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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

+ **W.P.(C) 6968/2024 & CM APPL. 29025/2024**

STRYKER INDIA PRIVATE LIMITED

..... Petitioner

Through: Mr. Amit Sibal, Sr. Advocate with
Ms. Krishna Sarma, Ms. Archita
Phookun and Mr. Shubhankar Gupta,
Advocates.

versus

UNION OF INDIA & ANR.

..... Respondents

Through: Ms. Arunima Dwivedi, CGSC with
Mr. Rahul Kumar Sharma, GP and
Ms. Pinky Pawar and Mr. Aakash
Pathak, Advocates.

CORAM:

HON'BLE MR. JUSTICE SUBRAMONIUM PRASAD

ORDER
20.05.2024

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1. The Petitioner has approached this Court challenging an Order dated 18.01.2024 passed by the National Pharmaceutical Pricing Authority (NPPA) directing the Petitioner to deposit a sum of Rs.1,23,47,100/- on the ground that the Petitioner has overcharged the amount and has violated Para 20(1) of the Drugs Price (Control) Order, 2013 in respect of 18 Triathlon Stem Parts covered under the category of 'Orthopaedic Implants' and is notified as 'Drugs' under the Drugs & Cosmetics Act, 1940.
2. By the impugned order, the Respondents have also directed the Petitioner to reduce the MRP to the level of 10% with effect from 2019 for a period of 12 months.
3. It is stated by learned Senior Counsel for the Petitioner that both the



directions are contrary to the Judgment dated 08.11.2023 passed by the Division Bench of this Court in Union of India & Anr. V. Bharat Serums and Vaccines Limited, LPA 118/2023. The Division Bench in the said Judgment has held as under:-

“64. In order to bring further clarity to the aforesaid interpretation of Para 20, the following illustrations may be referred to on how Para 20 of the 2013 DPCO may be interpreted in various instances. For the following illustrations, the consequences stated therein would be in addition to the penalty prescribed under Section 7 of the EC Act. Further, for the purpose of uniformity in the following illustrations, the MRP of the non-scheduled formulation manufactured by a manufacturer is taken to be Rs. 100/- on 01.02.2014. This would mean that on 01.02.2015, the MRP of the non scheduled formulation for the preceding twelve months is Rs. 100/-. Therefore on 01.02.2015, the manufacturer would be entitled to increase the MRP of the non-scheduled formulation to Rs. 110/-.

65. Keeping the aforesaid considerations in mind, the hypothetical illustrations to demonstrate the interpretation of Para 20 of the 2013 DPCO are as follows:

a. The manufacturer increases the MRP of the non-scheduled formulation to Rs. 110/- on 01.02.2015. Thereafter, on 01.02.2016, the manufacturer further increases the MRP to Rs. 121/-. In such a scenario, no penal consequences would ensue as the manufacturer has increased the MRP by 10% in accordance with Para 20 of the 2013 DPCO.

b. The manufacturer increases the MRP of the non-scheduled formulation to Rs. 110/- on 01.02.2015. He



then continues to increase the MRP by 10% on 01.02.2016 to Rs. 121/-, then further increases it to Rs. 133.1/- on 01.02.2017. Continuing this annual increase by 10%, the manufacturer increases the MRP to Rs. 146.41/- on 01.02.2018 and then to Rs. 161.05/- on 01.02.2019. On 01.02.2020 the MRP of the non-scheduled formulation is further increased to Rs. 177.16/-. In such a scenario, no penal consequences will follow. This is because, even though a 10% increase in MRP from Rs. 161.05/- comes to Rs. 177.155/-, the manufacturer is entitled to round off the said figure to two decimal places as per general mathematical practice.

c. Let us take the aforesaid example further, where the MRP is increased by 10% every year. The progression in such a case would be to Rs. 110/- on 01.02.2015; Rs. 121/- on 01.02.2016; Rs. 133.1/- on 01.02.2017; Rs. 146.41/- on 01.02.2018; Rs. 161.05/- on 01.02.2019; and to Rs. 177.16/- on 01.02.2020. On 01.02.2021, the manufacturer increases the MRP to Rs. 195/-. In such a case, the manufacturer is liable to roll back the MRP to Rs. 194.88/- from 01.02.2021 itself. This is because a 10% increase of Rs. 177.16/- comes to Rs. 194.876/-, which when rounded off to the nearest two decimal places would come to Rs. 194.88/-. Further, from 01.02.2021, the manufacturer is liable to deposit with the government the overcharged amount, i.e., the difference between Rs. 195 and Rs. 194.88, i.e., Rs. 0.12/-, along with interest.

d. The manufacturer, on 01.02.2015, increases the MRP of the nonscheduled formulation to Rs. 121/-. In such a case, the manufacturer is liable to reduce the MRP to Rs. 110/- from 01.02.2015 itself. Accordingly, on 15.02.2015, the manufacturer reduces the MRP to Rs. 110/-. In such a case, the manufacturer will be



required to keep the MRP at Rs. 110/- till 31.01.2016, i.e., till the next 12 months from the date of the transgression. The manufacturer will also be liable to deposit the amount overcharged, i.e., Rs. 11/-, between 01.02.2015 and 15.02.2015, along with interest.

e. The manufacturer increases the MRP of the non-scheduled formulation to Rs. 105/- on 01.02.2015. In such a case, no consequences would ensue as the increase in MRP is not above 10% of the MRP during the preceding twelve months. It is not necessary for a manufacturer to increase the MRP of the non-scheduled formulation to the maximum permissible increase of 10%, i.e., Rs. 110/- in the present scenario.

f. The manufacturer on 01.02.2015 maintains the MRP of the non-scheduled formulation at Rs. 100/-. Thereafter on 01.05.2015, the manufacturer increases the MRP of the non-scheduled formulation to Rs. 105/-. This is permissible as the MRP increase is less than 10% of the MRP during the preceding twelve months. If the manufacturer then on 01.02.2016 again increases the MRP of the non-scheduled formulation to Rs. 110/-, the same would not be permissible. This is because the manufacturer is required to preserve the increase in MRP for the next twelve months. The manufacturer in this case would be under an obligation to revert the MRP to Rs. 105/- from 01.02.2016 and also be liable to deposit the overcharged amount along with interest from 01.02.2016.

g. The manufacturer increases the MRP of the non-scheduled formulation to Rs. 105/- on 01.02.2015. In such a case, on 01.02.2016, the manufacturer would be entitled to increase the MRP up to Rs. 115.5/-. This



is because the MRP in the preceding twelve months from 01.02.2016 is Rs. 105/- and a 10% increase of Rs. 105/- would be Rs. 115.5/-. In such a case the manufacturer would not be entitled to charge Rs. 121/-, i.e., a 10% increase of Rs. 110/-. This is because the MRP increase permissible on 01.02.2016 is based on 10% of the actual MRP for the preceding twelve months (Rs. 105/-), and not based on 10% of the permissible MRP for the preceding twelve months (Rs. 110/-). In the aforesaid illustration, if the manufacturer on 01.02.2016 increases the MRP of the non-scheduled formulation to Rs. 121/- then from the date of the MRP increase i.e., 01.02.2016, the manufacturer is liable to reduce the MRP to Rs. 115.5/-, i.e., the permissible 10% increase, till 31.01.2017. From 01.02.2016 itself, the manufacturer will also be liable to return the amount overcharged, i.e., the difference between Rs. 121/- and Rs. 115.5/-, i.e., Rs. 5.5/-, along with interest.

h. On 01.02.2015, the manufacturer increases the MRP to Rs. 121/-. Then the manufacturer is liable to reduce the MRP to Rs. 110/- from 01.02.2015 itself. However, the manufacturer does not do so, and continues to keep the MRP at Rs. 121/- till 31.01.2017. In such a scenario, the manufacturer is liable to deposit the amount overcharged between 01.02.2015 and 31.01.2016, i.e., Rs. 11/-, along with interest. However, the manufacturer will not be liable to deposit any amount for the period of 01.02.2016 and 31.01.2017. This is because, the manufacturer is liable only to keep the MRP at Rs. 110/- for the period between 01.02.2015 and 31.01.2016. The manufacturer is entitled to increase the MRP to Rs. 121/- from 01.02.2016.

i. The manufacturer increases the MRP to Rs. 135/- on 01.02.2015. The manufacturer is liable to reduce



the MRP to Rs. 110/- from 01.02.2015 itself. The manufacturer however does not do so till 31.01.2018. In such a case, the liability of the manufacturer to deposit the overcharged amount will be: (i) Rs. 25/- for the period between 01.02.2015 to 31.01.2016; (ii) Rs. 14/- for the period between 01.02.2016 to 31.01.2017; and (iii) Rs. 1.9/- for the period between 01.02.2017 till 31.01.2018. On 01.02.2018, the manufacturer would be entitled to keep the MRP of the formulation as Rs. 135/- and he would be entitled to increase the MRP up to Rs. 148.5/- on 01.02.2019, i.e., a 10% increase from Rs. 135/-, which would be the MRP prevailing for the previous twelve months.

j. On 01.02.2015, the manufacturer increases the MRP to Rs. 121/-. Thereafter on 01.02.2016, the manufacturer increases the MRP to Rs. 133.1/-. In such a case, from 01.02.2015, the manufacturer is liable to reduce the MRP to Rs. 110/- from 01.02.2015 till 31.01.2016, and then reduce the MRP to Rs. 121/- from 01.02.2016 till 31.01.2017. Accordingly, the liability of the manufacturer to deposit the overcharged amount will be: (i) Rs. 11/- for the period between 01.02.2015 and 31.01.2016; and (ii) Rs. 12.1/- for the period between 01.02.2016 and 31.01.2017. In this case, even though the manufacturer increased the MRP by 10% on 01.02.2016 from Rs. 121/- to Rs. 133.1/-, he would not be entitled to do so as the prior increase was itself in contravention of Para 20 of the 2013 DPCO. In such a situation, where the MRP for the previous twelve months is itself in contravention of Para 20 of the 2013 DPCO, the manufacturer will only be entitled to increase the MRP on the basis of the MRP the manufacturer was entitled to keep for the previous twelve months. Therefore, in the present case, as the manufacturer was only entitled to increase the MRP to Rs. 110/- on 01.02.2015, he could not be permitted



to increase the MRP to Rs. 133.1/- on 01.02.2016, but only to Rs. 121/-. The manufacturer would be entitled to increase the MRP to Rs. 133.1/- only on 01.02.2017.

66. *To summarize:*

A. The 2013 DPCO, unlike the 1995 DPCO, only applies to drug formulations and not to bulk drugs. Further, the 2013 DPCO envisages a price control mechanism for scheduled drug formulations a price monitoring mechanism for non-scheduled formulations. The Government under the 2013 DPCO has the power to fix and revise prices of scheduled formulations only and in respect of non-scheduled formulations, the Government can only monitor the change in MRP of non-scheduled formulations. Therefore, under the 2013 DPCO, non-scheduled formulations do not form part of the price control regime but is a part of a price monitoring mechanism as envisaged under NPPP 2012. B. Para 20 of the 2013 DPCO is divided into two separate and identifiable parts. The first part provides that a manufacturer of a non-scheduled formulation may increase its MRP by 10% of the MRP during the preceding twelve months, preserve the said MRP for the next twelve mo

nths and casts an obligation upon the Government to monitor the increase in MRP of such non scheduled formulation. The second part of Para 20 of the 2013 DPCO deals with the consequences of a transgression by a manufacturer, if it increases the MRP of a non-scheduled formulation beyond 10% of the MRP during the preceding twelve months.

C. The price monitoring mechanism established for non-scheduled formulations under 2013 DPCO gives



paramount consideration to public/consumer interest and is in line with the object of the 2013 DPCO to ensure equitable distribution of drugs at a fair price.

D. Para 20 of the 2013 DPCO, as a whole cannot be said to be a penal provision. The term “penalty” used in Sub Para (2) of Para 20 of the 2013 DPCO refers to the penalty provided for under Section 7 of the EC Act, i.e., the parent legislation of the 2013 DPCO.

E. The phrase “preceding twelve months” in Para 20 of the 2013 DPCO means the time period of twelve months immediately prior to the date when the MRP of the non-scheduled formulation was increased. Similarly, the phrase “next twelve months” in Para 20 of the 2013 DPCO means the time period of twelve months immediately after the date when the price of the non-scheduled formulation was increased. Consequently, the date of transgression of Para 20 of the 2013 DPCO must mean the date from which a manufacturer has increased the MRP of a non-scheduled formulation by more than 10% in a period of twelve months.

F. A conjoint reading of Para 20 and Para 23 of the 2013 DPCO indicates that the date of transgression of Para 20 of the 2013 DPCO cannot mean the date on which a demand notice is issued to the manufacturer, but must be read to mean the date on which the manufacturer has increased the MRP of a non-scheduled formulation by more than 10% in a period of twelve months.

G. The consequences that ensue upon a transgression of Para 20 of the 2013 DPCO are: i. The manufacturer may be subject to penalty as prescribed under Section 7 of the EC Act. ii. The manufacturer is liable to reduce the MRP of such nonscheduled



formulation to the level of the 10% increase of MRP permissible, for the next twelve months. The obligation of the manufacturer to reduce the MRP for the next twelve months arises from the date on which the MRP was increased beyond 10%. iii. The manufacturer is liable to deposit the amount overcharged along with interest with the Government. The date from which the liability of a manufacturer to deposit the amount overcharged is the date from which the price of the non-scheduled formulation has been increased beyond the 10% increase permissible. The amount overcharged shall be calculated as the difference between the “actual increase in MRP” and “permissible increase in MRP”.

H. The benefit of rounding off as given in Para 5.2 of the NPPA's Minutes of the Meeting dated 12.04.2016 must be extended to non scheduled formulations as well. Limiting the benefit of rounding off provided therein, only to scheduled formulations is unreasonable and arbitrary.

I. The benefit of rounding-off is permitted only up to two decimal points as per general mathematical practice and only when non other mala fide intention on part of the company is evident. The mechanism for rounding-off as provided under the LMPC Rules is not applicable to drug formulations under the 2013 DPCO.

J. It is not necessary for a manufacturer to increase the MRP of the non-scheduled formulation to the maximum permissible increase of 10% in a year.

K. The 10% increase in MRP permissible under Para 20 of the 2013 DPCO must be calculated on the basis of the actual MRP of the non-scheduled formulation in the preceding twelve months and not on the basis



of what was the MRP permissible for the preceding twelve months.”

4. In view of the decision rendered by the Division Bench of this Court in Bharat Serums (supra), the impugned order is set aside. The Respondents are directed to re-calculate the amounts in the mode and manner prescribed by the Division Bench in Bharat Serums (supra). After the amount is calculated, the excess amount is directed to be refunded back to the Petitioner. This exercise be concluded within a period of six weeks from today in terms of Section 7 of the Essential Commodities Act.
5. The writ petition is allowed in above terms, along with pending application(s), if any.

SUBRAMONIUM PRASAD, J

MAY 20, 2024
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