No. 31015/20/2015-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. IPCA Laboratories Ltd. against Notification S.O 834(E) dated 25.3.2015 fixation of ceiling price of formulation ERYTHROMYCIN TABLETS (250mg and 500mg), ERYTHROMYCIN SUSPENSION 125mg/5ml and Chloroquine Injection 40mg/ml and S.O.No.855(E) dated 25.03.2015 fixing retail price for new drug Chlorthalidone + Amlodipine tablet under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant Review application dated 04.4.2015,06.04.15 and 15.04.15
2) NPPA notification under review S.O. No.834(E) dated 25/3/2015 and SO No.855(E) dt. 25.3.2015
3) Record Note of discussions held in the personal hearing held in the matter on 22.6.2016

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order Notification S.O 834(E) dated 25.3.2015 fixed ceiling price of their formulation ERYTHROMYCIN TABLETS (250mg and 500mg), ERYTHROMYCIN SUSPENSION 125mg/5ml and Chloroquine Injection 40mg/ml and S.O.No.855(E) dated 25.03.2015 fixed retail price for new drug Chlorthalidone + Amlodipine tablet under DPCO, 2013.

2. And whereas aggrieved by the above notifications, M/s IPCA Laboratories Ltd. submitted three review applications dated 04.04.2015, 06.04.15 and 15.04.15 under para.31 of DPCO, 2013 for the review of NPPA Price fixation Notification S.O 834(E) dated 25.3.2015 for fixation of ceiling price of their formulation ERYTHROMYCIN TABLETS (250mg and 500mg), ERYTHROMYCIN SUSPENSION 125mg/5ml and Chloroquine Injection 40mg/ml and S.O.No.855(E) dated 25.03.2015 fixing retail price for new drug Chlorthalidone + Amlodipine tablet under DPCO, 2013.

3. The grievances of the Company raised in their review applications were sent to NPPA and the comments of NPPA thereon were given to the Company through the Record Note of discussions held in the hearing on 22.6.2016. Record Note of discussion is made integral part of the review order. After considering the comments of NPPA, the Company 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. **Chloroquine Phosphate Injection 40mg/ml., 5ml ampoule, 30ml vial**

Company: It was submitted by the company that the price notified is not consistent with the provisions of DPCO, 2013 and NPPP-2012. Policy provides fixation of price based on dosages and strengths. As regards injectable preparations single dose is of 2 ml for children, 5 ml for adults and multiple dose is in 30 ml vial containing 15/6 doses for children/adults. Even following the policy, these should have been clubbed together to work out average PTR for fixing ceiling price. It was submitted that these formulations have been under price control from the very beginning. Norms notified for the industry as a whole for conversion cost, packing materials, packing charges under DPCO 1995 in December, 2012 by NPPA itself showed vide difference between cost pertaining to ampoules and vials and even based on this clubbing of PTRs of unlike was not desirable and against the policy. Supporting papers were also submitted during the hearing. Our view and submissions in this regard have also been upheld in the amendment to the first schedule notified by the Department of Pharmaceuticals vide SO No.771(E), dated 10th March, 2016. Explanation 6 below this notification provides that : "For injectable preparations the pack size (single and multi-dose packs) has not been mentioned. It is suggested that the single and multi-dose pack size to be considered as separate entities for purposes such as procurement/pricing etc."

In the context of the above position, when everything is made clear, NPPA of its own should have rectified the notification. We submit that as a part of review suitable directions may be issued to NPPA so that inconsistencies are not introduced in the system.

NPPA:- NPPA representative has mentioned in addition to their above mentioned submissions, there is no provision for cost based on pricing under DPCO, 2013. However, Department has amended in para 11 of the DPCO, 2013 by virtue of existing sub-Para 3 and 4. Cases submitted by the company are admissible the same may be examined by the NPPA in the next authority meeting.

Examination: As per the review order issued under DPCO 1995, NPPA fixed the price of subject formulations on 20.12.2013 separately for all these three packs. However, under DPCO, 2013, NPPA has merged all the packs for working out average price. The argument of the company is that it is true that DPCO provides for per ml price. However, it does not say that all heterogeneous packing materials will be clubbed together for working out the average price. Their argument is, therefore, that the price should be fixed packwise. The company had further stated that their 30 ml vial consist of preservatives and is, therefore, a different formulation. NPPA representative, however, mentioned that their averaging is based on per ml price which is being followed consistently in all cases in line with the provisions of para 11 of DPCO 2013.

As per para 11 of DPCO 2013, price has to be fixed on per ml basis and DPCO 2013 does not provide for separate pack sizes. The company representative has, therefore, no merit in this point and the same stands rejected.

5. **Erythromycin Estolate Syrup and Erythromycin Estolate Tablets(250 and 500mg)**

Our earlier submissions were rejected. It was submitted that PTR has not been correctly taken for the major producer Alembic and differences between PTR as per ORG mark and actual PTR as adopted in the website were shown highlighting the difference. It was also submitted that DPCO 2013 and NPPP-2012 had mandated that PTR would be taken as per ORG mark and no adjustment/tampering with PTR was permissible when the price was notified under DPCO 1995. Review of price cannot be deemed to be fresh price fixation and adjustment of PTR on such basis was not mandated in NPPA did not follow the policy consistently. It was also submitted that WPI is clearly seen to be not allowed in the workings of NPPA for the year 2012-13 and 2014 in respect of these formulations and that should be allowed to us. The contentions of NPPA were unjust and without any basis and are not supported by legal position. In support of the position as outlined above, kind attention was invited to Para 9 of DPCO and relevant provisions of the policy. It was submitted that correct on both these accounts be allowed to us.

NPPA: Representative of NPPA has stated that PTR for this formulation was derived as per existing practice. The PTR of major manufacturer formulator was restricted based on ceiling price. NPPA has fixed the ceiling price Rs.2.86 per tablet vide SO No.855(E) dated 25.3.2015 as per provisions of DPCO 2013.

Examination: The ceiling price of the subject formulation was issued vide notification No.3787(E) dt. 20.12.2013 based on Ministry's review orders dated 27.11.2013. As per provisions of DPCO 2013 contained in para 10(2) any formulations which were under price control under DPCO 1995 remained effective for one year from the date of notification of such prices under DPCO 1995 and immediately thereafter the manufacturer may revise the price as per the annual WPI. Since the price notification under DPCO 1995 was issued on 20.12.2013 the company was required to maintain the same price upto 20th December 2014 and thereafter it was entitled for WPI increase. As per the statement of the company during the personal hearing it is stated that they had taken WPI of 6.32% on 1.4.2014. The company has violated the provisions of para 10(2) of DPCO 2013 and have overcharged. Recoveries therefore requires to be made from the company for overcharging. The claim of the company that their stated PTR has not been taken is therefore unfounded for. On 1.4.2015 NPPA is required to give another WPI and their data after availing WPI on 20.12.2014 needs to be taken into consideration by NPPA. Revision of prices of their formulations i.e. Erythromycin Estolate Syrup and Erythromycin Estolate tablets before 20.12.2014 is not as per the provision of the DPCO,2013. NPPA may also check the same issue in the case of Choloroquine Phosphate Injection and if the company has overcharged the same should be recovered. NPPA may consider for overcharging from the company after collecting full details and consider the data of the company for price fixation w.e.f. 1.4.2015 after allowing WPI on 20.12.2014.

6. **CTD-AM**

Company: It was submitted that this was non-scheduled formulation and since one of the ingredients was under price control will submit application for fixation of price under para 5 of DPCO 2013 as per policy. While submitting our application, we have given the details of two manufacturers namely: Zydus Cadila and Mecleods, their

prices and PTRs. NPPA fixed the price using para 6 under which prices of only scheduled formulations can be fixed. Therefore, NPPA used the authority under DPCO 2013 wrongly to fixed the price based on monopoly angle. Even while doing so they took into consideration product group of this formulation and worked out reduction for tablets and other dosses forms like injectable, syrups etc. to apply in this case it was also wrong. The price should have been fixed under para 5 based on the average PTR of two manufacturers as provided in DPCO and, therefore, there has been wrong applicable of the provisions of DPCO 2013 also. In such cases, there is need for issuing directions by the DoP to the NPPA that they should consistently follow the provisions of DPCO and NPPP 2012 instead of destroying their sanctity and putting the manufacturers to hardship.

It was submitted that earlier rectification of the price needs to be carried out as our review application is pending for a long time. Since it is a mistake of NPPA it may also be directed to rectify the same.

NPPA: NPPA fixed the retail price for new drugs under para 5 and 15 of DPCO 2013 due to absence of competitors. NPPA applied para 6 for fixing the price for this formulation keeping in view of the consumer interest. NPPA in its authority meeting decided that PTR of the existing competitor alongwith 16% retailer margin may be allowed to fix the retail price for new drug but that was for prospective period.

Examination:

The company was manufacturers of Amlodopine under DPCO 1995 and have added Chlorthalidone to Amlodopine and, therefore, they have applied for a new drug. The company representative stated that the price should have been fixed under para 5 and that para 6 applies to only schedueled drugs and does not apply to them. The company representative stated that monopoly condition otherwise does not apply as there are already two formulators of the same drug i.e. M/s Zydus Cadila and other is M/s Macleoids and, therefore, monopoly condition does not apply. The NPPA representative stated that as per available data there was only one manufacturer and hence monopoly formula has been applied by NPPA.

In cases of new drug price fixation para 5(1) of DPCO 2013 refers to para 4(1). Para 4(1) provides methodology for fixing ceiling prices of scheduled formulations. Therefore intention of framers of DPCO is to fix new drug prices at par with scheduled formulations. Para 6(1) stipulates that if there is no reduction in case of application of para 4(1) the monopoly method contained in para 6 will apply. The company has no merit in arguing that their formulation is not scheduled and therefore monopoly condition does not apply.

As per para 9(1) of DPCO 2013 if deemed necessary Government may validate such data by appropriate survey or evaluation. NPPA may evaluate the data and if after appropriate survey it is found that there are two different manufacturers having more than 1% market share then the monopoly condition contained in para 6 will not be applied.

Government Decision:

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

In respect of Erythromycin Estolate Syrup and Erythromycin Estolate Tablets and Chloroquine Phosphate Injection, NPPA may allow WPI on 20.12.2014 i.e. after one year from the date of fixation of prices under DPCO 1995 and the same data after using the WPI will be considered by NPPA for price fixation with effect from 1.4.2015. Any increase taken by the company between 20.12.2013 and 20.12.2014 is not as per the DPCO provisions and, therefore, overcharging amount may be recovered from the company.

In respect of CTD-AM, NPPA is directed to undertake an appropriate survey and if there are more than one manufacturer the monopoly condition should not be applied.

Issued on this date, the 30th day of August, 2016.

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

To

1. M/s. IPCA Laboratories Ltd.
   142-AB, Kandivli Industrial Estate
   Kandivli (West)
   Mumbai-400067

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. Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. T.D., NIC for uploading the order on Department's Website.