

**Compliance Guidelines of  
Kedrion Biopharma GmbH**

## 1. TARGET GROUP AND AREA OF APPLICATION

KEDRION S.p.A., a company with registered offices in Barga, Lucca, Italy (“KEDRION”), along with its subsidiaries and affiliates (“KEDRION Group”), is an enterprise of international reach that collects and fractionates blood plasma to make and distribute therapeutic plasma products. Plasma-based therapeutics are used to treat grave illnesses, conditions and ailments such as hemophilia and immunodeficiency.

On 24 January and 27 January 2020, respectively, KEDRION introduced guidelines for ethical conduct and procurement, such guidelines to apply the entire KEDRION Group.

KEDRION is the sole shareholder of Kedrion Biopharma GmbH (KBIO GmbH). Its core business is the distribution of blood-plasma products. As a KEDRION Group company, it is subject to the KEDRION Group guidelines for ethical conduct of 24 January 2020 and must translate the same into guidelines of its own.

With a view to implementing the KEDRION Group guidelines, Kedrion Biopharma GmbH establishes its own compliance guidelines (“Compliance Guidelines”) as follows:

## 2. GUIDING VALUES KBIO GMBH strives:

- to elevate social responsibility to become the fundamental guiding value of any activity undertaken within the corporate group;
- to supply transparent and complete information in relations with its stakeholders;
- to continually boost confidence in the group through competent, honest and responsible conduct; and
- to demonstrate respect and diligence vis-à-vis the enterprise through the safety and quality of its products and procedures.

## 3. PRINCIPLES

### ○ GENERAL PRINCIPLES

Kedrion Biopharma GmbH introduces a compliance system that conforms to the law of the Federal Republic of Germany, authoritative guidelines as well as best pharmaceutical practices.

Kedrion Biopharma GmbH staff:

- participate in the group’s activities with professionalism and purpose;
- act in accordance with the principles of fairness and integrity, refraining from actions representing a conflict of interest with respect to their obligations; and
- treat in strict confidence any and all information being exchanged in their departments and will not exploit their position for direct or indirect personal gain.

## **○ ETHICAL PRINCIPLES**

### **Transparency and integrity**

Transparency means that all public information about Kedrion Biopharma GmbH is truthful and accurate, and this applies to all information contained in official disclosures, annual reports or other corporate documents provided to stakeholders, along with such data as may be accessible to the public.

- It is strictly prohibited to engage in deceitful or fraudulent acts in order to influence Kedrion Biopharma GmbH management or KEDRION Group's managing board with a view to manipulating the outcome of votes on the managing board or the decision-making process of management.
- Likewise, it is strictly prohibited to circulate false information – be it within or without the KEDRION Group, in reference to the KEDRION Group itself or its staff or third parties working on its behalf.

### **Money-laundering**

The KEDRION Group adopts precautionary measures in order to prevent its business and financial activities from being associated with criminal acts, such as money-laundering or receiving and handling stolen monies or goods. For this purpose, Kedrion Biopharma GmbH steers clear of business relationships with individuals or entities allegedly or evidently tied to organized crime, engaged in illegal operations or involved in money-laundering, drug abuse and/or bribery.

In all other respects, Kedrion Biopharma GmbH undertakes to respect and observe the provisions of the Money-Laundering Act

([https://www.bafin.de/SharedDocs/Veroeffentlichungen/EN/Aufsichtsrecht/Gesetz/GwG\\_en.html](https://www.bafin.de/SharedDocs/Veroeffentlichungen/EN/Aufsichtsrecht/Gesetz/GwG_en.html)) and the German Criminal Code ([https://www.gesetze-im-internet.de/englisch\\_stgb/index.html](https://www.gesetze-im-internet.de/englisch_stgb/index.html)).

### **Conflicts of interest**

KBIO GmbH employees must ensure that their activities do not – and do not appear to – collide with the company's best interests. A conflict of interest is present whenever an individual's private interests conflict with or run counter to the interests of the company (or appear to do so). In addition, a conflict of interest may exist if employees engage in actions or pursue interests that make it harder for them to complete their work on the company's behalf in an objective and effective manner.

Conflicts of interest may further arise if employees or any of their relatives come into inappropriate personal advantages as a result of the employees' position with KBIO GmbH – irrespective of whether such gains stem from the company itself or third parties. Employees should conduct themselves in keeping with the highest legal and ethical standards at all times.

Conflicts of interest are not invariably clear, which is why you should always coordinate with senior management if you have any questions. Moreover, employees learning of potential or actual conflicts of interest should immediately inform a superior or the Ethics Officer of KEDRION S.p.A. ([whistleblower.de@kedrion.com](mailto:whistleblower.de@kedrion.com)) – if applicable, before withdrawing from the situation in question – unless they received written approval from a senior executive of the company. Irrespective of potential conflicts with the company's interests, the provisions of this guideline are not intended to bar attendance of certain, protected, concerted employee actions.

Scenarios presenting conflicts of interests include:

- the use of company funds, property or other resources for unlawful or inappropriate purposes or ends not directly related to employees' work at KBIO GmbH;
- illicitly influencing decisions of customers, suppliers, government officials or candidates for public office, employees or other third parties related to their work with KBIO GmbH, be it directly or indirectly;
- accepting employment with or rendering services to one of KBIO GmbH competitors while remaining employed with KBIO GmbH;
- accepting gifts or invitations from sellers, suppliers or other third parties doing business with, potentially entering into a business relationship with or influencing the business of KBIO GmbH that either do not meet the company's principles / guidelines or, taken by themselves or in combination with other gifts and invitations, are inappropriate in terms of their value;
- situations in which personal activities are brought into direct conflict with KBIO GmbH interests;
- misusing confidential information;
- the presence of a significant financial interest in an enterprise with which KBIO GmbH does business or competes;
- accepting, passing on or securing employees' loan obligations, including loans granted to members of the managing board or management, which are prohibited by law; or
- violations of this guideline.

When selecting suppliers and in business dealings with customers or other third parties, team members must remain fully objective, and all decisions should be made exclusively in the best interest of Kedrion Biopharma GmbH and the KEDRION Group.

## **○ PRINCIPLES RELATED TO WORK ENVIRONMENT**

The most important objectives of the KEDRION Group include fostering and recognizing the talents of its workforce as well as seeing to the implementation of the highest standards of the biopharmaceutical industry at every workplace throughout the enterprise, which is why care is taken to ensure that the European guideline on transparent and predictable working conditions (Directive (EU) 2019/1152 of 20 June 2019) (see attachment) is applied as amended in order to guarantee a clean, healthy and safe workplace that sustains and respects diversity while penalizing each form of discrimination and abuse. The corporate group

is led in keeping with the principles of International Labor Organization (ILO)

(<https://www.ilo.org/global/standards/introduction-to-international-labourstandards/conventions-and-recommendations/lang--en/index.htm>), which is dedicated to formulating and enforcing international labor and social norms, including but not limited to core employment standards, the socially sustainable and fair implementation of globalization as well as the creation of humane working conditions as a central pillar of the fight against poverty.

## **Human rights, diversity and inclusion in work environment**

KBIO GmbH undertakes to create a working environment characterized by social responsibility as well as mutual respect and trust. For this purpose, it is necessary that employee relations are appropriate and mutually advantageous across all hierarchical levels.

KBIO GmbH further strives to foster and recognize individuality and diversity within the group in order to give each employee the opportunity to play an active role in determining his or her performance and to contribute successfully to the reputation and results of Kedrion Biopharma GmbH and the KEDRION Group.

There is to be a strong commitment to observing the guiding values and human-rights principles as set forth in international treaties, the United Nations Universal Declaration of Human Rights ([https://www.ohchr.org/EN/UDHR/Documents/UDHR\\_Translations/eng.pdf](https://www.ohchr.org/EN/UDHR/Documents/UDHR_Translations/eng.pdf)) and the UN Convention on the Rights of the Child (<https://www.ohchr.org/en/professionalinterest/pages/crc.aspx>).

KBIO GmbH has no tolerance for any kind of harassment, discrimination or intimidation of employees who report a potential violation of the principles of this guideline or any law or regulation in good faith (see Section 5).

## **Health and safety**

KBIO GmbH is determined to protect the health, safety and well-being of its employees, advisors and partners.

All activities are conducted in full compliance with applicable law in the Federal Republic of Germany.

Care is taken to ensure safe working conditions, including a thorough review of all health and safety risks, the introduction of preventive and protective measures, ongoing monitoring of their efficacy and an analysis of causes of accidents.

Relevant employees undergo training and continuing education in order to increase their awareness and competence as well as to encourage them to contribute to ongoing improvements in an active and effective manner, to observe all safety precautions and to report all unsafe or non-confirming situations to their superiors.

## **○ MARKET PRINCIPLES**

### **Product safety, procedural quality and reliability (efficiency and efficacy)**

Kedrion Biopharma GmbH's employees must observe national and international laws that regulate the plasma-derivatives business. Particular attention must be paid to the provisions of the German Medicines Act, Section 7 of which (§§ 43-53, which regulate the dispensing and distribution of pharmaceuticals) is of special significance to KBIO GmbH ([https://www.gesetze-im-internet.de/englisch\\_amg/index.html](https://www.gesetze-im-internet.de/englisch_amg/index.html)).

Quality is one of the special characteristics of the KEDRION Group and lends the enterprise a competitive edge. Guaranteeing quality means that the products offered are the result of the application of the highest standards as regards research and development, production processes and safety. The KEDRION Group pursues the goal of meeting the highest standards in effect at any given time, the better to exceed the expectations of patients and their families, physicians and the entire health community. In countries in which the KEDRION Group does business, it is at pains to ensure that plasma-based products are available for medical and scientific purposes to an adequate extent.

## **Supplier relations**

KBIO GmbH maintains mutually advantageous relationships with its suppliers and partners, all of which it informs of the principles and rules governing the corporate group's negotiations.

**Corruption or bribery are admitted or permitted in no shape or form.** Furthermore, suppliers and partners are called upon to share the same ethical and social principles and ensure a high standard in all business relationships.

## **Interactions with public administrations, healthcare sector and private institutions**

In interactions with officials or other public servants and agents of public institutions, all applicable laws and regulations must be strictly observed. In addition, such relationships should be reserved for such functions as may be needed to execute assigned roles in accordance with the expectations and requirements specified by the Group and the authority granted by the relevant corporate division.

KBIO GmbH strictly forbids each employee and other corporate representative to promise or offer officials or their relatives gifts or other benefits (cash, goods, services, favors or other material or immaterial advantages) that may bring about unlawful or illegal interests and/or advantages, be it directly or indirectly. For instance, it is prohibited to promise and/or offer a gift or benefit with a view to a) securing preferential treatment in any relation with officials or b) inducing officials and/or other public servants to bring their influence to bear on other members of the public administration.

This Compliance Guideline is based on the condition that decisions about the treatment of patients are informed by their actual needs rather than commercial interests. Kedrion Biopharma GmbH recognizes the importance of professional relationships with experts in the healthcare sector and believes that the following aspects are essential:

- a) providing information about the benefits and risks of KEDRION Group products;
- b) providing scientific information and educational materials;
- c) supporting medical research and teachings; and
- d) obtaining feedback and advice for their products from competent advisors from the medical sector.

Subject to local laws and regulations, KBIO GmbH may reach out to professionals in the healthcare sector, including consultants, provided that such relationship is proper and lawful in terms of relevance, appropriateness, expediency and documentation.

KBIO GmbH supports the fight against corruption involving interactions with healthcare professionals and/or individuals or entities that form part of public administrations and hereby affirms the illicit nature of the following conduct, among others:

- creating false expenditures – for example, by inflating actual costs – in order to pass monies on to managers of private institutions or individuals working under them with a view to inducing them to take or omit certain actions, thereby violating duties and/or obligations and inflicting damage on their organization;
- acquiring goods or services for managers of private firms or individuals working under them with a view to inducing them to engage in inappropriate or prohibited conduct that inflicts economic harm on their organization;
- procuring monies or other benefits for managers of private corporations or individuals working under them, making promises to that effect, with a view to obtaining an advantage for the KEDRION Group in exchange.

## **Competitive conduct**

In the current legal system, anti-trust regulations serve to protect against excessive market dominance and market distortion caused by unlawful and unfair arrangements made among enterprises.

Consequently, anti-trust regulations are designed, first and foremost, to advance a free market economy, which is why Kedrion Biopharma GmbH believes that free and genuine competition among enterprises promotes the efficient distribution of goods and services and facilitates sound pricing, higher quality and outstanding innovation.

Kedrion Biopharma GmbH urgently advises that, in relations with competitors:

- no information deemed sensitive from an anti-trust viewpoint be exchanged with competitors;
- any kind of concerted action, informal talks or “gentlemen’s agreements” intended to curtail competition or having that effect be strictly prohibited; and
- everyone be called upon to abide by fundamental anti-trust law principles.

Failure to comply with anti-trust or competition law may be subject to prosecution under criminal or civil law and significantly disrupt business operations. Specifically, reference is made to Section 26 of the Criminal Code (§§ 298 et seqq.), which governs offenses under competition law, including bribery and corruption in the healthcare sector.

Should you have questions or concerns about this section, please contact KEDRION's Antitrust Compliance Officer (ACO) at [antitrust@kedrion.com](mailto:antitrust@kedrion.com).

## **Procurement**

The above guidelines especially apply with regard to the procurement, processing and treatment of goods supplied and services rendered (i) to the KEDRION Group or (ii) by the KEDRION Group to third parties, along with any related contracts.

In this regard, it is strictly prohibited to create false expenditures or disbursements in order to fund slush funds as well as to facilitate or make payments to business partners or their staff or representatives using such funds with a view to inducing them to engage in unlawful conduct, including but not limited to behavior disloyal to their employers or organizations – i.e., bribing them with money.

Moreover, it is strictly prohibited to acquire goods or services in order to pass them on to business partners or their staff or representatives with a view to inducing them to engage in unlawful conduct, including but not limited to behavior disloyal to their employers or organizations – i.e., bribing them with goods.

It is also strictly prohibited to afford business partners or their staff or representatives other benefits with a view to inducing them to engage in unlawful conduct, including but not limited to behavior disloyal to their employers or organizations.

KBIO GmbH's business activities must not be associated with criminal acts, such as money-laundering or receiving and handling monies, goods or services from unlawful sources.

KBIO GmbH will not maintain relations with business partners involved in unlawful actions, including but not limited to arms or drug smuggling, money-laundering or terrorism, and the same is true for business partners associated with trespasses against fundamental rights (e.g., child labor or sex tourism).

Accordingly, all KBIO GmbH employees must purchase goods and order services with care and act at all times in accordance with the principles of correctness, economy, quality and legality.

It is further prohibited to accept gifts of inappropriate value from suppliers or service providers, with the fiscal value of – currently – EUR 35.00 per person and year (§ 4 (5) sentence 1 no.1 of the Income Tax Act) serving as a guidepost.

KBIO GmbH employees must not exploit their positions to derive any advantage for themselves or third parties, be it directly or indirectly, and this applies specifically to conflicts of interest of any kind.

All contracts to be entered into must be submitted to the Legal division for review before they are signed.

## **○ ENVIRONMENTAL PRINCIPLES KBIO GmbH**

undertakes to:

- ensure that its activities are pursued in full compliance with applicable law;
- boost its efficiency on an ongoing basis by analyzing economic feasibility and using the best technologies available on the market;
- improve its measures of environmental protection by focusing on its essential aspects, reducing the generation of hazardous waste, increasing the volume of recyclable waste, optimizing water and energy consumption, reducing noise emissions and improving the quality of its wastewater; and
- encourage all employees, suppliers and partners to be conscious of their impact on the environment.

## **○ DATA PROTECTION**

KBIO GmbH processes personal data in strict accordance with data-protection regulations, including but not limited to the General Data Protection Regulation and the Data-Protection Act. At all times, the collection, processing and use of personally identifiable data requires a legal basis, such as the consent of those concerned. If there is no legal basis, the purpose of data processing lapses, no retention periods apply and any data collected must be deleted without delay.

In addition, personal data should be:

- processed pursuant to applicable regulations in a fair and transparent manner;
- collected in an appropriate and relevant manner – and exclusively for legitimate, specific purpose – as limited to the extent needed for the realization of the purpose underlying such data collection;
- correct and updated as needed;
- retained in a way that allows the person concerned to be identified only for as long as is necessary for the purpose of processing the personal data; and
- processed in a way that ensures an adequate level of safety for the personal data, including its protection against unintended loss, destruction or damage.

Should you have questions or concerns regarding this section, please contact KBIO GmbH's Data Protection Officer Mario Krauß, kraussfirmengruppe GmbH & Co. KG, Streitheimer Straße 22, 86477 Adelsried, Germany, Tel.: +49 (8294) 511 48 0, Fax: +49 (8294) 511 48 29, [www.kraussfirmengruppe.de](http://www.kraussfirmengruppe.de).



#### 4. ENFORCEMENT AND CONTROL

Compliance with the principles of this Compliance Guideline is a critical and integral component of the contractual obligations of all employees.

KBIO GmbH's managing directors, senior employees and all other staff are responsible for the correct implementation of the principles of these guidelines.

Thee Compliance Guidelines may be viewed on KBIO GmbH's website as well as on the Intranet.

This is how you may report compliance violations to us:

We want to hear about unlawful conduct within our company in order to be able to shed light on and put an end to it. This is why we encourage everyone – employees, former staff, customers, suppliers or third parties – to bring potential or actual violations of law to our attention.

Such reports will be treated in confidence. While we encourage employees to turn to their superiors first, we understand that this may not always seem opportune. This is why anyone can also contact KEDRION's Ethics Officer directly at [whistleblower.de@kedrion.com](mailto:whistleblower.de@kedrion.com).

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