

No. 31015/28/2015-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. Reckitt Benckiser (India) Ltd. against fixation of ceiling prices of “Acetyl Salicylic Acid tablet 100 mg (ASA Tablets)” vide NPPA notification S.O. No. 1204(E) dt. 6.5.2015 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant Review application dated 22.5.2015
2) NPPA notification under review S.O. No. 1204(E) dt. 6.5.2015
3) Record Note of discussions held in the personal hearing held in the matter on 28.6.2016

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No. 1204(E) dt. 6.5.2015 fixed ceiling price of “Acetyl Salicylic Acid tablet 100 mg (ASA Tablets)” under DPCO, 2013 .

2. And whereas aggrieved by the above notification, M/s. Reckitt Benckiser (India) Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 22.5.2015 under para 31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No. 1204(E) dt. 6.5.2015 fixing ceiling price “Acetyl Salicylic Acid tablet 100 mg (ASA Tablets)”under DPCO, 2013.

3. The grievances of the Petitioner raised in their review application dated 22.5.2015 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 8.7.2015. The petitioner raised / filed additional submissions vide their letter dated 8.7.2015. The comments of NPPA on the same were given to the petitioner through record note of discussion on 18.11.2015. 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: The Petitioner had filed additional submissions dated 17.11.2015 which is taken on record.

5. Petitioner’s representative submitted that while fixing the ceiling price by S.O no. 1204 (E) dated 06.05.2015, NPPA had taken the price of ASA 100 mg tablets as Rs. 0.12 per tablet (PTR), which was fixed by S.O. No. 1097 (E) dated 15.02.2000 under DPCO, 1995. Whereas NPPA should have taken the price notified by them by S.O. No. 658 dated 24.03.2008, which was fixed as 0.197 per tablet of 100 mg (PTR), fixed under DPCO, 1995.

6. In addition, the Petitioner representative submitted that the formulation was under price control under DPCO, 1995; hence paragraph 6(1) of DPCO, 2013 has no application. This is for the reason that paragraph 6 (2) of DPCO, 2013 expressly states that paragraph 6 (1) would have no application, if the price of the formulation was fixed under DPCO, 1995 also. Therefore the price fixation order, treating the formulation as monopoly does not arise.

NPPA comments

7. NPPA mentioned that in 15.02.2000 they had notified only the price of ASA tablets, whereas the price notification issued on 24.03.2008, the price fixation order was passed in respect of tablet containing ASA plus calcium carbonate and Anhydrous citric acid. Therefore, the price fixed on 24.03.2008 cannot be taken into consideration, as it is different from ASA. Hence, they had rightly not taken into consideration in 24.03.2008 order while fixing the price.

8. NPPA informed that provisions of paragraph 6 (2) which excludes price fixation under paragraph 6 (1) of the DPCO, 2013, in case the price of the formulation was also fixed under DPCO, 1995. Therefore, they ought not to have treated the formulation as monopoly and paragraph 6 (1) has no application.

9. In response, the Petitioner submitted that their formulation contains ASA plus calcium carbonate and Anhydrous citric acid. In fact, the Petitioner had informed NPPA, in response to their query, by their letter dated 15.05.2013. Also, the Petitioner had filed Form-V dated 21.08.2009 and 29.03.2012 informing NPPA about the composition of their formulation, after the price fixation order of 24.03.2008 was passed.

10. Further, if NPPA submission is accepted and ASA tablet is to be treated as being a different formulation from ASA plus calcium carbonate and Anhydrous citric acid, then their formulation is not a scheduled formulation, as section 12.1.1 of the Schedule I under DPCO, 2013 only lists ASA tablet. ASA plus calcium carbonate and Anhydrous citric acid is not listed in section 12.1.1 of the Schedule I, therefore it would be a non-scheduled formulation and Ceiling price order cannot be passed in respect of ASA plus calcium carbonate and Anhydrous citric acid. The price of ASA plus calcium carbonate and Anhydrous citric acid can only be monitored and the Petitioner can fix the price treating it as a non-scheduled formulation.

11. Hence the price fixation order dated 06.05.2015 ought to be set aside and it may be ordered that the formulation in question i.e. ASA plus calcium carbonate and Anhydrous citric acid be treated as being outside price control.

12. Examination:

The Acetyl Salicylic Acid (ASA) 100 mg tablet is included in NLEM 2011 and under Section 12.1.1 of Schedule I of the DPCO, 2013.

Vide SO dated 24.3.2008 (p.36/c), NPPA has fixed retail prices of FDC, i.e. Acetyl Salicylic Acid with Calcium Carbonate and Anhydrous Citric Acid.

However, while fixing the ceiling price of Acetyl Salicylic Acid 100 mg tablet vide notification dated 6.5.2015, NPPA has not taken into account the PTR of the aforesaid FDC treating the same as different from ASA tablets.

The company has represented that their product Colspirin Effervescent tablet contain Acetyl Salicylic Acid + calcium carbonate as Active Pharmaceutical Ingredients (APIs) and Anhydrous Citric Acid as excipient. Petitioner company has, therefore, requested that price fixation dated 24.3.2008 should have been taken into consideration by NPPA for fixing the ceiling price of their product Colspirin vide NPPA Notification dated 06.05.2015.

NPPA has mentioned that the Calcium Carbonate and Citric Acid are not only used as excipients but they are also used as active ingredients e.g. Citric Acid is used as active ingredient in ORS. NPPA has further mentioned that their Order dated 24.3.2008 with regard to ASA+Calcium Carbonate+Anhydrous Citric Acid are different than Acetyl Salicylic Acid mentioned in Section 12.1.1 of DPCO, 2013. As such, they have not considered the PTR of the above FDC while fixing the ceiling price of ASA 100 mg tablets vide their SO No.1204(E) dated 06.05.2015.

Acetyl Salicylic Acid is a scheduled drug mentioned under Section 12.1.1 of DPCO, 2013. NPPA Order dated 24.3.2008 is with regard to an FDC i.e. ASA+Calcium Carbonate+Anhydrous Citric Acid. In view of this, if the product of the petitioner company is FDC, as above, the petitioner company should have applied in Form I to NPPA to consider their product as a new drug and for fixation of the price of the same under Para 2(u) of DPCO, 2013.

Acetyl Salicylic Acid (ASA) 100 mg tablet (ASA Tablet) is a scheduled drug of NLEM 2011 and included at Section 12.1.1 of Schedule I of DPCO 2013. There is no provision in DPCO 2013 to consider ASA tablet (effervescent) separately. Further, NPPA has mentioned that Acetyl Salicylic Acid tablet 100 mg effervescent tablet has been included in NLEM 2015 of DPCO, 2013 and hence included in revised Schedule-I of DPCO 2013.

Government Decision:

Acetyl Salicylic Acid (ASA) 100 mg tablet (ASA Tablet) is a scheduled drug of NLEM 2011 and included at Section 12.1.1 of Schedule I of DPCO 2013. There is no provision in DPCO 2013 to consider ASA tablet (effervescent) separately. Therefore, the request of the petitioner company is rejected.

Issued on this date, the 6th day of October, 2016.

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

To

- 1. M/s. Reckitt Benckiser (India) Ltd.
Plot 48, Sector 32, Institutional Area
Gurgaon - 122001**
- 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.**