No. 31015/4/2018-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 ceiling prices of Metoprolol 25 mg & Chlorthalidone 12.5 mg (STARPRESS-D-XL-25); Metoprolol 25 mg & Chlorthalidone 12.5 mg (STARCAD-CT 25); Metoprolol 50 mg & Chlorthalidone 12.5 mg (STARPRESS-D-XL-50); Metoprolol 50 mg & Chlorthalidone 12.5 mg (STARCAD-CT 50) and Moxifloxacin 400 mg & Cefixime 400 mg (Lupin'S MOXINOW).

2. The applicant has contended as under:-

1. The details of prices notified along with its composition and brand names of the company are as under:-

SR. NO.	COMPOSITION AS PER ORDER UNDER REFERENCE	COMPANY'S PRODUCT COMPOSITION	BRAND NAME
1.	Tablet contains: Metoprolol 25 mg Chlorthalidone 12.5 mg.	Each uncoated tablet contains: Metoprolol succinate 23.75 mg Equivalent to Metoprolol Tartrate 25 mg (in extended release form) Chlorthalidone 12.50 mg	STARPRESS-D-XL 25
2.	Tablet contains: Metoprolol 25 mg Chlorthalidone 12.5 mg.	Each uncoated tablet contains: S (-) Metoprolol succinate25 mg (in extended release form) Chlorthalidone 12.50 mg	STARCAD-CT 25
3.	Tablet contains: Metoprolol 50 mg Chlorthalidone 12.5 mg.	Each uncoated tablet contains: Metoprolol succinate 47.50 mg Equivalent to Metoprolol Tartrate 50 mg (in extended release form) Chlorthalidone 12.50 mg	STARPRESS-D-XL 50
4.	Tablet contains: Metoprolol 50 mg Chlorthalidone 12.5 mg.	Each uncoated tablet contains: S (-) Metoprolol succinate 50 mg (in extended release form) Chlorthalidone 12.50 mg	STARCAD-CT 50
5.	Tablet contains: Moxifloxacin 400 mg Cefixime 400 mg	Each film coated Sustained Release tablet contains; Moxifloxacin HCL equivalent to Moxifloxacin 400 mg Cefixime (as Trihydrate) equivalent to Anhydrous Cefixime 400 mg	Lupin's MOXINOW

2. All the formulations listed above are based on INNOVATIVE DOSAGE technology.

3. DPCO 2013 was introduced on 15th May 2013 and NLEM 2011 was adopted as Schedule I. *The said schedule mentions dosages as tablet/Capsule/Syrup and in some cases SR Tab/Caps against the active drug listed*. Since it does not specify SR/CR or other innovative dosage form against the drugs specified above, it is clear that innovative dosage forms are not included in Schedule I. Further as regards Cefixime, strength of 400 mg is not listed in NLEM 2011.

This view was also corroborated by DOP vide its letter dated 20th September, 2013 which opined that Innovative dosage should not be kept under price control. The 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.

4. The said Schedule I was amended in March 2016 by adopting NLEM 2015. *Innovative dosage was specified for the 1st time for Metoprolol*. Cefixime in 400mg strength was added in the amended Schedule I. In fact the new Schedule I has reiterated the DOP's views of not keeping the innovative dosages under price control by including Explanatory note 2.

It can be observed from the order that Metoprolol + Chlorthalidone has been repeated twice. This is probably due to the fact that company has one combination with Metoprolol & other with S (-) Metoprolol. The Company failed to understand the logic of the pricing authority, when the authority themselves have mentioned that S (-) Metoprolol does not come under Schedule category. Further all the company's FDC's having Metoprolol have been launched much before March 2016.

5. As regards the FDC of Moxifloxacin 400 mg + Cefixime 400mg, the company mentioned that plain Cefixime in 400 mg strength was 1st listed as part of DPCO 2013 on 10th March 2016, whereas company's FDC was launched much before March 2016 and that too as Sustained Release FDC. Thus, NPPA has erred in notifying the price, as the concept of new drug is not applicable to company's formulation.

6. Looking at the facts referred to above, its very much evident that the company's products does not fall under the definition of NEW DRUG as company's formulations are based on innovative dosages which are not in Schedule category. Thus NPPA has erred in notifying the prices exclusively for our company ERRONEOUSLY. The Company has implemented the price as notified. However, being aggrieved, the company requested this Department to quash the price notification fixed exclusively for company as it is not in concurrence with the provisions of DPCO 2013.

Comments of NPPA:

1. Retail prices of formulations are fixed by NPPA Vide SO No 3947 (E) dated 20 Dec 2017 as detailed below:-

S. No.	COMPOSITION AS PER SO	COMPANY,S PROUDCT COMPOSITION	BRAND NAME	NOTIFIED PRICE	
				Pre GST	Post GST
1	Tablet contains: metoprolol 25mg clorthalidone 12.5 mg	Each uncoated tablet contains: Metoprolol succinate 23.75 mg Equivalent to metoprolol tartrate 25 mg (in extended release form) clorthalidone 12.5 mg	STARPRESS-D XL 25	5.81	5.57
2	Tablet contains: metoprolol 25mg clorthalidone 12.5 mg	Each uncoated tablet contains: S (–) Metoprolol succinate 25mg (in extended release form) clorthalidone 12.5 mg	STARCAD – CT 25	5.81	5.57
3	Tablet contains: metoprolol 50mg clorthalidone 12.5 mg	Each uncoated tablet contains: Metoprolol succinate 47.50 mg Equivalent to metoprolol tartrate 50 mg (in extended release form) clorthalidone 12.5 mg	STARPRESS-D XL 50	7.22	6.92
4	Tablet contains: metoprolol 50mg clorthalidone 12.5 mg	Each uncoated tablet contains: S (–) Metoprolol succinate 50mg (in extended release form) clorthalidone 12.5 mg	STARCAD – CT 50	7.22	6.92
5	Tablet contains: Moxafloxacin 400 Cefixime 400 mg	Each film uncoated SR tablet contains: Moxafloxacin HCL equivalent to Moxafloxacin 400 Cefixime (as trihydrate) equivalent to anhydrous Cefixime 400 mg	Lupin,s MOXINOW	34.46	33.05

2. The grievances of the company and NPPA's reply is detailed below-

Company's Grievances	NPPA's comments
All the formulations against which review was filed are Innovative technology. NLEM 2011 was taken as scheduled I of DPCO, 2013. The said schedule mentions dosage as Tablets/ Capsules/Syrup and in some cases SR Tab/Caps against the active drug listed. Since it does not specify SR/CR or other innovative dosage form against the drug specified above, it is clear that innovative dosage forms are not included in Schedule I. This view was also corroborated by DoP vide its letter dated 20.09.2013 have opined that innovative dosage should not be kept under price control.	Since, under NLEM, 2011, Metoprolol 25mg and Metoprolo 50mg tablets were included without differentiating, therefore, all variants i.e. CR/SR/ extended release are considered as included. Hence, the contents of the company that Metoprolol 25mg and Metoprolo 50mg CR tablets are not included under NLEM, 2011 is not tenable.
Company also stated that the said scheduled I was amended in March 2016 by adopting NLEM 2015. In fact, the new schedule I has reiterated the DoP's views	With reference to explanatory note 2 of Amended schedule I, (NLEM 2015), the Authority in its 27th meeting decided that whenever any specific variant like

of not keeping the innovative dosages under price control by including explanatory note 2. An innovative dosage was specified for the first time for Metoprolol. Cefixime in 400mg strength was added in amended scheduled I.	SR/CR/TR etc is mentioned against any formulation the pricing will be done separately else the pricing of the formulation will be done by including all the variants of the formulation . Metoprolol 25mg & 50mg tablet , cefixime 100mg & 200mg tablets were included in NLEM 2011, therefore as per the definitions of new drug under DPCO, 2013, any formulations containing Metoprolol and cefixime in any other strength/combination will be considered as new drug.
In the notification the FDCs containing metoprolol + chlorthalidone has been repeated twice. This is probably due to the fact that this has one combination with metoprolo and other with S (-) metoprolol all our FDC,s having Metoprolol. The company fails to understand the logic of the pricing Authority, when the Authority themselves has mentioned that S(-) metoprolol does not come under schedule category as in SO 3770 (E) dated 20.12.2013, further all their FDCs having metoprolol has been launched much before March, 2016.	The formulation metoprolol was included in NLEM 2011 as well as in NLEM 2015 and the company has been manufacturing/marketing metoprolol tablet as per NLEM 2011 and 2015. Hence Company is an existing manufacturer/ marketer and hence the company,s claim that their product Moxinow Tablet does not comes under the Category of new drug under DPCO 2013 is not tenable. Therefore, NPPA fixed the retail prices of concerned formulations based on the information
Company reiterated that as regard the FDC of Moxifloxacin 400mg + Cefixime 400mg, plain cefixime in 400 mg strength was First listed as part of DPCO 2013 on 10.03.2016. Whereas company's FDC was launched much before March 2016 and that too as Sustained Release FDC. Thus, NPPA has erred in notifying the prices. We have implemented the price as notified, however being aggrieved, we request your office to quash the price notification fixed as it is not in concurrence with the provision of DPCO 2013.	The formulation cefixime was included in NLEM 2011 as well as in NLEM 2015 and the company has been manufacturing/marketing cefixime 200MG tablet as per NLEM 2011 and 2015. Hence Company is an existing manufacturer/ marketer and hence the company,s claim that their product Moxinow Tablet does not comes under the Category of new drug under DPCO 2013 is not tenable. Therefore, NPPA fixed the retail prices of concerned formulations based on the information available and in accordance with the provisions of DPCO,2013.

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 durg 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.

4.6 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 Metoprolol 25 mg & Chlorthalidone 12.5 mg (Brand: STARPRESS-D-XL

25); Metoprolol 25 mg & Chlorthalidone 12.5 mg (STARCAD-CT 25); Metoprolol 50 mg & Chlorthalidone 12.5 mg (STARPRESS-D-XL-50); Metoprolol 50 mg & Chlorthalidone 12.5 mg (STARCAD-CT 50) and Moxifloxacin 400 mg & Cefixime 400 mg (MOXINOW) 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 its Review Application, is devoid of any genuine basis for questioning the approach followed by NPPA while fixing the prices of Metoprolol 25 mg & Chlorthalidone 12.5 mg (Brand: STARPRESS-D-XL 25); Metoprolol 25 mg & Chlorthalidone 12.5 mg (STARCAD-CT 25); Metoprolol 50 mg & Chlorthalidone 12.5 mg (STARPRESS-D-XL-50); Metoprolol 50 mg & Chlorthalidone 12.5 mg (STARCAD-CT 50) and Moxifloxacin 400 mg & Cefixime 400 mg (MOXINOW) by treating them new drug under para 2(u) of DPCO, 2013. Therefore, the review application stands rejected."

Issued on this date, the 4th 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