

No. 31015/99/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

A- Wing, Shastri Bhawan,
New Delhi 110 001

Order

1. This is an order on an application dated 18.12.2017 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Lupin Limited (hereinafter called the applicant) against notification S.O. No. 3727(E), dated 23.11.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Voglibose 0.3mg + Metformin 500mg + Glimepirid 1mg and Voglibose 0.3mg + Metformin 500mg + Glimepirid 2 mg.

2. The applicant has contended as under:-

2.1 Company's formulations as listed in the order under reference are based on Sustained Release technology. The label claim of company's products are given hereunder:-

SR.NO.	COMPOSITION	BRAND NAME
1 (11 of Order)	Each uncoated bilayered tablet contains: Metformin HCL IP (in SR form) 500 mg Voglibose 0.3 mg Glimepiride IP 1.00 mg	GLUCONORM VG PLUS 1
2 (13 of order)	Each uncoated bilayered tablet contains: Metformin HCL IP (in SR form) 500 mg Voglibose 0.3 mg Glimepiride IP 2.00 mg	GLUCONORM VG PLUS 2

2.2 When DPCO 2013 was introduced on 15th May 2013, NLEM 2011 was adopted as Schedule I. The said schedule mentions only METFORMIN tablet. Since it does not specify SR/CR other innovative dosage form, it is very clear that innovative dosage forms are not included in Schedule I.

This view was also corroborated by DOP vide its letter dated 20th September, 2013 have opined that Innovative dosage should not be kept under price control. Company submitted that Ministry of Health & Family Welfare vide its OM dated 6/12/2013 have clarified that innovative dosages are not forming part of NLEM unless specified.

2.3 The said Schedule I was amended in March 2016 by adopting NLEM 2015, by replacing the old Schedule I. The new Schedule I incorporated METFORMIN 500, 750 & 1000mg both immediate as well as Controlled release.

2.4 All of company's formulations listed in the Order under reference are with Metformin SR. These formulations were launched much before the new Schedule I was

adopted in March 2016. Thus the definition of New drugs is not applicable to the company.

2.5 Looking at the facts referred to above, it's very much evident that Metformin being an innovative dosage was not in Schedule category and was incorporated only in March 2016. Since company's products were marketed much before the amendments, NPPA has erred in notifying the price exclusively for the company. Company mentioned that they have implemented the price as notified.

2.6 Accordingly company requested this Department to quash the price notification fixed exclusively for the company as it is not in concurrence with the provisions of DPCO, 2013.

3. Comments of NPPA:

3.1 Retail price of GLUCONORM VG PLUS 1/ GLUCONORM VG PLUS 2 for serial No. 11 & 13 (i.e. Metformin HCL IP 500 mg + Voglibose 0.3 mg + Glimpride 1/2 mg as Rs. 8.52/10.46 per tablet as per para 5, 11, and 15, of Drugs (prices control) order, 2013.

3.2 The company has stated that correct methodology was not followed in arriving at the Retail price of Metformin HCL IP 500 mg + Voglibose 0.3 mg + Glimpride 1/2 mg. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Company's Grievances	NPPA's comments
<p>Petitioner stated that when DPCO, 2013 was introduced on 15.05.2013, NLEM, 2011 was adopted as Schedule – 1. The said schedule mentions only Metformin Tablet. Since, it does not specify SR/CR other innovative dosage form, it is very clear that innovative dosage forms are not included in Schedule – 1.</p> <p>Company retreated that Schedule -1 was amended in March, 2016 by adopting NLEM 2015, by replacing the old schedule-1. The New schedule -1 incorporated Metformin 500, 750 and 1000 both immediate as well as controlled release. Petitioner is of the opinion that all their formulations listed in the order under reference are with Metformin SR. These formulations were launched much before the new schedule -1 was adopted in March, 2016 company enclosed the copy of manufacturing licence in support of their claim.</p>	<p>NPPA fixed the Retail price of GLUCONORM VG PLUS 1/ GLUCONORM VG PLUS 2 (i.e. Metformin HCL IP 500 mg + Voglibose 0.3 mg + Glimpride 1/2 mg as Rs. 8.52/10.46 per tablet as per the decision of 50th Authority meeting held on 23.11.2017 vide S. O. 3727(E) dated 23.11.2017. Since, under NLEM, 2011 of Metformin 500 mg tablet was included without differentiating its other variants therefore, all variants i.e. CR/SR/extended release are considered as included. Hence, the contents of the company that Metformin 500 mg tablet in sustained release form is not included under NLEM, 2011 is not tenable. Therefore, GLUCONORM VG PLUS 1/ GLUCONORM VG PLUS 2 tablet fall under the category of New Drug 2(U) of DPCO, 2013 and it was mandatory for company to get price approval from NPPA before manufacturing/marketing of subject formulation.</p>

<p>Company also stated they have implemented the Retail price notified by NPPA vide S.O. 3727 (E) dated 23.11.2017.</p> <p>In support of their claim petitioner referred DoP letter No. 31011/17/2012-PI-II dated 20.09.2013.</p>	<p>Launching of GLUCONORM VG PLUS 1/ GLUCONORM VG PLUS 2 (i.e. Metformin HCL IP 500 mg + Voglibose 0.3 mg + Glimpride 1/2 mg) by the company much before the new schedule -1 was adopted in March, 2016 without price approval is violation of DPCO, 2013 provisions and attracts the provisions of overcharging.</p>
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4. Examination:

4.1 DoP, vide its letter No.31026/63/2013-PI.II, dated 6th September, 2013 and reminder dated 27.9.2013, sought an advice from Ministry of Health and Family Welfare on “*wherever only conventional forms of a drug (like tablets/capsules/ injection) are mentioned under NLEM-2011, the dosage forms like modified release forms, dispersible, effervescent, soluble, enteric coated, lipid suspension/liposomal of that drug are part of NLEM-2011, or not?*”. In response to the query, the Ministry of Health & Family Welfare, vide its letter No.X.11035/9/2013-DFQC, dated 6th December, 2013, stated that the matter was examined by Central Drugs Standard Control Organization (CDSCO) and their comments are as under:-

“Conventional forms of a drug like tablet/capsule/injection of that particular drug as mentioned in NLEM 2011 shall be considered as a part of NLEM 2011 and not the dosage form like modified release forms, dispersible, effervescent, soluble, enteric coated, lipid suspension/liposomal of the drug unless these drugs are specified in non-conventional dosage forms in NLEM-2011.”

4.2 The Ministry of Health & Family Welfare opined that different dosage forms need not be treated as covered under NLEM unless such dosage forms are specifically included in the relevant NLEM. The opinion of Ministry of H&FW was deliberated at high level. It was decided that it is necessary to recognize that the NLEM prepared by the Ministry of Health & Family Welfare is primarily not for the purpose of price control and hence has to be read in conjunction of other relevant provisions of DPCO, 2013, failing which it can be easily misused by drug manufacturers to circumvent or escape from the DPCO, 2013, which should not be allowed.

4.3 As per DPCO, 2013, a manufacturer of a new drug as defined under the DPCO, 2013 is allowed to seek a separate price by making necessary application under para 15(2). In the case of new drug involving a new delivery system developed through indigenous research and development, the manufacturer can seek a 5 year exemption from price control under para 32(iii) following due procedure. Beyond these provisions, there is no other way in which a drug manufacturer can seek a price approval or exemption from price control for novel delivery systems/innovative dosage forms of the scheduled formulations.

4.4 The current DPCOs, issued in pursuance to the NPPP 2012, rely upon the ‘market prices of the relevant formulations’ in contrast to the earlier practice of ‘cost based pricing’. As such, the market prices of different dosage forms, relevant for any

NLEM, have already been taken into consideration during the exercise of fixation of Ceiling Prices of various NLEMs. Therefore, to exempt any dosage form of any NLEM (intended for same therapeutic indication) will defeat the purpose and sanctity of the pricing mechanism under DPCO.

4.5 The premise of the NLEMs essentially revolves around the therapeutic relevance of various formulations irrespective of their delivery systems. Mere inclusion of any additional delivery system in the NLEM (without any variation in the therapeutic category or indications), in addition to the hitherto included type of formulation, does not necessarily prove that the relevant additional category of delivery system, was not covered in the NLEM. Such additional entry of a different delivery system, may at best be treated as extension of the Schedule, more as a clarificatory exercise, instead of interpreting it as inclusion of any additional drug or molecule.

4.3 In view of the above, the contention of the applicant is devoid of any genuine basis for questioning the approach followed by NPPA while fixing the retail prices of formulations Gluconorm VG Plus 1 (containing Metformin HCL IP 500 mg + Voglibose 0.3 mg + Glimpride 1 mg and Gluconorm VG Plus 2 (containing Metformin HCL IP 500 mg + Voglibose 0.3 mg + Glimpride 2 mg) by treating them as new drug under para 2(u) of DPCO, 2013. Therefore, the review application is liable to be rejected.

5. Decision:

“The contention of the applicant, relied upon in their Review Application, is devoid of any genuine basis for questioning the approach followed by NPPA while fixing the prices of Voglibose 0.3mg+ Metformin 500mg+Glimepiride 1mg (Lupin Brand name: Glucnorm – VG Plus 1) and Voglibose 0.3mg+ Metformin 500mg+Glimepiride 2mg (Lupin Brand name: Glucnorm – VG Plus 2) by treating them new drug under para 2(u) of DPCO, 2013. Therefore, the review application stands rejected.”

Issued on this date, the 2nd day of July, 2018.

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

Copy to:-

1. M/s Lupin Limited, B/2, Laxmi Towers, Bandra Kurla Complex, Bandra (East), Mumbai-400 051.
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