Aquestive Therapeutics, Inc.
U.S. Marketing Code of Conduct

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1. PURPOSE

The purpose of this Aquestive Marketing Code of Conduct (the "Marketing Code") is to establish the principles and policies for interactions with Healthcare Professionals, Healthcare Organizations, and Patient Organizations, and the Promotion of Products.

2. SCOPE

This Marketing Code applies to all Aquestive Personnel who interact with Healthcare Professionals, Healthcare Organizations and/or Patient Organizations, and/or are involved in the design, development and implementation of promotional and/or professional activities related to the Promotion of Products to Healthcare Professionals, Healthcare Organizations and/or Patient Organizations.

3. DEFINITIONS

Term	Definition
Aquestive Personnel	Aquestive Personnel means all Aquestive colleagues, as well as agents, and approved contractors that provide services on behalf of Aquestive or represent Aquestive to third parties.
Fair and Balanced	Fair and Balanced refers to the presentation of accurate and fair assessment of the risks as well as the benefits of a Product or therapy as required by FDA regulations.
FDA	United States Food and Drug Administration
Grant Support	Provision of unrestricted funds to help educate or raise awareness of shared disease or scientific objectives such as the funding for the continuing medical education (CME), non-CME education and awareness events, screening programs, medical scholarships, medical fellowships and investigator initiated study programs.
Health Care Professional (HCP)	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 Product.
Healthcare Organization (HCO)	Any (i) hospital, health clinic, nursing home, extended care facility, health maintenance organization, managed care organization, or other institution or entity that provides healthcare services to sick, infirm, or aged persons; or (ii) entity that purchases goods or services directly or indirectly from Aquestive, including wholesalers, pharmacies, Pharmacy Benefit Managers (PBMs), and federal or state governments; or (iii) professional societies for specific therapeutic areas, healthcare and patient access groups and patient advocacy groups.

Labeling	Labeling means all written, printed, or graphic matter that is submitted for review and/or approval by a regulatory agency and that is affixed to or accompanies a Product (including product labels, package inserts, information leaflets, folding cartons, and any other Product-specific or lot-specific printed material which is included on or with the final Product package, and/or attached to the Product).
Off-Label Information	Information about the use (including potential uses and methods of or instructions for administration) of a Product that is not contained within the Product's regulatory authority approved prescribing information/package insert and/or regulatory authority approved instructions for use.
Patient Organization	Typically, a not-for-profit organization that primarily represents the interests and needs of patients, their families and and/or caregivers.
Product(s)	All pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) owned, manufactured or made commercially available by Aquestive which are intended to be used on the prescription of, or under the supervision of, a HCP, and which are intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body.
Promotion / Promotional	Any activity undertaken, organized or sponsored by Aquestive which is directed at HCPs or HCOs to promote the sale, purchase, advertisement, prescription, recommendation, supply, administration or consumption of its Product(s) through all methods of communications, including but not limited to the internet.

4. COMPLIANCE WITH LAWS, REGULATIONS AND INDUSTRY CODES

This Marketing Code defines minimal standards for the Promotion of Products by Aquestive Personnel. In addition, any Promotion activity must comply with all applicable laws, regulations, and industry codes, as well as with Aquestive's standards and any applicable SOP and policies, which may impose more stringent requirements. Aquestive Personnel are prohibited from providing any Off-Label Information unless specially allowed under applicable laws, regulations, and industry codes, as well as with Aquestive's standards set forth in the applicable Medical Affairs SOP.

5. BASIS OF INTERACTIONS

Aquestive's relationships with HCPs and HCOs must be focused on informing HCPs and HCOs about Products, providing scientific and educational information and supporting medical research and education. Materials relating to Products and their

uses, whether Promotional in nature or not, which is sponsored by Aquestive, should clearly indicate by whom it has been sponsored. Promotion should not be disguised. Aquestive Personnel may engage with HCPs in a variety of situations that are promotional in nature. Such situations could include sales calls, promotional speaker programs, conferences or other industry events held by professional organizations.

6. PRE-APPROVAL COMMUNICATIONS AND OFF-LABEL USE

No Product of Aquestive shall be promoted for use until the requisite approval for marketing for such use has been given by the FDA. 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 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 stockholders and others concerning any Product, as may be required or desirable under law, rule or regulation.

7. STANDARDS OF PROMOTIONAL INFORMATION

7.1. Consistency of Product Information

It is understood that federal laws and regulations dictate the format and content of the Product information communicated on labeling, packaging, leaflets, data sheets and in all other Promotional materials. Promotion should not be inconsistent with approved Product Labelling.

7.2. Accurate and Not Misleading

Promotional information should be clear, legible, accurate, balanced, Fair and Balanced, and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the Product. Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It should not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. Every effort should be made to avoid ambiguity. Absolute or all-embracing claims should be used with caution and only with adequate qualification and substantiation. Descriptions such as “safe” and “no side effects” should generally be avoided and should always be adequately qualified.

7.3. 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 HCPs or HCOs. Aquestive should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.

7.4. Direct-To-Consumer Promotion

All Product-related information used in direct-to-consumer Promotion of Products must comply with the requirements under this Marketing Code and FDA regulations applicable to all Promotional information, as well as be in appropriate language for lay persons. The same applies to information targeted at the general public.

8. PRINTED PROMOTIONAL MATERIAL

8.1. Necessary Content

All printed Promotional material, including advertisements, other than "reminder advertisements" (which are covered in Section 8.2. below) shall:

- Include:

  The trade name and generic name of the Product;

  The active ingredients, using approved names where they exist;

  The name, logo and address of Aquestive or its agent responsible for marketing the Product;

  The date of production of the advertisement (month/year);

  "Abbreviated prescribing information" which should include an approved indication or indications for use together with the dosage and method of use; and a succinct statement of the contraindications, precautions, and side-effects; and

- Be consistent with approved Labeling.

8.2. Reminder Advertisements

A "reminder advertisement" is defined as a short advertisement containing no more than the name of the Product and may also include a simple statement of indications to designate the therapeutic category of the Product. For "reminder advertisements", "abbreviated prescribing information" referred to above may be omitted.

9. ELECTRONIC MATERIALS, INCLUDING AUDIOVISUALS

The same requirements applicable to written Promotional materials under this Marketing Code shall apply to electronic Promotional materials, including audiovisuals. Specifically, in the case of Product related websites:

- The identity of Aquestive 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; and
- All content shall be in compliance with the requirements of this Marketing Code and FDA regulations.

10. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

10.1. Events and Meetings

10.1.1 Scientific and Educational Objectives

The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (each individually referred to as an "Event") for HCPs or HCO personnel organized or sponsored by Aquestive should be to provide scientific or educational information and/or inform HCPs or HCO personnel about the Product.

10.1.2 Appropriate Venue

All Events organized by Aquestive must comply with applicable Aquestive SOPs and policies including that they must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event. Aquestive must avoid using renowned or extravagant venues, in compliance with applicable Aquestive SOPs, regulatory standards and the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals.

10.1.3 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.

10.1.4 Entertainment

Entertainment or other leisure or social activities must not be provided or paid for by Aquestive.

10.1.5 Drawings/Give-Aways

Any items to be given to HCPs or HCO personnel must comply with the requirements set forth below in Section 10.5.

10.2. Sponsorships

Aquestive may sponsor HCPs or HCO personnel to attend Events provided such sponsorship is in accordance with the following requirements:

- The Event complies with the requirements in this Marketing Code as described in Section 10.1;
- Sponsorship to HCPs or HCO personnel is limited to the payment of travel, meals, accommodation and registration fees;
- No payments are made to compensate HCPs or HCO personnel for time spent in attending the Event; and
- Any sponsorship provided to individual HCPs or HCO personnel must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer, promote, or include in a formula any Product.

10.3. Guests

Aquestive should not pay any costs associated with individuals accompanying invited HCPs or HCO personnel.

10.4. Fees for Services

HCPs may be engaged as consultants and advisors for services such as speaking at and/or chairing Events, involvement in medical/scientific studies, clinical trials or training services, participation in advisory board meetings, and participation in market research where such participation involves remuneration. The arrangements which cover these genuine consultancies or other services must comply with the applicable Aquestive SOP and policies including, to the extent relevant to the particular arrangement, all of the following criteria:

- A written agreement must be signed in advance of the commencement of the services which specifies the nature of the services to be provided, expected work product or deliverable(s) 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 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 services (which may include the travel time) must be reasonable and reflect the fair market value of the services provided;
- A statement that any payments made under the agreement will be reported as required by local, state and federal requirements; and
- The consultant must not be debarred or sanctioned from participating in any federal health care program.

10.5. Gifts

10.5.1 Prohibition of Cash and Personal Gifts

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

10.5.2 Promotional Aids

Promotional aids, even if of minimal value and quantity (such as pens, notepads, and similar “reminder” items with Aquestive’s company or product logos) may not be provided or offered to HCPs or their staff unless such items advance disease or treatment education, and even if accompanied by patient or physician educational materials.

10.5.3 Items of Medical Utility

In accordance with applicable laws and regulations, items of medical utility may be offered or provided to HCPs if such items are of modest value, do not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care.

11. SAMPLES

In accordance with applicable laws and regulations, courtesy samples of a Product may be supplied to HCPs authorized to prescribe that Product in order to enhance patient care. Samples should be marked as such so that they cannot be resold or otherwise misused. Adequate systems of control and accountability for samples provided to HCPs must be utilized, including how to look after such samples whilst they are in possession of Aquestive Personnel.

12. CLINICAL RESEARCH AND TRANSPARENCY

12.1. Transparency

Aquestive is committed to the transparency of clinical trials which it sponsors. It is recognized that there are important public health benefits associated with making clinical trial information more publicly available to HCPs, HCOs, patients, and others. Such disclosure, however, must maintain protection for individual privacy, intellectual property and contract rights, as well as conform to FDA regulations as well as patent and intellectual property law.

12.2. Distinct from Promotion

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

13. GRANT SUPPORT

Aquestive may provide Grant Support to HCPs, Patient Organizations and HCOs, including hospitals and institutions of higher learning that provide medical education programs that may be of interest to Aquestive, in accordance with Sections 13.1 and 13.2 below and applicable Aquestive SOPs and policies.

13.1. Basic Concepts for Grant Support

- Grant Support to HCPs, HCOs and Patient Organizations by Aquestive are to be focused on medical and scientific endeavors consistent with its scientific and therapeutic areas of interest and are not be used as an opportunity to Promote Products to HCPs, HCOs and Patient Organizations;

- Aquestive Personnel may not solicit, suggest, or recommend that any individual or entity seek Grant Support from Aquestive;
- Grant Support provided by Aquestive shall always be clearly acknowledged and documented in a written agreement between Aquestive and the HCPs, HCOs and/or Patient Organizations;

- Aquestive shall disclose financial relationships with HCPs, HCOs and Patient Organizations, as well as any attendee, faculty, speaker, or organizer of any program funded by Aquestive, as required by applicable law and regulation and shall require HCPs, HCOs and Patient Organizations, as well as any attendee, faculty, speaker, or organizer of any programs funded by Aquestive, to disclose and/or agree for Aquestive to disclose any financial relationships with Aquestive as a condition of funding whenever asked or expected by legislation, codes of conduct or government inquiry to do so; and

- Aquestive encourages multi-sponsor support and does not require that Aquestive be the sole supporter of any HCP, HCO, Patient Organization or program. The objectives and scope of any interactions are to be transparent to Aquestive and to the HCP, HCO and Patient Organization.

13.2. Prohibited Matters for Grant Support

Aquestive should not engage in activities designed to affect the independent judgment of HCPs, HCOs and Patient Organizations such as:

- offering or providing any Grant Support in a manner or on conditions that such support would interfere with the independence of the HCP, HCO or Patient Organization;

- utilizing its Grant Support opportunities to Promote its Products to a HCP, HCO and Patient Organization or requesting that HCP, medical institution or Patient Organization promote its Product. This is not intended to restrict any Aquestive Personnel from purchasing exhibit or display space at fair market value and Promoting Products at a hospital or a conference or other Event organized by a HCP, HCO and/or Patient Organization; and

- providing and/or engaging in arrangements of Grant Support to HCPs, HCO and Patient Organizations as a means or method to:

    - Influence the registration, review or approval of Products;
    - Influence HCPs, HCOs and Patient Organizations services they provide for developing or disseminating branded or Promotional materials of Aquestive;
    - Create a favorable formulary or reimbursement decision;
    - Reward past, present or future prescriptions, referrals or recommendations of Products; or
    - Influence or directly support the development of clinical practice guidelines or formulary listings.

14. INTERACTIONS WITH PATIENT ORGANIZATIONS

Aquestive may have common interests with certain Patient Organizations. All interactions with Patient Organizations must be ethical and the independence of Patient Organizations must be respected. When working with Patient Organizations, Aquestive must ensure that the involvement of Aquestive, and the nature of that involvement, is clear from the outset. Aquestive may provide Grant Support for Patient 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. Venues and locations selected for the meetings for Patient Organizations must be appropriate and conducive to informational communication. In addition, any meals or refreshments provided by Aquestive must be modest as judged by Aquestive's standards.

15. PRESS RELEASES

All press releases must be approved by Aquestive's CEO and legal counsel. In general, press releases should not be used for Promotional purposes and any distribution of press releases to HCPs, HCOs or Patient Organizations requires prior MLR approval as the FDA and other government regulators may impute an inappropriate Promotional purpose even if the press release discusses FDA-approved Labelling.