

**No.31015/17/2016-PI.I**  
**Government of India**  
**Ministry of Chemicals & Fertilizers**  
**(Deptt. of Pharmaceuticals)**  
\*\*\*\*\*

**B Wing, Janpath Bhavan,**  
**New Delhi - 110 001**

**Subject: The review application of M/s Dr. Reddy's Laboratories Ltd. dated 15/03/2016 under para 31 of DPCO against NPPA order No. S.O. 701(E) dated 10/03/2016 & OM No.19(119)/2014/Div.II/NPPA, dated 6.4.2016 for price fixation of "Norilet-O Tablets, Becozinc Capsules, Optisulin Capsules, Redicate 100 Tablets and Atocor 5 mg. Tablets" – reg.**

M/s Dr. Reddy's Laboratories Ltd. has filed a review petition dated 28<sup>th</sup> April, 2016 against the price fixation notified by NPPA vide S.O.No. 701(E) dated 10/03/2016, for their formulation "Norilet-O Tablets, Becozinc Capsules, Optisulin Capsules, Redicate 100 Tablets and Atocor 5 mg. Tablets".

2. A personal hearing was given to the company on 7.6.2016 and the same was attended by Shri Anand Jhavar, Associate Director-Finance; Shri Rohan Jain, Manager-Finance; Shri Sukrut Mehta, Partner, KMCO and Shri Kirit Mehta, Partner, KMCO on behalf of M/s Dr. Reddy's Laboratories Ltd., Shri S.S.Gaur, Y.P. (Tech.) on behalf of NPPA and Shri V.K.Tyagi, Consultant (Technical), D/o Pharmaceuticals.

3. The written comments of the company and the comments of the NPPA in the matter are summarised below:-

(i) 4. Para 16 (1) of DPCO, 2013 reads as under:

**"The government shall revise the ceiling prices of scheduled formulations as per the annual wholesale price index (WPI) for preceding calendar 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."**

By virtue of S.O. 701 (E) dated 10<sup>th</sup> March, 2016 their aforesaid formulations have turned out to be non-scheduled formulation. With effect from 10<sup>th</sup> March, 2016 the provisions, notifications, office memorandum issued in respect of scheduled formulations cannot be applied to their aforesaid formulations.

(ii) Content of paragraph "b" of OM No. 19(119)/2014/Div. II dated 6<sup>th</sup> April, 2016 is an attempt is made to apply provision relating to scheduled formulations to a non scheduled formulations (aforesaid formulations) which is ultra vires and against the words and spirit of notification S.O. 701 (E) dated 10<sup>th</sup> March, 2016.

(iii) In case of non-scheduled formulation, a manufacturer can increase the price by not more than 10% of the price prevailing during preceding twelve

months. There is no provision in the DPCO, 2013 regarding freezing the price of any formulation. The price for the then scheduled formulations was last notified S.O. 619 (E) dated 26/02/2015. Hence a period of 12 months has already passed since the last fixation of price.

**The company representative requested the Department to consider and conclude that OM No. 19(119)/2014/Div. II dated 6<sup>th</sup> April, 2016 is ultra vires and contravention of provisions of Drugs (Prices Control) Order, 2013 in respect of their aforesaid formulations.**

**Comments of NPPA:**

- (i) The contentions, interpretations or assumption made by Dr. Reddy's Lab. Ltd. that the price of their scheduled formulations Norilet-O Tablets was last notified vide S.O. 619(E) dated 26.02.2015. NPPA revised the ceiling price of said formulation from Rs. 5.41 to Rs. 5.26 vide S.O. 644(E) dated 02.3.2016 based on WPI fixed by Ministry of Commerce and Industry.
- (ii) NPPA issued an Office Memorandum on 19.02.2016, wherein, inter-alia, it is stated that as confirmed by the Economic Adviser (Ministry of Commerce & Industry), the annual change in the wholesale price index (WPI) works out as (-) 2.7105% during the calendar year 2015 over the corresponding period in 2014. Further, by said OM, it was also brought to the notice of all concerned in terms of provisions of DPCO, 2013 to take further action as necessary. **WPI is a major measure of price of a representative basket of wholesale goods and inflation.** Due to decline in WPI benefit of price must be passed on to the consumers for scheduled formulations irrespective of their distinction as existing or first time. A consumer buying such scheduled formulations cannot be deprived of benefit of decline in WPI on such flimsy distinction. It is pertinent to state here that manufacturers are automatically authorized to revise their MRPs upto the limit of increase / decrease based on WPI for the previous year. In case of decline in WPI, a corresponding reduction in MRP is mandatory. Therefore, para a & b of OM No. 19(119)/2014/Div.II/NPPA dated 6.4.2016 is as per the provisions of DPCO, 2013.
- (iii) In previous years, there was an increase in WPI and NPPA allowed the manufacturers and marketing company of scheduled formulations to avail the benefits of WPI.
- (iv) NPPA / Government is mandated to ensure the availability of the medicines of mass consumption at reasonable and affordable prices.
- (iv) Review application is devoid of any merit and deserves to be rejected outright.

4. During the personal hearing, the company representatives stated that the annual WPI shall be applicable only to scheduled formulations as on 1.4.2016. However, considering NPPP, 2012, para 4(xii) notification, “...***In the proposed policy, all essential drugs are under price control. It would follow that non-essential drugs should not be under the controlled regime and their prices***”

***should be fixed by market forces.***” and also considering the recommendations of the Core Committee, the criteria for deletion of medicine from NLEM,2015 is as follows:

***“A source Document containing list of medicines with its dosage forms, strength and information regarding their presence in NLEM 2011, NFI 2011, WHO EML 2013 (later updated to include WHO EML 2015); as well specific information on efficacy and safety was prepared.”***

- ***“.....A medicine with better efficacy or favourable safety profiles and better cost effectiveness is now available”***
- ***The disease burden for which a medicine is indicated is no longer a national health concern in India.”***

Thus, formulations under consideration are not essential and non-scheduled in nature and are not deemed to be of public interest and a public health concern.

Hence, the MRP of products shifted to Non-scheduled category by notification issued by DoP on 10<sup>th</sup> March 2016, are permitted to be increased in April 2016 up to 10% of the MRP prevailing in April 2015 as provided in paragraph 20

Further, provisions of 13(3) and 16(4) of DPCO, 2013 mandating a corresponding reduction in MRP do not apply to the formulations under consideration, as the formulations under consideration are non-scheduled as on 1.4.2016 and hence WPI reduction cannot be mandated under para 16(1) ***“The Government shall notify the same on the 1<sup>st</sup> day of April every year.”*** Hence, the company representatives humbly submitted that the ceiling prices may be revised prior to 1<sup>st</sup> of April. However, they must notify the same only on 1<sup>st</sup> of April.

Para 16(1) is a fiscal statute and price fixation is a legislative function. With respect to price fixation under para 4 and 16, “2006(4) ALL MR 1 (Kshitij R.Vyas, Chief Justice of India & Dr. D.Y. Chandrachud, Justice of Supreme Court) stated in the case, the Secretary, All India Biodynamic and Organic Farming Association versus Principal Secretary to Government of Maharashtra that ***“price fixation is essentially a part of the legislative function.... Principles of natural justice would not be attracted to such an activity, which is a legislative flavour.... also the Court cannot issue directions in regard to such fixation.”***

2004(10) Supreme Court cases page 6 (Ruma Pal, B.N. Shrikrishna, Justices of Supreme Court) held in Union of India versus Azadi Bachao Andolan that ***“there is nothing like equity in a fiscal statute – either the statute applies proprio vigore or it does not apply. There is no question of applying a fiscal statute by intendment, if the expressed words do not apply.”***

2004(1) SCC page 391 (V.N. Khare, Chief Justice of India and S.B. Sinha and Dr. A.R. Lakshmanan, Justices of Supreme Court) held in Krishi Utpadan Mandi Smiti versus Pilibhit Pantnagar Beej Limited that ***“in fiscal statutes strict and literal construction is needed – In case of doubt, the same should be construed in***

***favour of the subject and against the State – for a person to be liable to follow provisions of such statutes, same should be clear and unambiguous.”***

Para 10(4) and NPPP para 4(xiv) are specific provisions for change from DPCO, 1995 to DPCO,2013. The same cannot be made applicable to a change in NLEM in the first schedule, which is governed by two specific provisions, namely, para 17 and 18. Further, OM 19(119)/2014/Div.II/NPPA, dated 6.4.2016 does not mention any provision of DPCO 2013 in support of the decision taken on the meeting held on 27<sup>th</sup> March, 2016. NPPA does not have the power under the DPCO 2013 to issue OM dated April 6, 2016, thereby mandating freezing of prices and WPI reduction shifted to non-scheduled category.

There is no provision enabling DPCO 2013 freezing prices of non-scheduled formulations for any period of time. Further, the last ceiling prices notified for the said formulations was vide SO 619(E), dated 25.2.2015, specifically notified and made effective on 1.4.2015.

The said action of the NPPA is in complete transgression of Para 17(2) of DPCO 2013. By freezing and WPI reduction of prices via OM dated April 06, 2016 in an indiscriminate manner, NPPA has exceeded its jurisdiction and powers under DPCO 2013 as there are no corresponding provision that empowers the DPCO 2013 to act in such a manner. The decision taken by the NPPA in its authority meeting is overreaching the scope of DPCO 2013. The source of power for such directions of NPPA could only be from DPCO 2013 and not on basis of decision taken in Authority Meeting. Needless to say that NPPA does not have the power to make laws, it can only implement DPCO as it exists. Thus, the provision of Para 17(2) of DPCO 2013 cannot be ignored or avoided.

**Paragraph 17(2) states that medicines omitted from first schedule shall fall under the category of non-scheduled formulations. As the Department of Pharmaceuticals (DoP) has amended the Schedule I on 10<sup>th</sup> March 2016, all medicines omitted from Schedule I have become ‘non-scheduled formulations’ with immediate effect, as there is no mention of effective date in the notification.**

**As it is clear that OM dated 6<sup>th</sup> April, 2016 is without any legal sanctity and we request DoP to direct NPPA to withdraw the said OM with immediate effect.**

AIR 1987 BOM 324 in Sandoz India Limited versus Union of India para 10, 11 and 13 – ***“Order for fixation of retail prices of formulations – fixing prices without specifying the norms or enabling legislation are therefore held invalid.”***

1987(12) ECR 119 Supreme Court Cases p.720 (Union of India versus Cynamide India Limited) – ***“price fixation under DPCO is not a quasi-judiciary or legislative activity and does not attract observation of the principles of natural justice.”***

## **NPPA Comments:**

The representative of NPPA denied the statements submitted by the company representatives that the last ceiling prices were notified vide SO 619(E), dated 25.2.2015. In this regard, it is stated that SO 619(E) was superceded by SO 644(E) because as on 2.3.2016, and these formulations were within the ambit of scheduled formulations.

The NPPA representative categorically submitted that the contentions raised by the companies are wrong and denied. At the outset, it is pointed out that it is obligatory for the companies to follow the prices against which review is applied. No documentary evidence in form V has been submitted. This review is against the Office Memorandum and not maintainable. It is also pointed out that the formulations referred in OM, dated 6.4.2016 were scheduled formulations as on 2.3.2016. It was obligatory for the company to carry out the revision due to decline in WPI as per notification, dated 19.2.2016 read with para 13(3) proviso and 16(4) which requires corresponding reduction in MRP as per WPI by the manufacturers before the date of notification. Thus, the price of these scheduled formulations is the legitimate price as per DPCO 2013 and it is before 10.3.2016. Many manufacturers have implemented prices notified on 2.3.2016 (IDMA letter copy enclosed) Further, it is pointed out that para 10(3) of DPCO 2013 and para 3(v) and 4(xiv) also mandates keeping these prices for one year, whenever there is a transition of drugs. These drugs were transitioned only on 10.3.2016 as admitted by the company representatives for the price applicable before the transition is the MRP as per 2.3.2016 is the price to be maintained as a preceding price of 12 months as per para 20 of DPCO 2013. Company is trying to mislead that they can increase the price or the prices when they were scheduled formulations, which is wrong. They have to maintain the prices, which were applicable last for the 12 months when on the transition to the non-scheduled category. This is also in clear cut analogy of para 10(3) of DPCO 2013 and Supreme Court Judgement in Glaxo Smithkline versus UOI 2014 (Sec-II 753), which held that benefit of price has to be passed on to the consumers and in price fixation is the prime consideration. DPCO 2013 is issued under EC Act, 1955. In EC 1955, all drugs are essential commodities. As held by Supreme Court in Cynamide case, reported in (1987)2 SCC 720, which is reproduced herewith :

“A price fixation measure does not concern itself with the interests of an individual manufacturer or producer. It is generally in relation to a particular commodity or class of commodities or transactions. It is a direction of a general character, not directed against a particular situation. It is intended to operate in the future. *It is conceived in the*

interests of the general consumer public. The right of the citizen to obtain essential articles at fair prices and the duty of the State to so provide them are transformed into the power of the State to fix prices and the obligation of the producer to charge no more than the price fixed.

Therefore, the action of the NPPA is in true letter and spirit of the DPCO 2013.

On this, the representatives of the Companies submitted that they have implemented the prices as mentioned in SO 644(E) dt.2.3.2016 for products available in the market within 45 days time and products manufactured after 1.4.2016 from the date of manufacturing. Form II NO.1024 as annexed herewith under IPDMS has been duly submitted to NPPA on 15.4.2016.

The implementation of ceiling price or revised ceiling price as maintained under para 13 and para 16 cannot be made effective before the notification of ceiling prices. The company representatives reiterated that as per para 16(1), the ceiling prices must be notified and implemented on the 1<sup>st</sup> of April, 2016.

NPPA's contention that many companies and IDMA's letter stating implementation of ceiling prices before date of notification is in contravention of para 13 and 16 of DPCO.

Para 3 and para 4 of NPPP 2012 and para 10(3) and 10(4) of DPCO 2013 are specific provisions for change over from DPCO 1995 to DPCO 2013 and the same cannot be applied to a change in NLEM which specifically falls under provisions of para 17 and 18 of DPCO 2013. Thus, no other provisions of DPCO 2013 may apply.

The Glaxo Smithkline case mentioned by NPPA was specific to formulations which are essential to public health and are scheduled in nature. The company representatives stated that they have already humbly submitted that their formulations as on 10.3.2016 are not essential and non-scheduled in nature courtesy para 4(xii) of NPPP 2012 and the criteria for deletion of a scheduled formulation from NLEM 2015, as stated by the recommendations of the Core Committee.

Thus, in conclusion, the company humbly submitted that implementation of ceiling price has been carried out and intimated to NPPA vide Form II No.1013, no section of DPCO 2013 relating to scheduled formulations can be applied to the formulations under consideration from 10<sup>th</sup> of March, 2016, implementation of ceiling prices under para 16 must be only on 1<sup>st</sup> April, 2016 and finally NPPA has not shared any legislation in support of OM 19(119) /2014/Div.II/NPPA,, dated 6.4.2016.

Finally, 2014(15) SCC p.753 (Ranjan Gogoi and M.Yusuf Eqbal, Justices of Supreme Court) held in Pune Municipal Corporation versus Kausarbag Cooperative Housing Society Limited that ***“administrative instructions cannot over-ride statutory regulations.”***

NPPA representative requested the Company to submit the copy of judgement referred to above, which will be examined by the Competent Authority of NPPA.

Thus, the company representatives humbly requested to direct NPPA to consider the said formulations as non-scheduled and withdraw the said OM, dt.6.4.2016.

## **5. Examination:**

The pharma associations/industry like IPA, IDMA and Wockhardt has filed Writ Petition in various courts against S.O. No.644((E) dated 2.3.2016. the matter is subjudice.

So far as instant review application filed by Dr. Reddy's Laboratories Ltd. is concerned, it is seen that S.O.No.701(E) fixing ceiling price of 530 formulations was issued on 2.3.2016 and its applicability was to take effect from 1.4.2016. In the meanwhile, schedule I of DPCO 2013 was substituted by NLEM 2015 as on 10.3.2016. As the five formulation of the said petitioner company was not in NLEM 2015, and revised Schedule I as on 10.3.2016, the WPI w.e.f. 1.4.2016 is not applicable in the instant case.

NPPA has relied upon para 10(4) of the DPCO 2013 in justifying the application of WPI impact in the instant case.

Para 10(4) of DPCO 2013 states as under :

***“The prices of scheduled formulations, which are specified in the Drugs (Prices Control) Order, 1995 but not specified in the First Schedule of this order, fixed and notified under the provisions of the said order, after 31<sup>st</sup> May, 2012, shall remain effective for one year from the date of notification of such prices and thereafter prices of such formulations shall be regulated as in case of other non-scheduled formulations as stated in paragraph 20 of this Order.”***

From the above, it is seen that para 10(4) stated above is applicable when there is change in DPCO i.e. switch over from DPCO 1995 to DPCO 2013. In the instant case, there is no change in DPCO but only there is Schedule I substitution by NLEM 2015 in DPCO 2013. The para 10(4) of DPCO 2013 may thus not be applicable in this case.

In view of the above, it is felt that price revision due to change in WPI made by NPPA vide their Notification dated 02<sup>nd</sup> March, 2016 may not be applicable to the

formulation referred to by the applicant on the ground that the formulation is not included in the revised schedule to the DPCO, 2013, issued vide S.O.No.701(E) dated 10.3.2016.

So far as regulation of non-scheduled drug is concerned, para 20(1) of DPCO, 2013 states as under:-

***“The Government shall monitor the maximum retail prices (MRPs) of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months.”***

6. **Government decision:**

Price revision due to change in WPI to be effective from 1.4.2016 made by NPPA vide their Notification dated 02<sup>nd</sup> March, 2016 may not be applicable to the five formulations referred to by the applicant on the ground that the formulation is not included in the revised schedule to the DPCO, 2013, issued vide S.O.No.701(E) dated 10.3.2016. The formulation, therefore, are in the category of non-scheduled drugs w.e.f. 10.3.2016.

The product may, therefore, be regulated as non-scheduled formulations in terms of para 20(i) of DPCO, 2013, w.e.f. 10.3.2016.

Issued on this day, the 22<sup>nd</sup> day of July, 2016.

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

To

1. M/s Dr. Reddy's Laboratories Ltd.,  
Global Generics – India,  
7-1-27, Ameerpet,  
Hyderabad-500 016.
2. The Member Secretary,  
National Pharmaceuticals Pricing Authority,  
YMCA Cultural Centre Building,  
New Delhi – 110 001.

Copy to:

- (i) PS to Hon'ble Minister (C&F), Shastri Bhavan, New Delhi for information.
- (ii) PSO to Secretary (Pharma), Shastri Bhavan, New Delhi for information.
- (iii) Technical Director (NIC) for uploading the order on Department's Website.