

No. 31015/33/2014-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhavan, New Delhi

ORDER BY REVIEWING AUTHORITY UNDER PARA.31 OF DPCO, 2013

Subject: Review application of M/s. Cadila Healthcare Ltd. against fixation/revision of ceiling prices of Dexamethasone Injection 4mg/ml vide NPPA notification S.O. No. 1157 (E) dated 28/4/2014 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

- Ref. 1) Review application No.NPPA/0514/06 dated 23.5.2014.
 2) NPPA notification under review S.O. No.1157 (E) dated 28/4/2014.
 3) Reviewing Authority decision/ order No.31015/33/2014-PI.I dated 23.7.2014.
 4) Hon'ble High Court of Delhi order dated 30.9.2014 in WP No.5864/2014 (M/s Cadila Healthcare Ltd. Vs. Union of India & Anr.)
 5) Record Note of discussions held in the personal hearing held in the matter on 16.10.2014.

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No.1157(E) dated 28/4/2014 fixed/revised ceiling price of Dexamethasone Injection 4mg/ml under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

2. And whereas aggrieved by the above notification, M/S Cadila Healthcare Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 23.5.2014 under para.31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No.1157 Dated 28th April 2014 fixing Ceiling price of Dexamethasone Injection 4 mg/ml under para.4 of DPCO, 2013 included in Schedule-I of DPCO, 2013 (and also covered under DPCO, 1995). After affording a personal hearing to the Petitioner on 17.6.2014 and due examination and approval of the competent authority a review order of even No. dated 23.7.2014 was issued in the matter.

3. And whereas the Hon'ble High Court of Delhi vide its order dated 30.9.2014 passed in the matter of WP No.5864/2014 (M/s Cadila Healthcare Ltd. Vs. Union of India & Anr.) has set aside the Government review order dated 23.7.2014, so far as the same relates to Dexamethasone Injection, subject to its observations contained therein, and remanded the said review order back to the Reviewing Authority to consider it afresh after affording

the petitioner an opportunity to be heard directing further that the Reviewing Authority shall conclude the proceedings and pass a final order on or before 28.10.2014.

4. In compliance to the Hon'ble Delhi High Court Order dated 30.9.2014 a fresh personal hearing was accorded to the Petitioner by the Department on 16.10.2014. The Petitioner was represented by S/Shri Manoj Kamra, Vice President (Corporate Affairs), C.P. Patel, Sr. GM-Finance and Mehul Pathak, Sr. GM -Legal. On behalf of the National Pharmaceutical Pricing Authority (NPPA) Shri Naresh Arya, Dy. Director attended the hearing.

5. The grievance of the Petitioner raised in their review application dated 23.5.2014 were sent to NPPA and the comments of NPPA thereon were given to the Petitioner through the record note of discussions held in the hearing on 17.6.2014. Record note of discussion is made integral part of the review order. After considering the comments of NPPA the Petitioner raised the following points, on which comments given by NPPA representative during the hearing and Department's comments on the issue is recorded subsequently against each point:

- i. Petitioner: Petitioner's representative mentioned that in November 2011 NPPA revised the conversion cost and packing material cost. However, the price notification of 1st April 2011 was not revised. NPPA did not revise the price after revision of the costs in November 2011.

NPPA: NPPA representative mentioned that NPPA has revised CC, PC norms annually as per provision of para 7 of DPCO 1995. The impact of these norms are given to the company who has applied for the price revision consequent upon revision in the norms. NPPA has not received any application from Cadila Healthcare Ltd. on the above. There is no provision in DPCO 1995 to increase the prices on suo-motto decision.

Department's comments: Since DPCO 1995 has already been superseded by DPCO 2013, the point raised by the Petitioner has no locus standi.

- ii. Petitioner: NPPA has issued an OM stating there that is a WPI increase of 6.32% for the year 2013 which they have not applied before issuing the price notification on 28.4.2014.

NPPA: NPPA representative mentioned that as per para 10 of DPCO 2013, the price fixed before May 2012 had to be fixed for one year i.e. upto 30 May 2013 and manufacturers may revise the price of such scheduled formulations as per the annual wholesale price increase for the previous calendar year announced by Deptt. of Industrial Promotion and Policy. It is not for the NPPA to revise the price. The companies are authorised to increase the price as per WPI as per provision of para 10(i) of DPCO 2013. Thereafter the formula given in sub-paragraph (1) of paragraph 4 of this order shall be applied for fixing the ceiling price of such

formulations. Accordingly NPPA has revised the price of medicines which are common in DPCO 1995 and DPCO 2013 as per data provided by IMS considering the formula given in sub-paragraph (1) of paragraph 4 of DPCO 2013. NPPA has not applied WPI increase of 6.32 % in such cases across the board.

Department's comment's: Under para 10(1) in respect of a formulation common to DPCO 1995 and DPCO 2013 the prices under DPCO 1995 fixed upto 31st May 2012, shall remain effective for further one year i.e. upto May 2013 and the manufacturers may revise the price of such scheduled formulations as per annual WPI for the previous calendar year i.e. WPI of 2012. This revision is of course at the discretion of the manufacturers. Thereafter formula as per para 4 (1) of DPCO 2013 shall be applied for fixing the ceiling price of such formulations.

However under para 16(1) of DPCO 2013 NPPA is required to revise the ceiling prices of scheduled formulations as per the annual WPI for preceding calendar year i.e. WPI of 2013. In the instant case WPI for 2013 was to be provided on or before 1st April of the year and notified the same as on 1st April. NPPA has not applied WPI 2013. Rather they have not applied WPI on or before 1.4.2014 and notified the same on 1st day of April, 2014. The prices issued by them in the instant case on 28.4.2014 need to be issued after revision as per WPI 2013 and notified on 1st April, 2014.

- iii. Petitioner: The Petitioner's representative mentioned that they have clubbed the small pack of 2 ml. and multi dose of 10 ml and 20 ml for deciding the ceiling price on 28.4.2014. This has caused reduction of small dose pack by 38.8%. This is causing losses to the Petitioner and their single dose formulation are unviable. This may lead to non availability of formulation in the longer run which will not be in the interest of the country. If there is shortage of Dexamethasone injection 2ml. which is most rightly used as a steroid, patients will have no other option but to use some other steroid which may be costly and outside NLEM. Vide representation dated 12 May 2014 the Petitioner has already raised this issue with NPPA whereby possible non-availability of this product has already been raised due to occurring losses in 2 ml. dosage. Zydus Cadila group have market share of 39%.

NPPA: NPPA representative mentioned that NPPA has not received any reference relating to shortage of this drug in the country. Whenever a shortage will be reported NPPA will take suitable action.

Department's comments: As in the subsequent Para No.7 relating to hearing held on 16.10.2014.

- iv. Petitioner: The Petitioner's representative mentioned that as per DPCO 1995 the price to retailer under para 19 has to be minus 16% and therefore, the PTR of the Dexasone of Cadila Pharma (Rs.5.60) and Decdan of Wockhardt Ltd. (Rs.7.06)

are not correct. The Petitioner's representative mentioned that NPPA may be directed to revalidate these two prices.

NPPA: NPPA representative mentioned that regarding error in PTR value of Cadila Pharma and Wockhardt Ltd., NPPA may refer this to IMS after receipt of the request from M/s Cadila Healthcare Limited.

Petitioner's representative mentioned that they have raised this point before reviewing authority and there is no separate need for a further request.

Department's comments: Para 9(1) itself provides that Government may validate such data (IMS Health data) by appropriate survey or evaluation.

6. In the order dated 30.9.2014 Hon'ble High Court has observed as under:

"It is seen that a limited relief was granted to the petitioner which is reflected in the notification dated 20.08.2014 whereby the prices of the said formulation were revised in accordance with the directions under the order dated 23.07.2014. Thus, although the order dated 23.07.2014 is liable to be set aside, the benefit accorded to the petitioner by virtue of that order cannot be denied."

7. Point-wise examination of the case as per the points as raised by the Petitioner during the hearing held on 16.10.2014, in pursuance of the above mentioned Court Order dated 30.9.20154 is as under:

- i) The Petitioner representative mentioned that each formulation pack i.e. 2 ml, 5ml., 10 ml and 20 ml. should be considered separately as the packing cost plays an important role in the total cost of the product and this is more true for a single vial. The cost of API and excipients . may go up in linear proportion but packing cost do not and consequently the per/ml cost in a 20 ml. multi dose vial will always be lesser than the per/ml. cost of 2 ml. vial. Thus, the average packing cost of 2 ml vial will be higher and taking an average of a 2 ml. vial, 10 ml. vial and 20 ml. Vial for determining per ml cost and ceiling price is illogical. As a result clubbing of the different packings of the product will make the smaller pack size unviable and will consequentially affect the availability.

Moreover, NPPA vide order dated 20 September 2011 has fixed ceiling price for 5 ml, 10 ml and 20 ml vial which order is not superseded by any subsequent order or notification and still holds good and is in force. In view thereof clubbing all these vials with 2 ml vial for working out per/ml ceiling price is untenable. It is to be noted that the ceiling price of 2 ml.vial has undergone change on more than one occasions and ultimately is superseded by a new notification dt. 28.4.14. Copies of notifications dt. 1.7.2011 (Annexure I) dt.

20.9.11 (Annexure II) and 28.4.14 (Annexure III) are enclosed with the record note of notification.

The Petitioner's representative mentioned that they are following all ceiling prices announced under DPCO 2013. However in this particular case of Dexamethasone injection of 4 mg/ml which is a common scheduled product under DPCO 1995 and DPCO 2013, prices were under control during DPCO 1995 and now have further been reduced under DPCO 2013 due to incorrect methodology of clubbing of 2 ml. vial and higher pack size vials. This makes our 2 ml. product totally unviable.

NPPA: NPPA representative stated that price of the said formulation has been fixed as per the provisions of DPCO 2013 on the basis of IMS data for the month of Sept. 2013. As per NLEM 2011 the dosage form is specified as injection i.e. 4 mg./ml. Therefore, NPPA considered vial and ampoule as well all packs irrespective of the size as was done in other cases of fixation of ceiling price under DPCO 2013 and fixed the ceiling price accordingly i.e. 4 ml. basis. This is in line with para 11 of the DPCO 2013. The contention of the review petitioner in this regard, therefore, has no merit and falls outside the scheme of DPCO 2013. The price fixation under DPCO 1995 was cost based and the present system of pricing under DPCO 2013 is market based data. Thus the point raised relating to packing cost or any other cost is not relevant. As regards the issue of supersession of notification dt.1st July, 2011 by the notification dt. 28.4.2014 is concerned it is important to mention that it is stated in Clause (i) of notification dt.28.4.14 that consequent to the issue of ceiling price of the scheduled formulation as specified in column (ii) of the table in the notification the price orders if any issued prior to the above said date of notification stand withdrawn. Thus all the notifications including of 1.7.2011 relating to Dexamethasone injection of 4 mg/ml strength stands withdrawn and superseded by the notification dt. 28.4.14.

NPPA representative further mentioned that NPPA has not received any reference relating to shortage of this drug in the country so far. Whenever a shortage will be reported NPPA will take suitable action. The methodology of averaging has been followed by NPPA in price fixation of all syrup, injection, tablets, capsules and suspension etc. and it is assumed that Cadila Healthcare is following the price notification and has only challenged this price notification relating to Dexamethasone in the Court.

Department's comments and recommendation:

DPCO 2013 is a deviation from the DPCO 1995 i.e. from cost based pricing to market based pricing. Under para 4 of DPCO 2013 prices are fixed based on price to retailer (PTR), MAT value and market share which are captured by IMS Health and that was taken into account by NPPA for consideration of calculation of ceiling price. In para 11(1) of DPCO 2013 the prices are to be fixed on dosage basis and for arriving at the price of the pack the dosage is to be multiplied with the quantity in the pack. Any further classification is not

specified in DPCO 2013. Hence request of the Petitioner is not in line with the provisions of DPCO 2013.

In regard to the issue pertaining to viability of the smaller packs it will be necessary to look into the market prices of per/ml available in the market at the time of price fixation and the price fixed under DPCO 2013. Calculation sheet which pertains to the then prevailing prices will show that the lowest price of 2 ml pack then prevailing in the market was Rs. 4.65 i.e. a 2ml. pack was available in the market at a unit price of Rs.2.33 per ml. The price fixed by the NPPA vide their notification No. SO 1157(E) dt. 28.4.2014 is Rs. 2.51 per ml. The question of unviability therefore does not arise. The question of larger packs having been sold at higher prices may not arise as the purchaser of the larger packs are normally people in the bargaining capacity and are in a position to select the cheapest brand of comparable quality. It was for this reason that 2 ml price difference between a large pack and a small pack was very high. In the case of small pack of 2 ml. the price difference in the highest cost pack and the lowest cost pack was more than 50% (Rs.4.65 and Rs.7.06). In the larger pack i.e. 20 ml pack the difference between the highest and the lowest is around 4% (Rs.21 and Rs.21.80). This was because of the primary reason that common patient is guided by the prescription of the doctor and is not educated enough to choose between highest and lowest price formulation available in the market with comparable quality. The action of NPPA is, therefore, in the larger public interest and also as per the provisions of DPCO 2013.

As regards the point raised by the Petitioner that NPPA has not superseded the earlier notification dt. 20.9.2011 it may be mentioned that sub para (i) under note attached to NPPA order SO 1157 (E) dt. 28.4.14 it has been made amply clear that the price order (s) if any, issued prior to the above said date of notification stands withdrawn. Therefore, the Petitioner has no merit in this point.

- (ii) Petitioner: The Petitioner's representative mentioned that the working sheet put up by NPPA on its website discloses an apparent error and failure to operating and complying with the manner of arriving at the ceiling price stipulated under para 4 of DPCO 2013. The said working sheet instead of taking sum of prices to retailer for all the brands and generic versions of the medicines having market share of more than or equal to 1% of the total market turn over on the basis of working annual turn over for that medicine, considers the company as the basis but so long as such company has at least one brand or generic version with the market share of more than or equal to 1% of the total market turn over on the basis of working annual turn over for the medicine. This is

distortion of the provision of DPCO 2013 and incorrect application of the method provided under para 4 of DPCO 2013.

NPPA: NPPA representative mentioned that this issue was not raised by the Petitioner during review hearing granted earlier to the Petitioner. Since the review authority has decided to consider this issue also NPPA would like to give its view. The data provided by IMS Health has been considered after clubbing the MAT value of specified medicine manufactured by the same company in different brands name /generic names for determining the market share of more than or equal to 1% for working out the ceiling price in terms of definition of the drug brand as given in para 2(i) of DPCO 2013. The price fixation of the specific formulation is done under the provisions of DPCO 2013 and is, therefore, correct.

NPPA representative also mentioned that as per para 31 of DPCO 2013 the Petitioner is bound to follow the ceiling prices notified before consideration of its review application. As per the available information with NPPA, M/s Cadila Healthcare has not provided form V to NPPA as an evidence of complying with the notification of 28.4.2014. Thus it is submitted that the compliance must be ensured before passing any review order.

Petitioner: The Petitioner's representative placed on record that M/s Cadila Healthcare has implemented the prices announced by NPPA vide Gazette notification dt. 28.4.14. The Petitioner has provided the copies of price lists to this effect to the review hearing authority.

Department's comments and recommendation:

The definition of brand as provided in para 2(c) of DPCO2013 seeks to identify one seller drug as distinct from other seller. In this connection it may be mentioned that if a manufacturer is adopting a strategy to market more than one brand they nevertheless remained its own brands. The Petitioner, therefore, cannot claim to get their data excluded from the price purview simply because of their marketing strategy. Further, market share is covered under para 2(o) of DPCO 2013. NPPA has, therefore, correctly included all brands of a seller as one product in fixing ceiling price under paragraph 4 and 11 of DPCO 2013.

8. Based on the above and other documents on record, the Government has decided as under:

"The points raised by the Petitioner in the hearing dated 16.10.2014 have therefore no merit and deserve to be rejected.

As regards the issue raised by the Petitioner during the hearing on 17.6.2014 relating to WPI increase for the year 2013 the corrective action

has already been taken, which has also been observed by Hon'ble Court in its order dated 30.9.2014".

Issued on this date 5th November, 2014.

(Roshan Lal)

Under Secretary to the Govt. of India
For and on behalf of the President of India

To

1. M/s. Cadila Healthcare Ltd.,
Zydus Tower, Satellite Cross Road,
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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. Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. PSO to the Chairman, NPPA, YMCA Cultural Centre Building, New Delhi for information