

**No. 31015/75/2016-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

B Wing, Janpath Bhawan,  
New Delhi 110 001

**Subject: Review application of M/s IPCA Laboratories Limited against price fixation of "Ondansetron Injectables" vide NPPA order No. S.O. 1351(E)[corrected SO No.1951(E)] dated 02.06.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

**Ref: 1) Review application dated 16.06.2016**  
**2) NPPA notification under review S.O. No. 1351(E)[corrected SO No.1951(E)] dated 02.06.2016**  
**3) Record Note of discussions held in the personal hearing held in the matter on 08.09.2016.**

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. 1351(E)[corrected SO No.1951(E)] dated 02.06.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Ondansetron Injectables.

2. The petitioner has contended as under:

- I. They said that anomaly in the recent announcement of prices by NPPA based on notification dated 10<sup>th</sup> March, 2016 which is being simply ignored. Recently vide notification **S.O. 1351(E) dated 02.06.2016** ceiling price of Ondansetron Injectables have been reduced from Rs.7.92 to Rs. 5.43 arbitrarily and without any basis. The worksheet of NPPA as available on their website is enclosed.
- 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. They found that price of Ondansetron Vials have also been considered along with the Ampoules for working out average PTR although vials are dispensing packs and Ampoules are consumer packs. 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. 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 2ml injection having 2mg/ml bulk drug Ondansteron. This dose is contained 2ml Ampoule only which is directly purchased by the consumers from retail chemists. On the other hand multi dose 10ml vial having 5 dosages is purchased by dispensing chemists and hospitals and it has no relevance to the pack containing single dose and as such clubbing PTR of both is as such is even inconsistent with the laid down policy.

IV. These acts 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 nobody can ignore costs, the implementation of notification dated 2<sup>nd</sup> June, 2016 may be held in abeyance as producers cannot be penalized for wrong acts of NPPA.

V. **Explanation no.6 of Notification dated 10th March, 2016** 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 and Vial packs are multi-dose packs and Ampoule packs are single dose packs. The said notification dated 2<sup>nd</sup> June, 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 10<sup>th</sup> March, 2016. When legal position is clear NPPA should not have acted contrary to the same and Ministry may independently issue directions in this regard.

VI. 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 vials and Ampoules alike in calculation although no logic would suggest that such a thing should have been ever done:-

Particular	PTR Total (Rs)	No of Packs	Average (Rs)	@16% Margin (Rs)	Ceiling price before WPI (Rs)	WPI reduction @2.7105% (Rs)	Final Ceiling price (Rs)
Ampoules	70.72	12	5.89	0.94	6.83	(0.19)	6.64
Vials	11.12	5	2.22	0.36	2.58	(0.07)	2.51
<b>Considered by NPPA (Ampoules + Vials)</b>	<b>81.84</b>	<b>17</b>	<b>4.81</b>	<b>0.77</b>	<b>5.58</b>	<b>(0.15)</b>	<b>5.43</b>

VII. When 2ml vial is not separable as distinct entity from 10ml vial and has to be taken through a syringe any sane person would understand that the same cannot be compared with 2ml Ampoule which exists distinctly as a tradable and directly usable product for the purpose of working out average PTR which is relevant for pricing. Even average PTR per ml as works out for 1ml of injection based on data used by NPPA is Rs.5.89 against Rs.2.22 for vial suggesting that all Ampoule producers have eventually to discontinue production and on the other hand the price of vials shoots up causing hardship to producers as well as hospitals and institutions with consumer being totally ignored through such a pricing.

- VIII. Ondansetron 10ml vial 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 vials and ampoules so that benefit of price is available to dispensing chemists/hospitals. It may be noted that Vials are multi dosage having a different packing material, conversion and packing charges as compared to Ampoules which are single dosages having different cost parameters. 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. Ondansetron Ampoule ceiling price would have been Rs.6.64/ml instead of Rs.5.43/ml had NPPA not considered Ondansetron vials in calculations with the Ampoules 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.
- IX. They requested this Department to look into all such issues and advise NPPA so that selectivity and arbitrariness could be removed from the functioning of NPPA.
- X. **They have uploaded Form V electronically in IPDMS and are following the ceiling price revised by NPPA.**

**Comments of NPPA:**

- (i) NPPA has fixed the ceiling price of Rs. 7.37/ml vide S.O. 1803(E) dated 21.6.2013 and the same was revised to Rs. 7.84, Rs. 8.14 & 7.92 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. 5.43/ml vide S.O. 1351(E) dated 02.6.2016 under NLEM 2015.
- (ii) Technical Committee has been constituted by NPPA under para 11(3) & (4) to consider separate price for different packs. However, M/s IPCA was not under any representation in this regard.
- (iii) As per information available with M&E division (through IPDMS report), company is following ceiling price notified vide S.O. 1351(E) dated 02.6.2016 for above mentioned formulation. DOP is also requested to verify the same from the company by insisting on verified copies of the control sample of price revision and relevant invoices in support.
3. During the personal hearing, the representatives of the petitioner further submitted that –
- (a) Average PTR has been worked out for unlike packs. This cannot be and is not the purpose of the NPPP-2012 and NPPA has been giving wrong interpretation to justify its actions. NPPA has to notify retail prices and it should take into consideration retail packs only and not the dispensing packs. Clubbing of both type of packs is not justified on any ground and reflects non application of mind. Neither it is mathematically correct nor it is technically correct. It is also against the NPPP-2012. In such matters views of Body of Experts need to be called instead of NPPA alone.

- (b) When First Schedule to DPCO, 2013 was amended on 10<sup>th</sup> March, 2016 and explanation (6) there under clearly lays down that the single and multi dose pack sizes be considered as separate entities for purpose such as procurement/pricing etc., even the mandatory position was ignored by the NPPA and producers were wrongly subjected to implement forced wrong prices for which they should be compensated and responsibility of all for doing activity against the statutorily laid down position be fixed. 2ml Ampoule is a single dose pack and 10ml vial which contains 5 doses is a multiple dose pack and after the said statutory position has been laid down the cannot be clubbed together to work out average PTR and fixing single price prohibited by statute itself.
- (c) NPPA has been deliberately doing such acts which have no justification. They have been doing so on the ground that cost is not relevant under new policy. However, nothing moves without cost. At the same time there is no mandate in the NPPP-2012 to club together unlikes for the purpose of working out average PTR. In the instant case out of 17 packs, five dispensing packs in vials and 12 packs in Ampoule ready for use which are retailed for direct use have been taken for the purpose of working out average PTR of unlikes and PTR variance between two type of packs based on own working of NPPA is between Rs.2.27 per per ml to Rs. 6.79 per ml. When purpose of both type of packs is separate and such large is the difference in the PTR only an impractical man bent upon destroying everything can take the average. This clearly shows that there is no application of mind. This is an undesirable situation and Ministry should take cognizance of the same and stop/effectively intervene in such acts of NPPA which are contrary to the Policy as is clear from our submissions.
- (d) The petitioner company invited attention to Notification S.O.No.2209(E) dated 24th June, 2006. It would be seen that for Glucose Injection, Sodium Chloride injection and Sodium Chloride and Glucose injection different ceiling prices have been fixed for different packing materials used, quantity per pack and ceiling prices fixed are not only different but also show wide variations. This also shows that NPPA has been using its discretion which again is not a desirable situation. The notification against which we have filed review is dated 2<sup>nd</sup> June, 2016 showing thereby that discrimination is willful as well as contrary to the laid down Policy on 10<sup>th</sup> March, 2016.
- (e) The companies cannot afford to lose due to wrong acts of NPPA and as such these matters are required to be resolved once for all so that such type of pricing can be avoided.

NPPA representative submitted that the fixation of ceiling price per ml in respect of Ondansetron 2mg/ml Injectables has been made by the authority as per the existing practice and the provision of DPCO, 2013. Further IPCA has not made in representation in this regard.

#### **4. Examination:**

In the instant case, as regards the contention of the petitioner company that the average PTR has been worked out for unlike packs while fixing the ceiling price in respect of Ondansetron Injectables, and it should take into consideration retail packs only and not the dispensing packs. In this connection, attention is invited to the Ministry

of Chemicals & Fertilizers (Deptt. of Pharmaceuticals) notification No.SO 701(E), dated 10<sup>th</sup> March, 2016, wherein it is suggested that for injectable preparations, the single and multi-dose pack sizes be considered as separate entities for purposes such as procurement/ pricing etc. In this case, it is observed, on going through the calculation sheet, that NPPA has erred in fixing the ceiling price and taken into account the pack size of 10 ml also while averaging the price. Hence, Hearing Authority is of the view that NPPA should consider only the prices of retail packs and not dispensing packs of similar formulations while fixing the ceiling price of the subject formulation.

5. **Government Decision:**

**“NPPA is hereby directed to consider only the prices of retail packs and not dispensing packs of similar formulations and to re-fix the ceiling price of Ondansetron 2 mg/ml Injectables within a period of one month, on merits.”**

Issued on this date, the 22<sup>nd</sup> day of December, 2016.

**(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**