

**No. 31015/39/2016-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

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B Wing, Janpath Bhawan,  
New Delhi 110 001

**O R D E R BY REVIEWING AUTHORITY UNDER PARA 31 OF DPCO, 2013**

**Subject:** Review application of M/s Reckitt Benckiser Healthcare India Pvt. Ltd. against price fixation of "Clotrimazole Cream 1%" vide NPPA order No. S.O. 1687(E) dated 09/05/2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref:** 1) Review application dated 06.06.2016  
2) NPPA notification under review S.O.1687(E) dated 09.05.2016  
3) Record Note of discussions held in the personal hearing held in the matter on 12.7.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Reckitt Benckiser Healthcare India Pvt. Ltd. (hereinafter called the petitioner) against notification S.O. No.1687(E) dated 09.05.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of "Clotrimazole Cream 1%"

2. The petitioner has contended as under:

- (1) Clotrimazole Cream 1 % was not under the price control regime under DPCO, 1995; hence it was a 'non-scheduled formulation', as defined in Para 2 (v) of the DPCO, 2013.
- (2) They submitted that the non-consideration of the PTR and MAT of Itchguard, violates the specific mandate of Paragraph 4 of the DPCO, 2013. Hence, the Impugned Order is liable to be set aside on this short ground alone.
- (3) They further submitted that NPPA took the market based data as of May, 2015. Since the impugned order, is based on consideration of market based data as of May, 2015 and not September, 2015 (in terms of Paragraph 9(2) of the DPCO, 2013), the impugned Order is liable to be set aside, on this ground also. As stated above, Itchguard manufactured by the applicant has a substantial market share of 19.5% and its PTR in August, 2015 was INR 10.00 – 5gm, INR 42.33 – 15gm and INR 56.42 – 25 gm. However, the same was not taken into consideration at all by NPPA.
- (4) As a consequence of the improper method adopted in collection of market based data, the ceiling price fixed by the NPPA, was arrived at without taking into consideration, the PTR and MAT of Itchguard and several other manufacturers/ products, having market share substantially in excess of 1%.

(5)

Current Calculation as per Working Sheet dated 09/05/2016		Updated calculation including Itch Guard (5 gm, 15 gm, 25 gm)	
Average PTR	2.09	Average PTR	2.68
16% Ret Mgn	0.33	16% Ret Mgn	0.43
Ceiling Price	2.42	Ceiling Price	3.11
PI reduction	0.07	PI reduction	0.08
Final Ceiling Price	2.36	Final Ceiling Price	3.03

- (6) They mentioned that Clotrimazole Cream 1 % was not a scheduled drug under DPCO, 2013, till March, 10, 2016 and the ceiling price came to be fixed only by the Impugned Order dated 09/05/2016. They requested this Department that the Impugned Order be set aside.

### **Comments of NPPA:**

In this regard, it is stated that NPPA has fixed the ceiling price of Rs. 2.35/gm for Clotrimazole 1% cream vide S.O. 1687(E) dated 9.5.2016 based on Pharma Trac data as per existing practice.

3. During the personal hearing, the petitioner further submitted that against the Ceiling Price order (**CP Order**) dated 09.05.2015, the Company filed an Appeal before the Review Authority on 06.06.2016. Thereafter it filed a writ petition before the Hon'ble Delhi High Court on the ground that the PTR and MAT of Itch Guard (having a market share of over 68%) has not been taken into consideration; hence violating Para 4 (1) of the DPCO, 2013. The PTR of Itch Guard 5 gm (is Rs. 2.0), 15 gms (is Rs.2.8) and 25 gms (is Rs. 2.3). If the same was taken into consideration, the Company would not have to reduce its PTR. Hence, keeping the CP Order in abeyance would not affect the consumer interest. After considering the submissions of the Company and NPPA, the High Court by its Order dated 20.06.2016 passed an order that ***"The impugned order dated 09.05.2016 qua the petitioner shall be kept in abeyance for seven days after the review petition is decided."*** Copy of High Court order produced.

The Company filed additional submissions dated 12.07.2016 with annexures and urged the following points during oral hearing:

- The Company produced a copy of market based data provided by IMS Health (mandated under Para 9 (1) of DPCO, 2013) and based on the same, MAT of Itch Guard is 30.9% and Clean & Dry is 3.4%. Admittedly both have been ignored by NPPA while passing the CP Order, which is in contravention of Para 4 (1) of DPCO, 2013. Para 4 (1) mandates that all products having a market share of 1% or more shall be considered for fixing Ceiling Price. NPPA admits that Clean & Dry has represented that their price has not been taken into consideration and they are considering the same. Therefore, undisputedly, the CP order is bad in law and has to be set

aside. The order of 20.05.2016 requesting the Company to submit data in support of its claim, is a post facto suggestion. Since the CP Order was passed on 09.05.2016, the same does not address the grievance of the Company. Hence, the Company has filed review application.

**NPPA's submission:**

The ceiling price calculation of Clotrimazole 1% cream has been done on the basis of data provided by Pharma Trac. The data relating to product brand Clean & Dry is under examination, based on the representation given by the company.

NPPA vide its OM No.19(714)/2016/Div.II/DP/NPPA, dated 20<sup>th</sup> May, 2016, gave an opportunity to the company to give relevant data which the company did not utilize.

**Company submission:**

- In terms of Para 9 (5) of the DPCO, 2013 the market based data for fixing Ceiling Price shall be the data available for the month ending immediately before six months of notification of revision in Schedule I to DPCO. In the present case Clotrimazole 1% Cream was included in Schedule I of DPCO, on 10.03.2016; hence the reference data ought to that of September, 2015. NPPA cannot arbitrarily fix the reference date as August, 2015, in violation of Para 9 (5) of DPCO, 2013.

**NPPA submission:**

NPPA decided that data of August, 2015 will be taken as base data for calculating ceiling price of scheduled formulation under NLEM 2015.

**Company submission:**

- NPPA has given WPI reduction of Rs. -2.7105 translating to Rs. 0.07 per gram of Clotrimazole 1% Cream, which is in violation of Para 16 of DPCO. WPI correction can be given only in respect of formulations for which ceiling price was fixed earlier. While WPI increase was given by Govt. w.e.f. April, 2014 and April, 2015, NPPA never took the same into consideration while fixing the Ceiling Price of formulations, in the last two years. Merely because there is a WPI decrease, the same cannot be taken into consideration. Second, Para 16 (2) of WPI only provides that manufacturers may increase based on WPI and it does not provide for decrease, based on WPI. Also, the order of 10.03.2016 ordering WPI decrease has been stayed by Bombay High Court in its order of 27<sup>th</sup> June, 2016.

#### **NPPA submission:**

The inclusion of WPI in calculation of ceiling price is based on the decision of the NPPA.

**The company prayed that the Ceiling Price Order dated 09.05.2016 be quashed/set aside and since it is the admitted position that Clean & Dry and Itch Guard have not been considered while fixing the ceiling price, NPPA may be directed to pass a fresh Ceiling Price Order for Clotrimazole 1% cream, after taking into consideration MAT and PTR of Itch Guard, Clean & Dry and other products, if any.**

#### **4. Examination:**

The petitioner company has challenged the S.O. No.1687(E) dated 9.5.2016 on the following grounds:-

1. Itchguard (Clotrimazole) manufactured by the applicant has a substantial market share of 19.5% and its PTR in August, 2015 has not been taken into consideration. Similarly, there are several other players in the market, i.e. Clean & Dry Cream etc., whose market share was not taken.
2. The product Clotrimazole Cream 1% has become Scheduled for the first time consequent upon Govt. of India Notification SO 701(E), dated 10.3.2016, as such the WPI impact of minus 0.27105% ought not to have been factored in by NPPA in their notification for the product, i.e. Clotrimazole Cream 1%.

In connection with (1) above, it is mentioned that NPPA issued OM dated 20.5.2016, wherein they have called for information regarding any further data duly authenticated by the companies. NPPA may be asked to examine the data furnished by the petitioner company.

As regards (2) above, it is seen that the impact of WPI should be taken into consideration in case of revision of prices under para 16(1), which reads as under:-

***“The Government shall revise the ceiling prices of scheduled formulations as per the annual wholesale price index (WPI) for preceding year on or before 1<sup>st</sup> April of every year and notify the same on the 1<sup>st</sup> day of April every year.”***

Therefore, the impact of consumer Wholesale Price Index (WPI) of the current year is passed on to the consumers during the ensuing year. Accordingly, the WPI of 2015 is to be applied while fixation of ceiling price of scheduled formulations after March, 2016, to pass on the benefits of WPI to the consumers.

In the instant case, the product of the petitioner company has been included in amended Schedule-I list of DPCO 2013 for the first time vide Govt. Notification No.

SO 701(E), dated 10.3.2016 due to its inclusion in NLEM 2015. As the fixation of the ceiling price of the medicine was done by NPPA in May, 2016 for the first time, the impact of WPI may not be applied in the instant case.

As this is a case, where the product is being included in Schedule-I medicine list of DPCO, 2013 for the first time, Para 9(5) is applicable, which reads as under:-

***“The market based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six month of notification of revision in the first schedule.”***

**5. Decision of the Government:**

NPPA is directed to re-fix the ceiling price of “Clotrimazole Cream 1%” after taking into consideration all data furnished by the petitioner company and for all such products on merit within a period of one month from the date of issue of this Order.

Besides, NPPA may re-fix and re-notify the price of the product of the petitioner company under Para 4 taking into account Para 9(5) of DPCO 2013 and effect of WPI will not be applicable on ceiling prices fixed for the first time after 1.4.2016. This generic principle may also be applied by NPPA to all such cases where WPI has been applied to cases where there is no ceiling price fixed as on 1.4.2016.

Issued on this date, the 1<sup>st</sup> day of November, 2016.

**(M.K. Bhardwaj)**  
**Deputy Secretary**  
**For and on behalf of the President of India**

**To**

- 1. M/s. Reckitt Benckiser Healthcare India Pvt. Ltd.  
Plot 48, Sector 32, Institutional Area,  
Gurgaon-122 001.**
- 2. The Member Secretary,  
National Pharmaceutical Pricing Authority,  
YMCA Cultural Centre Building, New Delhi-110001**

**Copy to :**

- 1. PS to Hon'ble Minister(C&F), Shastri Bhawan, New Delhi for information.**
- 2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.**
- 3. T.D., NIC for uploading the order on Department's Website**