



Apex Committee for Pharma Marketing Practices
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

ACPMP No. 01/2024

Dated the December 23, 2024

In the matter of: M/s. AbbVie Healthcare India Private Ltd
under the Uniform Code for Pharmaceutical Marketing Practices, 2024.

ORDER

On May 21, 2024, the Department of Pharmaceuticals received an anonymous complaint, accompanied by documents supporting the claims, concerning unethical marketing practices related to AbbVie Inc.'s subsidiary – AbbVie Healthcare India Private Ltd ("AbbVie"), alleging a breach of the Uniform Code for Pharmaceutical Marketing Practices ("UCPMP"). The complaint outlined that the pharmaceutical company – AbbVie provided travel tickets and hotel accommodations for extravagant pleasure trips under the guise of conferences (Aesthetics & Anti-Aging Medicine World Congress 2024), which took place from February 1 to 3, 2024, and from March 26 to 29, 2024, in Monaco and Paris, respectively, for 30 doctors connected to the medical aesthetics/anti-ageing products (Botox and Juvederm). The supporting documents comprised AbbVie's internal records, featuring a sales and expense tracker, outlining the expenditures for each doctor's travel and copies of flight tickets and hotel booking vouchers.

2. The conduct of the pharmaceutical company(s) with the Healthcare professionals ("HCPs") was initially regulated under UCPMP 2014, and later, following the new code under UCPMP 2024. Both the 2014 and 2024 codes are grounded in the shared principle: they forbid pharmaceutical companies from offering 'Travel and Hospitality,' to any healthcare professional. The 2014 code outlines restrictions in paragraphs 7.1 and 7.2, which state as follows:

"7.1 Travel facilities: Companies or their associations/ representatives or any person acting on their behalf shall not extend any travel facility inside the country or outside, including rail, air, ship, cruise tickets, paid vacations, etc., to HealthCare Professionals and their family members for vacation or for attending conference, seminars, workshops, CME programme etc., as a delegate. It is hereby clarified that in any seminar, conference or meeting organized by a pharmaceutical company for promoting a drug or disseminating information, if a medical practitioner participates as a delegate, it will be on his/her own cost.

7.2 Hospitality: Companies or their associations/ representatives shall not extend any hospitality like hotel accommodation to Healthcare Practitioners and their family members under any pretext."

3. Paragraph 8 of UCPMP-2024, along with other provisions, details the relationship between a company and HCPs, imposing restrictions on travel and hospitality. Paragraphs 8.2 and 8.3 of the Code state as follows:

"8.2 Travel: Companies or their representatives, or any person acting on their behalf, should not extend travel facilities inside or outside the country, including rail, air, ship, cruise tickets, paid vacations, etc., to healthcare professionals or their family members (both immediate and extended) for attending conferences, seminars, workshops etc., unless the person is a speaker for a CME or a CPD Program.

8.3 Hospitality: Companies or their representatives, or any person acting on their behalf, should not extend hospitality like hotel stay, expensive cuisine, resort accommodation etc., to healthcare professionals or their family members (both immediate and extended) unless the person is a speaker for a CME or a CPD program".

4. Despite the anonymity of the complaint, the allegations against the company were severe and explicitly contravened the schema of the UCPMP. The Department of Pharmaceuticals ("DoP") forwarded the complaint to the Ethics Committee for Pharma Marketing Practices ("ECPMP"), set up by the Organisation of Pharmaceutical Producers of India ("OPPI") as relevant in the case of M/s. AbbVie, to take appropriate action. Simultaneously, DoP, in accordance with paragraph 10.7 of the UCPMP 2024, decided to conduct a Special Audit of M/s. AbbVie given the seriousness of the allegations. *Vide* Order dated September 02, 2024, a special audit committee was constituted comprising officers of the DoP to examine the authenticity of the allegations.

5. ECPMP released its findings on September 20, 2024. While the OPPI sees no irregularities in M/s AbbVie's sponsorship of 30 HCPs to foreign destinations (thus exonerating them), the conclusions drawn by the Special Audit Committee are exactly the opposite. The results of the Special Audit validated that all facts mentioned in the complaint were accurate and that M/s. AbbVie was in breach of UCPMP 2014 and UCPMP 2024. The total expenditure for 24 doctors travelling to Paris and 6 doctors to Monaco amounted to INR 1,91,24,991/- (One crore ninety-one lakh twenty-four thousand nine hundred ninety-one rupees only) for travel tickets and hotel accommodations in foreign locations, which was an explicit contravention of the codal provisions.

6. After the Special Audit Committee presented its findings confirming the allegations, the Apex Committee commenced its hearing by providing the alleged violator with the chance to present their defense on September 30,



2024, and again on October 21, 2024. The alleged violator attempted to justify its breach as acceptable industry practice. M/s. AbbVie sought to persuade that Self Declaration determines when the Code takes effect. The Apex Committee explained that Self Declaration is only a sensitization provision that does not mean that the UCPMP 2024 is inapplicable prior to that date. As an example, the Code of 2014, which was announced on December 12, 2014, was given an effective date of January 1, 2015. Without any indication of relaxation, it can be concluded that the 2024 Code is effective from the date of its notification. In any case, the previous code is applicable till the new code takes effect.

7. Moving ahead, M/s. AbbVie claimed that it entered into a Professional Service Agreement ("Agreement") with these HCPs to compensate them for their services. These Agreements lack specifics on what services HCPs are expected to deliver. The paragraph is deliberately structured in a vague manner: *"Services. Counterparty will conduct a Knowledge Dissemination Activity ("KDA") as identified and in a manner required by AbbVie on a date that is mutually agreed in writing."* The Apex Committee observed that such Agreement(s) were a clever ploy to present an impression of compliance with the regulations, while facilitating foreign travel and hotel accommodations funded directly from the M/s. AbbVie's budget. The agreements entered into by M/s. AbbVie do not clarify why such highly trained HCPs need to be provided with foreign travel opportunities to gain knowledge about simple procedures in medical aesthetics, such as administration of "Botox and Juvederm." Such medical interventions are widely recognized as a lucrative commercial service and evidence attached to the complaint links HCPs directly to the sale, purchase, or administration of such aesthetic products of M/s AbbVie. There seems to be no justifiable reason for 30 healthcare professionals to journey abroad to Monaco and Paris for this purpose, nor can any prudent person overlook the conclusion that such preferential treatment or largesse towards HCPs will not aid in promotion of M/s AbbVie's products, regardless of the terms of the Agreement(s). This arrangement seriously undermines the scope and intent of UCPMP 2014 and UCPMP 2024 and fractures the tenet of public good that is sought to be achieved through these Codes.

8. Reference may be drawn to observations of the Hon'ble Supreme Court in *"Apex Laboratories (P) Ltd. v. CIT"* (2022) 7 SCC 98, highlighting that arrangement between pharmaceutical companies and medical practitioners to offer freebies to boost the sales of prescription drugs constitutes a breach of Section 23 of the Contract Act, 1872. The Hon'ble Apex Court also emphasized a known principle that what cannot be done directly, cannot be achieved indirectly. The instant matter is no different from Hon'ble Court's observation on the relationship between pharmaceutical companies and the healthcare practitioners.


9. Taking a holistic view that harmonises public trust in UCPMP with the necessity for equity, the Apex Committee gave an opportunity to M/s. AbbVie to consider remedial action by extending support to underprivileged patients receiving treatment at Government Hospitals for an amount equivalent to the violations computed by the special audit team. M/s. AbbVie was also given latitude to figure out the ways and mechanisms for providing such aid, whether



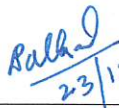
financially or otherwise. M/s AbbVie chose to reject the Apex Committee's offer dated November 7, 2024 as per its communication dated December 10, 2024.

10. Upon perusal of the facts and after hearing M/s. AbbVie at length, the Apex Committee is of the opinion that M/s. AbbVie has violated the provisions of the Uniform Code for Pharmaceutical Marketing Practices by sponsoring foreign vacations to Monaco and Paris for 30 HCPs in violation of the codal provisions. Therefore, in exercise of powers conferred by the UCPMP 2024:

- i. The Apex Committee **reprimands** M/s. AbbVie Healthcare India Pvt Ltd for unethical marketing practices. A copy of this order be published on the website in accordance with the provisions contained therein.
- ii. The Central Board of Direct Taxes (CBDT) is requested to evaluate the tax liability of M/s. AbbVie Healthcare India Pvt Ltd along with 30 HCPs and take action in accordance with the provisions of the Income Tax Act, 1961 read with the subordinate circulars issued in this regard.
- iii. The National Medical Council (NMC) is requested to take action against the 30 offending HCPs as per Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002.


23/12/2024

Arunish Chawla
(Chairman)


23/12/2024

Palka Sahni
(Member)


23/12/2024

Manoj Sethi
(Member)

To:

1. M/s AbbVie Healthcare India Pvt. Ltd.
2. Chairman, Central Board of Direct Taxes (CBDT)
3. Chairman, National Medical Council (NMC)