

# VIETNAM PHARMACEUTICAL COMPANIES ASSOCIATION

## Voluntary Codes on Business Ethics in Vietnam biopharmaceutical sector

### I. INTRODUCTION

September 2010 at Ministerial meeting (Ministers of Foreign Affairs and minister of trades), APEC member countries have launched an initiative to develop and put into practice the principles of voluntary ethical in all APEC member countries in the fields of Medical equipment; Biopharmaceutical and Construction. In response to this important initiative, Vietnam Pharmaceutical Companies Vietnam (VNPCA) developing and adopting common voluntary guidelines on business ethics in the biopharmaceutical sector, aiming to:

1. On the basis of the voluntary code of business ethics in the biopharmaceutical sector of APEC's initiative published in Mexico City and the ethical principles of Vietnam on drug business - a precious commodity particularly direct impact on the health and even the lives of users, VNPCA builds voluntary code of business ethics in the Vietnamese biopharmaceutical sector (hereinafter referred to as voluntary code of ethics) in order to Vietnamese Pharmaceutical Production and Trading companies actively participate in this process.
2. Making each company and entire community of Vietnamese production company, biopharmaceutical trading understand: how companies actively and voluntarily engage in cultural construction companies and practice the voluntary code of ethics that is a necessary step for the biopharmaceutical companies in Vietnam sustainable development and economic integration initiative internationally;
3. The companies voluntarily participated in the construction of business ethics according to the voluntary code of ethics is the process of company in building up the management team, technical staffs, and excellent employees professionally and technically, and always consider the product quality, the best interests of the patient as the target in the production and trading of his company.

### II. DEFINITIONS AND INTERPRETATIONS

In written / document following terms are construed as follows:

1. "**Biopharmaceutical Sector**" means including all companies / enterprises are not subject to the form of ownership (hereinafter referred to as the Company) that participated in market development, production, research, marketing, distribution and / or selling pharmaceutical products and / or biological products to patients.
2. "**Trading**" shall be construed as follows: trading is the work performing some or all of the stages of the investment process from production to consumption of the product in the market on a regular basis, continuously aimed at seeking profits.

3. **“Medicine”** indicates medicine, traditional medicine and biological products.
4. **“Patient-centric healthcare”** means that all the company, medical officials do / does has purpose to bring best benefit for the patient.
5. **“Integrity”** means to handle the matters and everything that companies, medical staffs do / perform on an ethical, honesty and respectful basic.
6. **“Independence”** means respect the needs of self-making decisions of all the parties, to avoid improper influence (not consistent with the spirit and values of these codes of ethics).
7. **“Legitimate purpose”** means all the companies, medical staffs do / perform is for the right, legitimate, and consistent with the spirit and values of these codes of ethics.
8. **“Transparency”** means a willingness to provide information accurately and promptly in general, is the openness of its actions while respecting the legitimate commercial sensitivity and intellectual property right.
9. **“Responsibility”** means readiness to take responsibility for the works / actions of the company to their partners
10. **“Professional healthcare”** is based solely on medical needs of each patient and on the basis of knowledge and medical experience.
11. **“Drug information”** is collected and/or provided information relating to drugs as indication, contraindications, dosage, administration, adverse drug reactions, medication to prevent the special groups (children, pregnancy, lactation, the elderly and other objects) of units and individuals have responsibility for drug information in order to meet information requirements of the units and individuals who are directly working in medical practice, pharmacy or drug users.
12. **“Drug Advertising”** is the activity whereas introducing their drugs or medicines by directly conducted or coordinated, or sponsored, authorized to another unit to promote the prescription, supply, sale and / or use of drugs based on rational, safe and effective drug use.
13. **“Drug advertising workshop”** means workshop that introducing pharmaceutical products or scientifically drug seminars for involved medical staffs organized by drug business unit.
14. **“Business ethics”** means the system of the ideas, concept of business ethics. It is the system that guiding codes of ethical behavior, business, and company.
15. **“Attitude of Business ethics”** is reflected in the attitude of the entrepreneur, the company (1) for the law, (2) to customers, (3) with respect to employees and (4) against competitors.

- a) For the law: ethical companies and entrepreneurs have always respected to the law, the proposed management decisions taking account of the legal basis of the decision.
- b) For the employees: ethical companies and entrepreneurs often have ethical attitude of respect and care for the legitimate rights of employees without taking advantage and exploiting of the employees.
- c) For the customers: ethical companies and entrepreneurs have often prestige ethics, fairness and respect for customer benefits.
- d) For the competitors: ethical companies and entrepreneurs have not aimed to eliminate their competitors, which should have attitude of fair competition, competing with intellect, talent and reputation, with product quality and price, with the spirit, customer service attitude is better and better.

16. **“Behavior of business ethics”** is expressed in not violating the law, not trading prohibited internationally products, not producing counterfeit goods, not privacy in production, not exploiting of employees and customers, attention to protect the environmental of business organizations, not tax evasion of government, etc.

### **III. VOLUNTARY CODE OF BUSINESS ETHICS IN THE VIETNAMESE BIOPHARMACEUTICAL SECTOR**

#### **A. General principles of business ethics in biopharmaceuticals.**

1. Companies that involved in market development, production, research, marketing, distribution and sale of drugs to target mainly beneficial for the patient.
2. Companies keep good relationship between them and with the ethics of medical professionals, government officials, patients and other stakeholders which are very important missions of the company to help patients by researching, producing high-quality medicines, affordable / competitive and ready for users (people easily access to medicines when necessary).
3. In the interaction with all the stakeholders, the company is committed to:
  - a) Implementing the highest ethical standards
  - b) Implementing fully and responsibly with all laws and regulations in force.
  - c) Encouraging medical professionals, government officials, and others to work with the company has always respected and applied the appropriate ethical standards that conformable to voluntary code of ethics.
4. The voluntary code of ethics mentioned above is to ensure that the interaction of the company is done in a professional manner and aimed to bring benefits to the patients and contributed to strengthening medical practice - medical professional. It is based

solely that patient healthcare is due to medical requirements of each patient themselves, and also based on the knowledge and expertise of the medical staffs.

5. The company has the obligation and responsibility to provide objective, truthful, balanced information about their drugs to medical professionals that have a clear understanding of the appropriate use of medicines for patients.
6. The company needs to introduce, sell and distribute their medicines ethically (the medicines should assure the quality of products and drug information is objective, balanced, responsible) and suitable to all laws and related regulations are being applied. The information in the brochures and product introduction has to support to properly assessment of the benefits and risks of medications as well as indications of an appropriate use of medicines.
7. The company is committed to implementing training and education (for all related subjects) on the safe, affordable and effective basis (achieve treatment with the lowest cost) for with all of the company's drugs, as the company business.
8. The company is responsible for the observance of voluntary code of ethics in business and to ensure that the organizational structure and internal procedures (including the continuously training program for the staff) are set up and taken seriously to ensure corporate activities that conducted responsibly and ethically.
9. The company is committed to complying with GP's standards (GMP, GLP, GSP, GDP, GPP) and standards related to ensure the quality of comprehensive medicine (as from research and development to production, storage, distribution and supplying medicines to the users) and continuously update, supplement or enhance these standards in order to constantly improve the quality of the company's drug.
10. The company is committed to complying with the provisions of all relevant standards to ensure the quality and safety of medicines at all stages from research and development to processing, manufacturing, and distribution, marketing and post-marketing.
11. The medicines are provided by companies shall be conformed to the high standards of safety, quality and efficiency as stipulated by the Vietnam Ministry of Health, the competent authorities related to pharmaceuticals in another countries& the WHO recommendations.
12. The company must ensure the transparency, responsibility and updates in the report of side effects or adverse drug reactions to the authorities, in accordance with current laws and regulations.
13. The company is committed to complying with codes of ethics of local industries, countries and regions concerned.

14. The company is committed and made sure that all relevant officers and agents operating on behalf of the company are trained in the voluntary code of ethics of the local industry, country and region concerned.
15. The company is committed to respecting the independence of the patient organizations.
16. The company is committed to respecting the privacy of patients.
17. The company ensures that all officers and third parties working on behalf of them comply with the provisions of the voluntary code of ethics and all laws and regulations in force.

**B. Activities company interactions with healthcare professionals.**

1. The company is committed to the interaction between the company and the medical professionals is just to provide information about science, clinical, products and policies aimed towards improving patient healthcare.
2. The company is committed to making sure that the interactive activities between the company and the medical professional primarily (1) to provide information to the medical staffs about the benefits and risks of medicines to help the in use of rational drug safety for patients; (2) to assist medical staffs in scientific research, training and education, and (3) to collect feedback and advice from medical officers about the products of company.
3. The company is committed to making sure that: All interaction of the company with the medical officers will be conducted in a professional and ethical. It means that:
  - a) Any interactions of the company with the healthcare professional are not intended to influence the healthcare professional improperly while choosing medicines to treat the patient and / or influence professional practice of them.
  - b) Do not use the interests or gifts in a way to influence improperly the prescribing practices of healthcare professionals.
  - c) Marketing and advertising activities of the company have always encouraged the use of rational drug safety by presenting an objective and not exaggerated the effects of the drug.
  - d) The relationship between the staffs of the company with the medical professional should be based on encouraging the development of networks of professional practice in medicine, committed for the benefit of patients and based on the truthful, accurate and up to date scientific evidence.

**C. Information activities, drug advertising.**

1. Only the drug products have received approval and issued marketing authorization from the competent authorities in Vietnam and other countries are allowed to provide and introduce the information of products to the healthcare professional.
2. Only those drugs have already issued the marketing authorization by Drug Administration of Vietnam and in the advertising list of permitted medication on mass media advertising can be advertised publicly.
3. Drug labels, package inserts (including drugs manufactured locally or imported drugs) and drug information, advertisements are to be written and printed in Vietnamese and presented with all appropriate contents in accordance with regulations.
4. Advertisement and information of drugs have to ensure the scientific, objective, accurate, truthful, clear and consistent with those of drug information which have been appraised by competent authorities before issuance of marketing authorization and updated by clear scientific evidence.
5. Necessary and appropriate information will be provided to all healthcare professionals consistent with the permission of the law and current regulations.
6. Contents of drug information must have reference source clearly, as reference in labeling documents, package inserts that be approved or by the clear scientific evidence. These evidences are readily available to provide as per requested of medical professional. Upon receiving a request, the companies should ensure providing objective information and data matching requests of the objects.
7. Contents in drug information must be clear, easy to read, accurate, fair, objective and sufficient to enable healthcare professional to propose their own opinion about the therapeutic value of the drug.
8. Information on drug advertising to be based on the updated assessment of all the relevant evidence and these are clear evidences. They should not mislead by distortion, exaggeration or undue emphasis.
9. Do not use clinical assessments, research programs or post-marketing report for the purpose of introducing the disguise. The research program and such assessments should be carried out with the primary purpose is for scientific and education.
10. The document, book or publication sponsored by the Company issued related to drugs and drug use, even with promotional content or not, it must also specify the sponsor by the Company.
11. Violations of ethics in the field of information and advertising of drugs are:
  - a) Advertising of prescription drugs, vaccines, and biological medical products used for disease prevention to the general public; non-prescription drugs but

recommended by the competent authorities in writing to be used under restrictions or supervision of physicians.

- b) Information and advertising of cosmetics, supplement and un-categorized as drug product with misleading contents may cause consumer confusing that the drug product.
- c) Using in-kind or financing benefits of any kind to influence healthcare professional, and drug users to induce the prescription and use of drugs.
- d) Taking advantage of marketing authorization issued by Drug Administration of Vietnam or the Drug Regulatory Agency in other countries for advertising drugs
- e) Using the nominal, symbol, image, position, prestige, correspondence of medical institutions, medical professional, a letter of appreciation from patients to advertise or recommend medication.
- f) Taking advantage of the advice of physician on prevention and treatment or medication use by means of with articles in newspapers, in radio and television programs to advertise or recommend medication.
- g) Utilizing the results of clinical research that is not enough scientific bases, insufficient medical evidence to drug information and advertising.
- h) Taking advantage of the test results, certified by the competent authority, or rewards granted by exhibition to the products and / or companies to advertise the drugs

**D. Conferences, seminars and activities to introduce the drug for medical professionals**

1. Conferences, seminars and activities relating to introduce drugs to healthcare professional that organized by the company or sponsored by company must comply with the provisions of the current law.
2. Seminars introduce drugs for healthcare professional that aims to bring benefits to patients and improve medical professionally practitioners and pharmacists. Therefore, the workshop should focus on providing for the healthcare professional about products, providing scientific information and / or supporting health education.
3. Any financing of companies offering to individual healthcare professional are not tied to conditions and / or obligations and / or suggestions to prescribe, usage recommendation, or to promote any medicines.
4. The workshop should be held at an appropriate venue and beneficial to operationally objective science or medical education. Companies should avoid using venues or lavish resort and should be limited to refreshments and / or meals in moderation, and only for healthcare professional attended the workshop.

5. Companies should not pay any costs for the individual accompanying medical staff attend seminars or introduce drug activity.
6. The company should not offer any forms of entertainment service for healthcare professional, such as tickets to the theater or tickets to sport events, sport equipment, entertainment appliances, vacation or any other reasons.
7. Companies should not pay / give cashes or gifts to healthcare professionals.

**E. Educationally natured gifts and items**

1. The company should not make the any payments in cash or cash equivalent (such as coupons, gift certificates) or gifts for medical staff personally.
2. The company may offer gifts that are items that have educational, medical or patient benefit (e.g. medical books) for health workers. These gifts are valuable not only exceed 500,000 VND, and must conform to the specialized field of health workers.

**F. Activities in clinical trials.**

1. Assessment and monitoring evaluation process of the clinical trial of medicines must be taken in accordance with the provisions of the state management agencies specialized scientific purposes and education.
2. All clinical trials (phase I to IV) and scientific studies related to patients that be sponsored or supported by the company would be carried out only with the purpose to develop scientific knowledge in order to bring benefits to patients and the advancement of science and medicine.
3. The company must ensure transparency and responsibility in the presentation of study and publication of research results.
4. Clinical trials should not be used as incentives for prescribing purchases from companies in the past or in the future.
5. Clinical trials should be done ethically, without causing undue influence to the competitors.

**G. Activities to support education and continuous medical education for healthcare professionals**

1. Companies can and should support the education and continuous training education(CME) for healthcare professionals to help doctors and other medical staffs have more information and knowledge to be able to contribute improving the quality of patient care and contributing to network practice of professional medical-pharmaceutical practices.
2. To support the education and continuous medical education to achieve desired goals, the company should develop objective criteria to ensure that: (1) the decision to grant



CME programs is sound; (2) educational and training program assure the quality, and (3) the company financial support is not conditional to promote the drug prescription and use of drugs.

3. Funding, scholarships, subsidies, supports, consulting contracts, education, etc. should not provide to the healthcare professional to exchange, set the conditions of recommended use, drug prescription or under influence to ethics and independence of related healthcare professional. Companies should only sponsor, grant scholarships, subsidizes, etc. with the purpose of supporting legal education, scientific research and / or medical research.

#### **H. Offering healthcare professional as consultants and rapporteurs.**

1. The company may invite the healthcare professional to work as a consultant to get information or advices on topics such as markets, products, therapeutic areas and patient needs. The companies can use these advices to self-assess the drug that companies are developing, manufacturing and / or marketing that are appropriate or inappropriate treatment and the patient needs. In addition, companies can invite healthcare professional to advice drug promotional programs to help companies' information, referral to other healthcare professional about the benefits, risks drugs and appropriate use of the drug.
2. The company should ensure that the consultants and rapporteurs were invited, not an incentive or a reward for making recommends or prescriptions, use of drugs or specific therapies.
3. Healthcare professional who renders counseling services and rapporteur should be paid a reasonable remuneration and travel expenses, accommodation and meals to provide services as per market cost.
4. The company is just allowed hiring healthcare professional for consulting services or rapporteurs for legitimate business purposes; should not use consultancy contracts to legalize the payments, travelling expenses, accommodation that unrelated to that healthcare professional.
5. The following factors should be taken when recruiting healthcare professional to provide counseling and / or rapporteurs:
  - a) a written contract specifying the nature of the services to be provided and as the basis for the payment of services;
  - b) the legitimate demand for services has been clearly identified and reached an agreement with potential consultants before requesting to provide the services;
  - c) Having criteria for selecting the consultants and rapporteurs. The persons who are responsible for selecting the consultants must have the professional qualification to evaluate whether the candidates meet the requirements or not;

- d) The number of consultants invited must not be greater than the justifiable number required to achieve identified purpose;
- e) The company achieves the relevant records as a basis for checking, monitoring and evaluation of the services provided;
- f) The circumstances and venue of meetings with consultants and rapporteurs should be plausible and consistent with job exchange purposes. The entertainment venues, resorts are not considered as suitable locations.

**I. The drug samples.**

- 1. The company is not allowed to use drug samples to health workers, except:
  - a) Samples for tendering as required by the hospital
  - b) Samples of vaccines and biological product that used for the purpose of safety testing by quality control organizations in vaccines and country biological products before circulating in the market
  - c) Other requirements of health authorities.

**J. The public procurement activities.**

- 1. The decision of the company and the government in relation to public procurement (including government procurement process) via tendering or any other procedures of government procurement, to ensure both professional and ethical. There should be no attempt to in appropriate influence.
- 2. The company must provide correct and balanced information to the government procurement agencies.
- 3. The company and government officials must ensure that their relationships and service fees comply with codes of ethics and procedures of government.

**K. Charitable activities**

- 1. Funding for charitable purposes is the evidence that clearly demonstrate the company has ethical responsibility to provide support to important activities of employees within the company and / or social community.
- 2. The company may direct in-kind charitable or may provide financing for organizations in and outside the company to promote activities such as cultural, educational, humanity, healthcare, charities, sports as prescribed by current law.
- 3. The company must ensure that such supports are not only for reasons of product advertisement, and not the sole purpose to product proliferations.

4. Funding and in-kind contributions by the company must be sent to a specific organization, together with documentation describing the nature of the funding. Accordingly with appreciate has to send to the recipient should be limited appropriately.
5. The company must ensure that they do not rely on the support to give preferential terms, offered to buy, supply or advertise their products and / or interfere with the independence of healthcare professional in their career practice.

#### **L. Training for staff to marketing drugs**

1. The marketing of drugs play an important role in providing correct, truthful and updated drug information for healthcare professional concerning the designated management agency has been approved for use, the benefits or risks of the product. Drug marketer is considered as the point of contact between the company producing and trading with healthcare professional who prescribes drugs. Thus the activities of those drug marketers represent the company in the market, demonstrating the professionalism and integrity of the company in business.
2. The company should ensure that all those represent the Company's drug, or by hiring, is the direct contact with the healthcare professional, to be trained in law, regulations and rules concerned, including the Voluntary Codes of Ethics.
3. The company must ensure pharmacy sale should be expertise and appropriate training in science and information of products to ensure they are able to present information precisely, and fully updated enough, as prescribed by the law and related regulations.
4. Companies should conduct periodic assessment of knowledge of pharmacy sale or drug marketer, both legal; regulations, rules and product information, as well as an assessment of work behavior that should make strictly comply with laws, regulations and ethics.
5. When an employee does not comply with company policies as well as the principle, the company takes appropriate disciplinary.

#### **IV. Conclusion:**

To establish and promote an ethical business environment in the biopharmaceutical sector requires the cooperation of many related parties, VNPCA requests and calls upon the biopharmaceutical business companies; the medical specialists and other stakeholders actively, researching and implementing Voluntary Codes OF Business Ethics in Vietnam Biopharmaceutical Sector in the companies.

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**Vietnam Pharmaceutical Companies Association**