No. 31015/3/2018-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 11.01.2018, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Unison Pharmaceuticals Private Limited (hereinafter called the applicant) against notification S.O. No.3947(E), dated 20.12.2017 and corrigendum SO 4041(E), dated 22.12.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Glimepride 1mg + Metformin Hcl SR 500mg + Pioglitazone 15mg. and Glimepride 2mg + Metformin Hcl SR 500mg + Pioglitazone 15mg.

2. The applicant has contended as under:-

2.1 Company has submitted that they aggrieved by NPPA order No. 3947 dated 20.12.2017 and Corrigendum dated 22.12.2017 published on 29.12.2017 by NPPA, company have already filed the appeal before the Department to direct NPPA to review company's case and delete/ drop out company's name from the said corrigendum.

2.2 Company further submitted that company's products were launched on 11/08/2012 which is prior to DPCO 2013 and NLEM 2015 wherein Glimepride and Metformin SR were incorporated. Therefore, price approval for "new drug" as per the para 2(u), 4, 5 and 15(2) of DPCO 2013 was never applicable to the company.

2.3 Company once again submitted that even today company's prices are very less as compared to prices fixed by NPPA in notification No. S.O 425(E) and 426(E) dated 17/02/2014 and another NPPA order No. S.Q.1793(E) dated 10.07.2014 for the same formulation. Company submitted price since date of introduction of company's products in market/ launch having same formulation is as under:

Formulation: Glimepiride ..1 mg + Metformin Hcl SR ...500 mg + Pioglitazone ..15 mg

SN	Name of Products	Price Per tablet	Excl. of VAT	Increased rate	With effect from
01	Glimison-MPl	2.00	1.90	-	11.08.2012
02	Glimison-MPl	2.20	2.10	9.52%	12.08.2013
03	Glimison-MPl	2.33	2.23	5.83%	14.08.2014
04	Glimison-MPl	2.56	2.44	9.01%	30.08.2015
05	Glimison-MPl	2.80	2.67	8.61%	17.09.2016
06	Glimison-MPl	2.80	2.50	Pre GST	as on today

Formulation: Glimepiride 2 mg + Metformin Hcl SR ...500 mg + Pioglitazone ..15 mg

SN	Name of Products	Price Per tablet	Excl. of VAT	Increased rate	With effect from
01	Glimison-MP2	2.20	2.10	-	11.08.2012
02	Glimison-MP2	2.42	2.30	9.09%	12.08.2013
03	Glimison-MP2	2.57	2.45	6.12%	18.08.2014
04	Glimison-MP2	2.80	2.67	8.98%	19.08.2015
05	Glimison-MP2	3.06	2.91	8.25%	27.08.2016
06	Glimison-MP2	3.06	2.73	Pre GST	as on today

3. **Comments of NPPA:**

3.1 The retail price of Glimepride 1mg +Metformin Hcl SR 500mg +Pioglitazone 15mg was notified as Rs 2.14 (Post GST)/tablet and Glimepride 2mg +Metformin Hcl SR 500mg +Pioglitazone 15mg Rs 2.35 (Post GST)/tablet, vide S.O. No. 3947(E) dated 20/12/2017 and corrigendum on 22.12.2017 as per Para 5, 11, and 15 of DPCO, 2013.

3.2 The company has stated that correct methodology was not followed in arriving at the ceiling price of Glimepride 1mg +Metformin Hcl SR 500mg +Pioglitazone 15mg**.** 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
Petitioner company stated that NPPA vide **S.O. No. 3947(E) dated 20/12/2017** fixed the retail price of Glimepride 1mg +Metformin Hcl SR 500mg +Pioglitazone 15mg & Glimepride 2mg +Metformin Hcl SR 500mg +Pioglitazone 15mg as Rs 2.23/- and 2.45/- (pre-GST) per tablet for the manufacturer quoted as M/s Jubliant Science Ltd and Marketed by M/s Hetro Labs Ltd and Biochem Pharmaceuticals Industries Ltd respectively wherein it was directed to read name of manufacturer and marketing company of sr no. 14 & 15 as Unison Pharmaceutical Pvt. Ltd. in place of the above two companies and also mentioned that all notes and other contents mentioned in the original order S.O. 3947 (E) dated 20.12.2017 shall remain same. In connection with the same, company informed that their products have been launched on 11.08.2012 which is prior to introducing DPCO-2013 and so we have not applied for price approval for said formulation. Company enclosed notification issued by NPPA vide SO No 425 (E) and SO No 426 (E) dated 17.02.2014 wherein the prices were fixed for the same formulation as Rs 5.36 + applicable VAT and	NPPA vide S.O. No. 3947(E) dated 20/12/2017 fixed the retail price of Glimepride 1mg +Metformin Hcl SR 500mg +Pioglitazone 15mg & Glimepride 2mg +Metformin Hcl SR 500mg +Pioglitazone 15mg as Rs 2.23/- and 2.45/- (pre-GST) per tablet for M/s Unision Pharmaceutical Private Limited, However there was a typo error in the Entry at Sl. No. 14 & 15 in the table of S.O. No. 3947(E) dated 20/12/2017, which was rectified as corrigendum dated 22.12.2017. The retail Prices of concerned formulations were fixed according to the information that M/s Unision Pharmaceutical Private Limited has been marketing /manufacturing Glimepride 1mg +Metformin Hcl SR 500mg +Pioglitazone 15mg & Glimepride 2mg +Metformin Hcl SR 500mg +Pioglitazone 15mg without price approval. M/s Unison Pharmaceutical Private Limited in its reply stated that they are following the price below the retail price notified by NPPA for Jubiglim TM

Rs 6.94 + applicable VAT for 10 Tablet respectively. Company reiterated that even today their prices are very less as compared to above said order (company depicted it via table). Company also informed that they are operating and manufacturing their product only in Gujarat State and Not in any other state or part of India. Company aggrieved by the order No. 3947 dated 20/12/2017 and corrigendum on 22.12.2017 published on 29.12.2017by NPPA and appeal to review the case and delete/drop out our company's name from the said corrigendum.	Trio 1 tablet / Jubiglim ^{TM} Trio 2 Tablet of M/s Hetro Lab Limited/M/s Jubilant Lifesciences Limited However, retail price fixation is company specific and other companies intending to market/manufacture the same formulation have to apply for price approval to NPPA. Since M/s Unison Pharmaceutical Private Limited did not apply for price approval, the retail price for M/s Unison Pharmaceutical Private Limited was fixed suo moto.

4. During the personal hearing, the company stated that the matter relates to alleged cases of "Without price approval (WPA)" for which NPPA has been bringing guidelines from time to time. It is another matter that those guidelines are arbitrarily being applied from a retrospective date that too without the approval of Department of Pharmaceuticals, Government of India. Nevertheless, in the present matter, NPPA issued a fresh Office Memorandum vide no. F. No. 37(1)/2016/Div-III/NPPA dated 24.11.2017. In Para 3 (a) to 3(h) of the above said Office Memorandum, NPPA had laid down certain cases in which alleged WPA (Without Price Approval) Cases will be dropped down if manufacturers submit evidence with respect to their claim. Para 3(a) is quoted as under:

> *"The company produces evidence (license issued by State Drugs controller (SDC)/Drugs controller General *India) (DCGI) and invoice and samples prior to 15th, May, 2013, Certified by Chartered Account (CA)/ Cost Accountant (CMA) in support of the claim that the formulation was launched before the DPCO 2013 came into effect;"*

In connection with the same, company has submitted all relevant documents to the office of NPPA on 04/01/2018 as per Para 3(a) of NPPA Office Memorandum stated herein above. Company also submitted copy of said letter duly acknowledged by NPPA office along with the review application. Copy of same was also submitted during the personal hearing for ready reference. Company stated that NPPA is yet to act on their submission dated 04/01/2018 and their name still erroneously finds mention as explained below.

4.2 NPPA issued order vide no. S.O. 3947(E) dated 20/12/2017 and corrigendum to S.O. 3947(E) on 29/12/2017 vide S.O. 4041(E) dated 22/12/2017 wherein NPPA had fixed prices for 15 formulations. Out of said 15 formulations, for the formulations mentioned in S.Nos.14 & 15 Glimepride 1mg + Metformin HCL SR 500mg + Pioglitazone 15 mg and Glimepride 2mg + Metformin HCL SR 500mg + Pioglitazone 15 mg respectively, wherein NPPA had fixed price of Rs.2.14+GST & Rs.2.35+GST respectively.

In connection with the same, company has drawn attention to Note (a) of S.O. 3947(E) dated 20/12/2017 wherein it was stated that *" The manufacturer of above mentioned formulations i.e. "**new drug**" **under paragraph 2(u) of the DPCO, 2013** shall fix the retail price as specified in column (6) of the table hereinabove.".* With respect to this point we would like to submit that as per Para 2(u) of DPCO-2013 definition of new drug is " ***"new drug" for the purposes of this Order*** *shall mean a formulation launched by an **existing manufacturer** of a drug of specified dosages and strengths as listed in the National List of Essential Medicines by combining the drug with another drug either listed or not listed in the National List of Essential Medicines or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in the National List of Essential Medicines.".* The above mentioned formulations stated in serial no. 14 & 15 of NPPA notification DO NOT fall under the definition of new drug as stated in Para 2(u) of DPCO-2013, as company's said formulations were launched before DPCO 2013 came into the existence i.e. before 15/05/2013, and that company had already submitted relevant supporting documents before NPPA vide its submission dated 04/01/2018, hence price fixed by NPPA is not in accordance with the provisions of para 5 and 15(2) of DPCO-2013.

4.3 That company was not required to file application under FORM-I to NPPA for price approval as above formulations were launched on 11/08/2012 which is much prior the implementation of DPCO-2013. Further there after company has not made any changes in formulation w.r.t. to dosage or strength or both, hence the provision of Para 2(u) of DPCO-2013 is not application to above stated formulation. Thus no case of WPA could potentially be brought against the company.

4.4 NPPA had issued S.O. 3947(E) dated 20/12/2017 and corrigendum to S.O. 3947(E) on 29/12/2017 vide S.O. 4041(E) dated 22/12/2017 regarding fixation of prices even without uploading draft/proposed worksheet for price fixation which is the standard operating procedure adopted by NPPA in every other case. Thus, NPPA denied the right to express observation/objection to NPPA along with supporting documents with a stipulated time period. In a clear departure from set procedure established by DoP and adhered to by NPPA in all previous cases, in this instant case, **NPPA neither uploaded worksheet on their web site nor did they give an opportunity to manufacturer to submit their representation sheet w.r.t to price fixation for these formulation.**

4.5 Company further stated that vide earlier notifications, S.O. 425(E) and S.O. 426(E) dated 17/02/2014 and S.O. 1793(E) dated 10/07/2014 NPPA fixed prices of above stated formulation at Rs. 5.36 + VAT per tablet and Rs 6.94 + VAT per tablet and Rs.53.56 + VAT for 10 Tablets and Rs. 6.94 + VAT per tablet respectively, which is much higher than company's existing price i.e. Rs. 2.50 + GST and Rs. 2.73 + GST for above stated formulation.

4.6 Company further stated that NPPA vide SO 3947(E) dated 20/12/2017 had fixed price for formulations mentioned in sr. no. 1 & 2 i.e. Glimepiride 1mg & Metformin 500mg. and Glimepiride 2mg & Metformin 500mg to Rs. 3.84/- and 4.32 respectively and had fixed price for formulations mentioned in sr. no. 14 & 15 i.e Metformin 500mg, Glimepiride 1mg & Pioglitazone 15mg. and Metformin 500mg, Glimepiride 2mg & Pioglitazone 15mg. to Rs. 2.14/- and 2.35 respectively in the same notification. Company submitted that if formulation mentioned in sr. no. 1 is compared with formulation mentioned in sr. no. 14 and formulation mentioned in sr. 2 with formulation mentioned in sr. no. 15, out of 3 ingredients in formulation mentioned in sr. no. 14 & 15,

2 ingredients are common with same strength and by adding one more ingredient i.e. Pioglitazone 15mg it is incomprehensible as to how the price can be fixed by nearly 50% less in case of a triple drug FDC when compared with a two drug FDC.

Company submitted snapshot of the price movement of their said 2 formulations namely Formulation: Glimepiride 1mg + Metformin Hcl SR …500 mg + Pioglitazone 15 mg to prove its bonafide.

SN	Name of Products	Price Per tablet	Excl. of VAT	Increased rate	With effect from
1	Glimison-MP1	2.00	1.90	-	11.08.2012
2	Glimison-MP1	2.20	2.10	9.52%	12.08.2013
3	Glimison-MP1	2.33	2.23	5.83%	14.08.2014
4	Glimison-MP1	2.56	2.44	9.01%	30.08.2015
5A	Glimison-MP1	2.80	2.67	8.61%	17.09.2016
5B	Glimison-MP1	2.80	2.50 Without GST	-	No rise since 17/09/2016 i.e. 17 months

Formulation: Glimepiride 2mg + Metformin Hcl SR …500 mg + Pioglitazone ..15 mg

SN	Name of Products	Price Per tablet	Excl. of VAT	Increased rate	With effect from
1	Glimison-MP2	2.20	2.10	-	11.08.2012
2	Glimison-MP2	2.42	2.30	9.09%	12.08.2013
3	Glimison-MP2	2.57	2.45	6.12%	18.08.2014
4	Glimison-MP2	2.80	2.67	8.98%	19.08.2015
5A	Glimison-MP2	3.06	2.91	8.25%	27.08.2016
5B	Glimison-MP2	3.06	2.73 Without GST	-	No rise since 27/08/2016 i.e. 18 months

It is most significant to note here that during the preceding 6 years when the above formulations were non-scheduled for the company, despite being eligible for a 10% increase every 12 months as per Para 20 of DPCO- 2013, the Company remained well below the allowable increase only in the interest of the patients.

4.7 **Prayer:** Having explained that Para 2(u) of DPCO-2013 did not even apply to the formulations of the company and in conjunction with the other facts stated as above, company reiterated that above formulations as mentioned in mentioned in sr. no. 14 & 15 of S.O. 3947(E) dated 20/12/2017 and corrigendum vide S.O. 4041(E) dated 22/12/2017 were launched on 11/08/2012 which is much prior the implementation of DPCO-2013. Company did not make any changes in formulation w.r.t. to dosage or strength or both, hence the provision of Para 2(u) of DPCO-2013 is not applicable to its above stated formulations. Company prayed that its name (Company/brand) may be omitted from the aforesaid serial nos.

Company further stated that if required additional documents will be furnished in support to their review application.

5. Examination:

5.1 In the review application, the company stated that retail prices notified vide SO 3947(E), dated 20.12.2017 and corrigendum SO 4041(E), dated 22.12.2017 in respect of formulations of their company do not fall under the definition of new drug as stated in Para 2(u) of DPCO-2013. The company stated that their said formulations were launched before DPCO 2013 came into the existence i.e. before 15/05/2013. According to company, the said formulations were launched by them on 11.08.2012, which is prior to introducing DPCO, 2013, so the company did not apply for price approval for said formulations.

5.2 NPPA issued certain guidelines for examination of cases of launch of "New Drugs" by Pharma companies without obtaining prior price approval as required under the DPCO, 2013, vide OM F.No.17(1)/2016/Div.III/NPPA, dated 24.11.2017. In the said guidelines, NPPA stated that WPA cases will be dropped in those cases where the Company produces evidence (licence issued by State Drugs Controller (SDC) / Drugs Controller General (India) [DGCI(I)] and invoices and samples of the formulations manufactured prior to 15th 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; and if AIOCD-Pharmatrac data confirm that the formulation was launched prior to 15th May, 2013.

5.3 The company submitted a representation to NPPA on 3.1.2018 and submitted all necessary documents required under OM, dated 24.11.2017 in support of its claim that the formulations were launched on 11.08.2012, prior to introduction of DPCO, 2013. The company also submitted copies of relevant documents, required as per NPPA's OM, dated 24.11.2017. However, NPPA, in its reply did not mention anything about the action taken by NPPA on the representation of the company and whether the products of the company fall under the purview of WPA cases or not. NPPA simply stated that since M/s Unison Pharmaceutical Private Limited did not apply for approval, the retail price for M/s Unison Pharmaceutical Private Limited was fixed suo moto.

5.4 In view of the position explained above, the suo moto fixation of retail price for the subject formulations for M/s Unison Pharmaceutical Private Limited, without considering the representation of the company is not in order. Therefore, NPPA needs to be directed to examine the documents submitted by M/s Unison Pharmaceuticals Pvt. Ltd. regarding the date of launch of the drugs Glimepride 1mg + Metformin Hcl SR 500mg + Pioglitazone 15mg. and Glimepride 2mg + Metformin Hcl SR 500mg + Pioglitazone 15mg. On verification, if it is proved that the claim of the company of launching its products prior to introduction of DPCO, 2013, is in order, then the name of the company be deleted/dropped from the Corrigendum SO 4041(E), dated 22.12.2017.

8. Government Decision:

"NPPA is hereby directed to examine the documents submitted by M/s Unison Pharmaceuticals Pvt. Ltd. regarding the date of launch of the drugs Glimepride 1mg + Metformin Hcl SR 500mg + Pioglitazone 15mg. and Glimepride 2mg + Metformin Hcl SR 500mg + Pioglitazone 15mg. On verification, if it is proved that the claim of the company of launching its products prior to introduction of DPCO, 2013, is in order, then the retail price of these two products fixed by SO No.3947(E), dated 20.12.2017 and the Corrigendum SO 4041(E), dated 22.12.2017 is quashed."

Issued on this date, the 29th day of May, 2018.

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

Copy to :-

1. M/s Unison Pharmaceuticals Private Limited, Unison House Near Prenatirth Derasar, Near Ratnadeep-11, Satellite, Jodhpur, Ahmedabad-380 015.
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