No. 31015/68/2014-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

……..

B Wing, Janpath Bhavan, New Delhi

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

Subject: Review application of M/s Biological E. Ltd. pursuant to the Hon'ble Delhi High Court Order/Direction dated 22.1.2015 against fixation/revision of ceiling prices of Tetanus Toxoid Vaccine vide NPPA notification S.O. No. 1673(E) dated 14.6.2013 and corrigendum order S.O. No.431(E) dt. 17.2.2014 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant Review application dated 30.1.2015
2) NPPA notification under review S.O. No. 1673(E) dated 14.06.2013 and corrigendum order S.O. No.431(E) dt. 17.02.2014
3) Record Note of discussions held in the personal hearing held in the matter on 11.2.2015

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No. 1673(E) dated 14.06.2013 and corrigendum order S.O. No.431(E) dt. 17.2.2014 fixed/revised ceiling price of under DPCO, 2013.

2. And whereas aggrieved by the above notification, M/s Biological E. Ltd**.,** (hereinafter referred to as the Petitioner) submitted review application dated 30.1.2015 under para.31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No**.** 1673(E) dated 14.06.2013 and corrigendum order S.O. No.431(E) dt. 17.2.2014 fixing Ceiling price of Tetanus Toxoid Vaccine under DPCO, 2013 included in Schedule-I of the order.

3. The grievance of the Petitioner raised in their review application dated 30.1.2015 were sent to NPPA and the comments of NPPA thereon were given to the Petitioner through the Record Note of discussions held in the review hearing on 11.2.2015. Record Note of discussion is made integral part of the review order. After considering the comments of NPPA, the Petitioner has raised the following points, on which comments given by NPPA representative, during the hearing and Government's comments on the issue is recorded subsequently on each point:

Petitioner's submission during personal hearing

Petitioner :The petitioner representative referred to para 4 (1) of the DPCO, 2013 which prescribes the procedure for setting the ceiling price of scheduled formulations, para 11(1) of the DPCO, 2013 which provides that pack size for the ceiling price should be determined on the basis of the size specified in the First Schedule to the DPCO, 2013. However, section 19.3.2 of the First Schedule of DPCO 2013 which refers to Tetanus Toxoid, does not prescribe a pack size for it. In this situation, para 11(2) provides that, in situations where the First Schedule does not specify a pack size, the lowest pack size must be determined in

accordance with the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945.

The petitioner then referred to the provisions contained in the Drugs and Cosmetics Rules, 1945. Attention was drawn to Rule 105 of Drug and Cosmetic Rule 1945 which specifies that the pack sizes must be determined in accordance with Schedule P1 of the Drugs and Cosmetics Rules, 1945. Schedule P1 also does not specify a pack size for Tetanus Toxoid vaccine. Rule 105, provides pack sizes for the formulations not covered by Schedule P1, however, this doesn't consider Tetanus Toxoid either. In view of this, reference must be drawn to the proviso to Rule 105 which provides that the pack size of 'new drugs' must be determined in accordance with the license granted for such 'new drugs'. New drugs are defined in Rule 122E the explanation to which states that all vaccines are covered under the expression 'new drugs'. Thus, a conjunctive reading of Rule 105, Rule 122E and Schedule P1 of the Drugs and Cosmetics Rules, 1945 clarify that the pack size of Tetanus Toxoid vaccine must be determined in accordance with the license granted for the sale and manufacture of Tetanus Toxoid. The petitioner then referred to the licence given to the petitioner issues by the Drug Controller of Govt. of Andhra Pradesh approved by DCGI. The licence clearly provides that the lowest pack size is a 0.5 ml ampoule.

Petitioner representative further mentioned that according to the licence, 0.5 ml is the lowest dosage and lowest pack size. Therefore according to terms of DPCO the ceiling price has to be fixed for 0.5 ml ampoule and cannot be fixed for 1 ml. There is no manufacturer that sells 1 ml. packs of the Tetanux Toxoid vaccine in the market.

NPPA comments: NPPA officials at the very outset humbly pointed out that review applicant has not complied with the provision of para 31 of DPCO 2013 as they have not furnished current price list in form V in implementation of notified price. This is a contravention of review provisions available under the DPCO 2013. They submitted that the Hon'ble Division Bench of the Delhi High Court Order dated 22.1.2015 clearly stipulates that the applicant petitioner shall be filing review application in terms of para 31 of DPCO 2013. However, the review applicant have not produced any current price list in compliance of impugned notified price under the provisions of DPCO 2013. The act of the petitioner is also against the judgement of Hon'ble Supreme Court in Union of India vs Cynamide reported in (1987) 2SCC720 and Glaxo Smithkline vs Union of India.

NPPA had fixed the ceiling price of Tetanus Toxoid vaccine on 14.6.2013 with a corrigendum issued on 17.2.2014 and the revised ceiling price notification SO No. 1156(E) dt. 28.4.2014. Calculation sheet of the price notification was put on website of the NPPA immediately after fixation of ceiling price on 14.6.2014 which clearly showed that ceiling price has been notified for a unit of 1 ml. It was upto the petitioner to represent within 15 days of issue of said price notification with their details to the NPPA or to apply for review within 30 days under para 31 of DPCO 2013 which they did not do so at that time. Para 31 of DPCO 2013 is reproduced below:-

"**Power to review**: Any person aggrieved by any notification issued or order made under paragraphs 4, 5 and 6 of this Order, may apply to the Government for a review of the notification or order within a period of thirty days of the date of publication of the notification in the Official Gazette or the receipt of the order by him, as the case may be, and the Government may make such order on the application as it may deem proper:

Provided that pending a decision by the Government on the application submitted under the above paragraph, no manufacturer shall sell a scheduled formulation or a new drug, as

the case may be, at a price exceeding the ceiling price or retail price, as the case may be, fixed by the Government of which a review has been applied for."

The petitioner pretended to have omitted to check the working sheet at the time of notification of 14.06.2013 at that time and deliberately did not comply the price notification with sole intention to overcharge from the consumers in relevant period and a preliminary notice was issued to the petitioner on 12.6.2014 by NPPA. The ceiling price of formulation has been notified by NPPA under para 4 and 11 of DPCO 2013. As per ORG-IMS various strengths of Tetanus Vaccines are mentioned therein. All strength and dosage as mentioned therein have been taken into the calculation for fixing ceiling price as per the provisions of DPCO 2013. It is pertinent to state here that when strength and dosage are not specified in the first schedule, all available strength and dosage as per IMS are taken into consideration for arriving at ceiling price uniformly in such cases. It was pointed out that Drugs and Cosmetics Act 1940 and rules made therein do not specify any lowest pack size for Tetanus Toxoid injection. Thus NPPA took the standard unit of 1 ml which has been consistently applied for liquid dosage form in accordance with the provisions of DPCO 2013. Accordingly per ml ceiling price was fixed for Tetanus Toxoid by multiplication /division of lower/higher pack size to arrive at 1 ml price. Hence the contention of the petitioner is wrong, misleading and denied. Further, the contention of the petitioner is that pro-rata pricing cannot be applied to vaccines and it makes manufacturing of 0.5 ml. ampoule unviable is also wrong, misleading and hence denied. DPCO 2013 is based on market based pricing and not on cost based pricing and the provisions of DPCO 2013 have been duly considered and applied in this case. The third contention of the petitioner regarding the data consideration in the working is also incorrect. As per the provision of para 9(1) NPPA have duly considered the data available in IMS for fixation of ceiling price. IMS data for relevant period shows Tetanus Toxoid for 1 ml also.

Petitioner: The petitioner representative mentioned that the NPPA, till date, has not fixed the ceiling price of 0.5 ml ampoule of Tetanus Toxoid vaccine. Thus the provisions of paragraph 31 of DPCO 2013 are not applicable. Further this review application has been filed under specific order/ direction of the Hon'ble High Court vide its order dated 22.01.2015.

The petitioner further respectfully submitted that DPCO 2013 is based on the principle of market based pricing. The NPPA is required to determine the ceiling price specifically for the available pack sizes in the market, by collecting data available with IMS and further collaborating with the market based data. The petitioner submits that the IMS data suffers from severe infirmities, and does not adequately reflect the pricing of Tetanus Toxoid followed in the market.

It would be impossible for the NPPA to fix the ceiling price for 1 ml pack size of Tetanus Toxoid, given that it is not manufactured by any petitioner in India and thus isn't available in the market. 0.5 ml Tetanus Toxoid is the only accepted human dosage by the licensing authority.

Further, the petitioner submitted that the clubbing of the 0.5 ml ampoules and 5 ml vials for calculating the ceiling price (as was done by the NPPA) would lead to impractical implications on the manufacturing cost and NPPA, thus, contravened the provisions of DPCO 2013 by fixing the ceiling price of 1 ml pack of Tetanus Toxoid paying no regard to the market situation. All the manufacturing companies have submitted their representation vide letter dated 16.11.2014 to which a reply from Director (Costing), NPPA dated 20.11.2014 was sent. The petitioner further clarified that all the manufacturers of Tetanus Toxoid have

followed the ceiling price set in the Notification dated 14.06.2013, for 0.5 ml ampoules of Tetanus Toxoid since it corresponded with the established market prices.

The petitioner respectfully submitted that for the reasons stated in the review petition and also the submissions made before this Hon'ble Review Authority, the petitioner prays that NPPA may set aside the Corrigendum dated 17.2.2014.

NPPA comments: NPPA representative denied the contentions of the applicant petitioner as the same are erroneous, misleading and untenable. They brought to the attention of reviewing authority of note mentioned in price notification 1673(E) dt. 14.6.2013 read with corrigendum order dated 17.2.2014. In the referred notification in note at sub clause 'C' it is clearly mentioned that the ceiling price for a pack of the scheduled formulation shall be arrived at by the manufacturer in accordance with the ceiling price specified in column of above table contained in para 11 of DPCO 2013. Thus, said note which is integral part of the notification clearly obligated the concerned manufacturer to adjust its price on pro-rata, accordingly**.** The provisions of DPCO 2013 stipulates that the manufacturer shall issue a price list in form V for implementation of notified price as per para 24(3) of DPCO 2013 which was not done in this case. It was submitted that the review applicant as on date found to be selling his formulation at a higher price than notified ceiling price (Copy of specimen sample enclosed). In addition to the above, NPPA displayed calculation sheet for relevant price on the website wherein pack size of 1 ml was clearly indicated as it was being shown by manufacturers. It was categorically submitted that the NPPA had fully considered available data as given by IMS as per stipulation laid down under paragraph 9 of DPCO 2013 of all packs in fixing the ceiling price of relevant vaccine. Kind attention is also drawn towards the Judgement of Hon'ble Supreme Court in Glaxo Smithkline case *supra* wherein the Hon'ble Supreme Court has laid down that the "current price list" has to be issued as per notified ceiling price and it is also held therein that the DPCO is the beneficial legislation under which consumer has to be given benefit of the lower price as per current price list or label, whichever is less. However, the review applicant has not followed the provision of the DPCO 2013 by not issuing any current price list in compliance of above said notifications. It is further submitted by NPPA officials that the petitioner cannot be absolved from its responsibility from price control of essential medicines under DPCO 2013 issued under the Essential Commodities Act 1955 by referring to certain representations as notified ceiling prices have to be followed in letter and spirit till the same are revised. It was further submitted that the review applicant has neither filed review application in terms of paragraph 31 of DPCO 2013 nor complied with ceiling price notifications of essential medicine to gain unjust enrichment in violation of the provisions of the DPCO 2013. Therefore review application may please be dismissed.

4. Department's comments: Points wise comments are given below:-

i) The first point raised by the petitioner is that the ceiling price has to be fixed for 0.5 ml ampoule and cannot be fixed for 1 ml. as there is no manufacturer that sells 1 ml pack for Tetanus Toxoide vaccine in the market. The petitioner in support of its argument has referred to Rule 105, rule 122 (E) and Schedule P.1 of the Drugs and Cosmetics Rule, 1945. The petitioner has also referred to the drug license given to them which stipulates that lowest pack size is 0.5 ml ampoule.

In this connection it may be mentioned that para 4(1) of DPCO 2013 clearly stipulates that sum of the prices to retailer of all brands and generic versions of the medicines having market share more than or equal to 1% has to be

considered while arriving at the average price to retailer and the ceiling price. It does not stipulate that the price of an ampoule of the lowest volume will only be considered. Therefore, as per para 4(1) of DPCO 2013 all brands and generic versions irrespective of the size have to be considered by NPPA. The calculation sheet as uploaded on the website of NPPA shows that though Tetanus Toxide injection of 1 ml ampoule is also available in the market its MAT value and the percentage share was very low. NPPA has, therefore, considered 0.5 ml pack and 5 ml packs which were available in the market.

Further para 11(1) states that average price to retailer shall be calculated as per provisions of para 4,5 & 6 and the ceiling price or retail price of a pack shall be reached by multiplying the same with the number or quantity in the pack. If the petitioner is manufacturing a formulation with less than 1 ml i.e. 0.5 ml they could reach pack price by multiplying 1 ml price with ½ . DPCO 2013 does not anywhere states that larger packs will be excluded. Even Tetanus Toxide Vaccine at sl. No.11 of the license issued to the petitioner clearly shows single dose vial – 0.5 ml and 10 dose vial – 5 ml. While arriving at the ceiling price NPPA has taken the data pertaining to both the packs . Thus the point raised by the petitioner has no merit.

(ii) The second point raised by the petitioner is that NPPA has not fixed the ceiling price of 0.5 ml ampoule within the provision of DPCO 2013. Thus the provisions of para 31 are not applicable.

As mentioned above in reply to point No. (i) the ceiling price issued by NPPA has to be multiplied with the quantity in the pack size for arriving at the ceiling price of the pack. DPCO 2013 does not anywhere state that the larger pack should be excluded for arriving at the ceiling price or retail price.

(iii) Third point raised by the petitioner is that DPCO 2013 is based on the principle of market based pricing. NPPA is required to determine the ceiling price specifically for the available pack sizes in the market. The petitioner submitted that IMS data suffers from severe infirmities and does not adequately reflect the pricing of their formulation.

DPCO 2013 has no where excluded larger pack sizes as already mentioned in reply to point (i). All brands or generic versions of the medicines have to be taken into account. If companies are giving discounted pricing for the larger packs to the doctors, etc. there is no reasons why the benefit of discounted prices should not be made available to the patients. A perusal of the cost sheet shows that there is more than 50% variation in prices within the same size of formulation. The DPCO,2013 by clubbing all packs and sizes seeks to rationalize the prices and the petitioner has no merit in this point.

(iv) The fourth point raised by the petitioner is that clubbing 0.5 ml ampoule and 5 ml vial for calculating the ceiling price would lead to impracticable implications on the manufacturing cost.

This point has already been discussed above as the DPCO 2013 provides in para 4(1) to include all brands and generic versions irrespective of their size or volume. Under para 11 the prices of the pack has to be calculated by

multiplying the ceiling price with the volume. There does not seem to be any practical difficulty in calculating the price of 0.5 ml. In regard to the point raised by the petitioner about the implication on manufacturing cost it is mentioned that DPCO 2013 is based on market prices and not on cost basis.

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

"The points raised by the petitioner have no merit and, therefore, the review application is rejected."

Issued on this date 4th March, 2015

(A. K. Sah)
Under Secretary to the Govt. of India
For and on behalf of the President of India

To

1. M/s. Biological E. Ltd
   Plot No.623, H. Road No.35,
   Jubilee Hills,
   Hyderabad-500 033

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. TD, NIC for uploading the Order on the Department's website