

No. 31015/82/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

**A- Wing, Shastri Bhawan,
New Delhi 110 001**

Subject: Review application of M/s Wallace Pharmaceuticals Private Limited against price fixation of "Walyte - Oral Rehydration Salts" vide NPPA order No. S.O. 1816(E), dated 18.05.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Review application dated 24.06.2016
2) NPPA notification under review S.O. 1816(E), dated 18.05.2016
3) Record Note of discussions held in the personal hearing held in the matter on 17.01.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Wallace Pharmaceuticals Private Limited (hereinafter called the petitioner) against notification S.O. No.1816(E), dated 18.05.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Walyte - Oral Rehydration Salts

2. The petitioner has contended as under:-

- I. National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceutical, Ministry of Chemicals and Fertilizers, Government of India issued a notification no S.O. 1816 (E) dated 18th May 2016, fixing prices of said Scheduled formulation based on the Moving Annual turnover as at August, 2015.
- II. AND WHEREAS the department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India issued worksheet of notification no S.O. 1816 (E) dated 18th May, 2016 clearly showing certain products which are not formulations and are registered with FSSAI.
- III. And whereas, "Oral Rehydration Salts" Medicines is World Health Organization (WHO) recommended composition under Section 20.6 and not under section 29.3 of DPCAO, 2016. Oral Rehydration Salts are listed in two sections of DPCAO, 2016 under section 20.6 and under section 26.1. Their formulation Walyte - ORS is having the WHO recommended composition for ORS powders to be used as replacement solution diarrheal rehydration. Further, considering NLEM 2011, NFI 2011, WHO EML 2013 and WHO EML 2015, certain compositions included in S.O. 1816 (E) have reduced osmolality recommended by WHO for the Diarrheal Diseases Control Programme and of the United Nations Children Emergency Fund (UNICEF).
- IV. They further submitted as under:-
 - a. For fixing ceiling price for Oral Rehydration salts powder for solution kindly consider only pack sizes of 4.2gms (+/- 2gms) and 21 gms (+/- 2gms) as these are Oral Rehydration Salts Medicines used in Diarrhea with composition and strengths

specified in section 20.6.1 of DPCAO, 2016.

- b. Compositions & strengths of other formulations appearing in worksheet are not limited to compositions defined in section 20.6.1 of DPCAO, 2013. Many other Non-WHO Recommended compositions are also appearing with different compositions and pack sizes. If these products are included in the calculations they will distort the prices as they refer to section 29.3.
- c. According to calculation as per para 4 of DPCO 2013, the ceiling price for Oral Rehydration salts Powder for Solution fixed for Rs.0.12648 ml as per order S.O. 1816 (E) appears to be incorrect.

- V. Further, in accordance with explanation (6) of DPCAO, 2016, where pack sizes have not been mentioned in the list, it is suggested that single and multi-dose pack sizes be considered as separate entities for purposes such as procurement / pricing, etc. Thus, separate ceiling prices must be considered for single dose Walyte 4.2gms for dilution in 200ml and multi-dose Walyte 21gms for dilution in 1000ml.

As per Indian Pharmacopoeia, Oral Rehydration Salts Powder for dilution are specified for 200 ml, 500 ml, and 1000 ml. The petitioner company is having two packs in the market - single dose Walyte 4.2gms for dilution in 200ml and multi-dose Walyte 21gms for dilution in 1000ml.

- VI. Further, NPPA has repeated the same error as committed in 2013 in respect of S.O 1692 (E) dated 14th June, 2013 notifying prices of Oral Rehydration Solutions at Rs. 0.58 per gm which WPL had challenged vide review petition filed on 9th July, 2013. NPPA finally corrected the ceiling price of said formulation to Rs. 0.84 per gm vide notification S.O 2531 (E) dated 21st August, 2013.
- VII. The Applicant requested this Department as under:

- a. **To consider and conclude that ceiling price of Oral Rehydration Solutions as mentioned under Para 20.6 of DPCAO, 2016 and notified under S.O 1816(E) dated 18th May, 2016 is ultra vires and in contravention of provisions of Drugs (Prices Control) Order, 2013 in respect of the captioned formulation.**
- b. **To direct separate ceiling prices for Oral Rehydration Solutions under para 20.6 and 29.3 of DPCAO, 2013.**
- c. **To direct separate ceiling prices for Oral Rehydration Solutions available in single dose and multi dose packs.**
- d. **Pass a speaking order in respect hereof.**
- e. **Any other order in interest of this manufacturer.**

Comments of NPPA:

- (i) NPPA fixed the ceiling price of Rs. 0.58/gm vide S.O. 1692(E) dated 14.6.2013 and the same was withdrawn vide S.O. 2257(E) dated 22.7.2013 NPPA again fixed the ceiling price Rs. 0.84/gm vide S.O. 2531(E) dated 21.8.2013 and the same was revised to Rs. 0.89, 0.92 & 0.90 per gm vide S.O. 1156(E), 619(E) & 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016 respectively under NLEM 2011. Under revised Schedule-I of DPCO, 2013 (NLEM 2015), NPPA fixed ceiling price of ORS as Rs. 0.71/gm vide S.O. 1816(E) dated 18.5.2016 under NLEM 2015 based on the data provided by pharmatrac for the month of August, 2015.
- (ii) NPPA sought clarification from DCG(I) vide letter no. 10(20.6.1)/2016/DP/NPPA/Div.II dated 16.11.2016 and reminder dated 06.01.2017 (copy enclosed) as to whether such products which have been licensed by FSSAI can be classified as pharmaceutical products. Comments from DCG(I) office are still awaited.
- (iii) Meanwhile DoP vide review order no 31015/30/2016-PI.I dated 14.9.2016 in case of M/s FDC Ltd. observed that a non-Pharmaceutical item was included in the calculation sheet in arriving at the ceiling price of **Oral Rehydration Salts**. DoP directed NPPA to fix ceiling price of product afresh with correct calculation (in respect of M/s FDC).
- (iv) DoP had earlier rejected the review petition of M/s Wallace, being time-barred, vide review order no 31015/82/2016-PI.I dated 19.9.2016.
- (v) Bombay High Court in WP (551/2016) dated 24.8.2016 directed examination of review petition.

3. During the personal hearing, in addition to written submissions already made, the representatives of the company further submitted that NPPA's claim that the ceiling price as notified vide SO 1816(E), dated 18.5.2016 was not followed by the company is incorrect. The company had reduced the price of its formulations to comply with the aforesaid ceiling price till 30th August, 2016. Thereafter, based on stay of Bombay High Court, the company revised its price in compliance with the previous SO 644(E), dated 3rd of March, 2016 to avoid further unnecessary losses as the company had already suffered financial loss for a period of six months in 2013 for the exact same mistake.

Further, the company representatives appreciated NPPA's clarificatory letter to DCGI for setting a precedence with respect to correct classification of pharma grade Oral Rehydration Salts (ORS) and non-consideration of FSSAI licensed products. The company has humbly made the following requests :-

- (i) NPPA has considered food products manufactured under FSSAI license in the calculation of ceiling price of Oral Rehydration Salts for SO 1816(E), dated 18.5.2016. The company requested for all non-pharmaceutical products to be excluded from the calculation while revising the ceiling price.
- (ii) Certain SKUs having market share less than 1% have also been considered in the calculation of ceiling price for ORS. The company requests that based

on DoP Order for Sun Pharmaceuticals Industries Ltd., dated 29.11.2016, all such SKUs having less than 1% market share must be excluded from calculation of ceiling price.

- (iii) The formulation ORS as approved under IP, WHO and various other countries' pharmacopeia allow for only 2 pack sizes, one single dose and another multiple doses. The permissible pack sizes of 4 gms (+/- 2gms) and 21gms (+/- 2gms) are provided different drug licenses and have separate therapeutic rationales and, therefore, must be considered separately for the purpose of calculation of ceiling price under the provisions of para 11(3) and 11(4) of DPCO 2013. The company representatives also submitted independent certificates from AWACS-AIOCD for the MAT value as on August, 2015 for both the aforesaid pack sizes.
- (iv) Certain formulations with pack sizes and composition different from the WHO and IP recommendations are available in the market. The company requests for these pack sizes not to be considered in calculation of ceiling price as they have been discontinued and are no longer available in the market. The aforesaid AWACS-AIOCD certificate verifies the same.

With regards to the clarification requested from DCGI, the company also requests for a clarification of the permitted pack sizes and osmolality which should be considered while calculating the ceiling price of ORS.

4. NPPA representatives submitted as follows:-

- (i) As regards inclusion of non-pharmaceuticals products in the ceiling price fixation of ORS, NPPA has sought clarification from DCGI. Based on their reply, suitable action will be taken.
- (ii) The issue regarding inclusion/non-inclusion of generic / brand having less than 1% market share is based on the least of the three alternatives decided by the Authority in its 27th meeting.
- (iii) The therapeutic rationale of ORS does not change with the change of pack size. Hence, the provisions of para 11(3) and (4) of DPCO, 2013 are not applicable.
- (iv) As regards discontinuation of certain products, the company may approach NPPA regarding their contention with supporting documents.

5. Examination:

The petitioner company has challenged the NPPA Order S.O. 1816(E), dated 18.05.2016 for price fixation of their formulation **Oral Rehydration Salts**. The main contention of the petitioner company is that to calculate average price to retailer, NPPA considered certain products which are not formulations and are registered with FSSAI. Further, NPPA has also considered different compositions and pack sizes for averaging purpose under section 26.1 of NLEM 2015. The company in the review application stated that the "Oral Rehydration Salts" medicine is WHO recommended composition and should be considered under Section 20.6 of NLEM 2015.

As regards the grievance of the company that certain products which are registered with FSSAI are also considered while calculating the ceiling price of the subject formulation, has got merit, as the products registered with FSSAI cannot be

treated as formulation but as energy drink. NPPA submitted that clarification from DCG(I) is sought as to whether such products which have been licensed by FSSAI can be classified as pharmaceutical products, and the reply of DCG(I) is awaited.

As regards the grievance regarding pack size, since there is no added therapeutic advantage mentioned by the company, there is no merit in the grievance and separate ceiling price cannot be considered based on pack size under para 11(3) of DPCO 2013.

Keeping in view the facts of the case, NPPA may be directed to consider revising/refixing the ceiling price of the formulation "Walyte – Oral Rehydration Salts" by excluding FSSAI licensed products, on getting clarification from DCG(I).

During the personal hearing, the petitioner company raised the issue of considering certain formulations having market share of less than 1%. It is seen from the calculation sheet (page 111-112/c) that there are only 12 formulations having more than 1% market share whereas NPPA has taken into account 31 formulations while calculating the average ceiling price. Accordingly, NPPA may be directed to refix the ceiling price in accordance with the provisions of DPCO by considering the PTR of 12 formulations only. The DPCO does not recognize a company for average PTR but only medicines / formulations.

6. Government Decision:

"NPPA is hereby directed to consider revising/refixing the ceiling price of the formulation "Walyte – Oral Rehydration Salts" by excluding FSSAI licensed products, on getting clarification from DCG(I).

NPPA is also directed to refix the ceiling price in accordance with the provisions of DPCO by considering the PTR of 12 formulations only having more than 1% market share."

Issued on this date, the 5th day of April, 2017.

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

To

1. M/s. Wallace Pharmaceuticals Private Limited
Dempo Trade Centre Bldg., 3rd Floor, Patto Plaza,
EDC Complex, Panjim-403001. GOA (India)
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