31015/45/2014-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhavan, New Delhi

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

Subject:Review application of M/s Seagull Pharmaceuticals Pvt. Ltd. against fixation/revision of ceiling prices of "Diclofenac Sodium Injection (Superspass AQ Injection)" vide NPPA notification S.O. No.1806 (E) dt. 10.7.2014 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013)

Ref. 1) Applicant's Review application dated 6.8.2014
2) NPPA notification under review S.O. No. 1806 (E) dt. 10.7.2014
3) Record Note of discussions held in the personal hearing held in the matter on 2.9.2014

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No. 1806 (E) dt. 10.7.2014 fixed/revised ceiling price of "Diclofenac Sodium Injection (Superspass AQ Injection)" under DPCO, 2013.

2. And whereas aggrieved by the above notification, M/s Seagull Pharmaceuticals Pvt. Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 6.8.2014 for the review of NPPA Price fixation Order S.O.No. 1806 (E) dt. 10.7.2014 fixing Ceiling price of Diclofenac Sodium Injection (Superspass AQ Injection) under DPCO, 2013.

3. The grievance of the Petitioner raised in their review application dated 6.8.2014 were sent to NPPA and the comments of NPPA thereon were given to the Petitioner through the Record Note of discussions held in the review hearing on 2.9.2014. 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. Petitioner :

i) The petitioner representative mentioned that their formulation "Diclofenac Sodium Injection (Superspass AQ injection)" is a new drug under the definition of DPCO 2013. Since it is a non-NLEM drug it should not be treated as scheduled drug and the information as required by NPPA under

note (f) in form III Schedule II of DPCO 2013 should not be required by NPPA as the formulation is a non scheduled formulation.

ii) The petitioner representative mentioned that a similar order was issued by the Department in the case of M/s Nitin Life Sciences vide order No. 31015/11/2014 dated 7th July 2014 against NPPA notification No. 945(E) dt. 27.6.2014 issued under DPCO 2013 where the Ministry has considered their formulation as a non-scheduled.

iii) The petitioner representative also mentioned that new drug is a non scheduled formulation in accordance with sub para 2 of para 11 of DPCO 2013. Therefore this does not fall under the category of scheduled formulation. Further, any such representation by NPPA of qualifying "New Drug" as scheduled formulation is not supported by any provision of DPCO 2013 and therefore it is incorrect to suggest by NPPA that "New Drug" is a scheduled formulation even for limited purpose of asking details.

5. NPPA comments: The NPPA representative mentioned that as per the comments of D/o Legal Affairs forwarded by DOP vide its letter dated 28.2.2013, once the price has been fixed by NPPA then the drug loses its character of scheduled formulation. On the same line NPPA has requested DOP to reconsider its order in respect of M/s Nitin Life Sciences Ltd. Further this formulation for the limited purpose of monitoring is also a scheduled formulation.

Department's comments:

6. As per definition of NLEM contained in para 2(t) only National List of Essential Medicines 2011 published by M/o Health & Family Welfare as updated from time to time and included in the 1st schedule of DPCO 2013 by the Government through a notification in the official gazette are scheduled drugs. Unless the NLEM 2011 is updated or revised and the amendment is included in the 1st schedule through a notification in the official gazette, no other drug can be said to be a scheduled drug. Method of inclusion of a new drug contained in para 5 and fixation of retail price contained in para 15 (4) clearly states that retail price of such new drug shall be applicable to such applicant of new drug. This shows that only retail price is applicable to the applicant. Making it a scheduled formulation will have an impact of general application for all manufacturers thus a ceiling price and will be against the provisions of DPCO. It is, thus concluded that retail price fixation for a petitioner product does not make it a scheduled formulation.

7. In regard to the legal opinion provided by D/o Legal Affairs that once the price has been fixed by NPPA then the drug loses its character for scheduled formulation, it may be mentioned that the price fixation provisions under DPCO 1995 were different as it was cost based and the price fixation under DPCO 2013 is market based. Further the specific case in which the advice of M/o Law was obtained

pertained to exercise of para 10(b) of DPCO 1995 which is more close to para 19 of DPCO 2013. Even price fixed under para 19 of DPCO 2013 by NPPA has been characterised as non-scheduled as they attract 10% increase provision rather than WPI provision. Further under para 17 of DPCO 2013 for amendment of the list of scheduled formulations a decision has to be taken by the Govt. within the 60 days of receipt of communication from the M/o Health & FW and after the amendment or revision of the first schedule has been notified. Thereafter the ceiling price for the medicine added in the First Schedule shall be fixed. Further para 17(2) clearly mentions that medicines omitted from first schedule shall fall under the category of non-scheduled medicines. As the drug "Diclofenac Sodium Injection" with its specific strength and dosage form in question has not been included in Schedule I and, therefore, it will be a back door entry to amend the first schedule without any specific provision under the DPCO.

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

> "NPPA may be directed not to consider subject formulation as a scheduled formulation.".
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> Issued on this 14th of July, 2015

(A. K. Sah)
Under Secretary to the Govt. of India
For and on behalf of the President of India

To

1. M/s Seagull Pharmaceuticals Pvt. Ltd.
   305-306, Imperial Tower,
   "C" Block, Community Centre,
   Naraina Vihar,
   New Delhi-110028

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. TD, NIC for uploading the Order on the Department's website