

No. 31026/38/2020-MD
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

Janpath Bhawan, New Delhi
Dated the 16th March, 2022

PUBLIC NOTICE

Subject:- Draft Uniform Code for Medical Device Marketing Practices – request for feedback / comments of the Medical Devices Industry and other stakeholders - reg

The Medical Devices Sector in India is an essential and integral constituent of the Indian healthcare sector, particularly for the prevention, diagnosis, treatment and management of medical conditions, diseases, illnesses, and disabilities. It forms an important pillar in the healthcare delivery system along with healthcare providers, pharmaceuticals and health insurance industry, thereby helping achieve the key values enshrined in the National Health Policy (NHP) 2017 in terms of provision of good quality, affordable, and comprehensive healthcare to all citizens.

02. The marketing practices of the Medical Device Sector are currently being voluntarily regulated by Uniform Code for Pharmaceuticals Marketing Practices (UCPMP). Based on the request of the MedTech Industry to have a separate uniform code and having realized such needs, the Department has prepared a separate Uniform Code for Medical Device Marketing Practices (UCMDMP) in consultation with the Industry.

03. To have a wider stakeholder consultation, the draft UCMDMP is hereby published (**Annexure**) to seek specific comments from the Public/ Medical Device Industry representatives and associations / other stakeholders.

04. While giving the inputs, it may be kept in mind that UCMDMP is proposed to be a voluntary code. **The feedback/inputs may be sent at ucmdmp-2022@gov.in (in both PDF and Word document) by not later than 15.04.2022.**

This issues with the approval of Competent Authority.



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Draft Uniform Code for Medical Devices Marketing Practices (UCMDMP)

This is a voluntary code of Marketing Practices for Indian Medical Device Industry for the present and its implementation will be reviewed after a period of six months from the date of its issue. If it is found that it has not been implemented effectively by the Medical Device Associations/Companies, the Government may consider making it a statutory code.

Definitions.

- i. **Medical Devices.** The definition of medical devices shall be as per Drugs and Cosmetics Act, 1940 (DCA) and Medical Device Rules, 2017 (MDR), as amended from time to time or any other Act enacted by Government of India in future to govern medical devices.
- ii. **Health Care Professional (HCP).** A health care professional is any person or entity (a) authorized or licensed in India to provide health care services or items to patients or (b) who is involved in the decision to purchase, prescribe, order, use or recommend a Medical Device in India. This term includes individual clinicians (for example, physicians, nurses, technicians and pharmacists, OT staff, Optometrists, Pathologists, Transfusion Professionals, Lab technicians, among others), provider entities (for example, hospitals, ambulatory surgical centers, Pathology Labs, Blood Banks amongst others), and administrative personnel at provider entities in India (for example, hospital purchasing agents). This term does not include health care professionals who are *bona fide* employees of a Company, while acting in that capacity.
- iii. **Regulatory Authority.** Central Drugs Standard Control Organization (CDSCO) or any other National Regulatory Authority as per Act & Rules laid thereunder.
- iv. **Medical Device Rules (MDR).** MDR means Medical Device Rules, 2017 as amended from time to time.
- v. **Act.** Act means Drugs and Cosmetics Act, 1940 or any other Act that may be enacted by the Government of India in future to govern Medical Devices.
- vi. **Company/ Companies.** An entity, whether a company, proprietorship, partnership or association that develops, distributes, resells, produces, manufactures, imports and/or markets Medical Devices and shall include agents and third parties acting on behalf of the Company.
- vii. **Promotional Materials.** Material used by the Company for the commercial promotion (for sales and marketing purpose) of its products & services distributed to

HCP or to the patients directly including but not limited to any audio visual material in print or digital, advertisements in journals or online media; but specifically excludes educational material such as surgical technique portrayal, disease awareness material, research/ clinical material, evaluation reports or information/ documents as mandated by regulatory provisions from time to time etc. The word promotion, promotional or promoted used in this code, shall be interpreted according to this definition.

- viii. **Third Party program:** An independent health care-related educational, scientific, business, and/or policymaking conference, meeting, or event put on by a third party other than a Company. This term includes programs that are accredited to provide continuing education credits and programs that are not accredited.

1. General Points

- 1.1 A Medical Device must not be promoted prior to receipt of the product registration (wherever applicable) by the Regulatory Authority, authorizing its sale or supply as per the Medical Device Rules.
- 1.2 The promotion of a Medical Device must be consistent with the terms of documents submitted by the Companies for obtaining product registration or licenses to manufacture, import and sell these Medical Devices in India; and specifically the Instructions For Use (IFU)/Directions For Use (DFU) of the relevant product.
- 1.3 Product Information about Medical Devices must be up-to-date, verifiable and accurately reflect current knowledge or responsible opinion.
- 1.4 Product Information about Medical Devices must be accurate, balanced, fair, objective, and must not mislead either directly or by implication.
- 1.5 Product Information about Medical Devices must be capable of substantiation.
- 1.6 Substantiation that is requested pursuant to para 1.5 above must be provided within a reasonable period of time, by the authorized sources of the Company at the request of HCPs.

2. Claims & Comparisons

- 2.1 Claims for the usefulness of a Medical Device must be based on evaluation of the available and published evidence and/or IFU/ DFU of the relevant product.
- 2.2 The word "safe" or "safety" must not be used without qualification and it must not be stated categorically that a Medical Device has no adverse consequences. All product

claims should be in accordance with the terms of documents submitted by the Companies for obtaining product registration or licenses to manufacture, import and sell the Medical Devices in India; and specifically the IFU/DFU/eIFU/ User manual of the relevant product.

2.3 Comparisons of Medical Devices must be factual, fair and capable of substantiation by way of available data. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis, omission or in any other way.

2.4 In order for a comparative advertisement to be considered permissible, it:

- (a) shall be factual, accurate and capable of substantiation; and
- (b) shall not present a good or service as an imitation or replica of a good or service with a protected trademark or trade name.

2.5 Advertisements/ Promotional Material containing comparisons with other manufacturers, suppliers, producers or with other products, including where a competitor is named, shall be permitted in the interest of promoting competition, where—

- (a) the features of the competitor's product being compared to the features of the advertiser's products are specified clearly within the advertisement;
- (b) the subject matter of the comparison is not of such nature so as to confer an artificial or unjustifiable advantage upon the advertiser; and
- (c) the nature of comparisons is such that they are factual, accurate and capable of being substantiated.

2.6 Other Companies, their products, services or promotions must not be disparaged either directly or by implication. Any discussions and substantiation in this regard shall be based on available and published evidence.

2.7 The clinical and/or scientific opinions of members of HCPs, which are based on available clinical evidence must not be disparaged either directly or by implication.

3. Textual and Audio-Visual Promotional Material

3.1 All Promotional Material issued by Company, must be consistent with the requirements of this Code and the applicable laws.

3.2 Where the purpose of Promotional Material is to provide persons qualified to prescribe or supply with sufficient information upon which to reach a decision for prescribing or for use, then the following minimum information, must be given clearly and legibly and must be an integral part of the Promotional Material:

- (i) The relevant Medical Device, the name and address of the holder of the manufacturer/importer of the Medical Device or the business name and

address of the part of the business responsible for marketing the Medical Device on the market;

- (ii) The name of the Medical Device and the generic name, of the Medical Device;
- (iii) Recommended use and method of use;
- (iv) Warnings and precautions for use and relevant contraindications of the product;
- (v) A statement that additional information is available on request; and
- (vi) The date on which the above particulars were generated or last updated.

3.3 Promotional material must not be designed to disguise their real nature. Where a Company pays for or otherwise secures or arranges the publication of Promotional Material in journals, such Promotional Material must not resemble editorial matter.

3.4 All Promotional Materials, the publication of which is paid for or secured or arranged by a Company and referring by brand name to any product of that Company, must comply with Clause 3.3 of this Code as appropriate, irrespective of the editorial control of the material published.

3.5 Promotional material must conform, both in text and illustration, to canons of good taste and must be expressed so as to recognize the professional standing of the recipients and not be likely to cause offence.

3.6 The names or photographs of HCPs must not be used in Promotional Material.

3.7 Promotional material must not imitate the devices, copy slogans or general layout adopted by other Companies in a way that is likely to mislead or confuse.

3.8 Where appropriate (for example, in technical and other informative material), the date of printing or of the last review of Promotional Material must be stated.

3.9 Audio-visual material must be supported by all relevant printed material so that all relevant requirements of the Code are complied with.

4. Medical Device Representatives and other third parties

4.1 The term "medical device representatives" means sales representatives, clinical specialists including personnel retained by way of contract with third parties and any other Company representatives who call on HCPs, pharmacies, pathology lab/ research lab, hospitals & health authorities, or other healthcare facilities in connection with the promotion of Medical Devices.

4.2 Medical representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties. They must comply with all relevant requirements of the Code.

- 4.3 Medical representatives must not employ any inducement or subterfuge to gain an interview. They must not pay, under any guise, for access to a HCP.
- 4.4 Companies are responsible for the activities of all their employees including Medical Representatives for ensuring compliance of the Code.
- 4.5 Company's medical representatives may play a role in the clinical setting by providing technical support on the safe and effective use of Medical Device, wherever required. Some examples include:
- (i) Medical representatives may need to explain how a Medical Device's unique settings and technical controls function and may make recommendations.
 - (ii) Medical representatives may assist the clinical/operating room team to ensure that the appropriate range of necessary devices and accessories are available during a procedure, especially when dealing with Medical Device that involves multiple devices and/or accessories.
- For above purposes, Company's medical representatives shall comply with applicable hospital or facility policies and requirements, including patient privacy and credentialing requirements as per the applicable laws, guidelines and codes.
- 4.6 Other third parties working for or on behalf of Companies, and those that do not act on behalf of Companies (such as joint ventures and licensees) commissioned to engage in activities covered by the Code should also have a good working knowledge of the Code and should abide by applicable laws.

5. Evaluation Samples

- 5.1 Free evaluation samples of Medical Devices shall not be supplied to any person other than HCPs or as per hospital protocol to reach the HCPs.
- 5.2 Where evaluation samples of products are distributed by a medical representative, the sample must be handed directly to a person qualified to use & prescribe such product or to a person authorized to receive the sample on their behalf.
- 5.3 The following conditions shall be observed in the provision of evaluation samples to a person qualified to prescribe such product:
- (i) Such samples are provided for the purpose of acquiring experience in using such a product, hands on experience and evaluation.
 - (ii) An adequate system of control and accountability must be maintained in respect of the supply of such samples by all Companies including maintaining proper documentation and rationale.

- (iii) Each sample shall be accompanied by a copy of the most up-to-date version of the Product IFU/DFU/ e-IFU (link to the website/digital IFU), wherever applicable, relating to that product.
- (iv) The number of evaluation samples (single use products) provided at no charge should not exceed the quantity reasonably necessary for the adequate evaluation of the products.

5.4 The Companies will maintain details, such as product name, HCP's name & contact information, Quantity of evaluation samples given, Date of supply of evaluation samples distributed to HCPs, relevant product traceability information.

5.5 Demonstration products: Company demonstration products are different from Evaluation Samples. Demonstration products can be either single use products, mock-ups, temporary software or equipment that are used for HCP and Patient awareness & education. Demonstration products are typically identified as not intended for patient use and demonstration equipment are taken back by Company after the demonstration period is over. However, consumables used in live procedural demonstration usually cannot be taken back. Clause 5 of this code does not apply to demonstration products and is limited to Evaluation Samples only. Demonstration products shall be specifically identified and tracked by the Company.

5.6 The documents/records required to be maintained under this Clause shall be maintained by Company for a period, as per applicable laws specific to category of document/record and in absence of such applicable laws as per Company's record management policy.

6. Gifts

6.1 No gifts, pecuniary advantages or benefits in kind shall be supplied, offered or promised to persons qualified to use, prescribe or supply Medical Devices, by a Medical Device Company or any of its agents i.e., distributors, wholesalers, retailers etc.

6.2 Gifts for the personal benefit of HCPs and family members (both immediate and extended) (such as tickets to entertainment events) shall not be offered or provided.

6.3 Companies may occasionally provide modest, appropriate educational items to HCPs that benefit patients or serve a genuine educational function for HCPs. Educational items can include but are not limited to product manuals and anatomical models. Hence, Companies can supply Medical education materials like books including e-books, and subscription to online portals (that can help download the materials for medical education and knowledge dissemination), anatomical models, bone/animal models, manuals and small products/educational material related to the training/Continued Medical Education (CME)/in hospitals or in clinic training, to HCPs or institutions.

Companies should maintain adequate records to support any expenses on above educational material.

6.4 Companies may occasionally provide modest, appropriate brand recall items/ brand reminders, which are customary business courtesies and are reasonable in value and frequency. However, the value of such brand recalls items/ brand reminders shall not exceed INR 1,000 (Rupees One Thousand). Companies shall maintain proper documentation with respect to expense incurred on such brand reminders.

6.5 The documents/records required to be maintained under this Clause shall be maintained by Company for a period, as per applicable laws specific to category of document/record and in absence of such applicable laws as per Company's record management policy.

7. Relationship with HCPs

A HCP's first and highest duty is to act in the best interests of their patients. Medical Device Companies should help HCPs meet this duty through necessary, collaborative interactions without interfering with their professional autonomy and the autonomy of the medical institutions that the HCPs may be associated with. Specifically, Companies may collaborate with HCPs and engage in activities including but not limited to providing consulting services, conducting clinical studies and doing research, participate in Company conducted training & education (physical and digital platform) including continued medical education, product trainings, business meetings, webinars etc. In no event, the engagements/collaboration with the HCPs shall be conditional upon any obligation for the HCPs to use, recommend, promote or purchase products of the Medical Device Companies or any of its affiliate's or intended to influence HCPs to do so.

7.1 Training and Educational Programs: Companies directly or in collaboration with health care professionals/ certain third parties conduct educational activities, with an objective of:

- advancing medical care and clinical science through **research, therapy development, standard treatment protocol development, product development, and product testing** that results in new or improved, innovative medical technology.
- **instruct, educate, and train** health care professionals on the safe and effective use of Medical Technology.
- provide **product service and technical support** for health care professionals to help ensure the safe and effective use of Medical Technology
- support health care professionals' **scientific and medical research, as well as the enhancement of clinical skills and educational opportunities** to improve patient care.

Following are the broad categories of Trainings and Educational Programs:

- i. **Company conducted Product and Procedure Training programs/ IN-Service program:** Company have a responsibility to train and educate IN-SERVICE team of the hospital and HCPs on the safe and effective use of the medical technologies, products, the procedures in which these medical technologies are used, and other related information. These programs may be delivered by Company professionals or by engaging HCPs/ experts. Such trainings of medical device or technology helps achieve its effective use in patients. This is the minimal training prescribed by the company to allow the HCPs to get access to the products and use them safely and effectively whether conducted by Company representatives or engaging experts in the domain.
- ii. **Company's Promotional Event:** This involves any company conducted seminar, conference, or meeting for or launch of a new product and/or technology or promoting an existing product or technology amongst HCPs viz. product showcase, branding, stalls and other promotional activities including offline and online media through various lectures and Seminars
- iii. **Third party conducted Continued Medical Education (CMEs) activities sponsored/ funded by Company (wholly or partially):** A Scientific program organized by and controlled by a HCP, HCPs Associations, Event companies or any other entity for the purpose of group learning and skill upgradation for HCPs. These events can either be accredited for continued medical education or otherwise.

HCPs may participate in above programs either as a faculty/Trainer/Proctor or as a delegate/Trainee.

Faculty/Trainer/Proctor: Any HCP who has expertise on the subject and has a capability to train or teach other HCPs on the effective and safe use of a medical device, Technology or Procedure.

Delegate/Trainee: Any HCP who intends to gain knowledge by interacting and getting trained by the Faculty /Trainer/Proctor/peers or a company during an event.

While engaging with HCPs for above programs, Companies shall strictly follow the guidance provided in **Annexure 1** of this Code.

- 7.2 Cash or monetary grants: Companies or their associations/representatives shall not pay any cash or monetary grants to any HCP for individual purpose in individual capacity under any pretext. However, Companies may provide educational grants to training institutions (such as medical schools, teaching hospitals, hospitals & institutions having approved teaching seats) and to other third-party entities in support of their legitimate scientific, educational and training programs and other activities ("Third Party Program"). This includes, but is not limited to, educational grants to support the education and training of health care and medical personnel (for example, physicians, medical students, residents, fellows, or other HCPs-in-training or in practice), patients, government officials and regulators (per approval from respective institutions and as

per applicable laws and applicable service rules), and the selected patient group/public about important health care topics. Such grants shall be made as per the modalities laid down by law/rules/guidelines adopted by such institutions, in a transparent manner. It shall always be fully disclosed, and Companies shall maintain adequate records of such grants in their books.

- 7.3 Consultancy/ Honorariums: Companies engage HCPs to provide a wide range of valuable, *bona fide* consulting services for education purposes under a consultancy contract/ agreement involving consultancy fee/ Honorariums based payment to HCPs based on fair market value for the specific scope of services. Some examples include arrangements for a HCP to provide education and training (including online), speaking services, proctorships (evaluate), preceptorships (instruct), reference center or center of excellence services, participation on advisory boards or focus groups, Medical Device development and research services arrangements (such as research and development, clinical studies, clinical trials, clinical investigator services, collaborative research, and post-market research), and arrangements for the development or transfer of intellectual property. Such consultancy contract shall record the agreed terms fully in transparent manner and shall be disclosed, if required to do by appropriate authority. Companies shall maintain adequate records for any expenses / fee paid as per such consultancy contracts.
- 7.4 Prohibition of Entertainment & Recreation: Companies shall not provide or pay for any entertainment or recreational event for HCPs, their staff or their family. Some examples of entertainment and recreational activities include, among others, theater, live comedy or musicals, sporting events, golf, skiing, cruises, spas, or vacation trips. This prohibition applies regardless of (1) the value of the activity; (2) whether the Company engages the HCP as a consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.
- 7.5 Third Parties educational activities /CMEs: Companies shall document a clear understanding that amount of sponsorship or education grant contributed by Company toward the third party conducted event, shall be spent only for legitimate purposes and in compliance with this UCMDMP code and/or applicable laws.

Further, for any such third-party events, no Direct sponsorship of a health care professional to a third-party program is permitted. Companies are not permitted to pay, offer to pay or offer to reimburse any expense (e.g., travel, stay, local travel, honorarium etc.) in support of attendance of health care professionals to third-party programs as faculty. Companies must not select or influence selection of health care professional attendance to third-party program. Companies may engage HCPs under a professional services agreement for a company-conducted **satellite symposium** held alongside third-party programs and may compensate in accordance with fair market value. Travel and lodging should be considered only if the health care professional is travelling solely for the **satellite symposia** which is organized by the Company.

- 7.6 The documents/records required to be maintained under this Clause shall be maintained by Company for a period, as per applicable laws specific to category of document/record and in absence of such applicable laws as per Company's record management policy.

8. Mode of Operation

- 8.1 All the Medical Device Manufacturer associations in India ("Association") will have UCMDMP uploaded on their website.
- 8.2 Once a complaint is lodged and Association receives information from which it appears that a Company may have contravened the Code, the managing director or chief executive or equivalent of the Company or authorized person(s) of the Company concerned will be requested to investigate, take corrective actions and provide a response to the matters of complaint to the Association.
- 8.3 All the associations will also have a provision on their website for uploading the details of complaints received i.e., the number of complaints received, the current status, time taken to close, the nature of complaint and the action taken in brief. The name of the Company shall be kept confidential only revealing the details of the matter. This information shall be updated frequently to reflect the latest status. Such details shall also be sent by the concerned Association on Quarterly basis, to National Pharmaceutical Pricing Authority, on following address:

Member Secretary, NPPA, 3rd Floor, YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi- 110001.

- 8.4 If a complaint received in a particular association is not concerned with its members, the receiving association will input the details of the complaint but in the column of action taken, it will mention that the complaint has been transferred to such and such association as the respondent Company is member of the other association. Also, if a Company is a member of multiple associations, the association who receives the complaint first shall communicate with Company with respect to investigation of complaint. Company shall not be responsible to report to any other association.
- 8.5 If a complaint is received by an association pertains to a Company which is not a member of any association, association's role will be to inform the complainant that the company is not a member of the association, and that complainant may directly reach out to the Managing director or Chief executive or equivalent of the Company to register the complaint.

9. Procedure of Lodging a Complaint

- 9.1 All complaints, related to the breach of the code should be addressed to Secretary General/Chairman/President, "Name of Association".
- 9.2 All complaints about any one activity of breach of code should to the extent practicable be made at one time. The complaint must be made within three months of breach of code.
- 9.3 Complaints must be in writing and for each case THE COMPLAINANT should:
- (i) identify itself (whether a Company or an individual) with a full mailing address (email ID and mobile telephone nos.). No anonymous complain will be entertained. When the complaint is from a Medical Device Company or any statutory body/association/ forum, the complaint must be signed or authorized in writing by the Company's/statutory bodies' managing director or chief executive or equivalent and must state those clauses of the Code which are alleged to have been breached.
 - (ii) identify the Company which is alleged to be in breach of the Code, and the name of any Company personnel, product or products which are specifically involved.
 - (iii) give the details of the activity which is alleged to be in breach of the Code
 - (iv) give the date of the alleged breach of the Code
 - (v) provide supporting evidence of the alleged breach(es)
- If the complainant fails to provide the necessary details as above, within the stipulated [period of three months of the breach of code, the said complaint shall be discarded.
- 9.4 A non-refundable amount of Rs.1,000/- (Rupees One Thousand Only) is to be deposited by the complainant along with the complaint. The associations will elaborate how this payment is to be made within a month of issue of the code and upload the same on their website.
- 10.5 The Association may take suo moto cognizance of any media reports (other than letters to the editor of a publication or any social media circulation) that a Company may have breached the Code, by treating such media reports as a complaint and the committee may request the concerned publication for further information. In case the complainant fails to provide the necessary details or substantiate the complain the same may be discarded.
- 10.6 The Association may take suo moto cognizance of any published letter, from which it appears that a Company may have breached the Code, and deal with as a complaint with the author being treated as the complainant. In case the complainant fails to provide the necessary details or substantiate the complain the same may be discarded.
- 10.7 Any complaint received by the Department of Pharmaceuticals will also be forwarded to the concerned Association for necessary action. In such cases, the concerned association will further take up the matter with the complainant directly.

11. Procedure of Handling of Complaints

Once a complaint is lodged and Association receives information from which it appears that a Company may have contravened the Code, the managing director or chief executive or equivalent of the Company or authorized person(s) of the Company concerned will be requested to investigate, take corrective actions and provide a response to the matters of complaint.

12. Self-Declaration

Finally, the Managing Director/CEO or an authorized signatory of the Company is ultimately responsible for ensuring the adherence to the code and a self-declaration, in the format given in Annexure 2 shall be submitted by the executive head of the Company within two months of date of issue of UCMDMP and thereafter within two months of end of every financial year to the Association for uploading the same on the website of the Association. The same must be uploaded on the website of the Company also.

Annexure 1

1. Travel and Hospitality: There may be Company conducted educational/training programs, products trainings or other scientific meetings for which a Company determines it is appropriate to pay for HCP's travel and lodging costs. This section of the Code provides Companies with guidance on paying for a HCP's travel and lodging costs. Following shall be the code practiced for incurring travel and hospitality expense by the Companies.

	Company conducted Product and Procedure Training programs/ IN- SERVICE programs	Company conducted Promotional programs	Third Party conducted CMEs sponsored by Companies for peer learning
Faculty/Trainer/ Proctor			
Modest Meals	YES	YES	YES (only for company owned session in CME)
Travel reimbursement	YES	YES	YES (only for company owned session in CME)
Hotel Stay	YES	YES	YES (only for company owned session in CME)
Honorariums for lectures	YES	YES	YES (only for company owned session in CME)
Delegate/ Trainee HCPs			
Modest Meals	YES	YES	YES (only for company owned session in CME)
Travel reimbursement	YES	NO	NO
Hotel Stay	YES	NO	NO
Honorariums for lectures	NO	NO	NO

Companies shall apply the following principles while incurring Travel and Hospitality expense:

- a) **Legitimate Need.** Companies should document the legitimate need for travel with clear purpose.
- b) **Modest and Reasonable.** Travel and lodging accommodations and costs must be modest and reasonable under the circumstances. Companies are encouraged to establish controls on the appropriate class of travel service and the appropriate level of lodging accommodations.
- c) **Travel Time & Destination.** Companies are also encouraged to ensure criteria are established and taken into consideration while making such arrangements for HCPs (for example, travel dates to be +/- 24 hours from the start and end of the event date(s), respectively, or travel to and from the place of the HCP's official residence/practice unless there is a justified need to make arrangements from some other place).
- d) **Guests/family.** Companies shall not pay for or otherwise subsidize the travel or

lodging of spouses or guests of HCPs or for any other person who does not have a bona fide professional interest in the information being shared at the Company's meeting.

- e) Personal Travel & Lodging. Companies shall not pay for a HCP's personal travel or lodging costs that are not connected to above mentioned events.
- f) Venue. The venue and setting for a Company-conducted program or meeting of HCPs should always be conducive to the exchange of information, suit the particular purpose of the program/ training/meeting, and should not be the main attraction of the event. Companies should consider the following principles when choosing a setting:
 - (i) The setting should be in a business/ clinical environment as deemed suitable for the purpose, preferably centrally located and easily accessible
 - (ii) Companies should not select a setting because of its entertainment or recreational facilities
 - (iii) Companies should avoid top category, luxury hotels, resort and/or cruise facilities without an appropriate justification.

2. **Meals and Refreshments:** Companies may occasionally provide HCPs with modest meals and refreshments subject to the following principles:

- a) Purpose. The meal or refreshments should be subordinate in time and in focus to the *bona fide* discussion and presentation of scientific, educational, or business information. [The meal or refreshments should be modest and not be part of an entertainment or recreational event.]
- b) Setting & Location. Meals and refreshments should be provided in a setting that is conducive to *bona fide* scientific, educational, or business discussions.
- c) Participants. Companies shall provide a meal or refreshments only to HCPs who attend and have a *bona fide* purpose for attending the meeting.
- d) Documentation. Companies should establish controls to ensure the purpose and execution of the meeting is reasonably documented.

Annexure 2

A. Self-Declaration By Executive Head Of The Company Regarding Compliance To The Uniform Code For Medical Device Marketing Practices, to be made within two months of issue of the code

"This is to declare that(name of the Company), Headquarters at ,will comply with the provisions laid down in the Uniform Code for Medical Device Marketing Practices."

Name and Designation
Seal of the Company

B. Self-Declaration By Executive Head Of The Company Regarding Compliance To The Uniform Code For Medical Device Marketing Practices, to be made within two months of end of every financial year:

"This is to declare that(name of the Company) , Headquarters at ,has complied with the provisions laid down in the Uniform Code for Medical Device Marketing Practices . This declaration is for the financial year... .. "

Name and Designation
Seal of the Company