

MCA FAQ'S (updated November 2023)

Question 1 – Sun City as a venue	2
Question 2 – Sponsoring HCP	2
Question 3 – Sponsoring medical conference with golf	3
Question 4 – Fair market value for local HCP activities	3
Question 5 – Payment & sponsorship of Key Opinion Leader	3
Question 6 – Grant to a government institution/hospital	4
Question 7 – Items of medical utility	4
Question 8 – Occasional gifts	5
Question 9 – Donations	5
Question 10 – Consumer Competitions	6
Question 11 – Product promotion before registration	6
Question 12 – Inviting staff from government hospitals to product launch	7
Question 13 – Specialist Forum meeting questions	7
Question 14 – Hospitality costs and provision of alcohol	8
Question 15 – May representatives pay for access to HCPs	9
Question 16 – MCA do's and don'ts for events	9
Question 17 – Sponsoring a retirement event / Christmas party for HCPs	10
Question 18 – S0 product advertising	11
Question 19 – Social Events in aid of a registered charity	11
Question 20 – MCA Ex-Parte Process	12
Question 21 – MCA endorsement on promo material	13
Question 22 – Advertising a vaccine	13
Question 23 – Internal company corporate Code/Guideline	14
Question 24 – Principle-based approval	14
Question 25 – How Fair Market Value (FMV) is determined	16
Question 26 – Reimbursement of HCPs	16
Question 27 – Market research data	16
Question 28 – Fair Market Value (FMV) for paying HCPs	17



Question 1

As suitable **venues** to host large cost-effective **conferences** are limited in South Africa, would Sun City be considered an appropriate venue?

Answer

Whilst the venue is a resort/casino – it is one of the very few cost effective venues in South Africa able to accommodate large Congresses – such as SA Heart with over 600 delegates. The number of venues able to accommodate larger meetings is restricted in SA.

The venue offers relatively inexpensive accommodation (Cabanas & even the Cascades) for Conference delegates – not ALL accommodation is 5 star! The options for such a large group is limited to certain venues in main cities which according to many organisers is more expensive than Sun City.

The venue has been used as a suitable conference facility for many years by Industry.

Security - it is a secure, safe venue.

Captive audience – ensures delegates don't leave the venue during the day or immediately after the educational component – allows suppliers greater opportunities to engage and interact with delegates.

It is important however that companies are deliberate in making arrangements that do not include sponsorship of sporting or entertainment activities. This should be made clear in sponsorship contracts and in promotion of the sponsorships.

Question 2

Can one sponsor an HCP to attend a site visit abroad? What about preceptorships abroad? Would the same rules apply with respect to travel, accommodation & hospitality as for HCPs who attend conferences?

Answer

Yes, it is appropriate for members to invite Healthcare Professionals to plant or factory tours in countries outside their country of residence if there is a legitimate business purpose and the tour complies with the guidelines in all respects. Accordingly, members should ensure that appropriate documentation is put in place, hotel accommodation is not normally provided at top category or luxury hotels, air travel is economy and meals are of a standard that Healthcare Professionals would routinely expect if they were paying for them out of their own pocket.



Question 3

Can our company sponsor a medical conference where an afternoon of golf is part of the agenda?

Answer

One needs to review the scientific / educational part of the agenda vs the time for other activities. The majority of the time should be on the educational aspects.

Have a transparent discussion with the organisers raising the concerns regards the golf and the optics thereof and request that they reconsider the agenda
Participants wanting to play golf – it should be at their expense and not part of the conference package

Should you consider sponsorship of the medical conference, one needs to make it clear (preferably in writing) to the organisers / faculty that your sponsorship is only for the educational part and not for the social aspects.

Question 4

What is 'Fair market value' for local HCP activities as we have detected inconsistent payments across industry for e.g. advisory board activity, consulting and delivery of speeches?

Answer

It would not be permissible for the MCA to publish what it considers/calculates to be 'fair market value' as this would be deemed anti-competitive in terms of SA legislation. Also, there are different valuation methods that may be used. In all instances, companies should use objective, verifiable criteria, for example, the level of expertise of the HCP, the type and length of service to be rendered, the preparation time required etc. The method or methods used should be documented. In all cases, a written contract or agreement must be put in place before commencement of the services which clearly specifies the nature and basis for payment of those services.

Question 5

Can we pay travel time for a Key Opinion Leader (KOL) to attend an international Ad Board? Can we sponsor a locum to cover the KOLs clinical practice, whilst s/he is at the Ad Board?

Answer

Clause 18 of the Code deals with Interaction with Healthcare Professionals.
Clause 18.5 permits the use of HCPs as for services such as Advisory board meetings.

Reimbursement for travel, accommodation and modest hospitality for the Ad Board attendees is permitted. You may also pay an honorarium.
It is not deemed acceptable to pay for a locum or travel time for the attendees.



Guideline:

Note 3 of the Guideline states that Companies may sponsor travel for HCPs for:

b. HCPs attending advisory boards

Note 14: Scientific advisory boards

If companies have scientific or advisory board meetings, there shall be bona fide consulting services agreements with the HCPs.

A written agreement is required.

It is important to note that Companies may not pay HCPs for their time whilst attending the CPD events under the guise that such events are scientific meetings or advisory board meetings. The general rules relating to spouses/partners, meals and refreshments and entertainment also apply in this context.

Question 6

What should we consider if we plan to give a grant to a government institution/hospital? In return we would like the hospital to train certain staff members in our company on disease entities, attend ward rounds etc.?

Answer

The two issues / activities should be separate and not linked i.e. the grant is not given on condition staff are trained on company related disease entities

A grant – should be clearly documented in an agreement specifying the amount, what the intended purpose is and that it is not based on the institution supporting/ prescribing your company products. For US and UK based companies – need to include clauses relating to FCPA.

The training – need to seek the HoD or senior hospital official permission to do training. Same applies to ward rounds and patients and HCP's written consent that you are allowed to be part of the ward around even if you are a HCP. The consent should

clearly explain the purpose of you attending the ward round. Ward rounds should not be used as an opportunity for product promotion.

Question 7

Items of medical utility

In a large radiology practice with a number of HCPs, could one give an international book as a gift if it costs > R3000 as it would be used by a number of HCPs?

Answer

For scientific medical reference books, the maximum value permitted for an individual practicing HCP or for a practice (irrespective of the number of HCPs in the practice) is R2500 (incl. VAT) per year. Only for training or academic institutions may this value be exceeded to a maximum of R10000 (incl. VAT) per year.

Only company branding allowed on the items. No product branding allowed.



Question 8

Occasional gifts

Can we give HCPs mugs, cell phone holders (for their desk), car cellphone charger, iPad covers? Would these be acceptable gifts in terms of the value & intent? What about gifts to staff of an HCP who are not themselves HCPs?

Answer

Note: Many companies have standards and rules that are stricter than the MCA Code. Company standards must take precedence.

Chapter 11 Promotional items and gifts

Items of general utility which have been held to be acceptable gifts to doctors as being inexpensive and of relevance to their work include but are not limited to pens, pads, diaries, nail brushes, desk trays, calendars, and desk clocks.

Items must be for the practice and not for the HCPs personal use.

The value of gifts must not exceed R300 inclusive of VAT.

Gifts given to the staff of a Healthcare Professional should be treated as though they were given to the Healthcare Professional and accordingly must comply with the provisions of the guidelines in all respects.

Occasional items may be branded with the company or the product name but no claims may be made.

Question 9

Donations

Can my company give a charitable donation by buying tickets for HCPs to a Sports and Cultural day? The proceeds will go towards the Nelson Mandela Children's Hospital?

Answer

Companies may support charitable events by making a donation to the sponsoring organisation but may not pay for individual HCPs to attend or participate in the charitable event. Furthermore, companies are not permitted to suggest to the sponsoring organisation the names of HCPs who could be invited to attend the event. The company may use some or all of its ticket allotment for its own employees and return any unused portion to the sponsoring organisation for use as the sponsoring organisation sees fit.

Charitable donations should also not be considered in response to requests by HCPs unless the HCP is an employee or officer of the charitable organisation and submits the request on behalf of the organisation.



Question 10

Consumer Competitions

What is the maximum prize value & would this be construed as promotion to the public?

Answer

9.2 Consumer Competitions

Invitations to Consumers to participate in competitions or quizzes which are linked directly or indirectly to a Schedule 2–6 Health Product are promotional in nature and are unacceptable.

Competitions must not require the purchase of product.

Competitions may not relate to product sales.

Guideline to Section 9.2

Note 1: Value of competition prizes

The total value of the prizes for a consumer competition must not exceed R100 000 (including VAT); and each individual prize may not exceed R5 000 (including VAT).

A donation of any nature linked to the competition needs to be included in the total prize money.

Competitions to wholesalers, the FMCG trade, spaza store owners, retailers, forecourt owners and the like are to be treated in the same manner as a competition to a HCP with similar criteria applying.

Clause 5.3.1

Companies shall not be involved in Promotional schemes, which are hazardous to consumers, or which bring or may bring the Industry into disrepute.

Question 11

Product promotion before registration

Pre-licence activity. – A health product requiring registration or an indication which is not registered in South Africa, must not be promoted, even if the congress is international in nature, unless exemption has been granted in terms of applicable legislation.

Can an unregistered product or unregistered indications be promoted at an international congress in South Africa?



Answer

The display and provision of Promotional Material for unregistered medicine and/or indications is permitted at international meetings in South Africa provided the following conditions are met:

1. Meeting is truly an international meeting of high scientific standing with a significant proportion of the attendees from countries outside South Africa in which the product is registered
2. Medicine or indications must be relevant and proportional to the purpose of the meeting
3. The registration status and/or approved indications in South Africa must be clearly and prominently displayed in the Promotional Materials
4. The names of the countries where the medicine / indication is registered must include one major developed country and it must state that registration conditions differ from country to country.

Question 12

We would like to find out if we are allowed to invite staff (Clinical and Technical Engineers) from Government Hospitals for a Product Launch on new technology for Operating Rooms?

Answer

- Different rules apply depending on the primary mode of action of a device or combination device
- Audience must comprise of persons who require specific information on the device in order to deliver a service to the patient i.e. you must be able to justify why a particular category of person was invited.

Question 13

I have been asked to sponsor a Specialist Forum meeting. The committee consists of 4 specialists (surgeon, oncologist, radiologist and pathologist) meeting once every 4 months to plan the meetings. I attend this planning meeting to facilitate logistics and have no input into the topic selection. Once the date and topic is selected, I source the venue, catering.

The Committee sources the speakers. (No honorarium is paid to these speakers)
I print the invitation on the Pharma Company X letter head. This invitation is distributed via two laboratories, to all doctors in the area. I am listed as RSVP, thus I manage RSVPs for catering numbers.

XX sponsor and apply for CPD accreditation.

On the evening of the meeting, I ensure the attendance register is completed and that CPD certificates are distributed.



- Can the rep sit in the planning meeting?
- Can the rep print the invites on Pharm Company X letterhead?
- Can the rep be responsible for the RSVPs?
- Can the rep attend the meeting?
- Can Pharma Company X pay for the venue and catering (sponsorship/grant)?

Answer

- The following documentation is advisable
- A letter of request from the Specialist Committee
- Signed contract of engagement between the Specialist Committee and the Pharma company

- **Can the Sales Representative sit in the planning meeting?**

Yes, as they provide no input into the agenda.

- **Can the Sales Representative print the invites on Pharma Company X letterhead?**

Yes, provided there is full disclosure and no product branding.
All sponsorship must be declared.

- **Can the Sales Representative be responsible for the RSVPs?**

Yes, there is no unfair or improper advantage to be gained, they are providing reasonable support

- **Can the Sales Representative attend the meeting?**

Yes, but only as a silent observer. No promotional activities.

- **Can Pharma Company X pay for the venue and catering (sponsorship/grant)?**

Yes

Clause 7.3 Sponsorship

Clause 10.3 Medical or Scientific Congresses, Conferences or Seminars

Question 14

Hospitality costs and provision of alcohol - What is a reasonable cost of a meal and drinks for an HCP for hospitality at a meeting?

Answer

Guideline to Section 10.1

Note 10: Hospitality and accommodation at congresses

The level of accommodation offered must be appropriate, modest in nature, and the costs involved must not exceed that level that the recipients would normally accept when paying for themselves.

The appropriateness of accommodation: Companies may not pay for or



reimburse HCP lodging expenses at top category or luxury hotels.

The accommodation must be limited to the duration of the conference – accommodation and/or other services provided to HCP delegates should not cover a period of stay beyond the official duration of the conference.

The registration fee: The registration fee should cover only the scientific programme and authorised activities and hospitality. Sporting activities and entertainment must not be sponsored.

Companies should have in place Standard operating procedure (SOP) providing a framework of costs including maximum amounts, quantity, costs and for which type of meals.

Question 15

May representatives pay for access to HCPs

Answer

- Company Representatives shall not employ any inducement or subterfuge to gain an interview with an HCP.
- No compensation, payment, reward or benefit shall be paid or offered for the granting of an interview by an HCP.
- Donations to charities in return for Company Representatives gaining interviews are prohibited.
- Company Representatives shall take reasonable steps to ensure that they are not misleading in respect of their identity or the Company that they represent.

Question 16

MCA do's and don'ts for events

DO'S
1. RED FACE TEST <ul style="list-style-type: none">• Ask yourself – can I substantiate this should it appear in the media? Is it justifiable, fair, transparent, balanced and in the interest of the patient?• Remember that this applies to both online and offline advertising (including social media)
2. MODESTY <ul style="list-style-type: none">• Consider how you interact with HCP's and how this can be perceived by patient• Is it reasonable, fair and modest?• Is there perhaps a gift or payment which could benefit of an HCP personally? This would not be acceptable.



3. RECERTIFICATION

- Remember to reapprove promotional material at least every two years and give it a new unique item number.
- Remember all customer facing staff need to redo their Code certify by taking the assessment every two years to be Code compliant

4. GIFTS

- Occasional gifts to healthcare professionals, appropriate administrative staff, sales and other staff are acceptable provided that they are: Inexpensive and of modest intrinsic value and allowed by the company policy
- The value of gifts should not exceed R300 (inclusive of VAT)

5. CPD MEETINGS AND CONFERENCES

- The main focus of CPD meetings and conferences must be only scientific in nature and/or educational
- The venue must be appropriate
- No product branding or mention by brand name
- The meeting and event must be appropriate to all delegates' scope of practice

DON'TS

1. SCHEDULED MEDICATION

- Do NOT advertise scheduled 2-6 medications directly to consumers

2. OFF-LABEL INFORMATION

- Do NOT have sales and marketing personnel disseminate off-label information

3. ENDORSEMENTS

- Professional endorsement of medicine by a named HCP is not acceptable as per the HPCSA and SAPC professional ethics codes.

4. REFERENCING

- Do NOT use promotional material without credible substantiation and correct referencing
- Reference documents must be made available on request from a HCP

5. STAND-ALONE ENTERTAINMENT

- NO stand-alone entertainment or other leisure, social or sporting activities may be planned, arranged or funded by companies

Question 17

Are we allowed to sponsor a retirement event / Christmas party for HCPs?

Answer

The Code prohibits healthcare companies from sponsoring / funding events that are



not bona fide medical educational events. Thus, year-end functions, Christmas parties, retirement events or any standalone entertainment events cannot be sponsored by member companies.

I refer you to clause 10.1.1.2 of the Code on Stand-alone entertainment, leisure, social or cultural events with healthcare professionals that states:

No stand-alone entertainment or other leisure, social or sporting activities is planned, arranged or funded by Companies as these are unrelated to the Promotion of scientific or educational objectives

Question 18

Is one allowed to put a sticker on the box of an S0 product advertising the promotional leaflet inside? The reason for my question is that it alters the design that is registered with the SAHPRA (albeit a temporary sticker for a limited duration)

Answer

- A S0 product is a registered medicine with an SAHPRA prescribed label
- You are not permitted to deface a medicine in any manner
- Putting a sticker on the product would deface it
- You are also not permitted to put a promotional leaflet inside the box of any medicine albeit in this instance you may advertise a S0 DTC

Question 19

Social Events in aid of a registered charity

- a) May a company representative participate in the social event with a HCP which is organised by a third party entity?
- b) May a company participate in the sponsorship of a registered charity social / golf event?
- c) May company staff members participate?
- d) Can we do product promotion and have a stand at the charity social event?
- e) May we sponsor gifts and prizes?

Answer

- a) Yes any company representative may participate in the social event with an HCP; however, the company representative may NOT pay for the HCP to participate in such an event.

The guideline is not absolute but states the following: Charitable donations to a bona fide organisation should not be made in response to requests made by healthcare professionals unless the healthcare professional is an employee or officer of the organisation and submits the request on behalf of the organisation. It would not be appropriate for a member to support the favourite charity of a Healthcare Professional in response to a request by that healthcare professional." The should is not an absolute. Rather quote the guidelines and suggest that charitable donations should go through a corporate charity committee to ensure that the support is based on the strength of a charity and not as an indirect reward to an HCP.



b) May a company participate in the sponsorship of a registered charity social / golf event?

Yes, a company may participate in the sponsorship of a charity social event, provided that the sponsorship is paid directly to the registered charity concerned and not to the organizers of the event. For multinationals bound by the Foreign Corrupt Practices Act (FCPA), this type of sponsorship at the request of an HCP or Government Official (GO) may be interpreted as an indirect benefit to the HCP / GO which is a contravention of the law.

c) May company staff members participate?

Staff members' participation in the social event may be at the company's discretion and in accordance with the company policy.

d) Can we do product promotion and have a stand at the charity social event?

No product promotion may take place at any social event. A company may however display their company logo at such an event. E.g. banner with Company logo at a sponsored hole at a charity golf day.

e) May we sponsor gifts and prizes?

Regardless of the type of social event, no prizes or gifts may be sponsored by the Company

Question 20

MCA Ex-Parte Process – how does this work?

Answer

Clause 16.22 Ex Parte Opinions

16.22.1

A member or a non-member of the MCA or a trade association representing members of the MCA may make an Ex Parte application to the MCA for a non-binding advisory opinion in relation to the application of the Code and/or Guidelines in a specific circumstance upon payment of the prescribed fee and in the prescribed format.

16.22.2

The Executive Officer shall appoint an Ex Parte Committee to provide the opinion.

16.22.3

It is specifically stated that should a complaint be lodged in respect of the matter, which is the subject of the advisory opinion, no member of the Ex Parte Committee which provided the advisory opinion shall sit on the Adjudicating or Appeal Committee to deliberate on the matter.



16.22.4

Ex Parte matters shall be undertaken in writing, provided that the Ex Parte Committee may request further information and/or clarity from the Applicant as deemed necessary.

16.22.5

An Ex Parte Committee may refuse to accept a request for an advisory opinion on the basis that the Applicant is attempting to address a dispute with another Company and/or on the basis that it is using the Ex Parte process to avoid lodging a complaint or an appeal.

16.22.6

In its consideration of the Ex Parte request, the Ex Parte Committee shall:

16.22.6.1 consider rulings previously made by Adjudicating and Appeal Committees (where applicable) in respect of the matter under consideration;

16.22.6.2 confine itself to the questions posed by the Applicant, i.e. whether a particular activity is permitted in terms of the Code and/or Guidelines, within the circumstances as outlined by the Applicant; and

16.22.6.3 provide a written analysis and application of the Code and/or Guidelines to the facts, a conclusion and the reasons for the conclusion.

16.22.7

It is specifically provided that when the Ex Parte Committee issues an advisory opinion, such an opinion shall be for guidance purposes only and shall not be binding on any Adjudication or Appeal Committee when adjudicating a complaint or hearing an appeal on that or a similar matter. The Executive Officer may, however, use advisory opinions to inform the Guidelines and may publish the opinions on the MCA's website without giving details of the parties or Ex Parte Committee members involved.

An Ex Parte opinion costs R5000 ex VAT.

Question 21

Is MCA endorsement via lapels and high visibility on promo material permitted?

Answer

- Yes - MCA member companies may make use of the MCA logo by including it on their promotional material or items should they so choose, as a benefit of membership.
- However, it goes without saying that the promotional material or items on which the logo is used must be Code compliant, and that inclusion of the logo should not be used to sanction any material or item that would not be acceptable in terms of the Code.

Question 22

Can a company advertise a vaccine to the general public?



Answer

Vaccines are scheduled medicines. Vaccines are schedule 2 and therefore need to comply with the laws on advertising regarding S2 and above medications. One can provide information on disease types/ states directly to the public as well as immunisation awareness posters in conjunction with the DoH and this is in line with the MCA Code.

In terms of Guidelines to the Code of Marketing Practice February 2015 Clause 20.9 Relations with the General Public and Media page 24 – it says the following:

- **Note 2: Information to the public.**

This clause allows for the provision of non-promotional information about S2 and above to the general public either in response to a direct inquiry from an individual, including inquiries from journalists, or by dissemination of such information via press conferences, press announcements, television and radio reports, public relations activities and the like. It also includes information provided by means of posters distributed for display in surgery waiting rooms.

This limitation does not apply to vaccination campaigns or other public health campaigns carried out by companies and approved by the Department of Health and/or Medicines Regulatory Authority. Any information so provided must observe the principles set out in this clause, that is, it should be factual, balanced and must not encourage members of the public, to ask their doctors to prescribe a specific health product.

Question 23

If an MCA member company has a Corporate Code that allows an activity which is disallowed by the MCA Code, can the MCA member's Corporate Code overrule the MCA Code?

Answer

The MCA Code is the minimum standard for advertising and promotion of health products in South Africa. Frequently companies have corporate Codes which are "stricter" than the MCA Code. If the corporate code requirements are less strict than the MCA Code then the MCA Code must be followed.

The MCA Code aligns well with global standards. The MCA Code is not however dictated to by any other Codes.

The MCA Code is informed purely by SA Legislation and further by the participation of MCA members in a regular, usually annual, consultative process.

Question 24

What is principle-based approval of promotional items or events?

Answer

The Code provides rules and guidance on what constitutes ethical marketing practices. In some situations, no applicable rule can be found in the Code, the situation where the Code is so-called "silent" on a matter.



A decision nonetheless needs to be made and the compliance officer and the commercial team are encouraged to ask questions to determine if the activity is ethically “right” to approve.

In some cases, as in the case of the determination of Fair Market Value (FMV), competition law prevents the Code from prescribing a value. Companies must therefore have their own internal system to determine FMV.

SOME BASIC PRINCIPLES THAT CAN BE APPLIED TO CHALLENGING OR AMBIGUOUS BUSINESS SITUATIONS.

1. The patient must be at the heart or centre of everything you do.
 - i. Is the patient at the centre/heart of this activity?
 - ii. Would the patient's interests (such as the need to receive the best care for their needs) or rights (such as right to accurate, scientific information on a product) be negatively impacted by the activity?
2. Activities must not compromise HCP independence in making treatment decisions.
 - i. Does the activity incentivise or intend to incentivise the HCP to recommend/prescribe/use a particular product and hence compromise independent judgement?
 - ii. Does the HCP stand to receive direct financial gain from the activity?
3. Promote the approved, appropriate and rational use of your product
 - i. Is the material or activity in line with the relevant approved/registered professional information or instructions for use? (e.g. no claims made that are not in the professional information or instructions for use).
 - ii. Is the activity in line with the Medicines and Related Substances Act? (e.g. is the audience appropriate with regard to the scheduling or the category of the product.)
 - iii. Does this activity respect the independent decision making of the relevant stakeholders?
4. Act lawfully, ethically and with integrity
 - a. Is the material or activity legal / legitimate?
 - b. Is the material or activity factual, accurate, and balanced? Check that material does not mislead.
 - c. What is the actual intent of the activity? Is the intent clear or designed to mislead? Examples:
 - i. Market research (ad boards/phase 4 studies etc.). Is the intent to promote a particular product or is it legitimate research?
 - ii. Is the intent of a CPD meeting to educate HCPs or to promote a product? (Note: Different approaches apply but both are permissible).
 - d. Is there any active or passive participation e.g. by staff or consultants, to hide or misrepresent the true intent of the activity?



5. Be transparent

- a. Are you willing to disclose all the information that leads to the approval and execution of this activity? This will involve at least (ref chapter 6 of the Code);
 - i. Documenting all transactions and information related to the activity such as invitations, payments, instructions.
 - ii. Recording all financial transactions in an agreement signed by the company and the recipient and kept on file in the company for 5 years.
- b. Will the activity appear as ethical/acceptable when viewed by patients / public / regulator / competitors?
- c. Can you substantiate how you determined the FMV? (See separate guidance on determination of FMV).
- d. Will this activity strengthen confidence and trust in the pharmaceutical industry?
- e. Have you considered what could go wrong and put measures in place to ensure correct procedures are followed.

Question 25

How is Fair Market Value (FMV) determined?

Answer

The Code provides for the contracting of HCPs for certain activities. The MCA cannot prescribe an amount for FMV (due to competition law). Companies must therefore determine and substantiate the FMV for reimbursing an HCP. HCPs may not be reimbursed for time out of their practice, (Refer to the Code Chapter 12 for guidelines on contracting with HCPs).

Question 26

How does one determine if reimbursement of HCPs complies with the Code?

Answer

REIMBURSEMENT OF HCPs MUST COMPLY WITH THE CODE. QUESTIONS TO CONSIDER IN DETERMINING FMV COULD INCLUDE:

1. Does the Code allow the engagement with HCPs that is intended in the activity?
2. Does the activity require special experience or qualifications of the HCP?
3. How many similarly competent HCPs would be available to do the presentation?
4. Is the HCP from an international jurisdiction?
5. What amount of time would be involved in preparation or research by the HCP?
6. How much time will be spent on the actual activity?

Question 27

Can one use market research data for product promotion?

Answer

Market research data can be used for product promotion but there are conditions attached.



The data must be properly substantiated meaning:

- Properly conducted research must be used
- The research must support the claims made
- The market research company report must be referenced
- The sample population must be specified: e.g.
 - o Geographic location
 - o Population group sampled
 - o Clinical conditions interrogated
- Date of publication of research results is very important. A product that was number 1 in class a year ago may no longer be no 1 in class.
- Member companies must verify that the data is correctly applied to the making of claims.

There is no one particular market research company approved by the MCA. It is up to companies to source reliable data and use it appropriately in line with the Code.

Question 28

Does the MCA have a recommendation on Fair Market Value (FMV) for paying HCPs? It would be very helpful.

Answer

The publication by the MCA of recommendations for FMV for reimbursing HCPs would amount to a transgression in terms of the Competition Act. The MCA therefore does not have such guidelines.

The Code gives clear guidelines on circumstances that can be considered in determining the FMV for an HCP engagement. Companies may however have additional criteria which they consider.

FMV paid must be clearly recorded in a contract to be signed by both the company and the HCP and approved by the CCCO.

It is up to every company to have a policy in place in this respect for referral in the signing off of payments to HCPs. The MCA cautions against engaging in collusion in this respect.