No. 31015/40/2018-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS
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A-Wing, Shastri Bhawan,
New Delhi -110 001

Order

1. This is an order disposing of two separate review applications, dated 03.08.2018, filed by M/s Biocon Limited (hereinafter called the applicant) under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against notification S.O. No. 3727(E), dated 23.11.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the retail price of Blistro Trio 1 (containing Metformin Hcl (SR/ER/PR) 500+Voglibose 0.2mg+Glimepride 1mg tablet) and Blistro Trio 2 (containing Metformin Hcl (SR/ER/PR) 500+Voglibose 0.2mg+Glimepride 2mg tablet).

2. The applicant also forwarded the Order, dated 10.8.2018 of Hon'ble High Court of Delhi in the Writ Petition WP(C)8317/2018 & CM No.31923/2018 and Order, dated 08.08.2018 in the WP(C)8314/2018 filed by the applicant praying for quashing price fixation Order SO 3727(E), dated 23.11.2017 and SO 3946(E), dated 20.12.2017 fixing the prices for Metformin Hcl(SR/ER/PR) 500+Voglibose 0.2mg+Glimepride 1 mg tablet and Metformin Hcl(SR/ER/PR) 500+Voglibose 0.2mg+Glimepride 2 mg tablet respectively and also quashing the demand notices F.No.30(33)2017Div.IV(OC-II)/NPPA, dated 8.6.2018 and 25.07.2018 and F.No.30(34)2017/Div.IV(OC-II)/NPPA, dated 25.5.2018 and 25.07.2018. The Hon'ble High Court observed that since the respondents are considering the petitioner's review petition, the impugned demands must be temporarily suspended, as enforcement of the same would effectively frustrate the petitioner's review petitions. The Court, vide its abovementioned orders dated 10.08.2018 and 08.08.2018, has further directed the department to dispose of the petitioner's review petitions as expeditiously as possible and forbade any coercive action against the petitioner pursuant to the impugned demand notices till the disposal of the petitioner's review applications.

3. The applicant filed both the review applications on the following grounds:-

(a) The applicant's formulation Blistro Trio 1 (containing Metformin Hcl(SR/ER/PR) 500+Voglibose 0.2mg+Glimepride 1mg tablet) and Blistro Trio 2 (containing Metformin Hcl(SR/ER/PR) 500+Voglibose 0.2mg+Glimepride 2mg tablet) are being manufactured by M/s Hetero Labs Ltd. M/s Biocon Ltd. is only marketing the said products. M/s Hetero Labs Ltd., prior to the launch of the said products, has already taken the retail price approval from NPPA. NPPA's stand of inclusion of M/s Biocon Ltd., fixing the retail prices of the said products, on the ground that the applicant company launched a new drug without obtaining a prior price approval is incorrect and erroneous.

(b) None of the ingredients of the said formulation namely Metformin Hcl(SR/ER/PR) 500+Voglibose 0.2mg+Glimepride 1mg and Metformin Hcl(SR/ER/PR) 500+Voglibose

0.2mg+Glimepride 2mg tablet on the date of launch of the formulations, were part of the NLEM 2011. Metformin Hcl(SR/ER/PR) 500 is different from Metformin Hcl 500. Thus, the said formulations could not be stated to be new drug in terms of DPCO.

(c) NPPA did not follow the procedure as laid down in paragraph 9(4) of DPCO. In terms of the said paragraph, the market data for fixing the retail price of the new drug for the month ending immediately before six months of receipt of application for fixing the prices of new drug is to be taken into consideration. Thus, the data for the month of November, 2016 should have been taken into consideration by NPPA, as the application was filed by the applicant in May, 2017.

(d) Since the applicant was not the existing manufacturer of the formulation and is only marketing the product being manufactured by M/s Hetero Labs, at a price less than what was notified for M/s Hetero Labs, the overcharged amount including interest and penalty levied by NPPA will not be applicable to them.

4. Comments of NPPA:

4.1 M/s Biocon Ltd. did not take price approval before launching of Blistro Trio 1 tablet containing Metformin Hcl(SR/ER/PR) 500+Voglibose 0.2mg+Glimepride 1mg. and Blistro Trio 2 tablet containing Metformin Hcl(SR/ER/PR) 500+Voglibose 0.2mg+Glimepride 2mg. The contention of the applicant that M/s Hetero Lab Limited, the manufacturer of the said formulations, has taken price approval for their formulation Glyree MV1 and Glyree MV2 is not tenable. The said approval is applicable for M/s Hetero Lab Limited / M/s Ipca Lab Limited only for their product Glyree MV1 and Glyree MV2.

4.2 In regard to the contention of the applicant that under NLEM 2011 only Metformin tablet 500 mg is mentioned but their products contains Metformin Hcl 500mg (SR/ER/PR) and hence their products do not fall under the definition of new drug, NPPA stated that since under NLEM 2011, Metformin 500mg was included without differentiating its other variants, therefore, all variants, i.e. CR/SR/ER are considered as included. Hence, the contention of the applicant that Metformin 500mg tablet CR/SR/ER is not included in NLEM is not tenable.

4.3 Since M/s Biocon Ltd. launched the product without taking prior price approval, NPPA issued show cause and demand notices as a follow up action.

5. Examination:

5.1 NPPA fixed the retail price of Metformin Hcl 500mg (in sustained release form)+Glimepride 1mg+Voglibose 0.2mg (brand name Glyree MV1) at Rs 8.46/tablet and Metformin Hcl (SR/ER/PR) 500+Voglibose 0.2mg+Glimepride 2mg (brand name Glyree MV2) at Rs 10.47/tablet for M/s Hetero Labs Limited and M/s IPCA Laboratories Ltd. vide SO 936(E) and SO 938(E), both dated 27th March, 2014, respectively. The retail price approval for new drug is given on the basis of Form I submitted by the manufacturer/marketer and is applicant specific. No other company can manufacture or market the said product with its own brand name. The contention of the applicant that since M/s Hetero Lab Limited, the manufacturer of the said formulation, has taken price approval for the subject formulations, and the applicant is only marketing the said

products and therefore was not required to take prior approval for retail price of its formulations, has got no merit.

5.2 The contention of the applicant is that under NLEM 2011 only Metformin tablet 500 mg is mentioned but their products contain Metformin Hcl 500mg(SR/ER/PR) and hence it do not fall under the definition of new drug. Under NLEM 2011, Metformin 500mg was included without differentiating its other variants, therefore, all variants, i.e. CR/SR/ER are considered as included. Hence the subject formulations qualify as new drug. In view of this, the second issue raised by the applicant in its review applications also has got no merit.

5.3 The contention of the applicant that NPPA should have considered the data of November, 2016 by following the procedure as laid down in paragraph 9(4) of DPCO has got no merit, as the applicant started marketing the products Metformin Hcl 500mg (in sustained release form)+Glimepride 1mg+Voglibose 0.2mg with its brand name Blisto Trio 1 and Metformin Hcl 500mg (in sustained release form)+Glimepride 2mg+Voglibose 0.2mg with brand name Blisto Trio 2 since November, 2014 without taking prior price approval. The Schedule-I of DPCO was revised in March, 2016 (NLEM 2015) and Metformin Hcl 500mg was in the list of scheduled formulations. In the cases of new drugs which were being manufactured/marketed without price approval, the retail prices were fixed taking the data of August, 2015 (six months prior to March, 2016, when the Schedule-I was revised). In view of this, NPPA has rightly fixed the retail price of said formulations by considering August 2015 data.

5.4 Since M/s Biocon Ltd. launched the products manufactured by an existing manufacturer without taking prior price approval, NPPA was justified in issuing show cause notices and demand notices as a follow up action.

5.5 In view of the above, all the issues raised by the company in its review applications are devoid of merit. Hence, the review applications deserve to be rejected.

6. Order:

The issues raised by the applicant in its review applications are devoid of merit. Hence, the review applications stand rejected.

Issued on this date, the 22nd day of February, 2019.

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

Copy to :-

1. M/s Biocon Limited, 20th KM Hasur Road, Electronics City, Bangalore-560 100.
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. Joint Secretary(Pharma), Shastri Bhawan, New Delhi for information.
7. T.D., NIC for uploading the order on Department's Website