No. 31015/91/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS
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A wing, Shastri Bhavan
New Delhi 110 001

ORDER BY REVIEWING AUTHORITY UNDER PARA 31 OF DPCO,2013

Subject: Review application of M/s Sun Pharmaceutical Industries Limited against Price fixation of Nitrofurantoin 100 mg capsule vide NPPA order no. S.O. 3180(E) dated 07/10/2016 issued under Drugs Prices Control Order, 2013 (DPCO 2013)

Ref: (1) Review application dated 20/10/2016
(2) NPPA notification under review. S.O. No. 3180(E) dated 07/10/2016
(3) Personal hearing held in the matter on 15/11/16.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharmaceutical Industries Limited (hereinafter called the petitioner) against notification S.O. No. 3180(E) dated 07/10/2016 issued by National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Nitrofurantoin 100 mg capsule.

2. The petitioner has contended as under:-

(i) Exclude NIFTRAN 100 mg capsule 30 ,NIFTRAN TM 100 mg capsule 10 from the ceiling price calculation of Nitrofurantoin 100 mg capsule as these two packs are not conventional formulations but are therapeutically advanced formulation. These should have been considered as per DOP notification S.O 701(E) dated 10/3/16.

(ii) NPPA has notified the Ceiling Price of NITROFURANTOIN 100 MG Capsule for the first time under DPCO 2013 on 07/10/16. WPI of calendar year 2015 should not be applied in ceiling price calculation as per DoP's

order dated 06.10.2016 on Review Application of M/S Alkem Laboratories Limited in File no. 31015/43/2016-PI-I.

(iii) Six months data prior to price notification should be considered in ceiling price calculation of NITROFURAMIN 100 mg capsule as per para 9(4) of DPCO 13 since NPPA has notified its ceiling price for the first time.

(iv) Product pack of U FREE 100 mg Capsule 14x10 of M/S Zydus Cadilla should be excluded from the ceiling price calculation as its MAT market share is less than 1% of SKU. This is also against DoP's order dated 06/10/16 in File No. 31015/23/2016-PI-I in M/S Lupin Ltd. The order clearly states that the DPCO does not recognize a Company for average PTR but only medicines/formulations

(v) Product pack URIFIST CP100 mg capsule of M/S Cipla should be included in ceiling price calculation as it is the formulation of NIROFURANTOIN 100 mg category.

3. Comments of NPPA

(i) NPPA has notified the ceiling price of Rs. 6.51/ Nitrofurantoin 100mg Capsule vide S. O. 3180(E) dated 07.10.2016 as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013 based on the data provided by pharmatrac for the month of August 2015 as per existing practice.

(ii) NPPA has rightly included Niftran 100mg Capsule 30's and Niftran TM 100mg Capsule 10's while fixing the ceiling price for Nitrofurantoin 100mg Capsule.

(iii) Reference is invited to Review order no 31015/12/2014-PI.I dated 30.8.2016 wherein review filed by M/s Abbott Healthcare Pvt. Ltd. in

respect of Famotidine Tablet 20mg was rejected on the basis of the presentation made by the company to the Standing Technical Committee Meeting held on 16.11.2015 that there is no therapeutic benefit for the gelatin coated tablet.

(iv) (a) It is submitted that when there is no separate mention in the NLEM regarding the Drug Delivery System, all versions of the Scheduled Drug in question are clubbed together irrespective of the Drug Delivery System for arriving at the Ceiling Price under the prescribed simple average price formula. On the other hand, if there is a separate mention of conventional and non-conventional versions, the two versions are considered separately for arriving at their respective Ceiling Prices. The underlying principle is that of the "essentiality" of a Drug, which is measured from therapeutic and intended use angle and hence, no drug can fall out of price control merely because it involves a New Drug Delivery System. It certainly cannot be argued that the DPCO, 2013 considers Scheduled Drugs with innovative delivery system as non-essential or that it is not interested in making them affordable to all, including poor masses. However, the DPCO, 2013 does provide for a five year exemption from price control under paragraph 32, if a drug involving a New Drug Delivery System (NDDS) has been developed with Indigenous Research and Development and has the approval of the Drugs Controller General (India) under Rule 122 E of the Drugs and Cosmetics Act and Rules, 1945. It should be noted that a Drug Delivery System is only a subset of the dosage form and cannot

override it. Hence, merely because a capsule is conventional or non-conventional does not make it cease to be capsule.

(b) It in this context that, it becomes necessary to refer to the definitions/ meanings of different terms used in the DPCO, 2013 such as, “Scheduled Formulation”, “Non-Scheduled Formulation”, “Active Pharmaceutical Ingredient or Bulk Drug”, “route of administration”, “Dosage Form”, “Strength”, and “Drug Delivery System” in order to come to a firm conclusion on whether or not a drug is a Scheduled Drug. Under Paragraph 2(zb) of DPCO, 2013, a “Scheduled Formulation” is defined as a formulation, which is included in the First Schedule to the DPCO, 2013 whether referred to by generic versions or brand name. Paragraph 2(v) defines a “Non-Scheduled Formulation” as a formulation, the dosage and strengths of which are not specified in the First Schedule. Paragraph 2(b) defines “an active pharmaceutical ingredient (API) or Bulk Drug” as pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to standards specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and which is used as such or as an ingredient in any formulation.

(c) The Schedule I contains the name of the medicine/molecule/API; route of administration; dosage form; and strength. Accordingly, when it is examined whether or not a formulation is scheduled, three things have to be looked into: (i) the API or bulk drug (ii) the route of administration/ the dosage form; and (iii) the strength. It is pertinent to submit here that the formulation in question matches with the

scheduled formulation on all these counts and is hence a scheduled formulation irrespective of the drug delivery system, and falls under the purview of price control. The subject formulation is a scheduled formulation as per the above and thus qualifies for price fixation.

(v) Ceiling Price of Nitrofurantoin 100mg Capsule is rightly fixed vide S.O. 3180(E) dated 07.10.2016 as per paragraph 17 and 9(5) of DPCO 2013. The market data considered for calculation is of August 2015 i.e. market data available for the month ending immediately before six months of notifications of the revised First Schedule (i.e. 10.3.2016), as per para 9(5) of DPCO 2013. Negative WPI, as prevalent for preceding year from Aug, 2015, is rightly considered for calculations in public interest.

4. **Examination:**

As regards the issue of exclusion of NIFTRAN 100 mg capsule 30 and NIFTRAN TM 100 mg capsule 10 from the ceiling price calculation on the ground that these two packs are not conventional formulations but are therapeutically advanced formulation, the underlying principle is that of the "essentiality" of a Drug, which is measured from therapeutic and intended use angle and hence, no drug can fall out of price control merely because it involves a New Drug Delivery System. Hence, merely because a capsule is conventional or non-conventional does not make it cease to be capsule. The Schedule I contains the name of the medicine/molecule/API; route of administration; dosage form; and strength. Accordingly, when it is examined whether or not a formulation is scheduled, three things have to be looked into: (i) the API or bulk drug (ii) the route of administration/ the dosage form; and (iii) the strength. It is pertinent to submit

here that the formulation in question matches with the scheduled formulation on all these counts and is hence a scheduled formulation irrespective of the drug delivery system, and falls under the purview of price control. The subject formulation is a scheduled formulation as per the above and thus qualifies for price fixation.

Regarding the grievance of the company about WPI impact, in this case, there is no ceiling price of the product on 1.4.2016. Ceiling price is fixed for the first time on 7.10.2016. So, when there is no ceiling price on 1.4.2016, there cannot be any revision of ceiling price due to WPI. Hence, applying WPI without the ceiling price having been fixed is not in accordance with the provisions of DPCO. In view of this, NPPA should fix the ceiling price of the product taking into account the data available for the month ending immediately before six months of the Notification of revision in the first schedule i.e. 10.03.2016 in the instant case in terms of Para 9(5) of the DPCO, 2013. NPPA has erred in applying WPI in this case where it is not applicable.

It is observed that the product pack of U FREE 100mg capsule 14x10 of M/s Zydus Cadilla has not been rightfully included in the price calculation of Nitrofurantoin 100 mg capsule by NPPA, as DPCO does not recognize a company for average PTR but only medicines/formulations. The issue of inclusion of Product pack URIFIST CP100 MG CAPSULE OF M/S Cipla has not been considered by NPPA. NPPA may be directed to look into the matter.

4. **<u>Government Decision:</u>**

NPPA is hereby directed to re-fix and re-notify the price of the products of the petitioner company under Para 4, taking into account Para 9(5) of DPCO, 2013, and without applying WPI change in ascertaining the ceiling price. The same principles should be applied to all other such cases also by NPPA.

NPPA is further directed to exclude the product pack of U FREE 100mg capsule 14x10 of M/s Zydus Cadilla in the price calculation of Nitrofurantoin 100 mg, verify the data of URIFIST CP100 MG CAPSULE OF M/S Cipla and to re-fix the ceiling price of Nitrofurantoin 100mg capsule, on merit.

Issued on this date, the 6th day of March, 2017.

(Jai Priye Prakash)
Secretary
For and on behalf of the President of India

To

1. Sun Pharmaceutical Industries Ltd
   8-C, 8th Floor, Hansalya Building,
   15, Barakhamba Road, Conaught Place,
   New Delhi-110001
2. The Member Secretary
   National Pharmaceutical Pricing Authority
   YMCA Cultural Centre Building, New Delhi – 110 001.

Copy to:

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