IFPMA Code Workshop Hands on Compliance Training

Interactions with HCPs

Part 1: Meetings, Sponsorship and Fees for Services





1

Samples

The company has agreed to provide the pharmacy of a city's leading hospital with free samples of 'Lowsug' on a regular basis for a one year period. The packs supplied will be the smallest commercial packs available and will be used so that patients discharged from hospital can have an initial supply of anti-diabetes medicine until they can obtain a prescription from their general practitioner. Representatives will deliver the samples from the central warehouse. The country has no specific legislation relating to samples of prescription medicines.

Depending on time available and group numbers the delegates may be split into groups that will each consider different scenarios above. If not all scenarios are considered choose which ones to consider based on relevance to the group.

1

Samples

The IFPMA Code (Clause 8) deals with samples. Many countries have national regulations that govern the number of permissible samples and the circumstances in which they can be provided, as do a number of national codes including all those in Europe. Differentiation between samples, free goods and starter packs may also vary. The country in question has no relevant national rules. The facilitator may ask delegates to explain any national rules in their countries.

The Code says that samples may be provided to healthcare professionals authorized to prescribe the product in order to enhance patient care. Samples must be specially marked so they cannot be resold or otherwise misused. If the arrangements described were treated as sample provision there is no mention of specially marking the packs. Also the supply is being made to the pharmacy, not directly to persons authorized to prescribe. It might be argued however that the supply was to prescribers through an indirect route in line with hospital policy. The group can debate whether the arrangements 'benefit patient care'.

Companies must have adequate systems of control and accountability for samples provided to healthcare professionals including how to look after such samples whilst they are in possession of medical representatives. The description suggests that such systems are not in place.

If the supply of 'Lowsug' is determined not to fall within the definition of 'samples' there may still be concerns under the Code. They might be considered as 'items of medical utility' (clause 7.5.3) and if so their value is unlikely to be 'modest' as required. Also the regular nature of the supply might be considered to 'offset routine business practice' which is not permitted by the IFPMA code. It is worth mentioning that distorting normal competition may contradict competition law in some countries.

2

Event Attendance Sponsorship

The company sponsored 25 leading national diabetes consultants, chosen by representatives, to attend the 5th annual European Congress on Diabetes' paying their airfare, hotel accommodation, registration fees and providing all meals at no cost to the participants. On a free evening a trip to the theatre was arranged and paid for by the company. Delegates were also able to claim the cost of providing locum cover while they were absent at the meeting providing they submitted valid receipts for the expense.

2

Event Attendance Sponsorship

The Code (clause 7.2) permits companies to sponsor healthcare professionals to attend events provided sponsorship is limited to the payment of travel, meals, accommodation and registration fees. No payments may be made to compensate healthcare professionals for time spent in attending the Event and therefore the payments made to cover locum costs are unacceptable. The theatre trip is also unacceptable. Clause 7.1.6 says that no entertainment or other leisure or social activities should be provided or paid for by companies.

Also any sponsorship provided to healthcare professionals must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product. The use of representatives to select delegates suggests that prescribing performance might have been a contributory factor in delegate selection. If so, this would be unacceptable.

3

KOL advocate plan

The company has prepared a Key Opinion Leader development strategy in preparation for the launch of new product in a new therapy area. Five national Key Opinion Leaders have been identified and a programme designed to enlist them as advocates for the new product has been described. Each has been offered a two year contract to provide advice on formulary acceptance and marketing strategy and also to speak on medical topics at sales and marketing training sessions. They will receive training on the new product's properties and will be expected to deliver lectures at regional HCP meetings for which slides will be provided and a separate honorarium will be paid.

3

KOL advocate plan

While it is acceptable to engage HCPS to provide legitimate, needed advice to the company (clause 7.4) this proposal appears to be a disguised way of paying for HCPs to promote the company's product. The hiring of a consultant must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine and this proposal is therefore unacceptable under the Code. Engaging KOLs to speak on medical topics at sales and marketing training sessions is, in principle, acceptable providing the remuneration represents fair market value for the work done. However in this case the speakers seem to have been chosen because of their influencing power over prescribing decisions rather than because of their capability to perform the training task. (clause 7.4: "..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;") Engaging HCPs to deliver lectures at regional HCP meetings for which slides will be provided is not contrary to the code providing they are suitably skilled, remunerated fairly and it is not a disguised incentive for them. Transparency about the arrangements for the meeting is important and the company's involvement must be clearly set out.

4

Advisory boards

Ten consultant level health care professionals were invited to national advisory boards. They attended two, day long, meetings six months apart to provide advice to the company as it planned a clinical programme on a new use of an established medicine. Each received a payment of \$1500 for their participation in each meeting plus their expenses, paid into their personal bank accounts. The meetings were held at a Hilton hotel in the capital's city centre. The meetings addressed a series of 7 clinically based questions which were presented by the company's medical director. A 25 page report of the meeting discussion is on file.

4

Advisory boards

As stated above it is acceptable to engage HCPS to provide legitimate, needed advice to the company (clause 7.4). The group should discuss whether these meetings were genuine advisory boards and whether the arrangements were acceptable. Overall the meeting does appear to be acceptable. However some delegates may query whether 10 participants is more than would really be necessary. The group can debate whether \$1500 represents fair market value for a day's work for consultant level HCPs. The codes do not set specific limits on consultancy rates. Some delegates may feel that in certain countries this is excessive but others could disagree. There can also be some debate on whether it is appropriate to pay fees into consultants' personal bank accounts. The code does not cover this but companies may have internal policies and the situation may vary between countries depending on local employment arrangements and tax systems. The company should not aid knowingly any attempt by consultants to break employers' employment terms or avoid paying tax due. The important thing is that the company can justify the rate as representing fair market value. A city centre Hilton hotel is likely to be an appropriate venue for a business meeting although some delegates may debate this and this could be another country specific judgement. The apparent clear agenda covering 7 questions, the leading role of the company's medical director and the presence of a detailed report of the meeting discussion on file all point to this being a genuine advisory board.

5

Meetings at doctors' offices

It is common practice in the country to hold educational/promotional meetings at the end of the morning surgery in practices with several general practitioners. Doctors gather in the waiting room or other suitable room at the doctors' premises and the representatives presents a short talk or shows and educational or promotional video. A light lunch is provided and paid for by the company. The national doctors association has recommended that companies make a payment of \$25 for each doctor who attends to practice funds and the company has documented this arrangement in their SOPs

5

Meetings at doctors' offices

It is acceptable for company representatives to run promotional and educational meetings for doctors (clause 7.1.1) and these meetings can be held at the doctors' premises if they provide suitable accommodation. However to pay for the use of the premises, particularly on a per capita attendance basis, appears to be paying HCPs in order to promote products. Such payments may not be made because clause 7.5.1 prohibits payments in cash or cash equivalents to healthcare professionals. If a meeting is held in a meeting room, say at a hospital, where a genuine hire charge applies to anyone who books the room this is likely to be acceptable. Modest refreshments may be provided if they are secondary to the main purpose of the meeting (clause 7.1.5)