

No. 31015/21/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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A Wing, Shastri Bhawan,
New Delhi 110 001

Order

This is an order on the two review applications dated 10.2.2017 and 23.02.2017 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Abbott Healthcare Private Limited (hereinafter called the applicant) against notification S.O. No.248(E), dated 24.01.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulation Gentamicin-40mg/ml 2ml pack.

2. The applicant has contended as under:

2.1 The Ceiling Price for Gentamicin Injection 40mg/ml 2ml Pack was notified by NPPA on 28.04.2014 at Rs 4.58 under NLEM 2011 which was based on per ml average and had erroneously included various packs of different sizes in the same basket - 2ml, 10ml, 20ml and 30 ml.

2.2 This resulted in a situation where the ceiling price of 2ml went below its production cost while for 20 ml manufacturers; there was scope of windfall price increase.

2.3 This being an injection, packaging cost plays an important role in the total cost of the product. Hence per/ml cost in a 20 ml multi-dose vial will always be lesser than that of per/ml cost in a 2 ml pack. While the cost of API and excipient goes up in linear proportion, the packaging cost does not go up in linear proportion. Hence taking an average of per/ml cost for determining the ceiling price was evidently incorrect at that juncture.

2.4 Acknowledging this anomaly, the expert committee on the NLEM corrected the same for future calculations of IV/injectable and infusions by recommending in the NLEM 2015 that single dose and multi-dose vials in case of injections must be treated as separate categories.

2.5 In its 161st Authority meeting dated 27.04.2016, the NPPA stated that the Committee of Experts in its meeting on 19.04.2016 discussed that with respect to small volume parentals (such as gentamicin 2ml) whose price has to be done (fixed) as per Para 11(3) of DPCO 2013, and wherever review orders are pending with the DOP, price fixation may have to be done with May 2012 or September 2013 data, as base data. This will require an amendment of the relevant para of DPCO 2013.

2.6 In August, 2016 when NPPA put up the draft working calculation to fix Ceiling price (vide O.M No. 8(34)/2016 Dated 12.08.2016), the applicant filed a representation dated 24.08.2016 to review the Ceiling Prices and highlighted that the draft working

sheet for ceiling price calculation for Gentamicin 40mg/ml in pack-size 2ml Injection was erroneous. This was due to the fact that the computation of ceiling price using MAT, Aug 2015 data was incorrect since the prices prevailing in Aug, 2015 are as per the ceiling price notified vide S.O. No. 1157 (E) dated 28.4.2014, which was based on per ml average and had erroneously included various packs of different sizes in the same basket - 2ml, 10ml, 20ml and 30 ml. This has only caused an inevitable unintended reduction from its previous level, merely due to the mechanical following of the process as per paragraph 11(3) of DPCO-2013.

2.7 Additionally, in the minutes of 3rd meeting of the Expert committee held on 28.12.2016 which were made public on 12.01.2017, the Committee has recommended for fixing of Ceiling Prices on pack wise basis rather than per ml basis for small volume parentals such as Gentamicin Injection 40mg/ml 2ml Pack.

2.8 Accordingly, the NPPA in its Authority meeting held on 23.01.2017 decided to notify the ceiling prices on pack wise basis, but this has only partially corrected the problem of abnormally low price of retail pack of 2ml.

2.9 The anomaly will only be adequately addressed if NPPA takes the September 2013 data as base price for arriving at the Ceiling Price, coupled with the applicable WPI for subsequent years. Only then, the anomaly will be addressed and will give a correct ceiling price to ensure the continuous and sustained supply of Gentamicin 2ml Injection. It is, thus, clear that the impact of the above two factors i.e. pack-wise CP segregation and the base data of September 2013 for computation of the CP has to be taken into consideration while re-fixing the price under Para 11 and para 4 of the DPCO 2013 to correct the injustice meted to manufacturers of this low cost, high volume medicine for the masses.

2.10 The NPPA has in the past, based on the directions of this Department, used back data to correct anomalies in price fixation and the IV Fluids CP's are an example which can be followed by others to correct injustice.

2.11 In view of above, Applicant has requested as under:

- (i) Correct the anomaly of Gentamicin Injection 40mg/ml 2ml pack by directing the NPPA to re-notify the Ceiling Price of Gentamicin Injection 40mg/ml 2ml by fixing Ceiling Price using the September 2013 data as base data and applying the WPI for the subsequent years.

3. Comments of NPPA:

The ceiling price of Rs. 4.47/Pack (2ml) for Gentamicin 40mg/ml each 2ml pack Injection was notified vide S. O. 248(E) dated 24.01.2017 as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

3.2 Applicant has stated that correct methodology was not followed in arriving at the ceiling price for Gentamicin 40mg/ml each 2ml pack Injection. The points raised by the applicant are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Applicant's Grievances	NPPA's comments
Applicant has pointed out that NPPA has fixed ceiling price of Rs. 2.18/ml vide S.O. 1157(E) dated 28.4.2014. NPPA has included various packs of different sizes in the same basket – 2ml, 10ml, 20ml & 30ml to derive PTR based on per ml basis, therefore, ceiling price worked out went below its production cost for 2ml pack.	NPPA has rightly fixed ceiling price of Rs. 2.18/ml vide S.O. 1157(E) dated 28.4.2014 as per the provisions of DPCO 2013 under NLEM 2011. There was no provision for working out the separate ceiling price for various packs before the existence of S.O. 1192(E) dated 22.3.2016, under NLEM 2015.
Applicant has point out the impact of packaging cost in the total cost of the product and stated that consideration of cost per ml base to derive the ceiling price is incorrect.	NPPA has followed the market based pricing exercise as there is no provision in DPCO, 2013 to consider cost base pricing exercise.
Applicant requested separate ceiling price for single dose and multi-dose	NPPA has followed the directions of DOP as well as Committee of Experts (COE) under para 11(3 & 4) and separate ceiling price has been fixed for different packs.
Applicant has requested to consider May, 2012/ September, 2013 data for working out the ceiling price.	Applicant request is not acceptable as it is against the Para 9 (5) of DPCO, 2013.
Applicant has stated that they have submitted the representation against draft working calculation to fix ceiling price (vide O.M. 8(34)/2016 dated 12.8.2016 and same was not considered by NPPA.	The representation of applicant was not considered as applicant did not submit the complete/legible documents required as per O.M. No. 8(34)/2016/DP/NPPA–Div.II dated 12.8.2016, 10.10.2016 & letter no. 7(34)/2016/DP/NPPA–Div.II dated 16.01.2017.
Applicant has stated that NPPA has only partially corrected the problem of abnormally low price of retail pack of 2ml.	DPCO, 2013 does not differentiate between low and high price NPPA has fixed the ceiling price as per the provisions of DPCO, 2013.
Applicant has again repeated the same request i.e. to consider the September, 2013 data as based price for arriving at the ceiling price coupled with applicable WPI for subsequent years.	Applicant's request is against the provisions of DPCO, 2013.

4. Examination:

The ceiling price of formulation was fixed, vide SO 248(E), 24.1.2017. The ceiling price was fixed this time, by NPPA by segregating the pack sizes on the basis of recommendation of Expert Committee under para 11(3&4) of DPCO, 2013. However, while doing this, as per provisions of para 9(5) of DPCO, 2013, the data of August, 2015 was considered.

4.2 The injectable fluids were in NLEM, 2011 and the ceiling price was already in existence for them, when the NLEM was revised in 2016. After revision of Schedule I of

DPCO, due to revision in NLEM, the price caps of injectable fluids were re-fixed, this time, by segregating the pack sizes on the basis of recommendation of Expert Committee. Since while fixing the ceiling price of subject formulation on 28.04.2014, the segregation of market based data on the basis of pack size was not done, this resulted in depressing the prices of smaller pack sizes. This lower base was taken while fixing the ceiling price of 2ml pack again on 24.1.2017, which resulted in further depressing the ceiling price of 2ml pack.

4.3 There is a merit in contention of the applicant that in peculiar circumstances of the case, considering August, 2015 data has resulted in a situation where the ceiling price of Gentamicin-40mg/2ml pack size went below its production cost. This anomalous situation needs to be rectified in the interest of the long term sustained availability of Gentamicin-40mg/2ml pack size in the market. This could be justifiably rectified if the segregated market data of September, 2013 is used to arrive at a ceiling price along with giving effect to WPI for subsequent years.

5. Order:

NPPA is hereby directed to re-fix the ceiling price of Gentamicin-40mg/2ml pack size by considering September, 2013 market based data instead of that of August, 2015 and apply the WPI for the subsequent years.

Issued on this date of 10th day of January, 2019.

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

Copy to:

1. M/s. Abbott Healthcare Private Limited, 1st Floor, D Mart Building, Goregaon – Mulund Link Road, Mumbai-400 080.
2. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001
3. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
6. T.D., NIC for uploading the order on Department's Website