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

Date of decision: 08th NOVEMBER, 2023

IN THE MATTER OF:

\+ **LPA 118/2023 & C.M. No. 7868/2023, C.M. No. 7871/2023**

UNION OF INDIA & ANR. ..... Appellant

Through: Mr. Kirtiman Singh, CGSC with Ms. Manmeet Kaur Sareen, Ms. Vidhi Jain, Advocates

versus

BHARAT SERUMS AND VACCINES LIMITED ..... Respondent

Through: Mr. Rohan Shah, Mr. Alok Yadav and Ms. Srisabari Rajan, Advocates.

\+ **LPA 229/2023 & C.M. No. 16268/2023, C.M. No. 16271/2023**

UNION OF INDIA & ANR. ..... Appellant

Through: Mr. Kirtiman Singh, CGSC with Ms. Manmeet Kaur Sareen, Ms. Vidhi Jain, Advocates

versus

CIPLA LIMITED ..... Respondent

Through: Ms. Archana Sahadeva, Advocate.

\+ **LPA 119/2023 & C.M. No. 7877/2023, C.M. No. 7880/2023**

UNION OF INDIA & ANR. ..... Appellant

Through: Mr. Kirtiman Singh, CGSC with Ms. Manmeet Kaur Sareen, Ms. Vidhi Jain, Advocates

versus

BHARAT SERUMS AND VACCINES LIMITED ..... Respondent

Through: Mr. Rohan Shah, Mr. Alok Yadav and Ms. Srisabari Rajan, Advocates.

\+ **LPA 142/2023 & CAV No. 115/2023, C.M. No. 9265/2023, C.M. No. 9268/2023**

UNION OF INDIA ANR & ANR. ..... Appellant

Through: Mr. Kirtiman Singh, CGSC with Ms.

Manmeet Kaur Sareen, Ms. Vidhi Jain, Advocates

versus

BARD HEALTHCARE INDIA PVT. LTD. ..... Respondent
Through: Ms. Krishna Sarma, Mr. Kumar and Ms. Archita Phookun, Advocates.

\+ **LPA 227/2023 & C.M. No. 16242/2023, C.M. No. 16245/2023**

UNION OF INDIA & ANR. ..... Appellant
Through: Mr. Kirtiman Singh, CGSC with Ms. Manmeet Kaur Sareen, Ms. Vidhi Jain, Advocates

versus

POLY MEDICURE LTD ..... Respondent
Through:

CORAM:
HON'BLE THE CHIEF JUSTICE
HON'BLE MR. JUSTICE SUBRAMONIUM PRASAD

JUDGMENT

1. The instant batch of letters patent appeals ("**LPAs**"), being LPA Nos. 118/2023; 119/2023;142/2023; 227/2023; and 229/2023,have been filed impugning judgments passed in W.P.(C) Nos. 7946/2018; 8190/2018; 9090/2020; 2521/2021; and 3358/2020 ("**Underlying Writ Petitions**") dated 22.09.2022 (common judgment passed in W.P.(C) Nos. 7946/2018; 8190/2018 and 9090/2020); 04.11.2022 (judgment in W.P.(C) 2521/2021); and 06.10.2022 (judgment in W.P.(C) 3358/2020) respectively.The UnderlyingWrit Petitions came to be filed by the Respondents herein, which are pharmaceutical companies, assailing the demand notices issued to them by the National Pharmaceutical Pricing Authority ("**NPPA**"), holding the Respondents guilty of overcharging consumers for certain drug formulations manufactured by them, in contravention of Paragraph 20 ("**Para 20**") of the

Drugs (Price Control) Order, 2013 ("**2013 DPCO**"). The Learned Single Judge allowed all the underlying writ petitions, and the Appellants herein have preferred a challenge to the same by way of the instant LPAs submitting that the learned Single Judge has erred in interpreting Para 20 of the 2013 DPCO and has failed to capture its true essence.

2. At this point, it would be apposite to reproduce Para 20 of the 2013 DPCO which reads as under:

> *"20.* ***Monitoring the prices of non-scheduled formulations.–*** *(1) The Government shall monitor the maximum retail prices (MRP) of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months.*
>
> *(2) The manufacturer shall be liable to deposit the overcharged amount along with interest thereon from the date of increase in price in addition to the penalty."*

3. A bare perusal of Para 20 of the 2013 DPCO shows that the same is divided into two separate and identifiable parts. The first part provides that a manufacturer of a non-scheduled formulation may increase the maximum retail price ("**MRP**") of such non-scheduled formulation by 10% of the MRP during the preceding twelve months and preserve the said MRP for the next twelve months. It also casts an obligation upon the Government to monitor the increase in MRP of such non-scheduled formulation so that the MRP is not increased over 10% in the succeeding year or in the same year. 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.

4. The Appellants in the instant appeals have confined themselves to the issue regarding interpretation of Para 20 of the 2013 DPCO and therefore this Court is not traversing into the facts of each case and limiting itself to the question regarding the interpretation of Para 20 of the 2013 DPCO. Suffice it to say that the Respondents herein (Petitioners before the learned Single Judge) had approached this Court *vide* the Underlying Writ Petitions challenging various demand notices issued to them by the Appellants for transgression of Para 20 of the 2013 DPCO.

5. The Ld. Single Judge, after hearing the parties at length and perusing the record, passed a detailed judgment dated 22.09.2022 in W.P.(C) 7496/2018, W.P.(C) No. 8190/2018 and W.P.(C) No. 9090/2020, which was followed in judgment dated 06.10.2022 passed in W.P.(C) No. 3358/2020 and judgment dated 04.11.2022 passed in W.P.(C) No. 2521/2021.The conclusions arrived at by the learned Single Judge in its judgment dated 22.09.2022 are reproduced as under:

> *97. Having traversed the issues which were raised in this batch, the Courtcomes to record the following conclusions: -*
>
> *A. The 2013 DPCO represents a conscious decision taken by theUnion to leave the price of non-scheduled formulations to bedetermined by market forces subject to the rider that the annualincrease would not exceed 10% and in case of overcharging themanufacturer would have to roll back the prices to the precedinglegally permissible price and preserve it at that level for the nexttwelve months.*

B. Viewed in that backdrop it is evident that a manufacturer of a nonscheduled formulation was entitled to fix the price of its drugsubject to the singular fetter of the same being compliant with thestipulation of 10% which was sanctioned.
C. Undisputedly, non-scheduled formulations are not subject to therigors of price control under the 2013 DPCO. That provision simplyplaces an obligation upon the Government to monitor and overseethat the maximum retail price of such formulations does not exceed10% of the price which was prevailing in the preceding twelvemonths. The salutary objective underlying this prescription isclearly manifest bearing in mind the fact that drug prices mustnecessarily be regulated by the Government in order to ensure thatpatients and consumers do not face the specter of runaway priceincreases and to control profiteering.

D. However, Para 20 undoubtedly permits a manufacturer to increasethe maximum retail price annually subject to the singular limitationthat the price increase would not exceed 10% of the price whichwas prevailing in the preceding twelve months. The consequencesof a breach of the aforesaid prescription is also not left open tospeculation with Para 20 in clear and unequivocal terms prescribingthe penalty as well as the remedial measures which must beadopted.

E. Significantly, Para 20 does not envisage a deprivation of the right toincrease the retail price of a drug annually in case of overcharging.Para 20 spells out and stipulates both the consequences as well asthe penalties which would visit a manufacturer in case it were toviolate its provisions. The stand taken by the respondents to theeffect that the right to seek such increase would stand lost till suchtime as the price is revised and brought down, would not onlyamount to a recasting of Para 20, it would also and on morefundamental terms, result in the introduction of a

penalconsequence which neither flows from a plain reading of thatprovision nor can be inferred.

F. The crucial expressions which would throw light on the intent ofPara 20 are the expressions "preceding" and "next". The word "preceding" acts as a pointer to the date or the period which wouldconstitute the focal point to identify the legally permissible MRPwith reference to which an infraction is liable to be examined. Theword "next" denotes and prescribes the period during which theMRP of the formulation must be kept static after being rolled back.For the purposes of identifying the valid MRP against which aperiodic 10% increase may be claimed, it is the price prevailing inthe preceding year which would govern and decide.

G. Similarly, the period during which the MRP must be revised andkept on hold is also prescribed to be the next twelve months whencomputed with reference to the date or period of the infraction.Both the commencement as well as the termination of the periodduring which the MRP must remain frozen has to be necessarilycomputed with reference to the date or the period during which themanufacturer may have overcharged.

H. While the Court is conscious of the fact that the issues involvedhere relate to drugs and the paramount consideration of the saidessential commodity being sold and distributed in a fair andequitable manner, it finds itself unable to introduce in or read intoPara 20 a penal consequence which has otherwise not beenincorporated by the authors of the statute. It is not for this Court tostructure or insert a penal consequence on its own understanding ornotions of righteousness.

I. Para 20 therefore must be read as providing a right to manufacturersof non-scheduled formulations to price their products subject to therider that the

increase complies with the 10% stipulation. That rightof the manufacturer would be entitled to be factored innotwithstanding it having transgressed the latter part of Para 20 andovercharged.

J. The increase of 10% shall stand effaced only for the period oftwelve months post the transgression of Para 20 where amanufacturer may have overcharged and violated that provision.

K. In case of a violation of Para 20 and an overcharging event havingoccurred, the manufacturer would be liable to roll back the price ofthe drug to the level at which it stood prior to the transgression andhold that price for twelve months post the date or the period ofovercharge.

L. For the purposes of computing the liability that would stand raisedin the case of an overcharging, the NPPA would be obliged toidentity the date or the period during which the price of the drugtransgressed Para 20 and require the manufacturer to revert to theprice which prevailed prior to that event for a period of twelvemonths.

M. However the liability to roll back the price of the drug and keep itstatic at that level cannot extend beyond the twelve month periodprescribed under Para 20 and continue up to the raising of a demandor till such time as the transgression is cured. The manufacturer inany case cannot be held liable to keep the price frozen for theperiod between the date or period of infraction till the date ofraising of a demand or till the infraction is rectified by themanufacturer itself.

N. While calculating the liability relating to overcharge, the NPPA would have to take into consideration the legally permissible pricewhich must be enforced over the next twelve months

commencingfrom the date or period of infraction, even if that may entail anotional computational exercise being undertaken.

O. In a case where the infraction is discovered many years down theline, in order to arrive at the actual liability owed, the authoritywould have to reverse the clock and calculate backwards in order toascertain the legally permissible MRP which is to be enforced andthe period of twelve months during which that price must bepreserved.

P. However, for successive periods post the "next twelve months", themanufacturer would be entitled to claim the 10% increase which isotherwise sanctioned by virtue of the first part of Para 20. Thecomputation of liability would have to necessarily factor that intoconsideration while notionally computing the ultimate overchargeamount.

Q. Para 20 has been worded in a manner which is starkly distinct fromPara 13. Para 20(1) clearly appears to put in place a self-regulatorymechanism which obligates the manufacturer to ensure that theprice that it fixes for non-scheduled formulations does not exceed10% of the price prevailing in the preceding twelve months. Thepenalty which would visit a manufacturer in case of a violation ofthe aforesaid provision is clearly and unambiguously spelt out inthat provision itself when it stipulates that in case a manufacturerbreaches the maximum permissible increase of 10%, it would beunder an obligation to deposit the amount overcharged in excesstogether with interest.

R. Significantly, the compliance with the aforesaid prescriptions is notmade dependent upon or subject to an order being made by theNPPA. What places Para 20 in a position distinct from Para 13 ofthe 1995 DPCO is that unlike the latter which envisages

interestbeing leviable from the date when a manufacturer fails to complywith a demand, the former is not premised on a demand beingraised at all. Under Para 20, the manufacturer becomes liable totake steps for reparation the moment an event of overchargingoccurs. The trigger event under Para 20 is thus the act ofovercharging itself.

S. Sub Para (2) in clear and unequivocal terms mandates that interestshall be payable on the overcharged amount from the date ofincrease in price. The expression ―date of increase in price‖ mustnecessarily be understood to be a categorical reference to the dateor the period from which interest is ordained to be leviable. Para20(2) thus appears to leave no room for doubt that interest has tobepaid from the date of increase of such price.

T. Para 20 neither contemplates the issuance of a notice nor does itadopt the principle of amount "accrued" as was envisaged under the1995 DPCO. T.C. Healthcare and all judgments which followedthereafter were essentially construing the provisions of Para 13 ofthe 1995 DPCO. However, the trigger point in terms of Para 20 isnot a notice or a demand but the event of overcharging itself.Secondly, sub para (2) in unequivocal terms prescribes that theinterest shall be leviable from the date of increase of price. Thelanguage of Para 20(2) thus leaves no room to introduce the conceptof a notice of demand being the precursor to the liability to depositthe overcharged amount along with interest.

U. The liability to pay amounts which are due together with interest isrelated to any sums that may be recoverable in pursuance of anyorder made under Section 3 of the Act. The 2013 DPCO, and ofwhich Para 20 is an integral part, is itself an order made underSection 3 of that Act. Thus, the liability to pay interest from thedate of increase of price which stands

created in light of Para 20 isitself liable to be recognised as one created in terms of an ordermade under Section 3 itself. The Court thus finds itself unable tointerpret Section 7A(1)(a) as stultifying the command of Para 20.

V. Bard did not dispute that medical devices did fall within thedefinition of ―drug‖ and would thus fall within the ambit of nonscheduled formulations under Para 20. Consequently, merelybecause the respondent did not call upon these manufacturers tosubmit a price list in a particular format, would not absolve Bardfrom their obligation to ensure compliance with Para 20. Bard inany case cannot assert that it was unaware of the legal obligation tobe compliant with Para 20. The reporting mechanism which wasdeveloped by NPPA in 2017 was only to aid them in the task ofmonitoring the price of non-scheduled formulations.

W. The Court has borne in mind that insofar as non-scheduledformulations are concerned, the NPPA only exercises the power tomonitor their prices. Having freed this category of manufacturersfrom the rigors of price control, there appears to be no justificationto restrict the applicability of the rounding off principle toscheduled formulations only.

X. The Court finds no justification in the stand taken by therespondents who contend that while it would be open for amanufacturer of a scheduled formulation to round off the price ofits products, that benefit should be denied to manufacturers of nonscheduled formulations. Once the NPPA had arrived at theconclusion that rounding off was a well-accepted mathematicalprinciple, the Court finds no justification to discriminate betweenscheduled and non-scheduled formulations.

Y. Depriving manufacturers of non-scheduled formulations of thefacility of rounding off which is

> *otherwise and generally acceptedby the NPPA itself as a well-recognized mathematical practicewould be manifestly arbitrary. The respondents have failed to pointout any justifiable or rationale basis on account of which theprinciple of rounding off would not apply to non-scheduledformulations."*

6. The learned Single Judge has observed that the 2013 DPCO does not envisage that non-scheduled formulations are subject to the rigors of price control. It was observed that Para 20 of the 2013 DPCO contemplates that the MRP of non-scheduled formulations is to be determined by market forces and is subject to the rider that the annual increase would not exceed 10%, and in case it exceeds 10%, the manufacturer has to roll back the MRP to the permissible MRP under the DPCO and keep it at that level for the next twelve (12) months. Para 20 of the 2013 DPCO merely places an obligation upon the Government to monitor and oversee that the MRP of non-scheduled formulations does not increase by more than 10% in an year.

7. The learned Single Judge also observed that the consequences of a breach of the aforesaid prescription are not left open to speculation and Para 20 of the 2013 DPCO in clear and unequivocal terms prescribes the penalty as well as the remedial measures which must be adopted by the manufacturers and the Government. The learned Single Judge held that Para 20 of the 2013 DPCO does not envisage a deprivation of the right to increase the MRP of a drug annually in case of overcharging. The Court arrived at this conclusion by taking note of the expressions "*preceding*" and "*next*" used in the provision. It was further observed that in case of overcharging the period during which the MRP must be revised and preserved by a manufacturer, is prescribed to be the next twelve months from the date of the infraction. The date of infraction was held not be the

date on which a demand notice is served to the manufacturer, but the date from which the MRP was increased beyond the permissible 10% limit prescribed.

8. It was observed by the learned Single Judge that in case where an infraction is discovered many years down the line, in order to arrive at the actual liability owed, the authority will have to calculate backwards, to ascertain the legally permissible MRP which is to be enforced and the period of twelve months during which that MRP must be preserved.

9. It was further observed by the learned Single Judge that there is a stark difference in Para 20 of the 2013 DPCO and Paragraph 13 ("**Para 13**") of the Drugs (Price Control) Order, 1995 ("**1995 DPCO**"). It notes that the latter envisages interest to be payable from the date when a manufacturer fails to comply with the demand notice, whereas the former mandates that interest is payable on the overcharged amount from the date of overcharging.

10. The Learned Single Judge notes that as the NPPA only exercises the power to monitor the MRP of non-scheduled formulations. In this vein, it observed that there was no justification to restrict the applicability of the rounding off principle to scheduled formulations only. Once the NPPA has concluded that rounding off was a well-accepted mathematic principle, there are no reasons to apply the principle in a discriminatory manner to scheduled and non-scheduled formulations. Depriving manufacturers of non-scheduled formulations to apply the principle was held to be manifestly arbitrary by the learned Single Judge.

11. It is in the aforestated background that the Union of India and NPPA have approached this Court, submitting that the learned Single Judge has erred in its interpretation of Para 20 of the 2013 DPCOand has failed to

capture the true intent behind the same, which the Appellants assert, is to safeguard the interests of the consumer which is paramount. The Appellants have clarified that they are not challenging in the instant LPAs, the observations made by the learned Single Judge regarding the interest payable by a manufacturer for overcharging.

12. Mr. Kirtiman Singh, Central Government Standing Counsel appearing on behalf of the Appellants submits that the 2013 DPCO has been issued by the Central Government in exercise of powers conferred on it under Section 3 of the Essential Commodities Act, 1955 ("**EC Act**"), the heading of which reads "Powers to control production, supply, distribution, etc., of essential commodities". He submitsthat 'drug' is an essential commodity in terms of Item No. 1 of the Schedule to the EC Act.Mr. Singh submits that that in matters concerning the procurement and availability of essential medicines and drugs, the interest of the consumer/public is paramount, and the regulatory regime must be construed accordingly. It was submitted that the element of public/consumer interest is all pervasive and ubiquitous element of the EC Act and the 2013 DPCO.In support of this submission, he relies upon the judgments delivered by the Hon'ble Supreme Court in Meenakshi Mills v. Union of India, (1974) 1 SCC 468 and Prag Ice & Oil Mills v. Union of India (1978) 3 SCC 459, wherein the Apex Court observed that profiteering and revenue earned by the producer of an essential commodity cannot be kept is not the paramount consideration and doing so would cause the element of equitable distribution and availability of the commodity at a fair price would be lost which would be contrary to the dominant objective of the Act.

13. Mr. Singh places reliance upon the judgment delivered by the Apex Court in Union of India v. Cynamide India, (1987) 2 SCC 720 in which, the

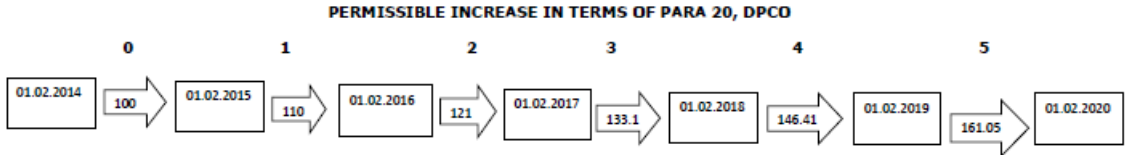
Court while dealing with a case under the Drugs (Price Control) Order, 1979, referred to profiteering in scarce resources like lifesaving drugs as 'diabolic' which are required to be fettered and curbed. The said judgment was followed by the Apex Court in GlaxoSmithkline v. Union of India, (2014) 2 SCC 753, wherein the Apex Court observed that price fixation under the DPCO is in the nature of a legislative measure, the dominant objective of which is to ensure equitable distribution and availability of commodities at a fair price. It was submitted that the Judgment in GlaxoSmithkline (supra) has been followed in Union of India v. CIPLA, (2017) 5 SCC 262.

14. It is submitted by Mr Singh that the aforesaid judgments firmly establishes that the Appellants are not just empowered but obligated to implement the provisions of the 2013 DPCO keeping in mind the underlying objective and all-pervasive foundation of the 2013 DPCO and EC Act,which is to act in furtherance of consumer interest by making sure life-saving drugs are equitably distributed and made available at a fair price. He therefore submits that Para 20 of the 2013 DPCO aims to curb unreasonable profiteering by the manufacturers which would be detrimental to the interests of the public/consumer.

15. It is further submitted by Mr. Singh that non-scheduled drugs are not outside the purview of the Price Control regime established under the EC Act and 2013 DPCO, and the objective of Para 20 is to act as a deterrent to the manufacturers from acting contrary to the interests of consumers/public. It is his submission that the fact that Para 20 finds a place in 2013 DPCO is an indicator that non-scheduled drugs were not intended to be taken out of the price control regime. He submits that even if no MRP is fixed and revised by the Government for a non-scheduled drug, it cannot mean that the

same is not subject to the price control mechanism. He contends that the Government's power to monitor MRP under Para 20 means that non-scheduled formulations are subject to price control.

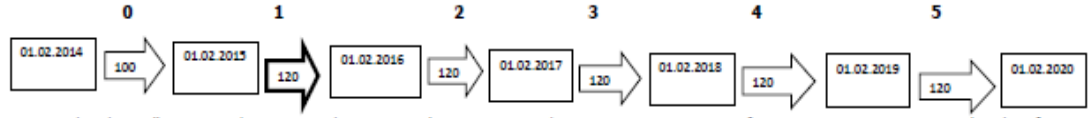
16. Mr. Singh has drawn the attention of this Court to an illustration to highlight how the MRP of a non-scheduled formulation increases as per Para 20 of the 2013 DPCO in the event there is no transgression. The illustration is reproduced as under:



He submits that in a situation where the MRP of a non-scheduled formulation is Rs. 100/- in 01.02.2014, then the manufacturer is entitled to increase the MRP of such non-scheduled formulation to Rs. 110/- after twelve months, i.e., 01.02.2015. Similarly, the manufacturer is entitled to increase the MRP of such non-scheduled formulation to Rs. 121/- in 01.02.2016 and so on, as shown in the illustration. He submits that this is how Para 20 of the 2013 DPCO is intended to work.

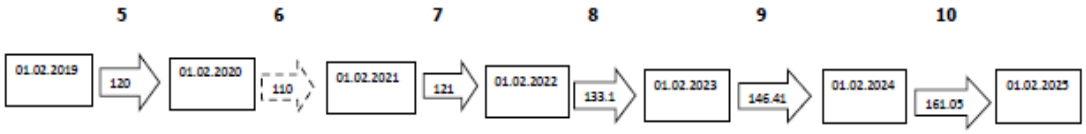
17. After highlighting the manner in which Para 20 of the 2013 DPCO is ideally supposed to operate, Mr. Singh has relied upon a chart to showcase the consequences of a violation of Para 20 of 2013 DPCO, as per the Appellants, which is extracted herein below:

ILLUSTRATION:



In the above illustration, the company has increased its price more than 10 per cent in terms of Para 20, DPCO in year 1, and is therefore in default from year 1 itself.

Consequently, the company would continue to be in violation of Para 20 till this default is cured. In terms of Para 20, the clock would be set back to the year of the default and the company could need to maintain the permissible price for the next one year. In the above example, if the default is cured in year 6 by the company it would need to go back to the price of year 1 and maintain it for the next one year. This can be demonstrated by the following chart:



18. Mr. Singh submits that the manner in which the terms '*preceding*' and '*next*' as used in Para 20 of the 2013 DPCO have been interpreted by the learned Single Judge is erroneous**.** By referring to the chart Mr. Singh submits that if the MRP of a particular non-scheduled formulation is fixed at Rs. 100/-in 01.02.2014, and if instead of increasing the MRP of such non-scheduled formulation to Rs. 110/- in 01.02.2015, it is fixed by the manufacturer at Rs. 120/-, and there is no further increase in the MRP of such non-scheduled formulation till 01.02.2020, then if the transgression is found in 01.02.2020, then from that date i.e., 01.02.2020, the manufacturer would be required to revert the MRP of such non-scheduled formulation to Rs. 110/-, i.e., the increase in MRP permissible for 01.02.2015, and keep it at the said MRP till 01.02.2021. He further submits that the manufacturer would not be entitled to the benefit of Para 20 of the 2013 DPCO for the five years where the MRP of the drug has not increased, i.e., from 01.02.2015 to 01.02.2020. He submits that after the MRP has been reverted to Rs. 110/- after the discovery of the transgression in 01.02.2020, the manufacturer would only be entitled to increase the MRP of such non-scheduled formulation by 10% of Rs. 110/- i.e., Rs. 121/- from01.02.2021.

19. Mr. Singh further submits that there is no right contemplated under Para 20 of the 2013 DPCO and the same only contemplates a restriction. He relied upon a judgment delivered by a Single Judge of this Court in Alembic Pharmaceuticals, 2019 SCC OnLine 7040 buttress this submission. He submits that in the said case, it has been observed that Para 20 of the 2013 DPCO imposes a restriction on the manufacturer to increase the MRP of drugs only as stipulated in Para 20.

20. It is vehemently submitted by Mr. Singh that Para 20 of the 2013 DPCO is penal in nature. He argues that there are three penal consequences that ensue in case a manufacturer increases the MRP of a non-scheduled formulation beyond the permissible limits of Para 20 of the 2013 DPCO. *Firstly*, the manufacturer would be required to reduce the MRP to the permissible level; *secondly*, it would be required to deposit the overcharged amount from the date of increase in MRP "… in addition to the penalty"; and *thirdly*, it would be required to deposit the interest on the overcharged amount from the date of increase in MRP "… in addition to the penalty". It is his submission that if a manufacturer is permitted to go on increasing the MRP, even after benefitting from charging an MRP beyond the permissible limit, the purpose behind Para 20 of the 2013 DPCO will be defeated.

21. It is submitted by Mr. Singh that the concept of "rounding off" is *ipso facto* not applicable to the prices of drugs. He submits that Rule 2(m) of the Legal Metrology (Packaged Commodities) Rules, 2011 ("**LMPC Rules**") defines "retail sale price" and includes a rule of rounding off, wherein an amount of less than 50 paisa is rounded off to the preceding rupee and an amount between 50 paise and 95 paise is rounded off to fifty paise. He thereafter refers to Chapter V of the LMPC Rules, wherein Rule 26 exempts the applicability of these rules to scheduled and non-scheduled formulations

under the 2013 DPCO. He submits that Paragraph 5.2 of the Minutes of the Meeting dated 12.04.2016 of the NPPA cannot be relied upon to apply the principle of rounding-off to non-scheduled formulations as the same deals only with an increase in MRP due to a change in the Wholesale Price Index (WPI) for scheduled formulations. It is his submission that Para 5.2 does not entitle a manufacturer to round off the MRP as a matter of right and even otherwise, the benefit of rounding off is permitted only up till two decimal points. He vehemently argues that the judgment of this Court in Obsurge Biotech Ltd. V. Union of India**, 2020 SCC OnLine Del 1744** cannot be relied on by the learned Single Judge on the facts that the benefit of rounding off for scheduled formulation is only permitted to a maximum of two decimal points was not brought to the notice of the Court and further the judgment in Obsurge Biotech (supra) has been stayed by a Division Bench of this Court *vide* order dated 20.10.2020 in L.P.A. No. 310/2020.

22. The Respondents before this Court support and rely upon the judgments of the learned Single Judge and the reasoning given therein.

23. Heard learned counsels for the parties and carefully perused the documents and material on record.

24. At this juncture it would be apposite to give a brief outline of the price control regime apropos 'drugs'as has been established through various legislations, orders and policies. In 1955, the Parliament of India passed the EC Act to control the production, supply, distribution,and pricing of certain essential commodities. Section 2A of the EC Act, defines "essential commodity" to mean those commodities specified in the Schedule to the EC Act, which features 'drugs' (as defined under Section 3(b) of the Drugs and Cosmetics Act, 1940) as Item No. 1 in the Schedule.

25. Section 3 of the EC Act grants the Central Government the power to control the price at which an essential commodity may be bought or sold, by passing an order to that effect. The relevant extracts of the said provision read as under:

> *"3.* ***Powers to control production, supply, distribution, etc., of essential commodities.—****(1) If the Central Government is of opinion that it is necessary or expedient so to do for maintaining or increasing supplies of any essential commodity or for securing their equitable distribution and availability at fair prices, 1 [or for securing any essential commodity for the defence of India or the efficient conduct of military operations], it may, by order, provide for regulating or prohibiting the production, supply and distribution thereof and trade and commerce therein.*
>
> *(2) Without prejudice to the generality of the powers conferred by sub-section (1), an order made thereunder may provide—*
>
> ***
>
> *(c) for controlling the price at which any essential commodity may be bought or sold;"*

26. The Drugs (Control of Prices) Order, 1963 came to be promulgated in exercise of the powers conferred upon the Central Government under the Defense of India Act, 1915. However, the subsequent series of Drug Price Control Orders notified in 1966, 1970, 1979, 1987 and 1995 came to be notified in exercise of powers given in Section 3 of the EC Act.

27. The 1995 DPCO was notified in light of the Drug Policy of India, 1994. The price fixation mechanism envisaged under the 1995 DPCO took into account the cost of production of a drug formulation with allowances relating to post-production expenses being permitted to be taken into consideration.The First Schedule to the 1995 DPCO, created a list of 76 bulk

drugs which were defined as "scheduled bulk drug" and the formulations based on the same were defined as "scheduled formulation". The 1995 DPCO conferred upon the Government the power to fix and revise theprice of both, "scheduled" and "non-scheduled"bulk drugs and formulations.

28. Para 13 of the 1995 DPCO dealt with the power of the Government to recover the amount overcharged by a manufacturer by way of a notice. Para 13 of the 1995 DPCO reads as under:

> *13. Price of scheduled formulations for the existing manufacturers.– (1) All the existing manufactures of scheduled formulations, selling the branded or generic or*
>
> *both the versions of scheduled formulations at a price higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price (plus local taxes as applicable):*
>
> *Provided, that in case of scheduled formulations produced or available in the market before the date of notification of ceiling price, the manufacturers shall ensure within a period of forty-five days of the date of such notification that the maximum retail price of such scheduled formulation does not exceed the ceiling price (plus local taxes as applicable).*
>
> *(2) All the existing manufactures of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price lower than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government shall maintain their existing maximum retail price.*
>
> *(3) Annual increase in maximum retail price may be carried out as per the increase in the wholesale price*

index with respect to previous year as per the provision of sub-paragraphs (2) and (3) of paragraph 16.

Provided that in case of decline in wholesale price index, a corresponding reduction in the prices shall be made as per the provision of sub-paragraph (4) of paragraph 16."

29. Thereafter in 2012, the Government announced the National Pharmaceuticals Pricing Policy 2012 ("**NPPP 2012**"), wherein the key principles based on which NPPP 2012 is formulated are stated in Para 3, of the NPPP 2012, which is reproduced as under:

*"**3. KEY PRINCIPLES OF NATIONAL PHARMACEUTICALS PRICING POLICY 2012***

The key principles for regulation of prices in the National Pharmaceuticals Pricing Policy 2012 are:

(1) Essentiality of Drugs
(2) Control of Formulations prices only
(3) Market Based Pricing"

30. Para 4 of the NPPP 2012 outlines the guiding principles for drugs price control and determination under the NPPP 2012, the relevant extracts of which are reproduced as under:

*"**4. PRINCIPLES FOR DRUGS PRICE CONTROL AND DETERMINATION IN NPPP-2012***

(i) Price regulation would be on the basis of 'Essentiality' of the drug as laid down in the 'National List of Essential Medicines - 2011' declared by the Ministry of Health and Family Welfare, and modified time to time, in public interest under Drug Price Control Order.

(ii) Price regulation would be applied only to formulations, i.e. the medicine actually used by the consumers, and not to any upstream products such as bulk drugs and intermediates.

(iii) The Span of Price Control shall be as per the dosages and strengths as listed in NLEM- 2011.

(iv) The methodology of fixing a ceiling price of NLEM medicines, by adopting the Simple Average Price of all the brands having market share (on the basis of Moving Annual Turnover) more than and equal to 1% ofthe total market turnover of that medicine, will be as per the formula below:
(Sum of prices of all the brands of the medicine having market share more than and equal to 1% of the total market turnover of that medicine) / (Total number of manufacturers producing such brands of the medicine)

(v) The formulations will be priced only by fixing a Ceiling Price (CP). Manufacturers would be free to fix any price for their products equal to or below the CP. The CP's would be fixed on the dosage basis, such as per tablet / capsule / standard injection volume as listed in NLEM-2011.

(vi) The Ceiling Price will be fixed on the basis of readily monitorable Market Based Data (MBD). To begin with, the basis for this readily monitorable market data would be the data available with the pharmaceuticals market data specializing company – IMS Health (IMS). Wherever required this data would be checked by appropriate survey/ evaluation by the National Pharmaceutical Pricing Authority (NPPA). As the IMS data gives price figures for stockist level prices hence in order to arrive at ceiling Price (which will be the maximum retail price), the IMS price will be further increased by 16% as margin to the retailer so as to arrive at a reasonable ceiling price chargeable from the consumers.

(vii) For drugs not in the IMS data, NPPA would collect data by commissioning the same.

(viii) For the medicines where there is no reduction of price due to absence of competition, the overall percentage reduction in the price of same molecule with other dosage and strength will be applied; otherwise the overall percentage reduction in the price of medicines in the same therapeutic category will be applied.

(ix) The CP for a drug listed in the NLEM would be the Simple Average of Prices as calculated on the basis of IMS data six months prior to the date of announcement of the new National Pharmaceutical Pricing Policy i.e the ―Appointed Date‖ for bringing the new Policy into effect. For a drug whose data is not available in IMS, the NPPA will commission the data within a reasonable time for determining the Simple Average Prices also on the basis of prices prevailing six months prior to the Appointed Date. Thus the Simple Average Prices data date for the drugs available in IMS data and collected by NPPA would be same. Once the Simple Average Price is fixed, NPPA would monitor its implementation on a continuous basis through a proper methodology and system.

(x) The prices of these NLEM-2011 medicines will be allowed an annual increase as per the Wholesale Price Index as notified by the Department of Industrial Policy & Promotion. It is proposed to fix the 1st April of every year as the reference date for this. Accordingly, on 1st April of every year, companies will be automatically authorized to revise their prices uptothe limit of the increase in the Wholesale Price Index for theprevious year. In case of decline in Wholesale Price Index, a corresponding reduction in the ceiling price will be obligatory. The NPPA itself will also separately notify the revised ceiling prices as

applicable as on the 1st of April each year, and in case any company has fixed the prices not consistent with the revised ceiling prices, the NPPA will take appropriate action to have these revised.

(xi) The Simple Average Price of all the brands of the medicine having market share (on the basis of Moving Annual Turnover) more than and equal to 1% of the total market turnover of that medicine - the Reference Prices for calculation of Simple Average Price - may also change on an annual basis due to changes in the MAT value. However, there would be no annual revision of Ceiling Prices on the basis of MAT. Revision of Ceiling Prices on the basis of MAT value would be carried out only once in five years or as and when NLEM is updated/revised. However, the Government will revise the ceiling price of a medicine under NLEM, if there is a significant change in the market structure of the particular medicine even in between 5 years.

(xii) Non-price Control Drugs: Under the existing price control regime, the prices of Non-Scheduled drugs are monitored, and in case the prices of such drugs increase by more than 10% in a year, subject to certain criteria, government fixes the prices of such medicines from time to time. In the proposed policy, all essential drugs are under price control. It would follow that non-essential drugs should not be under a controlled regime and their prices should be fixed by market forces. However, in order to keep a check on overall drug prices, it is proposed that prices of such drugs be monitored on regular basis, and where such price increase at a rate of above 10% per annum is observed, the Government would be empowered to have the price of these drugs reduced to below this limit, for next twelve months……."

31. A reading of the aforesaid principles highlights that price regulation of drugs under the NPPP 2012 would be based on the basis of "essentiality"

of a drug, which was determined on the basis of the National List of Essential Medicines, 2011 ("**NLEM**"), declared by the Ministry of Health and Family Welfare under the Drug Price Control Order. Unlike the 1995 DPCO, the price regulation would be applied only to formulations and not to bulk drugs. Points (iii) to (xi) of Para 4 of the NPPP 2012 describe the methodology and manner based on which prices for formulations based on drugs listed in the NLEM would be done. Para 4(xii) of the NPPP 2012 stipulates that for "non-essential" drugs or drugs that do not feature in the NLEM, there would not be a controlled regime and the prices of the same are to be fixed by market forces, however the Government shall monitor the price of such drugs to ensure the price of such "non-essential"drugs does not increase by more than 10% per annum, and in case there is an increase above 10% per annum, the Government is empowered to have the price of these drugs reduced to below this limit, for the next 12 months.

32. The Union Government has promulgated the 2013 DPCO in order to implement the policy decisions taken and stipulated in NPPP 2012. Following the NPPP 2012, the 2013 DPCO did away with the concept of fixing, regulating and revising the price of bulk drugs. The 2013 DPCO deals only with scheduled and non-scheduled formulations. Para 2(zb) of the 2013 DPCO defines "scheduled formulation" to mean any formulation, included in the First Schedule to the 2013 DPCO, whether referred to by generic versions or brand name. Similarly, a "non-scheduled formulation" was defined in Para 2(v) of the 2013 DPCO to mean a formulation that is not included in the First Schedule to the 2013 DPCO. The First Schedule to the 2013 DPCO contains a list of medicines included in the NLEM, as per Para 2(t) of the 2013 DPCO. Therefore, all essential medicines, included in the NLEM, are categorized as "scheduled formulations" and all "non-essential"

medicines are categorized as "non-scheduled formulations" under the 2013 DPCO.

33. Having outlined the development of the price control regime vis-à-vis drug formulations as it currently exists, this Court shall now deal with the issue pertaining to the interpretation of Para 20 of the 2013 DPCO, as raised by the Appellants. The short question which arises for the consideration in the present case is the interpretation of Para 20 of the 2013 DPCO.

34. As stated above, upon an *ex facie* reading of Para 20, it becomes clear that 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 the MRP of such non-scheduled formulation by 10% of the MRP in the preceding twelve months, preserve the said MRP for the next twelve months 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% in a period of twelve months. The consequences that entail such transgression is that the manufacturer is liable to deposit the overcharged amount along with interest from the date of transgression and reduce the MRP of the non-scheduled formulation to the level of 10% of MRP for the next twelve (12) months.

35. Upon reading Para 20 of the 2013 DPCO, it also becomes clear that that the said provision has been modelled upon Para 4(xii) of the NPPP 2012. As per the price control regime envisaged under the NPPP 2012, there has been a conscious decision by the Government to exclude non-scheduled or non-essential formulations from the rigors of price control so as to enable manufacturers of non-scheduled formulations to fix prices as per market

forces. It has been decided that the Government shall only monitor the prices of these drugs to ensure that the price of non-essential drugs does not increase by more than 10% in a year. It further goes on to say that when the price of such drugs increases at a rate more than 10% in a year, the Government is empowered to have the price of these drugs reduced to below this limit. In the opinion of this Court, there is no doubt that Para 20 of the 2013 DPCO has been incorporated to give effect to the policy of the Union Government as envisaged in NPPP 2012.

36. In this vein, this Court find it difficult to accept the contention of the Appellants that non-scheduled drugs are not outside the purview of the price control regime established under the EC Act and 2013 DPCO. It is undisputed that the 2013 DPCO has been promulgated to give effect to the policy stated in NPPP 2012. The NPPP 2012, is very explicit in stating that non-essential drugs arenot under a controlled regime and only essential drugs are under price control regime. The Schedule and definitions of the 2013 DPCO makes it clear that there is no distinction between essential medicines/drugs and scheduled formulations under the 2013 DPCO. Consequently, it would follow that non-scheduled formulations under the 2013 DPCO are non-essential medicines as per NPPP 2012. Accordingly, non-scheduled drugs formulations under the 2013 DPCO would not be subject to a price control regime.

37. The exclusion of non-scheduled drugs from a price control regime is further evinced when the 2013 DPCO is compared with its predecessor, the 1995 DPCO. Under the 1995 DPCO, the government had the power to fix and revise prices for scheduled as well as non-scheduled formulations. This power to fix and revise prices for non-scheduled formulations has been done away with under the 2013 DPCO which only gives the Government the

power to monitor the change in MRP of non-scheduled formulations. This indicates that the Government undertook a deliberate and conscious decision to exclude non-scheduled formulations from a price control regime. Thus, the submission by the Appellants that non-scheduled drugs are included in the price control regime cannot be accepted.

38. Therefore, the powers of the government to fix and revise MRP of drugs under the 2013 DPCO is limited to scheduled formulations and does not extend to non-scheduled formulations. In respect of non-scheduled formulations, the Government only has the power to monitor the MRP increase so as to ensure that the same does not increase by more than 10% in a year, and in case there is an increase beyond 10% in a year, there are penal consequences which are prescribed in Para 20 of the 2013 DPCO itself.

39. It is the case of the Appellants that Para 20 of the 2013 DPCO must be interpreted in a manner where consumer/public interest is held to be paramount. Reliance was placed upon the judgments delivered by the Apex Court in Meenakshi Mills (supra), Prag Ice (supra), Cynamide India (supra), Glaxo Smithkline (supra) and CIPLA (supra) to contend that the purpose of EC Act and 2013 DPCO was to ensure equitable distribution and availability of essential commodities like drugs at a fair price, and profiteering of such commodities cannot be permitted, otherwise the object of the EC Act and 2013 DPCO would be defeated.

40. Indubitably, the 2013 DPCO was brought into force keeping in mind the interest of the public and to ensure equitable distribution of drugs at a fair price. It is not the case of the Appellant that the mechanism provided under Para 20 of the 2013 DPCO which gives the Government the power to monitor the MRP of non-scheduled formulations and ensure that a manufacturer does not increase the MRP of such formulations by more than

10% in a year, does not give paramount consideration to public/consumer interest. It is also not the case of the Appellants that only a price control regime gives paramount consideration to public/consumer interest and a price monitoring system does not. In the considered opinion of this Court, the price monitoring system envisaged under Para 20 of the 2013 DPCO has been introduced keeping in mind public/consumer interest, and the Appellants have failed to establish the contrary.

41. In any event, this Court has carefully perused the aforesaid decisions relied upon by the Appellants and is of the opinion that the same are not applicable to the facts of the present case. The judgments delivered in the aforestated cases deal with various control orders issued by the Central Government in exercise of its powers under Section 3 of the Essential Commodities Act. In all the cases relied on by the Appellant, the control orders explicitly conferred upon the Government, the power to fix/revise prices of the essential commodity concerned. Further, the judgments in Cynamide India (supra), which dealt with the Drugs (Price Control Order), 1979 ("**1979 DPCO**") and the judgments in Glaxo Smithkline (supra) and CIPLA (supra), are distinguishable from the present case as the 2013 DPCO explicitly excludes the power to fix an MRP or ceiling price for non-scheduled drugs. Both the 1979 DPCO and the 1995 DPCO gave the government the power to fix an MRP or a ceiling price for both scheduled and non-scheduled bulk drugs and formulations, and neither of them included a power to monitor the MRP of non-scheduled formulations. The 2013 DPCO on the other hand specifically states that it only pertains to drug formulations and not bulk drugs. Moreover, it only provides the Government with the power to fix an MRP for scheduled formulations and only allows the Government to monitor the MRP of non-scheduled formulations. For the

aforestated reasons, this Court is of the opinion that the reliance placed by the Appellants on the aforesaid decisions is misplaced and do not aid the case of the Appellants.

42. The Appellants also contend that Para 20 of the 2013 DPCO is penal in nature. It is their case that three penal consequences ensue in case a manufacturer increases the MRP of a non-scheduled formulation beyond the permissible limits of Para 20 of the 2013 DPCO which are as follows: *firstly*, the manufacturer would be required to reduce the MRP to the permissible level; *secondly*, it would be required to deposit the overcharged amount from the date of increase in MRP "… in addition to the penalty"; and *thirdly*, it would be required to deposit the interest on the overcharged amount from the date of increase in MRP "… in addition to the penalty". This contention of the Appellants is based on the premise that the words "preceding" and "next" have been incorrectly interpreted by the learned Single Judge. It is their contention that the word 'preceding' must be interpreted in a manner to mean the twelve months immediately before the point of transgression, whereas the term 'next' means the subsequent twelve months from the point where manufacturer rolls back the MRP and not with reference to the point of transgression.

43. As stated by this Court above, Para 20 of the 2013 DPCO is divided into two parts. The first part provides that a manufacturer of a non-scheduled formulation may increase the MRP of such non-scheduled formulation by 10% of the MRP during the preceding twelve months, preserve the said MRP for the next twelve months 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.

44. It is difficult for this Court to accept the contention of the Appellants that Para 20 of the 2013 DPCO, as a whole, is a penal provision. This is established from the fact that Sub Para (2) of Para 20 of 2013 DPCO only mandates the manufacturers to return back the amount overcharged over and above the 10% increase of the MRP which is permitted under Para 20 along with interest thereon. Further, the term "penalty" in Sub Para (2) of Para 20 refers to the penalty mentioned under Section 7 of the EC Act.The 2013 DPCO has been passed by virtue of the power conferred under Section 3 of the EC Act and the penalty for violation of Orders under the EC Act is prescribed under Section 7 of the EC Act and not within the 2013 DPCO. Penalty is only stipulated under the parent legislation and cannot be a part of an Order under the same. Thus,the term "penalty" under Para 20 of the 2013 DPCO does not create an additional penalty beyond what is provided under the EC Act, which is the parent legislation of the 2013 DPCO. Therefore, Para 20 of the 2013 DPCO cannot be construed to be a penal provision.

45. Having established that Para 20 of the 2013 DPCO is not penal in nature, the question that arises before this Court is what are the consequences that ensue when a manufacturer increases the MRP of a non-scheduled formulation beyond 10% in an year.

46. At this juncture, it is apposite to refer to the charts reproduced above which is a part of written submissions filed by the Appellants herein before the learned Single Judge.The first chart describes the ideal situation where a manufacturer only increases the MRP of a non-scheduled formulation by 10% after twelve months.Therefore, if the MRP of such a formulation is fixed at Rs. 100/- on 01.02.2015, then on 01.02.2016, the manufacturer is

entitled to increase the MRP of such formulation to Rs. 110/- and on 01.02.2017, it is entitled to increase the MRP by 10% ofRs. 110/-, i.e., to Rs. 121/- and so on.

47. In the second chart, the manufacturer instead of increasing the MRPof the non-scheduled formulation from Rs. 100/- to Rs. 110/- in 01.02.2015, increases the MRP to Rs. 120/- and sustains the same MRP for the next 5 years i.e., till 01.02.2020. The question is that on 01.02.2020, when it is found by the authorities that a transgression of Para 20 of the 2013 DPCO has taken place,then what is the MRP of the non-scheduled formulation which the manufacturer is entitled to keep after01.02.2020 and how much should the manufacturer refund to the Government. The contention of the Appellants is that on 01.02.2020 when the discrepancy is found out, the manufacturer has to bring the MRP back to Rs. 110/- and it is permitted to increasethe MRP only from 01.02.2021by 10%, over and aboveRs. 110.

48. Per contra, the contention of the Respondents herein is that a proper reading of Para 20 of the 2013 DPCO would show that a manufacturer can increase the MRP of such non-scheduled formulation to Rs. 110/- on 01.02.2015, Rs. 121/- on 01.02.2016, to Rs. 133.1/- on 01.02.2017 and so on. The Respondents contend that in the event that the manufacturer increases the MRP to Rs. 120/- on 01.02.2015, when it was entitled to increase it to Rs. 110/-, then the manufacturer is only liable to refund difference between Rs. 120/- and Rs. 110/- i.e., Rs. 10, for the year starting 01.02.2015 till 31.01.2016, and the manufacturer cannot be forced to fix the MRP of its formulation at Rs. 110/- on 01.02.2020, when the transgression is found. They contend that on 01.02.2020, the manufacturer should be permitted to keep the MRP of the formulation at Rs. 177.16/- i.e., a 10% increase of Rs. 161.05.

49. As stated earlier, Para 20 of the 2013 DPCO deals with monitoring the MRP of non-scheduled formulation, which permits a manufacturer to increase the MRP of such formulation by 10% of the MRP of such formulation during the preceding twelve months. Para 20 also stipulates that if the increase in MRP is beyond 10% of the MRP, then it shall for the next twelve months, reduce the MRP of such formulation to 10% of the MRP as it existed in the preceding twelve months. To explain the same by way of an illustration, if the MRP of a non-scheduled formulation on 01.02.2014 is Rs. 100/-, then the manufacturer is permitted to increase the MRP of such formulation up to Rs. 110/-on 01.02.2015 as per Para 20 of the 2013 DPCO. However, in the event that the manufacturer increases the MRP of such a formulation beyond Rs. 110 on 01.02.2015, such as to Rs. 120/-, then it is required to reduce the MRP of such formulation to Rs. 110/- for the next twelve months.

50. At this point it becomes important to interpret the phrases "preceding twelve months" and "next twelve months" as used in Para 20 of the 2013 DPCO.Applying the principle of literal rule of construction [See: J.P. Bansal v. State of Rajasthan, (2003) 5 SCC 134, Nathi Devi v. Radha Devi Gupta, (2005) 2 SCC 271; and Vijay Narayan Thatte v. State of Maharashtra, (2009) 9 SCC 92] the phrase "preceding twelve months" must be interpreted to mean 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" must be construed to mean a time period of twelve months immediately after the date when the MRP of the non-scheduled formulation was increased. Therefore, the interpretation of the terms "preceding" and "next" as suggested by the Appellants would be against well-established principles of statutory interpretation and cannot be

accepted. Keeping the aforesaid principles in mind, Para 20 of the 2013 DPCO must be read in a manner that the date of transgression/infraction by the manufacturer means the date from which such manufacturer has increased the MRP of a non-scheduled formulation by more than 10% in a year.

51. Sub Para (2) of Para 20 of the 2013 DPCO postulates that in case a manufacturer overcharges the consumers then the said manufacturer shall be liable to deposit the overcharged amount along with interest thereon from the date of increase in MRP in addition to the penalty.This would imply that the liability of a manufacturer to deposit the overcharged amount would arise from the date from which the MRP has been increased beyond the 10% MRP increase permissible under Sub Para (1) of Para 20 of the 2013 DPCO. The duty of the manufacturer to deposit the overcharged amount does not depend upon the issuance of a demand notice. This further establishes that the date of transgression/infraction by the manufacturer means the date from which such manufacturer has increased the MRP of a non-scheduled formulation by more than 10% in a year.

52. Paragraph 23 ("**Para 23**") of the 2013 DPCO postulates that the Government shall by notice, require the manufacturers, importer or distributor or as the case may be, to deposit the amount accrued due to charging of prices higher than those fixed or notified by the Government under said Order. A conjoint reading of Para 20(2) and Para 23 of the 2013 DPCO further demonstrates that the date of transgression/infraction under Para 20 of the 2013 DPCO should be read to mean the date from which the manufacturer has increased the MRP of a non-scheduled formulation by more than 10% in a year, and should not be read to mean the date from which the demand notice is issued to such manufacturer.

53. Keeping in view of the aforesaid, the consequences that ensue when a manufacturer increases the MRP of a non-scheduled formulation beyond 10% per annum are as follows:

A. The manufacturer may be subject to penalty as prescribed under Section 7 of the EC Act.

B. The manufacturer is liable to reduce the MRP of such non-scheduled 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%. Therefore, if the MRP of a non-scheduled formulation is Rs. 100/- on 01.02.2014, he is entitled to increase the MRP to Rs. 110/- on 01.02.2015. However, if the manufacturer increases the MRP to Rs. 120/- on 01.02.2015, then from 01.02.2015, the manufacturer has an obligation to reduce the MRP to Rs. 110/- for the next twelve months, i.e., till 31.01.2016.

C. 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". Therefore, if the permissible increase in MRP is Rs. 110/-, but the MRP has actually been increased to Rs. 120/-, then the amount overcharged comes to a difference of Rs. 120/- and Rs. 110/-, i.e., Rs. 10/-.

54. Having dealt with the interpretation of Para 20 of the 2013 DPCO in terms of when a transgression/infraction of the said provision occurs and what are the consequences of such infraction, the only question left that requires the attention of this Court is whether a manufacturer is entitled to round-off the MRP of a non-scheduled formulation and if rounding-off is permitted, then what is the manner in which such rounding-off may be done.

55. The Appellants before this Court have stated that the concept of rounding-off is *ipso facto* not applicable to the prices of drugs as Rule 26 of the LMPC Rules excludes the applicability of these rules to scheduled and non-scheduled formulations under the 2013 DPCO. It is their case that Para 5.2 of the Minutes of the Meeting dated 12.04.2016 of the NPPA cannot be relied upon to apply the principle of rounding-off to non-scheduled formulations, and even if it is applicable, the benefit of rounding off is permitted only up till two decimal points. They argue that the reliance placed upon by the learned Single Judge upon the judgment in Obsurge Biotech (supra) is misplaced as the same has been stayed by a Division Bench of this Court.

56. *Per contra*, the Respondents support the interpretation and reasoning given by the learned Single Judgeto apply the principle of rounding-off to non-scheduled formulations. The learned Single Judge, while dealing with the issue of rounding-off has observed that there is no justification why the benefit of rounding-off may be extended to scheduled formulations only. The learned Single Judge relies upon Para 5.2 of the Minutes of the Meeting dated 12.04.2016 of the NPPA to state that the term "formulations" used therein must be read to mean both scheduled and non-scheduled formulations. The learned Single Judge kept in view the practical difficulties that may be faced by consumers and suppliers in having the MRP of a drug

being fixed in decimal points and thus held that the principle of rounding-off is applicable to non-scheduled formulations as well.

57. At the outset, it must be noted that the learned Single Judge has very clearly stated that the observations made are without being influenced by the judgment given in Obsurge Biotech (supra) because the said judgment is the subject matter of challenge in LPA No. 310/2020. The reasoning and analysis given by the learned Single Judge is independent of the judgment in Obsurge Biotech (supra) and it would be incorrect to state that the learned Single Judge has relied on the same.

58. At this juncture it would be appropriate to refer to Para 5.2 of the Minutes of the Meeting dated 12.04.2016 of the NPPA, which reads as under:

> *"**Agenda item no 5(ii):- Overcharging on account of fixation of ceiling price forformulation upto two decimal points based on WPI of preceding financial years.***
>
> *5.2 The agenda point was discussed. It was decided that NPPA would not pursue thoseovercharging cases which arose out of purely mathematical calculation due to rounding offof decimal points as per the general mathematical practice and no other malafide intentionon the part of the company was evident."*
>
> (emphasis supplied)

59. A reading of the aforesaid makes it clear that the NPPA has taken a conscious decision to not pursue those overcharging case which arise out of purely mathematical calculation due to rounding off of decimal points as per the general mathematical practice and no other mala fide intention on part of the company was evident. It is also clear that the NPPA in the said meeting was dealing primarily with scheduled formulations, as the same refers to

"ceiling price" and "Wholesale Price Index" ("**WPI**"), which are factors relevant for calculating the price of scheduled formulations. Further, the Agenda Item 5(ii) clearly stipulates that the benefit of rounding-off, even for scheduled formulations, extends only up to two decimal points.

60. While the Appellants are correct in stating that Para 5.2 of the Minutes of the Meeting dated 12.04.2016 of the NPPA dealt with only scheduled formulations, this Court finds it difficult to accept the contention that the benefit of rounding-off cannot be extended to non-scheduled formulations. As has been stated above, there has been a conscious decision on part of the Union Government to exclude non-scheduled formulations from the rigors of price control and instead adopt a more lenient price monitoring system instead. This Court finds it difficult to find any rationale or justification as to why the benefit of rounding-off may be limited to only scheduled formulations, which are governed by a much stricter price control regime. The price monitoring system, as envisaged under Para 20 of the 2013 DPCO is more lenient, and there is no reasonable basis for not extending the benefit of rounding-off to non-scheduled formulations as well.In the considered opinion of this Court, limiting the applicability of the principle of rounding-off only to scheduled formulations would be unreasonableand arbitrary. To this extent, this Court finds no infirmity with the judgment of the learned Single Judge.

61. This Court however is in agreement with the contention of the Appellants that the benefit of rounding-off is permitted only up to two decimal points. Para 5.2 of the Minutes of the Meeting dated 12.04.2016 of the NPPA clearly limits the benefit of rounding-off available to scheduled formulations to up to two decimal places as per general mathematical practice. Accordingly, even for non-scheduled formulations, the benefit of

rounding-off must be limited to two decimal places as per general mathematical practice.

62. It is pertinent to note that the Rule 26 of the LMPC Rules clearly excludes both scheduled and non-scheduled formulations from its ambit, and therefore the mechanism provided therein for rounding-off will not be applicable to either scheduled or non-scheduled formulations. This is also evident from the phrase "general mathematical practice" as used in Para 5.2 of the Minutes of the Meeting dated 12.04.2016 of the NPPA. In order to demonstrate how prices of non-scheduled formulations may be rounded-off, the following illustrations may be referred to:

S. No.	Actual Figure	Rounded-Off Figure
1.	Rs. 123.45/-	Rs. 123.45/-
2.	Rs. 123.455/-	Rs. 123.46/-
3.	Rs. 123.456/-	Rs. 123.46/-
4.	Rs. 123.991/-	Rs. 123.99/-
5.	Rs. 123.999/-	Rs. 124.00/-
6.	Rs. 123.001/-	Rs. 123.00/-
7.	Rs. 123.111/-	Rs. 123.11/-

63. Therefore, while the principle of rounding-off is applicable to non-scheduled formulations as well as scheduled formulations, the benefit of rounding-off is extended only to two decimal places, and only when no other malafide intention on the part of the company is evident. This is in line with the view adopted by the NPPA in Para 5.2 of the Minutes of the Meeting dated 12.04.2016.

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 non-scheduled 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 formulationto 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 months 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 non-scheduled 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 *malafide* 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.

67. With these observations, the appeals stand disposed of, along with pending application(s), if any.

SATISH CHANDRA SHARMA, C.J.

SUBRAMONIUM PRASAD, J

NOVEMBER 08, 2023
Arsh/S. Zakir