Code of Promotional and Marketing Practices

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A Message from the Board of Directors

Dear Colleagues,

Since its founding, Arabio's business practices have been governed by Integrity, excellence, and full compliance with all applicable laws and regulations. Arabio's employees have endorsed and lived this pledge in their every day's work. Our reputation is and will remain one of our most valuable assets. This Code of promotional and marketing practices (referred to in this document as "the Code") represents the commitment of Arabio to conduct its promotional and marketing practices in accordance with all applicable industry laws, rules and regulations and the highest ethical standards.

It is crucial for us to earn and maintain the trust of our communities, customers, governments, investors, and the employees wherever we operate. Each employee is required to abide by this Code and ensure that all business activities and decisions reflect our commitment to Ethics Excellence.

Our reputation and our success depends upon the personal commitment that each of us makes to exhibit Arabio's values of Acting with Integrity, performing with excellence and Communicating with respect for people in all of our business.

Remember, how we do things is just as important as what we do. All employees must seek guidance when they are in doubt about the proper action in a given situation, as it is the ultimate responsibility of each employee to "do the right thing right from the start".

Chairman of Arabio's Board of Directors

Saudi FDA Guiding Principles on Ethical Conduct and Promotion

The Saudi FDA Code of pharmaceutical promotional practices is considered as an ethical code for the pharmaceutical promotional and marketing activities in Saudi Arabia. All Pharmaceutical Companies/plants conducting business in Saudi Arabia to promote, sell and/or distribute their products, must all the time follow the guiding principles of the Saudi FDA Code.

The following are the objectives of the Saudi FDA code:

1. Organizing the marketing practices in line with ethics profession of medicines and pharmacy.
2. Provide accurate, fair and objective information about the pharmaceutical products to health care providers in order to reach the correct decisions about usage.
3. Create suitable and healthy environment for virtuous competition between the pharmaceutical companies.
4. Developing and organizing the pharmaceutical companies/plants relationships with health care sectors professionals through providing accurate and reliable information about the pharmaceutical products for patient benefit.

The following Guiding Principles set out basic standards that form the Saudi FDA Code of Practice:

1. The pharmaceutical companies are responsible to furnish the health care providers with accurate, up-to-date, balanced, and not prejudiced information about the medications that are prescribed by those HCPs, which is derived from the companies experience in developing of these medications.
2. Pharmaceutical companies/plants are sharing responsibility with health care providers to furnish the patients with the same information.
3. The continuous of education and availability of the information are essential to understand the appropriate usage of prescribed medications.
4. All promotional activities and practices should be done in accordance with clear standards that can be gauged.
5. The promotional information should be designed in a way that can help the health care providers to offer a better health service. In addition, this information should be done in conformance with the relevant laws and regulations and the companies should be committed to maintain internal and external regulations to ensure its conformance with the general basis of this code.

Code of Promotional and Marketing Practices

Preamble

- The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients. Ethical promotion helps to ensure that healthcare professionals have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.

- Whereas the Code provides the main framework for the local regulations and control of the importation, manufacture, distribution and advertising of medicinal products, there are areas of activities which they may not constitute breaches of the law, they may -if unrestrained- bring about undue harm to the public health and loss of credibility and respectability for the pharmaceutical industry.

- The Company Code of Promotional and Marketing Practices (hereafter refers to as Code) is to provide guidance for the proper conduct in the marketing and promotion of its medicinal products and is to serve as basis for self-discipline within the industry. This would include any activity undertaken by the company or distributors that promote the prescription, supply, sale, or distribution of pharmaceutical products, including vaccines.

- The Code includes standards for the ethical promotion of pharmaceutical products to healthcare professionals and helps ensure that all the Company's interactions with healthcare professionals and other stakeholders, such as medical institutions and patient organizations, are appropriate and perceived as such.

ARTICLE 1
Scope and Definitions

1.1 Scope

The Code covers interactions with healthcare professionals, medical institutions and patient organizations, and the promotion of pharmaceutical products. Where direct promotion to the public is allowed, this is covered by local laws, regulations and/or relevant codes of practice. The company should of course, comply with these local laws, regulations and codes.
In all matters of application, interpretation and enforcement of any section of the Code, it is to be understood that compliance with Saudi Arabia laws, regulations and regulatory decisions and requirements of the company will take precedence.

1.2 Definitions

For the purposes of the Code:
• "***Pharmaceutical product***" means all pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) which are intended to be used on the prescription of, or under the supervision of, a healthcare professional, and which are intended for use in the diagnosis, treatment or prevention of diseases in humans.

• "***Promotion***" means any activity undertaken, organized or sponsored by the company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all methods of communications, including the internet. Promotion of OTC products directed to HCPs is within the scope of this Code.

• "***Health-care professional***" means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product.

• "***Patient organization***" means typically a not-for-profit institution that primarily represents the interests and needs of patients, their families and/or caregivers.

• "***Medical institution***" means typically an organization that is comprised of healthcare professionals and/or that provides healthcare or conducts healthcare research.

ARTICLE 2
Basis of Interactions

2.1 Basis of Interactions

The company's relationships with healthcare professionals and other stakeholders are intended to benefit patients and community and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about medicines, providing scientific and educational information and supporting medical research and education.

2.2 Transparency of Promotion

Materials relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by the company, should clearly indicate by whom it has been sponsored. Promotion should not be disguised.

ARTICLE 3
Pre-Approval Communications and Off-Label Use

3.1. No pharmaceutical product shall be promoted for use in Saudi Arabia until the required approval for marketing for such use has been given by the Regulatory Authority.

3.2. This provision is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure of information to stakeholders and others concerning any pharmaceutical product, as may be required or desirable under local laws, rules and regulations.

3.3. Only Medical Department of The Company will respond to unsolicited queries pertaining to pre-approved label use.

ARTICLE 4
Standards of Promotional Information

4.1. General principles

In general, the standards of promotion should ensure that:
a) The company is responsible to ensure compliance with the Code.
b) Data are substantiated.
c) False or misleading claims are not promoted.
d) Unapproved products, indications, forms and dosage regimens are not promoted.
e) The materials and data are presented in good taste.
f) Unqualified superlative statements are not allowed.
g) New products are clearly identified.
h) Comparative statements must be used carefully and honestly.
i) Imitation that may give rise to confusion is not allowed.
j) Medical ethics are adhered to.
k) Distinction of promotional materials is clearly defined.

4.2. Consistency of Product Information

The company will follow all local laws and regulations and the company code related to the content of the product information communicated on labeling, packaging, leaflets, data sheets and in all promotional materials. Promotion should not be inconsistent with locally approved product information.

4.3. Transparency

Data from in vitro and animal tests should be clearly marked as such, and not be cited in such a way that it could give an incorrect or misleading impression.

4.4 Substantiation

Promotion should be capable of substantiation either by reference to the approved labeling or by scientific evidence. Such evidence should be made available on request to healthcare professionals. The company should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.

4.5 Opinions

The medical and scientific opinions of opinion leaders and health care professionals, and products, activities or representatives of other pharmaceutical companies must not be disparaged.

ARTICLE 5
Printed Promotional Materials

5.1. Printed promotional materials shall be presented in a legible manner. The scientific basis and presentation of the product information must be in conformity with the general principles set out in Section 4 of the Code and where applicable, with the authorized product information.

5.1.1. Promotional materials such as mailings and journal advertisements and loose inserts must not be designed to disguise its real nature.

5.1.2. Promotional material should conform, in both text and illustration, to principle of good taste and should recognize the professional standing of the recipient.

5.1.3. Materials should be in conformance with the Islamic Sharia, social traditions, ethical and cultural fundamentals of Saudi society.

5.1.4. Materials and articles from the lay press should not be used as promotional materials.

5.1.5. Illustrations must not mislead as to the nature of the claims or comparisons being made, or as to the purpose for which the product is used.

5.1.6. Artworks and graphics must conform to the letter and the spirit of the Code. Graphs and tables should be presented in such a way so as to give a clear, fair, balanced view of the matters with which they deal, and should only be included if they are relevant to the claims or comparisons being made.

5.1.7. Graphs and tables must not be used in any way which might mislead, for example by the incompleteness or by the use of unusual scales.

5.2. Reprints, abstracts and quotations in print or other media.

5.2.1. Such materials from medical literature or from personal communications received from doctors, must accurately reflect the meaning of the author and the significance of the study (which should not be distorted by the addition of highlighting or underlining to give prominence to selected portions of the material)

5.2.2. Care must be taken to avoid ascribing claims or views relating to the medical products to authors when such claims or views no longer represent or may not represent the current view of the authors concerned.

5.3. All Advertisements

5.3.1 All advertisements appearing in print must include:
- The name of the product (normally the brand name);
- The active ingredients, using an approved name.
- The name and address of the company or its agent responsible for marketing the product.

5.3.2. The mailing address of the contact from which further information may be obtained must appear, either in the advertisement itself or be readily accessible from the publication in which the advertisement appears.

5.4. Full Advertisements

Full advertisements are those which include promotional claims for the use of the products. In addition to the requirements of paragraph 5.3., full advertisements must also include prescribing information in the form of:
- The product approved indication for use together with the dosage and method of use;
- A succinct statement of the contraindications, precautions and side effects.
- Any locally obligated warnings relating to the product.
- A statement that full prescribing information is available on request;
- The name and address of the company from which full information can be obtained.
- In cases where journal advertisements and prescribing information are separated, it must be clear where in the journal the prescribing information can be found.
- The word "new" should not be used to describe products that have been available in a specific market for more than 12 months.

ARTICLE 6
Electronic Materials, including Audio Visuals

The same requirements shall apply to electronic promotional materials as apply to printed materials. Specifically, in the case of pharmaceutical product related websites:

- The identity of the company and of the intended audience should be readily apparent.
- The content should be appropriate for the intended audience.
- The presentation (content, links, etc.) should be appropriate and apparent to the intended audience.

- Country-specific information should comply with local laws, rules and regulations.

ARTICLE 7
Interactions with Healthcare Professionals

7.1. Events and Meetings

7.1.1 Scientific and Educational Objectives

The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an "Event") for healthcare professionals organized or sponsored by the company should be to provide scientific or educational information and/or inform healthcare professionals about products.

7.1.2 Events Involving international Travel

The company may not organize or sponsor an Event for healthcare professionals (including sponsoring individuals to attend such an Event) that takes place outside of their home country unless it is appropriate and justified to do so from the logistical or security point of view. International scientific congresses and symposia that derive participants from many countries are therefore justified and permitted.

7.1.3 Promotional Information at Events

Promotional information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the Event takes place, or which are registered under different conditions, provided that the following conditions are observed:

- Host country regulations should permit such an arrangement;
- The meeting should be a truly international scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the event takes place.
- Promotional materials for a pharmaceutical product not registered in the country of the event should be accompanied by a suitable statement indicating the countries in which the product is registered and makes clear that such product is not available locally.
- Promotional materials which refers to the prescribing information (indications, warnings, etc.) authorized in a country or countries other than that in which the Event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally; and an explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

7.1.4 Appropriate Venue

- All Events must be held in appropriate venues that are conducive to the scientific or educational objectives and the purpose of the Event or meeting. The company will always avoid using renowned or extravagant venues.
- Venues associated with activities such as gaming and entertainment are deemed not conducive to the conduct of scientific/educational meetings/activities and would be deemed as inappropriate.

7.1.5 Limits

- Refreshments and/or meals incidental to the main purpose of the Event can only be provided exclusively to participants of the Event; and if they are moderate and reasonable as judged by local standards.
- Providing hospitality in relation to food and drinks as per social/cultural norms in a local setting to members of the medical and allied professions should be limited to maximum of SAR 280 per person per meal. This is applicable to Saudi Arabia only and excludes Service Charge. However, this must be accompanied with dissemination of scientific or educational information.

7.1.6

No stand-alone entertainment or other leisure or social activities may be provided or paid for any HCP.

7.2. Sponsorship

The company may sponsor healthcare professionals to attend Events provided such sponsorship is in accordance with the following requirements:

- The Event complies with the requirements in this Code and in the Saudi FDA Code.
- The event is primarily dedicated, in both time and effort, to objective scientific and educational activities.
- When a Congress/Symposium is organized, majority of the time should be spent on core activities of the Congress/Symposium and minority of the time devoted to Hospitality, refreshments and/or meals.
- Sponsorship of healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees.
- No payments are made to compensate healthcare professionals for time spent in attending the Event.
- Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.

- The company should only provide Economy Class tickets for air travel of less than 4 hours. This should apply to all faculty members e.g. speakers, members of Advisory Boards as well as attendees.

N.B. For invited HCPs whom during their regular business travel are by default entitled for higher class by their employers, an approval from the GM must be obtained in case a higher than economy class air ticket is required.

- When an event sponsored by the Company is to be held in an out of town location, majority of the attendees must be from the location at which the event is held.

7.3. Accompanying Persons

The company will not pay any costs associated with individuals accompanying invited healthcare professionals.

7.4 Fees for Services

The company may engage Health care professionals as consultants and advisors for services such as speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration. The arrangements which cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfill all the following criteria:

- A written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services;
- A legitimate need for the services must be clearly identified and documented in advance;
- The criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service. The criteria for selection along with the names selected should be approved by qualified medical personnel in The Company.
- The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need.
- The hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine.
- The compensation for the service must be reasonable and reflects the fair market value of the service provided.

7.5 Gifts and Other Items

7.5.1 Prohibition of Cash & Personal Gifts

Payments in cash or cash equivalents (such as gift certificate) must not be provided or offered to healthcare professionals. Gifts for the personal benefit of healthcare professionals (such as sporting or entertainment tickets, electronics items, etc.) must not be provided or offered.

7.5.2 Gifts

Promotional items valued at no more than 50 SAR may be provided to HCPs as long as the items are related to the HCP's practice and/or entail a benefit to patient care.

7.5.3 Educational Materials & Items of Medical Utility

Textbooks or references, subscriptions to on-line journals and other educational materials including models and illustrative tools may be given to health care providers if they serve a genuine educational function and must not exceed 3000 SAR per year for an individual HCP with the approval of qualified medical personnel within The Company.

7.5.4 Donations & Grants

- The company may offer scholarships, grants, charitable contributions or non-commercial sponsorships to support the advancement of knowledge in science, vaccination, healthcare, or to support other socially beneficial purposes. They must never be used to obtain an improper advantage to The Company or be made conditional upon an individual's or organization's agreement to recommend or promote The Company's products. When The Company provides this kind of economic support, it shall apply appropriate review and approval procedures, including an evaluation of the proposed recipient's reputation, track record, the suitability for the intended purpose, and the socially responsible benefits in terms of healthcare, science, medicine and public welfare.
- The company may provide grants towards financial support strictly for educational programs (including but not limited to requests to fund accredited CME programs, non-accredited educational programs, fellowships, advocacy organizations, societies) if they are:
    - Unsolicited
    - From an institution or organization, not an individual healthcare Practitioner.
    - Unrelated to the prescribing, purchasing, registration of any products
    - Substantiated by written documentation of details of program.
    - Able to withstand public scrutiny.

ARTICLE 8
Samples

8.1. Giving away of 'samples' as an inducement to purchase is prohibited. When allowed by the Saudi FDA Code, reasonable quantities of samples clearly identified as such, may be supplied to the health care professionals who are qualified to prescribe in order to familiarize them with the products, and to enable them to gain experience with the use of the products in their practice.

8.2. Each sample must be marked by the phrase *"Free Medical Sample, Not for Sale"* and a copy of the package leaflet must be attached to the sample.

8.3. Samples must not be used for clinical studies.

8.4. The company's staff must follow all internal systems of control and accountability for managing the samples Log and for monitoring the storage and handling of samples by the medical representatives.

ARTICLE 9
Clinical Research and Transparency

9.1. Transparency

The company is committed to the transparency of The Company's sponsored clinical trials. It is recognized that there are important public health benefits associated with making clinical trial information more publicly available to healthcare practitioners, patients, and others. If The Company has to do such disclosure, it must maintain protections for individual privacy, intellectual property and contract rights, as well as conform to legislation and current local rules and regulations and the company code.

9.2. Distinct from Promotion

All human subject researches must have a legitimate scientific purpose. Human subject researches, including clinical trials and observational studies, must not be disguised promotion.

ARTICLE 10
Market Research

Market research must be consistent with the company guidelines. Market research must not have the promotion of products as its purpose and must not be disguised

promotion. Statistics and data derived from market research may subsequently be translated into marketing activities/promotional content. Any payment to individuals participating in market research must be fair market value for the services performed.

If market research involves the collection of information and data from patients, the following principles must be adhered to:

- All safety data processing and reporting obligations must be fulfilled;
- Patient or caregiver data must only be collected, used and disclosed in accordance with applicable privacy laws and policies, and all notices and other privacy requirements must be met.
- The company must be transparent, clear and unambiguous with patients or patient caregivers about the collection of the data and how will it be used.
- All required consents must be obtained;
- Only the minimum amount of data needed for the disclosed purposes should be collected and retained for only as long as needed to achieve the disclosed purpose.

ARTICLE 11
Patient Support Programs

Patient Support Programs ("PSPs") should be designed with clearly stated objectives and to protect the rights and privacy of the participants. PSPs must not be designed or used to encourage the use of the company's products in a manner that is inconsistent with the approved product labeling (e.g., no targeting of patient populations outside of the approved product label). All PSPs must comply with applicable laws, regulations and industry codes in the countries where they are conducted.

If a PSP involves the collection of information and data from patients, the following principles must be adhered to:

- All safety data processing and reporting obligations must be fulfilled.
- Patient or caregiver's data must only be collected, used and disclosed in accordance with applicable privacy laws and policies and all notices and other privacy requirements must be met.
- The company must be transparent, clear and unambiguous with patients or patient caregivers about the collection of the data and how will it be used.
- All required consents must be obtained.

- Only the minimum amount of data needed for the disclosed purposes should be collected and retained for only as long as needed to achieve the disclosed purpose.

ARTICLE 12
Support for Continuing Medical Education

- The company believes that Continuing Medical Education (CME) helps ensure that healthcare professionals obtain the latest and most accurate information and insights on therapeutic areas and related interventions that are critical to the improvement of patient care and overall enhancement of the healthcare system.
- The primary purpose of an educational meeting must be the enhancement of medical knowledge and therefore financial support from companies is appropriate.
- When the Company provides content to CME activities and programs, such Materials must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognized opinions. Content must be limited to medical, scientific or other information that can contribute to enhancing patient care.

ARTICLE 13
Interactions with Patients' Organizations

13.1. Scope

All the Company's interactions with patients' organizations must be ethical. The independence of patients' organizations must be respected.

13.2. Declaration of Involvement

When working with patients' organizations, The Company will ensure that its involvement and the nature of that involvement are clear from the outset. The company will not require that it be the sole funder of the patients' organization or any of its programs.

13.3. Written Documentation

When the Company provides financial support or in-kind contribution to patients' organizations, it must have in place written documentation setting out the nature of support, including the purpose of any activity and its funding.

13.4. Events

The company may provide financial support for patients' organization meetings provided that the primary purpose of the meeting is professional, educational, and scientific in nature, or otherwise supports the mission of the patient organization. When The Company holds meetings for patients' organizations, it will ensure that the venue and location is appropriate and conducive to informational communication. In addition, any meals or refreshments provided by the company must be modest as judged by local standards.

ARTICLE 14
Communications to the Public

14.1.

Where it is permitted by law to communicate directly with patients regarding their prescription medicines, all such information should be accurate, fair and not misleading.

14.2.
Communications to the public may include the provision of patient package inserts and other leaflets and booklets, etc., made available to inform patients about products prescribed by health professionals.

14.3.
Where The Company assists in the conduct of public/patient disease awareness programs providing information on, signs and symptoms of medical conditions, illnesses, and available treatments, such activities should comply with the Disease Awareness Guidelines of the Saudi FDA regulations.

14.4.
Request from individual members of the public for information or advice on personal medical matters, including the product which has been prescribed, should be redirected to his or her own doctor.

ARTICLE 15
MEDICAL RERESENTATIVES

15.1.
The company will ensure that all medical sales representatives are familiar with the relevant requirements of the applicable codes and all applicable laws and regulations.

15.2.
The company will ensure that all medical sales representatives are adequately trained and possess sufficient medical and technical knowledge to present information on the company's products in an accurate, responsible and ethical manner.

15.3.
The company medical sales representatives must comply with all requirements of the applicable laws and regulations and the company code. They must also notify the medical and regulatory departments within the company about any information they receive on the use of the company products and particularly reports of side effects.

15.4.
During each visit, medical sales representatives must provide a summary of the product characteristics for each pharmaceutical product they present to the visited HCP.

15.5.
It is the obligation of the company to familiarize all employees of the sales, marketing, regulatory, medical and other relevant functions with the principles of the code of conduct and practices of The Company and of local legislation.

15.6.
Medical sales representatives should ensure that the frequency, timing and duration of their visits to HCPs, together with the manner in which they are made, are not to cause inconvenience to the health care professional.

15.7.
Medical sales representatives must not use any inducement or subterfuge to get an appointment for interview with HCP. During the interview or when seeking an appointment for an interview, medical sales representatives must take all practical steps to ensure that they don't mislead and provide a false information about their identity or the company they represent.

15.8.
The company will assume the responsibility, under the SFDA Code, for correcting breaches of the Code resulting from misconduct or misrepresentation of facts by any representative.

15.9.
Any promotional materials to be conveyed to the HCPs during an interview must be developed in accordance with the requirements of the applicable laws and regulations and the company code and must be reviewed and approved by the medical and regulatory departments within The Company.