A distinction is made between active corruption (the fact of offering the gift or any advantage to the person entrusted with the determined function) from passive corruption (the fact, for the person invested of the determined function, of accepting the gift or the advantage). Corruption can occur directly (between the payer and the payee)

or indirectly (via a third-party).

"**Bribe**" is anything of value given, directly or indirectly, to improperly or illegally influence a business decision or give Orphalan an unfair advantage. Examples may include cash payment (or equivalent such as gift cards), kickbacks, gifts, entertainment, or donations.

II. ORPHALAN ETHICAL VALUES

Orphalan's interactions with healthcare professionals ("HCPs") are based on the following ethical standards and principles, which we expect not to be contradicted by our Distributors when representing Orphalan:

- Orphalan will encourage ethical business practices and socially responsible industry conduct.
- Business must be conducted free from the unfair influence of bribery and corruption. No improper payment must ever be made, directly or indirectly.
- At Orphalan, we believe that enduring customer relationships are based on integrity and trust. We seek to gain advantage over competitors through superior products, research, engineering, manufacturing, marketing and service; never through improper business practices.
- Orphalan's relationships with HCPs are intended to benefit patient care and enhance the practice of medicine.
- Orphalan will not, directly or indirectly, offer or solicit any kind of payment or contribution for the purpose of obtaining, giving, keeping or rewarding business.
- The law forms a foundation for Orphalan's business conduct. We must conduct our business in accordance with the laws of the cities, states and nations where we operate on behalf of Orphalan.
- Orphalan expects its employees and its business partners to act in a way that not only conforms to the letter of the law, but promotes the spirit of fairness and honesty underlying the laws.

III. ESSENTIAL PRINCIPLES GOVERNING THE RELATIONSHIPS WITH HEALTHCARE PROFESSIONALS

➤ Principle of prohibition

French, U.K., U.S. and other national laws impose criminal and civil penalties on pharmaceutical companies that improperly influence any HCP to purchase, order or recommend a healthcare product or service.

These same laws also generally prohibit pharmaceutical companies from inducement (payment in cash or in kind such as gifts; payments for non-business meals; invitations and payments for entertainment in the form of golf or theatre, for example) of HCPs to purchase, order or recommend their product. These prohibitions are motivated by the protection of Public Health and anti-bribery politics; monetary penalties for violation of these laws can be substantial for both HCPs and companies (including their directors, officers and employees).

➤ No Improper Payments

It is contrary to Orphalan's policy to pursue any business that would require employees or business partners to engage in dishonest, unethical or illegal activity. Likewise, customers should not be given preferential treatment - such as special contract terms - unless such treatment is approved in advance by management. HCPs' relationships must be based on integrity and advantage over competitors should be gained through superior products, never through improper business practices.

We do not directly or indirectly offer or solicit any kind of payments, contributions or other consideration for the purpose of:

- Influencing HCPs, suppliers or governmental entities, including their officials or employees, to purchase or provide products or services.
- Obtaining, giving, keeping or rewarding business.

IV. PERMITTED EXCEPTIONS

➤ Hospitality, Gifts, Meals and Entertainment

Applicable laws, including French Sapin 2 Law, UK Bribery Act 2010, US Foreign Corrupt Practices Act allow room for some exceptions under very specific conditions. Hospitality may be offered to HCPs for promotional, professional or scientific events restricted to the conditions below:

- it must be “modest and reasonable”;¹
- it must be related to the purpose of the meeting; and
- it must not be extended to anyone other than the participating HCP.

Giving or receiving gifts, meals or entertainment in our business relationships is prohibited unless:

- they are of limited value, have a valid business purpose, are related to HCPs’ practices, are appropriate as to time and place, are infrequent in occurrence, do not influence or give the appearance of influencing the recipient and are not likely to be viewed by a reasonable person as a bribe, kickback or payoff;
- they do not violate any law or generally accepted honest and ethical standards including the standards of the recipient’s professional association or organization; and
- they are in compliance with Orphalan’s policies and procedures.

Under no circumstances may a gift of money be given or received.

Summary of guidelines:

- ⇒ Event must have legitimate scientific / informational content ✓
- ⇒ Under no circumstances should the hospitality be in any way dependant upon the purchase of our products ✓
- ⇒ Accommodation and travel expenditures should be “modest and reasonable” ✓
- ⇒ Invitations should never be extended to anyone other than the HCP ✓
- ⇒ Any hotel stay should coincide with the event (not more than 12 hours before and after the event) ✓
- ⇒ No expenses other than reasonable meals, travel or accommodation, (i.e., no purchase of sport equipment, club membership, entertainment or sporting events) ✓
- ⇒ Expenses should be pre-paid and not reimbursed to the HCPS whenever possible ✓
- ⇒ Invitation letters should be sufficiently explanatory ✓

¹ The term “modest” means of moderate or low value, taking into account regional differences. The term “reasonable” means appropriate to the circumstance, nature and location of the work being performed.

➤ **Payment to HCPs, Clinical Studies and Registries**

- **No payment to a HCP without a written contract**

Any payment to all consulting, proctoring, training or speaking conducted by a HCP should be covered by an agreement. Compensation must be fair market value for the services provided by the HCP.

Sufficient evidence of the performance of the services shall be gathered before payment and all payments must be duly recorded in the company's accounts.

- **No clinical studies or registries launched without Orphalan's prior approval**

Our Distributor shall not launch, promote, and sponsor any clinical study or registry on Orphalan's products without Orphalan's Clinical and Regulatory Departments' prior written approval.

V. COMMITMENT TO ACCURATE AND COMPLETE FINANCIAL REPORTING

➤ **Books and Records**

We require full compliance with the spirit and letter of applicable laws, rules and regulations which require that all accounting books and records be accurately maintained and fully disclose the nature of transactions reflected in them. We require honest and accurate recording and reporting of information, including such data as quality, safety, personnel records, financial records, customer invoices, expense reimbursement vouchers, and payments or anything of value provided to or for (i) physicians and other healthcare professionals and (ii) governmental officials.

➤ **Creation and Retention of Records**

All business records and communications should be clear and accurate. This applies to all forms of communications, including emails and informal notes. Legal and regulatory practice requires the retention of certain records for various periods of time, particularly in the tax, personnel, health and safety, environment, contract, and corporate structure areas. In addition, when litigation or a government investigation or audit is pending, imminent or reasonably foreseeable, relevant records must not be destroyed until the matter is closed and the Legal Department has instructed it is appropriate to destroy such documents.

VI. BUSINESS LICENSES

In some countries, Orphalan products can be sold only after the securing of relevant business licenses with the local authorities on a basis of licenses. Under these licenses, local governments may exclude certain hospitals or types of healthcare institutions and/or certain products on our catalogue. In these cases, Orphalan expects the highest degree of compliance with these rules.