



CODE OF INTERACTION WITH
HEALTHCARE PROFESSIONALS
AND ETHICAL PROMOTION



ALKALOID
SKOPJE

Health above all

CONTENTS

1. INTRODUCTION AND PURPOSE	2
2. PREAMBLE	2
3. DEFINITIONS	3
4. APPLICABILITY OF CODE	4
5. MAIN GUIDELINES FOR INTERACTION WITH HEALTHCARE COMMUNITY	5
5.1 ENGAGING HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANIZATIONS FOR VARIOUS SERVICES AND COUNSELING	5
5.2 EDUCATIONAL SUPPORT FOR HEALTHCARE PROFESSIONALS	6
5.3 PROFESSIONAL MEETINGS AND CORPORATE HOSPITALITY	6
5.4 SITE VISITS TO ALKALOID AD SKOPJE	7
5.5 SPONSORSHIP OF EVENTS	8
5.6 SOCIAL CONTRIBUTIONS	8
5.7 EDUCATIONAL MATERILAS, MEDICAL UTILITY ITEMS AND SMAL VALUE GIFTS	8
5.8 FREE SAMPLES	9
5.9 PROMOTIONAL MATERIALS AND INFORMATION	9
5.10 PATIENTS AND PATIENT ORGANIZATIONS/ASSOCIATIONS	10
6. ETHICAL PROMOTION	12
7. MARKETING TEAMS	13
8. MARKET RESEARCH AND POST-MARKETING CLINICAL TRIALS	14
9. TRANSPARENCY	15
9.1 TRANSFER OF VALUES	15
9.2 METHODOLOGY FOR REPORTING TRANSFER OF VALUES	16
9.3 DATA PRIVACY AND CONSENT	16
9.4 DISCLOSURE PLATFORM	17
10. ADVERSE EVENT REPORTS	18
11. CODE VIOLATION PROCESS.....	18
12. PERIOD FOR ADAPTATION AND IMPLEMENTATION	20

1. INTRODUCTION AND PURPOSE

The Code comprises promotion, communication and interactions of ALKALOID with any healthcare professional and any healthcare organization. Our interactions with healthcare professionals are legal and ethical, focused on strengthening their knowledge and practice in medicine for the greater benefit of patients. Interactions with healthcare professionals are aimed at providing them with detailed information about our products, sharing novelties and scientific and educational information.

The information shared in interactions with healthcare professionals, whether at individual visits or organized events (congresses, workshops, educational events etc.), should be accurate, clear, precise, up-to-date, balanced, fair and complete, to enable the recipient to form their own opinion. The shared information must not be misleading or causing any doubt, but it should encourage rational use of medicinal products by presenting them objectively.

The ALKALOID Code of Interaction with Healthcare Professionals and Ethical Promotion aims to demonstrate that the decisions made on recommended drugs and medical devices of ALKALOID are solely based on the features of each product and on the patients' needs for the recommended drug.

2. PREAMBLE

Good Pharmaceutical Promotion requires adherence to international rules, as well as efficient legislation implemented at a national level.

The ALKALOID Code of Interaction with Healthcare Professionals and Ethical Promotion is based on the Medicines for Europe Code of Conduct. As its member, ALKALOID has adopted the requirements set forth in the Medicines for Europe Code of Conduct and transposes them in this Code.

The ALKALOID Code is compliant with the national legislation and regulation pertaining to promotion and marketing of medicinal products, as well as with ALKALOID'S internal rules. If national legislation imposes stricter requirements, ALKALOID is obliged to meet such national requirements.

The Code founds standards for ALKALOID which refer to the interaction with healthcare community. The Code does not aim to address or regulate commercial terms and requirements regarding pricing, sales and distribution of medicines, which must always be in compliance with the applicable local legislation.

3. DEFINITIONS

- **ALKALOID** - ALKALOID AD Skopje and all its subsidiaries and representative offices in the countries where it conducts business operations. A subsidiary of ALKALOID AD Skopje is an entity registered in accordance with the Law on Trade Companies of the Republic of North Macedonia or in accordance with the relevant regulations on trade companies in other countries, which is at least 49% owned by ALKALOID AD Skopje or by another subsidiary of ALKALOID AD Skopje, comprising also the representative offices of ALKALOID AD Skopje registered in other countries, in accordance with applicable legislation. Pertaining to the context of the provisions of this Code, should the meaning of the provision require, ALKALOID AD Skopje or its subsidiaries may be referenced specifically.
- **Healthcare community** - healthcare professionals, healthcare organizations and institutions, patients and patient associations, i.e. patient organizations.
- **Healthcare professional** - Any natural person that is a doctor, a member of medical, dental, pharmacy or nursing professions or any other person who, in the course of their professional activities may prescribe, purchase, supply, recommend or administer a medicinal product. For the avoidance of doubt, the definition of a healthcare professional includes: (1) any official or employee of a government agency or other organization (whether in the public or private sector) that may prescribe, dispense, purchase or administer medicinal products and (2) any employee of a pharmaceutical company whose primary occupation is that of a practicing healthcare professional, but excludes (a) all other employees of a pharmaceutical company and (b) employees in wholesale and distribution of medicinal products.
- **Healthcare organization** - any entity (1) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form), such as a hospital, clinic, foundation, university or other teaching institution or learned society or (2) through which one or more healthcare professionals provide healthcare services. For the avoidance of doubt, wholesalers, distributors and similar commercial intermediaries are not considered healthcare organizations.
- **Medical representatives** - Employed or engaged medical and commercial representatives performing direct interaction with the healthcare community for purpose of promotion of medicinal products of ALKALOID.
- **Line manager** - A manager who is directly responsible for managing the teams of medical representatives or other members of the sales and marketing teams.
- **Patient organizations/associations** - Not-for profit organizations that are patient-focused and in which patients and their careers represent a majority of members in governing bodies.
- **Fair market value** - The criteria for defining remuneration for engaging members of the healthcare community for performing services, or when sponsorship or contributions are provided and must be fair market value. This means the value that would be paid as a result of bona fide negotiations between well-informed parties, in arm's length transactions for the goods or services to be provided. The value should consider the nature and quality of the goods to be provided, the qualifications and experience of the provider, the geographic location, the type of services and the prevailing prices for such services.

- **Applicable local regulation** – All laws, regulations, codes of practices and standards that apply to ALKALOID in the country where it conducts its business operations.

4. APPLICABILITY OF CODE

The Code for Interaction with Healthcare Professionals and Ethical Promotion (hereinafter the Code) applies to all medicinal products promoted to the healthcare professionals.

The Code applies to all employees of ALKALOID who, within their scope of responsibilities and activities are concerned with the provisions of this Code.

All employees, in the course of their activities, are obliged to directly apply the standards, rules and requirements set forth in the Code, or to apply rules and requirements which are applicable and as comprehensive as the Code rules.

In the event that the existing regulations impose measures stricter than the principles of the Code, ALKALOID shall implement the stricter rules.

By adopting the Code, ALKALOID demonstrates its commitment to ethical standards in its marketing activities and its dedication to the fundamental company values:

- **People above all,**
- **Integrity and honesty,**
- **Creating the best outcomes together,**
- **Value based leadership.**

5. MAIN GUIDELINES FOR INTERACTION WITH HEALTHCARE COMMUNITY

We, in ALKALOID, are committed to ensuring highest ethical and good business practice standards in our interactions with the healthcare professionals or healthcare organizations, as required by the legislation and the industry practices.

The line managers and the accountable

Corporate Compliance Officer are responsible for providing regular education and updated information for the employees regarding local regulations on interaction with the healthcare professionals. They are obliged to regularly monitor their knowledge and implementation of the relevant regulation.

5.1 ENGAGING HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANIZATIONS FOR VARIOUS SERVICES AND COUNSELING

To broaden the knowledge in a certain field and to make decisions based on expert opinion and experience, professional advice and expertise from healthcare professionals are essential. Engaging healthcare professionals from various fields of medical areas is to the benefit of both the patients and the healthcare community as a whole.

The services for which healthcare professionals or healthcare organizations may be engaged include:

- preparation of expert opinion;
- participation in advisory board;
- inclusion in medical/scientific studies or research;
- expert presentations and/or speaker engagements;
- participation in market research;
- training and education on products for internal needs and
- similar engagements for professional and educational objectives.

There always should be a relevant and legitimate need for engaging healthcare professionals or healthcare organizations for the aforementioned services, with the following requirements fully met:

- a written listing inside the services for which the healthcare professional or organization has been engaged, with defined terms and responsibilities of the contractual parties;
- the selection must be made in accordance with previously defined and objective criteria for selection and engagement of a healthcare professional or a healthcare organization, consistent with the ALKALOID's needs. The selection is made by responsible persons from ALKALOID, competent enough to assess whether the respective consultant meets the criteria for the relevant need;
- the number of engaged healthcare professionals should be reasonable, necessary for meeting the identified need;
- the compensation for the services must always be reasonable and justified, and it should reflect the real market value of the services offered and

- ALKALOID shall keep record of the consultants' services and use them appropriately.

ALKALOID does not establish or realize cooperation with healthcare professionals and healthcare organizations entered into any service engagement with the intention to induce, influence or award past or future prescription, purchase, supply or recommendation of any product of ALKALOID.

Payment should be made only for services provided.

5.2 EDUCATIONAL SUPPORT FOR HEALTHCARE PROFESSIONALS

ALKALOID may support scientific, medical, pharmaceutical and professional education of healthcare professionals for the purpose of advancement of their scientific knowledge and improvement of patient care.

ALKALOID may provide educational support for individual healthcare professionals or healthcare organizations.

Individual educational support is related to the field relevant to their scientific and medical practice and it includes: registration fees for participation at the event, travel and accommodation costs and reasonable corporate hospitality. Educational support may be provided for events organized by ALKALOID or for congresses, conferences and other professional events organized by third parties, only their scientific, educational and professional content is of the therapeutic areas practiced by the healthcare professional, or directly related to ALKALOID's therapeutic areas.

ALKALOID must not invite other guests, spouses, family members or friends of the healthcare

professionals at these events and they may not receive corporate hospitality. ALKALOID must not approve of uninvited guests on company funded travel.

The decision about which healthcare professional shall receive educational support shall be based on objective criteria previously defined by ALKALOID that are directly related to the educational needs of the healthcare professional and consistent with the contents and the quality of the educational program.

5.3 PROFESSIONAL MEETINGS AND CORPORATE HOSPITALITY

Professional meetings between ALKALOID, healthcare professionals and healthcare organizations (to the extent that the participants from the healthcare organizations are healthcare professionals) may be organized for educational, scientific, research and promotional purposes.

Location

ALKALOID should organize the meetings at locations which are logistically most justified for the participants and the required resources. Locations primarily known for their touristic or recreational character shall not be preferred. Such locations may be used if there are no other available facilities, regarding the size of the event, the number of anticipated participants and the technical facilities required for its realization.

Venue

All professional events (promotional, scientific, professional meetings, congresses, conferences, symposia etc.) organized or supported by ALKALOID shall be realized at a location appropriate and adequate to the main purpose of the meeting. Appropriate venues include clinical/healthcare facilities, educational, conference or business settings, such as business hotels or conference centers. Luxury hotels, resorts, venues known for entertainment and recreation are not considered appropriate. ALKALOID may organize the professional events in the respective country or abroad.

It is allowed for ALKALOID to organize or sponsor a professional event, taking place out of the respective country in cases where:

- A. Most of the invitees come from a country other than the respective country, which makes it logical the event to take place in that country or
- B. Considering the location of the relevant source or expertise, subject of the professional event, it is more logical that it takes place in another country (international professional event).

Corporate hospitality

Reasonable hospitality of ALKALOID may be allowed for realization of such events.

Depending on the nature of the event, corporate hospitality may include hotel accommodation, meals and beverages, as long as it is necessary, justified and secondary to the main purpose of the meeting. Corporate hospitality, alone, unless related to a professional meeting, is prohibited. Hospitality may only be extended to the participants of the event and shall be consistent with its duration.

Travel

Travel related to the participation at professional events should be on the most direct and logical route, taking into account costs for ALKALOID. Arrival and departure, whenever logistically possible, should always correspond with the beginning and end of the meeting. Flights should be booked in economy class; business class may only be used in exceptional circumstances, if justified and approved in written by responsible persons in ALKALOID and based on written request from relevant HCP/HCO.

5.4 SITE VISITS TO ALKALOID AD SKOPJE

The visits to the company manufacturing and research & development facilities by healthcare professionals and associates help to better understand the high standards and quality of the business operations, necessary for providing quality products and services. Healthcare professionals and associates, when visiting ALKALOID, have the opportunity to get acquainted with the high standards maintained by ALKALOID, thus building mutual faith regarding product quality.

A visit to the company facilities should have educational and informative values, and may never be provided as a means for improperly influencing healthcare professionals.

The realization of a visit to the company manufacturing and research & development facilities should be based on a specific agenda, prepared in coordination with all relevant corporate departments. The agenda should have precisely defined duration and assigned responsible persons included in its realization. During the visit, all corporate standards must be observed, along with the standards of good manufacturing practice.

5.5 SPONSORSHIP OF EVENTS

Subject to the applicable local rules and requirements, ALKALOID may provide sponsorship to third-party organized meetings, events or projects intended for healthcare professionals, provided the events are relevant to ALKALOID's therapeutic areas and its business operations. In recognition of its support, ALKALOID may receive commercial advertising opportunities, booth or exhibit space, distribution or promotional material, company branding of banners and materials etc.

The nature of the event, its program content and the planned topics, as well as the associated hospitality must be known before making a decision on its sponsorship.

Participation in or organization of any event and meeting, whether for medical or promotional objectives, for us bears a clear scientific, medical and educational focus regarding the content we present.

Using sponsorship as a method of indirect financing of activities which could not be undertaken due to legal constraints, are prohibited. ALKALOID does not provide sponsorship which finances or supports recreational or entertainment activities for healthcare professionals.

5.6 SOCIAL CONTRIBUTIONS

As a socially responsible company, ALKALOID continuously contributes to improvement of the health and the quality of the community life.

Contributions in the form of grant/donation may be provided to recognized charities, civic organizations and non-profit institutions, but never to natural persons or for-profit entities.

Contributions can take the form of financial or in-kind donations, for the purpose of realization of scientific research, medical education, patient education, patient access to healthcare and the overall development of healthcare system. ALKALOID may also support various charitable initiatives.

Contributions may be supported by a voluntary and independent request from an institution, including a detailed description of their needs, the program or project and the planned budget. Contributions, including details of the project/program, must be recorded in writing. ALKALOID must ensure it has understanding of how the donated funds will be used.

Contributions to healthcare organizations must serve the purpose – realization of healthcare goals, such as research and education, and they should be duly documented and kept on record. Contributions must never be a means for influencing a healthcare professional or a healthcare organization, and must not influence decisions on research and on persons benefiting from donations (unrestricted grants). With the exception of legitimate research and/or educational grants, donation/grants to individual healthcare professionals are not allowed. Unrestricted contributions to healthcare organizations that are not tied to a specific project of activity are not allowed.

5.7 EDUCATIONAL MATERIALS, MEDICAL UTILITY ITEMS AND SMALL-VALUE GIFTS

ALKALOID may occasionally provide educational materials, medical utility items and small value gifts to healthcare professionals, in accordance with the applicable rules and requirements.

These items must be relevant to the professional duties of the healthcare professionals and

ultimately benefit patients, patient care and the medical or pharmaceutical practice. Such items should never provide personal benefit to a healthcare professional, or be used as means to encourage recommendations, prescription, purchase or sales of medicinal products by the healthcare professionals.

ALKALOID must not provide small value gifts or medical utility items which may reduce the costs of operating medical practice. Therefore, providing medical supplies required for day-to-day practice in medicine (e.g. tongue depressors, latex gloves etc) is prohibited. Items that could be easily resold or used to generate income are also prohibited. ALKALOID must not provide gifts in the form of cash or items whose value is higher than the value set forth in the local regulations.

The educational materials, medical utility items or small value gifts intended for healthcare professionals may carry the ALKALOID logo, the registered trade name of a product (brand) and/or its international unregistered name, in accordance with applicable local regulations.

5.8 FREE SAMPLES

Samples of medicines may be only provided on exceptional basis to help healthcare professionals authorized to prescribe them to familiarize themselves with the product and acquire experience in order to enhance patient care.

Medical samples must not generate income for a healthcare professional and they cannot be resold by the healthcare professional. Healthcare professionals must be duly informed, but also the packaging must clearly indicate that the medicinal product is not for sale.

Medical samples should be given only on an occasional basis, in accordance with the applicable legal limits on amounts and frequency, and only upon the prior written

request of the healthcare professional.

Alkaloid establish an adequate system of control for distribution of free samples operating by our medical representatives. The medical representatives should be appropriately trained to manage and keep record of the samples as long as they fall within their scope of responsibilities.

Samples must not be provided as inducement to recommend, prescribe, purchase, offer, sell or administer certain medicinal products or to onset a therapy in patients.

5.9 PROMOTIONAL MATERIALS AND INFORMATION

ALKALOID may promote to the public corporate facts about the company and non-prescription drugs through regular advertising channels and the social media, to the extent permitted by applicable rules and requirements.

Promotion of prescription-only drugs (Rx) is solely intended for healthcare professionals and the same may be realized through published advertisements in professional literature, professional journals and other professional publications, as well as through direct sharing of information between the healthcare professionals and the professional teams (medical-commercial representatives, line and product managers) of ALKALOID.

All promotional materials and information (whether printed, electronic or oral) produced by ALKALOID must be clear, readable, accurate, up-to-date, balanced, fair and complete to enable the healthcare professional to form their own opinion on the therapeutic value of the respective pharmaceutical product. They must not be misleading and must encourage the rational use of the medicinal products

by presenting them objectively and without exaggeration.

The promotional materials of ALKALOID's medicinal products and their use in a therapeutic area are prepared in compliance with the latest approved Summary of Product Characteristics (SmPC) and the applicable local regulations.

Scientific promotional claims and comparisons must always be up-to-date, referenced, clinically relevant and consistent with the licensed indications. 'Off-label' promotional messages are prohibited.

All illustrations, including charts, figures and tables taken from already published research, included in the promotional materials of ALKALOID:

- shall clearly and accurately state the source and
- shall be authentically reproduced, except in cases where adaptation or modification are necessary, which shall be duly stated.

Comparison with other pharmaceutical products must be based on relevant data and in compliance with SmPCs of all mentioned products. Comparative data contained in the promotional material must be based on objective facts, supported by a reference from a relevant source.

All promotional materials and information prepared by ALKALOID, such which refer to pharmaceutical products, before distribution and utilization should be revised and approved by the Corporate Department for Medical and Portfolio in cooperation with the responsible persons from the subsidiaries, in line with the applicable corporate procedure. During the preparation of all promotional materials and information, ALKALOID shall ensure full regulation of the intellectual property rights to third parties.

5.10 PATIENTS AND PATIENT ORGANIZATIONS/ ASSOCIATIONS

The interaction of ALKALOID with patients and patient organizations/associations is in accordance with the EU and local regulations, which clearly state that advertising of prescription-only medicines (Rx) to the general public is prohibited.

- Written agreements

ALKALOID, as a socially responsible company may provide financial and/or non-financial support to patient organizations and associations, such which shall benefit the healthcare system or the society. To this end, it must have in place a written agreement which shall prescribe the amount and purpose of the funding or a description of the non-financial support.

- Use of logos and proprietary materials

If ALKALOID seeks to use a logo and/or proprietary material of a patient organization/association, written permission from the patient organization/association for such use is required. In seeking such permission, the specific purpose and the way the logo and other proprietary material shall be used must be clearly stated.

- Editorial control

ALKALOID must not influence the work of the patient organization/association or the contents of their materials in a way which is favorable to the commercial interests of ALKALOID. This does not preclude ALKALOID from correcting certain factual inaccuracies. In addition, at the request of patient organizations/associations, ALKALOID may contribute to the drafting of texts from a fair and balanced scientific perspective.

- Contracted services

Contracts between ALKALOID and patient organizations/associations, under which they provide services for ALKALOID, are only allowed if the services are provided for the purpose of supporting healthcare and research. In this sense, ALKALOID may engage experts or consultants who are members of patient organizations/associations, for providing professional services. The arrangements that cover consultancy or other services must fulfill the following criteria:

- a. A written contract is signed prior to engaging the organization/association, such that shall specify the nature of the services and the basis for payment of such services by ALKALOID;
- b. A legitimate need for the services has been clearly defined and documented in advance of requesting the services and signing the contract;
- c. The criteria for selecting services are directly related to the identified need, and the persons from ALKALOID responsible for selecting the services have the expertise necessary to evaluate whether the particular experts and advisors meet those criteria;
- d. The extent of the service is not higher than is reasonably necessary to achieve the identified need;
- e. ALKALOID maintains records and makes appropriate use of the services;
- f. The engaging of a patient organization/association is not an inducement to recommend a particular medicinal product from the ALKALOID portfolio;
- g. The compensation for the services should be justified and should not exceed the fair market value of the services provided;
- h. ALKALOID may not require to be the sole funder of a patient organization/association or any of its major programs and
- i. In the written contracts with patient organizations/association, ALKALOID should include provisions regarding the obligation of the patient organization/association to declare that they have provided paid services to ALKALOID, whenever they write or speak in public about a matter that is a subject of the agreement or any other issue related to ALKALOID.

6. ETHICAL PROMOTION

The promotion of our medicinal products must always be accurate, balanced and ethical, and must not mislead the healthcare professionals. The information contained in our promotional materials provides appropriate assessment of the benefits and risks of our products pertaining to their use, in accordance with the information stated in the Summary of Product Characteristics. ALKALOID encourage rational use of medicinal products by presenting them objectively and without exaggeration.

- Only products with approved marketing authorization may be promoted in interaction with healthcare professionals.
- The products are promoted only within the approved indications and other particulars stated in the approved SmPC.
- Rational use of products shall be promoted, by means of objective presentation and without exaggeration of their properties.

Comparison between various medicines is made in a way based on relevant and comparable aspects based on scientific evidence. In comparative advertising we must ensure that

the information is not inappropriately favorable for our product. We respect privacy and personal data of the patients if we come into contact with them during our promotional activities.

The medical representatives of ALKALOID, who act as our extended arm in the interaction with the healthcare professionals, must comply with all relevant codes of the industry, the applicable local legislation and other applicable regulations. We expect them to fulfill their duties responsibly and ethically, to ensure frequency and duration of the appointments in a manner which will cause unpleasant effect on with the healthcare professionals or with patients. Our medical representatives are mindful of their personal integrity and the corporate identity during promotional activities aimed at healthcare professionals. Our employees must not offer or give items of value with the intent to influence or encourage directly or indirectly the recipient to prescribe, recommend or purchase our products.

7. MARKETING TEAMS

The promotion of medicinal products is conducted by marketing teams, which shall fully comply with the provisions of this Code and the applicable local regulations in the respective country.

- ALKALOID provides all its medical representatives, including employees contracted by a third party and all other employees who cooperate with healthcare professionals, pharmacies, hospitals or other healthcare organizations and are involved in activities for promotion of medicinal products and medical devices with complete information regarding relevant requirements pertaining to the applicable code, as well as with all applicable local legislation and regulations.
- The medical representatives of ALKALOID are appropriately trained and have sufficient scientific knowledge to offer accurate and complete information about the medicinal products they promote and make known to the healthcare professionals and healthcare organizations.
- The medical representatives must always act in accordance with all relevant requirements defined in the applicable codes of ALKALOID or the industry and in the applicable legislation and regulations in the country where they are engaged, while the company is responsible for implementation of such adherence to the respective legislation.
- The medical representatives shall fulfill their duties responsibly and ethically. The medical representatives shall act in a way that the frequency, timing and duration of the appointments, along with the manner in which they are conducted, should not cause any inconvenience to the other party and should be adapted to their capabilities and conditions.
- During every visit to HCP and in compliance with the applicable legislation and regulations, the medical representatives should always carry the SmPC of the medicinal product or medical device and present and share it upon need and request.
- The medical representatives shall forward to their local Medical accountable person for that affiliate the information that is not contained in the SmPC, which they received during their field activities and is related to a medicinal product of ALKALOID. This is mandatory for information regarding adverse drug events.
- Adverse event reports shall be forwarded to the responsible person for pharmacovigilance in the respective country.
- Medical representatives must not resort to any inducement or deceit in order to make an appointment with a healthcare professional. At the appointment or when scheduling one, medical representatives should not mislead the healthcare professionals about their identity or the identity of ALKALOID.
- The provisions apply to all activities of the medical representatives directed at promoting medicinal products to healthcare professionals or healthcare organizations.
- ALKALOID has set up Corporate Department for Medical and Portfolio, headed by a medical doctor who is responsible for issues related to our medicines. This department also deals with issues associated with a medicinal product which are not covered in the respective SmPC.
- All employees of ALKALOID and any employees contracted by a third party who are involved in the preparation or approval of promotional material and promotional activities, shall be fully familiarized with the requirements set forth in this Code and the relevant legislation and regulations.

8. MARKET RESEARCH AND POST-MARKETING CLINICAL TRIALS

• EPIDEMIOLOGICAL STUDIES AND OTHER MARKET RESEARCH

Medical representatives may assist in conducting market research and epidemiological studies if the applicable local regulations permit. Permission/approval for inclusion in market research and epidemiological studies is acquired/obtained by the local management, in accordance with applicable rules and requirements.

Medical representatives may compile data in electronic form or hard copies and shall forward the same to the local responsible person appointed for conducting the study. Involvement of medical representatives in market research must be clearly separated from the promotional activities, approved by the local management and the competent authorities, if required.

• POST-MARKETING (NON-INTERVENTIONAL) TRIALS ON DRUGS WITH MARKETING AUTHORIZATIONS

ALKALOID supports conducting non-interventional, post-marketing clinical trials in accordance with the needs and requirements of a particular country. They should be designed

and carried out in strict compliance with the local regulations, in coordination with the Corporate Department for Medical and Portfolio of ALKALOID AD Skopje.

9. TRANSPARENCY

Through transparency, as one of its key values, ALKALOID conveys to the public and the community the authenticity of its business operations and sets conditions and mechanisms for preventing risks of unethical and illegal behavior. Through transparency we are assured that all decisions we take are appropriate, permitted and consistent.

ALKALOID keeps accurate records of all engagements, payments and transfers of value to all healthcare professionals and healthcare organizations in precisely defined formats. In accordance with applicable regulations, ALKALOID makes these data public on relevant platforms or directly to the competent authorities.

In addition, transparent relations and interactions between ALKALOID and patient organizations/associations are also essential for preventing unethical and illegal behavior. For that purpose, ALKALOID maintains, and in accordance with applicable requirements, provides available to the general public, a list of patient organizations/associations for which it provides financial and/or non-financial support based on an agreement. The list shall include a short description of the nature of the support/services, and the monetary value of the financial support.

9.1 TRANSFER OF VALUE

A transfer of value includes anything of value that is provided (or transferred) by ALKALOID (directly or indirectly via a third party acting at its direction) to a recipient - a healthcare professional, healthcare organization or patient organization - including monetary payments or in-kind benefits, such as meals, travel costs, hospitality etc.

ALKALOID documents and maintains a database of all transfers of value to healthcare professionals and healthcare organizations. The competent organizational units in ALKALOID submit reports on all transfers of value to healthcare professionals and healthcare organizations to the Corporate Compliance Officer in ALKALOID and to the member of the Corporate Compliance Commission who is responsible for pharmaceutical compliance, by 15 February of the current year at the latest, for the reporting period which includes the previous calendar year.

ALKALOID maintains all documentation and keeps records of all transfers of values for a period of at least 5 years following the reporting period in which they are stated.

ALKALOID, if the local regulations require, shall disclose the transfer of values data on the relevant platforms (websites) or directly to the competent authorities, by stating the amounts of the transfers of value allocated to a category stated below.

1. Transfers of value to healthcare professionals

- Fees for consulting services: aggregated honoraria (excluding expenses for meals and beverages, travel and accommodation) paid by ALKALOID to a healthcare professional in exchange for the provision of services, such as serving as an expert on an advisory board, speaking at an educational event organized by ALKALOID, participating in a focus group etc. Fees paid in connection with research and development activities or market research are excluded from the scope of this documentation.

2. Transfers of value to patient organizations/associations

- Financial or in-kind support.
- Fees for services: contracted services per each patient organization/association, including a description of the nature of the transfer of values and the amount provided

3. Transfers of value to healthcare organizations

- Financial or in-kind support.
- Fees for services: contracted services per each healthcare organization, including a description of the nature of the transfer of values and the amount provided.
- Transfers of values are documented individually, stating the name of the recipient. When the transfer of value refers to a healthcare professional, in accordance with the local tax regulations, ALKALOID submits to the healthcare professionals an annual report on the aggregate transferred value and the tax obligations pertaining to the same transfer.
- Regarding meetings, educational support and site visits to ALKALOID, documentation and disclosure for this transfer of values category is provided in a way explained below.
- Aggregate number (but not the actual monetary value) of events for which a particular healthcare professional received financial support/aid (including paid registration fees, travel and/or accommodation). The support is documented per each healthcare professional for the following categories and sub-categories:
 - sponsorship for attending third-party organized congresses, where ALKALOID pays the registration fees, travel and accommodation:
 - meetings sponsored by ALKALOID for which the accommodation and/or travel costs for the healthcare professional are paid by the sponsor.
 - site visits to ALKALOID AD Skopje and

9.2 METHODOLOGY FOR REPORTING TRANSFER OF VALUES

ALKALOID shall apply a strictly defined methodology for disclosing and identifying transfers of value.

9.3 DATA PRIVACY AND CONSENT

In compliance with the applicable regulations for personal data protection, to the extent required, ALKALOID shall seek the consent from the individual healthcare professional if his/her personal data are published in connection with transfers of value data concerning him/her.

If a healthcare professional refuses to provide the consent required under applicable data privacy laws and regulations, ALKALOID shall nonetheless publish the transfers of value related to the healthcare professional on an anonymous basis. If multiple healthcare professionals refuse consent, then the transfer of value data shall be aggregated and shall indicate the total number of healthcare professionals included in the aggregation.

Regarding healthcare professionals' personal data protection, ALKALOID, within its corporate system, applies technical and organizational measures which support a standard of compliance with the EU general regulations on personal data protection (GDPR). GDPR

compliance standards imply that ALKALOID's subsidiaries in the countries where GDPR is not implemented shall ensure personal data protection of healthcare professionals and patients at a standard much higher than

imposed by local regulations. Each compiling, processing and disclosing of personal data of healthcare professionals or patients implies previously obtained consent on their part.

9.4 DISCLOSURE PLATFORM

If ALKALOID, or a subsidiary, separately, is obligated to disclose transfers of value, it should be done in a way in which the public can easily access such information. This means via

ALKALOID's or the subsidiary's website and/or a central platform (provided by the Government, regulatory or professional authority body).

10. ADVERSE EVENT REPORTS

Safety of the patients, users and timely reporting of adverse events are of utmost importance. All ALKALOID's employees, representatives and third parties acting on behalf of ALKALOID shall report to the Pharmacovigilance Department within a

working day any adverse event or other data relevant to pharmacovigilance for which they become aware, regardless of whether they believe that they are related to the use of a medicinal product of ALKALOID.

11. CODE VIOLATION PROCESS

ALKALOID requires and expects a high level of corporate responsibility from all its employees, in all activities directed to healthcare professionals. On all occasions we expect implementation of high ethical standards in the approach and interaction with our partners and in achieving our business goals. In all countries where ALKALOID has its direct operations our employees are obliged to adhere to ALKALOID's policies and standards, the local laws and regulations and the local industry codes which regulate the interaction with healthcare professionals.

ALKALOID has a set system of corporate compliance, which means an integrated system of policies, acts, functions, processes, control mechanisms and tools, which are applied towards ensuring compliance with the Code of Interaction with Healthcare Professionals and Ethical Presentation, i.e. towards reducing the risk of its violations committed by any ALKALOID employee, thus preserving and cultivating the corporate integrity.

In ALKALOID, there is a network of employees who, within the scope of their duties, are responsible for acting and deciding upon Code violations:

- Corporate Compliance Officer in ALKALOID AD Skopje,

- Corporate Compliance Commission and
- Compliance Officers in ALKALOID's subsidiaries.
- All employees of ALKALOID and its business partners and associates are encouraged to report all actual and potential violations of the Code through the following channels:
- AlkaSpeakUp web-form, set on ALKALOID's website;
- contacting the Corporate Compliance Officer in ALKALOID AD Skopje at the telephone number +38972918245, or the Compliance Officers in the subsidiaries at their respective telephone numbers or via
- Corporate Compliance Officer in ALKALOID AD Skopje email address: complianceofficer@alkaloid.com.mk or the email addresses of the compliance officers in the subsidiaries.

The Commission of Corporate Compliance is responsible for the cases when there is a justified report for violation of The Code on interaction with the healthcare professionals and ethical promotion.

The Commission is a body of ALKALOID with responsibilities to conduct investigations for

establishing all facts and circumstances related to the complaint about the Code violation filed by an ALKALOID employee, an external person, a business partner or associate of ALKALOID or at the request of a manager of ALKALOID, in order to establish the actual state, on which basis the company management may take a sound decision for imposing measures and sanctions to the breaching party.

Under the procedure for establishing the violation of Code of Interaction with Healthcare Professionals and Ethical Presentation, if the evidence provided clearly and undoubtedly proves that a violation of the Code is committed, the Commission issues its findings for the existence of violation of the Code with proposed

measures or sanctions which is submitted to the management of ALKALOID or the relevant subsidiary, who subsequently impose the corrective measures and sanctions.

The procedure for establishing and deciding upon a violation of the Code of Interaction with Healthcare Professionals and Ethical Presentation applies at a corporate level, i.e. the Corporate Compliance Commission decides upon violations of the Code committed by employees in the subsidiaries. The local Compliance Officer of the relevant subsidiary takes part in the work of the Commission and is part of the investigation and the decision.

12. PERIOD FOR ADAPTATION AND IMPLEMENTATION

This Code of Interaction with Healthcare Professionals and Ethical Presentation enters into force as of the date of its adoption by the Managing Board of ALKALOID AD Skopje and is effective as of 1 January 2021.

All subsidiaries of ALKALOID AD Skopje have a period of adaptation and implementation to

the end of 2020, starting from the date of its enforcement.

All subsidiaries shall document and submit to the responsible corporate departments all transfers of value allocated in 2021 by 15 February 2022 at the latest, and/or publish them, where applicable.





www.alkaloid.com.mk
e-mail: alkaloid@alkaloid.com.mk

Health above all