

市場行銷規範行政作業程序

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序言

IRPMA 會員為善盡醫藥業界之義務,訂定有「市場行銷規範」,以規範行銷醫 藥產品時之適當行為,並作為醫藥業自我約束的行為基準。茲為確保該「市場 行銷規範」之遵行,並落實醫藥業者自我約束,自我規範的精神,並制定「市 場行銷規範行政作業程序」以為具體執行之依據。

IRPMA 會員及其代理商、經銷商應一律接受本規範之約束。IRPMA 會員須每 年定期簽署同意書確認願意接受本規範之約束,並願意負責督促其代理商、經 銷商接受本規範之拘束。

如 IRPMA 會員("申訴會員")認為他會員("被申訴公司")或其代理商、經銷 商有違反本規範之行為時,建議宜於提出申訴前,先行與被申訴公司直接聯繫 澄清疑似違規案件。

違反前述任一自律規範及細則之會員,經調查確認,應就每一事件繳交罰款予 IRPMA,作為 IRPMA 推廣市場行銷規範之專款。

調解及仲裁程序

- (一) 自律委員會
- 自律委員會根據本會組織章程設立·由理事會授權管理與自律規範相關的 事務。
- 自律委員會通過之自律規範的建議、修訂和實施事項,經理事會核准後生 效並可執行。
- 3. 自律委員會主席和共同主席由理事會指派。

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- 自律委員會由十三名委員組成,自律委員會委員由其他十一名理事(非自 律委員會主席和共同主席)提名後,由理事會指派。
- 5. 每一理事可提名自己或其所屬公司之一名人員為自律委員會委員。
- 6. 自律委員會委員每屆任期兩年·
- 7. 自律委員會委員於任期屆滿後可再被指派為委員。
- 8. 遇理事出缺,其所屬公司之自律委員會委員可留任至任期屆滿。
- 遇自律委員會委員出缺,由所屬公司之理事提名遞補,以補足原任者留下 之任期。
- 10. 如遇需表決之提案,唯自律委員會委員具正式表決權,應於表決當日至少十五日之前,事先通知。
- 開會時間、出席人數及會議決議等事宜依理監事會議議事規則(如附件) 辦理。
- (二) 適用範圍

申訴之有效期限為自申訴會員知悉此違規事件起十二個月內。

- (三) 經由自律委員會調查及裁決
- 申訴會員認為被申訴公司有疑似違規案件,得填具申訴書(如附件),以書 面向秘書處要求自律委員會介入調查該疑似違規案件。
- 秘書處於收受申訴會員之申訴書後,應聯繫被申訴公司,取得進一步資料, 如有需要並應進行調查,秘書處應將所取得資料與調查之結果提供自律委員會參考。秘書處應於接獲申訴書後一個月內完成調查。如有必要,秘書處 得於調查時由第三方取得專業或法律意見。
- 自律委員會可依需要進行相關調查,或舉行會議聽取雙方意見。自律委員 會之調查應由秘書處作成機密書面記錄,以利日後查考。
- 自律委員會必須秉持公正、中立、客觀以及獨立,自律委員會委員不得與任何一方就該申訴案件私下聯繫、討論或會見。



- 自律委員會應於收到秘書處調查資料後二個月內,就申訴事件作成裁決。
 若裁決結果符合以下情形,
 - 5.1 申訴事件不違反現行市場行銷規範,但自律委員會認為現行規範應 修改,可直接朝修改方向進行。
 - 5.2 申訴事件違反現行市場行銷規範,但自律委員會認為現行規範已不 合時宜,而導致無法決議對該違規公司進行具體處罰。在此情形下, 則由IRPMA發函提醒該違規公司:全體會員公司都必須尊重、遵守 現行市場行銷規範;若會員公司認為現行規範應修改,則應提出自律 委員會討論,朝修改方向進行。
 - 5.3 申訴事件違反現行市場行銷規範,而規範內容並無不妥及需要修改 之處。在此情形下,可依據案件情節輕重,給予書面提醒、罰款或其 他自律委員裁決之適宜處分。自律委員會之裁決及罰款處分,應作 成書面,由自律委員會主席簽名後由秘書處執行。
- 若屬其他申訴案件(例如:匿名或經由第三方提出等),由秘書處與自律 委員會依本節第二點以下進行調查及裁決。
- (四) 覆議
- 如被申訴公司不能信服自律委員會之裁決,得於收到裁決書後十五日內以 書面向理事會申請覆議。
- 2. 理事會於接到覆議申請後,於二個月內作成覆議決定。
- 3. 理事會得就覆議申請之內容,修改原裁決及罰款處分。
- 理事會之覆議決應為最後裁決。被申訴公司不得再表示不服。

(五) 處罰之執行

 當自律委員會確認被申訴公司有違反本規範之情事,而被申訴公司無覆議, 秘書處應在覆議期間屆滿後對 IRPMA 會員公開覆議決定。如被申訴公司

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申請覆議,理事會確認被申訴公司有違反本規範之情事,秘書處應在理事 會確認違反本規範後對 IRPMA 會員公開覆議決定

- 每次違規處以新台幣二十萬元罰款。二十四個月內連續三次違規者,於第 三次違規時,自律委員會將行文該會員之母公司。
 當案件同時違反其他法令規範並經判定處罰,自律委員會將不會就相同違 規緣由重覆處罰。
- 若會員公司之代理商或經銷商有違反前述自律規範及細則之情事,經申訴 及調查確認者,會員公司應負保證付款之責任。
- 罰款應於三十日內繳交秘書處。如罰款未於三十日內繳交,自律委員會將 行文該會員公司之母公司。

Introduction

IRPMA members are dedicated in fulfilling the responsibilities of the pharmaceutical industry. The "Code of Marketing Practices" (hereafter "Code") was devised to moderate behaviors in marketing pharmaceutical products, and to serve as a

self-regulatory mechanism. In order to ensure conformity and the faithful pursuit of self-regulation of the industry, IRPMA members have established "Measures for Resolving Disputes" (hereafter "Measures") as the basis of concrete execution.

Acceptance and observance of the Code is mandatory for membership with IPRMA, distributors, commissioned agents or representatives acting on behalf of any IRPMA company. IRPMA members shall sign the agreement of the Code annually, and be willing to oversee that their distributors, commissioned agents or representatives abide by the rules set in the Code.

If one member of IRPMA ("the Requesting Party") suspects the activity of another member of IRPMA ("the Responding Party"), or its agent or distributor, to violate COP Guidelines, the Requesting Party is encouraged to contact the Responding Party directly to clarify the suspected violation before filing the complaint.

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A member who has been verified as in violation with the Code and Benchmarks may be fined, and the penalty would be used as IRPMA Code of Marketing Practices promotional fund.

Detailed Regulations & Procedures

I. Code of Practice Committee

- 1. The Committee is established in accordance with the IRPMA Article of Association and therefore authorized by the Board to manage the affairs related to the code of practice.
- 2. The suggestions, revisions and implementation matters of the code of practice adopted by the Committee become effective and enforceable after they have been approved by the Board.
- 3. The Chairperson and Co-chairperson of the Committee will be appointed by the Board.
- 4. The Committee should comprise thirteen (13) members who will be nominated by the other eleven (11) Directors (other than the Chairperson and Co-chairperson of the Committee) and then appointed by the Board.
- 5. Each Director may nominate himself/herself or a staff of his/her company as a Committee member.
- 6. The term of a Committee member is two (2) years.
- 7. The Committee members may be re-appointed after the expiration of the term.
- 8. If any of the regular Directors vacates their positions, the Committee member of his/her company may stay for the expiration of the term.
- If any of Committee members vacates their positions, a member should be nominated by the Director of his/her company to fill in and serve out the remaining term of any vacancies.
- 10. If a proposal requires voting, only the Committee members shall have the rights to vote, and a notification shall be given at least 15 days prior to the date of voting.
- 11. Meeting time, attendance and meeting resolution are subject to the "IRPMA Board of Directors and Supervisors Meeting Procedures



Rules" (as attached).

II. Statute of Limitation

The validity of complaint is within twelve months from Requesting Party's acknowledgment of the suspected violation.

III. Investigation and Arbitration by the COP Committee

- 1. For any suspected violation of a Responding Party, the Requesting Party may request, in writing, by submitting the required complaint form (see attachment) to the Secretariat, the COP Committee to investigate the dispute over the suspected violation.
- 2. After receipt of the complaint form, the Secretariat shall contact the Responding Party for more information and conduct an investigation, if necessary, and then provide the collected information and investigation result to the COP Committee for its reference and arbitration. The Secretariat shall complete the investigation within one month of receipt of the complaint form. If necessary, the Secretariat could take professional or legal advices for the investigation from third parties.
- The COP Committee may conduct all necessary investigations and hold conferences to hear the arguments of both parties. All the investigations should be recorded and kept confidential by the Secretariat.
- 4. The COP Committee should be just, neutral, objective and independent, and the members of the COP Committee should not contact, discuss or meet either party for the case privately.
- 5. The COP Committee should make a decision on the reported case within two months after receipt of the Secretariat's report. If,
 - 5.1 The reported case doesn't violate the current Code, but the COP Committee believes that the current Code should be modified. In this case, it may proceed directly in the direction of modification.
 - 5.2 The reported case violates the current Code, but COP Committee is unable to decide on a specific penalty for the



Responding Party since the current Code is considered as outdated and needed to be modified. In this case, IRPMA will send a letter to the Responding Party reminding that all member companies must respect and abide by the current Code. If member companies believe that the current Code should be modified, any suggestion should be raised for COP Committee discussion and proceed directly in the direction of modification.

- 5.3 The reported case violates the current Code, and the current Code is not inappropriate or in need of revision. In such cases, depending on the severity of the cases, IRPMA may issue a written reminder, a fine, or other appropriate degree of penalties decided by the COP Committee. The decision of the COP Committee and the imposition of fines shall be made in writing, signed by the Chairman of the Committee, and executed by IRPMA Secretariat.
- 6. For any other complaint, for example, anonymous, third party, or extra, the Secretariat and the COP Committee should conduct the investigation and make a decision in accordance with the above provisions.

IV. Appeal to the Board

- If the Responding Party disagrees to the decision rendered by the COP Committee, it may appeal to the Board within 15 days after receipt of the written decision.
- 2. The Board should discuss and make a decision on the appeal within two months after receipt of the appeal.
- 3. The Board may revoke or revise the decision and the penalty of the COP Committee by resolution.
- 4. The Board's decision should be final. The Responding Party may not further appeal against the decision of the Board.

V. Enforcement (Fines & Penalties)

 In the case that the COP Committee confirms the violation of the COP Guidelines and the Responding Party does not appeal against

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the decision, the Secretariat should release the decision to the members of IRPMA after the expiration of the appeal period. If the Responding Party appeals and the Board confirms the violation of the COP Guidelines, the Secretariat should release the decision to the members of IRPMA after the decision of the Board is made.

- 2. Each violation shall be fined NT\$200,000.
- 3. With three consecutive violations in a 24-month period, the COP Committee will issue a letter to the headquarters of the member company in violation at the third violation.
- 4. The COP Committee will not double punish member companies for the conduct that has already been punished for breaching other laws and regulations.
- 5. Member companies are responsible to pay the penalties of their distributors, commissioned agents or representatives who are in violation of the Code.
- 6. Fines and penalties shall be paid by the IRPMA member company in violation within 30 days. If the fines and penalties are not paid within 30 days, the COP Committee will issue a letter to the headquarters of the member company in violation.