

## **Voluntary Code of Business Ethics in Vietnamese Biopharmaceutical Sector**

### **I/ Preamble:**

In September 2010 at the conference at ministerial level (Ministers of Foreign Affairs and Ministers of Trade), APEC member countries proposed initiatives on the establishment and introduction of implementation of voluntary codes of ethics in all the APEC member countries in the sectors of Medical Equipment; Biopharmaceutical Products and Construction. Responding to this important initiative, Vietnam Pharmaceutical Companies Association (VNPCA) will establish and disseminates the application of voluntary codes of ethics in the biopharmaceutical sector in an aim to:

1. Based on the voluntary codes of ethics in the biopharmaceutical sector in accordance APEC's initiative as announced in Mexico city with Vietnam's moral principles about drugs business - a special commodity category that directly affects the health, even the life of an user, VNPCA establishes the voluntary Code of Ethics in the Vietnamese biopharmaceutical sector (hereinafter referred to as the Voluntary Code of Ethics) in order that Vietnamese Pharmaceutical Production and Trading Companies take the initiatives in involving in this process.
2. Make each company and a community of Vietnamese Biopharmaceutical Production and Trading Companies understand thoroughly that taking the initiatives in, volunteering for involvement in the process of establishment of their companies' culture and practicing the voluntary Codes of Ethics by the companies is a necessary step so that the Vietnamese Biopharmaceutical Companies will develop sustainably and take the initiative in integrating the international economy;
3. The process of the companies' voluntary involvement in establishing the Business Ethics under the voluntary code of ethics is also the process of building up managerial staffs, technical staffs and laborers who are good at their professional and technical aspects and consider the quality of products and best interests of patient to be a target in the production and business activities of their companies.

### **II/ Terminology.**

In the document, the following words and expressions terms are construed as follows:

1. The term ***Biopharmaceutical Sector*** is used to indicate companies/enterprises not subject to ownership form (hereinafter referred to as the Company) that participate in developing a market, producing, studying, marketing, distributing and / or selling pharmaceutical products and / or biological products to the patients.
2. The term ***Trading*** is construed as follows: Trading is the work that entities carry out some or all the stages of an investment process from the production to the consumption of products in the market on a regular and continuous basis so as to seek profits.
3. The term ***medicine*** is used to indicate western medicine, traditional medicine and

biological products.

4. ***Patient-centric Healthcare*** means that everything that a company, medical staff does / performs is aimed to be of the greatest benefits to the patients.
5. ***Integrity*** means dealing with matters and everything that the company, medical staff does / performs on an ethical, honesty and respectful basis.
6. ***Independence*** means respect for needs of self-making decisions by all the parties, avoiding incorrect influences (unconformable to spirit and value of these Codes of Ethics).
7. ***Legitimate purpose*** means everything that the company, medical staff does / performs is because of right, legal reasons and suitability for the spirit and value of these Codes of Ethics.
8. ***Transparency*** means preparedness for providing information exactly and opportunely in general, and openness on the company's actions while respecting legitimate commercial sensitivity and intellectual property right.
9. ***Accountability*** means preparedness for assuming responsibility for actions / work performed by the company to his partners.
10. ***Professional Healthcare*** means the one that is fully based on medical demand of each patient and based on medical knowledge and experience.
11. ***Pharmaceutical product information*** means the collection and / or provision of information related to a pharmaceutical product like indication, contraindication, dosage, instructions for use, adverse reactions of drugs, prevention when using drugs for special communities (children, pregnant women, lactating women, the elderly and others) of any entity, any individual responsible for the medicine information to meet information requirement of the entities, individuals who are directly practicing medicine, pharmaceuticals or of drug users.
12. ***Drug Promotion & Advertising*** means the activity of drug introduction which is directly conducted or coordinated, or sponsored, authorized by drug trading company to another entity to conduct to boost the prescription, supply, sale and / or use of drugs based on reasonable, safe and effective drug use.
13. ***Drug Promotional Symposia*** is the performances of medicine product introduction or scientific seminars for medical staffs relating to the medicine as organized by drug trading companies.
14. ***Code of Business Ethics*** is the system of ideology and concepts on the business ethics. It is the system of ethical act guidelines for businesses and for the company.
15. ***Business ethics attitude***: is expressed in the attitude of the businessman, of the company (1) towards the laws, (2) towards customers, (3) towards employees and (4) towards competitors.

a) Towards the laws: An ethical company & an ethical businessman always abides by the laws when making leading decisions with consideration of legal bases of such decisions.

b) Towards the employees: An ethical company and an ethical businessman usually has the attitude in respecting and giving his / her mind to the legitimate interests of the employees without taking advantage of and exploiting the employees.

c) Towards the customers: An ethical company & ethical businessman usually keeps his / her words, being fair and respectful to his / her customers' interests.

d) Towards the competitors: An ethical company & ethical businessman is not aimed at eliminating his / her competitors, but has the attitude of fair competition and competition by means of intelligence, talent and prestige, quality and product prices, spirit and better service to his / her customers and etc.

16. ***Business ethics behavior*** is expressed by not breaking the laws, not trading in forbidden goods, not producing counterfeit articles, not piracy in production, not exploiting the employees and partners, paying attention to environmental protection when organizing the business, not avoiding and evading taxes of the State and etc.

### **III/ Voluntary code of business ethics in the Vietnamese Biopharmaceutical sector.**

#### **A. General voluntary code of business ethics in biopharmaceutical industry.**

1. The companies participate in the market development, production, research, marketing, distribution and sale of drugs in a main goal to bring about benefits to their patients.
2. A Pharmaceutical Trading Company' keeping ethical relationship with medical specialists, government officials, patients and other related parties is a very important task for the company's mission so as to help the patients by doing research, producing medicines with high quality, reasonable / competitive prices and making the medicines available (the medicines are easily accessible to the people when necessary).
3. In the interaction with all the related parties, the company undertakes at all times to:
  - a) Conduct the highest ethical standards,
  - b) Abide by in full and have the responsibility for all the laws and existing regulations.
  - c) Encourage the healthcare professionals, government officials, and others, when working with the company, in respecting and applying the ethical standards conformable to these Voluntary Codes of Ethics.
4. The Voluntary Codes of Ethics as mentioned above to ensure that the Company's interactions must be "conducted in a professional manner and designed to bring about benefits to the patients and contribute to strengthening professional medical - pharmaceutical practice".
5. The company has the obligation and the responsibility to provide objective, truthful and balanced information about their medicines to the healthcare professionals so that the healthcare professionals have a sufficient knowledge of proper use of these medicines for the patients.
6. The company should promote, sell and distribute their medicines ethically (the medicines are guaranteed in respect of quality and information about the medicine is objective, balanced and responsible) and suitably for all the laws and related regulations under

application. Information in advertising literatures must support right assessment on benefits and risks of the medicine as well as appropriate instructions for use of the medicine.

7. The company undertakes to educate and train (any related persons) in using medicines on a safe, reasonable and effective basis (achieving the purpose of treatment with the possible lowest cost) for all the medicines of the company or traded by the company.
8. The company is responsible for complying with the voluntary Codes of ethics in the business and must ensure that structures and internal procedures (including continuous training programs for the staff) are set up and implemented strictly.
9. The company undertakes to comply with GP's standards (GMP; GLP; GSP; GDP; GPP) and standards related to the comprehensive drug quality assurance (as from doing research, developing to producing, maintaining, distributing and directly supplying the medicines to users) and continue updating, supplementing and enhance these standards to sustainably improve the medicines supplied by the company.
10. The company undertakes to follow any standard related to the quality guarantee and safety of medicines at all stages from the developmental research to processing, production, distribution, marketing and after-sales monitoring as required.
11. The medicines supplied by the company shall conform to high standards of safety, quality and effectiveness in accordance with the Vietnamese Ministry of Health's regulation & competent authorities on pharmaceuticals in other countries and WHO's recommendations.
12. The company must ensure the transparency, responsibility and updating in reporting side-effects or adverse reactions of any medicine to authorities in due compliance with the existing law and regulations.
13. The company undertakes to comply with Codes of Ethics of the related local, national and regional industries.
14. The company undertakes and ensures that all the relevant employees and agents operating on behalf of the company are trained in the voluntary Codes of Ethics of the related local, national and regional industries.
15. The company undertakes to respect independence of patient organizations.
16. The company undertakes to respect privacy of the patient.
17. The company ensures that all the employees and third parties on behalf of the company comply with regulations of the voluntary Codes of Ethics and all the laws and regulations in force. .

#### **B. Voluntary code of ethics in the interactions between the company and the healthcare professionals.**

1. The company undertakes and ensures that the interactions between the company and the healthcare professionals are aimed mainly to (1) Supply information to healthcare professionals about the benefits and risks of medicines to enable them to use the medicine

reasonably and safely for the patients; (2) Assist the healthcare professionals in scientific research, training and education, and (3) Collect feedbacks and consultancy from the healthcare professionals about the products of the company.

2. The company undertakes and ensures that all the interactions of the company with the healthcare professionals will be carried out professionally and ethically. It means that:
  - a) Every interactions of the company with the healthcare professionals are not aimed at influencing the healthcare professionals incorrectly when choosing the medicine to treat the patients and / or affecting their professional practice.
  - b) Drug promotional and advertising activities of the company always encourage reasonable and safe drug use by presenting objectively and not overstating drug effects.
  - c) A relationship between the company's employees and the healthcare professionals must be primarily aiming at enhancing professional medical – pharmaceutical practice network, undertaking to be for the benefits of patients and based on honesty, accuracy and updating of scientific evidence.

### **C. Voluntary code of ethics in drug advertising and information activities.**

1. Only the drugs with marketing authorization in Vietnam or other countries by competent authority are allowed to be presented and introduced to the healthcare professionals.
2. Only the drugs with marketing authorization in Vietnam granted by Vietnam Drug Administration and enlisted in the list of drugs allowed to be advertised on the mass media, can be advertised to the public.
3. Drug labels, instructions for drug use (including the drugs produced by the company or imported drugs) and drug information and advertising literatures shall be written in Vietnamese and presented with all the contents in due accordance with regulations.
4. Information and advertisement for drugs must be scientific, objective, truthful, clear and conformable to the drug information which have been appraised by competent authority before issuing the marketing authorization and updated by clear scientific evidence.
5. Necessary and appropriate information shall be supplied to the healthcare professionals in strict adherence to the laws and regulations in force.
6. Drug information contents must be capable of demonstrating its reference to the approved labeling documents, instruction sheets or by clearly scientific evidences. Such evidences are made available as requested by the healthcare professionals.
7. The drug information contents must be clear, easy-to-read, accurate, balanced, equitable, objective and sufficient so as to enable the healthcare professionals to propose their own opinions on medical treatment values of drugs.
8. Drug promotional information must be based on an updated assessment of all the related evidences and clear proofs. It should not deceive itself because of deformation, exaggeration and over-emphasis.
9. Behaviors considered breaching ethical standards in the field of drug promotion and

advertisement:

- a) Advertise to the public the prescription drugs, vaccine, biologics used to prevent diseases; the non-prescription drugs but recommended in writing by the competent authority that they must be restricted in use or used under the strict supervision of a physician.
- b) The information and advertisement of cosmetics, food supplements and products which are not the drugs with the misleading contents can make consumers mistake such products as drugs.
- c) Use in-kind or financial benefits in any form to influence the healthcare professionals and drug-users to induce the prescription and use of drugs.
- d) Take advantage of marketing authorization issued by Vietnam Drug Administration or pharmaceutical authorities in other countries to advertise the drugs.
- e) Use title, symbol, image, position, prestige, correspondence of medical organization, healthcare professional, letter of thanks of the patient to advertise or recommend the use of drugs.
- f) Take advantage of physicians' advice on disease prevention and treatment or the drug use by means of articles on newspapers, radio and television programs to advertise or recommend the use of drugs.
- g) Use results of any clinical research which does not have enough scientific base or medical evidence in the drug information and advertisement.
- h) Take advantage of test results, certificates issued by competent authority, or rewards granted by exhibition fairs to a product and / or a company to advertise the drugs.

#### **D. Voluntary code of ethics in drug promotional activities and symposia to the healthcare professionals.**

1. Drug symposia & other promotional activities towards healthcare professionals organized by the company or funded by the company must be carried out in full compliance with the existing laws & regulations.
2. Drug symposia & other promotional activities towards healthcare professionals must aim at taking care of benefits to the patients and enhance the capacity of professional medical – pharmaceutical practice. Therefore, the activity should focus on presenting product information to healthcare professionals and providing scientific information and / or enhancing medical education to healthcare professionals.
3. Any funding by the company to the individual healthcare professionals shall not be conditioned or obliged for product promotions.
4. The promotional symposia should be organized at an appropriate location and conducive to scientific activity or medical education. The company should avoid using luxurious locations or resorts and should limit to modest refreshment and/or meals when justifiable.
5. The company should not pay any cost for any accompanying persons to healthcare professionals to attend symposia.

6. The company should not provide in any form of entertainment and recreations to the healthcare professionals, such as ticket to theatres or tickets to sporting events, sport tools, recreation tools or vacation trips for any reason.
7. The company should not pay / give cash or gifts to the healthcare professionals.

#### **E. Voluntary code of ethics in clinical research activities.**

1. Clinical assessment of drug and supervision of the drug clinical assessment process must be carried out in due accordance with regulations of relevant authorities for the purpose of medical science and education.
2. All the clinical studies (stages I to IV) and scientific research related to the patients funded or supported by the company will be carried out only for the purpose of scientific knowledge development, to bring about the benefits to the patients and the scientific and medical advancement.
3. The company must ensure transparency and take accountability for presenting the research and publishing research results.
4. The clinical studies should not be used as the compensation of sales/purchase of company's products in the past or in future.
5. The clinical studies should be conducted ethically and should not put any undue impact to any competitors.

#### **F. Voluntary code of ethics in support of educational activities and continuous medical education to healthcare professionals.**

1. The company is allowed and should provide support to educational activities and continuous medical education (CME) to healthcare professionals to help doctors and other healthcare professionals have updated medical information and knowledge to enable them to contribute to improving quality of healthcare services for the patients and to promoting the professional medical – pharmaceutical practice network.
2. In order for the support to educational activities and continuous medical education (CME) meet with the expected deliverables, the company should develop objective criteria to ensure that: (1) the decision to grant CME programs is sound; (2) educational and training program maintain highest quality, and (3) the company's providing financial support is not conditional on drug prescription and use.
3. Funding, scholarship, subsidies, supports, consulting contracts, education and etc. should not be provided to the healthcare professionals in exchange of and conditional on influencing the ethics and independence of related healthcare professionals. The company should only fund, grant scholarship, subsidize and etc. for the purpose of legal educational support, scientific research and / or medical research.

#### **G. Voluntary code of ethics in use of consultant and drug announcer.**

1. The company can arrange / invite healthcare professionals as consultants to get necessary information or advices from the healthcare professionals on such topics as market, product, treatment and patients' need. The company can use these advices to self-assess the drugs

under development, production and / or marketing by the company to see whether their own products and/or strategies are suitable or unsuitable for the treatment demand and the patients' demands. In addition, the company can invite the healthcare professionals to advise in drug promotional programs that helps the company to promote and present to the other healthcare professionals about benefits and risks of the drugs and appropriate use of such drugs.

2. The company should ensure that the arrangements with consultants and the drug advocates in these programs must not be any form of rewards or preference on the condition of drug prescription and use.
3. The healthcare professionals who render consulting services and product speaker/advocacy services should be only paid to their services and related traveling, accommodation costs as per fair market value on a reasonable basis.
4. The following elements should be implemented when the healthcare professionals are invited to render the consulting services and speaker/advocacy services:
5. Written contract is in place which specifies the nature of the rendered services and bases for payment of such services;
6. Legitimate demand of services has been clearly identified and an agreement has been sought for with the potential consultants before formulating the services request;
7. Criteria for selecting the consultant and the drug speaker/advocacy must be specified. The person responsible for selecting consultants must hold required professional qualifications so as to evaluate whether candidates meet the criteria or not;
  - a) The number of the consultants invited must not be more than the justifiable number required to achieve the defined goal;
  - b) The company keeps relevant records to checking, verifying and evaluating the rendered services;

#### **H. Voluntary code of ethics in use of sample drug.**

1. When being used reasonably, the sample drug can be an important tool for the healthcare professionals and brings about benefits to the patients.
2. The sample drugs can be supplied free of charge to healthcare professionals to improve the quality of healthcare services for the patients. The sample drugs shall not be resold or misused and shall be compliant with provisions of the existing laws.
3. The companies should organize the system of inspection and supervision of distribution as well as use of sample drugs as supplied to the medical specialists and / or medical establishments.
4. The sample drug should not be used as a means of payment for services, payment for the medical staff, medical establishment to speed up drug prescription and use.

#### **I. Voluntary code of ethics in public procurement activities.**

1. The process of making a decision by the company and the government in a public

procurement relationship (including the process of governmental procurement) via bidding or any other procedures of the governmental procurement shall be ensured in terms of profession and ethics. It should not have endeavors which cause inappropriate influences.

2. The company must supply correct and balanced information to the Government's procurement agencies.
3. The company and the government officials must ensure that their relations and charges for service arrangement comply with codes of ethics and procedures of the Government.

#### **J. Voluntary code of ethics in charitable activities.**

1. Funding for the charitable purpose presents an evidence that the company is well aware of their ethical responsibility to provide supports to important activities of the employees in the company and / or social community.
2. The company can directly carry out activities for charity in kind or can supply funds to organizations inside and outside the company to promote such activities as culture, education, humanity, healthcare, charity, sports in accordance with provisions of the existing laws.
3. The company must ensure that such supports are not only for the reason of product advertisement and not the unique purpose for the product proliferation.
4. The company's funding and contributions in kind must be delivered to a specific organization, enclosed with description of nature of such funding. Accordingly, thanks sent by recipient organization should be properly limited.
5. The company must ensure that the company will not be based on supports to set preferential terms, requests for purchase, supply or product proliferation and / or interference in the independence of the medical specialists in their professional practice.

#### **IV/ Conclusion :**

To establish and promote one business ethics environment in the biopharmaceutical sector, it will be required to have a cooperation of many related parties so VNPCA requests and asks for the biopharmaceutical trading companies, the medical specialists and other related parties to be active and take the initiative in doing research and implementing the voluntary Codes of Business Ethics in the Vietnamese Biopharmaceutical Sector in the companies.

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**Vietnam Pharmaceutical Companies Association.**