

**No.31015/01/2020-Pricing**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

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Room No. 207, D Wing, Shastri Bhawan,  
New Delhi-110 001.

**Order**

This is an order disposing review application dated 21.12.2020 filed by M/s Win Medicare Private Limited (referred as 'applicant' hereinafter) under Para 31 of Drugs Prices Control Order, 2013 (referred as DPCO, 2013 hereinafter) against National Pharmaceutical Pricing Authority (referred as 'NPPA' hereinafter) price notification S.O. No. 4336(E) dated 03.12.2020 in respect of "Betadine Alcoholic Hand Rub".

2. The main contentions raised by the applicant include:

i. As per minutes of the 21<sup>st</sup> meeting of Multi-Disciplinary Committee (MDC) of Experts held on 28.08.2020, a price of Rs. 92 for a pack of 200 ml was recommended evidently considering ceiling price of Ethyl Alcohol 50% on the justification that data of Isopropyl Alcohol not available.

ii Representations dated 11.09.2020 and 17.09.2020 were filed by the applicant before NPPA bringing out the alleged erroneous basis of price recommendation along with copies of invoices of Ethyl and Isopropyl Alcohol. Subsequently, on query of NPPA, vide email dated 10.11.2020 therapeutic advantages of using 2-Propanol (Isopropyl Alcohol) over Ethyl Alcohol (denatured) was provided by the applicant.

iii The fact that the cost of Isopropyl Alcohol was substantially higher during the relevant period than that of Ethyl Alcohol was allegedly ignored by the MDC of Experts, which is in violation of norms of DPCO, 2013 and principles of natural justice.

iv Once a drug is approved by the DCGI in a particular form, no one has the authority to alter the ingredients of the said drug. NPPA has no authority to alter or change the approved combination merely because the price of one of the ingredients of the approved combination is not available.



v NPPA has allegedly no power under DPCO, 2013 to ignore the price of one of the approved ingredients of the combination and in its place take the price of another ingredient (which is not approved by DCGI).

2.2 In view of the contentions referred above, the applicant has sought for setting aside the Order dated 3<sup>rd</sup> December 2020 fixing the retail price and for directing the NPPA to re-fix the retail price on the basis of considering the price of 2-Propanol (Isopropyl Alcohol) instead of Ethyl Alcohol.

2.3 The applicant has informed that it has launched the product at the price notified by NPPA.

2.4 During the personal hearing, the contentions raised in their review application were again reiterated by the applicant in detail.

3. The contentions of NPPA are as under:

i. As the data of the subject formulation was not available in AIOCD-Pharmatrac, the matter was placed before the MDC of Experts in its 21<sup>st</sup> meeting held on 28<sup>th</sup> August, 2020.

ii. MDC of experts, after detailed deliberations, recommended the retail price of Betadine Alcoholic Hand rub in which each 100 ml contains Povidone Iodine IP 1.0g (Available Iodine 0.1 g) and 2-Propanol IP 50 g for the applicant at Rs. 92.00 per 200 ml pack excluding GST. While recommending this price, the Committee took the ceiling price of Ethyl Alcohol (Denatured) 70% since the price of 2-Propanol was not available.

iii. The matter was discussed again in the 22<sup>nd</sup>, 23<sup>rd</sup> and 24<sup>th</sup> meetings of the MDC of Experts. In the 24<sup>th</sup> meeting held on 11.11.2020, Dr. Arti Kapil, Professor, Department of Microbiology, AIIMS was also invited as a special invitee, who observed as under:

*“The efficacy of ethyl alcohol and Isopropyl alcohol is similar when used as hand rub or skin disinfectant as per the international guidelines and recommendations on Hand hygiene by CDC (<https://www.cdc.gov/infectioncontrol/guidelines/disinfection/>) and WHO ([www.who.int/infection-prevention/publication/handhygiene/](http://www.who.int/infection-prevention/publication/handhygiene/)). Therefore, there is no justification or advantage of using one over the other.*



*Dr. Arti Kapil also reiterated that the matter had also been discussed with other experts in infection control and Microbiology at AIIMS who are in agreement with the view mentioned above. “*

iv. The Committee noted that there was no/negligible therapeutic efficacy in the usage of Isopropyl alcohol over ethyl alcohol. As such, it reiterated its earlier decision taken in the 21<sup>st</sup> meeting dated 28.08.2020.

v. Based on recommendations of MDC of Experts, the Authority in its 81<sup>st</sup> Authority Meeting held on 24.11.2020 approved the Retail Price of Betadine Alcoholic Handrub at Rs. 92.00 per 200 ml pack excluding GST, which was subsequently notified.

vi. Ministry of Consumer Affairs, Food and Public Distribution vide its S O. No. 1197 (E) dated 21.03.2020 had notified that *“The Retail prices of Hand Sanitizer shall not be more than Rs. 100 per bottle of 200 ml, the prices of other quantities of hand sanitizers shall be fixed in proportion of these prices”* which remained in force up to 30.06.2020 from the date of its publication in official gazette.

#### **4. Examination**

4.1 The contention of the applicant is that while the formulation with ingredient Iso-propyl Alcohol (which has substantially higher price) was approved by DCGI, the NPPA has fixed the price based upon the ingredient Ethyl Alcohol (denatured 70%).

4.2 NPPA's response is that as AIOCD-Pharmatrac's data was not available, it was referred to MDC of experts, which pointed out that there was no significant difference in efficacy with any of the ingredients used.

4.3 Considering the rival contentions, it is noted that as per provisions of National Pharmaceutical Pricing Policy, 2012 and DPCO 2013, the price fixation of formulation is to be based on market based data and not on cost based. NPPA has its own mechanism of collecting the data from AIOCD-Pharmatrac and the applicant has not challenged unavailability of data on Pharmatrac. While reference to Ministry of Consumer Affairs' price notification valid up to 30<sup>th</sup> June 2020 cannot be a valid reason/ justification for price notification issued subsequently by NPPA on 3<sup>rd</sup> December 2021. It is further noted that the matter was deliberated upon in detail by MDC of Experts in its four different meetings and after detailed deliberations and hearing the expert of AIIMS, it has concluded that the said ingredient has no/ negligible therapeutic efficacy. Further, it is noted while the

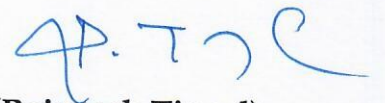


applicant has referred to the product having been approved by DCGI, the MDC of experts of NPPA, which recommended the price of the formulation also had senior representative of DCGI as its member.

**5. Decision**

Based upon the examination and analysis of contention of both parties, the present review application is not sustainable and stands rejected.

Issued on this, the 14<sup>th</sup> day of November, 2022.



**(Rajneesh Tingal)**

Joint Secretary to the Government of India  
(For and on behalf of the President of India)

**To**

M/s Win Medicare Private Limited,  
1311, Modi Tower,  
98 Nehru Place,  
New Delhi-110019

**Copy (for information) to:**

1. Chairperson, NPPA, YMCA Cultural Centre Building, New Delhi-110001.
2. PS to Hon'ble Minister(C&F)
3. Sr PPS to Secretary (Pharma)
4. Technical Director, NIC for uploading the order on Department's Website.