Solution 2: The pharmaceutical company contracts with an entity for services. The entity employs or uses more than one HCP to provide services and the services are not associated with a specific HCP. In this case, disclosure of the entity under an aggregated basis is appropriate.
Disclosure shall include Transfers of Value made by a third party on behalf of a Medicines for Europe member company for the benefit of a recipient and where the Medicines for Europe member company knows or is informed about the recipient who will benefit from the Transfer of Value, using the same analysis above.

12. Is a pharmacy considered to be an HCO?

Yes, a pharmacy likely falls in the definition of HCO, to the extent that it is an organization "through which one or more Healthcare Professionals provide healthcare services", as defined in section 6 of Medicines for Europe's Code.

13. What happens if the doctor requests Medicines for Europe's members to support his/her practice or company generally in order to perform screening activities? Shall we disclose such financial supports? If so, under which sub-category?

Support should be provided, limited, and directly related to the specific activity requested. Additional "general funding" requests could be considered a request for a bribe, and paying it could be considered a bribe. The category of transfer of value disclosure depends on the nature of the support.

14. Is market research subject to the transparency reporting?

As indicated in Section 7.1 "Fees paid in connection with research & development activities or market research, are excluded from the scope of this disclosure."

15. Are distributors vs. meeting planners and KOL agencies to be considered as "third party acting on the company behalf"?

As a rule, the Medicines for Europe Code of Conduct is not intended to address or regulate commercial terms and conditions relating to the price, sale and distribution of medicines, which must always be in compliance with applicable rules and requirements (Code Preamble, paragraph 3). However in some countries distributors offer additional services of promotional nature.

This is why from a disclosure perspective it is important to know the scope of the interaction as well as the legal status of the the contractor (licensee, agent, distributor, etc.). In general terms, if a pharmaceutical company controls actual activities performed through third parties and falling within the scope of the Medicines for Europe Code, these activities must be disclosed, even if a a third party is a distributor.

On the other hand, travel agencies or event planners hired by a pharmaceutical company as a rule are required to collect transparency data that arises in the course of their business and provide it to the pharmaceutical company for reporting. This results from the nature of services they offer. Since third party relationship require case by case assessment, you would need to consult with your legal counsel.

16. HCP provides services in Italy for an Italian company. Do we disclose in Italy or France?

Companies must consider the rules of both the home country of the HCP and the place where services are provided: Section 7.4 states «Disclosures shall be made pursuant to the national rules and regulations, including

the Medicines for Europe national association's code, in the country where the Medicines for Europe member company or the affiliate holding the contractual relationship with the recipient is located, or where the physical address of the recipient is located." The company may elect one of these options.

17. How should companies manage consent collection with HCPs that work with both with on and off patent medicines and the ethical divisions of the same pharmaceutical company?

This decision is left to the companies. There are various software tools and companies that can provide this service or advice on how best to collect the consents.

18. Does a Medicines for Europe member company need to report Transfers of Value made by parent or sister companies of the Medicines for Europe member company, which are not made on behalf of the Medicines for Europe member company and over which the Medicines for Europe Member company has no influence?

No. According to section 7.1, only Transfers of Value provided (or "transferred") by a Medicines for Europe member company (directly or indirectly via a third party acting at its direction) to a recipient, must be disclosed.

19. Not all countries have a local association which will implement a local transparency code. What disclosure rules apply to our subsidiaries in those countries?

In countries without a national association, the member company will follow the Medicines for Europe Code. Under Section 3, the Code states "The subsidiaries of Medicines for Europe member companies must either adopt the Medicines for Europe Code or the codes that has been adopted by the Medicines for Europe national associations."

20. Is it required to sum up the total Transfer of Value given to a Healthcare Professional in different categories? In case of Healthcare Professionals who provide services through their company, the name of the company will be listed in this category (without the indication of the name of the Healthcare Professional) and the name of the Healthcare Professional will be listed in the category of event participation. Is that correct or should the name of the Healthcare Professional also be included besides the name of their company?

Please see answer to question 1 above.

21. If certain Healthcare Professionals refuse the consent to the disclosure, the Transfer of Value given to such Healthcare Professionals may be aggregated. This would result in a name based disclosure in respect of only those Healthcare Professionals who gave their consent and an aggregated disclosure in respect of those who refused the consent. Is that correct?

Yes, that is correct. In the situation of an aggregated disclosure, the number of HCP recipients should be indicated in the table as provided by the template. Please refer to section 7.3 of the Code of Conduct. Also see answer to question 1 above.

22. How much time will the organization have to update information in the report in case the healthcare professional (HCP) withdraws consent for disclosing?

In case the HCP withdraws consent for disclosing data, the organization must update the report as soon as possible, but no later than 30 days from the date the withdrawal request was received.

23. The Code of Conduct states that the inclusion of VAT is recommended. Would it be acceptable to disclose the net amounts and describe the applicable taxes in the methodological note?

Yes, that would also be correct.

24. Since we deleted "hospitality" from the new template, what kind of costs should be disclosed in the template on transfer of value to HCPs?

Under Option 1 on transfers of value to HCPs for meetings, educational support, and site visits, the Code of Conduct does not require disclosure of monetary values.

Under Option 2, the Code of Conduct requires an aggregate amount of support provided to HCPs. For example, this would be the total amount of all HCP-related costs at a conference or seminar including travel, accommodation, registration fees, and meals that are not included as part of the conference "package". The reason for this is pragmatic. If the aggregated amounts transferred are in line Code of Conduct, the disclosure of detailed costs would not make a difference.

However, the guiding principle is always that companies should disclose what can be reasonably allocated as a transfer of value to HCPs. The manner of this allocation can be explained in the methodological note.

25. For company organized meetings, what kind of costs should be disclosed? Could you please specify and give some examples? What about rental for rooms/premises, costs of technical infrastructure (sound and light system services), travel (if any). Are these costs appropriate for disclosure?

Items such as room rental and technical infrastructure are basis costs of the meeting, and are not a value that is transferred to the benefit of the HCP. Under the Code of Conduct, transfers of values to the HCP include items such as travel, accommodation, and meals.

26. On the other hand, how should we proceed if there is no direct cost (other than hospitality) connected to the conference and meeting? If we do not have rental fees, no cost for infrastructure, because all of these items are in our possession (for example, our conference room is fully equipped and Budapest based doctors travel
to us by their own car/public transportation). This would mean that we cannot indicate any "Yearly Amount" but only the "Number of Recipients".

If there was no transfer of value, there is nothing to report. For purposes of good documentation, we recommend that your internal records reflect the number of participants and a "zero" value if that is the case, with an explanation as to why there was no transfer for value to the HCPs.

However, the guiding principle is always that companies should disclose what can be reasonably allocated as a transfer of value to an HCP individually or a group of HCPs in the aggregate. The manner of this allocation can be explained in the methodological note.

27. Transfer of Values to HCOs include fees for services and consultancy and grants and donations. There is an exception that R&D and market research is not to be disclosed. Does that mean that equipment donation for R&D activities provided to HCO are to be disclosed?

There are three parts to this question, and three answers. (1) Equipment provided for the purpose of typical R&D and market research activities does not need to be disclosed as long as the equipment is taken back at the end

of the activity. Otherwise the amount of the Transfer of Value must be at Fair Market Value of the equipment (see section 6 of the Code of Conduct). (2) Social contributions (whether funding or items) cannot be made to individuals or for-profit entities. (3) Social contributions of equipment under section 4.7 to charities, civic organisations, and non-profit institutions must be disclosed.

28. How long does a company need to retain information of the disclosure process?

For one year, unless a local law or regulations requires a longer retention period.

29. Is it mandatory to disclose Transfers of Value regarding OTC products?

No. OTC is out of scope of the Code of Conduct.

30. Can organization publish the disclosure report in a form of a searchable database?

Yes, provided that the searchable database must be available by:

- name of the HCP, HCO, or patient organization (PO),
- city where the HCP practices his/her profession or where the HCO/PO is based or by the HCP's licensing number if the city is not available. The use of a drop-down list of cities is suggested.

The report excerpt from the searchable database should provide information corresponding to the selected search as follows:

- For HCPs, HCOs, and POs who agreed to disclosure, information should be provided for the individual HCP, HCO, and PO and in the aggregate for all HCPs, HCOs, and POs.
- For HCPs, HCOs, and POs who did not agree to disclosure, information should be provided in the aggregate for all HCPs, HCOs and POs.

31. What should I do if the local association's rules or code of conduct have different disclosure requirements?

The Code of Conduct of Medicines for Europe sets a minimum threshold for disclosure of Transfers of Value. Local associations may have additional requirements. If you are a member of the local association, or have agreed to follow that association's rules, you must follow the more restrictive disclosure requirements. Please note the difference in the methodological notes in the disclosure report.

32. Do we have to disclose transfers of value to pharmacists?

If a pharmacy provides consulting or other services typical of those provided by HCPs or healthcare organizations (HCOs), then the Transfers of Value related to such services must be disclosed.

If the pharmacy provides standard commercial services (for example, placement of products on shelves at set rates), then these amounts do not need to be disclosed.

Enforcement Procedure

1. What is the Review procedure?

As pointed out in Section 5 of the Medicines for Europe Code, their member companies should follow, in the first instance, the enforcement procedures set out by the relevant Medicines for Europe national association. National associations should therefore establish enforcement, complaint and appeal procedures, preferably by self-regulatory mechanisms and if appropriate by additional co-regulatory mechanisms.

In the exceptional event that a Medicines for Europe national association member does not have adequate enforcement procedures, the following procedures apply. A national association may also transfer a claim to the Medicines for Europe Secretariat for adjudication.

2. From when can a member company put forward a complaint based on the Medicines for Europe Code against other Medicines for Europe member?

As the Medicines for Europe Code has been implemented by national associations and member companies as of 31st July 2015 a complaint can be put forward following the enforcement rules of procedure, provided that the matter cannot be resolved to the members' mutual satisfaction through inter-company dialogue.

Medicines for Europe member companies should follow the complaint and enforcement procedures set out by the relevant Medicines for Europe national association, or the national accepted procedure/guidelines as adopted by the relevant national association, where the alleged infringement occurred.
In the exceptional case where no Medicines for Europe national association or accepted national complaint and enforcement procedure exist in an EU member state, the complaint may be directly filed with Medicines for Europe[9].

3. If the Code of Conduct has not been adopted during the initially agreed period, Can we extend the adoption period for a National association?

No. The Medicines for Europe Code has been implemented by national associations and member companies since 31st July 2015.

4. What is the procedure if a Medicines for Europe Member Company or subsidiary violates the Medicines for Europe code, but is not a member of a national association?

The Medicines for Europe Code applies to all European operations of all Medicines for Europe members. Subsidiaries of Medicines for Europe member companies must adopt either the Medicines for Europe Code or the Code that has been adopted by Medicines for Europe national association.

Therefore, if Medicines for Europe Member Company or subsidiary violates the Medicines for Europe Code, it will be subject to Medicines for Europe Enforcement Guidelines.

5. The code does not seem to take into account the possibility that a non-member company (or other stakeholder), may make a complaint.

Indeed, complaints from non-Medicines for Europe member companies may not be addressed under the enforcement procedure of the Medicines for Europe Code