



# CODE OF ETHICS





## SCOPE

This Code applies to the activities of Actoverco's employees who interact with Stakeholders for the purpose of commercializing prescription medicines.





# DEFINITIONS

## **HEALTH CARE PROFESSIONAL**

The term Health Care Professional means a person who by education, training, certification, or licensure is qualified to and is engaged in providing health care. This can include any of the following: an individual who is currently practicing medicine, nursing, or dispensing medicines or any other person who, in the course of his or her professional activities, may prescribe, recommend or administer a Prescription Medicine or be involved in related treatment or disease management.

## **GOVERNMENT**

The term Government means a body of people that sets and administers public policy, and exercises executive, political, and sovereign power through customs, institutions, and laws within Iran.

## **DISSEMINATION OF SCIENTIFIC INFORMATION**

The term dissemination of scientific information refers to any activity undertaken, organized or sponsored, which is directed at Stakeholders relating to the prescription, recommendation, supply, administration or consumption of its prescription medicines or relating to a disease state.



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# GUIDING PRINCIPALS

The Guiding Principles are intended to provide interpretations of the Code and to assist the employees where no specific provisions of the Code apply.

1. The health and well-being of patients is our first priority.
2. All interactions with Stakeholders are to be conducted in a professional and ethical manner.
3. We must be cognizant of potential conflicts of interest and manage them.
4. All interactions shall be in accordance with all applicable laws and regulations.
5. We must adhere to the Code in both the spirit and the letter.
6. We are committed to engaging in relationships that are trustworthy and credible.
7. All clinical (phase I to IV) trials and scientific research sponsored or supported by Actoverco will be conducted with the intent to develop knowledge that will benefit the patients and advancement of science and medicine. We support transparency in the presentation of research and study results.
8. We will ensure that all Stakeholders have access to education and information about the appropriate uses of our products and services. All products information provided to Stakeholders must be accurate and fair balanced.
9. We will not give or offer any payments or inducements that are either unlawful or improper, directly or indirectly, to any individual stakeholder.





# I - PRIVACY OF PATIENT INFORMATION

Actoverco employees must abide by the laws and regulations pertaining to the privacy of patient information.





## II - TRANSPARENCY OF PRODUCT INFORMATION

- 2.1. Material relating to Prescription Medicines and their uses, whether promotional in nature or not, which is sponsored by Actoverco in part or in whole must clearly indicate by whom it has been sponsored.
- 2.2. Where congresses, symposia, conventions and similar events are sponsored in whole or in part by Actoverco, such sponsorships should be appropriately disclosed.
- 2.3. Upon a Health Care Professional's request, our employees must inform him/her that they have prescription data information available from various sources.



## III - PROMOTIONAL ACTIVITIES

- 3.1. Actoverco employees must provide full and factual information on products, without misrepresentation or exaggeration. Statements must be accurate and complete. They should not be misleading, either directly or by implication.
- 3.2. With respect to their promotional activities Actoverco employees agree to comply with all applicable laws and regulations.
- 3.3. Occasional reasonable meals/refreshments may be offered in connection with promotional presentations to Health Care Professionals and other Stakeholders attending the presentation.



## IV - BUSINESS MEETINGS AND DISCUSSIONS

- 4.1. Actoverco recognizes the responsibility in ensuring that the selection of venues is appropriate and conducive to the purpose of the business meeting or events they organize. Actoverco employees may provide reasonable meals/refreshments to Stakeholders. The provision of meals/refreshments must be ancillary to the activity associated with it.
- 4.2. For business meetings and events held outside of the country, Actoverco employees must respect the applicable laws, regulations and self-regulatory Codes of the country where the business meeting or event is being held.





## V - RETAINING THE SERVICES OF A STAKEHOLDER

5.1. Agreements with Stakeholders allow Actoverco to obtain information and/or advice from experts.

5.2. Actoverco employees may retain Stakeholders, whether in groups or individually and compensate them for their services, travel and other expenses in connection with activities such as speaking at and/or chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, participation in market research, development of material or other related services.

5.3. The agreements between Actoverco and Stakeholders must be in writing and, to the extent relevant to the particular agreement, must fulfill all the following criteria:

- A legitimate need for services must be clearly identified in advance of requesting the services and entering into an agreement with the prospective Stakeholder. The selection of the Stakeholder must be based solely on his/her qualifications to provide the service required;
- The number of Stakeholders retained must not be greater than the number reasonably necessary to achieve the identified need;
- The hiring of the Stakeholder to provide the relevant service must not be an inducement for: prescribing, supplying, recommending, buying or selling.

5.4. Compensation for the services (or honorarium) must be reasonable and reflect the fair market value of the services provided. Reimbursement of reasonable out-of-pocket expenses, including travel and accommodation, may be provided where the Code allows it.

5.5. Agreements must specify the nature of the services to be provided and the basis for payment of those services.



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## VI - CONSULTANT MEETING

- 6.1. Where appropriate, Actoverco may retain Stakeholders to perform professional services including, but not limited to, consulting meetings, advisory boards and investigator meetings, all of the above being referred to as consultant meetings for the purpose of this section.
- 6.2. Actoverco's advisory board consists of a continuous relationship with a limited group of Stakeholders that meet on multiple occasions during their mandate to advise Actoverco on different aspects of their business.
- 6.3. A consultant meeting is an ad hoc meeting held with an individual or a group of expert Stakeholders where input is required on a specific aspect of the business.
- 6.4. When entering into consultant meeting agreement, We must ensure that:
- The purpose and objectives of the interaction are clearly defined in the initial correspondence related to the event or in the ongoing advisory relationship agreement;
  - There is a written agreement confirming the purpose and objectives of the consultation
  - Remuneration must be in the form of an honorarium and reasonable travel, accommodation and out-of-pocket expenses where warranted, may be reimbursed in accordance with the requirements of this Code.



## VII - CONFERENCES AND CONGRESSES

7.1. Actoverco has a role to play in ensuring that Stakeholders are educated and kept informed on developments in health research, health sciences, clinical practice and their profession. Actoverco may receive and consider requests for sponsorship of conferences and congresses organized by academic societies and professional associations or organizations.

7.2. Actoverco may sponsor third-party educational or professional conferences and congresses, under the following conditions:

7.2.1. The responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conference or congress in accordance with their guidelines.

7.2.2. The primary purpose of the event must be scientific, medical and/or educational in nature.



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## VIII - PATIENTS PROGRAMS

8.1. Actoverco may provide patients with support programs, devices or tools. Such programs should aim at increasing patient understanding of a disease and/or treatment, or to facilitate adherence to treatment, which will result in enhanced patient outcomes. All elements/devices/tools offered to patients should be reasonable in value and in accordance with treatment protocol/guidelines. Support programs should be reasonable and appropriate.

8.2. These Programs must:

8.2.1. Have clear and written objectives to improve disease prevention, diagnosis, treatment or management of disease and adherence to treatment.

8.2.2. Never be offered or provided to Health Care Professionals and Patients, their agents, or healthcare facility in exchange for, as an inducement to, or any way in consideration of their past, current, or future prescribing, purchasing, use, recommending for use, formulary position, or dispensing of Actoverco's products.

8.2.3. Never be sold, distributed, or included on a claim for reimbursement or other submission for payment.

8.3. The Programs must maintain patient confidentiality.





## IX - POST REGISTRATION CLINICAL STUDIES

- 9.1. A post registration clinical study (for the purposes of this Section IX, "study" or "studies") is any study within the approved indications that is conducted after MOH Notice of Compliance has been issued for a Prescription Medicine.
- 9.2. A study with the underlying purpose to familiarize Health Care Professionals and/or patients with the use of a Prescription Medicine or encourage its prescription, often referred to as "seeding" or "experience" trials, is not an acceptable post registration clinical study.
- 9.3. The main purpose of a study will be to answer scientific question(s) which requires obtaining and evaluating data on safety and/or efficacy, effectiveness, cost effectiveness, quality of life, functional or other socio-economic factors that have to do with clinical use of the Prescription Medicine.
- 9.4. Studies must provide a scientific framework for investigation of the medicine in broader or special populations.
- 9.5. All studies must have a clearly defined objective which is amenable to scientific review and testing. Duplication or redundancies in studies must be medically and ethically justifiable.
- 9.6. Actoverco must ensure that studies are designed/ approved and administered by qualified people in the scientific department, using the same kinds of methodology (i.e. the planning, protocol development, monitoring and data interpretation) that apply to pre-marketing trials.



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9.7. As the post-registration clinical study may include the dissemination of devices or diagnostic equipment (including, without limitation, blood pressure monitors and glucose meters) for use by the Health Care Professional or the subject as part of the clinical study, it is our responsibility to ensure that this material is appropriately distributed prior to the study and collected subsequent to the study, by the medical/scientific department. Actoverco must maintain a record of dissemination to Health Care Professionals and use reasonable methods to retrieve this equipment from the Health Care Professionals upon the completion of the study.

9.8. Sales Representatives and their direct supervisors' role in the process must be limited to the distribution and collection of materials pertinent to the study, on behalf of the medical/scientific department.

9.9. Studies must be carried out in accordance with the MOH

9.10. Studies must be carried out using a written protocol that will provide answers to specific research questions. All studies must be consistent with good clinical practice. The protocol must be designed to ensure scientifically meaningful results, and should contain details about the following:

- A. Study background/scientific rationale;
- B. Study objective;
- C. Study design;
- D. Study population;
- E. Adverse event reporting;
- F. Sample size based on primary and/or secondary endpoint;
- G. Description of measures to minimize bias (such as randomization or blinding);
- H. Study methodology;
- I. Duration of subject participation and study duration;
- J. Data collection method;



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9.11. Researchers must collect data according to the protocol and keep the research results on file as required by applicable law and/or regulations.

9.12. After the data are collected but before the study is published, the researchers and medical/scientific department must jointly review the scientific evaluations of data.



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