CODE OF CONDUCT OF PHARMACEUTICAL PRACTICES IN INDONESIA

CODE OF CONDUCT OF PHARMACEUTICAL MARKETING PRACTICES OF ETHICAL PRODUCTS IN INDONESIA

Ratified in the Munas XII / 2003 in Bali on 30 May 2003

CENTRAL BOARD
INDONESIAN PHARMACEUTICAL ASSOCIATION
(GP. FARMASI - INDONESIA)

Jakarta, 17 August 2003
No : 01/SK/MPKE/GPFI/2003
Re : Code of Ethics

To :
- Management of Pharmaceutical Industry
- Management of PBF
- Management of Apotek
- Management of Toko Obat

Dear Sirs,

As we are all aware of, the Revision of Code of Pharmaceutical Marketing Practices in Indonesia, which is an improvement version of the previous Code of Ethics, has been ratified the Munas XII/2003 in Bali on 30 May 2003. The decision to improve the Code is a long awaited one and this Code is expected to boost the performance and improve the image of the pharmaceutical industry in Indonesia.

In implementing the Code, it will certainly need some time to go through the stages of technical preparation and its socialization. This will also give the members enough time to carefully study and thus achieve a better understanding of the Code. Therefore, the Ethics Council and the Central Board of GP Farmasi Indonesia, after careful considerations, have decided and hereby announce that this new Code will become effective as of January 1, 2004.

Thanking you for your kind attention, we remain.

Yours sincerely,

GP Farmasi Indonesia
Central Board

Code of Ethics Council

Anthony Ch Sunarjo, MBA
Chairman

Dorodjatun Sanusi
Chairman
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CHAPTER II
THE CODE OF CONDUCT

Article 1
IMPLEMENTATION OF THE CODE

1. Scope
The scope of this Code covers the marketing of pharmaceutical or biological products intended for use in the diagnosis, treatment or prevention of human diseases or influencing the function and structure of the human body, which are used on the advice of or under the supervision of a healthcare professional.

Promotional activities related with distribution (e.g. price lists, trade catalogues) and the promotion of OTC (Green or Blue Dot) products, Infant Nutritional, In-Vitro Diagnostic Tests, Surgical and Medical Devices are not subject to this Code.

2. Application and Execution
In all matters related to the application, interpretation and execution of any part of this Code, it is to be understood that adherence to the prevailing laws and regulations should come first.

3. Responsibility
Full adherence to this Code is a pre-requisite for a membership in the GP Farmasi Indonesia. The President Director and other Board members are responsible for the best compliance with this Code. Companies with licensing or agency agreements in Indonesia should require their licensees or agents to adhere to this Code.

Article 2
INFORMATION AND CLAIMS

1. General Criteria
Information and claims on pharmaceutical products should be honest, objective, accurate and should present a balance of the proofs. Information and claims should also be presented meeting highly ethical standard, in conformity with the product information latest approved by Badan POM and in such a way as not to be misleading or ambiguous.

2. Scientific Evidence
Information provided should be based on the latest evaluation data which are supported by scientifically valid evidence, accurate, clear and presented in a way that is not misleading. The scientific data should be referenced and traceable. In-vitro and animal test data should be clearly marked as such, in order not to give an incorrect or misleading impression. These criteria are applicable for the product(s) being promoted as well as for other products being quoted for reference or comparative purposes.

3. Requests for Information
Companies should handle requests for information from healthcare professionals with objectivity and good intention by providing accurate and relevant data. Responses to requests for data to support promotional claims should be completed within a maximum of 3 months from the date of the request.
4. Safety Data

4.1 Information on the product safety, as well as contraindications, warnings and side effects should conform with those approved by Badan POM.

4.2 The word "safe" should not be used without qualification or explanatory notes.

4.3 All companies are obliged to report to Badan POM and/or related institutions on any unexpected and serious adverse drug reactions associated with their products in accordance with the prevailing regulations.

5. Incorrect or Misleading Claims/Data

Information, promotional claims, supporting data, graphic or other visual presentations of a product shall not be directly or indirectly misleading by omission of certain parts or distortion of evidence or expert opinion. Information should be based on scientifically valid evidence and in conformity with product information as approved by Badan POM. Some examples of what is not permissible and therefore considered as violations of this Code:

5.1 Quoting vague inferences from clinical evidence or experience that can not be validated. Therefore, it is recommended to quote results of specific, published studies.

5.2 Using or quoting data from a study, which is not relevant to the claim(s) being made. Presenting data to support a claim without a reference to a published study.

5.3 Claims based on data that are no longer applicable, e.g. data that have been proven invalid or replaced by the results of more recent research.

5.4 Dosage recommendations or claims for an indication that do not conform with the Badan POM approved product information.

5.5 Using In-Vitro data or data from animal studies which are not clearly identified as such or which is presented in a way that is misleading or implying that it is In-Vivo and/or human data.

5.6 Presentations or layouts that lead to an incorrect or misleading interpretation e.g. important and relevant data but actually not supporting the promotional claims, relegated to fine print; manipulating scales on graphs/charts etc to distort comparisons with competitor’s product.

5.7 Negative statements concerning competitive products bearing no scientific basis or are refutable based on current evidence or having no relevance to the product being promoted.

5.8 Claims implying a product’s efficacy for a certain indication but ignoring the warning or caution applicable to its use in such circumstances.
5.9 Claims utilizing evidences or quotations:
- Which are selectively presented to misleadingly highlight advantages
- Which are presented or quoted beyond or out of context
- Which are quoted or presented in such a way as to distort the meaning or objective of the author.

5.10 Non-medical or non-scientific claims with no evidence.

5.11 Unqualified superlative claims or hanging comparatives – (see Paragraph 6 below)

5.12 Comparisons with competitive products that are not based on scientifically valid evidence or which distort the evidence or which are not objective and reasonable (see Paragraph 7 below).

6. Unqualified Superlative and Hanging Comparative Claim

6.1 Making unqualified superlative claims are not allowed, e.g.
- "Product X is the best treatment for condition Y"
- "Product X is the fastest treatment for condition Y"
- "Product X is the strongest/most powerful treatment for condition Y"
- "Product X is the safest treatment for condition Y"

If these or other superlatives are to be used, then the claims must be provable supported by scientifically valid evidence.

6.2 Hanging comparative claims should not be made, e.g. "Product X is better/stronger/faster/safer for condition Y" A comparative claim must include a statement that indicates against what the product is better/stronger/faster/safer etc and that this superiority is supported by current scientifically valid evidence (for more explanations see point 7 below).

7. Comparisons

7.1 Comparisons between products should be honest, based on facts proven by scientific evidence. In presenting the results there should be no attempt to deceive by distortion, unreasonable emphasis or other means. Comparisons in bad taste or insulting to the competitors’ or their products should be avoided.

7.2 Comparisons on efficacy and safety should not be based on data that does not reflect the current published literature or that come from different database not comparing the same thing.

7.3 Comparisons on efficacy and safety should consider all aspects of efficacy and safety. If a comparison is made based on one parameter only, then this should be clearly stated.
7.4 Data used to support comparative claims should satisfy the requirements of statistical significance. If the data do not meet these conditions, then they should be clearly marked as such and should not be used to generalize or to support claims indicating equality or superiority against another product. The statistical significance indicator (i.e. the “P” value) should accompany the comparative data.

8. Imitating or Copying Other Companies’ Materials
A company should not deliberately imitate or copy other company’s marketing/promotional/advertising materials, which might lead to misleading or confusion.

9. Healthcare Professionals in Promotional Materials
Names or photographs of healthcare professionals or institutions should not be used in the promotional/advertising materials in a way that violates the medical code of ethics. It is, however, acceptable to use the names and photographs in proceedings of scientific meetings (e.g. where a healthcare professional makes a presentation) but it is not allowed to do so in promotional brochures, journal advertisements and the like.

10 Hidden Promotion/Advertising
10.1 Promotional materials such as mailings and medical journal advertisements should be clearly marked as such so that its real nature is not disguised e.g. advertisement in journal which is part of the editorial should be marked “PROMOTIONAL ADVERTISEMENT” or “ADVERTORIAL” in capital letters of the largest pitch used in the body text of the advertisement.

10.2 All Clinical Trials should be conducted in accordance with the Good Clinical Practice (GCP) guidelines. Post-Marketing studies should not be conducted merely as a means to promote a product or to influence healthcare professionals with little or no scientific basis.

11. Pre-Registration Communications
A product shall not be promoted until the prerequisite license to market has been granted by Badan POM.

This provision, however, is not meant to limit the rights of the scientific community and the general public to gain complete information on advances in the scientific and medical fields, provided that the results of the research have been acknowledged internationally. It is also not meant to limit the full and proper exchange of scientific information on a product, including the dissemination of research findings in the scientific or general communications media or through scientific congresses. Likewise, this provision should also not limit disclosure to the shareholders and other parties related with the product as may be required by law or regulation. In the event an international or regional conference is being held in Indonesia, research findings on a product not yet approved for the Indonesian market by BPOM are allowed to be communicated therein provided that this is conducted in a proper and responsible manner and in accordance with Article 2 of this Code. It should also be clearly stated
that the product is not yet registered by Badan POM in Indonesia.

12. Company Procedures
   12.1 All promotional communications should undergo a medical clearance process (i.e. approved by a medically qualified person) or, where appropriate, approved by the person-in-charge before being released.
   12.2 Companies should establish and maintain appropriate procedures to ensure full compliance with this Code and to review and monitor all existing promotional activities and materials.

Article 3
MEDICAL REPRESENTATIVES

1. The company is fully responsible for the quality and conduct of their medical representatives.
2. Medical representatives must have appropriate educational background and the company is responsible for providing the required technical training concerning their obligations. Medical Representative should preferably be accredited, the system of accreditation might be ruled by GP Farmasi in cooperation with other professional organization and related government institution.
3. Medical representatives should be able to give technical explanations on their company's products in a balanced, accurate and in an ethical manner to the members of the healthcare professionals' organization.
4. Medical representatives should be prohibited to give or offer rewards to the members of healthcare professions other than as specified in the point 5 below.
5. Medical representatives in doing their duties should show good conducts when visiting the members of healthcare professions.
6. The ruling on Medical representative should be adjusted from time to time in order to be in compliance with the prevailing regulations/laws issued by the relevant government institution governing the manufacturers and distributors (PBF) as well or other similar companies.

Article 4
SYMPOSIA, CONGRESSES & CONTINUOUS MEDICAL EDUCATION

1. Understandings and Objectives
   Symposia, congresses, Continuous Medical Education (CME) and the like are essential for the dissemination of science and experience. Scientific objectives should be the prime focus in arranging such meetings.

2. Symposia & Congresses
   2.1 The participation of a company or an association in a symposium, congress or the like should be declared clearly during the meeting and in any printed proceedings from the meeting. Printed, audio-visual or electronic materials from the meeting should accurately reflect the presentations and discussions of the event.
   2.2 If the meeting program is accredited for post graduate education by a medical association or other healthcare professional organization, the responsibility for the program
content remains with that organization. Any support from the pharmaceutical industry should be sufficiently stated or disclosed.

2.3 Companies are prohibited from offering any kind of induction, gift/appreciation, incentive, donation, financial reward and other form whatsoever to the medical profession.

3. Sponsoring Healthcare Professionals

3.1 Any support provided to an individual healthcare professional to attend a scientific meeting should not be made conditional upon any obligation to promote or prescribe certain product.

3.2 Companies shall keep individual sponsorship within reasonable level e.g. payment for the registration fee, accommodation and meals, transportation to and from the event.

3.3 It is not allowed for companies to pay for any expenses of accompanying person/s, be it the spouse or family member of the invited medical participant.

3.4 It is prohibited to give honorarium or compensation to a healthcare professional for attending a scientific meeting. (Honorarium is however permitted for speakers/moderators at a meeting – see Article 3.5 below).

3.5 Speaker/Moderator Honorarium
Payment for reasonable honorarium and out-of-pocket expenses, including travel expenses for speaker/moderator are customary and proper. The amount of the honorarium for local speaker/moderator at a local meeting should not be more than USD 300 or IDR equivalent. The honorarium for local speaker at overseas meeting should be adjusted to conform with the normal practice in the country where the meeting is held. The honorarium for foreign speaker at local meeting should be fixed at the usual rate of the speaker's home country.

4. Exhibition & Hospitality Stalls/Counters

4.1 Exhibition booth, hospitality room, and the like should be secondary to and not detract from - the scientific objectives of the event.

4.2 Exhibitions are to be organized solely for the benefit of medical profession. The name of the company/exhibitor should be clearly visible and the exhibition itself should meet the terms as set by the organizing committee.

4.3 Distribution of product samples should refer to the applicable regulation as stipulated by Badan POM.

4.4 Other activities such as games, raffles, and the like should not be held at times when the scientific sessions are in progress so as to avoid disturbing or distracting participants from the prime objectives of the meeting.
5. Miscellaneous Programs

5.1 Companies should not hold hospitality programs such as tours, social events, contests, sports, games or the like in such a manner that will disturb or distract participants from the official program of the event.

5.2 Companies are permitted to invite healthcare professionals to dining or cocktail events. Such events should be reasonable and modest rather than lavish.

5.3 Companies should not deliberately interfere or attempt to undermine a single company sponsored scientific event (e.g. a meeting which is not a part of national, regional or international congress).

Article 5
PRIZE AND DONATION TO HEALTHCARE PROFESSIONALS

1. General Principles
No gifts/rewards, incentives, donations, financial, and the like shall be offered to healthcare professionals in return for prescriptions or recommendations for the company’s medicine(s)/product(s).

2. Gifts
2.1 Gifts are permissible only if granted to institution, and are strictly prohibited to be given directly to healthcare professional.

2.2 The gifts should entail a benefit for the patients and/or the work or education of the healthcare professionals in that institution.

2.3 No gifts shall be given in return for products purchased or inclusion in the products standardization, prescriptions or use of a company’s product(s) at that institution.

3. Donations
3.1 Donations are permissible only if granted to institution, and are strictly prohibited to be given directly to healthcare professional.

3.2 The donations should entail a benefit for the patients and/or the work or education of the healthcare professionals in that institution.

3.3 No donations shall be given in return for products purchased or inclusion in the products standardization, prescriptions or use of a company’s product(s) at that institution.

Article 6
PRINTED PROMOTIONAL OR ADVERTISING MATERIALS

1. General
This section takes care of printed promotional or advertising material of each ethical product intended for the healthcare professional. Printed promotional or advertising material should be presented in a legible manner. The scientific basis and presentation of the information on a product should conform with the principles as described in Article 2 of this Code and should conform with the product information as approved by Badan POM.
2. Full/Complete Printed Promotional Material or Advertisements
   Since the objective is to provide the healthcare professionals with adequate information to make a rational decision on the prescription or use of a product, the information provided must include, clearly and concisely, the following:
   - Product name (Brand/Trade Name)
   - Generic name of active ingredient(s) or INN (International Non-proprietary Name)
   - Name and address of the marketing company
   - Approved indications for use of the product (Minimum of 1 indication)
   - Dosage, method of use/recommended application
   - A brief statement on side effects, clinically important cautions and warnings, contra-indications and major interactions at the recommended dosage.
   - A statement that further information is available upon request.

3. Brief (“Reminder”) Promotion/Advertisement
   In short promotional materials and advertisements which provide only a simple statement on the indications to denote the relevant therapeutic category and why the product is recommended for that indication, the following minimum information should be stated:
   - Product name (Brand/Trade Name)
   - Generic name of active ingredient(s) or INN (International Non-proprietary Name)
   - Name and address of the marketing company.

4. Brand Reminders/Gimmicks
   Promotional give-away items/gimmicks distributed to healthcare professionals should be related to their work and should be of reasonable value (maximum USD20 or IDR equivalent). On small items with little space for printing and where no promotional message or scientific information is presented, it is acceptable for just the Brand or Company name/logo to appear.

5. References
   5.1 Promotional materials containing information from published studies should include clear and traceable references to those studies.
   5.2 The use of reprints, abstracts and quotations should be compliant with the copyright conditions of such material.
   5.3 Quotations or opinions from medical literature or from personal communications must not be modified or distorted so as to mislead or confuse or alter the intended meaning of the author.

6. Mailings
   6.1 Promotional materials should only be sent to appropriate individuals considered to have a professional interest in the information being supplied.
   6.2 The frequency and volume of promotional mailings to healthcare professionals should be reasonable. Requests from healthcare professionals to be removed from the mailing lists for promotional materials must be respected. However, companies must maintain a complete list for other important information such as contra-indications, adverse reactions, warnings etc.
Article 7
AUDIO-VISUAL AND ELECTRONIC PROMOTIONAL MATERIAL

Promotional information for the healthcare professionals using these media should comply with the requirements relevant to printed materials as described in Article 6. Product information may be omitted provided the full product information is available on request from interested parties.

Article 8
SAMPLES

In accordance with Ministry of Health Decree No. 437/MEN.KES.SK/VI/1987 of 11th June 1987, providing free samples of pharmaceutical products to the medical profession is prohibited. Hence, companies are not allowed to send samples to the healthcare professionals, except in the case of specifically approved by the respective authority.

Article 9
MARKET RESEARCH

Market research should not employ methods that in any way might discredit, or reduce public trust in the pharmaceutical industry. This requirement is applicable in any case, whether the research is being conducted by the marketing company or other organization acting on its behalf.

Devious or coercive methods to influence respondents are prohibited. Fees for research respondent should be lowest possible and in proportion with the work involved. (maximum USD 50 or IDR equivalent per respondent per project)

Article 10
COMMUNICATION WITH THE PUBLIC AND MASS MEDIA

Unless stipulated otherwise by BPOM or related institution, ethical products may only be promoted and advertised to the healthcare professionals and shall not be advertised to the general public. Companies should not place articles or advertorials in the mass media to promote a prescription medicine or for the purpose of encouraging the general public to request a certain product through their physician.

CHAPTER III
STANDARD PROCEDURES FOR SUBMISSION OF COMPLAINTS RELATED TO CODE OF ETHICS

1. Complaints
   1.1. The Council of Code of Ethics (‘Ethics Committee’) receives and investigates an official complaint against a person and/or a legal body/pharmaceutical company, which is alleged to be in breach of the Code of Ethics of Marketing.
   1.2. On its own initiative, the Ethics Committee may conduct activities to gather information and/or facts and then to discuss it in the Ethics Committee meeting in the case of a strong indication of violation of the Code by one pharmaceutical company or in cooperation with other party/ies. After further investigation and due deliberation, the Committee has to decide whether there is a breach of the Code or not.
1.3. Complaints may be submitted by:
   1.3.1. Pharmaceutical companies being members of GP Farmasi Indonesia
   1.3.2. Official of Badan POM or related institutions
   1.3.3. Board of Advisory, Chairman and Head of Divisions of GP Farmasi Indonesia
   1.3.4. Central Board of Medical Profession Organization
   1.3.5. Foundation of Consumers Protection Indonesia.

2. Investigation
   The investigation on any submitted complaint will be conducted by the Ethics Committee.

   3.1 The complainant should file an official complaint in writing stating the identity of the company or the represented institution, addressing it to the Ethics Committee and also providing copies of all necessary documents for the consideration of the Ethics Committee. The letter of complaint should be addressed as follows:

   The Chairman of Code of Ethics Council
c/o Secretariat of GP Farmasi Indonesia
Jl. Angkasa No. 20A Kemayoran Jakarta Pusat, 10620 INDONESIA  Telp (021) 4203040, Fax (021) 4203047 / 48.

   The letter of complaint should include the following points for the members of the committee to review:

   a. **Effort for Settlement**
      Has there been any attempt for a direct settlement prior to referral to GP Farmasi Indonesia. Any effort to approach the company, which allegedly is in breach of the Code and the outcome of these efforts, have to be stated in the letter of complaint.

   b. **The violating company**
      For each complaint case, the identity of the possibly offending company, and the name of each product(s) / marketing activities specifically related to the case should be mentioned.

   c. **Reference Material**
      The original sample copy being the subject of the grievance (the “violated article of the Code”).

   d. **Date and Place of the case**
      The exact date and venue wherefrom the actual offending item was retrieved as evidence, for example: Poster in the waiting room of Clinic A.

   e. **Presentation of Alleged Breach of Code**
      A summary of how and why the Code was violated, with a specific reference to the chapter, article and other relevant information.

   Upon receipt of the complaint, the Secretariat of GP Farmasi shall check whether or not the complaint contains the required data and relevant documentation as mentioned above for the Ethics Committee to act upon.
If the submission is incomplete, the complaining party will be informed accordingly to make a resubmission with the necessary documentation. The case will only be processed by the Code of Ethics Council of GP Farmasi Indonesia after completion of the required documents. Submitted complaints which are complete and proper will be immediately distributed under confidential cover to all Ethics Committee members for their review. To expedite prompt handling of the complaints, the Secretariat of GP Farmasi Indonesia will concurrently write thereof to the company/industry, which allegedly is in breach of the Code. A photocopy of the letter of complaint with the identity of the complainant's name and company being concealed/deleted will be extended to the offending company. The violating company will be given a period of 10(ten) working days to respond in writing to the allegations.

If necessary, this can be extended up to max. 3 times. If requested, the violating company must provide the relevant scientific documentation to substantiate its scientific claims. The response from the offending company with sufficient copies of the corresponding supporting documents will then be distributed by the Secretariat of GP Farmasi Indonesia to all members of the Code of Ethics Council for evaluation. If a summon is not respected, the Ethics Committee may proceed to process this issue further without any hearing with the offending company. Meanwhile, the Ethics Committee shall table the complaint in a meeting at the earliest possible date.

In that meeting, the Committee shall review and decide whether further investigation is warranted, or whether further references are required to facilitate better interpretation of the case. If further opinion from medical/legal experts is regarded necessary and payment is required for such services, the complainant will be asked for their willingness to bear these costs and whether or not the Committee should continue the case. Whenever necessary, the offending company shall be obliged by the Committee to give rebuttal to the allegations. After sufficiently investigating and evaluating the facts as presented by both sides, the Committee will cast a secret ballot to decide if there is indeed a breach of the Code.

When after due consideration, the Committee concludes that there has been a breach of the Code, the offending company shall be requested to give an agreement in writing to stop with immediate effect the activity which is in breach of the Code, not to commit a similar offence in the future, as well as to institute corrective action.
The respective company shall respond to the decision of the Committee within 14 (fourteen) days. In the event the offending company is unwilling to give such an agreement, and/or the breach of the Code is perpetuated, the Committee may decide to give sanctions such as to terminate the company from the membership or any other actions, such as to file a notification to Badan POM or other authorities, an announcement to the organizations of healthcare professionals for its further action, to notify the offender’s parent company or headquarter, or to publish the issue in the GP Farmasi Indonesia bulletin, OR take all actions of the above mentioned.

In the case that it is established that there has been no breach of the Code, a notification to this effect shall be made by the Ethics Committee to such relevant parties as the Ethics Committee may decide.

The Chairman of the Ethics Committee will submit a report to the Chairman of the Central Board of GP Farmasi Indonesia on all cases finalized by the Ethics Committee. Such report whether in writing or in verbal form will be delivered with all details including the names of the companies involved at a subsequent Board Meeting following the finalization of a case. However, the minutes of the Board Meeting shall not reveal any confidential information nor the names of the companies to ensure complete confidentiality.

4. Exception

The Ethics Committee will automatically discontinue or be requested to discontinue all activities in connection with a complaint procedure of a certain case, as soon as the Badan POM and Balai Besar/ Balai POM has started conducting an investigation and/or examination of the same case in accordance with the Decree of the Head of Badan POM No. HK.00.05.3.02706 of 2002, concerning Drug Promotion or other related regulations governing the above subject.

CHAPTER IV
CLOSING

All members of GP Farmasi Indonesia should be well versed in this Code of Conduct and all Board levels of GPFI are instructed to pass this on to the management of all pharmaceutical companies under their jurisdiction.
As ratified in Denpasar
Dated 30 May 2003

Chairman
(Presidium)

Tirto Kusnadi
Chairman
(Pengda DKI Jaya)

A.Tjahjono
Vice Chairman
(Pengda Jawa Tengah)

M.Soleh Depati
Member
(Pengda Sumsel)

Liansyah Lokmansyah
Secretary
(Pengda Kalsel)

Tb.Dede Sutardi Bioel
Member
(Pengda Banten)