Code of Pharmaceutical Marketing Practices - Controlled Medicines (Ethical Products)

OUR MISSION

To participate, drive and contribute, with the other healthcare Stakeholders, in ensuring the equitable, affordable and accessibility of quality, safety and efficacy of medicinal and healthcare products and services in the Healthcare Industry.

OUR OBJECTIVES

- To contribute towards better healthcare through the provisions of products and services.
- To collaborate, and be partners, with all Stakeholders in the Healthcare Industry, be they Government Bodies or other healthcare players, in achieving our mission
- To be responsible in the delivering of products and services.
- To ensure that the ecosystem of the Industry is competitive, healthy and fair with a "level playing field" in the best interest of the Country.
- To build and encourage the provision of adequate human capital and to upgrade the skills and knowledge of the workforce.
- To promote healthy life-style and wellness program to the Rakyat.

MAPS CODE OF PHARMACEUTICAL MARKETING PRACTICES

INTRODUCTION

The Code of Pharmaceutical Marketing Practices is received and adopted by the members.

The objective of the Code is to provide as clear as possible guidelines in disseminating accurate, fair and objective information to the medical and allied profession so that rational prescribing decisions can be made. In so doing, members are obliged to adopt the high standard of conduct and professionalism in the marketing of pharmaceutical products.

Notwithstanding any provision made under the Code, all marketing activities under the Code must conform to all existing and relevant government legislations.

MAPS, through its Ethics Committee shall be responsible for receiving and deliberating on all complaints, and in making decisions on each of them, and for communicating their decision to the complainant.

Self-regulations and restraints are an integral part of the Code, which must be applied not only in spirit but as well as to the letter.

PROVISION OF THE CODE

1. **Objective & Scope** :

1.1 **Objective**: MAPS Code sets out standards for the ethical promotion of pharmaceutical products to healthcare professionals to ensure that member companies' interactions with healthcare professionals are appropriate and perceived as such.

1.2 **Scope**: For the purposes of the MAPS Code:

- **"pharmaceutical product"** means any pharmaceutical or biological product (irrespective of patent status and/or whether it is branded or not) which is intended to be used on the prescription of, or under the supervision of, a healthcare professional, and which is intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body.

- **"promotion"** means any activity undertaken (or material prepared) by a member company or any third party acting on behalf of the company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all media.

- **"healthcare professional"** means any member of the medical, dental or pharmacy professions or any other person who in the course of his or her professional

activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product.

- **"company"** means any company that is a member of MAPS. "Company" can refer to national companies and/or the worldwide parent company

1.3 Exclusions: This Code does not seek to regulate the following activities:

- Promotion of self-medication products that are provided "over the counter" with or without prescription.
- Pricing or other trade terms for the supply of pharmaceutical products.
- The conduct of clinical trials.
- The provision of non-promotional information by member companies.

2. General Principles

2.1 Methods of promotion: Methods of promotion or marketing must never be such as to incite unfavourable comments or to bring discredit upon, or reduce confidence in the pharmaceutical industry.

2.2 Basis of Interaction: Members' relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information and supporting medical research and education.

2.3 Independence of Healthcare Professionals: No financial benefit or benefit-in-kind (including grants, sponsorships, gifts, scholarships, subsidies, support, consulting contracts or educational or practice related items) may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on a healthcare professional's prescribing practices.

2.4 Appropriate Use: Promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their properties.

2.5 Transparency of Promotion: Promotion should not be disguised. Clinical assessments, post-marketing surveillance and experience programmes and post-authorization studies must not be disguised promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose. Material relating to pharmaceutical products and their uses, whether promotion in nature or not which is sponsored by a company should clearly indicate by whom it has been sponsored.

2.6 **Pre-Approval Communications and Off-label Use:** No pharmaceutical product shall be promoted in Malaysia until the requisite approval for marketing for such use has been given.

This provision is not intended to prevent the right of scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure of information to stockholders and others concerning any pharmaceutical product as may be required or desirable under law, rule or regulation.

3. Standard of Promotion

3.1 Promotional material for pharmaceutical products should be accurate, fair and objective and presented in such a way as to conform not only to legal requirements but also to high ethical standards and to be in good taste. Claims should not be stronger than scientific evidence warrants, and every effort should be made to avoid ambiguity.

3.1.1 Promotion should also be capable of substantiation either by reference to the approved labelling or by scientific evidence. Such evidence should be made available on request to healthcare professionals. Companies should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.

3.2 Nature and availability of information

3.2.1 Information provided to the medical profession on pharmaceutical products must accurately reflect, where relevant, on updated data, current medical opinion or expert consensus based on latest references. The approved Malaysian prescribing information remains the main guide for decision.

3.2.2 Information about pharmaceutical products should also be clear, legible, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the pharmaceutical product concerned.
Claims for superior potency per unit weight are meaningless and best avoided unless they can be linked with some practical advantage, e.g. reduction in side effects or cost of effective dosage.

3.2.3 Information must be capable of substantiation based on clinical and pharmacological evidences from properly conducted investigations. Such substantiation when requested by members of the medical and allied profession should be provided without delay.

3.3 Claims and comparisons

3.3.1 Claims for a medical product must be based on an up-to-date evaluation of all the evidence and must reflect this evidence accurately and clearly including the reference of this substantiating evidence.
Up to date implies that if the information does not alter with time, the most recent available data is acceptable
E.g. of time sensitive information is the resistance pattern for antibiotics.

3.3.2 Exaggerated or all-embracing claims must not be made and superlatives must not be used unless based on substantial scientific evidence and other responsible medical opinion. Claims should not imply that a pharmaceutical product or an active ingredient has some special merit, quality or property.

3.3.3 Any statement about side effects should be specific and based on data approved by the DCA or on published data to which references are given. It must not be stated that a product has no side effects, toxic hazards or risks of addiction

3.3.4 The word “new” should not be used to describe any product or presentation or any therapeutic indication which has been registered in Malaysia for more than 18 months.

3.3.5 Comparisons of products must be factual, fair and capable of substantiation. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis, or in any other way, including omissions. “Hanging” comparatives, which merely claim that a product is “better” or “stronger” etc. must not be used.

3.3.6 Brand names of products of other companies must not be used unless prior consent of the brand owners has been obtained.

3.4 Disparaging references

3.4.1 The products or services of other companies should not be disparaged either directly or by implication. Substantiated comparative claims inviting fair comparisons with a group of products or with other products in the same field are permissible, provided that such claims are not presented in a way which is likely to mislead, whether by distortion, undue emphasis or otherwise.

3.4.2 The clinical and scientific opinions of members of the medical and allied professions should not be disparaged either directly or by implication.

4. Printed promotional material

4.1 All printed material (including journal advertising) which is issued for promotional purpose by the product licence holder or with his authority, must include the name and address of the product licence holder or the business name and address of the part of his business responsible for the sales of the product.

4.2 When promotional material relates to published studies a clear reference to these should be given in the printed material. Quotations from medical literature must not change or distort the intended meaning of the author or clinical investigator or the significance of the underlying work or study.

4.3 Promotional material such as mailings and journal advertisements and loose inserts must not be designed to disguise its real nature.

4.4 Advertisements in journals should not be designed so as to resemble editorial material.

4.5 Promotional material should conform, both in text and illustration, to canons of good taste and should recognise the professional standing of the recipient.

4.6 All printed promotional material, including advertisements should include the name of the product (normally the brand name) generic name of the product and the date of production of the advertisement.

4.7 Doctors' names or photographs must not be used in a prominent manner in promotional material or in any way that is contrary to the ethical code of the medical profession.

4.8 Promotional material should not imitate the devices, copy, slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.

4.9 Material and articles from the lay press should not be used as promotional material unless it can be substantiated and correct scientifically.

4.10 Scientific and technical information shall fully disclose the properties of the pharmaceutical product as approved in Malaysia based on the minimum abbreviated prescribing information and approved Product Package Inserts (PPI).

Minimum abbreviated PPI must include the following:
Contraindications
Precautions
Dosages
Indications
Side effects

A minimum font size of 6 points is to be used for printed materials.

5. Brand Reminders

5.1 Reminders are designed just to remind a prescriber of a product's existence and must not contain promotional claims which include the mention of any indication. A reminder must contain:

(a) Brand name of the product;
(b) Approved name(s) of the active ingredient(s);
(c) Name of the Supplier

5.2 If a reminder contain tag lines or slogans, the name of supplier as well as a statement that further information is available on requests, must be included.

5.3 Such reminders should be of appropriately modest value

6. Electronic and Audiovisual Materials

6.1 The same requirements shall apply to electronic promotional materials as apply to printed materials. Specifically, in the case of pharmaceutical product related websites:

- the identity of the pharmaceutical company and of the intended audience should be readily apparent;
- the content should be appropriate for the intended audience;
- the presentation (content, links, etc.) should be appropriate and apparent to the intended audience; and
- specific country information should comply with local laws and regulations.

7. Dissemination of Information of unapproved product or Indication

7.1 **Local Meetings inclusive of CME's:** Dissemination of scientific information for a pharmaceutical product or indication, which has not been approved for marketing by the Drug Control Authority (DCA), or for a registered product with a new unapproved indication can be undertaken by a member company provided:

- No brand name is mentioned.
- Declare that it is still unapproved in Malaysia.
- Organised under the auspices of a Professional body or hospital-based CME committee.
- Based on verifiable (e.g. poster/abstract/publication) data or peer review reprints as a CME event endorsed by a professional body.
- Relevant permission from authorised bodies (if required)

7.2 **International Meetings:** Information provided at International meetings/Symposia/Congress held in Malaysia, which appear on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in Malaysia, or which are registered under different conditions, provided that the following conditions are observed:

- The meeting should be a truly international, scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the Event takes place;
- Information (excluding promotional aids) for a pharmaceutical product not registered in Malaysia should be accompanied by a suitable statement indicating that the product/indications/dosage form is not registered and make clear that the product/indication/dosage is still unapproved in Malaysia;
- Information which refers to the prescribing information (indications, warnings etc.,) authorized in a country or countries other than Malaysia but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally.

7.3 **Appropriate Venue:** All Events should be held in an appropriate venue that is conducive to the scientific or educational objective and the purpose of the Event or meeting.

Companies should not organize Events nor provide financial support including sponsoring HCPs to any event at renowned or extravagant venues associated with leisure, golf, island resorts (not accessible by land transport with the exception of locations within Malaysia) and gaming activities. The venue should be appropriate for the meeting (e.g. adequate facilities for the number of attendees/good internet access)

- appropriate and conducive to the scientific or educational objective and purpose of the event or meeting
- located so as to minimise travel for attendees
- having adequate security
- able to successfully withstand public and professional scrutiny.

8. Artwork, graphics, illustrations etc in print and other media

8.1 Illustrations must not mislead as to the nature of the claims or comparisons being made nor as to the purpose for which the product is used.

8.2 Artwork and graphics must conform to the letter and the spirit of the Code. Graphs and tables should be presented in such a way so as to give a clear, fair, balanced view of the matters with which they deal, and should only be included if they are relevant to the claims or comparisons being made.

8.3 Graph and tables must not be used in any way which might mislead, for example by the incompleteness or by the use of suppressed zeros or unusual scales.

8.4 If a graph has been adapted from a paper, it must be stated so. A graph can be adapted, provided it is clear and its true meaning is not distorted.

9. Reprints, abstracts and quotations in print or other media

9.1 Material from medical literature or from personal communications received from doctors, must accurately reflect the meaning of the author and the significance of the study (which should not be distorted by the addition of printed highlighting or underlining to give prominence to selected portions of the material).

9.2 Care must be taken to avoid ascribing claims or views relating to the medical products to authors when such claims or views no longer represent or may not represent the current view of the authors concerned.

10. Distribution of promotional material in print or other media

10.1 Promotional material should only be sent or distributed to those categories of persons whose need for or interest in the particular information can reasonably be assumed, but must not exceed the categories sanctioned by law.

10.2 Any information with regards to the use of pharmaceutical products in clinics or industrial concerns must be addressed to the medical advisor or medical officer or to the medical auxiliary staff.

10.3 No promotional material shall be issued unless the final text and layout have been certified by a senior official of the company, preferably a doctor or a pharmacist.

10.4 The certificate shall certify that the signatories have examined the material and that in their belief it is in accordance with all legal and ethical requirements of the Code.

10.5 Companies shall preserve all certificates, together with the material in the form certified, for not less than 3 years and produce them upon request from the Ethics Committee.

11. Symposia, congresses and other means of verbal communication

11.1 Objectives: Symposia, congresses and the like are indispensable for the dissemination of knowledge and experience. Scientific objectives should be the principal focus in arranging such meetings and entertainment and other hospitality shall not be inconsistent with such objectives.

11.2 Sponsorship: When a pharmaceutical company or association organizes or sponsors a symposium, congress or other medical/health care or educational programme:

On a professional basis, a doctor or pharmacist under the employment of a member company is allowed to attend Scientific meetings under the umbrella of a professional Society or Organisation of which he is a member (e.g., MMA, MPS) even though it may be organized by a competitor company.

Sponsorship is limited to travel, meals, registration fee, accommodation and limited entertainment. Entertainment should be modest and secondary to the main purpose of the meeting. As a guide, at least 75% of the time involved in the meeting should be dedicated to scientific and educational contents.

Sponsorship to attend overseas scientific meetings (excluding internal company meetings) will:

- Only cover basic economy travel (if travelling time is less than 6 hours), meals, lodging and registration fee.
- Limited to maximum twice per year/company for each healthcare professional.
- The cost of the most direct route will be funded.
- Exclude accompanying persons.

No company may organize or sponsor an Event for healthcare professionals that takes place outside Malaysia, where the majority of the attendees are Malaysians. International scientific congresses and symposia that derive participants from different countries are therefore justified and permitted to be hosted in any of the countries that are represented by the delegate.

No payments are made to compensate healthcare professionals for time spent in attending the Event; and

Any sponsorship provided should also not be conditional upon an obligation to prescribe and recommend any pharmaceutical product.

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

11.3 **Appropriate Venue:** All Events should be held in an appropriate venue that is conducive to the scientific or educational objective and the purpose of the Event or meeting. Companies should not organize Events and/or provide financial support including sponsoring doctors to medical society, hospital or clinic organized Events at renowned or extravagant venues associated with leisure, golf, island resort (not accessible by land transport) and gaming activities. The choice of venue must be able to successfully withstand public and professional scrutiny.

11.4 **Payments for Speakers and Presenters:** The payment of reasonable expenses such as cost of air travel, meals and lodging may be provided to healthcare professionals. If an honorarium is paid, a guidance amount of no more than RM1,000.00 per engagement with up to max of RM2,000.00/day, with a detailed signed contract on the services, for auditing purposes and proof that it is not an inducement, is required. However, if it concerns international speakers, then members are advised to check with the speaker's home country code and apply accordingly. The same proposal on a signed contract remains.

12. Medical Representatives

12.1 Medical representatives must be adequately trained and possess sufficient medical and technical knowledge to present information on the company's products in an accurate and responsible manner.

12.2 Medical representatives should at all times maintain a high standard or ethical conduct in the discharge of their duties. They are required to be instructed in and possess a copy of the Code.

12.3 The requirements of the Code which aims at accuracy, fairness, balance and good taste apply to verbal representations as well as printed material.

12.4 Medical representatives must not employ any inducement or subterfuge to gain an interview. No payment of a fee should be made for the grant of an interview.

12.5 A company will assume responsibility, under the Code, for correcting breaches of the Code resulting from misconduct or misrepresentation of fact by any representative.

13. Samples

13.1 Except when provided for specific clinical trials, samples of products given out should be no larger than the smallest commercial pack of each strength and clearly labelled as "free promotional samples – not for sale" or similar wording allowed by the law. (Supply for organised trial of registered products should be adequate to fulfil protocol requirements).

13.2 Where samples of products restricted by law to supply on prescription are distributed by a representative, the sample must be handed directly to the doctor or given to a person authorised to receive the sample on his behalf.

13.3 An adequate recording system should be established for all samples distributed.

13.4 Samples which are sent by post must conform to the Postal and Poisons Regulations governing it, and must be packed so as to be reasonably secure against the package being opened by children.

13.5 Samples must not be used as unofficial bonus and an inducement to purchase.

13.6 **Control and Accountability:** Companies should have adequate systems of control and accountability for samples provided to healthcare professionals including how to look after such samples whilst they are in the possession of medical representatives.

13.7 Notwithstanding the clauses stated here, the standards of current "Good Pharmaceutical Trade Practices" on sampling or the higher standard of either should be adhered to.

14. Gifts and Hospitality

14.1 Inappropriate financial or material benefits, including inappropriate hospitality, should not be offered to healthcare professionals to influence them in the prescription of pharmaceutical products.

14.2 Subject to Section 14.3 no gifs or financial inducement shall be offered or given to members of the medical and allied professions for purpose of sales promotion.

14.2.1 **Cash:** Payments in cash or cash equivalents (such as gift certificate) must not be offered to healthcare professionals.

14.2.2 **Personal Gifts:** Gifts for the personal benefit of the healthcare professionals (including, but not limited to, music CDs, DVDs, sporting or entertainment tickets, electronic items) must not be provided or offered.

14.2.3 **Items of Medical Utility:** Items of medical utility may be offered or provided, provided that such items are of modest value, do not exceed RM500.00 and are beneficial to the provision of medical services and for patient care. For medical educational material, e.g. journals, textbook & models, the limit is up to RM1,000.00/year for institutions only.

14.2.4 **Cultural Courtesy:** An inexpensive cultural courtesy such as cakes, cookies, dates and mandarin oranges of not more than RM100.00 may be given to a healthcare professional in acknowledge of significant festive occasions.

14.3 Promotional aids whether related to a particular product or of general utility, may be distributed provided the promotional aids is of small value (not more than RM100.00) and relevant to the practice of medicine or pharmacy or of benefit to patient care. For medical educational materials e.g. journals, text books & models, the limit is up to RM1,000.00.

14.4 Hospitality offered to members of the medical and allied profession should always be modest and secondary to the main purpose of the meeting.

14.5 Hospitality should not extend beyond members of the medical and allied professions.

14.6 The level of hospitality should be appropriate and not out of proportion to the occasion. Its cost should not exceed that level which the recipients might normally adopt when paying for themselves.

14.7 **Limits of Hospitality:** Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the Event and should only be provided to participants of the Event; and if it is moderate and reasonable as judged by local standards.

14.8 **Entertainment:** No stand-alone entertainment or other leisure or social activities should be provided or paid for by member companies. At Events, entertainment of modest nature which is secondary to refreshments and/or meals is allowed.

(MAPS shares the opinion that medical and group meetings are desirable and are to be encouraged. However, the advertising content should be supported by clear educational motive).

14.9 Lotteries / lucky draws should not be part of symposia / exhibitions / company organized smaller group meetings.

14.10 Notwithstanding the clauses stated here, the standards of current "Good Governance for Medicine on Giving and Receiving of Gifts" or the higher standard of either should be adhered to

15. Marketing Research

15.1 Methods employed for marketing research must never be such as to bring discredit upon or to reduce confidence in the pharmaceutical industry. This provision applies whether the research is carried out directly by the company concerned or by an organisation acting on the company's behalf.

15.2 Questions intended to solicit disparaging references to competing products or companies must be avoided.

15.3 Any incentives offered to the informants should be kept to a minimum and be commensurate with the work involved.

15.4 Marketing research must not in any circumstances be used as a disguised form of sales promotion.

15.5 Marketing research must not have the direct objective of influencing opinions of the informant.

15.6 The identity of an informant must be treated as confidential, unless he has specifically agreed otherwise. (In the absence of this agreement, it follows that the information provided as distinct from the overall results of the research must not be used as the basis upon which a subsequent approach is made to that informant for the purpose of sales promotion).

16. **Relations with the general public and lay communication media**

16.1 Request from individual members of the public for information or advice on personal medical matters must always be refused and the inquirer recommended to consult his or her own doctor.

16.2 Promotional material issued for distribution or display anywhere to which the public has access must not include any message likely to arouse a demand for all Scheduled Poisons.

16.3 Patient education leaflet related to disease condition must be fair, unbiased and not contain any product name and restrict reference to the company providing the leaflet to its name & logo. Therapeutic class/option or chemical name of drug or generic class is allowed, as long as it is unbiased.

16.4 Leaflets for instruction in the use of a specific medicine containing reference to the name and illustration of the product must only be provided to the public by a medically qualified practitioner or health care professional.

17. **Valid patent rights**

All valid patent rights of products and processes must be respected by members.

18. **Company Procedures and Responsibilities**

Companies should establish and maintain appropriate procedures to ensure full compliance with relevant codes and applicable law and to review and monitor all of their promotional activities and materials. A designated company employee, with sufficient knowledge and appropriate scientific or healthcare qualifications should be responsible for approving all promotional communications. Also, a senior company employed could be made responsible, provided that scientific advice is taken.

OPERATION OF THE CODE

1. A name list of the person(s) responsible for the approval of Advertising and Promotion activities/materials for all companies will be kept / filed in the MAPS Secretariat – known as "List of Signatories".
   (It is the responsibility of the companies to advise the Secretariat on any changes to the List of Signatories).

   (In the event that there is a dispute in the submission of the complaint, comments from the signatories of both parties will be sought).

   Any complainant company should first initiate contact with the company alleged to be in breach, in order to discuss the issue and endeavour to settle the dispute / disagreement of any subject matter, prior to forwarding such complaints in writing to the Ethics Committee for deliberation.

   The complainant should provide proof or evidence that the parties concerned have communicated but were unable to come to a decision, when lodging a complaint.

   (This is to encourage companies to talk to one another, in order to attempt to amicably settle any issues. Often, CEO's are not aware of such complaints. CEOs should be responsible for activities within their respective companies).

   Every case should be treated as a fresh complain, however the Ethics Committee has the right as provided for in the MAPS Code of Conduct to proceed without insisting on prior communication between two parties in cases of repeated breaches.

   The term 'repeat breaches' is defined as being 'the breaches of the same clause or clauses of the Code with the same product claim'.

   A penalty of up to RM50,000.00 will be meted out repeat offenders.

   In cases of repeated breaches of the same clause or clauses of the MAPS Code of Pharmaceutical Marketing Practice, the complainant may choose not to communicate further with the defendant prior to lodging a formal complaint. If so, the Ethics Committee has the absolute discretion to decide if the case should be considered.

   All alleged breaches in the observance of the Code against any member reported to MAPS, must be made in writing and submitted by the CEO of the complainant company (in order that the CEO of that company is aware that a complaint has been submitted) together with an administrative fee of RM3,000.00 to MAPS. The administrative fee cannot be used to offset the fine. It will first be validated to ensure that:

   It appears to be a genuine matter, submitted in good faith.

   - There is sufficient evidence to enable the complaint to be processed.
   - It is not a duplicate of a case, which has already been resolved under the Code.

The minimum information required is:

- A specific reference to the source of the advertisement / activity which is the subject of the complaint and the name of the product and products involved.
- The identity of the company concerned with the alleged breach of the Code.
- The date of the alleged breach of the Code.
- Clause(s) of the Code alleged to be breached.

Where the case concerns printed promotional material, the complainant is asked to provide copies of the offending material. Where the case concerns an activity, if there is no documented proof, this needs to be reported by or confirmed by an independent witness.

2. The Ethics Committee shall meet soonest after the receipt of the complaint from the Secretariat to decide if there is a case for the subject company to answer.

3. In the event that the Ethics Committee decided that there is a case to be answered, the companies must submit the relevant copies required of the referenced documents and highlight the relevant clauses in its response to support its case.

All documents from the plaintiff and defendant, pertaining to the cases lodged to the Ethics Committee must be submitted in 10 copies.

The Committee may decide not to preside over the case should the required number of copies not be made available.

The Plaintiff and Defendant will be called to the Ethics Committee's case deliberation meetings, if there is a need for information to be presented that has not been presented in written form.

During the deliberation of the Ethics Committee, the Defendant & Plaintiff may make representation to the Committee, limited to one person to a period of not more than 20 minutes, unless more time is requested by the Committee.

4. The company judged to be in breach of the Code will be asked to discontinue the offending material or practice. Nor must the offending text be employed in any other media e.g. if promotional literature is in breach, the offending text cannot be used in journal advertisements, mailings etc. In addition, the company may be required to issue a Retraction Statement, details of which will be determined by the Ethics Committee. The Ethics Committee may at its discretion recommend to the MAPS Board of Directors to also notify the Medicine Advertisement Board (MAB) and / or the Drug Control Authority (DCA).

   (The Board will only endorse the decisions made by the Ethics Committee and the Ethics Appeal Committee. It suffices for the decision to be e-mailed to the Board prior to forwarding them to the relevant parties).

   The Committee may inform the regional office regardless of whether there is compliance to the Ethics Committee's decision.

5. Appeals can only be made on the merits of the case and should be made within two weeks of receipt of the formal notice of the Committee's decisions, after which, the party concerns, loses the right to appeal.

   The appeals fee is RM3,000.00. The complainant does not have any right to appeal (where defendant is found not guilty). In such a case, should the plaintiff like to pursue the issue, the plaintiff would be required to lodge a separate complaint.

   In the event that there is no appeal against the Committee's decision by the defendant within 2 weeks of receipt of this decision, the complainant's administrative fee of RM3,000.00 will be refunded / forfeited depending on the Committee's findings. The defendant if found to be in breach will be fined up to RM20,000.00 or RM50,000.00*. (See Appendix 2).

6. If the defendant is found not guilty, the complainant's administrative fee of RM3,000.00 will be forfeited.

   If the defendant company wishes to appeal against the Committee's decision, the appeal accompanied with an administrative fee of RM3,000.00 should be submitted to the Secretariat within 2 weeks of receipt of the decision, provided that the company undertakes to discontinue the offending material or practice and the text should not be reproduced in any other media (See Section 3 above) pending a decision on the appeal. (The administrative fee of RM3,000.00 is to contribute towards the cost of outside advice).

7. The appeal will be considered by the Ethics Appeal Committee, which may include personal representation by the company. The Committee may also invite external sources of advice. The cost of such fees will be borne by the fees submitted by the appellant.

   The Ethics Appeal Committee shall only preside on clause(s) which was initially raised at the regular Ethics Committee only.

   (Should the plaintiff like to forward a new clause(s) for deliberation, the plaintiff shall lodge a fresh complaint, and submit the lodging fee of RM3,000.00 to the regular Ethics Committee).

8. In the event that the Ethics Appeal Committee decides that there is a case to be answered, the company judged to be in breach of the Code will be asked to give an undertaking to withdraw the offending material or discontinue the practice. In addition, the company may be required to issue a retraction statement, details of which will be determined by the Ethics Committee. The subject company's administrative fee of RM3,000.00 will be forfeited, and the complainant's administrative fee of RM3,000.00 will be refunded.

   The administrative fee cannot be used to offset the fine.

   In the event that the Ethics Appeal Committee decides that there is no case to be answered, the company judged will have the earlier decision of the Ethics Committee reversed. The administrative fee of RM3,000.00 will be refunded to the subject

company, while the complainant company's administrative fee of RM 3,000.00 will be forfeited.

9. If a reply is not received confirming acceptance of the Ethics Committee's decision or the Ethics Appeal Committee's decision and providing the undertaking requested by the Committee within 3 weeks of receipt of the decision, it will be taken that the company has refused to abide by the decision.

10. If the company refuses to abide by the decision of the Ethics Committee or the Ethics Appeal Committee, the Board of Directors may apply the following sanctions:

    A.1 the subject company is suspended from membership for the same 4 weeks' period under the relevant Rule of the MAPS Rules and Constitution.

    A.2 If no indication of the withdrawal of the material or discontinuance of the practice is received by the set deadline, then the Board of Directors may:

    - Suspend the company under the relevant Rule of the Rules and Constitution for a period up to the date of an Extraordinary General Meeting.
    - Take action under the convened Extraordinary General Meeting for the expulsion of the subject company form the Association.

11. The decision of the Board of Directors in the matter shall be final and information on above sanctions may be made known to the Medicine Advertisements Board (MAB) and / or the Drug Control Authority (DCA), and any other relevant publications, and included in the regular reports of the Ethics Committee and the Annual Report of the Board of Directors to members.

12. The Ethics Committee and the Ethics Appeal Committee reserves the right to release the whole or part of the information relating to the complaint and its resolution to any interested person or bodies as it may so decide.

13. Any details of complaints on alleged breaches of the Code, the decisions of the Ethics Committee and the Ethics Appeal Committee and subsequent actions taken by all parties in the matter may not be used by the complainant or the subject company for any publicity or promotional purposes.

14. The Ethics Committee, the Ethics Appeal Committee, the Board of Directors, MAPS and its staff, including individuals serving in any capacity in these committees, shall not be subject to any legal action by any party on decisions taken relating to the complaint.

15. Procedure Review for 3rd party complaints.

    Complaints by third party would be dealt with in a similar procedure to a member company to member company complain.

    The following procedures would be adopted, for complains by a third party (company / individual/any other organisation).

If the company being complained is not a member of MAPS, MAPS will revert to the complainant and request that it lodge a complaint against the relevant trade associations concern.

On receiving the complaint against a member company of MAPS, the Ethics Committee will revert to advise the complainant to contact the defendant directly in order to settle the matter amicably, prior to forwarding such complaints in writing to the Ethics Committee for deliberations.

Should the parties concern have communicated but were unable to agree to a decision, and the complaint comes back to the Ethics Committee and the Ethics Committee will deliberate on the case.

(In such an event, both complainant and defendant must submit 10 copies of all relevant documents and highlight the relevant sections in its response to support its case).

The Plaintiff also have a right to appeal provided they pay the RM3,000.00 appeals fee.

*In cases of repeated breaches of the same section or sections of the MAPS Code of Conduct with the same product claim.

APPENDIX 1
MAPS Ethics Review Committee – Normal Case

NO	POSITION	NO
Chairman	**Director of the BOD & Ethics Committee Chairman**	**1**
Committee members	**Pharmacist Marketing Personnel Compliance or Regulatory Personnel**	**Min 3**
Secretariat Staff	**Executive Director Manager**	**Min 1**
External Representation by MMA	**(By Invitation only)**	**1**

Punitive Action:

1) As per "Code of Pharmaceutical Marketing Practices".
2) For repetitive cases, the committee will advise the DCA/MAB for assistance to enforce its decision.
3) A heavier penalty of up to RM50,000.00 will be meted out in cases of repeat breaches of the same clause or clauses of the "Code of Pharmaceutical Marketing Practices".
4) Committee members who are not a Medical doctor nor pharmacist may attend the case deliberations meeting. However, only one vote per company is allowed at any one time.

Note:
BOD = Board of Directors, MAPS
MMA = Malaysian Medical Association

APPENDIX 1A

MAPS Ethics Appeal Committee – Appeal Case

NO	POSITION	NO
Chairman	**Director of the Board**	**1**
Committee member	**Ethics Committee Chairman**	**1**
Committee members	**Pharmacist** **Marketing Personnel** **Compliance or Regulatory Personnel**	**Min 2**
Secretariat Staff	**Executive Director** **Manager**	**Min 1**
External Representation by MPS, **MMA & BC**	**(By invitation only)**	**1 each**

Punitive Action:

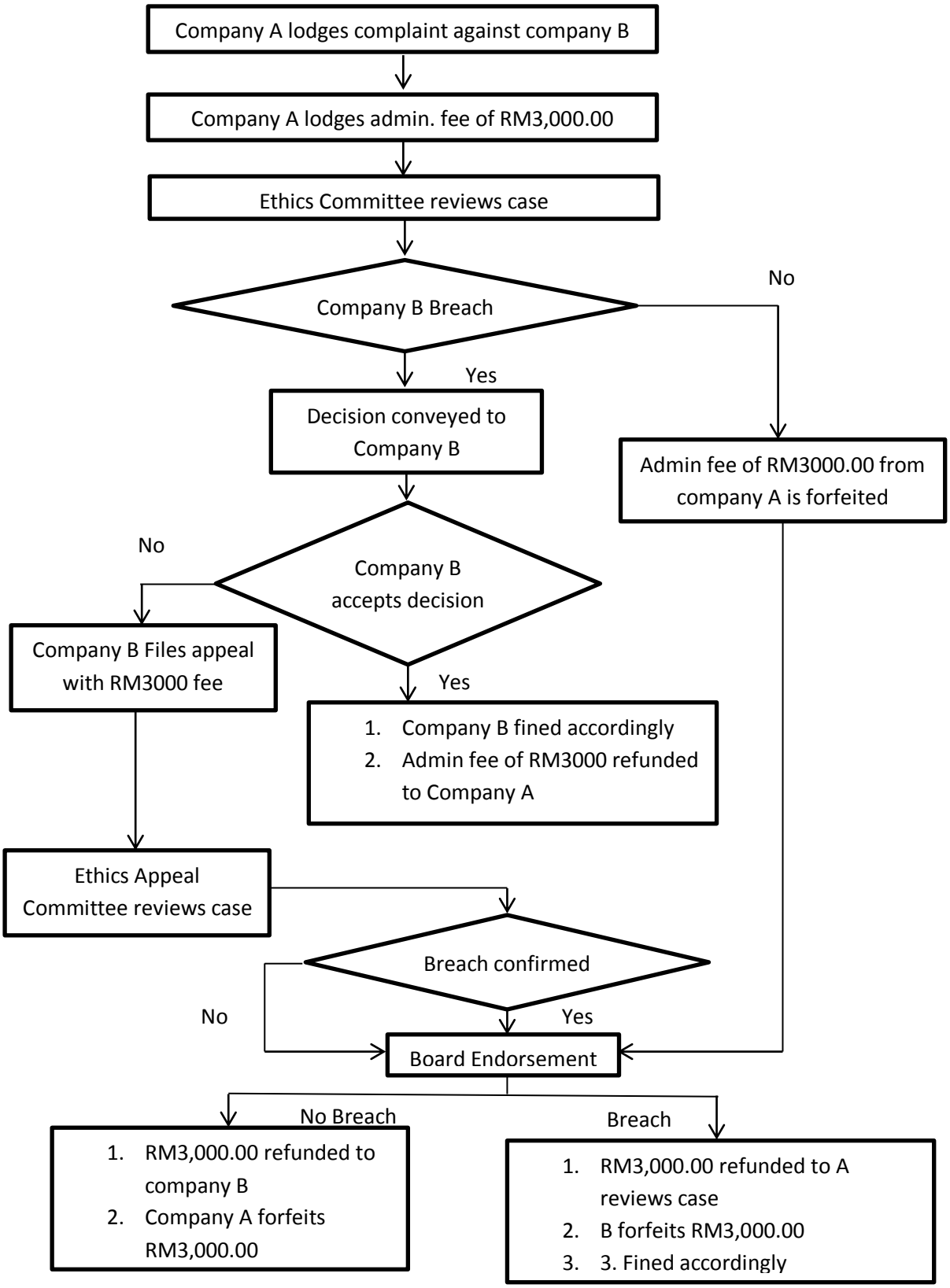
1) As per "Code of Pharmaceutical Marketing Practices".
2) The Committee may, at its discretion, copy its letter to the MAB/DCA for information.
3) The Committee may at its discretion, copy the company's Regional Office/Head office for information.

Note:

BOD = Board of Directors, MAPS
BC = Bar Council
MMA = Malaysian Medical Association
MPS = Malaysia Pharmaceutical Society
MAB = Medicine Advertisements Board
DCA = Drug Control Authority

APPENDIX 2

SUMMARY OF ETHICS COMPLAINTS PROCEDURE



***(Up to RM20,000.00) / (Up to RM50,000.00: repeated breach)

APPENDIX 3

THE USE OF THE INTERNET FOR PHARMACEUTICAL INFORMATION

The internet has the potential to be a vital and positive resource for society. Although it is continuing to evolve, it has already demonstrated its remarkable ability to inform and educate global audiences on a wide range of subjects including healthcare and medicinal products.

- The research-based pharmaceutical industry, represented by MAPS strongly supports the rights to use the Internet as a means for providing accurate and scientifically reliable information on medicines in a responsible manner, for the benefit of both patients and healthcare professionals.

- Measures to regulate the Internet require caution as they could inadvertently impose unacceptable constraints on legitimate communication and information flow. The unscrupulous will always evade controls whilst the law-abiding will comply. Inappropriate regulation could result in a situation where unregulated and unreliable sources of information remain on the Internet, unchallenged by reliable, authentic sources and legal authorities.

Regulation and Self-Regulation

- MAPS is convinced that self-regulation is the method of choice for controlling the type and quality of information provided by pharmaceutical companies via the Internet, on pharmaceutical products.

- Wherever they market their products, pharmaceutical companies within the membership of MAPS are bound by the self-regulatory MAPS Code. The Code sets out principles and standards for the information provided by companies about their products, and these requirements are equally valid for and applicable to information made available via the Internet.

Sale and Supply via the Internet

- MAPS is concerned that the Internet can be misused by the unscrupulous, as a means to by-pass normal controls and to sell prescription medicines directly to patients, without appropriate professional consultation. Patients' health may be put at risk by such practices and industry supports measures to prevent such activities and to educate consumers about the dangers of procuring medicines in this way.

- Other forms of commerce involving the sales and supply of medicines via the Internet may also result in medicines being handled outside regulated distribution channels, with the danger that poor quality products, unlicensed medicines and counterfeits will be supplied.

- The nature of the Internet makes it difficult to enforce effective controls over those who misuse the Internet to advertise illegal and undesirable services and products. Regulation and enforcement activities by the government should, therefore, focus on the physical

movement of products via vendors, agents and dealers who are handling medicines and distributing them outside legitimate, approved channels.

- MAPS recognises its responsibility to ensure that its products are only provided through legitimate and reputable channels. MAPS has and will continue to work co-operatively with the government, regulatory bodies and any other agencies to prevent the sales of medical products outside lawful distribution channels.

Future challenges

MAPS recognises the healthcare challenges presented by the global dimensions of the information available on the Internet but believes that these should be regarded as an opportunity for constructive changes, with the interests of the patient / consumer as the priority.

- Patients and consumers are seeking more information about medicines and medical treatment but laws and regulations differ widely throughout the world, with regard to the information which may be provided by companies on the products that they supply.
- Similarly, patients in remote areas, the elderly and incapacitated are seeking better access to medicines but there are major differences in the acceptability of “distance selling”, even with appropriate safeguards for prescription controls.

Laws, regulations and medical culture differ in different parts of the world and the evolution of the Internet has brought the need for greater harmonisation into sharp focus. Greater uniformity in the international norms for disseminating accurate and reliable information on the use and availability of pharmaceutical products would make implementation and enforcement a much more tangible goal to the benefit of the patient / consumer and healthcare providers in all regions and in Malaysia.

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