IN THE HIGH COURT OFDELHI AT NEW DELHI

% Judgment delivered on:20.03.2019

\+ **W.P.(C) 7589/2018 and CM Nos. 28999/2018 & 44988/2018**

SANOFI INDIA LTD. AND ANR. ..... Petitioners

versus

UNION OF INDIA AND ORS. ..... Respondents

WITH

\+ **W.P.(C) 7619/2018**

SANOFI INDIA LTD. AND ANR ..... Petitioners

versus

UNION OF INDIA & ORS ..... Respondents

WITH

\+ **W.P.(C) 7632/2018 and CM No. 29189/2018**

SANOFI INDIA LTD. AND ANR. ..... Petitioners

versus

UNION OF INDIA AND ORS. ..... Respondents

AND

\+ **W.P.(C) 7634/2018**

SANOFI INDIA LTD. & ANR ..... Petitioners

versus

UNION OF INDIA & ORS ..... Respondents

Advocates who appeared in these cases:

For the Petitioners :Mr Gaurab Banerji, Senior Advocate with Mr Manoj, Ms Aparna Sinha, Mr Mohit Pandey and Mr S.P. Mukherjee in W.P.(C) 7589/2018.

Mr Manoj and Ms Aparna Sinha in W.P.(C) Nos. 7619/2018, 7632/2018 & 7634/2018.

For theRespondents :Mr Kirtiman Singh, CGSC and Mr Ajay Digpaul, CGSC with Ms Madhuri Dhingra, Mr Waize Ali Noor and Mr Parth Semwal for UOI.

CORAM
HON'BLE MR JUSTICE VIBHU BAKHRU

JUDGMENT

VIBHU BAKHRU, J

1. Petitioner no. 1 (Sanofi India Ltd. – hereafter 'the petitioner') is a company, *inter alia*, engaged in the manufacture and supply of pharmaceutical products, which includes 'Amaryl MV- 1 mg' and 'Amaryl MV- 2 mg'. The petitioner has filed the present petitions, *inter alia*, impugning the order dated 2.07.2018 (No. 31015/1/2018 – hereafter the 'impugned order') passed by respondent no. 1. The petitioner had filed a review application under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereafter 'the DPCO'), challenging the notifications issued by the National Pharmaceutical Pricing Authority (hereafter the 'NPPA'),fixing the ceiling price of the aforesaid pharmaceutical products – 'Amaryl MV- 1 mg' and 'Amaryl MV- 2 mg' – under paragraph 5 of the DPCO. By the said impugned

order, respondent no. 1 has rejected the aforementioned review application filed by the petitioner.

2. The petitioner also impugns the price notification dated 23.11.2017 (S.O. no. 3727 (E) – hereafter the 'impugned notification dated 23.11.2017'), wherein the retail price for Amaryl MV 1 mg and Amaryl MV 2 mg was fixed at ₹7.14 and ₹9.05 per tablet, respectively. The petitioner also impugnsthe price notification dated 20.12.2017 (S.O. no. 3946 (E) – hereafter 'the impugned notification dated 20.12.2017'), wherein the price of Amaryl MV- 1 mg and Amaryl MV- 2 mg was fixed at ₹ 6.85 and ₹8.68 per tablet, respectively (Post GST).

3. In addition, the petitioneralso impugned the following show cause notices:

(i) Show cause notice dated 19.12.2017 (F. No. 30 (23)/2017/ Div IV (OC-II)/NPPA – hereafter 'the impugned show cause notice dated 19.12.17')calling upon the petitioner to show cause as to why an amount of ₹1,92,09,822/- (inclusive of interest) be not recovered from the petitioner on account of manufacturing and marketing the drugs in question,without obtaining prior approval.;

(ii) Show-cause notice dated 19.12.2017 (F. No. 30 (24)/2017/ Div IV (OC-II)/NPPA – hereafter 'the impugned show cause notice dated 19.12.17') calling upon the petitioner to show cause as to why an amount of ₹4,73,44,016/- (inclusive of

interest)be not recovered from the petitioner on account of manufacturing and marketing the drugs in question without obtaining prior approval.

(iii) Show cause notice dated 20.12.2017 (F. No. 30 (25)/2017/ Div IV (OC-II)/NPPA – hereafter ' the impugned show cause notice dated 20.12.17') issued by the NPPA, wherein the petitioner was asked to show cause as to why the overcharged amount of ₹1,16,66,824/- (inclusive of interest) with reference to manufacture of Amaryl MV –2 mg (10 strips), should not be recovered; and

(iv) Show cause notice dated 21.12.2017 (F. No. 30 (26)/2017/ Div IV (OC-II)/NPPA – hereafter 'the impugned show cause notice dated 21.12.17') issued by the NPPA, wherein the petitioner was asked to show cause as to why the overcharged amount of ₹28,01,39,782/- (inclusive of interest) with reference to the manufacture of Amaryl MV – 2 mg (15 strips), should not be recovered from it.

4. The petitioner has also challenged the following demand notices issued by the NPPA, subsequently:

(i) demand notice dated 20.02.2018 (F. No. 30 (23)/2017/ Div IV (OC-II)/NPPA – hereafter 'the impugned demand notice dated 20.02.2018') issued by the NPPA, wherein the petitioner was directed to deposit an amount of

₹2,25,06,249/- for manufacturing Amaryl MV- 1 mg, (10 strips), without obtaining prior approval.

(ii) The demand notice dated 22.02.2018 (F. No. 30 (24)/2017/ Div IV (OC-II)/NPPA – hereafter 'the impugned demand notice dated 22.02.2018') issued by the NPPA, wherein the petitioner was directed to deposit an amount of ₹5,15,39,351/- for manufacturing Amaryl MV- 1 mg (15 strips), without obtaining prior approval.

(iii) demand notice dated 18.05.2018 (F. No. 30 (23)/2017/ Div IV (OC-II)/NPPA – hereafter 'the impugned demand notice dated 18.05.2018') wherein the NPPA, on account of finding the contentions of the petitioner to be untenable, directed the petitioner to deposit ₹2,29,28,602/-, as the overcharged amount with reference to the manufacture and marketing of Amaryl MV- 1mg, in pursuance of the previous demand notices issued by it.

5. The principal controversy in the present petition relates to whether the drugs in question (Amaryl MV- 1 mg and Amaryl MV- 2 mg) areto be considered as 'New Drugs', within the meaning of paragraph 2(u) ofthe DPCO. Admittedly, the NPPA has fixed the price of the drugs in question in terms of paragraph 5 read with paragraph 15 of the DPCO, 2013, which are applicable for the fixation of the retail price of 'New Drugs'. It is the petitioner's case that the drugs in question are not 'New Drugs' and, therefore, the

entire approach of NPPA in fixing the ceiling prices under paragraph 5 and paragraph 15 of the DPCO, is contrary to the provisions of the DPCO.

Factual Background

6. The petitioner manufactures Amaryl MV 1 mg (in a pack of 10 and 15 strips), which contains Metformin Hydrochloride IP 500 mg (sustained release dosage form), Glimepiride IP 1 mg and Voglibose IP 0.2 mg. The petitioner also manufactures Amaryl MV 2 mg, which contains Metformin Hydrochloride IP 500 mg (controlled/ sustained release dosage form), Glimepiride IP 2 mg and Voglibose IP 0.2 mg(in a pack of 10 and 15 strips).

7. Glimepiride IP 1 mg and Voglibose IP 0.2 mg, were not included in National List of Essential Medicines, 2011 (NLEM, 2011). However, Metformin (conventional tablets) was included in NLEM, 2011, which was incorporated as Schedule I of the DPCO,as notified on 15th May 2013. However, Metformin in its modified dosage form, being Controlled Release or Sustained Release, was not included in NLEM, 2011.

8. The petitioner launched the pharmaceutical products in question, 'Amaryl MV- 1 mg' and 'Amaryl MV- 2 mg', in January 2015. The aforesaid pharmaceutical products were not included in NLEM, 2011.

9. NPPA issued an Office Memorandum/Public Notice dated 17.05.2017, wherein it was stated that certain pharmaceutical companies had launched 'New Drugs', as defined under Paragraph 2(u) of the DPCO, without taking any price approval from the NPPA, and a list of such products was annexed thereto. In the said list, four of the products were mentioned which were manufactured/marketed by the petitioner:(i) Amaryl MV 1 mg (10 strips);(ii) Amaryl MV 1 mg (15 strips); (iii)Amaryl MV 2 mg (10 strips); and(iv) Amaryl MV 2 mg (15 strips). The said products were mentioned at Sr. No. 147, 148, 149 and 150, respectively.

10. Pursuant to the issuance of the Office Memorandum, the petitioner issued a communication dated 26.05.2017 to the NPPA, giving details of the composition of each of their products mentioned in the list, and submitted that the said pharmaceuticals donot fall within the meaning of 'New Drugs', as defined under Paragraph 2(u) of the DPCO.

11. NPPA did not accept the same and issued the impugned Notification dated 23.11.2017, in exercise of its powers conferred by Paragraphs 5,11 and 15 of the DPCO, fixing the retail price of Amaryl MV 1 mg tablet at ₹7.14 per tablet, and the retail price of Amaryl MV 2 mg tablet at ₹9.05 per tablet.

12. Aggrieved by the abovementioned Notification, the petitioner filed a review application dated 05.12.2017 under Paragraph 31 of the DPCO, before the Secretary, Department of Pharmaceuticals(DOP).

The principal ground urged by the petitioner was that Amaryl 1 mg and Amaryl 2 mg were not covered under the definition of "New Drugs" under Paragraph 2(u) of the DPCO, and therefore their pricing could not be fixed under paragraph 5 of the DPCO.

13. On 19.12.2017, NPPA issued the impugned show cause notice dated 19.12.2017, calling upon the petitioner to show cause as to why an amount of ₹1,92,09,822/- (inclusive of interest) should not be recovered from the petitioner since the petitioner had manufactured and marketed Amaryl MV- 1 mg tablets (10 strips), without obtaining prior approval. NPPA also issued a show cause notice dated 19.12.2017, asking the petitioner to show cause as to why an amount of ₹4,73,44,016/- (inclusive of interest) should not be recovered from the petitioner for the aforesaid reasons with reference to Amaryl MV- 1 mg tablets (15 strips).

14. NPPA issued the impugned show cause notice dated 10.12.2017 to the petitioner, wherein the petitioner was asked to show cause as to why ₹1,16,66,824/- (inclusive of interest) should not be recovered for manufacturing Amaryl MV- 2 mg (10 strips), without obtaining prior approval. On 21.12.2017, NPPA issued another impugned show cause notice to the petitioner, wherein the petitioner was asked to show cause as to why ₹28,01,39,782/- should not be recovered, (inclusive of interest) for manufacturing/ marketing of New Drug formulation of Amaryl MV – 2 mg (15 strips), without obtaining prior price approval.

15. Thereafter, on 20.12.2017, NPPA issued the impugned Notification dated 20.12.2017 fixing the retail price, post GST, of Amaryl MV 1 mg andAmaryl MV- 2 mg at ₹6.85 per tablet, and₹8.68 per tablet, respectively.

16. Aggrieved by the fixation of the retail price of Amaryl MV 1 mg vide the impugned notification dated 20.12.2017, the petitioner filed another Review Application dated 02.01.2018, under paragraph 31 of the DPCO, 2013 before the DoP, reiterating the grounds as raised in the earlier review petition dated 5.12.2017.

17. The petitioner responded to the show cause notices, by its letter dated 11.01.2018, *inter alia*, stating that NPPA had failed to consider the detailed reasons and evidence furnished in its letter dated 26.05.2017.

18. On 20.02.2018, the NPPA issued the impugned demand notice to the petitioner, wherein the petitioner was asked to deposit an amount of ₹2,25,06,249/- (inclusive of interest) for manufacturing "Amaryl MV 0.2/500/1 MG Tablets", (10 strips), without obtaining prior approval.

19. On 22.02.2018, the NPPA issued another impugned demand notice, wherein the petitioner was asked to deposit an amount of ₹ 5,15,39,351/- (inclusive of interest) for the manufacture of "Amaryl MV 0.2/500/ 2 MG Tablets, 15's" containing Voglibose 0.2 mg + Metformin - 500 mg + Glimepride - 2 mg, without obtaining prior price approval.

20. Upon receipt of the impugned demand notices dated 20.02.2018 and 22.02.2018, the petitioner issued a letter dated 5.03.2018, asking NPPA to withdraw the demand notices or keep the same pending, till a decision was rendered in the pending review petitions.

21. However, NPPA continued to press its demand and issued another demand notice dated 18.05.2018, wherein it directed the petitioner to deposit ₹2,29,28,602/- as the overcharged amount, with reference to the manufacture and marketing of the drugs in question.

22. In the forgoing circumstances, the petitioner filed writ petitions (bearing ***W.P. (C) No. 6102 of 2018*** and ***W.P. (C) No. 6096 of 2018***) for quashing of the impugned show cause notices and demand notices. This court disposed of the said petitions on 30.05.2018, restraining the respondents from taking any coercive steps, pendingdisposal of the review applications.

23. By the impugned order, respondent no.1 rejected the review application filed by the petitioner, and held that the petitioner did not have any genuine basis for questioning the approach of the NPPA while fixing the prices of Amaryl MV 1 mg and Amaryl MV 2 mg, by treating them as new drugs, under Paragraph 2 (u) of the DPCO, 2013.

Reasons and Conclusion

24. The drugs in question – Amaryl MV- 1 mg and Amaryl MV- 2 mg – comprise of three formulations. The composition of the same are set out below:-

Formulation	Composition
Amaryl MV 1 mg Tablets	Each uncoated bilayered tablet contains Metformin Hydrochloride IP 500 mg (in sustained release form) Glimepiride IP 1 mg Voglibose IP 0.2 mg.
Amaryl MV 2 mg Tablets	Each uncoated bilayered tablet contains Metformin Hydrochloride IP 500 mg (in sustained release form) Glimepiride IP 2 mg Voglibose IP 0.2 mg.

25. The petitioner launched the drugs in question in January, 2015. At the material time, NLEM, 2011 was incorporated as Schedule I of the DPCO.Metformin Hydrochloride IP (in sustained release form), Glimepiride IP and Voglibosewere not included in the said Schedule. However, NLEM, 2011 included the formulation Metformin under table 18.5.1.The relevant entry is set out below:-

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Metformin	P, S, T	Tablets	500mg

26. It is the petitioner's case that Metformin Hydrochloride IP 500 mg in sustained releaseformwasnot a "scheduled formulation" at the material time, as only the conventional form of Metformin was included in the Schedule I to the DPCO. Thus, the first and foremost issue to be addressed is whether Metformin Hydrochloride IP 500 mg

(in sustained release form) was a "scheduled formulation" at the material time when the drugs in question were launched,that is, in January, 2015.

27. Before proceeding to address the said issue, it would be relevant to note that the DPCOhas been issued,in exercise of the powers conferred under Section 3 of the Essential Commodities Act, 1955,andin order to give effect to the National Pharmaceutical Pricing Policy - 2012 (NPPP - 2012). One of the stated objectives of NPPP-2012 is to *"put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – "essential medicines" – at reasonable prices."* This is to ensure that essential medicines are made available to the masses at reasonable prices.

28. NPPP-2012 was materially different from the Drug Policy of 1994, and sought to put in place an entirely different regulatory framework, in respect of price control or essential medicines. The approach under the Drug Policy, 1994 was to control prices of bulk drugs and the formulations that included the Active Pharmaceutical Ingredient (API). Thus, all formulations which included the scheduled bulk drugs would fall within the price control regime of the Drug Policy, 1994 that found its statutory expression in Drugs Prices (Control) Order, 1995. However, NPPP-2012 sought to restrict the price regulation to certain essential formulations only. Although, the prices of all drugs were required to be monitored, the ceiling price could be fixed only in respect of specified formulations that were considered essential medicines.

29. The aforesaid is clearly indicated in paragraph 3.2 of NPPP-2012, which is set out below:-

> "3.2 The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2012 would be on the basis of regulating the prices of formulations only. This is different from the earlier principle of regulating the prices of specified Bulk Drugs and their formulations adopted in the Drug Policy 1994. The reasons for adoption of this principle of price control of "Formulations Only" are:
>
> (i) That the Bulk Drug – API (Active Pharmaceutical Ingredient) – may not fully reflect the 'Essentiality' of the actual drug formulation – now the subject of focus – due to the possible applicability of the API in manufacture of various formulations which may or may not be considered "Essential" for the larger healthcare needs of the masses.
>
> (ii) The emphasis on price control starting at the bulk drug stage itself has in recent times, resulted in amongst other reasons shifting of manufacture of drugs away from the notified bulk drugs under price control. In fact only 47 bulk drugs out of 74 notified in the First Schedule of the DPCO, 1995 are now under production. This has had a cascading effect on the formulations manufactured from the concerned bulk drugs which in turn has affected the availability of such formulations. The consumer-patient has been adversely affected in the process.
>
> (iii) The task of pricing both the bulk drug and the formulation makes it complicated and time consuming without commensurate direct benefits to the consumer

who is actually affected only by the price of the final end product, i.e. the formulation – made from the bulk drug rather than its bulk constituents.

(iv) The price control in the form of formulations only ensures more specific pricing control of the required medicine which is in the interest of the consumer from the point of view of the actual prescription by the Doctor. This aspect is more important for a country like India where there is large asymmetry in the information between the doctor and the patient.

(v) Since the bulk drug manufacturer is constrained to sell at a fixed price, the manufacturer is always likely to give preference to an existing buyer rather than to a potential new entrant. This constrains the emergence of new companies and formulations in the price-controlled segment and is inherently anti-competitive and also does not benefit the consumer-patient for the same reason."

30. The relevant provisions of the DPCO are required to be examined, keeping the aforesaid in mind.

31. The expression 'scheduled formulation' is defined under sub-clause (zb) of paragraph 2(1) of the DPCO, 2013. The same is set out below:-

> "(zb) "**scheduled formulation**" means any formulation, included in the First Schedulewhether referred to by generic versions or brand name;"

32. The term 'non scheduled formulation' is defined underclause (v) of paragraph 2(1) of the DPCO. Prior to 09.03.2015, the said clause reads as under:

> "(v) "**non-scheduled formulation**" means a formulation, the dosage and strengths of whichare not specified in the First Schedule."

33. The definition of the expression 'non scheduled formulation' was amended on 09.03.2015, to read as under:-

> "2(1)(v) "**non-scheduled formulation**" means a formulation, which is not included in Schedule-I."

34. It is apparent from the conjoint reading of paragraph 2(1)(zb) and 2(v) of the DPCO as existing in force in January, 2015, that even though those medicines which were included in Schedule I to the DPCO would stand excluded from the expression 'scheduled formulation', if the specific dosages and strengths were not specified in Schedule I. Plainly, those medicines which were not included in Schedule I would be 'non scheduled formulations', however, even those medicines that were included in Schedule I, and thus would fall within the definition of the expression 'scheduled formulation', wouldstand excluded by virtue of paragraph 2(1)(v) of the DPCO, if the specific dosages and strengths were not specified in the said schedule.

35. This Court in ***Indoco Remedies Limited v. Union of India and Anr.: W.P.(C) 7597/2018*** had interpreted the expression 'non

scheduled formulation' in the context of those medicines that were included in Schedule I to the DPCO, but not of specified dosages and strengths. This Court was of the view that paragraph 2(1)(v) of the DPCOinsofar as it excludes formulations of specified strengths and dosages from the scope of scheduled formulations, must be read in a meaningful manner. It was held that merely tweaking the strengths and dosages that do not result in any qualitative difference in the formulation, would not be sufficient to exclude the formulation from the scope of the definition of the term 'scheduled formulations'. In other words, in order to exclude the formulation from the scope of the definition of scheduled formulation, in the context of formulation, which is otherwise specified in Schedule I, it would be necessary that the change in the dosages and strengths have a material qualitative effect on the formulation.

36. In this case, there can be little dispute that the dosage form of sustained release is a qualitative innovation over conventional dosage form. The petitioner has also produced material on record to establish the same.

37. At this stage, it is also relevant to state that NPPA had sent a letter dated 01.08.2013 to the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India (hereafter 'DOP'), pointing out that Indian Pharmaceutical specifies different types of dosage forms, and tablets could otherwise be also categorized under different categories such as "uncoated tablets, coated tablets, film coated tablets, dispersible tablets, effervescent tablets, modified-

release tablets, enteric-coated tablets, prolonged-release tablets", etc. It was stated that under DPCO, 1996, separate norms for conversion cost were notified for each category of tablets, and separate prices were fixed based on manufacturing permission granted by the concerned Licensing Authority. In this regard, NPPA sought further clarification from DOP as the DPCO (DPCO, 2013) did not provide such distinction, except in few cases.

38. The said issue was considered by DOP at a meeting held on 21.08.2013, 29.08.2013 and 03.09.2013 between officials of DOP and NPPA, and after much deliberation, it was decided that since the NLEM, 2011 was prepared by the Ministry of Health and Family Welfare by following due process in the Ministry, it would be appropriate if the Ministry of Health and Family Welfare is requested to give their advice on the following questions.

> "i) wherever only conventional forms of a drug (like tablets/capsules/injection) are mentioned under NLEM-2011, the dosage forms like modified release forms, dispersible, effervescent, soluble, enteric coated, lipid suspension/liposomal of that drug are part of NLEM-2011 or not? and
>
> ii) wherever any conventional forms of a drug (like tablets/capsules) are mentioned under NLEM-2011 as dosage form, the forms like film coated, uncoated, sugar coated tablets, hard gelatin capsules and soft gelatin capsules are considered as the conventional dosages forms of drugs under NLEM-2011 or not?

39. Accordingly, on 06.09.2013, a reference was made to the Ministry of Health and Welfare, seeking advice on the aforesaid queries. This was also informed by the DOP to the Organizations of Pharmaceutical Producers of India.

40. In response to the aforesaid request, the Ministry of Health and Family Welfare issued an Office Memorandum dated 06.12.2013. The said Office Memorandum is set out below:-

"X-11035/9/2013-DFQC
Government of India
Ministry of Health & Family Welfare
(DFQC Section)

Nirman Bhavan, New Delhi
Dated the 6th December, 2013

"**OFFICE MEMORANDUM**

Subject: Drugs (Prices Control) order dated (DPCO), 2013-regarding

The undersigned is directed to refer to Department of Pharmaceuticals' communication No. 31026/63/2013-PI.II dated 27.09.2013 on the subject cited above and to say that the matter was examined by Central Drugs Standard Control Organization (CDSCO) in consultation with DR. Y.K.Gupta, Prof. & Head, Department of Pharmacology, AIIMS who was also the Chairman of the Core Committee constituted to prepare the NLEM-2011. The comments of CDSCO on the points referred to in Department of Pharmaceuticals' aforesaid communication dated 27.09.2013 are as under:

Point No.1 - Conventional forms of a drug like tablet/capsule /injection of that particular drug as

mentioned in NLEM 2011 shall be considered as a part of NLEM-2011 and not the dosage form like modified release forms, dispersible, effervescent, soluble, enteric coated, lipid suspension/liposomal of the drug unless these drugs are specified in nonconventional dosage forms in NLEM 2011.

Point No.2 - Conventional dosage form includes tablet/capsule including the forms coated, uncoated, sugar coated tablets hard gelatin capsules and gelatin capsules. Unless and otherwise specified, capsules are considered as Hard Gelatin Capsules."

Sd-
6/12
(Om Prakash)
Section Officer
Telefax: 23062419"

41. In view of the above, there could be little doubt that the framers of NLEM, 2011 had not included non conventional forms of formulations in NLEM, 2011.

42. Mr Kirtiman Singh, learned counsel appearing for the respondents had submitted that the aforesaid view was not accepted by NPPA and it had sent a letter dated 20.06.2014 to DOP, *inter alia*, stating as under:-

"3. In this context it may be noted that the clarification on National List of Essential of Medicines (NLEM), 2011 received from the Ministry of Health and Family Welfare vide their letter No.X-11035/9/2013-DFQC dated 6th December, 2013 does not imply that scheduled drugs of non-conventional dosage forms would lie outside price control. It is necessary to recognize that the NLEM

> prepared by the Ministry of Health & Family Welfare is primarily not for the purpose of price control and hence, was to be read in conjunction of other relevant provisions of DPCO, 2013, failing which it can be easily misused by drug manufacturers to circumvent or escape from the DPCO, 2013 which should not be allowed."

43. It is relevant to note that a copy of the aforesaid letter was not on record,but was handed over by Mr Kirtiman Singh, learned counsel appearing for the respondents, during the course of hearing.

44. Although, it does appear that NPPA has expressed a view contrary to that expressed by the Ministry of Health and Welfare, however, it cannot be disputed that the Core Committee constituted to prepare NLEM, 2011 had not included non conventional dosage forms ofvarious medicines in 2011. And,indisputably, NLEM, 2011 was incorporated as Schedule I to the DPCO.

45. In the aforesaid context, it would be necessary to examine whether the DPCO contained any material provisions, which would require NLEM, 2011 to be interpreted differently as Schedule –I,than as originally contemplated by the Ministry of Health and Family Welfare, Government of India.

46. In this regard, it is relevant to note that at the material time – that is, in January, 2015 – paragraph 2(1)(v) expressly included formulations of which dosage and form was not specified as non-scheduled formulations. Thus, this Court is of the view that in January, 2015,Metformin Hydrochloride IP 500 mg (sustained release dosage form)was not a scheduled formulation.

47. Subsequently, there were material amendments totheDPCO which resulted in Metformin controlled/sustained release also being included as scheduled formulation. First of all, paragraph 2(1)(v) of the DPCO, 2013 was amended by GSR 686(E), w.e.f. 09.03.2015, and the definition of the expression 'non scheduled formulation' was amended to read as under:-

> "2(1)(v) "**non-scheduled formulation**" means a formulation, which is not included in Schedule-I."

48. Subsequently, with effect from 10.03.2016, Scheduled I of the DPCO was substituted by NLEM, 2015. The relevant entry relating to the formulation Metformin, as included in NLEM, 2015, is set out below:-

	Medicine	**Level of Healthcare**	**Dosage form and strength**
21.4.1.4	Metformin	P,S,T	Tablet 500 mg Tablet 750 mg Tablet 1000 mg (Immediate and controlled release)

49. Undoubtedly, the aforesaid amendments are material, however, the introduction of the said amendments strengthen the petitioner's case that in January, 2015, Metformin Hydrochloride IP 500 mg (sustained release dosage form) was not a scheduled formulation.

50. Although, Mr Kirtiman Singh earnestly contended that the demands raised must be viewed in the context of the three different periods. First, prior to 09.03.2015 (the date on which the paragraph 2(1)(v) definition 'Scheduled Formulation' was amended); second, between 09.03.2015 and 10.03.2016, when Scheduled I of the DPCO, 2013 substituted by NLEM, 2015; andthird, the period after 10.03.2016. The said contention is unmerited as the question whether the drugs in question were 'New Drugs', is required to be determined in reference to the date on which the drugs were launched, that is in January, 2015. This question cannot be addressed in reference to the provisions of the DPCO, as in force after 09.03.2015 or 10.03.2016.

51. In the aforesaid view, the principal question to be examined is whether the price determined pursuant to paragraph 5 and 15 of the DPCO,are sustainable. At this stage, it would be relevant to refer to paragraph 5 and 15 of the DPCO, which are set out below:-

> **"5. Calculation of retail price of a new drug for existing manufacturers of scheduled formulations**.– (1) The retail price of the new drug available in domestic market shall be calculated as provided in sub-paragraph (1) of paragraph 4.
>
> (2) (i) the price to retailer of a new drug, not available in domestic market, shall be fixed by the Government on the principles of "Pharmacoeconomics" of the new drug, on the recommendation of a Standing Committee of Experts formed under paragraph 15.
>
> (iii) the retail price of such new drug shall be fixed by adding sixteen percent margin to retailer on the price to retailer as fixed in item (i)

15. Fixation of retail price of a new drug for existing manufacturers of scheduled formulations.– (1) The Government shall form a Standing Committee of such Experts, as it may deem fit, within sixty days of notification of this order with a view to recommend the retail prices of new drugs on the principles of "Pharmacoeconomics".

(2) Where an existing manufacturer of a drug with dosages and strengths as specified in National List of Essential Medicines launches a new drug, such existing manufacturers shall apply for prior price approval of such new drug from the Government in Form-I specified under Schedule-II of this Order.

(3) On receipt of the application under sub-paragraph (2), in the event of the new drug available in domestic market, the Government shall fix the retail price of the new drug in accordance with the provision of sub-paragraph(1) of paragraph 5 and in the event of the new drug not available in domestic market, the Government shall forward the same to the Standing Committee of Experts who shall examine the application on the principles of "Pharmacoeconomics" and make recommendations of retail price of the new drug to the Government within thirty days of the receipt of application.

(4) The Government shall, on receipt of recommendation under sub-paragraph (3), within thirty days, fix the retail price of such new drug and such price shall be applicable to such applicant of such new drug.

(5) Where existing manufacturer of scheduled formulation fails to apply for prior approval of the price of the new drug in Form-I, such manufacturer shall be liable to deposit the overcharged amount over and above such price fixed and notified by the Government, if any, along with interest thereon from the date of launch of the new drug, in addition to the penalty.

> (6) No existing manufacturer of a scheduled formulation shall sell such a new drug at a price higher than the retail price (plus local taxes as applicable) fixed by the Government for such new drug and in case such a manufacturer is found to sell such a new drug at a price higher than the retail price (plus local taxes as applicable) fixed by the Government, such manufacturer of the new drug shall be liable to deposit the overcharged amount along with interest from the date of overcharge, in addition to the penalty."

52. It is apparent from the above that the NPPA had calculated the price of the drugs in question, treating them as 'new drug'. The term 'new drug' is defined in paragraph 2(1)(u) of the DPCO, 2013, which is set out below:-

> "(u) "**new drug**" for the purposes of this Order shall mean a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in the National List of Essential Medicines by combining the drug with another drug either listed or not listed in the National List of Essential Medicines or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in the National List of Essential Medicines."

53. A plain reading of the expression 'new drug' indicates that for a drug to be considered as a 'new drug', it must be launched by an existing manufacturer of a drug of specified dosages and strengths as listed in NLEM.

54. Admittedly, the petitioner was not manufacturing Metformin in the conventional form at the time of the launch of drugs in question

and, therefore, could not be considered as an existing manufacturer of such a formulation.

55. The rationale of including provisions relating to the 'new drug' is to ensure that the existing manufacturer does not escape the rigorsof Price Control under the DPCO by modifying its existing product by combining it with another, or otherwise altering the same without seeking prior price approval from the government in terms of para 15(2) of the DPCO. This Court is of the view that in the present case, the petitioner was not an existing manufacturer of a drug of specified dosages and strengths as listed in NLEM, at the material time when the drugs in question ('Amaryl MV- 1 mg' and 'Amaryl MV- 2 mg')were launched, and, therefore, the drugs in question could not be considered as 'new drugs'.

56. Since, it is admitted that the impugned price notifications had been issued determining the price of the drugs in question under paragraph 5 of the DPCO, 2013 by treating the same as 'New Drugs', the impugned serial nos. of the said notifications cannot be sustained and are, accordingly, set aside. Consequently, the impugned show cause notices and the impugned demand notices issued by NPPA are also not sustainable and are set aside.

57. The impugned order sustaining the approach of NPPA in treating the drugs in question as 'new drugs' under paragraph 2(u) of the DPCO, also cannot be sustained and is set aside.

58. The petition is allowed in the above terms. The pending applications stand disposed of.

VIBHU BAKHRU, J

MARCH 20, 2019
MK