Frequently Asked Questions

The purpose of this FAQ is to provide additional interpretation and further guidance towards the relevant provisions of the updated Code of Practice (the "Code of Practice" or the "Code"). This document is neither binding nor exhaustive by itself.

Practical examples and guidance offered must be read together with the spirit of the Code of Practice and all applicable laws and regulations. Each case must be considered on a case-by-case basis. Please apply ethical decision-making based on the principles of trust and take into account various considerations given when implementing the Code of Practice in your daily practice.

Section 4 – Methods of Promotion to Healthcare Professionals

1. **Is a gimmick (promotional item) considered a "reminder promotion"?**

   Per Section 2.1 of the revised Code of Practice, gimmicks and reminder promotions are two different types of promotional categories. A "reminder promotion" is a short advertisement targeting health care professionals ("HCPs") containing no more than the brand and generic names, a simple statement of indication(s) to designate the therapeutic category of the product, the company name, and the company contact information. A gimmick, which is a type of "promotional item," is a non-monetary item given for a promotional purpose (which does not include "promotional materials"). For details on use of promotional items, please refer to Section 6.2 of the Code.

   Examples of promotional items are pens, notepads, USB drives, T-shirts and mugs, etc.
   An example of promotional materials is a detailing aid.

2. **Do we need to include all the information listed under section 4.1 for "patient education material" that is distributed by HCPs to patients?**

   Patient education material is classified as "informational or educational items" under Section 6.3 of the Code. These materials should **not** be regarded as promotional materials under Section 4.1 even if they are distributed by HCPs to patients. Promotional material is issued for promotional purposes of the medicinal products. Disease awareness / patient education material should not be used similarly as product promotional materials.

Section 5.1 Symposia, congress and other communication means

1. **Section 5.1(b) of the Code states, "The fact of sponsorship by the company should be clearly stated in advance, at the meeting and in any proceeding." What should the company do if the third-party organiser of the meeting (e.g., medical society) does not allow the company to state its sponsorship? Can the company continue to support this event?**

   The involvement of a company in a scientific event should be clearly indicated in order to be transparent to the participants. Companies should carefully assess whether sponsorship / support are appropriate when disclosure of identity or involvement cannot be done.

2. **Can a company present or show investigational molecule information or drug development pipeline information in the exhibition booth? Does the requirement stated in 5.1(c) apply to "Sales & Marketing" booth only?**

   The disclosure of drug development pipeline information is not acceptable at Sales and Marketing booths or in a promotional context; however, drug development pipeline information,

limited to molecular names, therapeutic areas, and clinical trial status (e.g., Phase 1, 2, 3), is not considered to be scientific information and can be proactively shared at a medical booth. No pharmaceutical product should be promoted in Hong Kong or Macau unless marketing approval has been granted. The display of unapproved drug information in an exhibition booth in a congress is prohibited if it is intended for promotional purposes. The Code is not intended to restrict or limit the dissemination of investigational findings in scientific conferences or media communication. Companies should assess the intention of such investigational information when displaying it in any exhibition booth funded by the companies, and under no circumstances should companies promote off label use of pharmaceutical products.

Section 5.2 Travel, Venue and Accommodation

1. **What is the meaning of standard economy class? Can we arrange upgradable economy class air ticket when sponsoring healthcare professionals (travel time < 5 hours)?**

   Standard economy class is any seat located within economy class of an airplane, for example premium economy, business class and first class are regarded as outside of standard economy class by definition. The Code has not specified the booking class within standard economy class and the companies should practice sound judgment.

2. **Is standard economy class a mandatory if the one-way flight time is more than 5 hours? What does "prioritized consideration" mean?**

   If the one-way flight time exceeds 5 hours, standard economy class is not the mandatory travel class but it should be considered first when sponsoring HCPs to such event.

3. **Is there any exception to offer business class or above to healthcare professionals with health issue to attend events (travel time < 5 hours)?**

   Standard economy class is mandatory when sponsoring an HCP to attend an event with one-way flight time less than 5 hours. HCP's health status should be carefully considered by the company whether long haul flight is manageable by the HCP.

4. **Can we support the nomination or administration fee charged by local medical society to sponsor an HCP to an international congress?**
   The decision should be based on the company's internal policy.

5. **How should the companies define lavish or extravagant venue?**

   According to the IFPMA Note for Guidance on Sponsorship of Events and Meetings (the "IFPMA Note"), the venue must be conducive to the scientific and educational purpose of the meeting. The criteria to consider when assessing the appropriateness of a venue of an event (non-exhaustive) include:
   - The venue has the necessary business and technical facilities to accommodate the meeting and its participants.
   - The meeting facilities should only be accessible to intended audience.
   - In the case of cities that are both major scientific or business centres and locations highly desirable for tourists, it is important to select venues that are away from the main tourist spots.
   - The venue must not be renowned for its entertainment, sports, leisure or vacation facilities (e.g., golf clubs, health spas, Beach /River/ Lake side locations, or casinos).
   - The venue provides safe & secure accommodation when considering the chosen location.

- The venue must not be lavish even if the cost is low compared to other venues (e.g., ranking by the tourism department of the country and/or the average ranking by travel agencies can help with this assessment).

The IFPMA Note serves as guidance for the companies and the companies should apply their own judgement to determine if the venue is deemed appropriate.

6. If the event is organized by a third party in a lavish venue and with scientific/educational objectives, is it appropriate for the companies to sponsor it?

No, the Code is also applicable to those events organized by third parties (e.g., medical societies), and the company should follow the guidelines in section 5 to consider whether support or sponsorship deem appropriate.

7. What other specific comment or evaluation process HKAPI can provide to its member companies to streamline the interpretation of appropriate venue for event organized by a 3rd party?

According to the 7.1.4. of the IFPMA Code of Practice ("IFPMA Code"):

"All events must 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."

According to IFPMA, extravagant venues must be avoided, even where the cost might be low compared to other venues. If a venue is renowned for its entertainment, sports, or other leisure activities, and companies still choose to proceed with sponsorship, companies must be able to compellingly demonstrate and document that it nevertheless remains appropriate for scientific and educational meetings. In their assessment, companies should always consider how the public, media and/or authorities may perceive the venue, including whether it could be viewed as a solely luxury, touristic, holiday and/or entertainment facility.

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- In the case of cities that are both major scientific or business centres and locations highly desirable for tourists, it is important to select venues that are away from the main tourist spots.
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- The venue provides safe & secure accommodation when considering the chosen location.
- The venue must not be lavish even if the cost is low compared to other venues (e.g., ranking by the tourism department of the country and/or the average ranking by travel agencies can help with this assessment).

The IFPMA Note serves as guidance for the companies and the companies should apply their own judgement to determine if the venue is deemed appropriate.

Section 5.4 Fees for Services

1. **In case the healthcare professional is engaged for permitted services and no honorarium is provided, does a written contract or agreement still require?**

   It is recommended that agreement or written contract be signed between the company and the HCP which specifies the nature of the service to be provided and the basis of any payment involved.

2. **Can we pay for contracted HCP to attend speaker training workshop/meeting to train them to be our speaker in the upcoming speaker program?**

   No, please refer to COP 5.4
   HCPs 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.

3. **How should the selection criteria and process be documented when identifying a speaker for an educational event?**

   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 HCP's curriculum vitae or bibliography can be used as a reference when considering the selection criteria. The company should have an internal process in place to identify and approve the engagement of an HCP as a speaker for an educational event

4. **Will HKAPI share Fair Market Value (FMV) rates among different companies to provide a reference for determining a fair value in the Hong Kong market? Is there a plan to standardize FMV for HCPs? If not, what is the reason for not doing so?**

   Given restrictions under the Competition Ordinance (Cap 619), the HKAPI advises members to seek third-party support and conduct independent research and negotiations when entering into HCP service agreements. The Association cannot partake in related surveys or share pricing data due to rules against anti-competitive coordination. Members should utilize external references as needed to comply with regulations while pursuing these engagements.

Section 6 Promotional Items and Non-Promotional Items (such as Educational Items and Items of Medical Utility)

1. **Section 6.2 of the Code prohibits promotional items for prescription-only medicines. Does this also apply to the provision of pens and notepads in the context of company organized or third-party events?**

   No, pens and notepads can be provided to HCPs in the context of company-organized events for the purpose of taking notes during the meeting, but they must not bear the name of any medicine but may bear the name of the company providing them. In addition they must be of minimal value and only the necessary quantity for the purpose of the event are distributed. In third party organized events, the only time that company branded pens and notepads can be provided by the company is exclusively to the participants of a company-organized satellite meeting or symposium that takes place at the third party event.

2. **Some conference sponsorship packages include pens, conference attendee bags, and other promotional items with the sponsoring company logo on them. Is this still acceptable?**

No, even though the third party conference organizer is producing the promotional items and not the company itself, member companies may no longer distribute or sponsor company-branded conference pens, notepads, conference attendee bags, or other promotional items at third party events. If a conference sponsorship includes these types of promotional items, the sponsoring company must indicate that while the conference organizers can still use the sponsorship to pay for these types of items, the items cannot include sponsor companies' logos. Alternatively, sponsor company logos can be displayed on conference banners/signage and in conference programs for transparency to disclose company sponsorship.

3. What are examples of items of medical utility which offset business practices?

Items such as stethoscopes, surgical gloves, blood pressure monitors and needles are examples of routine business expenses, and they are expected to be supplied by the HCPs themselves or their employers.

Section 6.3 Non-Promotional Items

1. Why should non-promotional materials be free of promotional messaging and product branding? Why are we having more stringent requirements on non-promotional materials for patient use under our Code than the Undesirable Medical Advertisements Ordinance (UMAO) framework for drug advertisements?

This is fully in line with the international standard of IFPMA and to act with clear intent. Under Section 6.1 of our Code, all items (including promotional and non-promotional items) must be properly designed with clear intent. Thus, non-promotional materials shall be free of promotional elements to avoid disguised promotion. Different principles and requirements are applicable to materials of different nature, promotional or non-promotional materials, and shall not be confused with the intended purposes of the materials.

Since the 2019 Code revision, the requirement that informational and educational materials provided to HCPs for patient use must not be branded has already been put in place, unless the product's name is essential for the correct use of the item by the patient. Section 6.3 of our Code provides clarification as to the overall principle of non-promotional materials together with some non-exhaustive examples. We have also elaborated on the linkage to promotional messaging and product branding. The rationale is that non-promotional materials for patient use, whether distributed to patients directly or by HCPs to patients (whether to prescribed patients only or not), shall follow the overall principle of non-promotional materials under Section 6.3 of our Code:

Non-promotional items must not be designed or used to promote any pharmaceutical products with any promotional messaging and product branding. Examples of such items include disease awareness materials.

2. Section 6.3(a) provides that informational and educational items provided to HCPs for patient use can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item for patient. What does "product branded" mean?

Non-promotional information and educational items provided to HCPs for educating the patient or providing information to the patient must not contain any brand elements. Brand elements, such as brand colour, shape, name, slogan and logo are in general considered to be an element of the brand which do not provide additional information to the patient concerning the drugs prescribed or the diseases. Use of these brand elements are not allowed in non-promotional material. The rules against promotional information in non-promotional material applies equally to all pharmaceutical products and medical devices, whether or not the particular product

concerned represents the only molecule or the only device in the foreseeable future. Member companies should also refer to Section 1.8 of our Code.

3. How do you define perception?

Perception is determined by an objective standard. There are cases where a reasonable person would consider as in compliant with our Code and there are other cases which clearly violate our Code. But different cases will have different circumstances and all the relevant circumstances should be taken into consideration. Member companies are reminded to bear in mind the overall spirit and principles of our Code concerning the prohibition of using brand elements in non-promotional information and educational items.

4. How do you define promotion?

Promotion is an ordinary word and should be given its ordinary meaning. HKAPI shall not provide a definition to restrict its meaning. Member companies may wish to refer to the Decision Tree in Appendix for reference.

5. Is 1-page advertisement on medical newsletters to HCPs considered as "advertisement" or "promotional material" under COP guidance?

Content:
If the advertisement contains product information, it will be considered promotional in nature. However, if the advertisement focuses solely on discussing the disease without any mention of the product, it can be considered non-promotional.

Distribution channel:
If this material is intended for HCPs and it is not publicly available, it would fall under the guidelines outlined in COP section 4. (Printed and Digital Promotional Materials to Healthcare Professionals). However, if the same material is disseminated to the public, making it publicly available, the intended target audience shifts from HCPs to the general public. In such a case, there is a risk of violating the UMAO.

For guidance in properly categorizing material types and their compliance needs as set forth by the COP, please refer to the Decision Tree.

6. Can we compare drug class?

Any comparison of drug class would inevitably have the effect of showing a given product is more desirable than the others or that a given product is more superior. It is therefore promotional in nature and is not allowed. If the comparison is done in a fair and balanced manner, for example, a clear picture of the advantages and side effects of each drug class is shown, and the comparison does not aim at showing a given product is more superior than the others, it may be acceptable.

7. Can we mention frequent side effects in non-promotional items?

Mentioning frequent side effects of a product is allowed. But any comparison of side effects of different products should be avoided as the comparison will be perceived as promotional in nature.

8. Can we mention dosage information in non-promotional items?

When the material is used by the HCPs as part of his professional advice to the patient already prescribed with the drug, the dosage information will be considered as essential for the correct use of the product and is therefore allowed.

9. Can we list out all treatment options without comparison?

All the available treatment options should be presented in a fair and balanced manner, for example, the advantages and side effects of each of the treatment options should be clearly set out. However, no product should be included in comparing different treatment options. In presenting all the treatment options, care must be taken to ensure that the product brand names are not mentioned. Also, words suggesting that one treatment option is better than the others are not allowed. To give a non-exhaustive list, words such as “better quality of life”; “more effective”; “the best”; “traditional”; “the newest” should be avoided. All the relevant factors and circumstances will be taken into consideration in determining whether the treatment options are presented in a fair and balanced manner. Member companies should also take notice of Sections 3.2 and 3.3 of our Code.

10. If we provide non-promotional education on a first-in-class drug class, could it be perceived as promotional? Would it be considered a violation of the code if we mention the availability of drug treatment options in a disease booklet for a first-in-class product?

The critical factor in determining whether a presentation is considered promotional or not is the fairness and balance of its content, regardless of whether the drug being discussed is first in class or not.

11. Is information concerning improved quality of life allowable?

Member companies should adopt the “how” and “why” principle. Information concerning improved quality of life relates to an outcome or expected outcome of a product and this is related to why a particular product is used and not how a product should be used. Such information is considered to be promotional in nature and is therefore not allowed. It is also considered as information relating to efficacy. Information on efficacy of a product is not allowed.

12. How to distinguish efficacy information and mechanism of action?

If information on mechanism of action relates to how a product should be used, such information may be distributed by the HCPs to patients already prescribed with the product. Efficacy information is generally regarded as promotional and is not allowed.

13. Is it acceptable to have more in-depth information of a particular treatment and less information for other treatments?

No, this will be perceived as promoting that particular treatment with more in-depth information. Member companies must bear in mind that the information in a non-promotional materials must be presented in a fair and balanced manner.

14. For non-promotional materials intended for prescribed patients only, can we put the product brand name as a general exception under Section 6.3?

No, non-promotional materials for prescribed patients only are not exempted from the requirements under Section 6.3. All non-promotional materials for patient use, whether distributed to patients directly or by HCPs to patients (whether to prescribed patients only or not), shall follow the overall principle of non-promotional materials under Section 6.3 of our Code. A product brand name may only be used if it is essential for the correct use of the item by the patient. In this regard, member companies are also reminded to consider all relevant factors in the context and comply with all applicable laws and regulations including the UMAO.

15. Does the requirement under Section 6.3 apply to consumer products (non-drug) and over-the-counter ("OTC") drug products?

In line with the definition of “pharmaceutical product” under Section 2.2 of our Code and the IFPMA Code of Practice, the requirements under Section 6.3 apply to all pharmaceutical products, including OTC drug products. However, consumer products (non-drug) such as dietary supplements/nutritional products and cosmetics are not under the scope of our Code.

16. Can we include our product brand logos, brand colours and other brand elements linked to the product brand if we can justify the use of the product brand name is essential for the correct use of the item by the patient under Section 6.3?

Non-promotional materials must not be designed or used to promote any pharmaceutical products with any promotional messaging, product branding or indirect links such as product brand colouring. Product brand logos and brand colors or other brand elements which may be associated with the brand should be avoided. Product brand elements are diverse and the list is not exhaustive. Any elements which may be reasonably and objectively associated with the product brand should be avoided for non-promotional items.

However, if there is a specific need, such as highlighting red blood vessels, the use of red color can be deemed essential. Similarly, using the brand name of a device can also be acceptable if it is necessary to aid patients in correctly using the device. Determining the permissibility of such cases requires a case-by-case assessment based on the specific circumstances and needs involved.

17. Can you provide guidelines for using brand colour in non-promotional items?

Brand colour is in general an element which is reasonably associated with a brand. Therefore, use of brand colour is not allowed in non-promotional material. Where the colour has not become a clear element of the brand, use of the colour in non-promotional material for distribution by the HCPs to the patients prescribed with the drug is not objectionable, provided that the brand colour should not be used in non-promotional material in a way which may be perceived as promotional in nature. However, where a colour or a combination of different colour has become an element of a brand, such colour or combination of colour should not be used. Different shades of the colour may be used provided that use of the colour will not be perceived as promotional in nature, for example, when the colour may not be perceived as associated with a given brand.

If there is a specific need, such as highlighting red blood vessels, the use of red color can be deemed essential. Similarly, using the brand name of a device can also be acceptable if it is necessary to aid patients in correctly using the device. Determining the permissibility of such cases requires a case-by-case assessment based on the specific circumstances and needs involved.

18. Can we include images of the product or the device for proper usage training for a standalone injection guide and safety precaution booklets which contain the product brand name?

The use of product brand name for standalone injection guide and safety precaution booklets can be justified as being essential for the correct use of the item by the patient. Images of the product or the device may be shown provided that no brand logos, brand colours and any other brand elements are included.

19. Can we use celebrity in non-promotional material without mentioning brand elements such as brand name, brand colour and brand slogan, etc?

Celebrities are customary engaged as a marketing strategy to promote a particular product or service. Some companies may also have long collaboration relationship with a particular celebrity, the purpose of which is to create consistent marketing image for the product or service. On such premises, use of celebrity is promotional in nature. Further, celebrity's information, such as their image, name, and endorsement, should not be included in any non-promotional material.

20. Is a celebrity image considered as a brand element?

There is no exhaustive list of brand elements. Whether a celebrity image may be considered as a brand element will depend on all relevant circumstances of the case. One of the factors to consider is whether the celebrity would be reasonably and objectively associated with the product brand.

21. Does the Code allow the companies to mention mechanism of action (or mode of action) of a drug class/ molecule in non-promotional items?

Information concerning mechanism of action (or mode of action) can be quite diverse. The question must be understood from the perspective of why such information needs to be included in non-promotional materials distributed by the HCPs to the patients. Member companies should adopt the "how" and "why" principle in answering the question. Where the information on mechanism of action relates to how a product should be used, such information may be included in the non-promotional material provided by the HCPs to the patients already prescribed with the drug concerned. If the reason for including information relates to why the product should be used, then it is not allowed as it is promotional in nature. The same rule applies regardless of whether a particular drug is first in class. Member companies should bear in mind that information on mechanism of action is allowed if it relates to how a product should be used, not why a particular product is more desirable.

22. Can we include disease indication, therapeutic class, product class, manufacturing method, etc. in a patient booklet that contains the product brand name? Would this be considered differently if we use the INN (generic name) instead of the product brand name?

Member companies shall act with clear intent and properly design separate materials for different purposes. Under Section 6.3 of the Code, non-promotional materials are primarily for educational purposes and must not be designed or used to promote any pharmaceutical products with any promotional messaging, product branding or indirect links such as product brand colouring. Product brand name may only be used if it is essential for the correct use of the item by the patient and in compliance of all applicable laws and regulations including the UMAO. In addition to Section 6.3, other relevant sections of the Code such as Sections 12.2 and 12.3 should be considered to ensure fair balance and non-promotional intent. Member companies should consider all applicable laws and regulations including the UMAO which may define the contents and use of non-branded elements differently and consider if there may be a connection with the product as a whole. Member companies are reminded to be compliant with the UMAO and other applicable laws and regulations. The statutory enforcement of the UMAO is by the Department of Health (DoH). If a complaint case is received solely on UMAO issues, HKAPI may refer it to the DoH.

23. Can we include disease indication in a patient booklet for patient support program (PSP) which contains the product brand name?

Similar to the above, for the use of a product brand name in a PSP patient booklet, member companies should consider whether the product brand name is essential for the correct use of the item by the patient. For disease indication and other elements related to the program details,

other relevant sections of the Code such as Sections 12.2 and 12.3 should also be considered to ensure fair balance and non-promotional intent. Member companies should also comply with all applicable laws and regulations, including the UMAO, and consider whether linking the disease indication with the product brand name may constitute a regulatory violation.

24. If a QR code of patient group (links to disease info in website) is put on PSP material, is it a disguised promotion?

If a website solely provides information on a disease and lacks any product-related details, it can be considered non-promotional.

The distribution of Patient Support Program (PSP) materials should be carried out by HCPs specifically to prescribed patients. When there is a need to provide information without any product details, such as disease-related information, it can be considered non-promotional, and no issues arise in this context.

PSP materials, on the other hand, do contain product information and are designed for prescribed patients. It is important to ensure that disease information is presented in a fair and balanced manner.

Please refer to the Decision Tree for guidance in properly categorizing material types and their compliance needs as set forth by the COP.

25. Does the Code allow members replacing the API section on promotional materials for healthcare professions with a QR code?

In principle, it is allowable to replace the printed API with a QR code. However, reasonable control for access to API must be in place to make sure only the targeted healthcare professionals could access the information, and the prescribing information is not publicly available.
In Addition, please also pay attention to the HKAPI Code of Practice, particularly Section 3 and 4 on promotional materials. This section outlines the standards and guidelines for the promotion of pharmaceutical products in Hong Kong. And all these materials must comply with all local laws and regulations

26. Would pharmacy assistant or ward assistant be considered HCP in the context of disease and product education?

In Department of Health's previous seminar for HKAPI, HCPs means pharmacists and doctors. You should also consider if there is delegation of duties in particular institutes. The HCPs should also be accountable for the actions of these delegates.

Section 8 Samples

1. What should be sample packs used for?

Sample packs should only be used to familiarize doctors with the medicine in clinical practice. It is not necessarily used to assess medicine's clinical profile including its efficacy and safety result and / or patient experience. Medicine's clinical profile and patient's experience are to be addressed through clinical research trials and doctors are encouraged to refer to the published clinical data for such information.

2. Can samples be offered to a lapsed account again?

The sampling policy is not applied retrospectively. After the first delivery of sample(s) on or after April 1st 2017, any inactive or lapsed accounts subsequent to the maximum of 6-month sample distribution limit should not be offered sample(s) again.

3. Is Macau in scope of the Section 8 sampling requirements?

No, Macau is currently out of scope of the Section 8 sample policy, but will be evaluated at a later date.

4. Is trade sector included?

Sampling is for familiarization of the product by the doctors only. Hence, drug sampling in trade sector would not be deemed serving the purpose and not allowed. Over the counter product samples and non-drug samples (e.g., devices) are out of scope.

Although over the counter product samples and non-drug samples are out of scope under this sampling policy, member companies should apply the same principles around managing the perception of inducement when offering these samples to customers.

5. Are third parties assigned by member companies covered in this Code of Practice update?

Yes. This is the same as for other Code clauses, where member companies are responsible for ensuring that their third parties act in accordance with the Code.

6. What happens if the 6-month sampling period ends in a hospital during the 1st pre-DAC submission and the DAC has NOT yet approved the medicine?

Samples as defined in the Code are intended for the doctors' familiarization of the drug. They are not to be used to supply product indefinitely pre-DAC approval. According to CPO, HA already requires that doctors alert patients that their prescribed sample drugs could be stopped and that patients may need to switch drugs or purchase the medicines themselves. It is also important that companies remind doctors so that patients are adequately informed about these risks, and also consider this possible situation when deciding whether or not to provide samples in the first place.

7. Doctors and colleagues may comment that placing a limit on samples may reduce access of medicines to patients?

Samples are not to be used as an access solution for patients. The sole purpose of a sample is for the doctors' familiarization with the drug. Such practice can already be considered in breach of the Code prior to this update, since the volume of samples should be limited. Companies can still provide access to medicines for patients via patient access programs.

8. Can different departments in hospitals have different timelines?

Companies should make a reasonable decision based on:

- HKAPI Code of Practice Section 8
- Whether the doctor has previous experience with the medicine
- Whether the doctor has accessibility of the medicine now
- Whether the sample will lead to potential inducement

9. Can different indications have different timeline?

A sample is meant to familiarize a doctor with a medicine only. After the doctor has started purchasing the medicine, they have had sufficient time to familiarize him/herself with its use.

Thus no further samples should be provided for the purpose of familiarizing the doctor with the use of a medicine for a different indication alone. However, sampling of new formulations, preparations or major differences in dosage within the same department or account is allowed.

Companies should carefully assess whether the sample will lead to potential inducement.

10. Is the principle account based (one clinic account code based on distributor list) or individual doctor based, or clinic based?

Sample is generally recommended to be given based on individual account; however companies should make a reasonable decision based on:

- HKAPI Code of Practice Section 8
- Whether the doctor has previous experience with the medicine
- Whether the doctor has accessibility of the medicine now
- Whether the sample will lead to potential inducement

11. What's the requirement for tracking system?

Member companies need to set up an internal control system and procedures for sampling approval and tracking to comply with the Code effectively, as mentioned in Section 3.6 of the Code.

12. Do a non-member company need to comply with the Code? Will it reduce the competitiveness of our members?

Samples are for physicians' familiarization with medicines, and the amount sampled should not be linked in any way to the member company's competitiveness.

The spirit of the sampling policy is to align the industry and reduce our risk of any potential perception of samples being an inducement to prescribe, administer or recommend particular medicines. It is not currently mandatory for non-member companies to adopt this change, however we will encourage all non-member companies to adhere to the principles outlined in the Code . In this case, the use of samples as an inducement to prescribe a medicine would be considered highly questionable practice by the public and exposes companies and the doctors to serious reputational risk. We will continue to educate our key stakeholders on our Code and the rationale behind this clause. For example, the Hospital Authority has been requested to change their own policy on sampling to adopt the change. HKAPI will also notify the IFPMA on the change of the Code, for those non-HKAPI members but IFPMA members, they will be notified by their headquarters.

13. What if a member company is found to be in breach of the sampling policy?

Any member company found to be in breach of this policy will be subject to the same penalties outlined in our Code. Refer to Section 14 of the Code.

14. How will we communicate the Code of Practice changes to our external stakeholders?

The Ethics and Compliance Taskforce has been communicating these changes to key external stakeholders for many months. HKAPI has already shared the revised sample policy with key stakeholders and this engagement will be continued. All member companies should also play a role in the communication of the revised sample policy.

15. When will the effective date for no-sample after purchase?

1st April 2017 – there is no grace period for implementation. Companies are expected to fully align their internal processes accordingly.

16. **If HA/private hospital has purchased the product as named patient item for specific patient use, will it count as purchased account and not allow for sample?**

    If the product is purchased as named patient item (e.g., purchased before drug registration or as a non-formulary item for specific patient use), the provision of sample(s) is still allowed. However, members are recommended to keep proper justification as to why further familiarization of the doctor with the new medicine is warranted and the sample arrangement is subject to hospitals' policies.

17. **Will the sample invoice date be used instead of delivery date? It's more difficult to record the delivery date/ or risk to be delayed due to holiday?**

    The principle of the sampling policy is based on delivery date (i.e., the date from which the doctor has the opportunity to familiarize themselves with the medicine). Member companies could establish the internal control by recording the invoice date and ensuring the delivery date of last sample pack is within 6 months. For example, company can use the invoice date for the internal record and set the last invoice date 7 days before delivery deadline to ensure enough time for delivery.

Section 9 – Grants & Donations

1. **How details should the purpose be addressed for the grants or donations to Healthcare Organization (HCO) or Medical Society?**

   The HCO or medical society should provide all the necessary information to the company to evaluate whether it is legitimate to support the event in which clear benefit to public institutions or patients can be demonstrated. Grants and donations should not be provided to subsidize routine activities or operation of any medical practice and the amount should be proportionate to the purpose without unnecessary perception of excess and unreasonable.

2. **In case the healthcare professional is engaged for permitted services with honorarium provided, the healthcare professional asks the company to donate the honorarium to another organization (e.g., university, charity, medical society or patient group, etc.), is it appropriate for the company to support the donation?**

   The decision should be based on the company's internal policy. Grants and donations to HCOs or Medical Societies shall not be made with the intention of receiving in exchange any direct benefit or preferential treatment, of obtaining or retaining business or a commercial advantage.

Section 11 – Clinical Research and Transparency

1. **Can information in pipeline products or ongoing clinical trials be provided to patient organizations members on request by the patient organization? Could we share "Trials information website" to patient groups, have they circulate among patients to recruit subjects, for studies on an unregistered indication?**

   Please refer to COP Section 11.1 and 11.2.

It is recognized that there are important public health benefits associated with making clinical trial information more publicly available to HCPs, patients, and others. Such disclosures, however, must ensure protection for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices under patent law. Member companies should only 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) or equivalent.

All human subject research (including clinical trials and observational studies) must have a legitimate scientific purpose and must not be used as a disguised form of sales promotion.

Section 12 – Relations with the General Public and Lay Communication Media

1. Can we display product promotional materials in a third party organized event that is open for the general public to register and attend?

The UMAO governs direct-to-consumer promotion of pharmaceutical products, both OTC and prescription medicines. While there are certain purposes for which advertising is permitted under the UMAO which may be relevant in particular for OTC medicines, promotional materials visible or distributed to the general public that state that a product/treatment has an effect on a specific disease or class of disease may be prohibited. It should be of note that UMAO does not distinguish between generic and brand names. Companies should always consider and adhere to the UMAO when determining the appropriateness of any displayed or distributed promotional materials in settings accessible by the general public, such as print (e.g., newspapers) or digital advertisements, public billboards and signs, third party organized public health talks, patient advocacy events, and patient conferences. Member companies are advised to seek for legal advice should they have any doubts.

2. **How can the Communication Media handle materials available from press release, press conference and pictures of products?**

Materials prepared by member companies to be available for press release or to be presented at press conferences need to be factual, fair, balanced and not misleading. The media, when using such materials and/or product pictures, should observe the UMAO and/or other applicable laws and regulations, as well as their own industry's Code of Practice. Member companies are ultimately responsible for any such releases into public, and should take all necessary steps to mitigate any risk of UMAO violations.

3. What kind of information should be provided in patient information materials given to patients about the drug he/she is being prescribed?

Patients should obtain information of the drug prescribed to him/her from trained medical professionals, e.g., physicians, pharmacist. In these materials, if brand names/logos are used, member companies should assess whether the information being provided is necessary and essential use of the drug, and to avoid any promotional claims on such material. As such, member companies shall consider and avoid any risk of such materials being accidentally displayed or made available to the general public which may trigger potential UMAO violations.

4. Should information such as brand logo and disease be included in patient assistance program (PAP) materials on publicly available domains?

Information that is on publicly available domains can be seen by anyone from the general public.

For product specific PAPs, information available on such domains should only be limited to the product brand name and the relevant program mechanisms. Information such as disease, indication or efficacy is not considered necessary as the patient would have been prescribed on the drug. The purpose of such platform is not for the promotion on use of drugs being supported by PAPs, but rather a source of information for the patient to check his or her eligibility and the mechanism they should follow for the PAP, after it is being prescribed by the HCP.

However, for non-drug related (e.g. pre-prescription) PAPs, these would be more specific to disease or therapeutic area. Hence it would be appropriate to keep the information to the relevant disease or therapeutic area according to the program design and objectives without the need to mention the product brand name as these non-drug related PAPs shall not induce the use of a particular drug/treatment.

Member companies working with third parties on PAPs that have public domains should take necessary measures to avoid unnecessary information being made available publicly via these third party domains.

Section 13: Interactions with Patients and Patient Organizations

1. What kind of due diligence actions is expected for member companies to fulfil "member companies should avoid being the majority annual funder of a patient organization" under Section 13.3?

Companies should avoid being the majority annual funder of a patient organization, and patient organizations should be encouraged to seek financial support from a wide variety of sources. Therefore, due diligence of patient organizations should be performed and here are some suggested areas for consideration (not an exhaustive list):

- Mission and background of the key personnel / management / executive board
- Profile and engagement history with the member company
- Annual financial report/statements (where available)
- Media / internet search
- Rationale for the engagement

2. Can a company make regular sponsorship to a single patient group? Is there a limit? For some patient organizations (e.g., rare disease patient organisations) which only have one treatment choice, it is likely that they can only seek support from only one pharmaceutical company. So how can member companies support this kind of patient organisations in a compliant way?

With reference to the guidance from IFPMA, patient organizations should be encouraged to seek support from a wide variety of sources, including pharmaceutical companies and non-pharmaceutical companies. Regular sponsorship to a single patient group is not recommended, as it may be considered as supporting the operation of the patient organization. According to COP 13.3, Member companies should avoid being the majority annual funder of a patient organization.

In circumstances where only one member company agrees to provide support, the member company and the patient organization are encouraged to adopt in advance, a set of ethical guidelines in writing that will govern their relationship and ensure that the member company's funding does not compromise the patient organization's independent and unbiased decision-making.

3. Can we have activities that are direct engagement with patients, e.g. patient advisory board meeting?

The fundamental requirement is that these activities must maintain a non-promotional nature. To guide your decision, we need to think about the purpose and objective of this advisory board meeting, and who would be involved.
It is essential for member companies to proactively develop their own internal Standard Operating Procedures (SOPs) to govern their activities. These SOPs may include provisions for engaging patients in services such as disease management experiences, but typically under specific criteria and guidelines.

4. Any concern or additional consideration if HCPs (says doctor) sit in the board of the patient organization?

The HKAPI COP does not specifically address this issue. However, it is important to consider the structure of the patient organization that a significant representation of patients or caregivers sit on the board.
At the same time, individual interactions with HCPs shall refer to related sections in the COP.

5. Is it mandatory to display the company logo in all promotional and communication materials? In the case of a company-sponsored patient group for media activity (e.g. press conference), does sponsorship need to be disclosed in that event material/ venue? Can the company's logo be displayed in press releases when the company is a sponsor?

When the company is a sponsor to the event, the company should disclose its support by displaying company's name or its logo in the event material or venue. When sponsoring an event for a patient organization, it is not mandatory to display the company logo. Instead, a description of the company's support is acceptable.
However, it is expected that some form of disclosure regarding the company's support is provided.

Section 14 Complaint Procedure

1. How do we calculate the "3-year period" for the purposes of calculating the monetary penalty for repeated offences under Section 14.5(b)?

As defined under Section 14.5(b), the "3-year period" is from the date of any Code of Practice Committee ("CPC") decisions after the effective date of this updated Code, i.e. counting from the date of 1st CPC decision against a member company decided on or after 1st May 2022. This is for the sake of fairness and not to have retrospective effect from prior CPC decisions (before 1st May 2022).

For example, if Company A was found to be in violation of the Code by CPC decisions on numerous occasions, e.g., 1st February 2022, 1st June 2022, 1st May 2024, 31st May 2025, 1st June 2025. Company A's annual subscription fees in 2024 and 2025 are HKD70,000 and HKD110,000 respectively. For calculating the number of repeated offences during the "3-year period", CPC decision on 1st February 2022 would not be counted as it was before the effective date of this updated Code on 1st May 2022. CPC decisions on 1st June 2022, 1st May 2024 and

31st May 2025 will fall within the 3-year period. The monetary penalty for the 2nd violation on 1st May 2024 will be HKD200,000, i.e. HKD100,000 x 2. The monetary penalty for the third violation on 31st May 2025 will be HKD330,000, i.e. HKD110,000 x 3. As 1st June 2025 falls outside the 3-year period (commencing on the 1st violation by the CPC decision on 1st June 2022), the 3-year period will start afresh.

2. **If a member company is in breach of a different section of the Code or in breach of a number of various sections in one single complaint, does CPC determine the amount of monetary penalty differently?**

   No. For the purposes of determining whether it is a repeated violation or not, this depends on the number of CPC decision(s) against the same company within the "3-year period", whether the CPC decisions are on the same section or not and whether the CPC decision is on a number of different sections in one single complaint or not. Of course, for situations where the violation (even if not as a repeated violation) is of a grave and serious nature affecting public interest, other non-monetary penalty may be recommended under Section 14.6.

3. **If Company A is not a member of HKAPI, is it subject to the HKAPI's complaint procedure?**

   No, non-member companies are not subject to the Complaint Procedure. However, in the preamble of our latest Code, we strongly encourage non-member pharmaceutical companies to comply with the Code and to uphold the industry standard to a higher ethical standard and to build trust with patients and society. For matters of serious and grave nature affecting public interest involving a non-member pharmaceutical company which is an affiliated company of a member company of the IFPMA, HKAPI may refer such to the IFPMA for appropriate resolutions and recommendations.

Appendix: ***Section 6 Promotional Items and Non-Promotional Items (such as Educational Items and Items of Medical Utility)***

Decision Tree

The Decision Tree is designed to assist in determining the appropriate classification and compliance requirements for various types of materials, ensuring adherence to the guidelines outlined in the COP. Please refer to this Decision Tree for guidance in properly categorizing material types and their compliance needs as set forth by the COP.