No.31015/15/2016-PI.I
Government of India
Ministry of Chemicals & Fertilizers
(Deptt. of Pharmaceuticals)
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B Wing, Janpath Bhavan,
New Delhi - 110 001

Subject: **The review application of M/s Abbott India Ltd. dated 19th April, 2016 for price fixation of "B-Crip (Bromocriptine Mesylate IP) Tablets (1.25 mg & 2.5 mg)"and review application of M/s Abbott Healthcare Pvt. Ltd. dated 19th April, 2016 for their 52 formulations under para 31 of DPCO against OM No.19(119)/2014/Div.II/NPPA, dated 6.4.2016 – reg.**

M/s Abbott India Ltd. has filed a review petition dated 19th April, 2016 for their formulation "B-Crip (Bromocriptine Mesylate IP) Tablets (1.25 mg & 2.5 mg)" and review petition dated 19th April, 2016 by M/s Abbott Healthcare Pvt. Ltd. for their 52 formulations against NPPA OM No.19(119)/2014/Div.II/NPPA, dated 6.4.2016.

2. A personal hearing was given to both the companies on 6.6.2016 and the same was attended by Shri Arun Roy, General Manager-Finance; Shri Sukrut Mehta, Partner, KMCO and Shri Kirit Mehta, Partner, KMCO on behalf of M/s Abbott India Ltd. and Abbott Healthcare Pvt. Ltd., Shri S.S. Gaur, Y.P. (Tech.) on behalf of NPPA and Shri V.K. Tyagi, Consultant (Technical), D/o Pharmaceuticals.

3. The written comments of the company and the comments of the NPPA in the matter are summarised below:-

(i) It is submitted by the company that S.O No. 644 (E) dated 02/03/2016 includes the above said medicines after giving effect of reduction in Wholesale Price Index (WPI) for the calendar year January to December, 2015.

(ii) S.O No. 701 (E) dated 10/03/2016 substituting schedule 1 appearing in DPCO, 2013 by a new Schedule I adding few more formulations to and deleting few existing Scheduled product from Schedule I issued with DPCO, 2013. As per provisions for DPCO, 2013 dated 15th May, 2013, S.O 701 (E) dated 10/03/2016 comes into force immediately on notification of the same. Thus on 10th March, 2016, the aforesaid Scheduled formulation, which are removed from Schedule I do not form part of Schedule I to DPCO, 2013. The formulations included and appearing in first schedule notified on 10th March, 2016 is complete and no formulation other than those included in schedule I as notified vide S.O 701 (E) dated 10/03/2016 can be called and classified as scheduled formulations.

(iii) With effect from 10/03/2016, their formulations are discontinued to be as scheduled formulation. Under the circumstances:

a. It needs to be appreciated by virtue of S.O 701 (E) dated 10/03/2016, their formulations have turned out to be non-scheduled formulations.

b. With effect from 10/03/2016, the provisions, notifications, office memorandum issued in respect of scheduled formulations cannot be applied to these products.
c. It also needs to be appreciated that though Para 16 (1) of DPCO 2013 allows government to revise ceiling price of scheduled formulations based on WPI of preceding calendar year, on or before 1st April of every year, **the notification has to be issued on 1st April of every year**, not on any other day.
d. Their formulations have lost the characteristic or qualification of being scheduled formulation on 10/03/2016. In case of non- scheduled formulation, as per paragraph 20 of DPCO, 2013, a manufacturer can increase the price by not more than 10% of the price prevailing during preceding twelve months.

Under the circumstances, the petitioner company requested this Department as under:

(i) To consider and conclude that Office Memorandum F. No. 19(119)/Div. II/NPPA dated 06/04/2016 is ultra vires and contravention of provisions of Drugs (Prices Control) Order.

(ii) Pass a speaking order in respect of -

(a) The price reduction based on the reduction of WPI, which is effective from 1st April, 2016 does not apply to the captioned formulation.

(b) That the direction to freeze price for 12 months is beyond the provisions of DPCO, 2013 and therefore cannot be imposed by OM No. 19(119)/2014/Div. II/NPPA dated 06/04/2016 of NPPA.

4. **Comments of NPPA:**

NPPA issued a Office Memorandum on 19.02.2016, wherein, inter-alia, it was stated that as confirmed by the Economic Adviser (Ministry of Commerce & Industry), the annual change in the wholesale price index (WPI) works out as (-) 2.7105%) during the calendar year 2015 over the corresponding period in 2014. Further, by said OM, it was also brought to the notice of all concerned in terms of provisions of DPCO, 2013 to take further action as necessary. **WPI is a major measure of price of a representative basket of wholesale goods and inflation**. Due to decline in WPI, benefit of price must be passed on to the consumers for Scheduled formulations irrespective of their distinction as existing or first time. A consumer buying such scheduled formulations cannot be deprived of benefit of decline in WPI on such flimsy distinction. It is pertinent to state here that the manufacturers are automatically authorized to revise their MRPs up to the limit of increase / decrease based on WPI for the previous year. In case of decline in WPI, a corresponding reduction in MRP is mandatory. Therefore, para a & b of OM No. 19(119)/2014/Div.II/NPPA dated 6.4.2016 is as per the provisions of DPCO, 2013.

In previous years, there was increase in WPI and NPPA allowed the manufacturers and marketing company of scheduled formulations to avail the benefits of WPI.

NPPA / Government is mandated to ensure the availability of the medicines of mass consumption at reasonable and affordable prices.

Review application is devoid of any merit and deserves to be rejected out rightly.

5. During the personal hearing, the company representatives submitted that the annual WPI shall be applicable only to scheduled formulations as on 1.4.2016. However, considering NPPP, 2012, para 4(xii) notification, "…***In the proposed policy, all essential drugs are under price control. It would follow that non-essential drugs should not be under the controlled regime and their prices should be fixed by market forces."*** and also considering the recommendations of the Core Committee, the criteria for deletion of medicine from NLEM,2015 is as follows:

"A source Document containing list of medicines with its dosage forms, strength and information regarding their presence in NLEM 2011, NFI 2011, WHO EML 2013 (later updated to include WHO EML 2015); as well specific information on efficacy and safety was prepared."

- ***"…..A medicine with better efficacy or favourable safety profiles and better cost effectiveness is now available"***
- ***The disease burden for which a medicine is indicated is no longer a national health concern in India."***

Thus, formulations under consideration are not essential and non-scheduled in nature and are not deemed to be of public interest and a public health concern.

Hence, the MRP of products shifted to Non-scheduled category by notification issued by DoP on 10th March 2016, are permitted to be increased in April 2016 up to 10% of the MRP prevailing in April 2015 as provided in paragraph 20

Further, provisions of 13(3) and 16(4) of DPCO, 2013 mandating a corresponding reduction in MRP do not apply to the formulations under consideration, as the formulations under consideration are non-scheduled as on 1.4.2016 and hence WPI reduction cannot be mandated under para 16(1) ***"The Government shall notify the same on the 1st day of April every year."*** Hence, the company representatives humbly submitted that the ceiling prices may be revised prior to 1st of April. However, they must notify the same only on 1st of April.

Para 10(4) and NPPP para 4(xiv) are specific provisions for change from DPCO, 1995 to DPCO,2013. The same cannot be made applicable to a change in NLEM in the first schedule, which is governed by two specific provisions, namely, para 17 and 18. Further, OM 19(119)/2014/Div.II/NPPA, dated 6.4.2016 does not mention any provision of DPCO 2013 in support of the decision taken on the meeting held on 27th March, 2016. NPPA does not have the power under the DPCO 2013 to issue OM dated April 6, 2016, thereby mandating freezing of prices and WPI reduction shifted to non-scheduled category.

There is no provision enabling DPCO 2013 freezing prices of non-scheduled formulations for any period of time. Further, the last ceiling prices notified for the said formulations was vide SO 619(E), dated 25.2.2015, specifically notified and made effective on 1.4.2015.

The said action of the NPPA is in complete transgression of Para 17(2) of DPCO 2013. By freezing and WPI reduction of prices via OM dated April 06, 2016 in an indiscriminate manner, NPPA has exceeded its jurisdiction and powers under DPCO 2013 as there are no corresponding provision that empowers the DPCO 2013 to act in such a manner.

The decision taken by the NPPA in its authority meeting is overreaching the scope of DPCO 2013. The source of power for such directions of NPPA could only be from DPCO 2013 and not on basis of decision taken in Authority Meeting. Needless to say that NPPA does not have the power to make laws, it can only implement DPCO as it exists. Thus, the provision of Para 17(2) of DPCO 2013 cannot be ignored or avoided.

Paragraph 17(2) states that medicines omitted from first schedule shall fall under the category of non-scheduled formulations. As the Department of Pharmaceuticals (DoP) has amended the Schedule I on 10th March 2016, all medicines omitted from Schedule I have become 'non-scheduled formulations' with immediate effect, as there is no mention of effective date in the notification.

As it is clear that OM dated 6th April, 2016 is without any legal sanctity and we request DoP to direct NPPA to withdraw the said OM with immediate effect.

The representative of NPPA denied the statements submitted by the company representatives that the last ceiling prices were notified vide SO 619(E), dated 25.2.2015. In this regard, it is stated that SO 619(E) was superceded by SO 644(E) because as on 2.3.2016, and these formulations were within the ambit of scheduled formulations.

The NPPA representative categorically submitted that the contentions raised by the companies are wrong and denied. At the outset, it is pointed out that it is obligatory for the companies to follow the prices against which review is applied. No documentary evidence in form V has been submitted. This review is against the Office Memorandum and not maintainable. It is also pointed out that the formulations referred in OM, dated 6.4.2016 were scheduled formulations as on 2.3.2016. It was obligatory for the company to carry out the revision due to decline in WPI as per notification, dated 19.2.2016 read with para 13(3) proviso and 16(4) which requires corresponding reduction in MRP as per WPI by the manufacturers before the date of notification. Thus, the price of these scheduled formulations is the legitimate price as per DPCO 2013 and it is before 10.3.2016. Many manufacturers have implemented prices notified on 2.3.2016 (IDMA letter copy enclosed) Further, it is pointed out that

para 10(3) of DPCO 2013 and para 3(v) and 4(xiv) also mandates keeping these prices for one year, whenever there is a transition of drugs. These drugs were transited only on 10.3.2016 as admitted by the company representatives for the price applicable before the transition is the MRP as per 2.3.2016 is the price to be maintained as a preceding price of 12 months as per para 20 of DPCO 2013. Company is trying to mislead that they can increase the price or the prices when they were scheduled formulations, which is wrong. They have to maintain the prices, which were applicable last for the 12 months when on the transition to the non-scheduled category. This is also in clear cut anology of para 10(3) of DPCO 2013 and Supreme Court Judgement in Glaxo Smithkaline versus UOI 2014 (Sec-II 753), which held that benefit of price has to be passed on to the consumers and in price fixation is the prime consideration. DPCO 2013 is issued under EC Act, 1955. In EC 1955, all drugs are essential commodities. As held by Supreme Court in Cynamide case, reported in (1987)2 SCC 720, which is reproduced herewith :

> "A price fixation measure does not concern itself with the interests of an individual manufacturer or producer. It is generally in relation to a particular commodity or class of commodities or transactions. It is a direction of a general character, not directed against a particular situation. It is intended to operate in the future. *It is conceived in the interests of the general consumer public. The right of the citizen to obtain essential articles at fair prices and the duty of the State to so provide them are transformed into the power of the State to fix prices and the obligation of the producer to charge no more than the price fixed*.

Therefore, the action of the NPPA is in true letter and spirit of the DPCO 2013.

On this, the representatives of the Companies submitted that they have implemented the prices as mentioned in SO 644(E) dt.2.3.2016 for products available in the market within 45 days time and products manufactured after 1.4.2016 from the date of manufacturing. Form II NO.1013 under IPDMS has been duly submitted to NPPA on 14.4.2016.

The implementation of ceiling price or revised ceiling price as maintained under para 13 and para 16 cannot be made effectve before the notification of ceiling prices. The company representatives reiterated that as per para 16(1), the ceiling prices must be notified and implemented on the 1st of April, 2016.

NPPA's contention that many companies and IDMA's letter stating implementation of ceiling prices before date of notification is in contravention of para 13 and 16 of DPCO.

Para 3 and para 4 of NPPP 2012 and para 10(3) and 10(4) of DPCO 2013 are specific provisions for change over from DPCO 1995 to DPCO 2013 and the same

cannot be applied to a change in NLEM which specifically falls under provisions of para 17 and 18 of DPCO 2013. Thus, no other provisions of DPCO 2013 may apply.

The Glaxo Smithkline case mentioned by NPPA was specific to formulations which are essential to public health and are scheduled in nature. The company representatives stated that they have already humbly submitted that their formulations as on 10.3.2016 are not essential and non-scheduled in nature courtesy para 4(xii) of NPPP 2012 and the criteria for deletion of a scheduled formulation from NLEM 2015, as stated by the recommendations of the Core Committee.

Thus, in conclusion, the company submitted that implementation of ceiling price has been carried out and intimated to NPPA vide Form II No.1013, no section of DPCO 2013 relating to scheduled formulations can be applied to the formulations under consideration from 10th of March, 2016, implementation of ceiling prices under para 16 must be only on 1st April, 2016 and finally NPPA has not shared any legislation in support of OM 19(119) /2014/Div.II/NPPA,, dated 6.4.2016.

The company representatives requested to direct NPPA to consider the said formulations as non-scheduled and withdraw the said OM, dt.6.4.2016.

6. <u>Examination:</u>

So far as instant review application filed by M/s Abbott India Ltd. and Abbott Healthcare Pvt. Ltd. is concerned, it is seen that S.O.No.644(E) fixing ceiling price of 530 formulations was issued on 2.3.2016 and its applicability was to take effect from 1.4.2016. In the meanwhile, schedule I of DPCO 2013 was substituted by NLEM 2015 vide SO No.701(E), dated 10.3.2016. As the formulations of the said petitioner companies were not in NLEM 2015, and revised Schedule I as on 10.3.2016, the WPI w.e.f. 1.4.2016 is not applicable in the instant case.

NPPA has relied upon para 10(4) of the DPCO 2013 in justifying the application of WPI impact in the instant case.

Para 10(4) of DPCO 2013 states as under :

"The prices of scheduled formulations, which are specified in the Drugs (Prices Control) Order, 1995 but not specified in the First Schedule of this order, fixed and notified under the provisions of the said order, after 31st May, 2012, shall remain effective for one year from the date of notification of such prices and thereafter prices of such formulations shall be regulated as in case of other non-scheduled formulations as stated in paragraph 20 of this Order."

From the above, it is seen that para 10(4) stated above is applicable when there is change in DPCO i.e. switch over from DPCO 1995 to DPCO 2013. In the instant case, there is no change in DPCO but only there is Schedule I substitution by

NLEM 2015 in DPCO 2013. The para 10(4) of DPCO 2013 may thus not be applicable in this case.

In view of the above, it is felt that price revision due to change in WPI made by NPPA vide their Notification dated 02nd March, 2016 may not be applicable to the formulations referred to by the applicant on the ground that the formulations are not included in the revised schedule to the DPCO, 2013, issued vide S.O.No.701(E) dated 10.3.2016.

In the light of the above, the clarificatory Order of NPPA, dated 6.4.2016 regarding formulation shifted to non-scheduled category due to amendment of Schedule-I of DPCO, 2013 needs to be withdrawn, as requested by the Petitioner Company.

So far as regulation of non-scheduled drug is concerned, para 20(1) of DPCO, 2013 states as under:-

"The Government shall monitor the maximum retail prices (MRPs) of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months."

7. **Government decision:**

Price revision due to change in WPI to be effective from 1.4.2016 made by NPPA vide their Notification dated 02nd March, 2016 may not be applicable to the formulations referred to by the applicant on the ground that the formulations are not included in the revised schedule to the DPCO, 2013, issued vide S.O.No.701(E) dated 10.3.2016. The formulations, therefore, are in the category of non-scheduled drugs w.e.f. 10.3.2016. NPPA is also hereby directed to withdraw the clarificatory OM No.19(119)/2014/Div.II/NPPA, dated 6.4.2016 issued by them.

The products may, therefore, be regulated as non-scheduled formulations in terms of para 20(i) of DPCO, 2013, w.e.f. 10.3.2016.

Issued on this day, the 14th day of September, 2016.

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

To

1. M/s Abbott India Ltd., 271, Business Park, 6th Floor, Model Industrial Colony, Off Aarey Road, Goregaon (E), Mumbai-400063.
2. M/s Abbott Healthcare Pvt. Ltd., D Mart Bldg., Goregaon Mulund Link Road, Mulund West, Mumbai-400080.
3. The Member Secretary, NPPA, YMCA Cultural Centre Building, New Delhi – 110 001.

Copy to:

(i) PS to Hon'ble Minister (C&F), Shastri Bhavan, New Delhi for information.
(ii) PSO to Secretary (Pharma), Shastri Bhavan, New Delhi for information.
(iii) Technical Director (NIC) for uploading the order on Department's Website.