

## **MCA Guidance Note on Principle Based Decision Making for Approval of Promotions**

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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 an 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.

## **GUIDANCE ON DETERMINATION OF FMV**

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).

### **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. How influential is the HCP?
6. What is the “value” to the company of the audience being addressed?
7. What amount of time would be involved in preparation or research by the HCP?
8. How much time will be spent on the actual activity?

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