2019

市場行銷規範
IRPMA Code of Practice

IRPMA

2019年6月 印製

IRPMA

2019
市 場 行 銷 規 範

中華民國開發性製藥研究協會

IRPMA

目　　錄

IRPMA

IRPMA 行為與產品行銷倫理指導原則

中華民國開發性製藥研究協會(International Research-based Pharmaceutical Manufacturers Association, IRPMA)會員公司致力投入醫療和生物製劑研究，以增進病患福址與提升病患照護品質為目標。會員藥廠在行銷、銷售或配送產品時，必須以符合倫理規範的方式執行，並遵守藥物與醫療相關的法律規範。

2012年IRPMA市場行銷規範之訂定，乃以下列指導原則為基準。所有IRPMA會員公司及其代理商皆應遵守IRPMA市場行銷規範，以確保與所有相關單位的正當互動。

1. 製藥公司應以病患的醫療與福祉為第一優先考量。
2. 製藥公司應達到法規單位對品質、安全性及療效的高標準要求。
3. 與相關單位或人士互動時，製藥公司必須確保其行為時時符合倫理、妥切適當並表現專業。製藥公司不得提供或供應任何會直接或間接造成不當影響的物資或勞務。
4. 製藥公司應負責提供正確、平衡且具科學效度的產品資料。
5. 產品行銷活動必須符合倫理、正確和平衡，且不可有誤導之虞。產品行銷資料必須包含正確的產品風險與利益評估及適當使用方法。
6. 製藥公司應尊重病患的隱私及個人資料。
7. 製藥公司贊助或支持的臨床試驗或科學研究，均應以追求新知為目的，以期能提升病患 利益、促進醫療科技進步。製藥公司應致力維護由產業贊助之人體臨床試驗的透明性。
8. 製藥公司應切實遵循所有適用之產業規範所明訂的條文與制訂精神；因此，製藥公司必須確保所有相關人員接受適當訓練。

前言

(i) 製藥工業研究、發展、行銷新藥以協助病患，符合倫理的處方藥行銷方式對此使命 深具影響。符合倫理的行銷方式能確保全球醫護人員可取得所需資訊、病患得以使用所需藥物，並保障處方開立及藥品使用係以病患最大醫療利益為原則。

(ii) IRPMA為一非營利性之非官方組織，會員包括歐、美、日、台開發性製藥公司。所 有會員公司及其代理商、經銷商都須遵守本規範所訂之倫理標準。

(iii) IRPMA市場行銷規範係依據International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) 2012年之版本，訂定廠商對醫護人員進行藥品行銷的道德標準，並提供與醫護人員其他相關單位（如醫療院所、病患組織）合宜互動的依據。

(iv) IRPMA市場行銷規範符合本地法令的規範。

(v) IRPMA會員公司有義務處理並改正任何違反相關規範之情形。會員公司的內部組織 與程序（包括員工訓練）須能確保各項行銷活動妥靠且符合倫理。非IRPMA會員亦可選擇採行IRPMA市場行銷規範與其申訴處理程序。

(vi) IRPMA開放接受任何與IRPMA市場行銷規範相關且符合作業程序的真實申訴。經調查，若有違反IRPMA市場行銷規範情事，將以迅速改正違規事項為處理目標。

(vii) IRPMA市場行銷規範從2012年9月1日起生效，以2012修訂版取代2007年版本。

IRPMA會員公司須在2012年9月1日前將此新規範導入各公司現行規範。

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1. 適用範圍與定義

1.1 適用範圍

IRPMA市場行銷規範涵蓋廠商與醫護人員、醫療院所和病患組織間的互動，以及行銷醫藥產品的行為。各會員公司應當遵守當地法律規定和相關規範。

Q&A 1-3

1.2 定義

IRPMA 規範用語

- 「藥品」係指所有須按處方或由醫護人員指導使用之藥物或生物製劑（無關專利或品牌）、或應用於診斷、治療或預防人體疾病、或能影響人體構造或機能者。
- 「行銷」係指由會員公司執行、舉辦或贊助之直接以醫護人員為對象的藥品行銷活動，包括透過各種溝通方式（含網路）行銷處方或推薦、供應或指示使用某產品。
- 「醫護人員」係指所有醫學、牙醫、藥劑或護理等專業人員，其專業職責包含開立處方、推薦、採購、供應藥品或給藥等項目。
- 「病患組織」基本上係指為病患、病患家屬或照護者表達利益為主要目的之非營利機構。
- 「醫療院所」基本上係指成員包含醫護人員的組織機構，負責提供醫療服務或執行相關研究。
- 「會員公司」指所有IRPMA團體會員、個人會員及其代理商、經銷商。

2. 互動基礎

2.1 互動基礎

會員公司與醫護人員及其他相關單位和人士之關係須以病患福利與促進醫療為基礎。互動關係須著重於提供醫護人員藥物訊息、科學和教育資訊，並支持醫學研究與教育。

施行細則 2

2.2 透明的行銷

不論是否具有行銷性質，任何由公司贊助的有關藥品及其用途的資訊，均須明確註明贊助廠商。行銷活動不可矯飾偽裝。

3. 查驗登記前的傳播與標示外用途

尚未取得該國許可前，任何藥品不得行銷販售及使用。

然而，此條款並不意謂欲限制醫療界及民眾取得科學和醫學發展的資訊，也不欲限制有關醫藥資訊之交流，包括：在學術會議中，對學術雜誌或一般大眾媒體發佈研究結果。同時，亦非限制對股東揭露產品相關訊息，或依據其他相關法律及規定，在對產品有所疑慮時，必須揭露產品資訊。

4. 行銷訊息的標準

4.1 產品訊息的一致性

藥品標示、包裝、仿單、資料、行銷文件等，其格式和內容通常受各國的法律規範限制。行銷活動內容應與當地核可之產品訊息一致。

開發中國家之醫護人員應能取得在已開發國家中流通之類似資訊，惟產品之行銷須符合當地核准的標示用途。

4.2 正確、不誤導

行銷資訊應該清晰、易懂、正確、平衡、公正、完備，使資訊接受者能獨立判斷該藥品的治療效果。行銷訊息須基於最新的科學實據，並清楚呈現，不得扭曲、誇大、 渲染或漏失以誤導讀者。更應避免語意模糊，謹慎使用絕對或概括性的敘述，並須適當舉證。盡量避免使用「安全」、「無副作用」等詞彙；使用時須提出佐證。

4.3 實證

行銷內容應有實據基礎，例如核可之標示或科學證據。對醫護人員正當提出之要求，會員公司須提供相關證明以回應，並秉持客觀態度，確實提供適當的資料。

Q&A 4-5

5. 行銷用印刷品

優先遵從當地法規。

5.1 行銷用印刷品

除條文5.2所述外，行銷用印刷品必須包含下列資訊：

- 產品名稱（通常為品牌名稱）；
- 主要成分（使用其核准之名稱）；
- 藥廠或其代理廠商之名稱與地址；
- 本行銷用印刷品的製作日期；
- 「處方資訊摘要」須包括核准的適應症、配合的使用劑量和使用方法，以及簡單明確的禁忌、警語和副作用說明。

Q&A 6
(2019年5月修編)

5.2 提醒性行銷用印刷品

提醒性行銷用印刷品指僅包含產品名稱與其適應症治療類別之簡短處方訊息。提醒性行銷用印刷品可免遵守條文5.1所述有關「處方資訊摘要」的規定。

Q&A 7
(2019年5月修編)

6. 電子資訊（包括影音資訊）

印刷品之相關規定亦適用於電子行銷資訊。藥品相關網站尤其應遵守以下規定：

- 藥廠和目標受眾應明確；
- 內容適合目標受眾；
- 呈現方式（內容、連結等）明確且適合目標受眾；
- 資訊需符合當地法律規定。

7. 與醫護人員的互動

7.1 活動與會議

7.1.1 科學及教育目的

由廠商舉辦或贊助之醫護人員研討會、年會及各項行銷、科學或專業會議（統稱「活動」），均須以告知產品訊息或提供科學或教育資訊為主要目的。

Q&A 8

7.1.2 國外活動

除非基於安全和合理考量，廠商不得主辦或贊助國外活動（包括贊助個人參加國外活動，見條文7.2）。邀請各國人士參加的國際科學討論會議和專題研討會則不在此限。

Q&A 9

7.1.3 活動中之行銷資訊

於國際科學討論會和專題研討會現場發送或於展示攤位提供的產品行銷資訊，可包括尚未於會議所在國登記上市或以不同條件登記的藥品資訊；惟須符合以 下規定：

- 應為主辦國法律規定所允許；
- 此會議必須確實為國際科學會議，非主辦國之講者及與會者須佔顯著比率；
- 尚未於主辦國登記上市之藥品行銷資料（不含如條文7.5.2所述的行銷贈品）須列出該藥品目前已核准上市的國家，並說明該產品目前在該國仍不可取得；
- 含處方訊息之行銷資料，若與主辦國核准之處方訊息（適應症、警告語等）不一致時，須特別註明此訊息與該國登記條件不同；
- 說明文件須列出該藥品已登記的國家，並指出在主辦國內尚無法取得。

7.1.4 適當的地點

所有的活動均須在適當的地點舉辦，以配合其科學與教育目的。廠商應該避免選擇有名或豪奢的場地。其他規定請見本規範第七條。

施行細則 4

Q&A 10-11

7.1.5 款待的限制

款待應侷限於附加於活動本身的點心或餐點，並符合下列規定：

- 僅提供與會者本人；
- 款待須為當地可接受的程度。

Q&A 12

7.1.6 娛樂

會員公司不得提供或支付其他娛興節目或社交活動來招待醫護人員。

Q&A 13-14

7.1.7 指引

一般而言，醫護人員接受的款待不應超過其願意自費負擔的水平。

7.2 贊助

會員公司可贊助醫護人員參與各項活動，但須遵守下列原則：

- 該活動須符合條文7.1之規定；
- 對醫護人員的贊助僅限於旅費、食宿及註冊報名費用；
- 不得補償醫護人員因參加會議所費時間的損失；
- 不得以贊助行為交換醫護人員開立處方或推薦、採購、供應藥品、給藥或行銷藥品的義務。

施行細則 5

Q&A 15-16

7.3 同行者

廠商不得支付與受邀醫護人員同行者的任何費用。

Q&A 17

7.4 服務費用

醫護人員可受邀提供會議或活動之諮詢顧問服務，例如演講、主持會議、參與醫學／科學研究、臨床試驗、訓練計劃、顧問團會議或市場研究等涉及報酬之服務。這些確實提供的顧問服務或勞務，必須符合下列條件：

- 提供服務之前必須先簽定書面合約，合約中載明提供服務的性質及支付標準；
- 須先確立該項服務需求的合理性，並以書面記錄；
- 顧問的遴選標準必須呼應預先確立的服務需求。顧問必須具備提供該項服務的專業；
- 聘用顧問人數不得多於達成該服務需求所需的合理人數；
- 不得以聘用顧問為誘因，影響開立處方、推薦、採購、供應藥品或給藥等行為；
- 提供服務的報酬應適當反應合理市場價值。

施行細則 3

Q&A 18-20

7.5 贈品與其他項目

7.5.1 禁止現金及個人饋贈

不得提供醫護人員金錢，其他金錢形式的贈品（如：禮券）或與醫護人員之專業無關，且屬於醫護人員個人利益的私人服務，亦不得餽贈醫護人員個人用品（如運動比賽或表演門票、電子產品等）。(2018年9月修編)

7.5.2 禁止行銷贈品

不得提供醫護人員行銷贈品（定義於施行細則 6. (2)）。
* 此規範自 2018 年 5 月 16 日起生效

Q&A 22-23

7.5.3 醫療用品

在不違反當地法規的情形下，廠商可提供能提升醫療服務或對病患有益的低價醫療用品，惟該用品不得用以補貼例常營運費用。醫療用品不能加印產品名稱(包含商品以及學名)，但可以加印公司名稱。

Q&A 24

8. 樣品

8.1 樣品

在符合當地法規情形下，廠商可免費提供藥品樣品給具有該藥品處方權的醫護人員，以增進病患照護。提供之藥品必須明確標示為樣品，以杜絕轉售或移作他用。

8.2 監控與責任

廠商須有適當的樣品監控系統，包括監控業務人員持有的樣品。廠商不得收集臨床資訊，亦不應提供醫護人員任何酬勞。

9. 臨床研究與透明性

9.1 透明性

會員公司須致力提升贊助的臨床試驗之透明性。一般公認，增進醫護人員、病患或相關人士對臨床試驗資訊之取得，將有利於公共衛生的提升。然而公布資訊須顧及個人隱私、智慧財產及合約，並符合法律規範及國家現行的專利法規。

公布臨床試驗時，會員公司應遵循由IFPMA、EFPIA、JPMA和PhRMA共同簽定之「透過臨 床試驗登記資料庫公布臨床試驗資訊之聯合聲明(2009)」和「於科學文獻刊載臨床試驗 結果之聯合聲明(2010)」相關規定。

9.2 與行銷活動之差異

所有人體臨床試驗皆須有合法的科學目的。不得藉人體研究之名行產品行銷之實。人體研究包括臨床試驗和觀察性研究。

施行細則 9

Q&A 30-33

10. 支持繼續醫學教育（CME）

CME可確保醫護專業人員可獲得治療領域和相關技術的最新最正確的資訊和觀念，以促進病患照護及提升醫療系統。教育會議必須以增進醫學知識為主要目的。據此，會員公司提供之財務贊助方為適當。

由會員公司提供的CME活動和計劃，內容須公正、平衡與客觀。活動設計必須容許各方表 達不同理論與論點。活動內容必須涵蓋促進病患照護的醫學、科學或其他資訊。

會員公司應適當遵循IRPMA市場行銷規範第七條條文規定。

施行細則 5

Q&A 15-16

11. 與病患組織之互動

11.1 範圍

製藥業與病患組織間存在許多共同利益。與病患組織的任何互動皆須符合倫理規範，且 須尊重病患組織的獨立性。

11.2 參與宣告

與病患組織合作時，會員公司須在合作開始之時便明確宣告其參與之事實與性質。會員公司不得要求成為病患組織或其下計劃之唯一出資人。

施行細則 10

Q&A 34

11.3 書面文件

會員公司對病患組織提供財務贊助或實質捐助時，須有書面文件說明贊助之性質，包括 所有活動的目的與資金來源。

11.4 活動

除協助病患組織達成其成立的使命之外，會員公司亦得協助病患組織舉行會議，惟會議 本質須為專業性、教育性和科學性。協助病患組織舉行會議時，會員公司須選擇適當的會議場所及地點以有助於資訊溝通。此外，會員公司提供之餐飲或點心須以當地水準來判斷為適當。

12. 會員公司的作業程序和責任

12.1 程序

會員公司應建立並維持適當的作業程序，以確保落實執行此規範及相關法規，並對所有行銷活動和資訊就其合規性進行審核及監控所有行銷活動和資訊。

12.2 訓練

會員公司須提供員工與其角色相關的訓練。

12.3 行銷溝通的核准權責

會員公司須指派具科學或專業背景的員工負責審核所有行銷溝通；會員公司亦可指派公司資深員工負責，但必須有具科學背景的適當人士提供科學意見。

13. 申訴及執行

13.1 申訴

若有違反IRPMA市場行銷規範之情事，歡迎各界提出申訴。

13.2 確保本規範實施的措施

IRPMA鼓勵會員公司採取適當措施，以落實此規範。

IRPMA

市場行銷規範施行細則

2012 年 7 月 18 日通過
2012 年 9 月 1 日生效

本施行細則係參考歐、美、日及其他鄰近國家之實施規範、本地現行市場常規以及社會各界對醫藥界之期望所訂定。本細則應由IRPMA市場行銷規範委員會定期（每半年）審議及修正， 交由理事會討論決議後執行。

1. 本規範實施將不包括OTC藥品之行銷，但需醫師處方或於醫院內使用之OTC用藥受此行銷規範之約束。

2. 廠商代表應時時維持高水準的倫理標準並展現專業行為，遵守醫院在相關範疇內的政策。

   Q&A 3

3. 支付醫護人員的服務款項：邀請醫護人員在座談會、諮詢委員會、專題討論會、研討會或類似活動中擔任講師／主持人／主席／小組或座談會討論成員／諮詢顧問時，所支付之酬 勞以每小時**新台幣五千元**為上限。（可包含討論所費時間。未滿30分鐘者，以半小時計算；未滿60分鐘者，以一小時計算。）

   會議主持人／主席：以每場會議**新台幣一萬元**為上限。

   小組／座談會討論成員：以每場會議**新台幣一萬元**為上限。

   講師同時擔任同一活動同一場地的會議主持人／主席／小組或座談會討論成員／諮詢顧問時，另行支付的酬勞以**新台幣一萬元**為上限。

   會議主持人／主席人數不得超過講師人數。會議主持人／主席人數及講師人數須與參加者人數取得適當平衡。原則上，主持人／主席人數應採最低 所需人數即可。主持人／主席須有促進討論進行的功能，而非僅止於引介講師出場。

   （國際演講者／顧問可依國際慣例支付）

   *此規範自2013年1月1日起生效 (2016年2月修編)

   Q&A 18-20

4. 適當的場地：不應在豪華奢侈場所舉行會議或活動。選擇活動場地時應根據下列標準：

   - 應選擇多數參與者可輕鬆抵達的場所；

- 應避免選擇以提供休閒活動、娛樂設施或奢華著稱的場所；
- 場地等級不得高於相當於五星級飯店的等級；
- 不得以包場或（及）預訂整個場地的方式提供娛樂招待活動，如表演、電影欣賞等；
- 以下列出部份不得選作會議場所的場地：
  - 運動場地：例如，高爾夫球場、鄉村俱樂部、體育場等；
  - 觀光點：例如，主題樂園等。
  - 娛樂場所：例如，夜店、戲院、卡啦 OK、KTV 等。

Q&A 10-11

5. 贊助本地及國際性之醫學會議、學術討論會及其他類似活動時：

   給付旅費和註冊報名費用應限受邀者本人，不得包括其眷屬或同行人士。

   給付機票時，其機票等級不應高於商務艙。

   若為兩天的學術活動則必須安排每半日至少三小時學術議程。

   若有爭議，會員公司須提供文件證明，如行程計畫、每日簽到表、費用相關文件收據（住宿費用、會議支出、演講者酬勞、演講者契約協議等）。

   Q&A 15-16

6. 贈品與其他項目

(1) 禁止現金及個人饋贈：不得提供醫護人員金錢或其他金錢形式的贈品（如：禮券），亦不得餽贈醫護人員個人用品（如運動比賽或表演門票、電子產品等）。

(2) 禁止行銷贈品：不得提供醫護人員行銷贈品，行銷贈品是指以行銷為目的，提供給醫護人員，加印公司或（及）產品名稱之價格低廉的小物品。

* 此規範自 2018 年 5 月 16 日起生效

(3) 醫療用品：學術用途的醫學期刊或教科書僅能致贈給個別醫院部門。至於其他醫療用品，若為價格低廉，且非用以補貼例常營運費用，同時對促進醫療照護或對病患有益時，則可提供給醫院或診所。且醫療用品不得提供給個別醫護人員做個人使用。

(4) 不得提供習俗性禮品，包括（但不限於）傳統節慶致送禮品給醫護人員、喪禮時致贈鮮花輓聯等。

Q&A 22-26

7. 捐款與學術教育捐贈必須與商業營運清楚分開。捐款或學術教育捐贈之意圖不可影響藥品 之採購、處方開立及訂價。

   所有捐款款項及學術教育捐贈不可匯入私人帳戶，或醫療機構的個別部門帳戶。

   所有捐款款項及學術教育捐贈只可給予於政府註冊之醫療機構、醫學會、協會及基金會。

   本協會強烈建議各會員公司建立適當之捐款與學術教育捐贈的內部審核機制。

   Q&A 29

8. 學術活動附屬之款待應僅限於附帶之點心或餐飲，且每人每日不應超過**新台幣 3,500 元**。若為國外之學術活動，原則上每人每日金額不應超過新台幣 3,500 元。然而，若是所赴國家之國際或當地規範金額限制高於新台幣 3,500 元，則可依循當地規範之標準。

   Q&A 12

9. 所有上市後藥品試驗必須經過人體試驗委員會同意。

   所有人體試驗包括上市後藥品試驗必須由會員公司之醫藥部門處長或臨床試驗經理核准 及管理。

   所有上市後藥品試驗必須登錄於IRPMA網站之上市後藥品試驗登記系統。相關研究文件必須載明人體試驗委員會之同意文號或日期。

   Q&A 30-33

   上市後藥品試驗之強制要件包含：

   - 調查計畫書須載明具科學性之研究目標
     - 具有特定的科學價值
   - 按研究內容預先決定樣本人數
     - 應有臨床及統計顯著意義

- 取得病患同意書
- 取得人體試驗委員會同意
- 根據優良臨床試驗準則實施
  - 至少須遵從台灣衛生署優良臨床試驗規範之要求
- 登錄於IRPMA網站
- 研究費支付額度必須與研究設計相稱，不得藉以影響處方開立行為
  - 須反應試驗主持人投入之時間與精力

上市後監視調查研究必須是非介入性質，且不得影響治療決定。

- 上市後監視研究必須客觀、有科學或醫學價值、且研究之設計或執行方式不得具有行銷性質。
- 上市後監視研究必須以蒐集產品安全性參數資料為目的。所研究的產品必須通過核准登記，且根據產品說明使用。
- 上市後監視研究屬於臨床試驗的一部份，藥廠代表唯一參與的部份在於建議或找出適合參與該研究的醫護人員。研究必須由藥廠的醫藥部門負責管理。
- 上市後監視研究必須有正式的計劃書，並包含資料蒐集與報告撰寫二項要件。
- 廠商計劃執行上市後監視研究時，必須登錄於IRPMA網站之上市後藥品試驗登記系統。
- 只有產品核准適應症適用的病患才可參加上市後監視研究。
- 醫護人員必須完全以臨床判斷作為開立處方的依據。分配病患接受不同治療方式時，必須根據現行做法進行分配，而不是在計劃書中事先指定。同時，病患是否參與研究之決 策應與處方開立互相獨立。發送試用品或免費產品不得列為上市後監視研究的一部分。

- 支付給醫護人員的任何費用都必須合理且與提供的勞務相符。不可用處方開立的數量作 為支付依據。
- 研究結果必須立即提供給參與研究的醫護人員，不可無故拖延。
- 研究相關文件均應註明人體試驗委員會的核准號碼或核准日期。
- 應確實遵守藥品優良臨床試驗規範。
- 應取得病患同意書。

市場調查之必要條件包含：

- 須採取科學研究方法
  - 抽樣方法
  - 資料蒐集方法
  - 分析方法
- 樣本人數：通常採用具代表性的小樣本
- 取得受試者同意書
- 不得蒐集可辨識個別受試者之醫療資訊（如療效、有效性或安全性資料）
  - 禁止蒐集個人資料
- 若以病患為受試者，則調查必須由獨立之第三者執行
- 不得作為對病患宣傳之工具
  - 不得提及品牌或藥品複方名稱
- 只能進行以研究為目的之調查，且溝通方式僅能由受試者對調查委託者之單向溝通
  - 試驗委託者不得逕自與個別受試者（病患／醫師）聯繫
  - 准予分享一般報告
- 不得影響受試者的看法與行為
- 研究費支付之款項必須與研究設計相稱，不得藉以影響處方開立行為

病患支持計畫(Patient Support Program/PSP)之定義

病患支持計畫係指直接與病患或病患照護者互動/接觸之服務，用以協助其用藥及/或疾病管理(例如服藥順從性、疾病之認識及衛教)，或是提供醫護人員支援以幫助病患。

病患支持計畫也可包含會員公司提供協助以減輕病患藥品方面的財務負擔 (例如補助或折扣方案)。

病患支持計畫應著重於增進病患照護、改善醫療系統及達成健康照護之目標，而非用於促銷藥品及/或影響處方判斷。

(2019年1月修編)

病患支持計畫之基本要求：

- 若欲蒐集病患之個人資料，病患及醫師須簽署同意書。
- 病患之隱私須受保護。
- 建議由第三方單位辦理，且該單位須能保障病患之隱私及分辨與通報不良反應事件。
- 藥物安全監視人員須參與病患支持計畫之啟動及管理以確實監測及通報不良反應事件。
- 醫護人員不得因招收病患加入支持計畫而獲得金錢或任何有價物品之報酬。

Q&A 35

10. 公眾衛教活動對公眾進行一般醫藥相關教育時，例如：提高疾病意識等，藥廠有責任維持最高倫理標準並遵守相關法律規定。

    台灣藥事法禁止對一般大眾推銷處方藥物。直接針對一般大眾的文宣教材，內容不應包含特定產品資訊，而應著墨於特定疾病狀況或治療領域。這類文宣教材不得用來推銷特定產品；但內容必須真實、正確和平衡，確保內容充份涵蓋其他現有替代治療方式的優缺點。

    公眾衛教活動的主要任務在於將最新、有實證依據、且公正的現有資訊傳遞給一般大眾。任何相關的重要訊息都不可缺漏。訴求點不應誇大超出科學證據能佐證的範圍。內容應極力避免含混模糊。惟有以最新實證為依據、具正確性、無誤導之嫌的科學資料，才可以納入文宣教材中。教材必須經過良好編輯並提供索引，以便與經科學驗證的相關數據資料交互參考。所有教材都必須建議民眾應向醫護人員諮詢有關個人健康狀況或疾病治療方面的問題。

    由會員公司贊助的教材及（或）活動，會員公司應盡一切可能明確傳達其贊助者的身份。

    * 此規範自 2013 年 1 月 1 日起生效

    Q&A 32

上市後藥品試驗登記系統

公司名稱	
計畫編號	
研究題目	
主要目的	
試驗中心數	
研究期限 起始日期/預計結束日期	
病患人數	
人體試驗委員會之同意日期	
公開發表之計畫/日期	

*所有欄位皆須填寫

常見問題

1. 適用範圍

Q1: 與大眾溝通事宜是否也在IRPMA市場行銷規範的範圍內？

A1: 是的。IRPMA市場行銷規範包含有關病患衛教材料的指導原則。根據藥事法第69條規定，藥廠不得直接對大眾推銷處方藥。會員公司應當遵守當地法規。

Q2: 何謂IFPMA？

A2: IFPMA為一全球非營利性之非官方組織，由27家跨國大藥廠及51個各國製藥廠協會所組成。IFPMA會員公司及會員協會均須在符合當地法規的情況下，遵守IFPMA市場行銷規範。（IFPMA網站：www.ifpma.org）

Q3: 哪些類型的互動或活動不在IRPMA市場行銷規範範圍之內？

A3: 以下活動不在本規範限制範圍之內：
- 直接對大眾行銷不需處方箋之自我醫療OTC藥品的活動
- 有關藥品供應的價格或交易條件，包括對藥品商業採購者之促銷或行銷活動
- 某些類型之非行銷性資訊或活動
- 醫療器材的行銷推廣

2. 學術活動

Q4: IRPMA市場行銷規範可否允許產品銷售文宣上包含不同產品的比較資訊？

A4: 可以，但有關產品比較資訊必須謹慎使用。所有產品比較資訊必須清楚、正確、平衡、公正、與時俱進且客觀，以具公信力的科學證據為依據，並且可經證實。比較性數據和聲明資料必須主要依據經周全設計的臨床試驗結果，該等試驗應為具直接比較和隨機對照性之臨床試驗(head-to-head randomized controlled clinical trial（RCT)），或對照性臨床試驗的統合分析結果(meta-analysis of RCTs)，且引用結果必須彼此一致。其他高品質醫學證據亦可作為比較資訊的依據，亦即，由數個世代研究結果所做的系統性文獻回顧

(systematic review of cohort studies)，且其結果需經專業同儕審查學術期刊證實，並不得與已存在之直接比較和隨機對照性之臨床試驗(head-to-head RCT(s)，或其統合分析(meta-analysis of RCTs)之結果相牴觸。比較過程中所有引用的證據均應具備客觀合理根據。比較性數據和聲明資料必須具備統計上的顯著性。如差異不具統計上顯著性，則於呈現時不得誤導使他人誤認。比較性數據和聲明資料不得誤導，內容須符合當地衛生主管機關核准的產品處方資訊，且不應詆譭其他產品或藥廠。受比較產品之資訊應被充分揭露於行銷資料中，以確保其公平及客觀性。若使用被比較藥廠的產品品牌時，須先取得該公司書面同意。

(2019年3月修編)

Q5: IRPMA市場行銷規範是否允許在行銷資料中引用言論？

A5: 是的。引用醫學或科學文獻或個人言論時，應保持原意，並提供確實的來源（若內容須修改以符合法律規定，則須註明引語內容已經修改）。引用言論不應改變或曲解原作者 或研究人員之原意。

Q6: IRPMA市場行銷規範是否視翻印文章(Reprint)為行銷用印刷品？

A6: 否。若單獨呈現翻印的科學或醫學文章給醫護人員，因其並非藥廠所製作，故該文章本身不視為行銷用印刷品。但是若與　行銷用印刷品一起呈現給醫護人員，則翻印文章便視為行銷用印刷品之一部分，應確保整體呈現符合第5條之規定。附在行銷用印刷品中的任何科學或醫學研究文獻都應清楚標示出處索引。附於行銷用印刷品中之所有翻印自研究文獻的圖稿（包括圖表、插圖、照片或表格），應明確註明出處並忠於原圖。

(2019年5月修編)

Q7: 「簡短處方訊息」的定義為何？

A7: 「簡短處方訊息」須與產品仿單內容相符，不得包含任何產品推銷訴求。

(2019年5月修編)

Q8: 贊助專題研討會、學術討論會或其他醫療學術演講會時，住宿及參加人數是否有上限？

A8: 根據IRPMA市場行銷規範7.1，由廠商舉辦或贊助之活動應以提供科學或教育資訊為主，會議及住宿地點應適當選擇，避免使用奢華之地點。

Q9: 廠商主辦或贊助醫護人員出席國外活動，在何種條件下方為適當？

A9: 廠商主辦的活動須符合下列條件：

(a) 邀請參加的外國醫護人員人數應佔顯著比例。在國外舉辦活動須基於合理或安全的 考量；

(b) 此活動之主、客觀資源或專才不在本國境內。

Q10: 若為一日之學術活動，而與會者因交通問題無法於當日返回，應該如何處理？

A10: 在選擇活動地點時，應當考量交通便利性。然而，若上述情況發生，可提供給當日返回有困難之與會者住宿，但不應安排其他的社交活動。

Q11: 某醫學會舉辦其年度大會，地點安排於日月潭，與會者除了台灣，也邀請來自中國大陸的醫護人員。會員公司可以贊助此活動嗎？

A11: 會員公司贊助科學資訊會議之目的是持續支持醫護人員專業發展，以增進病患照護或醫療服務品質。然而，在觀光景點、奢華度假場所或飯店舉辦此類會議，將造成大眾對於會議主辦單位及贊助單位的負面觀感根據IRPMA施行細則第4條，以“觀光景點”為活動或會議場所被視為“不適當”。地點的選擇，不因受邀與會者來自台灣以外而有所放寬。就地點而言，會員公司不應贊助在任何觀光景點舉辦的會議活動，地點包括但不僅限於日月潭、墾丁、太魯閣等

(2016 年 2 月 新增)

Q12: 「所有款待僅限於學術活動附屬之點心或餐點」，「學術活動」的定義為何？

A12: 學術活動應如IRPMA市場行銷規範7.1.1所定義。與醫療人員之午晚餐會議是被允許的，因為醫護人員工作繁忙，獲取資訊時間有限。惟這些餐會之目的須以教育、提供科學資訊或討論業務議題為主，但此類型餐會並不屬於「學術活動」（見第7條）。這些特定會議必須事先同意或於會後紀錄。於上述會議之餐點或點心，每人每日不應超過新台幣3,500元。

Q13: IRPMA市場行銷規範禁止對醫護人員或相關人士提供休閒娛樂或社交活動。這項規定是否有例外？

A13: 沒有例外。會員公司企劃會議時，可提供附帶的餐飲點心，但其重要性不得超過會議主旨。會員公司也不得贊助參加音樂會、提供娛樂票券、或支付任何形式的娛樂活動。若會議場地中有背景音樂或當地演出，只要不是由藥廠支付且不影響會議進行，則可被允許。

Q14: 與醫護人員的社交活動，如：高爾夫、音樂會等，是否允許？

A14: 根據IRPMA市場行銷規範7.1.6，會員公司不得提供或支付其他娛興節目或社交活動來招待醫護人員。款待應侷限於附加於活動本身的點心或餐點。

Q15: 贊助醫護人員出席國外活動是否有任何限制？

A15: 贊助醫護人員出席國外活動以一年二場會議為限。但若是代表藥廠在國際會議發表演講，而接受藥廠資助者，則不在此限。臨床試驗相關會議不在此範圍內。

*此規範自 2013 年 1 月 1 日起生效

Q16: 公司贊助機票時，若無商務艙機票可供選擇，只有頭等艙與經濟艙，該如何處理？

A16: 依據施行細則第5條，機票贊助等級不應高於商務艙。所以此種情況下旅客必須搭乘經濟艙機位。

Q17: 出席會議時，受邀者可否攜伴參加？

A17: 會員公司應勸導受邀者勿攜伴參加由公司主辦的活動。若受邀者攜伴同行，會員公司不得支付或補貼未受邀之同行者的任何旅費支出。未受邀之同行者亦不可參加由公司主辦的晚宴或餐會。例如，未受邀之同行者不得參加贊助晚宴及（或）必須進行商務討論的會議。

Q18: 邀請醫護人員擔任演講者或主持人的酬勞和相關旅行、食宿費用，是否需要簽訂書面契約？

A18: 是。根據IRPMA市場行銷規範7.4所定義，支付演講者或主持人酬勞之雙方須簽訂書面契約。此契約亦可用於決定費用應由何者支付之參考。

Q19: 本國演講者赴國外講演或在台灣舉辦的國際會議講演時，其酬勞支付應適用國際慣例或應遵循每小時新台幣五千元的上限規定？

A19: 國際慣例適用於在國外舉行的國際會議。此外，亦可適用於由國際組織主辦在台灣舉行的國際性活動，惟屬國際活動之附屬衛星會議者不在適用範圍內。任何不適用國際慣例的情形，支付本國演講者的酬勞應遵循每小時新台幣五千元的上限規定。

Q20: 如何計算另行支付的酬勞？

A20: 顧問委員會主席／主持人並兼任委員：支付上限為新台幣二萬元（委員部份每場最高支付新台幣一萬元，主席／主持人部份每場最高支付新台幣一萬元）。主席／主持人並兼任講師：講師部份每小時新台幣五千元，主席／主持人部份每場最高支付新台幣一萬元。

準備時間不應支付額外酬勞。

Q21: IRPMA會員公司針對醫護人員舉行之活動，議程當中安排何種主題是合適的？

A21: 活動主題應與增進醫護人員專業能力有關，對其日常醫療照護行為有益。

建議活動議程若有無關產品 / 疾病之主題，「產品 / 疾病相關之教育類主題」所需時間與「與增進醫療照護執業能力有關主題」所需時間的比例宜維持在3:1。

(2013年10月新增)

3. 贈品與其他項目

Q22: (本條刪除)

Q23: (本條刪除)

Q24: 哪些項目被歸類為醫療用品？

A24: 例如在診間可用得到的解剖人體模型，或醫學教科書，價格須低廉且能於病患有益。DVD 放影機或 CD 音響都不可。即使醫療用品符合要求，也只能偶爾為之。

然而，以下範例物品不得提供，如該物品

- 用以補貼例常營運費用，包含但不限於，手術手套 紙巾， 聽診器等類物品。
- 提供醫護人員個人使用，包含但不限於，DVD 機或 CD 音響、馬克杯、背包、文具、記事本、日曆等類物品。

Q25: 是否允許抽獎活動？

A25: 是。但根據IRPMA市場行銷規範7.5.1，廠商不得餽贈個人用品。因此抽獎活動之獎品須受限於醫療用品，個人用品則不被允許。

Q26: 可否提供「婚禮」禮金或禮品？

A26: IRPMA市場行銷規範已明確禁止提供醫護人員金錢餽贈，故不可提供婚禮禮金或禮品。

Q27: 若受邀參加婚禮宴會，應如何處理？

A27: 婚禮宴會為私人活動，任何由該活動產生之費用皆不可由會員公司支付。

Q28: 若未排定會議，是否允許業務代表提供餐飲予醫護人員？

A28: 推展市場行銷規範亦期望能增進醫藥代表之專業形象。因此提供醫護人員的餐飲僅限於 有教育目的或提供科學資訊之會議，因為醫護人員工作繁忙，獲取資訊時間有限。

4. 捐款與學術教育捐贈

Q29: 若醫院個別部門要求贊助國外演講者之費用（機票費、演講費等），應如何處理？

A29: 會員公司可依據實際發生的費用贊助主辦該活動之醫院、學會或協會，但不可經由醫院個別部門贊助或直接贊助演講者。

5. 上市後藥品試驗

Q30: 上市後藥品試驗之定義為何？

A30: 為防止以不同名稱之臨床試驗（觀察性試驗、回溯性試驗… ）進行產品促銷，任何相關人體的試驗都必須經過人體試驗委員會同意，以保障病患權益。並根據人體試驗委員會之定義來決定應登錄於IRPMA網站的上市後藥品試驗。

Q31: 須於IRPMA網站登錄的上市後藥品試驗，可能包括哪些試驗種類？

A31: 下列所述之試驗型式，均包含於IRPMA網站登錄的範疇之內：

- Phase IV臨床試驗
- 藥物醫療經濟學相關之臨床試驗（不含僅使用現有電腦資料庫進行分析之藥物經濟學 研究）
- 流行病學研究計劃
- 無介入性之上市後監視調查試驗
- 回溯性資料收集及分析研究計劃 所有在台灣藥品上市後執行之上述試驗，不論為台灣本地之研究或為多國多中心的試驗，均應登錄。

Q32: 經人體試驗委員會同意後，上市後藥品試驗應於何時登錄於IRPMA登錄系統？

A32: 上市後藥品試驗應於第一位病人篩選前登錄於IRPMA登錄系統。

Q33: 上市後藥品試驗登錄系統的項目須全部填寫嗎？（主要目的、試驗中心數、病患人數）

A33: 這些項目皆必須填寫，以利其他會員公司及民眾查詢試驗是否合法且非具行銷目的。

6. 與病患組織的互動

Q34: 廠商可以贊助特定的病患組織嗎？

A34: 可以。很多病患組織都接受不同廠商的贊助。然而有時會發生某個組織或某項活動只有 一家贊助廠商的情形。IRPMA市場行銷規範准許這種情形，但是廠商不得以獨立出資 為條件要求成為唯一贊助者。

Q35: 病患支持計畫有哪些種類？

A35: 常見的病患支持計畫包含：

- 服藥順從性計畫：聯繫同意加入該計畫之病患以確認其用藥管理之狀況。
- 服務專線：以備病患或病患照護者可聯繫會員公司，以取得更詳盡之醫療或特定疾病之資訊。
- 「衛教護理師」計畫：係會員公司從第三方聘用護理師直接協助病患進行適當之用藥及 / 或疾病管理。

IRPMA

IRPMA Code of Practice 2019

International **R**esearch-Based **P**harmaceutical **M**anufacturers **A**ssociation
(IRPMA)

IRPMA

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IRPMA Guiding Principles on Ethical Conduct and Promotion

The International Research-based Pharmaceutical Manufacturers Association (IRPMA) member companies engage in medical and biopharmaceutical research in order to benefit patients and support high-quality patient care. Pharmaceutical companies, represented by IRPMA, promote, sell and distribute their products in an ethical manner and in accordance with all the rules and regulations for medicines and healthcare.

The following Guiding Principles set out basic standards to inform the 2012 IRPMA Code of Practice which applies to the conduct of IRPMA Member Companies and their agents. This helps ensure that their interactions with stakeholders are appropriate.

1. The healthcare and well-being of patients are the first priority for pharmaceutical companies.
2. Pharmaceutical companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities.
3. Pharmaceutical companies' interactions with stakeholders must at all times be ethical, appropriate and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence.
4. Pharmaceutical companies are responsible for providing accurate, balanced, and scientifically valid data on products.
5. Promotion must be ethical, accurate, balanced and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use.
6. Pharmaceutical companies will respect the privacy and personal information of patients.

7. All clinical trials and scientific research sponsored or supported by companies will be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. Pharmaceutical companies are committed to the transparency of industry sponsored clinical trials in patients.

8. Pharmaceutical companies should adhere to both the spirit and the letter of applicable industry codes. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained.

Preamble

(i) The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and promoting new medicines. Ethical promotion helps to ensure that healthcare professionals globally have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.

(ii) The IRPMA is a non-profit, non-governmental organization comprising European, American, Japanese, and Taiwanese research-based pharmaceutical companies. Member companies and distributors, commissioned agents or representatives acting on behalf of any IRPMA member company, are committed to the ethical standards set out in this Code.

(iii) The IRPMA Code of Practice (the "IRPMA Code") based on the IFPMA Code of Practice 2012 version includes standards for the ethical promotion of pharmaceutical products to healthcare professionals, and helps ensure that member companies' interactions with healthcare professionals and other stakeholders, such as medical institutions and patient organizations, are appropriate and perceived as such.

(iv) The IRPMA Code is consistent with local laws and regulations.

(v) IRPMA member companies are accountable for addressing and correcting infringements under relevant codes. They should also ensure that internal structures and procedures (including adequate training of employees) are created to ensure responsible and ethical promotional activities. Companies not in membership with IRPMA may elect to be

subject to the IRPMA Code and its complaints handling processes.

(vi) The IRPMA is open to receive genuine complaints from any source on any aspect of the IRPMA Code, in accordance with its operating procedures. Where it is determined that there has been a breach of the IRPMA Code, the objective is to correct the matter as rapidly as possible.

(vii) Effective 1st September 2012, the IRPMA Code of Practice (Updated 2012) replaces the 2007 IRPMA Code of Marketing Practices. Member companies of IRPMA must incorporate this Code into existing internal codes no later than 1st September 2012.

* * * * *

THE IRPMA CODE

1. Scope and Definitions

1.1 Scope

The IRPMA Code covers interactions with healthcare professionals, medical institutions and patient organizations, and the promotion of pharmaceutical products. Member companies should of course, comply with these local laws, regulations and/or codes.

Q&A 1-3

1.2 Definitions

For the purposes of the IRPMA Code:

- "pharmaceutical product" means all pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) which are intended to be used on the prescription of, or under the supervision of, a healthcare professional, and which are 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, 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 methods of communications, including the internet.
- "healthcare professional" 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 product.
- "patient organization" means typically a not-for-profit institution that primarily represent the interests and needs of patients, their families and/or caregivers.
- "medical institution" means typically an organization that is comprised of healthcare professionals and/or that provides healthcare or conducts healthcare research.
- "member company" means all corporate members and individual members of IRPMA and distributors, commissioned

agents or representatives acting on behalf of any IRPMA member company.

2. Basis of Interactions

2.1 Basis of Interactions

Member companies' relationships with healthcare professionals and other stakeholders are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about pharmaceutical product, providing scientific and educational information and supporting medical research and education.

Benchmark 2

2.2 Transparency of Promotion

Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by a company should clearly indicate by whom it has been sponsored. Promotion should not be disguised.

3. Pre-Approval Communications and Off-Label Use

No pharmaceutical product shall be promoted for use in a specific country until the requisite approval for marketing for such use has been given in that country.

This provision is not intended to prevent the right of the 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.

4. Standards of Promotional Information

4.1 Consistency of Product Information

It is understood that national laws and regulations usually dictate the format and content of the product information communicated on labeling, packaging, leaflets, data sheets and in all promotional material. Promotion should not be inconsistent with locally approved product information.

Respecting the requirement that promotion should be consistent with the label and approved uses locally, healthcare professionals in developing countries should have access to similar data to those being communicated in developed countries.

4.2 Accurate and Not Misleading

Promotional information should be clear, legible, accurate, balanced, fair, and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the pharmaceutical product concerned. Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It should not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. Every effort should be made to avoid ambiguity. Absolute or all-embracing claims should be used with caution and only with adequate qualification and substantiation. Descriptions such as 'safe' and 'no side effects' should generally be avoided and should always be adequately qualified.

4.3 Substantiation

Promotion should be capable of substantiation either by reference to the approved labeling 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.

Q&A 4-5

5. Printed Promotional Materials

Where local regulations or codes are in force which define requirements, those take precedence.

5.1 Printed Promotional Materials

Printed promotional materials other than those covered in 5.2 below must include:

- the name of the product (normally the brand name);
- the active ingredients, using approved names where they exist;
- the name and address of the pharmaceutical company or its agent responsible for marketing the product;
- date of production of the printed promotional materials;
- "abbreviated prescribing information" which should include an approved indication or indications for use together with the dosage and method of use; and a succinct statement of the contraindications precautions and side effects.

Q&A 6

(Revised in May, 2019)

5.2 Reminder printed promotional materials

A "reminder" printed promotional materials is defined as a short printed promotional materials containing no more than the name of the product and a simple statement of indications to designate the therapeutic category of the product. For "reminder" printed promotional materials, "abbreviated prescribing information" referred to in 5.1 above may be omitted.

Q&A 7

(Revised in May, 2019)

6. Electronic Materials, including Audiovisuals

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
- country-specific information should comply with local laws and regulations.

7. Interactions with Healthcare Professionals

7.1 Events and Meetings

7.1.1 Scientific and Educational Objectives

The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an "Event") for healthcare professionals organized or sponsored by a company should be to provide scientific or educational information and/or to inform healthcare professionals about products.

Q&A 8

7.1.2 Events Involving Foreign Travel

No company may organize or sponsor an Event for healthcare professionals (including sponsoring individuals to attend such an Event as described in Article 7.2) that takes place outside of their home country unless it is appropriate and justified to do so from the logistical or security point of view. International scientific congresses and symposia that derive participants from many countries are therefore justified and permitted.

Q&A 9

7.1.3 Promotional Information at Events

Promotional information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the Event takes place, or which are registered under different conditions, provided that the following conditions are observed:

- Host country regulations should permit such an arrangement;
- 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;
- Promotional material (excluding promotional aids as described in Article 7.5.2) for a pharmaceutical product not registered in the country of the Event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally;

- Promotional material which refers to the prescribing information (indications, warnings, etc.,) authorized in a country or countries other than that in which the Event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally; and
- An explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

7.1.4 Appropriate Venue

All Events should be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. Companies must avoid using renowned or extravagant venues. The additional requirements set forth in Article 7 of this Code also apply accordingly.

Benchmark 4

Q&A 10-11

7.1.5 Limits of Hospitality

Refreshments and/or meals incidental to the main purpose of the Event can only be provided:

- exclusively to participants of the Event; and
- if they are moderate and reasonable as judged by local standards.

Q&A 12

7.1.6 Entertainment

No entertainment or other leisure or social activities should be provided or paid for by member companies.

Q&A 13-14

7.1.7 Guidance

As a general rule, the hospitality provided should not exceed what healthcare professional recipients would normally be prepared to pay for themselves.

7.2 Sponsorship

Member companies may sponsor healthcare professionals to attend Events provided such sponsorship is in accordance with the following requirements:

- The Event complies with the requirements in this Code as described in 7.1;
- Sponsorship to healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees;
- No payments are made to compensate healthcare professionals for time spent in attending the Event; and
- Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.

Benchmark 5

Q&A 15-16

7.3 Guests

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

Q&A 17

7.4 Fees for Services

Healthcare professionals may be engaged as consultants and advisors for services such as speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration. The arrangements which cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfill all the following criteria:

- a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services;

- a legitimate need for the services must be clearly identified and documented in advance;
- the criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service;
- the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
- the hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine; and
- the compensation for the services must be reasonable and reflect the fair market value of the services provided.

Benchmark 3

Q&A 18-20

7.5 Gifts and Other Items

7.5.1 Prohibition of Cash & Personal Gifts

Payments in cash, cash equivalents (such as gift certificate) or personal service (any service unrelated to the HCP's profession and that confer a personal benefit to the HCP) must not be offered to healthcare professionals. Gifts for the personal benefit of healthcare professionals (such as sporting or entertainment tickets, electronic items, etc.) must not be provided or offered.
(Revised in Sep, 2018)

7.5.2 Prohibition of Promotional Aids

Promotional aids (defined in benchmarks 6. (2)) should not be provided to healthcare professionals.

*This article becomes effective from May 16, 2018.

Q&A22-23

7.5.3 Items of Medical Utility

In accordance with local laws and regulations, items of medical utility may be offered or provided if such items are of modest value, do not offset routine business practices and are beneficial to enhancing the provision of medical services and for patient care. A Medical Utility must not bear the name of product (both of branded and generic name) but may bear the company logo.

Q&A 24

8. Samples

8.1 Samples

In accordance with local laws and regulations, free samples of a pharmaceutical product may be supplied to healthcare professionals authorized to prescribe that product in order to enhance patient care. Samples should be marked as such so that they cannot be resold or otherwise misused.

8.2 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 possession of medical representatives. Companies should not collect clinical data and should not make any payment to physicians.

9. Clinical Research and Transparency

9.1 Transparency

Companies are committed to the transparency of clinical trials which they sponsor. It is recognized that there are important public health benefits associated with making clinical trial information more publicly available to healthcare practitioners, patients, and others. Such disclosure, however, must maintain protections for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices in patent law.

Companies disclose clinical trial information as set out in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (2009) and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (2010) issued by the IFPMA, the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Japanese Pharmaceutical Manufacturers Association (JPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA).

9.2 Distinct from Promotion

All human subject research must have a legitimate scientific

purpose. Human subject research, including clinical trials and observational studies, must not be disguised promotion.

Benchmark 9

Q&A 30-33

10. Support for Continuing Medical Education

Continuing medical education (CME) helps ensure that healthcare professionals obtain the latest and most accurate information and insights on therapeutic areas and related interventions that are critical to the improvement of patient care and overall enhancement of the healthcare system. The primary purpose of an educational meeting must be the enhancement of medical knowledge and therefore financial support from companies is appropriate.

When companies provide content to CME activities and programs, such material must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognized opinions. Content must consist of medical, scientific or other information that can contribute to enhancing patient care.

Companies must follow Article 7 of the IRPMA Code where applicable.

Benchmark 5

Q&A 15-16

11. Interactions with Patient Organizations

11.1 Scope

The pharmaceutical industry has many common interests with patient organizations. All interactions with patient organizations must be ethical. The independence of patient organizations must be respected.

11.2 Declaration of Involvement

When working with patient organizations, companies must ensure that the involvement of the company and the nature of

that involvement is clear from the outset. No company may require that it be the sole funder of the patient organization or any of its programs.

Benchmark 10

Q&A 34

11.3 Written Documentation

Companies that provide financial support or in-kind contribution to patient organizations must have in place written documentation setting out the nature of support, including the purpose of any activity and its funding.

11.4 Events

Companies may provide financial support for patient organization meetings provided that the primary purpose of the meeting is professional, educational, and scientific in nature, or otherwise supports the mission of the patient organization. When companies hold meetings for patient organizations, companies must ensure that the venue and location is appropriate and conducive to informational communication. In addition, any meals or refreshments provided by a company must be modest as judged by local standards.

12. Company Procedures and Responsibilities

12.1 Procedures

Companies should establish and maintain appropriate procedures to ensure compliance with relevant codes and applicable law and to review and monitor all of their activities and materials in that regard.

12.2 Training

Companies should also ensure that relevant employees receive training appropriate to their role.

12.3 Responsibilities for Approving Promotional Communications

A designated company employee, with sufficient knowledge and appropriate qualifications should be responsible for approving

all promotional communications. In the alternative, a senior company employee(s) could be made responsible provided that he or she receives scientific advice on such communications from adequately qualified scientific personnel.

13. Infringement, Complaints, and Enforcement

13.1 Complaints

Genuine complaints relating to infringements of the IRPMA Code are encouraged.

13.2 Measures to Ensure and Enforce Compliance

IRPMA strongly encourages member companies to adopt procedures to assure adherence to this code.

Benchmarks of Code of Practice

Approved on July 18, 2012

Effective from September 1, 2012

The benchmarks of IRRMA Code is set referring to the Code of Practice of European countries, United States, Japan, and other neighboring countries, current local market common rules, and the social expectation to the pharmaceutical industry. This Implementing Regulations should be periodically reviewed and revised by the COP Committee of IRPMA (once half a year). The revision will be adopted after being discussed and resolved by the Board of Directors and Supervisors.

1. The marketing of OTC drugs is excluded, but OTC drugs used under physician prescriptions or in hospitals are included.

2. Company representatives should at all times maintain a high standard of ethical conduct and professionalism and should follow hospital policies in their respective territory.

Q&A 3

3. HCP Payment for Service: the honorarium of the Lecturer/ Moderator/ Chairperson/ Panelist/ Members of Focus Group or Advisory Board of symposia, congresses and alike may be paid up to **NT$5,000**/hr (might include the time spent for discussion. The time calculation can be round up as half hour if less than 30 minutes and one hour for time more than 30 minutes.) Moderator/ Chairperson: up to **NT$10,000**/specific venue.

   Panelist/ Members of Focus Group: up to **NT$10,000**/event.

   Additional payment to a lecturer for concurrently serving as Moderator/ Chairperson/ Panelist/ Members of Focus Group or Advisory Board in the same event at the same venue should not exceed **NT$10,000**.

   The number of moderator/chairperson cannot exceed the number of the lecturers. The number of moderator/ chairperson, and lecturers needs to be properly balanced with the number of participants. In principle, the moderator/ chairperson should at the minimum moderate questions and facilitate discussions, not just introduce the lecturers.

   (International norms will be applied for international speakers/ advisors).

**This article becomes effective from January 1, 2013. (Revised in February, 2016)*

Q&A 18-20

4. Appropriate venue: venues for the Event or meeting must not be lavish or deluxe. The selection of the location must be based on the following criteria:

   • should be easy for the majority of participants to reach

   • should avoid venues renowned for their leisure offerings or entertainment facilities or extravagant

   • be limited to the venue that is under/equivalent to 5 star hotel

   • blanket reservation and/or utilization of the entire place for entertainment or hospitality, e.g. shows, movies, etc. are prohibited

   • The following venues are considered inappropriate and not permitted (not limited to):
     - Sports Venues: e.g. golf courses, country clubs, stadiums, etc.
     - Tourist Attractions: e.g. theme parks
     - Entertainment Venues: e.g. nightclubs, theaters, karaoke, KTV

Q&A 10-11

5. In the case of sponsoring domestic or international symposia, congresses or alike:

   The travel reimbursement and registration fee should be exclusively limited to the attendees, not to family members or accompanied guests.

   The flight tickets being sponsored should be up to business class only.

   There must be at least 3-hour educational programs per half day to justify an overnight CME program.

   Programs, daily sign-in sheet of participants, documents/ invoices of expenses in relation to the event (such as hotel

expenses, meeting expenses, speaker fee, and speaker contract/agreement) must be provided as evidences when there is a dispute.

Q&A 15-16

6. Gifts and Other Items:

   (1) Prohibition of Cash & Personal Gifts: Payments in cash or cash equivalent (such as gift certificate) must not be offered to healthcare professionals. Gift for the personal benefit of healthcare professionals (such as sporting or entertaining tickets, electronic items, etc.) must not be provided or offered.

   (2) Prohibition of Promotional Aids: Promotional aids (such as gimmick) should not be provided to healthcare professionals. A promotional aid is a non-monetary item, printed with names of companies and/or products, given to healthcare professionals for a promotional purpose.

   **This article becomes effective from May 16, 2018.*

   (3) Items of Medical Utility: Medical journal or textbooks for academic use can only be offered to individual hospital departments. Other items of medical utility with modest value may be offered to hospital or clinics if such items do not offset routine business practices and are beneficial to enhancing the provision of medical services and for patient care. Other items of medical utility must not be provided to individuals for their personal benefit.

   (4) Cultural courtesy gifts are not allowed, including but not limited to, gifts offered to healthcare professionals on traditional festivals or flowers and funeral scrolls for funeral.

   Q&A 22-26

7. Donation and educational grants must be clearly separated from business. The intention of making a donation or providing an educational grant must not be associated with influencing purchasing, prescribing and pricing of medicines.

   Donation and educational grants must not be given to personal accounts or the accounts of individual departments of hospitals.

Donation or educational grants must only be given to the government registered medical institutions, medical societies, associations and foundations.

IRPMA strongly recommends each member company establishes a proper review and approval process for Donation & Educational Grant.

Q&A 29

8. The expenses of hospitality should be limited to refreshments and/or meals incidental to the main purpose of the Event and should not exceed **NT$3,500** person/day. For overseas events, the principle is that the amount should not exceed NT$3,500 person/day. However, if the amount limits of the international/local regulations in the visiting countries exceed NT$3,500 person/day, the regulations of the visiting can be followed.

Q&A 12

9. All PMS shall go through JIRB, IRB or Ethics Committee.

   All human studies including PMS must be approved and managed by Medical Director or equivalent CR Manager of member companies.

   All PMS must be registered on the website of IRPMA PMS registry system.

   IRB approval code or approval date should be shown on study-related documents.

Q&A 30-33

Mandatory Medical Components for Post-Marketing Studies:

- Protocol to address scientific objectives
  - To have specific scientific interest
- Pre-determined sample size justification based on study description
  - Should be based on clinical & statistical significant meaning
- Patient consent obtained

- IRB approval secured
- Follow GCP Guideline
  - Minimum to comply with TW DOH GCP
- Registry on IRPMA website
- Payment must be appropriate and according to study design. It must not be set to influence prescribing behavior
  - Must reflect time & efforts from investigators

Post-Marketing Surveillance Studies must be non-interventional, no interference on treatment decision:

- PMS studies must have scientific or medical merit and objectivity and not be designed for, or conducted as, a promotional exercise.
- PMS studies must be research which is intended to generate data on safety parameters of a product that has been approved for registration when used in accordance with the product information.
- PMS studies are part of clinical research and the only extent of involvement of medical representatives is in recommending or identifying healthcare professionals to participate in the study. The study must be managed through the company's medical department.
- PMS studies must have a formal protocol, a requirement for data collection and generation of a report.
- When a company is intending to carry out a PMS study it must be registered on the website of IRPMA PMS registry system.
- Only patients being treated for approved indications of the product are to be enrolled in the PMS study.
- Decisions by HCPs to prescribe the product should be based solely on their clinical judgment. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. Starter packs or free trade packs must not be distributed as part of the PMS study.

- Any payment to a healthcare professional must be reasonable and commensurate with the work involved and not based upon the number of prescriptions written.
- A prompt report on the outcome of the study should be provided to participating healthcare professionals without undue delay.
- IRB approval code or approval date should be shown on study-related documents.
- Follow GCP principle
- Patient consent obtained

Essential Components for Market Research:

- With scientific research methodology:
  - Sampling techniques
  - Data collection techniques
  - Analysis techniques
- Samples size: usually relatively small, and representative
- Subjects (respondents) consent required
- Must not collect medical information (e.g. efficacy, effectiveness or safety data) which can be linked to identifiable individuals
  - Individual data collection is prohibited
- If the subjects are patients, the research must be conducted by independent third party
- Must not be used as a tool for direct patient promotion
  - Brand and/or compound name should not be mentioned
- Can only be used for research purposes; with one-way communication from subjects to the sponsors
  - No communication from sponsor to individual subjects (patients/physicians)
  - General report sharing allowed
- Must not be used to influence subjects' view or behaviors
- Payment must be appropriate and according to study design. It must not be set to influence prescribing behavior.

Definition of a Patient Support Program (PSP)

A PSP is defined as a service for direct patient or patient carer interaction/engagement designed to help management of medication and/or disease outcomes (e.g. adherence, awareness and education), or to provide HCPs with support for their patients.

PSPs may also include the companies providing assistance to ease patients' financial burden of their medication (e.g. reimbursement or discount schemes).

PSPs should be designed and used to enhance patient care, benefit healthcare system and achieve healthcare outcome rather than to promote pharmaceutical products and/or to influence the prescribing decisions.

(Revised in Jan, 2019)

Basic Requirements for PSP

- Patients and physicians written informed consent required if PSPs involve the collection of personal data
- Patient privacy must be protected
- Recommended to be conducted by a third party, and that third party is capable of ensuring appropriate patient data privacy protection and identifying and reporting of AEs
- Initiation and management of PSPs requires the involvement of the personnel in charge of PV to ensure appropriate monitoring and reporting of AEs
- HCPs should not be paid or obtain anything of value for enrolling patients in PSPs

Q&A 35

10. Educational activities towards the general publicIt is the responsibility of pharmaceutical companies to adhere to highest ethical standards and applicable laws and regulations when educating the general public on general medical related aspects, e.g. by conducting disease awareness programs.
In according with the Pharmaceutical Affairs Act in Taiwan, the promotion of prescription drugs to the general public is prohibited. Direct-to-consumer materials that are not product specific, but are disease state or therapy area related, should not be used to promote a specific product but must nonetheless still be accurate, truthful and fair balanced, by ensuring pros / cons of available treatment alternatives are fully referred to.
The principal responsibility of educational activities to the general public is to provide the most current, evidence-based and unbiased information available. Important information must not be omitted if relevant. Claims should not be stronger than scientific evidence can support, and every effort should be made to avoid ambiguity. Only information that is based on the most up-to-date evidence that is scientifically valid and endeavor to avoid incorrect or misleading impressions of scientific information can be included and must be well-documented by reference to scientifically valid, verifiable data. All educational materials must contain a recommendation to consult with a healthcare professional to seek for guidance on their health status or disease treatment.
When sponsoring materials and/or activities, member companies shall undertake every effort to clearly indicate the sponsor.
*This article becomes effective from January 1, 2013.

Format for PMS Registry System

Company Name	
Protocol Number	
Title of Study	
Primary Objective	
Number of Sites	
Period of Study Starting Date / Expected Ending Date	
Number of Patients	
IRB Approval Date	
Publication Plan / Date	

*All items must be specified.

Questions & Answers

1. Application Scope

Q1: Does the IRPMA Code regulate communications with the public?

A1: Yes. The IRPMA Code provides guiding principle for patient education materials. However, according to Article 69 of "Pharmaceutical Affairs Act", direct promotion to the public is not allowed. Member companies should of course, comply with the local law.

Q2: What is IFPMA?

A2: The IFPMA is a non-profit, non-governmental organization comprising 27 leading international companies and 51 national and regional industry associations.

It is a requirement of IFPMA membership that member companies and member associations accept the conditions of the IFPMA Code and, subject to local laws and regulations, adopt codes that meet local requirements but are consistent with, and as comprehensive as, the IFPMA Code.

IFPMA Website: www.ifpma.org

Q3: Which interactions or activities of pharmaceutical companies are specifically outside the scope of the IRPMA Code?

A3: This Code specifically does not seek to regulate the following activities:

- Promotion of self-medication products that are provided "over-the-counter" (OTC) directly to consumers without prescription;
- Pricing or other trade terms for the supply of pharmaceutical products, including promotion and marketing of pharmaceutical products to commercial customers;
- Certain types of non-promotional information or activities; and
- Promotion of medical devices

2. Medical Education

Q4: Does the IRPMA Code allow for comparisons between different products to be included in promotional materials?

A4: Yes. Comparative statements must be used carefully. Any comparison made between different pharmaceutical products must be clear, accurate, balanced, fair, up-to-date and objective based on credible scientific data and be capable of substantiation. Comparative data and/or claims should mainly be based on well-established, head-to-head randomized controlled clinical trial (RCT) results or meta-analysis of RCTs or both, and these results should be consistent with each other. Alternative high quality evidences, i.e. systematic review of cohort studies that can be substantiated by peer-reviewed journals, should also be considered acceptable, but its conclusion should not overwhelm that from evidence, such as head-to-head RCT(s) or their meta-analysis, if they existed; the context of overall evidence of the topic should be considered for fair justification. Care must be taken to ensure that there is a sound statistical basis. Differences which do not reach statistical significance must not be presented in such a way as to mislead. Under no circumstances should comparative data and/or claims be misleading. It must be consistent with the local health authority-approved package insert. Any disparaging reference to other product or manufacturer must be avoided. The information of the comparison drug should be sufficiently mentioned in the promotional material in order for a fair and objective judgement. The use of comparison drug's brand name requires written consent from that company.

(Revised in Mar, 2019)

Q5: Does the IRPMA Code allow for quotations to be included in promotional materials?

A5: Yes. Quotations from medical and scientific literature or from personal communications should be faithfully reproduced (except where adaptation or modification is required in order to comply with any applicable codes, in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified. Quotations should not change or distort the intended meaning of the author or the significance of the underlying work or study.

Q6: Are reprints considered as printed promotional materials under the IRPMA Code?

A6: No. Reprints of scientific and medical articles, when used and presented to healthcare professionals as stand-alone documents, are not developed by pharmaceutical companies and as such cannot be considered as printed promotional materials. If, however, they are proactively presented to a healthcare professionals together, with other, printed promotional materials, they then become part of the printed promotional materials. It has to be ensure the whole package of the printed promotional materials should be presented in align with Code 5. In all cases, where promotion refers to, includes, or is presented together with scientific or medical articles or studies, clear references should be provided. Any reprint of artwork (including graphs, illustrations, photographs or tables) taken from articles or studies and included or presented with printed promotional materials should clearly indicate the source of the artwork and be faithfully reproduced.

(Revised in May, 2019)

Q7: What is the definition of “simple statement of indication”?

A7: Simple statement of indication should relate to the PI label and must not contain promotional claims.

Q8: Is there any restriction for accommodation, number of participants, or ceiling when sponsor a symposium, congress or other medical health care or educational program?

A8: According to IRPMA Code 7.1, the purpose and focus of all Events for healthcare professionals organized or sponsored by a company should be to provide scientific or educational information. The venue and accommodation should be selected appropriately; member companies should avoid using renowned or extravagant venue.

Q9: When is it appropriate and justified for a company to organize or sponsor an event for healthcare professionals outside of their home country?

A9: A company can only organize events involving travel if it is justified, i.e.:

(a) A significant proportion of the invited healthcare professionals are from outside of the company's home country, and it makes greater logistical or security sense to hold the event in another country; or

(b) The relevant resource or expertise that is the object or subject matter of the event is located outside of the company's home country.

Q10: In case of one-day program, if participants who have difficulties to return to their hometown on that day due to traffic problem, what shall we do?

A10: Basically companies should select an appropriate venue that is in city areas for convenient transportation. However, if the case above happens, we may provide accommodation for limited participants who cannot return on the same day. In this case, on the 2nd day, no other social program should be arranged for those participants.

Q11: One medical society schedules its annual scientific conference to be held at a hotel by Sun Moon Lake. In addition to HCPs based in Taiwan, HCPs from China have also been invited to join the event. Can member companies sponsor the event?

A11: The intent of sponsoring a scientific program at an independent meeting is to support continuous professional development of HCPs that will lead to improved patient care or healthcare delivery. However, a meeting organized in a tourist attraction, lavish/resort location/hotel can generate negative publicity for conference organizers and its sponsors.

As stated in the IRPMA Code of Practice Benchmark 4, "tourist attractions" as event or meeting venues are considered "inappropriate". The selection should be followed even with participants invited from outside Taiwan. In terms of location, member companies SHOULD NOT sponsor events at any tourist attractions, including , but not limited to, Sun Moon Lake, Kenting, Taroko Gorge… etc. (added in February, 2016)

Q12: "Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the Event". What is the definition of "the Event"?

A12: An Event is as defined by the IRPMA Code 7.1.1. Lunch and dinner meetings with healthcare professionals are allowed as healthcare professionals have very limited time allocated for information. Provided the main purpose of the lunch or dinner meeting is educational, to provide scientific information, or to discuss a business issue, it is not considered an Event (Article 7). The particulars of a meeting over a meal should either be agreed in advance or recorded retrospectively. Refreshments and meals connected with these activities should not cost more than NT$3,500 person/ day.

Q13: The IRPMA Code prohibits companies from providing entertainment, leisure and social activities to healthcare professionals and other stakeholders. Are there exceptions to this rule?

A13: No. When a company organizes a meeting, refreshments and/or meals incidental to the main purpose of the event can be provided. It would not be appropriate for a company to fund attendance at a concert, purchase of entertainment tickets or pay for entertainment in any form. However, if there is background music or a local performance at the venue where the event is taking place, which is not paid for by a pharmaceutical company and not interfering the main purpose of the meeting or event, this may be permitted.

Q14: Are individual social activities with healthcare professionals such as golf, music concert, etc. allowed?

A14: According to the IRPMA Code 7.1.6, no entertainment or other leisure or social activities should be provided or paid for by member companies. Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the Event.

Q15: Is there any consideration for sponsoring HCPs attending overseas event?

A15: Sponsorship of HCP to international events is limited to 2 meetings per year. This limitation does not include or apply to programs where a HCP's attendance has been funded (paid for his/her services) because the individual is giving a presentation at the international event on behalf of member company. Clinical trial related meetings are out-of-scope.

*This article becomes effective from January 1, 2013.

Q16: In regard to flight tickets under sponsorship, in case that there is no business class but only economy and first class available, what shall company do?

A16: According to the COP Benchmark Article 5, the flight tickets being sponsored should be up to business class only. Therefore, in this case the traveler must take economy class only.

Q17: While attending an event, are the invitees allowed to bring guests?

A17: Member companies must discourage invitees from bringing guests to company-organized events. In case they do, or in case an uninvited guest shows up, the company must not make any payments or reimburse/subsidize any costs associated with an individual accompanying an invitee, and uninvited guests are not permitted for the company hosted dinner/meal events. For example, the uninvited guests are not allowed to be part of the sponsored dinner and/or the meeting where business discussions must occur.

Q18: Is it necessary to have a contract with the invited healthcare professional as speakers or presenters for the payment of honorarium and related travelling and boarding expenses?

A18: Yes. The IRPMA Code 7.4 states that there should be a written contract about the payments to speakers or presenters. The contract can also be used as a reference to decide who should pay the expenses.

Q19: For the honorarium for local speaker to lecture overseas or to lecture in international symposia in Taiwan, should the international norms or a limit of up to NT$5,000/hr be applied?

A19: For international congress held overseas, the international norms should be applied. For the symposia held in Taiwan, the international norms can only be applied when the international event is organized by an international society and it is not a satellite program within the international event. Otherwise, the honorarium for local speaker should be limited up to NT$5,000/hr.

Q20: How to calculate additional payment?

A20: Chairperson / Moderator of the advisory board and concurrently serve as advisory board member: may be paid up to NT$20,000 (up to NT$10,000 per event as member, up to NT$10,000 as the Chairperson).

Chairperson / Moderator and concurrently serve as a Lecturer: NT$5,000/hr as a Lecturer, up to NT$10,000 as the Chairman / Moderator per event.

There is no additional payment for preparation time.

Q21: What types of topics are considered appropriate as part of a program agenda for IRPMA member company-supported events targeting healthcare professionals?

A21: Event topics should be related to professional capability building for the benefit of HCPs' daily healthcare practice.

For events that involve non-product / disease-related topics, the recommended ratio for the time spent on "product/ disease-related educational topics" versus time spent on "topics related to healthcare practice capability building" is 3:1 (added in October, 2013)

3. Gifts and Other Items

Q22: (Deleted)

Q23: (Deleted)

Q24: What kinds of items are envisaged as being items of medical utility?

A24: Items might include an anatomical model for use in an examination room, or medical textbooks, as they are of modest value and both primarily involve a patient benefit.

However, items would not be permissible if such items are

- Provided to offset routine business practice including but not limited to surgical gloves, tissues, stethoscopes and the like.
- Provided to individual HCP for personal benefit including but not limited to DVD or CD player, mugs, backpacks, stationary, diaries, calendars and the like.

Items should not be offered on more than an occasional basis, even if each individual item is appropriate.

Q25: Are lucky draws allowed?

A25: Yes. However, according to the IRPMA Code 7.5.1, companies should not give items for personal benefits. Therefore, the prizes for the lucky draw should be limited to items of medical utility, and no personal gifts allowed for lucky draw.

Q26: Could we provide cash gifts or gifts for “Wedding”?

A26: IRPMA Code indeed prohibits payments in cash to healthcare professionals. Providing gifts for wedding is not allowed.

Q27: What should I do if I am invited to a wedding party?

A27: The wedding party is a personal event, and any expense incurred from this should not be at the cost of the company.

Q28: Are sales representatives allowed to send or provide refreshments for healthcare professionals if the meetings are unplanned?

A28: The purpose of the IRPMA COP is to improve the professional image of medical representatives. Refreshments for HCPs are allowed only if the meeting is for educational purpose or to provide scientific information as HCPs have very limited time allocated to meetings.

4. Donation and Educational Grants

Q29: If the department requests sponsorship for a foreign speaker's expenses (airfare, honorarium, etc.), what shall we do?

A29: Companies can provide actual expenses to hospitals or associations organizing the events, but not through the department nor to the speaker directly.

5. PMS (Post-Marketing Study)

Q30: The definition of PMS?

A30: In order to stop commercial exercise under the different name of clinical studies (observational study, retrospective study...etc.), any study involving human subjects should be reviewed and approved by IRB to protect patients' right. PMS that has to be posted on the IRPMA website is as defined by the IRB.

Q31: What are the scopes of the post marketing studies that should be posted on IRPMA website?

A31: The following study formats are within the scope of IRPMA PMS registry requirement:

- Phase IV clinical studies
- Pharmacoeconomic / Healtheconomic related studies (excluding PE studies using existing computerized database only)

- Epidemiological studies
- Non-interventional post marketing surveillance
- Retrospective data collection and analysis

All above mentioned post marketing studies conducted in Taiwan, including Taiwan local study or multi-country; multi-center studies, should be posted.

Q32: Following the approval by the IRB, JIRB, when should the PMS be posted on IRPMA website?

A32: The PMS should be registered on IRPMA website prior to the first patient screening.

Q33: Are all items in the template for PMS registry system necessary? (The Objective, No. of Sites, No. of Patients)

A33: Those items are essential for other companies and the public to examine if the study is valid and not for marketing purpose.

6. Interactions with Patient Organizations

Q34: What happens if only one pharmaceutical company wishes to support a particular patient organization? Is this allowed?

A34: Yes. Many patient organizations are supported by a number of pharmaceutical companies. There may, however, be situations where only one pharmaceutical company wishes to support a particular patient organization or one of its activities. It would be acceptable under the IRPMA Code for that pharmaceutical company to be the only pharmaceutical company providing funding as long as that company did not make its support conditional on it being the sole funder.

Q35: The examples of PSP?

A35: Common examples of PSPs include:

i. Compliance programs where consenting patients on a medication are contacted to see how they are managing with their medication.

ii. Call centers where patients or patient carers can contact the Companies to obtain further information on medication or a particular disease area.

iii."Nurse Educator" programs where the Companies have hired third party nurses to interact directly with patients to help them properly administer medications and/or manage their disease.

IRPMA

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