

Decision in matter of violation of UCPMP by Micro Labs

1. Complaint:

The National Pharmaceutical Pricing Authority (NPPA) shared news articles dated 18.08.2022 and 19.08.2022 on “PIL filed by the Federation of Medical and Sales Representatives Association of India, stating that Dolo had invested 1,000 crores in freebies to have its anti-fever drug prescribed to patients”.¹ As per the UCPMP, the association is required to examine the matter further especially in wake of the media reports.

Earlier, a Press Note issued by Central Board of Direct Taxes (CBDT), Department of Revenue dated 13.07.2022 stated that Income Tax Department carried out search and seizure operations on 06.07.2022 on a major Bengaluru-based pharmaceutical group, engaged in the business of manufacturing and marketing of pharmaceutical products and Active Pharmaceutical Ingredients (API). It is alleged in the press release that the company adopted some unethical practices to promote its products/brands. IPA had examined the matter, decision attached hereto as *Annexure 1*. Basis the press note, NPPA has requested to provide action taken in the matter under the UCPMP, by IPA.

2. Process:

With regard to the earlier complaint through NPPA email dated 16 July 2022 along with press note of CBDT, the IPA examined the matter. The IPA Ethics Committee for Pharma Marketing Practices (ECPMP)² examined the matter.

The allegation in the current complaint basis the media reports is whether the manufacturers of the paracetamol drug 'Dolo', spent over Rs 1,000 crores as freebies to doctors. Further, it is to be examined if Dolo 650 is correct dosage to be administered to patients and if the drug is under drug price control.

Upon the receipt of the complaint, we intimated Managing Director of Micro Labs of the complaint and asked for a response. The Managing Director of the respondent company sent the reply along with supporting document denying the allegations which is attached herewith as *Annexure 2*.

¹ Links of articles:

<https://www.indiatoday.in/law/supreme-court/story/dolo-makers-freebies-crores-doctors-prescribing-tablet-supreme-court-pil-1989551-2022-08-18>

<https://www.livelaw.in/amp/top-stories/dolo-650-pharma-companies-freebies-to-doctors-supreme-court-206870>

<https://indianexpress.com/article/india/supreme-court-dolo-tablets-freebies-doctors-8098830/>

<https://www.indiatoday.in/law/supreme-court/story/dolo-makers-freebies-crores-doctors-prescribing-tablet-supreme-court-pil-1989551-2022-08-18>

<https://www.businessworld.in/article/Manufacturers-Of-Dolo-650-Tablet-Spent-1000-Cr-On-Freebies-To-Doctors-For-Prescribing-The-Drug-SC-Told/19-08-2022-442860/>

<https://economictimes.indiatimes.com/news/india/dolo-650-makers-spent-rs-1000-cr-on-docs-for-prescribing-drug-sc-asks-centre-to-file-a-reply/articleshow/93642719.cms?from=mdr>

² Three Members of the ECPMP are - Sandeep Singh, MD, Alkem; Aman Mehta, ED, Torrent Pharma and Sharvil Patel, MD Zydus Life Sciences

The internal committee examined the complaint and the response received. IPA spoke and investigated thoroughly with the officials of respondent company. Several rounds of discussion were held with the company on implementation of Code of Conduct and marketing promotion expenses.

3. Details related to the matter

Whereas, the alleged complaint is related to marketing expenses and related tax deduction, IPA Committee thoroughly investigated into the marketing practices adopted by the company and the alleged freebies given to doctors and whether they are aligned with the UCPMP Code.

Regarding the correctness of dosage of Dolo 650, the respondent company responded that paracetamol 650 mg is an official formulation approved by Indian Pharmacopoeia in the year 2018. Its strength has been approved in all the treatment protocols issued by the Government of India and various state governments including ICMR during the pandemic. Besides, it is a recommended dose across the world, and has been available in many countries such as the U.S., European countries. The company submits that 650mg strength is accepted as the appropriate dosage regimen for mild to moderate fever. The summary note in this regard is attached as *Annexure 3*.

Furthermore, the respondent submits that Dolo 650 mg is covered in the National List of Essential Medicines and its prices to the consumer are controlled by NPPA since 2016. The price of Paracetamol 650 was Rs 1.84/-per tablet in the year 2021. *Annexure 4*, note attached.

The respondent company has stated that it has been misrepresented that they have incurred expenses of 1000 crores in one year. The total turnover of the company is Rs 4500 crores, out of which around Rs 2500 crores is domestic sales. The overall expenses on domestic sales in last four years (year by year on all activities) on an average is Rs 200 crores, please refer to the table below:

Total Expenses on all products (Rs crores)

EXPENSES	FY 20-21	FY 19-20	FY 18-19	FY 17-18	FY 16-17
Product Management Team expenses	65	93	89	84	84
Scientific and Academic Services	67	101	99	88	76
Sales and Promotion Activities	53	67	62	48	39
Total Sales and Marketing Spend	186	260	249	220	199

According to the respondent, the total expenses on Dolo 650 incurred by the company in last five years and the details as under:

Dolo 650 Spend (FY 2016 to FY 2022) - Rs. Lacs						
Promotional Activities	2021 - 22	2020 - 21	2019 - 20	2018 - 19	2017 - 18	2016 - 17
Sales	36287	15771	12461	9581	8869	7345
Visual Aids, Literature & Print Promotional Inputs	28	7	35	49	21	7
Brand Reminders	124	190	177	209	252	53
Physician Samples	111	76	79	71	46	82
Scientific and Academic Services	890	439	603	978	472	376
TOTAL	1152	712	894	1307	791	518

The respondent company has conveyed that it will provide all the necessary information needed by the authorities.

Decision

In view of interaction with the management of the company and the detailed reply, it is clear Rs 1000 crore expenditure on single brand Dolo 650 on freebies in one year is not correct.

As far as the CBDT allegation regarding violation of tax provisions against the respondent company, the Committee and the Indian Pharmaceutical Alliance, association of Indian pharmaceutical companies, has neither the mandate nor the resources to investigate into such matter. Nonetheless, the respondent company has submitted that they are cooperating with the tax authorities for requisite information/clarification on marketing expenses and related tax implications.