

No. 31015/5/2018-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 01.01.2018 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. 3947(E), dated 20.12.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the retail prices of Glimepiride + Metformin tablet containing Glimepiride 1mg + Metformin 500mg and Glimepiride + Metformin tablet containing Glimepiride 2mg + Metformin 500mg tablets.

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 as well as launch date are given hereunder:-

<u>S. N O</u>	<u>COMPOSITION AS PER ORDER</u>	<u>OUR COMPOSITION AS PER LICENSE</u>	<u>BRAND NAME</u>	<u>LAUNCH DATE</u>
1.	Each tablet contains: Metformin 500 mg Glimepiride 1 mg	Each uncoated bilayered tablet contains: Metformin HCL IP (in SR form) 500 mg Glimepiride 1 mg	GLUCONORM-G 1 GLADOR M 1	FEB. 2003 SEPT. 2012
2.	Each tablet contains: Metformin 500 mg Glimepiride 2 mg	Each uncoated bilayered tablet contains: Metformin HCL IP (in SR form) 500 mg Glimepiride 2 mg	GLUCONORM-G 2 GLADOR M 2	FEB. 2003 SEPT. 2012

2.2 Company also enclosed a certificate issued by PHARMATRAC, confirming the Launch date, which is much before the date of DPCO 2013 coming into force.

2.3 Additionally, when DPCO 2013 was introduced on 15<sup>th</sup> 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.

2.4 This view was also corroborated by DOP vide its letter dated 20<sup>th</sup> September, 2013 have opined that Innovative dosage should not be kept under price control.

Company also 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.

2.5 The said Schedule I was amended in March 2016 by adopting NLEM 2015. The new Schedule I incorporated METFORMIN 500,750 & 1000mg both immediate as well as Controlled release. The revised schedule I reiterated the DOP's views on Innovative Dosages by incorporating in Explanation Note 2.

2.6 Looking at the facts referred to above it's very much evident that company's product does not fall under the definition of NEW DRUG as company's formulations have been launched much before DPCO came into force. Further Metformin in innovative dosage were not in Schedule category and was incorporated only in March 2016. Thus NPPA has erred in notifying the prices exclusively for company ERRONEOUSLY. Since the price has been notified erroneously, company has not implemented the prices so notified.

2.7 Company requested this Department to quash the price notification fixed exclusively for company as NPPA has not withdrawn the price notification till date in spite of their representation made to NPPA for the same. Further the same it is not in concurrence with the provisions of DPCO 2013 as well as NPPA's own guidelines dated 24/11/2017.

### 3. Comments of NPPA:

3.1 Retail prices of the subject formulations fixed by NPPA vide S.O. No. 3947 (E) dated 20.12.2017 are detailed below:-

Sl. No.	Composition As Per Order	Company's Product Composition	Notified Price (Rs)	
			Post - GST	Pre - GST
1	Each tablet contains: Metformin 500 mg Glimepride 1mg	Each uncoated bilayered tablet contains: Metformin IP 500 mg + Glimepride 1mg	4.0	3.84
2	Each tablet contains: Metformin 500 mg Glimepride 2mg	Each uncoated bilayered tablet contains: Metformin IP 500 mg + Glimepride 2mg	4.5	4.32

3.2 NPPA fixed the retail price of GLUCONORM G 1 and GLUCONORM G 2 as Rs.4.00 and Rs.4.50 per tablet respectively, vide S.O. 3947(E) dated 20.12.2017 on the basis of decision taken in the 51<sup>st</sup> Authority Meeting, wherein it was decided that wherever the application has been received by NPPA for any drug for which NPPA had already notified the price, the same would be extended to the subsequent applicant also. This decision has been taken as discussed at a high level meeting which has

been communicated to all concerned. Accordingly, the price was fixed as per the above decision.

3.3 Since under NLEM, 2011, Metformin 500 mg tablet was included without differentiating its other variants therefore, all variants i.e. CR/SR/extended release are considered as included and prices of all variant were considered for calculating the ceiling/retail price, as applicable. Hence, contention of the company that Metformin 500 mg sustained release tablet is not included under NLEM, 2011 is not tenable. Therefore, GLUCONORM G 1 and GLUCONORM G 2 tablets fall under the category of New Drug 2(U) of DPCO, 2013 and it was mandatory for the company to get price approval from NPPA before manufacturing/marketing of subject formulations.

3.4 The launch of GLUCONORM G 1 and GLUCONORM G 2 by the company before DPCO, 2013 is a matter of fact and may be verified the new schedule –I was adopted in March, 2016 may be verified on submission of document by the company.

#### 4. Examination:

4.1 M/s Lupin Limited, In its review application dated 1.1.2018, stated that their formulations Gluconorm G1 and Gluconorm G2 Tablets containing Metformin were launched by them in February, 2003 and the other brands Glador M1 and Glador M2 were launched in September, 2012, which is prior to introducing DPCO, 2013. In support of its claim that their formulations are based on innovative dosage technology, company also submitted documentary proof of drug manufacturing licences issued by the Licensing Authority, J&K Govt. to the company. Company also furnished certificate dated 26.12.2017 of Pharmatrac confirming the launch dates of the above formulations.

4.2 However, the company has not submitted invoices and samples of the products prior to 15<sup>th</sup> May 2013, certified by Chartered Accountant (CA) / Cost Accountant (CMA) in support of the claim that the formulations were launched before the DPCO 2013 came into effect.

4.3 Since the company has not submitted the required documents as per OM F.No.17(1)/2016/Div-III/NPPA, dated 24.11.2017, the review application needs to be negated.

#### 5. Decision

“The company has not submitted the required documents as per NPPA’s OM F.No.17(1)/2016/Div-III/NPPA, dated 24.11.2017 in support of its claim that the formulations were launched before the DPCO 2013 came into effect. Therefore, the review application stands negated.”

Issued on this date, the 25<sup>th</sup> day of September, 2018.

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

Copy to:-

1. M/s Lupin Limited, C/4, 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