DG OPPI

From:

DG OPPI

Sent:

13 December 2019 14:46 'Manoj Kumar Bhardwaj'

To: Cc:

Kanchana TK; 'doctorajaysharma'

Subject:

RE: Grievance of Mr. Anup Dinesh Gupta

Attachments:

Annexure A - Information regarding complaints received under UCPMP dated Oct.

2015.pdf

Dear Mr. Bhardwaj,

Thank you for the email.

We confirm having received the compliant from Mr. Anup Dinesh Gupta against one of our member companies, i.e., AstraZeneca on January 19, 2019.

At the outset, we wish to state that Organisation of Pharmaceutical Producers of India (OPPI) follows the OPPI Code of Pharmaceutical Practices (OPPI Code 2019) that is based on the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code 2019. The OPPI Code ensures that its member companies are committed to the ethical standards set out in this Code.

We also wish to state here that vide our letter dated October 9, 2015, we had represented before your Department that pending a clarity sought particularly in respect of 'Complaint Handling & Quarterly Reporting to NPPA' proposed under the 'Voluntary' Uniform Code for Pharmaceuticals Marketing Practices (UCPMP), OPPI will continue to adhere to the OPPI Code and that it will not expect to receive any complaint related to violation of the voluntary UCPMP Code. The said representation dated October 9, 2015 is attached as **Annexure A**. It is to be noted that OPPI has till date not received any clarification from your Department in the said regard and therefore, continues to follow the OPPI Code which is more stringent than the Voluntary UCPMP of the Department of Pharmaceuticals.

We wish to state that the process set out in the OPPI Code was duly followed while considering the subject complaint. AstraZeneca Pharma India Limited, an OPPI member, was forwarded the complaint and asked to respond. Based on the response received, OPPI put a closure to the same. Vide an email dated March 12, 2019, the complainant was duly informed of the said closure.

You may also be aware that Clause 10.2 of the voluntary UCPMP states that 'the complaint must be made within three month of breach of Code'. The subject complaint was clearly filed much beyond the period of said three months.

We hope that the above clarifies and is sufficient for the closure of the complaint from your end.

Regards,

Kanchana TK
Director General

Carolina Dsa

Executive Assistant

Tel: +91 22 2491 8123/6662 7007

E-mail: Carolina.dsa@indiaoppi.com

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Website: https://www.indiaoppi.com/



About OPPI

The Organisation of Pharmaceutical Producers of India (OPPI) established in 1965, represents the research-based pharmaceutical companies in India. OPPI remains committed to supporting the nation's healthcare objectives and collaborating with all stakeholders to find sustainable solutions. OPPI believes the need for innovation must be balanced with the necessity for more accessible medicines, within a robust IP environment. For more information, please visit https://www.indiaoppi.com/

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From: DG OPPI

Sent: 12/06/2019 12:32

To: Manoj Kumar Bhardwaj <mk.bhardwaj32@nic.in>

Cc: Kanchana TK <kanchana.tk@indiaoppi.com>; doctorajaysharma <doctorajaysharma@gmail.com>

Subject: RE: Grievance of Mr. Anup Dinesh Gupta

Dear Sir,

Apologies for the delay in responding, as our Director General has been out of office of the last few days. We will send our detailed response to you by mid of next week.

Regards,

(on behalf of)
Kanchana TK
Director General

Carolina Dsa

Executive Assistant

Tel: +91 22 2491 8123/6662 7007
E-mail: <u>Carolina.dsa@indiaoppi.com</u>
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From: Manoj Kumar Bhardwaj < mk.bhardwaj32@nic.in >

Sent: 12/06/2019 11:41

To: Kanchana TK <kanchana.tk@indiaoppi.com>; DG OPPI <dg@indiaoppi.com>; doctorajaysharma

<doctorajaysharma@gmail.com>

Subject: Fwd: Grievance of Mr. Anup Dinesh Gupta

REMINDER

It is regretted that no response is received from OPPI so far. The grievances received on CPGRAM are monitored by JS(P) and Secretary (Pharma) on weekly SOM meeting. Since the grievance is long pending, the matter is being taken very seriously. It is once again requested to expedite the reply by 3.00 pm today positively.

With regards,

M.K. Bhardwaj Deputy Secretary(Pricing/Policy) Department of Pharmaceuticals

From: "Manoj Kumar Bhardwaj" < mk.bhardwaj32@nic.in>

To: "kanchana tk" < kanchana.tk@indiaoppi.com >, dg@indiaoppi.com, doctorajaysharma@gmail.com

Sent: Wednesday, December 4, 2019 5:07:54 PM **Subject:** Grievance of Mr. Anup Dinesh Gupta

Madam,

DoP received grievance of Mr. Anup Dinesh Gupta in portal vide registration number PMOPG/E/2019/0588680 and PMOPG/E/2019/ 0012020 (copies enclosed). The grievances were settled requesting the complainant to send his complaint to the Ethics Committee of OPPI for further necessary action. However, being not satisfied with the reply, the complainant filed another grievance vide registration number PMOPG/E/2019/0131080, dated 7.3.2019. DoP vide its letter F.No.31026/3/2019-Policy, dated 22nd April, 2019 again requested him to send his complaint to DG, OPPI (copy enclosed).

However, Mr. Anup Dinesh Gupta again filed grievance on the portal vide registration Numbers PMOPG/E/2019/0623992 & PMOPG/E/2019/0629977 (copies enclosed). Mr. Gupta also forwarded the response received by him from OPPI vide e-mail dated 12th March, 2019 (copy enclosed).

In order to settle the repeated grievances received from Mr. Anil Dinesh Gupta, it is requested to confirm whether OPPI has adopted UCPMP. If yes, please confirm whether the procedure given in UCPMP is followed by OPPI in the instant case.

The matter may please be given priority to enable DoP to settle the grievance of Mr. Anup Dinesh Gupta.

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Ranjana Smetacek Director General

UCPMP-1-2015//38

October 9, 2015

Mr Raj Kumar Under Secretary Department of Pharmaceuticals Ministry of Chemicals and Fertilizers Government of India Shastri Bhavan New Delhi -110 001.

Dear Mr Kumar,

Subject: Information regarding complaints received under UCPMP [Confidential]

This is with reference to your letter No. 5/3/2009-PI-I/PI-II(Vol.III) October 6, 2015 on the subject, please find below OPPI's response.

The UCPMP was formalized by Government, in January 2015, as a voluntary code for the entire industry.

OPPI made a representation to DOP vide letter dated February 12, 2015, seeking some clarification. Pending clarity on the specific aspects of UCPMP, including complaint handling process, OPPI members continue to adhere to the stringent OPPI Code of Pharmaceutical Practices which is based on the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). This code ensures that all our member companies conform to the highest standards of ethical practices in pharmaceutical marketing and covers most aspects of UCPMP, sometimes with greater stringency. This code also contains a well-established complaint handling process for complaints pertaining to OPPI members.

In these circumstances, we would not expect to receive any complaint, from OPPI member companies, of violations relating to the voluntary UCPMP code.

The OPPI Secretariat does receive all concerns and complaints pertaining to OPPI member companies. We address these, in line with our well-established procedure, to arrive at a satisfactory conclusion.

Please note, OPPI concludes every monthly Executive Committee meeting with an agenda item 'Any matter relating to Ethics & Compliance' where any concerns/complaints relating to the OPPI Code are tabled before the Chairman.

Sincerely,

Ranjana Smetacek

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Director General