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Association for Accessible Medicines

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Code of Business Ethics

May 2022

Introduction

Improving patient access to affordable medicines is a core value of companies that develop and manufacture generic and biosimilar medicines. Our companies produce and distribute the medicines that make up more than 90% of all prescriptions filled in the United States – but at just 16% of total prescription drug spending. Our industry is an indispensable pillar of our national healthcare system.

Through our membership in the industry's trade association, the Association for Accessible Medicines, we promote marketplace competition and support strategic enhancements to the Food and Drug Administration's (FDA) generic drug and biosimilar approval process. We do this for one purpose: to put affordable medicines within the reach of patients who need them. Every dollar saved at the pharmacy counter is a dollar that patients can spend on life's essentials and other pursuits — or put away for future use. We help patients live better lives, and we do so in a way that saves precious resources for patients, taxpayers, and our economy.

The practices discussed in the Association for Accessible Medicines' (AAM) Code of Business Ethics. represent behaviors that our companies have been demonstrating for years. And yet, it is incumbent on us to declare to our patients and customers the values upon which our industry is based, and the ethical and business standards upon which we are committed to operating with other members of the healthcare ecosystem.

AAM endorses international principles of business ethics as set forth in this Code, including the Asia Pacific Economic Cooperation (APEC) Mexico City Principles on Voluntary Codes of Business Ethics in the Biopharmaceutical Sector. Yet our companies are often distinct from the business of the signatories to those Principles and from that of the global brand name pharmaceutical industry. The generic and biosimilar drug industry is characterized by intense competition among our companies who race to be the first to obtain FDA approval for new versions of brand name drugs which typically bring welcome cost savings to patients and our healthcare system when multiple generic and biosimilar drug products enter the market.

We must never take the ethics of healthcare access for granted. Our companies believe in our ethical mission, and AAM's Board of Directors has approved this Code. AAM looks forward to working with all stakeholders to expand access to generic and biosimilar medicines — the proven, reliable way to drive down the cost of medicine, which helps patients, strengthens our economy, and benefits our society.

This AAM Code of Business Ethics is applicable to the operation of generic drug and biosimilar companies who adopt the Code in the United States and interactions with United States healthcare professionals. It was adopted by the Board of Directors of AAM on **February 12, 2018** and originally effective on **September 1, 2018**. Subsequently, this Code was updated and the revisions approved by the Board of Directors of AAM on February 14, 2022 and effective on September 1, 2022.

Summary of Guiding Principles

Ethical behavior and interactions help ensure that patients may access medicines that improve their lives. In order to achieve this goal, generic medicine and biosimilar companies ("Companies") are committed to:

1. Engaging in the development, manufacturing, research, marketing, distribution, and/or sale of medicines to benefit patients.
2. Vigorous competition, which is the lifeblood of the generic drug and biosimilar industry. Competition allows our companies to drive enormous savings and pass them on to patients, taxpayers, and healthcare payors. Our Companies believe in the ethical value of access to affordable medicines and compete vigorously to provide them to patients.
3. Following high ethical standards as well as all applicable laws and regulations when interacting with all stakeholders. Companies encourage healthcare professionals, government officials, and others who work with Companies to respect these Principles and adopt consistent standards if applicable.
4. Complying with relevant codes of ethical business practices. Companies should also ensure that internal structures and procedures (including adequate training of employees and third parties who act on their behalf) are created to help ensure responsible and ethical behavior.
5. Complying with relevant standards regarding the development, manufacturing, distribution, commercialization and safety of medicines.
6. Respecting the independence of patient organizations.
7. Respecting patient privacy.
8. Ethical relationships with healthcare professionals, government officials, buyers, patients, and other stakeholders, which are critical to the mission of Companies to help patients by developing and making available safe, effective and affordable medicines.
9. Industry relationships with healthcare professionals that support, and are consistent with, the professional responsibilities healthcare professionals have towards their patients. When they interact with healthcare professionals, Companies have an obligation and responsibility to provide objective, accurate, balanced information about their medicines in order to establish a clear understanding of the appropriate use of these medicines by healthcare professionals for their patients.

Consistent with these Guiding Principles, Companies agree to abide by the following AAM Code of Business Ethics.

I. General Provisions

1. Safety of Medicines

A. Medicines provided by Companies will conform to high standards of quality, safety, and efficacy as determined by regulatory authorities in each economy in which they operate.

B. Companies will report adverse events or adverse drug reactions to regulatory authorities, subject to applicable laws and regulations.

2. Competition

A. Companies will compete fairly in accordance with all applicable competition and antitrust laws.

3. Clinical Trials

A. All clinical trials (phases I to IV) and scientific research involving patients sponsored or supported by companies will be conducted with the intent to develop bona fide scientific knowledge that will benefit patients and advance science and medicine. Companies must comply with applicable laws and regulations to ensure transparency and accountability in the presentation of research and publication of study results.

B. Clinical trials will be undertaken in an ethical manner.

C. Clinical trials will not be used as inducements for past or future sales.

4. Company Donations for Charitable Purposes

A. As a demonstration of good corporate citizenship, Companies may choose to support worthwhile activities both within and outside their communities.

1. Donations, including donations in kind, may be provided to charitable organizations and institutions involved in promoting activities such as artistic, charitable, cultural, community, educational, humanitarian, health, philanthropic, and sporting activities in accordance with applicable laws and regulations.

2. Companies may provide financial support for patient organization meetings or other activities provided that the primary purpose of the activity is professional, educational, or scientific in nature, or otherwise supports the mission of the patient organization.

3. Funding and donations in-kind should be directed to organizations and documented in a manner that outlines the nature of the donation provided.

4. Acknowledgement by the recipient organization of such support should be restricted to appropriate

recognition of support.

5. Companies should ensure that there are no incentives to prescribe, recommend, purchase, supply, or administer a product based on such financial support and that nothing should be offered or provided that would interfere with the independence of a healthcare professional's prescribing or dispensing practices.

5. Patient Organizations

If Companies interact with patient organizations,

A. Companies should respect the autonomy of patient organizations and their independence.

B. Support of patient organizations through grants or charitable contributions from Companies must not be conditional on the promotion of a specific medicine.

6. Compliance Procedures and Responsibilities

A. It is the responsibility of Companies to ensure that internal compliance procedures exist that facilitate compliance with this Code. These procedures should be documented and provided to employees to further enhance compliance.

7. Adherence to Code

A. All Companies should adopt procedures to assure adherence to this Code and other relevant local, national, and regional industry codes of ethics. Healthcare professionals, government officials, buyers, and other stakeholders should respect this Code and adopt consistent standards if applicable.

II. Relationships with Healthcare Professionals

Many generic drug companies are devoted almost exclusively to the research and development necessary to bringing new generic drugs through the FDA approval process and the subsequent work with other members of the pharmaceutical supply chain to deliver high- quality affordable prescription drugs to patients. In such cases, there may be very little marketing of medicines directly to prescribers or advertising to patients. However, in some cases, for example, developers of biosimilars or complex generic medicines may choose to engage with researchers and physicians to develop these medicines and educate about their benefits and risks. When a generic or biosimilar drug developer interacts directly with healthcare professionals, the following standards apply to applicable business units and Company personnel:

8. Interactions with Healthcare Professionals

A. Interactions between Companies and healthcare professionals can provide valuable scientific, clinical, product, and policy information about medicines that may lead to improved patient care.

B. Appropriate educational activities and training can help to ensure that medicines are used correctly for optimal patient benefit. Company relationships with healthcare professionals can help to achieve these goals because they enable Companies to:

1. inform healthcare professionals about the benefits and risks of medicines to help advance appropriate patient use;

2. provide scientific and educational information;

3. support medical research and education; and

4. obtain feedback and advice about our products through consultation with medical experts.

C. All interactions with a healthcare professional are to be conducted in a professional and ethical manner.

1. Companies must not seek to improperly influence healthcare professionals.

2. Nothing should be offered or provided by a Company in a manner that inappropriately influences the independence of a healthcare professional's prescribing practices.

3. Education and promotional activities should encourage the appropriate use of medicines by presenting them objectively and without exaggerating their properties, and should be in compliance with the provisions prescribed by this Code and other applicable laws, regulations, and regional industry codes of ethics.

4. Relationships between Company personnel and healthcare professionals should encourage the development of a medical practice committed to patients' well-being and be based on truthful, accurate, and updated scientific evidence.

9. Samples

A. It is appropriate to provide samples for patient use in accordance with the Prescription Drug Marketing Act.

B. In accordance with local laws and regulations, samples of medicines supplied at no charge may be provided to healthcare professionals in order to enhance patient care. Samples must not be resold or otherwise misused.

1. Companies should have adequate systems of control and accountability for samples provided to healthcare professionals including how to look after such samples while they are in the possession of Company representatives.

2. Samples should not be used as payment for services, return for favorable treatment, or other inappropriate inducements.

10. Promotional Information and Activities

A. Promotion about approved uses of medicines should be consistent with FDA-approved product information and all laws and regulations pertaining to the communication of information about medicines to healthcare professionals.

B. Promotional information should be clear, legible, accurate, balanced, fair, objective, and sufficiently complete to enable a healthcare professional to form his or her own opinion of the therapeutic value of the medicines concerned.

1. 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.

2. Promotional information 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. Companies should deal objectively with requests for information made in good faith and should provide data that are appropriate to the source of the inquiry.

3. Companies are responsible for compliance with applicable laws and regulations, including local, national, and regional industry codes of ethics.

4. Clinical assessments, postmarketing surveillance and experience programs and post-authorization studies must not be disguised promotion. Such assessments, programs, and studies must be conducted with a primarily scientific or educational purpose.

5. Materials sponsored by a Company relating to medicines and their uses, whether promotional in nature or not, should clearly indicate by whom they have been sponsored.

11. Informational Presentations by Company Representatives

A. In order to provide important scientific information and to respect healthcare professionals' abilities to manage their schedules and provide patient care, Company representatives may take the opportunity to present information during healthcare professionals' working day, including mealtimes, in accordance with applicable laws and regulations.

1. In connection with such presentations or discussions, it may be appropriate for occasional meals to be offered to the healthcare professional as well as members of their staff attending presentations, so long as the presentations provide scientific or educational value and the meals (a) are reasonable as judged by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to informational communication. Any such meals offered in connection with informational presentations made by field sales representatives or their immediate managers should be limited to in-office or in-hospital settings.

2. Inclusion of a healthcare professional's spouse or other guest in a meal accompanying an informational presentation made by or on behalf of a Company is not appropriate. Offering "take-out" meals or meals to be eaten without a Company representative being present is not appropriate.

12. Educational Items and Gifts

A. Payments in cash or cash equivalents (such as gift certificates) or gifts for the personal benefit of healthcare professionals should not be provided or offered to healthcare professionals.

1. It is appropriate for Companies, where permitted by law or local codes of ethics, to offer to healthcare professionals items designed primarily for the education of patients or healthcare professionals if the items are of modest value and do not have value to healthcare professionals outside of his or her professional responsibilities. Such items should not be offered on more than an occasional basis, even if each individual item is appropriate.

2. These items should not subsidize normal routine operations of a medical practice.

3. Providing items for healthcare professionals' use that do not advance disease or treatment education – even if they are practice-related items of minimal value (such as pens, note pads, and similar "reminder" items with Company or product logos) – may foster misperceptions. Such non-educational items should not be offered to healthcare professionals or members of their staff, even if they are accompanied by patient or physician educational materials.

13. Support for Continuing Medical Education

A. Continuing medical education (CME) helps physicians and other medical professionals to obtain information and insights that can contribute to the improvement of patient care and the medical practice.

1. Companies that support CME should separate their CME grant-making functions from their sales

and marketing departments and should develop objective criteria for making CME grant decisions to ensure that programs funded are bona fide and quality educational programs and that financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment.

2. Since the giving of any subsidy directly to a healthcare professional by a Company could be viewed as an inappropriate cash gift, any financial support should be given to the CME provider, which, in turn, can use the money to reduce the overall CME registration fee for all participants. The Company should respect the independent judgment of the CME provider and should follow standards for commercial support established by the Accreditation Council for Continuing Medical Education (ACCME) or other entity that may accredit the CME. When Companies underwrite CME, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines. The Company should not provide any advice or guidance to the CME provider, even if asked by the provider, regarding the content or faculty for a particular CME program funded by the Company.

3. Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending CME, either directly to the individuals participating in the event or indirectly to the event's sponsor (except as set out in Section C below). Similarly, funding should not be offered to compensate for the time spent by healthcare professionals participating in the CME event.

B. Grants, scholarships, subsidies, support, consulting contracts, educational, or practice-related items should not be provided or offered to a healthcare professional in exchange for recommending and prescribing medicines, or otherwise in a manner that would interfere with the ethics and the independence of a healthcare professional's prescribing practices. Companies should have a reasonable expectation that the grant is for the purpose of supporting legitimate education, scientific, or medical research.

C. Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution. "Carefully selected educational conferences" are generally defined as the major educational, scientific, or policymaking meetings of national, regional, or specialty medical associations.

14. Symposia and Congresses

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

B. Company relationships with healthcare professionals are regulated by multiple entities and intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing

healthcare professionals about products, providing scientific and educational information, and supporting medical education.

C. Since the giving of any subsidy directly to a healthcare professional by a Company may be viewed as an inappropriate cash gift, any financial support should be given to the conference's sponsor, which, in turn, can use the money to reduce the overall conference registration fee for all attendees. When companies underwrite medical conferences, symposia, or meetings other than their own, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizer of the conferences, symposia, or meetings in accordance with their guidelines.

D. All Events should be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. Companies should avoid using extravagant venues or resorts.

E. Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the Event and should only be provided:

1. to participants of the Event and not their guests; and

2. when modest and reasonable as judged by local standards.

3. Companies should not pay any costs associated with individuals accompanying invited healthcare professionals.

15. Consultant and Speaker Arrangements

A. Consulting arrangements with healthcare professionals may allow companies to obtain information or advice from medical experts on such topics as the marketplace, products, therapeutic areas, and the needs of patients. Companies may use this advice to inform their efforts to ensure that the medicines they develop, produce, and/or market are meeting the needs of patients. In addition, healthcare professionals participate in Company-sponsored speaking programs in order to help educate and inform other healthcare professionals about the benefits, risks, and appropriate uses of medicines.

1. Companies should continue to ensure that consultant and speaking arrangements are neither inducements nor rewards for prescribing or recommending a particular medicine or course of treatment.

2. It is appropriate for consultants and speakers who provide services to be offered reasonable compensation for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Any compensation or reimbursement made in conjunction with a consulting or speaking arrangement should be reasonable and based on fair market value. It is not appropriate to pay honoraria or travel or lodging expenses to non-faculty and non-consultant healthcare professional attendees at Company-sponsored meetings, including attendees who participate in interactive sessions.

3. Speaker training is an essential activity because the FDA holds Companies accountable for the

presentations of their speakers. It is appropriate for healthcare professionals who participate in programs intended to train speakers for Company-sponsored speaker programs to be offered reasonable compensation for their time, considering the value of the type of services provided, and to be offered reimbursement for reasonable travel, lodging, and meal expenses.

4. Each Company should, individually and independently, cap the total amount of annual compensation it will pay to an individual healthcare professional in connection with all speaking arrangements. Each Company also should develop policies addressing the appropriate use of speakers, including utilization of speakers after training and the appropriate number of engagements for any particular speaker over time.

5. The purpose of speaker programs is to present substantive educational information to address a bona fide education need among attendees. Invitations to speaker programs should be limited to those who have a bona fide educational need for the information presented at the program. In addition, repeat attendance at a speaker program on the same or substantially the same topic is not appropriate.

6. Speaker programs should be conducted at modest locations conducive to the presentation of information. There should be no entertainment; high-end restaurants are not appropriate venues. Any meals provided should be modest by local standards and an incidental business courtesy to attendees. Alcohol should not be paid for or provided by Companies to attendees at speaker programs. Consulting or advisory arrangements lacking a bona fide business purpose should not be used to justify compensating healthcare professionals for their time or their travel, lodging, and other out-of-pocket expenses.

7. At speaker program events Companies and speakers should be clear that the Company is sponsoring the presentation, and the speaker is being paid to present on behalf of the Company. Companies and speakers should limit presentations to information that is consistent with FDA or other applicable guidelines.

8. Beyond providing all speakers with appropriate training, Companies should periodically monitor speaker programs for compliance with FDA or other applicable regulatory requirements for communications on behalf of the Company about its medicines.

9. To avoid even the appearance of impropriety, Companies should require any healthcare professional who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or commercial consultant for the Company to disclose to the committee the existence and nature of his or her relationship with the Company. This disclosure requirement should extend for at least two years beyond the termination of any speaker or consultant arrangement. Upon disclosure, healthcare professionals who serve as speakers or consultants should be required to follow the procedures set forth by the committee of which they are a member, which may include recusing themselves from decisions relating to the medicine for which they have provided speaking or consulting services.

10. Consulting or advisory arrangements lacking a bona fide business purpose should not be used to

justify compensating healthcare professionals for their time or their travel, lodging, and other out-of-pocket expenses.

B. The following factors support the existence of a bona fide consulting or speaking arrangement (not all factors may be relevant to any particular arrangement):

1. a written contract specifies the nature of the services to be provided and the basis for payment of those services;

2. a legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;

3. the criteria for selecting consultants and speakers are directly related to the identified purpose, and the persons responsible for selecting the consultants and speakers have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;

4. the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;

5. the retaining Company maintains records concerning, and makes appropriate use of, the services provided;

6. the venue and circumstances of any meeting with consultants or speakers are conducive with the primary focus of the meeting; specifically, resorts are not appropriate venues.

16. Prohibition on Entertainment and Recreation

A. Company interactions with healthcare professionals are professional in nature and are intended to facilitate the exchange of medical or scientific information that will benefit patient care.

1. To ensure the appropriate focus on education and informational exchange and to avoid the appearance of impropriety, Companies should not provide any form of entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare professional who is not a salaried employee of the Company. Such entertainment or recreational benefits should not be offered, regardless of (1) the value of the items or (2) whether the Company engages the healthcare professional as a speaker or consultant.

2. No stand-alone entertainment or other leisure or social activities for healthcare professionals should be provided or paid for by Companies.

17. Conduct and Training of Company Representatives

A. Company representatives play an important role in delivering accurate, up-to-date information to healthcare professionals about the approved indications, benefits, and risks of medicines. These representatives often serve as the primary point of contact between the Companies who research, develop, manufacture, and market medicines and the healthcare professionals who prescribe them. As

such, Company representatives must act with the highest degree of professionalism and integrity.

1. Companies should ensure that all representatives who are employed by or acting on behalf of the companies, and who visit healthcare professionals, receive training about the applicable laws, regulations, and industry codes of ethics that govern the representatives' interactions with healthcare professionals. In addition, Companies should train their representatives to ensure that they have sufficient knowledge of general science and product-specific information to provide accurate, up-to-date information, consistent with applicable laws and regulations.

2. Companies should provide updated or additional training in all of the areas needed for their representatives who visit healthcare professionals. Companies should also assess their representatives periodically to ensure that they comply with relevant Company policies and standards of conduct.

3. Companies should take appropriate action when representatives fail to comply with relevant Company policies that are consistent with this Code and other relevant national and local industry codes of ethics.

Appendix

For the purpose of this Code, the following definitions are provided:

"Congress" means an event sponsored and organized by a society, college, university, or other non-Company entity for the purpose of providing medical and/or scientific information.

"Consultant" means an external, independent healthcare professional, scientist, patient association/ patient representative, public, or private payer retained individually or through an entity (e.g. university, hospital or research organization) to provide advice, information, or other services.

"Representative" means a person calling on healthcare professionals and/or their staff on behalf of a Company regarding the promotion or discussion of medicines.

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