

No. 31015/97/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

A Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Review application of M/s IPCA Laboratories Limited against price fixation of "Metoclopramide Syrup 5mg/5ml (Perinorm Syrup 30 ml)" vide NPPA order No. S.O. 3431(E), dated 10.11.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 15.11.2016
2) NPPA notification under review S.O. No. 3431(E), dated 10.11.2016
3) Record Note of discussions held in the personal hearing held in the matter on 10.01.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s IPCA Laboratories Limited (hereinafter called the petitioner) against notification S.O. No. 3431(E), dated 10.11.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Metoclopramide Syrup 5mg/5ml (Perinorm Syrup 30 ml).

2. The petitioner has contended as under:

- I. Vide the above mentioned S.O. No. 3431(E) dated 10/11/2016, NPPA has decided to further reduce the prices of Metoclopramide Oral Liquid 5mg/5ml to **Rs.0.41 per ml** from the revision given on March 2, 2016, **S.O.644 (E) of Rs 0.51 per ml**, giving effect to the Whole sale price index changes of -2.7105%.
- II. They referred to worksheet for price calculations displayed on the website of NPPA in respect of Metoclopramide 5mg/5ml Syrup. **It is seen from the calculations that out of five packs being taken into consideration, four packs are of 30ml and one pack is of 450ml. 30ml pack is for consumer whereas 450ml pack is not for consumer and is a dispensing pack.** The quantity in this pack is 15 times the quantity in a consumer pack. The bigger pack is dispensing pack for use in hospitals or by dispensing Chemists. PTR of this pack cannot be clubbed with PTR of consumer packs to work out average PTR for determining ceiling price. Therefore 450ml pack needs to be omitted from calculations and if necessary separate prices need to be fixed for two types of packs intended for different purposes.
- III. They further submitted that average PTR of four consumer packs (30 ml) varies between Rs.0.38 per ml to Rs 0.44 per ml whereas average PTR of 450ml pack comes to Rs.0.16/ml. Therefore average cannot be worked out of heterogeneous packs showing wide variation in PTR per unit as indicated above.
- IV. They also referred Notification **S.O. No. 1993(E) dated 3rd June, 2016**. It would be observed that in this notification price for the same product(s) (Glucose 5% etc) has been notified for glass bottles in pack size of 100ml, 250 ml, 500ml and 1000ml in

glass bottles, PVC bottles and non PVC bottles. Therefore, for computing PTR not only different volumes but different packing materials have been recognized. When the said decision is of the Body of experts subsequently separate and inconsistent decision cannot be taken and as such calculation displayed on the site is not only wrong but inconsistent with own decisions of NPPA. They requested that PTR of 450ml pack should not be clubbed with 30 ml pack as proposed in the calculation sheet.

Comments of NPPA:

- (i) NPPA has fixed the ceiling price of Rs. 0.47/ml vide S.O. 1656(E) dated 14.6.2013 and the same was revised to Rs. 0.50, Rs. 0.52 & 0.51 per ml vide S.O. 1156(E), 619(E) & 644(E) dated 28.4.2014, 26.02.2015 & 02.3.2016 respectively under NLEM 2011 and Rs. 0.41/ml vide S.O. 3431(E) dated 10.11.2016 under NLEM 2015.
- (ii) DPCO, 2013 does not differentiate between consumer and dispensing pack while calculating the ceiling price for Scheduled formulations. Ceiling price has been fixed based on the data provided by IMS for the month of May, 2012 under NLEM 2011 and the data provided by pharmatrac for the month of August, 2015 under NLEM 2015 as per existing practice.
- (iii) The request of company to revise the ceiling price based on S.O. 1993(E) dated 03.6.2016 is not tenable as the same is applicable for IV Fluid where therapeutic safety and efficacy is involved pertaining to the special type of packing material used.
- (iv) Company has made the representation based on OM no. 8(34)/2016/DP/NPPA/Div.II dated 21.9.2016 but the same was rejected on the ground that DPCO, 2013 does not specify for any separation between hospital/ dispensing and retail pack.
- (v) As per information available with NPPA company has challenged S.O. 1656 (E) dated 14.6.2013 in respect of Metoclopramide 5mg/5ml Syrup in Bombay High Court vide WP No. 1161/2014 decision is pending.

3. During the personal hearing, the representatives of the petitioner further submitted that –

- (i) There is an anomaly in the recent announcement of ceiling price of Metacloperamide Syrup 5mg/5ml (30ml pack) notified on 10th Nov, 2016. Ceiling price of the said pack have been reduced from Rs.16.16 to Rs. 12.99 that is by 19.62% arbitrarily and without any basis making the product highly uneconomical.
- (ii) The basic issue is whether dispensing packs can be clubbed with retail consumer packs despite difference in costs and the purpose they intend to serve. The price of Metacloperamide 450ml pack(5mg/5ml) have also been considered along with 30ml pack for working out average PTR although 450ml pack is a dispensing pack and 30ml pack is a consumer pack. Market based

pricing does not mean that unlikes in cost and other parameters can be clubbed together for the purpose of working out average PTR. The average can only be of the likes otherwise it becomes an exercise in selectivity.

- (iii) The drug is used for nausea and vomiting and is required to be taken a maximum of 2 to three times a day. The dosage depends upon age and body weight from as low as 1 mg twice daily to as high as 10mg/ml thrice daily. This necessitates a calibrated dropper for correct dosage administration in a patient with the help of dosage markings on the dropper. In correct dosage administration can result in over dosage which may lead to drowsiness, disorientation and extra pyramidal reactions. Syrup is meant for use in pediatrics. The leaflet provided with the product indicates description, composition, clinical pharmacology, Pharmacokinetics, indications, contradictions, warnings, precautions, usages in pregnancy/Lactation usage in pediatrics, dosage and administration for young adults, adults and children and over dosage symptoms etc. The show boxes are required to accommodate Amber bottle with label leaflet and calibrated dropper. As a result cost of product and its packing charges go up due to manual packing operations involved. 30ml pack as such is only retail pack which can cater to all such requirements.
- (iv) 450ml pack is a dispensing pack not having any calibrated dropper. The volume in this pack is 15 times the volume in a retail pack and so is the position of drug content and as such it has no rationale in so far as consumer and retail sale is concerned. Even if a consumer buys it such a pack has no use for him as it would not only be very costly but quantity beyond 30ml would be total waste.
- (v) Paragraph 11(1) of DPCO, 2013 provides that price to retailer shall be calculated on the dosage basis (per tablet, per capsule or injection in volume as listed in the First Schedule). The dose to be administered is 1 mg to 10mg two to three times daily in the form of syrup having 5mg/5 ml bulk drug Metacloperamide Hcl. In other words dose is 1 mg/ml. Depending upon the age dose is administered with the help of Calibrated dropper. Dosage requirements of all age groups could be catered by 30ml bottle pack which is directly purchased by the consumers from retail chemists. On the other hand multi dose 450ml pack having 15 times dosages is purchased by dispensing chemists, nursing homes, institutions and hospitals and it has no relevance to the pack containing only 30 ml to meet the requirements of all age groups dosage requirements and as such clubbing PTR of both is as such even inconsistent with the laid down policy. Direction in paragraph 11(3) introduced as a result of amendment is to this effect.
- (vi) These acts of NPPA are totally against the spirit of NLEM-2015 policy. It shows the high handedness of NPPA with total disregard to the new policy and the ground reality. Since no body can ignore costs and their relevance to the end objective of the policy to fix prices for the retailers, the implementation of notification dated 10th Nov, 2016 may be held in abeyance as producers cannot be penalized for wrong acts of NPPA.
- (vii) Explanation no.6 of Notification S.O. No. 701(E) dated 10th March, 2016 issued by the Ministry amending the First Schedule reads as under:

“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 sizes be considered as separate entities for purposes such as procurement/pricing etc.”

It is clear from the above explanation that multi-dose packs cannot be clubbed with single dose packs. What is true of injectables is true for other dosage forms as explained above. The said notification dated 11th Nov, 2016 and the working done by NPPA is contrary to the letter and spirit of the policy as laid down by the Ministry vide notification dated 10th March, 2016 and even otherwise. When legal position is clear NPPA should not have acted contrary to the same and Ministry may independently issue directions in this regard.

Ministry vide their review order No.31015/75/2016-PI.I dated 22nd Dec, 2016 has taken the following decision:-

“NPPA is hereby directed to consider only the prices of retail packs and not dispensing packs of similar formulations and to refix the ceiling prices of Metacloperamide 5mg/5 ml injection within a period of one month on merits.”

The above case also falls within the ambit of said decision and as such similar direction be issued to NPPA. NPPA is claimed to be a body of experts and they should not have taken such decisions.

- (viii) From the workings on the website it is clear that no distinction has been made by the NPPA in the two type packs despite clear legal position and arbitrariness have been used. The calculation shown in table below make it clear as to how the price/PTR is impacted by considering Dispensing Pack and retail packs alike in calculation although no logic would suggest that such a thing should have been ever done when the objective was to fix retail prices:-

Particulars	PTR total per ml(Rs)	No. of packs	Average(Rs)	16% margin (Rs)	Ceiling price(Rs) per ml
30ml pack of Metacloperamide (5mg/5ml)-retailer pack	1.65	4	0.4125	0.066	0.48
450ml pack of Metacloperamide(5mg/5ml)-Dispensing pack	0.16	1	0.16	0.0256	0.19
NPPA working	1.81	5	0.36	0.06	0.42

- (ix) When 30ml pack which is retailer/consumer requirement is not separable as distinct entity from 450ml pack and has to be taken not exceeding 30ml at one time(not exceeding three days) as is clear from medical literature by various age groups any sane person would understand that the same cannot be compared with 30ml pack which exists distinctly as a tradable and directly usable product by consumers for the purpose of working out average PTR which is relevant for pricing. Even average PTR per ml as worked out for 30ml of syrup pack based on data used by NPPA is Rs.0.4125 against Rs.0.16 for 450ml dispensing pack suggesting that all 30ml pack producers have eventually to discontinue

production and on the other hand the price of Dispensing pack shoots up causing hardship to producers as well as hospitals and institutions, nursing homes, dispensing chemists etc. with consumer being totally ignored through such a pricing. Medicine is administered to the patients as dose by such institutions and they are charged for the same but such a dose is not trade able. Only a few chemists in each city are separate license for dispensing and they keep these dispensable packs as well. from them nursing homes etc also buy such dispensing packs.

- (x) Metacloperamide 450ml is a dispensing pack and not a retail pack and it should not have been taken into consideration at all for working out average PTR. Separate price should have been worked out for 30ml and 450ml packs so that benefit of price is available to dispensing chemists/hospitals. It may be noted that 450ml packs are multi dosage having a different packing material, conversion and packing charges as compared to 30ml packs which are enough to meet dosage requirements of all age groups. The policy does not say that all heterogeneous packing materials will be clubbed together for working out the average PTR and selectivity being resorted to by NPPA has to be discontinued if the new policy is to be made a success. Metacloperamide Syrup 30ml ceiling price would have been Rs.0.48/ml instead of Rs.0.42/ml had NPPA not considered Dispensing pack of 450ml in calculations with the retail pack of 30ml which was not permissible under the Policy/DPCO, 2013 as explained above. Such inconsistent pricing which is without basis would neither help the consumer nor would it result in the growth of the industry in the country.
- (xi) The company also invited attention to S.O. No.1993(E) dated 3rd June, 2016 where ceiling prices of various types of Intravenous Fluids have been notified. It would be observed that prices with same packing materials and composition have been notified for different volumes like 100ml, 250ml, 500ml etc. Even on this ground NPPA should not have clubbed dispensing pack with retail pack. It was submitted that safety and efficacy cannot be associated with IV fluids only but it is relevant for all dosage forms. The issue is not which packing material is used but even for the same packing material different prices have been fixed volume wise and if volume is relevant for IV fluids than same cannot be ignored for liquids
- (xii) The company requested you to look into all such issues and advise NPPA so that selectivity and arbitrariness could be removed from the functioning of NPPA.

4. Examination:

The petitioner company has challenged the NPPA Order S.O. 3431(E) dated 10.11.2016 for price fixation of their formulation **Metoclopramide Syrup 5mg/5ml (Perinorm Syrup 30 ml)**. The main contention of the petitioner company is that to calculate average price to retailer, NPPA has clubbed PTR of consumer pack with dispensing pack while calculating the ceiling price for formulation **Metoclopramide 5mg/5ml**. In this connection, it is observed that in DPCO 2013, there is no provision to differentiate consumer pack and dispensing pack while calculating the ceiling price. The formulation under consideration is only a syrup and not IV Fluid / injectable and has got

no added therapeutic advantage being in consumer pack. The request of the company to revise the ceiling price based on S.O. 1993(E) dated 03.6.2016 is also not tenable as the same is applicable for IV Fluid where therapeutic safety and efficacy is involved pertaining to the special type of packing material used.

5. **Government Decision:**

“The request of the company that PTR of consumer pack with dispensing pack should not be clubbed while calculating the ceiling price of Metoclopramide Syrup 5mg/5ml cannot be acceded to, as there is no provision in DPCO, 2013, and the review petition stands rejected.”

Issued on this date, the 5th day of April, 2017.

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

To

1. **M/s. IPCA Laboratories Limited,
125, Kandivli Industrial Estate,
CTS No.328, Kandivli (West),
Mumbai-400 067.**
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**