

No. 31015/9/2015-PLI
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS
(Pricing Division)

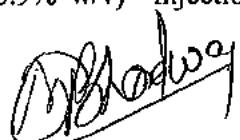
B Wing, 3rd Floor, Janpath Bhavan, New Delhi

ORDER BY REVIEWING AUTHORITY UNDER PARA.31 OF DPCO, 2013

Subject: Review Applications filed by various pharma companies against the ceiling prices fixed by National Pharmaceutical Pricing Authority (NPPA) vide their notifications S.O. No. 2863 (E) dated 20.09.2013 and S.O. No. 3127 (E) dated 10.12.2014 and S.O. No. 3131(E) dated 10th December, 2014 – reg.

Following Review Petitions have been filed under Para 31 of DPCO, 2013:-

- (i). Review petition dated 7.1.2015 filed by M/s Fresenius Kabi India Pvt. Limited against notification No. S.O. 3127(E) dated 10.12.2014 fixing ceiling price of scheduled medicine "Glucose (Dextrose) injection (5%w/v), Glucose (Dextrose) (5% w/v) + Normal Saline (Sodium Chloride) (0.9% w/v) Injection and Normal Saline (Sodium Chloride) injection (0.9%).
- (ii). Review petition dated 29.12.2014 filed by M/s Amanta Healthcare Pvt. Limited under para 31 of DPCO 2013 against notification No. S.O. 3127(E) dated 10.12.2014 fixing ceiling price of scheduled medicine "Dextrose injection (5%w/v), Sodium Chloride Injection (0.9%) and Sodium Chloride (0.9% w/v) and Dextrose (5% w/v) Injection"
- (iii). Review petition dated 18.10.2013 filed by M/s B.Braun Medical (India) Pvt. Limited (against notification No. S.O. 2863(E) dated 20.9.2013 fixing ceiling price of scheduled medicine "Ringer Lactate Injection".
- (iv). Review petition dated 8.1.2015 filed by M/s Claris Otsuka Pvt. Limited against notification No. S.O. 3127(E) dated 10.12.2014 fixing ceiling price of scheduled medicine "Glucose (Dextrose) injection (5%w/v), Glucose (Dextrose) (5% w/v) + Normal Saline (Sodium Chloride) (0.9% w/v) Injection and Normal Saline (Sodium Chloride) injection (0.9%).
- (v). Review petition dt. 7.1.2015 filed by M/s B. Braun Medical (India) Pvt. Limited against notification No. S.O. 3127(E) dated 10.12.2014 fixing ceiling price of scheduled medicine "Glucose (Dextrose) injection (5%w/v), Glucose (Dextrose) (5% w/v) + Normal Saline (Sodium Chloride) (0.9% w/v) Injection and Normal Saline (Sodium Chloride) injection (0.9%).
- (vi). Review petition dated 29.12.2014 filed by M/s Shree KrishnaKeshav Laboratories Limited against notification No. S.O. 3127(E) dated 10.12.2014 fixing ceiling price of scheduled medicine "Glucose (Dextrose) injection (5%w/v), Glucose (Dextrose) (5% w/v) + Normal Saline (Sodium Chloride) (0.9% w/v) Injection and Normal Saline (Sodium Chloride) injection (0.9%).
- (vii). Review petition dated 5.1.2015 filed by M/s Nirma Limited (Healthcare Division) against notification No. S.O. 3127(E) dated 10.12.2014 fixing ceiling price of scheduled medicine "Glucose (Dextrose) injection (5%w/v), Glucose (Dextrose) (5% w/v) + Normal Saline (Sodium Chloride) (0.9% w/v) Injection and Normal Saline (Sodium Chloride) injection (0.9%).



- (viii). Review petition dated 7.1.2015 filed by M/s Ahlcon Parenterals Limited against notification No. S.O. 3127(E) dated 10.12.2014 fixing ceiling price of scheduled medicine "Glucose (Dextrose) injection (5%w/v), Glucose (Dextrose) (5% w/v) + Normal Saline (Sodium Chloride) (0.9% w/v) Injection and Normal Saline (Sodium Chloride) injection (0.9%).
- (ix). Review petition dated 7.1.2015 filed by M/s AXA Parenterals Ltd. against notification No. S.O. 3127(E) and 3131 (E) dated 10.12.2014 and fixing ceiling price of scheduled medicine " Glucose (Dextrose) injection (5%w/v), Glucose Injection (10%), Glucose (Dextrose) (5% w/v) + Normal Saline (Sodium Chloride) (0.9% w/v) Injection and Normal Saline (Sodium Chloride) injection (0.9%).
2. Attention is invited to this Department's Order No. S.O. 1192 (E) dated 22.03.2016 published in the Gazette of India 'Extraordinary, which inter alia provides as under:

In the Drugs (Prices Control) Order, 2013 in Paragraph-11, after sub-paragraph (2), the following sub-paragraphs shall be inserted, namely :-

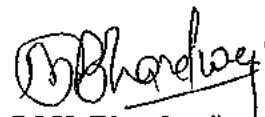
- "(3) Notwithstanding anything contained in sub-paragraphs (1) and (2), in the case of injections or inhalation or any other medicine for which dosage form or strength or both are not specified in the Schedule-I of the Drugs (Prices Control) Order, 2013, the Government may fix and notify separate ceiling price or retail price for such formulations with specific therapeutic rationale, considering the type of packaging or pack size or dosage compliance or content in the pack namely liquid, gaseous or any other form, in the unit dosage as the case may be, conforming to Indian Pharmacopoeia or other standards as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder for the same formulation.
- (4) The Government shall form a Committee of Experts, as it may deem fit, within a period of fifteen days from the date of issue of this order, to recommend fixing of separate ceiling price of scheduled formulations or retail price of a new drug as per the above parameters".

3. **Decision of the Government:-**

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

"Since the contents and issues are similar in all the above review petitions, these review petitions are disposed off with the instructions to NPPA to examine these cases in the light of this Department's Order No. S.O. 1192 (E) dated 22.03.2016."

Issued on this date of 5th May, 2016



(M.K. Bhardwaj)

Deputy Secretary (Pricing)

For and on behalf of the President of India

1. The Member Secretary,
National Pharmaceutical Pricing Authority,
YMCA Cultural Centre Building, New Delhi-110001
2. M/s Fresenius Kabi India Pvt. LTD, 5th Floor, A-Wing, Ashoka Plaza, Pune Nagar Road,
Survey No. 32/2, Vadgaon Sheri, Viman Nagar, Pune - 411014.

3. M/s Amanta Healthcare LTD, 5th Floor, Heritage, Nr. Gujarat Vidhyasapth, Ashram Road, Ahmedabad-380014.
4. M/s B.Braun Medical India Pvt. Ltd, 3rd Floor, 23/A Shivaji Marg, Najafgarh Road, New Delhi-110015.
5. M/s Claris Otsuka Pvt. Ltd, 5th Floor, Claris Corporate Head Quarters, Nr. Parimal Crossing Elisbridge, Ahmedabad - 380006 .
6. M/s B. Braun Medicals India Pvt. Ltd. 3rd Floor, 23/A Shivaji Marg, Najafgarh Road, New Delhi-110015.
7. Shree KrishnaKeshav Laboratories Ltd, Devashish, 3rd Floor, Near Hotel Klassic Gold, Off C,G, Road, Ahmedabad-380006
8. M/s Nirma LTD, Nirma House, Ashram Road, Ahmedabad-380009.
9. Ahlcon Parenteral (Inida) LTD, Unit NO. 201-205, ND Mall-1, 2nd floor Netaji Subhash Place, New Delhi - 110034.
10. M/s AXA Parenterals Ltd, C-268, 11th Floor, Opp. Vivekanand Mahila College, Vivek Vihar, Delhi - 110095.

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. PS to JS (SP)
4. T.D., NIC for uploading the order on Department's Website

