

## POLPHARMA BIOLOGICS GROUP / THIRD PARTIES RULES

### INTRODUCTION

**Polpharma Biologics Group** conducts business in compliance with the highest ethical standards, adhering to its established system of values which is based on compliance, honesty, responsibility and cooperation.

**Polpharma Biologics Group** supports Pharmaceutical Industry Principles for Responsible Supply Chain Management.

Being aware of cultural differences and having deepest respect for partners worldwide all principles are universal and in accordance with global regulations, supporting also United Nations Global Compact.

If in any partners' country of business the laws or internal regulations concerning the issues covered under this Rules are more restrictive, we recommend that the more restrictive regulations will be followed.

#### 1. MANAGEMENT AND ETHICS

**Polpharma Biologics Group Partners shall conduct business in accordance with generally accepted ethical principles for business and to manage their business in a manner that facilitates compliance with the applicable laws and this Rules.**

**Polpharma Biologics Group Partners** are recommended to ensure that their employees continually broaden their knowledge on ethical standards in business and the laws regulating the rules of conduct covered under this Rules.

**Polpharma Biologics Group Partners** will continually improve their ethical standards by setting objectives, executing implementation plans and taking corrective actions for deficiencies identified by internal or external assessments, inspections and management reviews.

##### **1.1 Integrity and Responsibility in Conduct**

**Polpharma Biologics Group Partners** will apply the highest business standards, such as compliance with the rules of free and fair competition, honest communication, protection and nondisclosure of confidential information obtained in the course of cooperation, respecting intellectual property, author's moral and economic rights, industrial property rights, and other rules and regulations applicable to the specific business activity.

##### **1.2 Preventing all Forms of Corruption**

No corrupt practices on the part of **Polpharma Biologics Group Partners** are allowed, both in dealing with officials (corruption in the public domain) and in dealing with contractors (corruption in the private domain). Giving or offering any improper advantage or gifts to any person in order to impact their act or omission with the intent of obtaining or retaining a business relationship is strictly forbidden. This

prohibition also applies to giving or offering any benefits through the intermediary of a third party.

In particular, it is forbidden to give or offer any money or its equivalent, gifts, services or other financial or personal benefits to politicians, public officials, auditors, employees of regulatory, certification or supervisory authorities, which could induce them to take or refrain from certain actions as part of their official duties.

**Partners** are forbidden to give or offer any gifts of cash or its equivalent to the **Polpharma Biologics Group** employees and associates. It is only allowed to give small business gifts permitted by the applicable laws and standard business practice and only where such gifts are occasional or promotional and do not result in a commitment to reciprocity or to take or refrain from certain actions. The value of such gift shall not exceed 50 EUR or equivalent in other currency.

No Partners are allowed to Lobbying misused for illegal purpose.

No partners are allowed to enter into any relationship between them and Public Officials that are not in strict compliance with the rules and regulations of country law referring to public officials.

### **1.3 Conflict of Interests**

The **Polpharma Biologics Group Partners** will prevent and avoid any situations conducive to a conflict of interest in the process of applying for cooperation with the **Polpharma Biologics Group** and then in the course of such cooperation. This applies to all relationships connected with applying for cooperation or with the cooperation established between the Partners representatives and the **Polpharma Biologics Group** representatives who are related due to a kinship, affinity, adoption, personal relationship, capital or organizational participation. In order to preserve objectivity and honesty in mutual relations, the **Polpharma Biologics Group Partners** are required to disclose information that could give rise to a conflict of interest.

### **1.4 Risk Management**

The **Polpharma Biologics Group Partners** should have in place and continuously improve their risk management systems, including business continuity or any risk of corruption or fraud, in all fields of business. No such solutions may conflict with the provisions of this Rules. **Polpharma Biologics Group Partners** should actively promote the culture of ethics, including creation of solutions to allow the employees and contractors to report any irregularities in a manner that protects personal data and prevents retaliation.

### **1.5 Sustainable Development**

**Polpharma Biologics Group** expects that our **Partners** will take into account and limit any negative impact of their activities on the social and natural environment. All efforts to limit a negative impact on the environment and, in a longer perspective, to bring positive changes to the environment, are strongly advised. **Polpharma Biologics Group Partners** will make their best endeavors to conduct safe handling, movement, storage and recycling, reuse or manage the waste.

**Polpharma Biologics Group Partners** will optimize use of all relevant resources such as not limited to energy, water, materials and minerals.

## **2 CONDITIONS OF EMPLOYMENT AND EMPLOYEE RIGHTS**

**The Polpharma Biologics Group Partners are required to respect human and labor rights and prevent any violation of such rights in the entire value chain in the course of their business.**

### **2.1 Child Labor and Young Workers**

The minimum age for employees of the **Polpharma Biologics Group Partners** must comply with the national laws and must not conflict with compulsory education. Employing minors for work that is hazardous to health and safety is forbidden. **Polpharma Biologics Group Partners** are recommended to have internal regulations and systems assuring proper management and monitoring of young workers.

### **2.2 Freely Chosen Employment**

It is forbidden to make use of indentured or forced labor. The employees of the **Polpharma Biologics Group Partners** must be employed of their own will. They may terminate their employment subject to the notice period defined by the laws. The employer must not deposit personal documents of the employees.

### **2.3 Equality and Non-Discrimination**

Discrimination at a workplace due to gender, age, ethnic origin, nationality, religion, sexual orientation, appearance, health, physical capabilities or any other aspect of diversity among the employees is forbidden. The employees must be afforded fair treatment and the employee policies must be implemented in a transparent manner with due respect to diversity.

### **2.4 Employment Relationship, Wage and Working Hours**

The **Polpharma Biologics Group Partners** are required to employ their employees in accordance with the applicable laws. This rule applies both to the employment relationship and to any concluded agreements, including collective agreements, working hours, and the amount of wage. Overtime work is voluntary and its duration and manner of settlement should be defined under internal regulations in accordance with the applicable labor law.

### **2.5 Freedom of Association**

The employees of **Polpharma Biologics Group Partners** have the right to communicate freely with their supervisors as regards the working conditions, without fear of punishment, humiliation or other retaliation. Pursuant to the provisions of the law, the employees have the right to association, negotiation and the right to information and consultation, and also the right to participate in the creation and improvement of the working conditions and the working environment.

### **2.6 Continuous Professional Development**

The employees of the **Polpharma Biologics Group Partners** have the right to continuously improve their competences necessary at a given job position. They also receive support in their long term professional development.

## **3 OCCUPATIONAL HEALTH AND SAFETY**

**Polpharma Biologics Group Partners are required to ensure healthy and safe workplace conditions.**

### **3.1 Working Conditions**

**Polpharma Biologics Group Partners** are required to ensure safe and healthy working conditions to their employees and to any employees performing work on their behalf, in accordance with the laws and the occupational standards in a particular industry. Special attention is given to the protection of the employees against chemical, biological and physical hazards. The **Polpharma Biologics Group Partners** are required to identify and monitor any hazards in order to undertake effective prevention measures.

### **3.2 Safety of the Production Processes**

**Polpharma Biologics Group Partners** are required to manage the production processes in a manner compliant with the applicable laws and safety standards, perform risk analysis on a regular basis and record its results, and also implement any necessary hazard prevention measures, especially for hazardous work.

### **3.3 Prevention through Education**

**Polpharma Biologics Group Partners** should provide, on a regular basis, employee training as regards safety, any possible hazards that may occur, and the methods for their prevention. The employees should receive clear information on any identified hazards and be aware of the implemented contingency plans and the procedures to be followed in emergency situations.

**Polpharma Biologics Group Partners** who designate employees or sub-contractors to work in the plants of the **Polpharma Biologics Group** companies are required to monitor, on an ongoing basis, the rules and standards applicable in the plants of the **Polpharma Biologics Group** companies as those referring to safety at work and fire protection, and to provide such information to the designated individuals. The employees of the **Polpharma Biologics Group Partners** or any individuals who perform work on their behalf for the **Polpharma Biologics Group** are required to comply with the rules and standards applicable in the plants as regards safety at work and fire protection.

## **4 PRODUCT QUALITY AND SAFETY**

**The Polpharma Biologics Group Partners are strictly required to meet all requirements as regards product quality and safety and they must regard this issue as of the highest priority.**

### **4.1 Product Quality and Safety Requirements and Regulations**

Product suppliers, at each stage of product manufacture, storage, shipment and sale, are required to comply with the applicable laws, international standards, including Good Manufacturing Practice, Good Distribution Practice, and in accordance with the detailed requirements set forth under the agreement with the **Polpharma Biologics Group** companies. All activities of the **Polpharma Biologics Group Partners** that may impact the **Polpharma Biologics Group** product quality and safety are subject to special control and restrictions.

**Polpharma Biologics Group Partners** that are subject to GMP requirements shall:

- a) Hold and maintain the necessary licenses, permits or registrations

- b) Ensure that data relevant for any activities are controlled, accurate, protected from any manipulation or loss, compliant with industry standard for data integrity
- c) Ensure security and integrity of supply chain.

## **5 RESEARCH**

**Polpharma Biologics Group Partners conducting research on human subjects or animals must do so in a responsible manner, in accordance with the applicable laws and the relevant ethical standards.**

### **5.1 Medical Human Subject Research**

**Polpharma Biologics Group Partners** who conduct research on human subjects for the **Polpharma Biologics Group** are required to comply with the applicable laws and accepted international ethical and scientific standards, including Good Clinical Practice guideline ICH E 6 and the Declaration of Helsinki .

### **5.2 Research on Animals**

**Polpharma Biologics Group Partners** should conduct research on animals only if required by the law or if no alternative scientifically justified and accepted methods exist. **Polpharma Biologics Group Partners** are required to comply with the laws and generally accepted international standards, including “International Guiding Principles for Biomedical Research Involving Animals” of the Council for International Organization of Medical Science, and to treat animals in a humanitarian manner, minimizing their stress, fear and pain.

## **6 NATURAL ENVIRONMENT**

**Polpharma Biologics Group Partners should act in a responsible manner towards the natural environment, striving to minimize any negative impact their activities may have on the environment.**

### **6.1 Environmental Requirements and Regulations**

**Polpharma Biologics Group Partners** are required to comply with the laws and international agreements, as well as the standards of environmental protection. They should have a rational environmental management system in place and have all valid required authorizations and licenses for their business activities, which they must be able to present at any time. They should also comply with all registration requirements.

### **6.2 Pollution Release to the Environment**

The pollution release (including air, water and ground) management methods applied by the **Polpharma Biologics Group Partners** should ensure limitation of pollution release and continuous improvement of its management. **Polpharma Biologics Group Partners** should limit the environmental risk through undertaking effective preventive and interventional action.

### **6.3 Preserving Natural Resources**

**Polpharma Biologics Group Partners** should use the natural resources in an economic manner, respecting the rights of other entities to use the same resources. The **Polpharma Biologics Group Partners** should limit and eliminate the impact of their activities on the environment through continuous process optimization and through the use of those substances, materials and techniques, and technology which have the least negative impact on the environment.

## **7 COMMUNICATION AND REPORTING IRREGULARITIES**

**Polpharma Biologics Group** is committed to achieving compliance with this Rules and wants the practices to be constantly improved by all **Polpharma Biologics Group Partners**. In the case of any questions or concerns concerning the requirements of the Rules, or if you want to inform the **Polpharma Biologics Group** about implemented solutions, please e-mail us at: [ethics@polpharmabiologics.com](mailto:ethics@polpharmabiologics.com)

Also all irregularities or violations of the Rules must be reported to the Compliance Officer who is responsible for compliance with the ethical principles in **Polpharma Biologics Group**. In order to report any violation of the provisions of the Rules, send an e-mail to the address: [ethics@polpharmabiologics.com](mailto:ethics@polpharmabiologics.com).

The employees of the **Polpharma Biologics Group Partners** should first report any internal issues connected with no ethical conduct to their Employer, using the solutions available at their company.