No. 31015/37/2015-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, 3rd Floor, Janpath Bhawan, New Delhi

O R D E R BY REVIEWING AUTHORITY UNDER PARA.31 OF DPCO, 2013

Subject: Review application of M/s. Bayer Zydus Pharma Pvt. Ltd., against fixation/revision of ceiling prices of "Hormone Releasing IUD (Levonorgesterol Releasing" vide NPPA notification S.O. No. 2943(E) dt. 29.10.2015 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant Review application dated 26.11.2015
2) NPPA notification under review S.O. No. 2943(E) dt. 29.10.2015
3) Record Note of discussions held in the personal hearing held in the matter on 21.06.2016

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No. 2943(E) dt. 29.10.2015 fixed/revised ceiling price of "Hormone Releasing IUD (Levonorgesterol Releasing)" under DPCO, 2013.

2. And whereas aggrieved by the above notification, M/s. Bayer Zydus Pharma Pvt. Ltd., (hereinafter referred to as the Petitioner) submitted review application dated 26.11.2015 under para.31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O. No. 2943(E) dt. 29.10.2015 fixing Ceiling price "Hormone Releasing IUD (Levonorgesterol Releasing)**"** under DPCO, 2013.

3. The grievances of the Petitioner raised in their review application dated 26.11.2015 were sent to NPPA and the comments of NPPA thereon were given to the Petitioner through the Record Note of discussions held in the hearing on 21.06.2016. Record Note of discussion is made integral part of the review order. After considering the comments of NPPA the Petitioner has raised the following points, on which comments given by NPPA representative during the hearing and Government's comments on the issue is recorded subsequently against each point:

4. **Company:** The Advocate representing the company submitted that, in addition to the earlier submissions in the meeting held on 18.12.2015, they intend to state that the impugned order had been issued under para 4 read with para 10, 11, 14 & 16 of DPCO, 2013. It is further submitted that the Schedule I of DPCO, 2013 did not specify the dosage and strength of the Levonorgesterol Releasing IUD. It is further submitted that para 4 of DPCO, 2013 can be exercised by the NPPA only in a case where (a) the formulation is specified in Schedule I of DPCO 2013 and (b) the strength and dosage of the said formulation are specified under the Schedule I. In view of the fact that dosages and strength of the product in question were not specified in the Schedule I of DPCO 2013, para 4 cannot be made applicable in the present case. The Advocate appearing on behalf of the applicant has relied upon the judgment of Hon'ble Delhi High Court, titled as "Reckitt Benckiser (India) Ltd., & J.K. ANSELL LIMITED versus UOI and Anr." cited as 221(2015) DLT 618(DB), wherein the issue before the Hon'ble High Court was

whether ceiling price of condoms can be fixed under para 4 when its strength and dosages have not been specified in the Schedule I of DPCO, 2013. Hon'ble High Court has categorically held that ***"in the light of the legal position noticed above and for reasons state supra, we are of the view that the NPPA exceeded the powers conferred by paras 4, 6 and 14 of DPCO 2013 while fixing the ceiling price for condoms. The language of para 4 is unambiguous and makes clear the legislative intent that the ceiling price can be fixed only for scheduled formulations of specified strengths and dosages as specified under the First Schedule. Therefore, according to us, the provisions of para 4 cannot be made application to 'condoms', the dosage and strength of which admittedly not been specified under the First Schedule."***

5. Therefore, the provisions of para 4 cannot be made applicable to the products where dosage and strength have not been specified under the Schedule I of the DPCO, 2013. The counsel for the applicant further stated that the judgment of Delhi High Court was challenged by Reckitt Benckiser (India) Ltd., & J.K. ANSELL LIMITED before the Hon'ble Supreme Court on another aspect, i.e., whether condoms can be held to be drugs under the provisions of Drugs & Cosmetics Act. The observations of the Hon'ble High Court qua the applicability of para 4 of DPCO, 2013 in that case has not been challenged before the Hon'ble Supreme Court by the said companies.

6. **NPPA:** It is pointed out by the representative of NPPA that UOI has also challenged the Order of Delhi High Court. However, no stay has been granted by the Hon'ble Supreme Court on the operation of the said order of the Delhi High Court.

7. **Company:** The Counsel for the applicant has cited a judgment titled as "Atma Ram Properties (P) Ltd. versus M/s Federal Motors Pvt. Ltd." Manu/SC/1047/2004 to argue that mere filing of an appeal does not amount to automatic stay of the judgment which is challenged. In view of the aforesaid judgment, it is contended that the Order of Delhi High Court is still binding on NPPA and all other authorities.

8. **NPPA:** The representative of NPPA stated that Hormone Releasing IUD and IUD containing copper were included in the NLEM 2011 as well as in NLEM 2015. In NLEM 2011, there was no specified dose for hormone releasing IUD while under NLEM 2015, the strength 52 mg. of Levonorgesterol is specified. It is mandatory for every manufacturer or marketer to mention the strength of Levonorgesterol for this device, as per IP/EPC/NF. NPPA considered the PTR of two other competitors while calculating the ceiling price for this device including M/s Bayer Zydus also. Therefore, price fixation of this device cannot be linked with condom. However, no strength of IUD containing copper has been mentioned in NELM 2015. The strength/dose for a medicine or device is decided by the Ministry of Health under the Drugs & Cosmetics Act. NLEM 2011 is substituted by NLEM 2015, but there is no amendment in Drugs & Cosmetics Act with reference to the strength/dose of this device. The NPPA representative submitted that hormone releasing IUD of the specific strength and other competitors also marketing and manufacturing this device as per the strength prescribed in NLEM 2015.

9. **Company:** In response to the submission of NPPA, the counsel of the company contended that reliance on the allegedly revised list of NLEM, 2015, as referred to by the representative of NPPA, is misplaced as the same did not exist when the S.O. 2943(E)

dated 29.10.2015 was issued by the NPPA. It is further submitted that the alleged revision in the Schedule I of DPCO, 2013 cannot have a retrospective effect. It is in fact admitted by the representative of NPPA that during the relevant time, dosages and strength of the products, in question, were not specified in Schedule I of DPCO, 2013. The counsel for the applicant further submitted that it is not the case of the applicant that its product was not listed in Schedule I during the relevant time, but it is argued that while the product was listed in the Schedule I, dosages and strength of the same were not mentioned in the Schedule I of DPCO, 2013. It is argued that the applicant is not comparing its product to condom as the case was before the Hon'ble Delhi High Court, but is only relying upon the observations of the Delhi High Court on the question of whether para 4 is applicable in cases where dosages and strengths of a formulation is not specified under Schedule I of DPCO, 2013.

10. **NPPA:** NPPA representative stated that M/s Bayer Zydus Pharma Pvt. Ltd. vide letter dated 25.06.2015 has intimated that their device contains strength 52 mg. of Levonorgesterol, which is the same as specified in NLEM 2015. NPPA has fixed the ceiling price for the said device, therefore, attracts the provision of para 4 of DPCO, 2013. There is no provision in DPCO, 2013 to fix the ceiling price based on the type of packing material.

11. **Company:** In response, the counsel for the applicant submitted that for the purposes of determining applicability of para 4, only dosages and strength as specified in the Schedule I of DPCO, 2013 has to be seen. Whether any dosage or strength is mentioned by a particular company or not, is not relevant for determining applicability of para 4. In the present case, as dosage and strength of the product in question is not mentioned, there is no question of applicability of para 4 of DPCO, 2013.

12. The counsel for the applicant further stated that even otherwise the product of the applicant cannot be compared with the product of EMILY, which is one of the products considered for fixing the ceiling price. It is submitted that there are material differences in terms of quality and longevity of the applicant's product as compared to EMILY. While the applicant's product (Mirena) has life of 5 years, EMILY has life of only 3 years. Also the design of Mirena is highly advanced and ensure no/minimum pain at the time of insertion into the patient. On the other hand, in the case of EMILY, the patient is subjected to substantial pain at the time of insertion. In view of the above, no comparison can be and ought not to have been made between Mirena and EMILY product for fixing the ceiling price of Levonorgesterol Releasing IUD.

Examination:

13. Under the review petition the petitioner has referred the judgment of the Hon'ble Delhi High Court in the case of condoms and pleaded to make a point that like condoms the ceiling price of Hormone Releasing IUD also cannot be fixed under para 4 as the dosage and strength of Hormone Releasing IUD is not mentioned in Section 18.3.1.3. In the judgment dated 10.7.2015 Hon'ble High Court of Delhi has decided in favour of Govt. that condom is a drug within the meaning of Drug & Cosmetics Act, that it is a scheduled formulation and that definition of ceiling price does not distinguish between scheduled and non-scheduled formulation. However, Hon'ble Court has decided that

under para 4 only the price of drugs can be fixed where the strength and dosage has been specified. NPPA representative has however stated that they have sent an SLP to the Centre Agency Section for filing in the Supreme Court. M/s Reckitt Benckiser has also filed an SLP on points on which Hon'ble Delhi High Court has not agreed to their view.

14. The judgment of Hon'ble Delhi High Court is applicable only in the case of condoms and there is no order for application of judgment in the case of IUD. Moreover either an SLP has been filed or is being filed. Therefore, the point made by the company has no merit.

15. Other points raised by the company that "Mirena" is superior to others, in terms of duration of effect, technique, designing and the materials used have no merit as DPCO, 2013 does not distinguish on these grounds and any manufacturer unless passes the quality test cannot get a drug license.

Government Decision:

16. Based on the above and other documents on record, the Government has decided as under:

> "The points raised by the petitioner have no merits and, therefore, the review application may be rejected."

Issued on this date, the 4th day of August, 2016.

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

To

1. M/s. Bayer Zydus Pharma Pvt. Ltd.,
   Bayer House, Central Avenue,
   Hiranandani Estate
   Thane (West)
   Maharashtra - 400607

2. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001.

Copy to:

1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. T.D., NIC for uploading the order on Department's Website.