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Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

New Delhi, the 26th April, 2018

ORDER

S.O.1769(E) Whereas the National Pharmaceutical Pricing Authority(NPPA), Department of Pharmaceuticals, Ministry of Chemical and Fertilizers had fixed the ceiling price under paragraph 6 of the Drug (Prices Control) order 2013 of BCG Vaccine vide S.O. 3723(E) dated 23.11.2017 based on the Pharmatrac report of AIOCD –AWACS. The ceiling prices were revised on the basis of WPI vide SO 1461(E) dated 2.4.2018.

02. Whereas NPPA had uploaded the worksheet of draft ceiling price calculation on the website of NPPA and M/s Serum Institute of India Pvt Limited had submitted its representation, wherein it was claimed that

(i) reduction under para 6 has been carried out to the extent of 45.64% in 2014 and another further downward reduction of 20.024% in price would only render manufacturing of BCG vaccine unviable; and

(ii) the reduction is not applicable in this case as each vaccine has distinct therapeutic usage and criteria of reduction based on sub-therapeutic group cannot be applied to vaccines.

03. Whereas the Authority in the meeting dated 22.11.2017, whereby the Authority noted “M/s Serum has filed the application for repeat monopoly reduction in the ceiling price of BCG Vaccine and stated that the product will become unviable on reduction. M/s Serum Institute of India Ltd has represented against it. However, as the reduction applied in the draft ceiling price as per para 6 of the DPCO 2013, the Authority decided to notify the uploaded ceiling price of BCG vaccine at Rs. 4.32 per dose. As and when their detail application in para 19 is received, it will considered by the NPPA.”

04. Whereas M/s Serum Institute of India Pvt Limited has submitted its application under para 19 of the DPCO 2013 for revising the price upward.

05. Whereas the NPPA in its 188th Authority meeting held on 23.4.2018, decided that ceiling price may be fixed/revised under para 19 of the DPCO 2013 without applying reduction under monopolistic condition to address the grievance of the applicant as well as to ensure sufficient availability of the drug In the market.

06. Now, in exercise of the powers conferred by paragraphs 19 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S.O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby fixes/revises the prices as specified in column (5) of the table herein below as ceiling price exclusive of goods and services tax applicable, if any, in respect of the Scheduled formulations specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

Sl. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)
(1)	(2)	(3)	(4)	(5)
1.	BCG Vaccine		Each dose	5.59

Note:

- (a) All manufacturers of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.
- (b) The manufacturers may add goods and services tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.
- (c) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form-V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

- (d) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.
- (e) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.
- (f) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.
- (g) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.
- (h) This notification shall be valid for one year from the date of issue.
- (i) Consequent to the issue of ceiling price of such formulation as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

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F. No. 8(56)/2018/D.P./NPPA-Div.-II

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