Code of Pharmaceutical Marketing Practices

On Prescription (Ethical) Products

Revised November 2016

MOPI AIMS & OBJECTIVE

The overall objective of the Malaysian Organisation of Pharmaceutical Industries (MOPI) is to ensure that all patients have access to affordable quality medicines. As a matter of basic principle the Malaysian Organisation of Pharmaceutical Industries shall:

- **Support** the development of international, regional and domestic policies which seek to ensure access to affordable medicinal care for all patients;
- **Promote** balanced and generic-friendly intellectual property rights in the pharmaceutical sector which ensure that timely access to markets is guaranteed for generic pharmaceutical products;
- **Encourage** the scientific development, professional awareness and general knowledge of medicines, biosimilars, health supplements and traditional medicines produced by domestic manufacturers;

MOPI AIMS & OBJECTIVE *Cont'd*

- **Promote** the global and regional harmonisation of regulations relating to pharmaceutical products, biosimilars, health supplement and traditional medicines produced by domestic manufacturers;
- **Provide** guidance to international organisations and national governments in improving the regulatory and legal expertise relating to the registration and marketing of medicines, biosimilars, health supplement and traditional medicines produced by domestic manufacturers;
- **Promote** uniform and effective GMP standards and quality controls for pharmaceuticals, biosimilars, health supplement and traditional medicines produced by domestic manufacturers and their active ingredients;
- **Seek** strict and effective controls to prevent the production and trade in counterfeit versions of medicines;

MOPI AIMS & OBJECTIVE *Cont'd*

- **Support** open competition in the pharmaceutical industry which shall include supporting the rights of Governments to regulate their own substitution, prescribing and reimbursement policies;
- **Assist** the various Malaysian government ministries in the development of the domestic pharmaceutical manufacturing sector;
- **Contribute** towards better healthcare for all Malaysians by promoting accessibility to quality, efficacious and cost-effective pharmaceutical products;
- **Liaise** with and encourage the co-operation of all allied healthcare organisations and government institutions for the enhancement of health standards in Malaysia;

MOPI AIMS & OBJECTIVE *Cont'd*

- **Promote** a positive view of the industry's role, motives and performance through effective dialogues and communications with consumer organisations and the government sector;
- **Encourage** the provision of adequate competent manpower for the pharmaceutical industry and to upgrade the skills and knowledge of the industry's workforce;
- **Promote** awareness among members to take due cognizance of their responsibility to protect the environment and take the necessary measures towards this end in their operations or manufacture of their products;
- **Protect** the consumer's right of choice and promote the maintenance of a free and fair market for pharmaceutical products.

PREAMBLE:

Notwithstanding any provision made under this Code, all marketing activities must conform to all existing and relevant government legislation governing the practice of the Pharmaceutical Industry.

MOPI Code of Pharmaceutical Marketing Practices On Prescription (Ethical) Products

The Code owes its existence to the determination of the Organisation to voluntarily secure the acceptance and adoption of high standards of conduct in the marketing of pharmaceutical products which the industry makes available for prescription purposes to the public. For this reason, members of the Organisation have voluntarily concurred in the promulgation of this Code and submitted to its restraints. This Code essentially adopts The Mexico City Principles as developed by the APEC SME Working Group and endorsed by APEC Ministers (Foreign & Trade) at the APEC Ministerial Meeting in November 2011 in Honolulu, USA. The Mexico City Principles were further endorsed in the Statement of the 2012 Meeting of APEC Ministers Responsible for Trade held in Kazan, Russia in June 2012.

Adoption of this Code shall be voluntary by members of the Organisation and the Code will be periodically reviewed to reflect the highest standard of conduct within the Organisation.

The major sanction against any company that transgresses the Code is the sanction of adverse publicity.

The objective of the Code is to provide as clear as possible guidelines in disseminating accurate, fair, unbiased 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.

There are obvious difficulties in drawing up exacting standards for the Code, especially where the success of application depends not only on strict adherence by members, but also the co-operation of non-members in the medical and allied professions. Self-discipline and restraints are an integral part of the Code, which must be applied not only in spirit but as well as to the letter.

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21. Interactions with Patient Organization and NGOs

The Code

1. **Objective**

   The MOPI Code sets out standards for the Pharmaceutical Marketing Practices on Prescription (Ethical) Products to healthcare professionals to ensure that member companies' interactions with healthcare professionals are appropriate and are perceived as such.

1.1 **Scope:** For the purposes of the MOPI Code:

- **"Company"** means any company that is a member of MOPI.
- **"Healthcare professional/s"** means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical products.
- "**Manufacture"** means any act having the meaning assigned to it by the Control of Drugs and Cosmetics Regulations 1984. MOPI members shall observe and comply with cGMP in the manufacture of their pharmaceutical products. This will also include Distributors and Re-packers.
- **"Pharmaceutical product/s"** means any product having the meaning assigned to it by the Control Drugs and Cosmetics Regulations 1984.
- **"Promotion"** means any activity undertaken, organized or sponsored by a member company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all media, including the internet.
- **"Territory"** This code is only intended to govern practices within Malaysia and therefore will comply with the laws of Malaysia.

1.2 **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 provision of non-promotional information by member companies.

2. General Principles

- Healthcare and Patient Focus
- Integrity
- Independence
- Legitimate Intent
- Transparency
- Accountability

3. Standards of Promotion

3.1 Promotional Material

3.2 Nature and availability of information

3.3 Claim and comparisons

3.4 Disparaging references

4. Printed Promotional Material

4.1 All printed material including journal advertising

4.2 Promotional material relates published studies

4.3 Promotional material such as mailing, journal advertisement

4.4 Advertisements in journals

4.5 Promotional material in text & illustration

4.6 All printed promotional material including generic name & date of production in advertisements

4.7 Doctors' and healthcare professionals' names

4.8 Promotional material should not imitate the devices

4.9 Material and articles from the lay press

4.10 Scientific and technical information

5. Electronic and Audiovisual Materials

5.1 The same requirements shall apply to electronics promotional materials

6. Dissemination of Information of products or Indication

6.1 Local Meetings inclusive of Continuing Medical/ Professional Education. (CME's)

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

7.1 Artwork and graphics must conforms to the letter and spirit of the Code.

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

8.1 Material from medical literature or from personal communications.

8.2 Care must be taken to avoid ascribing claims or views

9. Distribution of promotional material in print or other media

9.1 Promotional material should only be sent or distributed

9.2 Any information designed to encourage the use of pharmaceutical products

9.3 No promotional material shall be issued unless the final text and layout

10. Symposia, congresses and other means of verbal communication

10.1 Symposia, congresses and the like are indispensable for the dissemination of knowledge and experience

10.2 When a Member Company sponsors a symposium, congress or other medical/health care

10.3 Appropriate Venue

10.4 Consultant and Speaker Arrangements

11.0 Medical Representatives

11.1 Medical representatives must be adequately trained

11.2 Medical representatives maintain a high standard of ethical conduct in the discharge of their duties.

11.3 The requirements of the Code

11.4 Medical representatives must not employ any inducement or subterfuge

11.5 A company will assume responsibility, under the Code

11.6 The system of remuneration of representatives

12. Samples

12.1 Except for specific trials, samples of products given out should be modest

12.2 Where samples of products restricted by law to supply

12.3 An adequate recording system

12.4 Samples which are sent by post

12.5 Samples must not be used as unofficial bonus

12.6 Member Companies should have adequate systems of control and accountability

13. Gifts and Other Items

13.1 Inappropriate financial or material benefits

13.2 No gifts or financial inducement

13.3 Promotional Aid

13.4 Entertainment

14. Marketing Research

14.1 Methods employed for marketing research

14.2 Questions intended to solicit disparaging references

14.3 Any incentives offered to the informants

14.4 the identify of an informant must be treated as confidential

15. Relations with the general public and lay communication media

15.1 Request from individual members of the public for information or advice

15.2 Promotional material issued for distribution or display

15.3 Patient education leaflet

15.4 Leaflets for instruction in the use of a specifc medicine

16. Valid Patent rights

17. Company Procedures and Responsibilities

18. Public Sector Relationships and Procurement

- 18.1 The decision-making process
- 18.2 Member Companies must provide accurate and balance information
- 18.3 Member Companies and Government officials complies with this Code and Government ethics rules

19. Clinical Research and Transparency

- 19.1 Transparency
- 19.2 Distinct from Promotion

20. Company Donations for Charitable Purposes

20.1 Member Companies recognize their responsibility to support worthwhile activities

21. Interactions with Patient Organization and NGOs

21.1 Member Companies should respect the autonomy of patient organizations and their independence

21.2 Support from Member Companies must not be conditional on the promotion of a specific medicine

COMPLAINT PROCEDURE

Malaysian Organisation of Pharmaceutical Industries
Global Business & Convention Centre,
Mezzanine Floor, Block A,
No. 8, Jalan 19/1, Section 19, 46300 Petaling Jaya
Selangor Darul Ehsan Tell: 603-79319003 Fax: 603-79322730

(M1/16)

ETHICS COMPLAINT FORM

COMPLAINT INFORMATION	
1. Complainant Company *(Please state Name , Address & Contact Details)*	
2. Defendant Company *(Please state Name, Address & Contact Details)*	

3. Details of Complaint

3.1 Source of advertisement/promotional material:
(Please state the name of the media where applicable)

3.2 Date of publication *(if available)***:**

3.3 Statement(s)/claim(s) alleged to be in breach:
(Please quote the text)

3.4 Section(s) of the Code alleged to be breached:
(Please quote relevant section)

4. Proof of prior communications with the defendant company *(Please provide dates of all communications)*
5. Administration Fee of RM1,500.00 addressed to "Malaysian Organisation of Pharmaceutical Industries" *(Please provide cheque details)* Bank : Cheque No : Date :

COMPLAINT SUBMITTED BY:

Signature :
Name :
Designation :
Date :

Check list

Documents to be submitted in 6 complete sets when filing a complaint:

- ☐ Ethics Complaint Form (M1/16) duly completed and signed by CEO of the Complainant Company
- ☐ Promotional Material(s)/advertisement(s) with alleged breaches
- ☐ Copies of prior communications with Defendant Company
- ☐ Cheque for RM1,500.00 being Administration Fee addressed to "Malaysian Organisation of Pharmaceutical Industries"

STANDARD OPERATING PROCEDURE

STANDARD OPERATING PROCEDURE

LODGING OF COMPLAINTS & ADJUDICATION BY MOPI

1. The Complainant, Party A (MOPI Member or 3rd Party) should first initiate contact with the Member Company, Party B alleged to be in breach of the MOPI Code of Ethics to settle the matter. Party B should acknowledge the complaint within 1 week and settle the matter with Party A within 1 month.

2. If both parties are unable to settle the dispute/disagreement, Party A can lodge a complaint with MOPI against Party B, and this must be made in writing and submitted by the CEO of Party A. Sufficient copies of complete documentation comprising of the following should be submitted:
   - 2.1 Using the prescribed MOPI format
   - 2.2 Documentary evidence of alleged breach/es
   - 2.3 Documentary proof of communications between the 2 parties
   - 2.4 Administrative Fee ofRM1,500 (Non Refundable)

3. The MOPI Secretariat will acknowledge receipt of the complaint within 1 week. MOPI will write to Party B informing them of the complaint received, and request for a response.

4. would be The Complaints Review Committee comprising of a Vice President and 2 Exco members formed to review and adjudicate the complaint. Should one or more of the 3 committee members be deemed to be interested parties, other Exco members would be appointed in their place.

5. The Complaints Review Committee would schedule a meeting, within 1 month of receiving the complaint, if the complaint is found to be valid. Both Party A and Party B alleged to be in breach would be invited to present their case at the meeting.

6. Party B if judged to be in breach of the Code by the Complaints Review Committee would be asked to discontinue the offending material or practice. A penalty commensurate with the nature and severity of the breach will be imposed by the Complaints Review Committee.

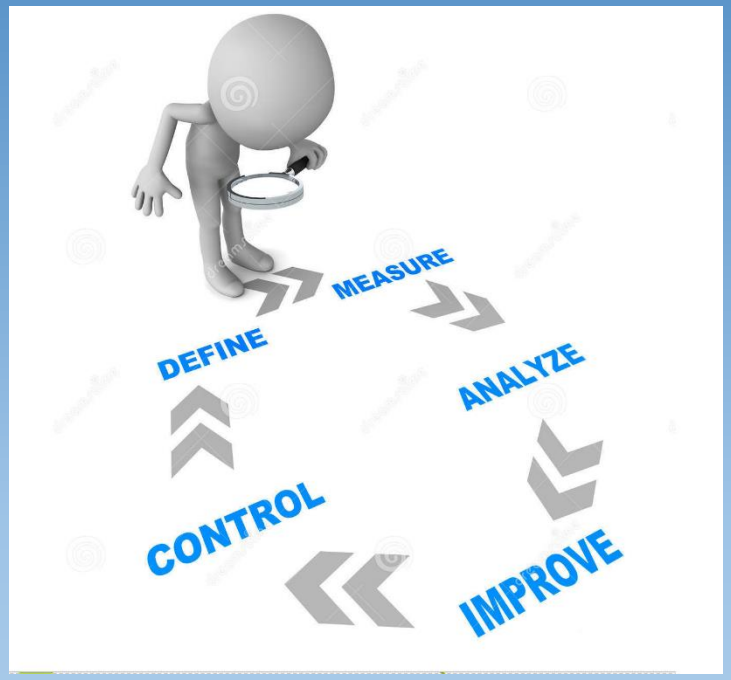
7. If Party B is dissatisfied with the Complaints Review Committee's decision, Party B may appeal to the Appeals Committee within 1 week of receiving the decision of the Complaints Review Committee with the submission of the supportive documents & Administrative fee of RM1,500.00 (non-refundable).

8. The Appeals Committee comprising of the President, a Vice President and a representative from the Bar Council would be formed to consider the appeal. Should the President, Vice President or both be deemed to be interested parties, other Exco members would be appointed in their place.

9. The Appeals Committee would schedule a meeting, within 1 month of receiving the complaint, if the complaint is found to be valid. Both Party A and Party B alleged to be in breach would be invited to present their case at the meeting.

10. Party B if judged to be in breach of the Code by the Appeals Committee would be asked to discontinue the offending material or practice. The penalty imposed by the Complaints Review Committee would stand.

11. The decision of the Appeals Committee shall be final.



FLOW CHART FOR ETHICS

Flow Chart for Ethics Complaint Adjudication

Party A contacts Party B on breach of MOPI Code

↓ Party B acknowledges receipt of complaint (within 1 week)

Party B responds to complaint

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Parties A & B unable to settle dispute (within 1 month)
Party A lodges complaint with MOPI

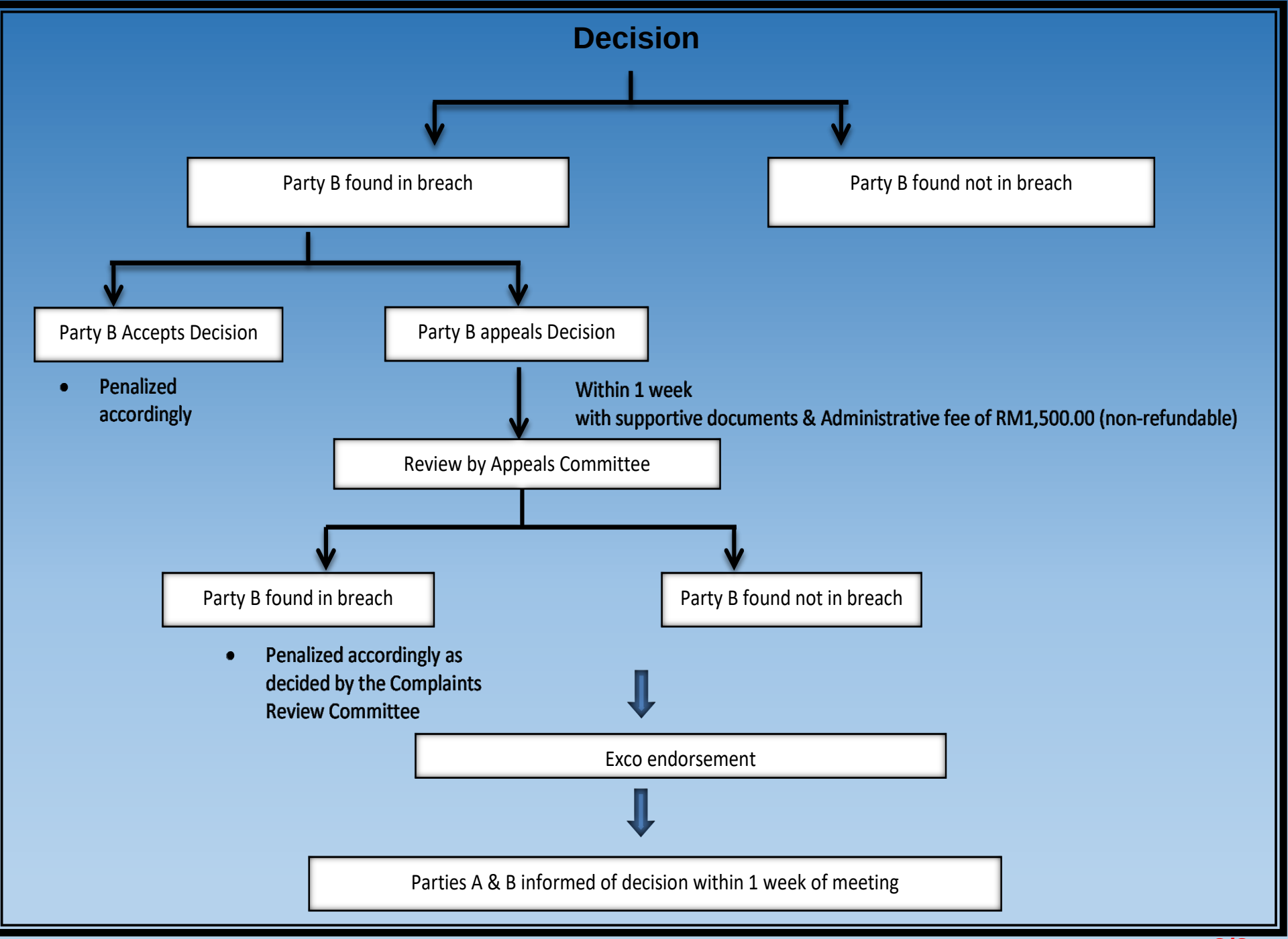
↓ With supportive documents & Administrative fee of RM1,500.00 (non-refundable)

MOPI Secretariat

↓

- Acknowledges Party A's Complaint (Within 1 week)
- Write to Party B for explanation
- Convene Complaints Review Committee meeting (Within 1 month of receipt of compliant)

Adjudication by Complaints Review Committee


Decision
Party B found in breach
Party B found not in breach
Party B Accepts Decision
Party B appeals Decision
Penalized accordingly
Within 1 week
with supportive documents & Administrative fee of RM1,500.00 (non-refundable)
Review by Appeals Committee
Party B found in breach
Party B found not in breach
Penalized accordingly as decided by the Complaints Review Committee
Exco endorsement
Parties A & B informed of decision within 1 week of meeting

Notes:

1. Complaints Review Committee

I. Comprises of a Vice President and 2 Exco Members.
II. In the absence of 1 or 2 of the 3 members, other MOPI Exco members would be co-opted.
III. If one or more of the members are interested party, other Exco members would be co-opted.

2 Ethics Appeal Committee

I. Comprises of the President, a Vice President and a representative from the Bar Council.
II. In the absence of 1 or 2 of the 3 members, other MOPI Exco members would be co-opted.
III. If one or more of the members are interested party, other Exco members would be co-opted.

3 Honorarium

A meeting allowance of RM200 and travel allowance would be paid to committee members attending the Complaints Review or Appeals Meeting.

4 Penalties

To be decided by the Complaints Review Committee depending on severity of breach:-

- Warning Letter
- Suspension from MOPI membership for a period of time
- Expulsion from MOPI

OPERATION OF THE CODE

Any complainant Member Company, or third party, should first initiate contact with the Member Company alleged to be in breach with a copy sent to the Organization, in order to discuss the issue and endeavour to settle the dispute / disagreement of any subject prior to forwarding such complaints in writing to the relevant authorities, or other organizations concerned, for further action by the aggrieved party.

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 and issues.)

OPERATION OF THE CODE *(Cont'd)*

Any mediation required by the Organization after having duly received confirmation that the Complainant has attempted to resolve the dispute with the Member Company said to be in breach of this Code shall be handled by the President and two Vice Presidents of the Organization. In the event a conflict of interest exists, then the non conflicted office hearers may choose suitable members of the Executive Committee of the Organization to mediate between the members concerned.

Every case should be treated as a fresh complaint.

The term 'repeat breaches' is defined as being 'the breaches of the same section or sections of the code with the same product claim'.