THE HIGH COURT OF DELHI AT NEW DELHI

% Judgment delivered on: 17.07.2018

\+ **W.P.(C) 11802/2016 and CM Nos. 8215/2017, 8217/2017 and 19029/2017**

MODI-MUNDIPHARMA PVT. LTD. ..... Petitioner

versus

UNION OF INDIA & ORS. ..... Respondents

Advocates who appeared in this case:

For the Petitioner	:	Mr Akhil Sibal, Senior Advocate with Mr Navpreet Singh Ahluwalia, Mr Salil Seth, Mr Pradeep Chhindra and Mr Adhesh Sharma.
For the Respondents	:	Mr Kirtiman Singh, Mr Prateek Dhanda, Mr Waize Ali Noor, Ms Ruchi Jain and Mr Saeed Qadri.

CORAM:-
HON'BLE MR JUSTICE VIBHU BAKHRU

JUDGMENT

VIBHU BAKHRU, J

1. The petitioner is a Pharmaceutical Company and has filed the present petition impugning the Standing Order No. 1687 (E) dated 09.05.2016 (hereafter 'the impugned notification') passed by the Assistant Director, National Pharmaceutical Pricing Authority (hereafter 'NPPA') to the extent that it includes the formulation, TRD Contin 100 mg. tablet CR 10 (hereafter 'the Formulation'), within the scope of the 'ceiling price fixed for Tramadol tablet'.

2. The petitioner also impugns the order dated 19.09.2016 (hereafter 'the impugned order') passed by the Deputy Secretary, NPPA whereby the petitioner's review petition under paragraph 31 of the Drug (Price Control) Order, 2013 (hereafter 'DPCO-2013'), was rejected.

3. In addition, the petitioner also impugns a communication dated 05.07.2016 ('the impugned communication') issued by the Director, NPPA whereby it was asserted that the ceiling price of Tramadol 100 mg. tablet was fixed as per Section 2.2.3 of the National List of Essential Medicines, 2015 (NLEM-2015) and it included all variants like Controlled Release (CR) and Sustained Release (SR). The petitioner was further called upon to comply with the requirement of pricing the formulations below the ceiling price of ₹18.25 per tablet and submit its compliance report to NPPA.

4. In exercise of powers conferred under Section 3 of the Essential Commodities Act, 1955, respondent no.1 notified the DPCO-2013 on 15.05.2013. This was in supersession of the Drug (Price Control) Order 1995 (hereafter 'DPCO-1995'), which was in force prior to the notification of the DPCO-2013.

5. On 10.03.2016, respondent no. 1, issued a notification amending Schedule-I to the DPCO-2013 by substituting NLEM-2015 in place of NLEM-2011. Schedule-I (NLEM-2015) now included formulations of Tramadol Tablet and injection having strength of 50 mg, 100 mg and 50mg/ml respectively; however, there was no reference or mention of CR/ SR technology.

6. According to the petitioner, the Formulation is not included in the list of NLEM-2015 and, therefore, not a 'scheduled formulation' within the meaning of the DPCO-2013. In this view, the petitioner claims that the Formulation cannot be subject to price fixation under the DPCO-2013.

7. The petitioner further rely on Explanation (2) to NLEM-2015 in support of its claim that formulations developed through incremental innovations like Sustain release/Control release are included in NLEM-2015 only if specifically mentioned. The formulations manufactured by the petitioner uses a Continus Controlled Release Dual Mechanism Drug Delivery System (referred to as 'CR-Technology'). The petitioner claims that this is an innovative drug delivery system and since the same is not specifically mentioned in NLEM-2015, the Formulation cannot be read as included therein.

8. The respondents dispute the above contentions. They state that the CR-Technology merely relates to the strength and dosage of the medicine Tramadol. It is contended that non-inclusion of such strength or dosage in NLEM-2015 does not mean that the formulation of such strength and dosage is excluded from the said list or is outside the sweep of the DPCO-2013; it only means that a formulation can be considered separately for the purposes of price fixation.

9. Mr Kirtiman Singh, learned counsel appearing for the respondents contended that Tramadol was included in the NLEM-2015 and, therefore, the said drug in all forms of dosage or strength would be subject to price fixation under the DPCO-2013. He referred to paragraph 32 of the

DPCO-2013 and contended that only the cases that are referred in the said paragraph are excluded from the scope of DPCO-2013 and in all other cases, medicines referred to in NLEM-2015 would be covered under the DPCO-2013. He also referred to the definition of the term 'Scheduled formulation' as provided under paragraph 2(zb) of the DPCO-2013 and contended that any formulation included in Schedule-I (NLEM-2015), whether referred to by generic versions or brand name, would fall within the scope of DPCO -2013.

10. He further contended that in matters concerning procurement and availability of essential medicines, the interest of public is paramount and the regulatory regime must be interpreted accordingly. He referred to the decisions of the Supreme Court in ***Shree Meenakshi Mills Ltd. v. Union of India: (1974) 1 SCC 468***; ***M/s. Prag Rice & Oil Mills &Anr. v. Union of India: (1978) 3 SCC 459***; ***Union of India v. Cynamide India Ltd. : (1987) 2 SCC 720*** and ***Glaxo Smithkline v. Union of India: (2014) 2 SCC 753*** in support of his contention.

11. Next, Mr Kirtiman Singh contended that as long as the 'Scheduled Formulation' is utilized for production or manufacture of a drug, it would fall within the scope of price control. He stated that if the manufacturer combines, tweaks or modifies its product either in terms of a composition or on mode of administration, the same would not result in excluding the medicine from the purview of the price control regime under the DPCO-2013. He referred to the decision of this Court in ***M/s. Glaxo Smithkline Pharmaceuticals v. Union of India & Ors.: 2009 (107) DRJ 539*** and ***Shimal Investment and Trading Co. v. Union of India and Ors.:***

W.P.(C) 3125/2001, decided on 21.10.2013 and the decision of the Supreme Court in ***Union of India v. Swiss Garnier and Ors.: (2013) 8 SCC 615*** in support of his above contention. He also referred to the decision of the Allahabad High Court in ***T.C. Healthcare Pvt. Ltd. v. Union of India***: ***W.P.(C) 33753, decided on 20.04.2010***, whereby the contention that the formulation Unicontin was based on a different technology, was rejected.

12. Mr Kirtiman Singh referred to the decision of ***Reserve Bank of India v. Peerless General Finance & Investment Co. Ltd. and Ors.: (1987) 1 SCC 424*** and contended that the interpretation of a statute must depend on the context of the statute. He contended that in the present case, DPCO-2013 was issued in the context of placing a price ceiling on certain essential drugs to ensure that the same are within the reach of public. Therefore, the provisions of the DPCO-2013 must be interpreted in the manner so as to include all variations of the medicines mentioned so as to serve the object of the statute.

13. Lastly, Mr Kirtiman Singh referred to the decision in the case of ***S. Sundaram Pillai etc. v. V. R. Pattabiraman etc: (1985) 1 SCC 595*** and contended that an explanation in a statute can neither enlarge the scope of the statute nor interfere with or change the enactment or any part thereof. He submitted that the Explanation (2) to NLEM-2015 could not be read in a manner so as to exclude the Formulation from NLEM-2015.

Reasoning and Conclusion

14. At the outset, it is necessary to observe that most of the decisions referred to by Mr Kirtiman Singh were rendered by Courts in the context of the DPCO-1995 and not in the context of the DPCO-2013. Admittedly, DPCO-1995 was issued to implement the Drug Policy of 1994. The First Schedule to the DPCO-1995 specified a list of 75 bulk drugs, and any formulation containing any of the bulk drugs specified in that Schedule would fall within the price control regime of the DPCO-1995. Paragraph 2(u) and 2(v) of the DPCO-1995 defined the terms 'Scheduled bulk drug' and 'Scheduled formulation' as under:-

> "2(u) "Scheduled bulk drug" means a bulk drug specified in the First Schedule;"
>
> 2(v) "Scheduled formulation" means a formulation containing any bulk drug specified in the First Schedule either individually or in combination with other drugs, including one or more than one drug or drugs not specified in the First Schedule except single ingredient formulation based on bulk
> drugs specified in the First Schedule and sold under the generic name;

15. The 1994 Drug Policy was replaced by the National Pharmaceutical Pricing Policy-2012. Concededly, there was a paradigm shift in the policy and instead of regulating the price of the bulk drugs and the formulations including such bulk drugs, the emphasis had shifted to regulating the prices of formulations, which are to be determined on the basis of the market prices.

16. The DPCO-2013 was issued incorporating the principles of the National Pharmaceutical Pricing Policy-2012.

17. At this stage, it would be relevant to refer to the definition of some of the terms uses in the DPCO-2013. Paragraphs 2(i), 2(t), 2(v) and 2(zb) define the terms 'formulation', 'National List of Essential Medicines', 'non-scheduled formulation' and 'scheduled formulation' as under:-

> "2(i) "**formulation**" means a medicine processed out of or containing one or more drugs with or without use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease and, but shall not include –
>
> (i) any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines;
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> (ii) any medicine included in the Homeopathic system of medicine; and
>
> (iii) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply;
>
> 2(t) "**National List of Essential Medicines**" means National List of Essential Medicines, 2011 published by the Ministry of Health and Family Welfare as updated or revised from time to time and included in the first schedule of this order by the Government through a notification in the Official Gazette;
>
> 2(v) "**non-scheduled formulation**" means a formulation, the dosage and strengths of which are not specified in the First Schedule;
>
> 2(zb) "**scheduled formulation**" means any formulation, included in the First Schedule whether referred to by generic versions or brand name;"

18. Paragraphs 4 to 8 of the DPCO-2013 provide for the mechanism for calculating the price of scheduled formulations under the DPCO-2013. Paragraph 14 of the DPCO-2013 proscribes any manufacturer from selling any scheduled formulation at a price higher than the ceiling price so fixed and notified by the Government.

19. NLEM-2015 has been adopted as the Schedule-I to the DPCO-2013. The medicine Tramadol is included at Serial No. 2.2.3 of NLEM-2015. The relevant entry reads as under:-

	Medicine	Level of Healthcare	Dosage form and strength
2.2.2	Tramadol	S,T	Capsule 50 mg Capsule 100mg Injection 50mg/ml

20. It is apparent from the above that only Capsules (50 mg and 100 mg) and Injection of 50mg/ml are specified. On a plain reading, the Formulation, which involves CR Technology is not expressly mentioned. The principal question is whether the same should be read as impliedly included. In this regard, it is material to note that in cases of several other medicines, tablets having a different delivery system have been expressly provided. As an illustration, entries at Serial No. 2.1.1, 5.1, 5.8 and 5.9 of Schedule-I (NLEM-2015) may be referred to. The said entries of NLEM-2015 are set out below:-

	Medicine	Level of Healthcare	Dosage form and strength

2.1.1	Acetylsalicylicacid	P,S,T	Tablet 300 mg to 500 mg Effervescent/ Dispersible/ Enteric coated Tablet 300 mg to 500 mg
5.1	Carbamazepine	P,S,T	Tablet 100 mg Tablet 200 mg CR Tablet 200 mg Tablet 400 mg CR Tablet 400 mg Oral liquid 100 mg/5 ml Oral liquid 200 mg/5 ml
5.8	Phenytoin	P,S,T	Tablet 50 mg Tablet 100 mg Tablet 300 mg ER Tablet 300 mg Oral liquid 30 mg/5 ml Oral liquid 125 mg/5 ml Injection 25 mg/ml Injection 50 mg/ml
5.9	Sodium valproate	P,S,T	Tablet 200 mg Tablet 300 mg CR Tablet 300 mg Tablet 500 mg CR Tablet 500 mg Oral liquid 200 mg/5ml

21. The Explanations (1) and (2) to the Schedule-I to the DPCO-2013 are at the core of the controversy in the present case. The said Explanations read as under:-

"(1) Any dosage form of a medicine, other than the dosage form included in this Schedule, but in same strength and route of administration, which does not have significant difference in terms of pharmacokinetics or pharmacodynamics or efficacy-safety profile over the dosage form mentioned in the list shall be considered as included. To elaborate, if a tablet is included, other dosage forms like conventional tablets and capsules are considered as included. However, such different dosage forms should be considered differently for purposes such as procurement policy, pricing, etc. This principle also applies to all other dosage forms e.g. oral liquid dosage forms, injectables, topical dosage forms, etc.

(2) Innovation in medicine must be encouraged. The formulations developed through incremental innovation or novel drug delivery systems like lipid/liposomal formulations, sustained release/ controlled release etc. should be considered as included only if specified in the list against any medicine. Such different formulations should be considered differently for purposes such as procurement policy, pricing, etc."

22. A plain reading of Explanation (2) to Schedule-I to the DPCO-2013 indicates that formulations developed through innovation or novel drug delivery systems like sustained/controlled release should be considered as included only if specified in the list against any medicine. The aforesaid explanation has been included pursuant to the "Report of the Core Committee for Revision of National List of Essential Medicines 2015".

The said report indicates that the Committee had deliberated on certain specific issues including dosage form/formulations and formulations of Modified release/Sustained release/extended release etc. The relevant extract of the Core Committee Report is set out below:-

> "**Specific issues Deliberated during the Revision Process**
>
> The following specific dimensions were considered during deliberation:
>
> 1. Dosage forms/formulations
> 2. Strengths of medicines.
> 3. Salts of active moieties of medicines
> 4. Isomers/analogues/derivatives etc. of medicines
> 5. Medicines in national health programmes.
> 6. Pack size of formulations
> 7. Incremental innovation
>
> I. Formulations of Modified release/Sustained release/extended release etc.
>
> II. Improved or novel drug delivery systems.
>
> **Dosage Forms/Formulations of Medicine**
>
> Formulation of a medicine may be available in different dosage forms.
>
> **Oral solid dosage** forms include tablet, capsule, sachet, etc.
>
> Tablets include film coated, uncoated, sugar coated etc.
>
> Capsules include hard gelatine capsule, soft gelatine capsules etc. (Unless specified, capsules mentioned in the NLEM are considered as hard gelatine capsules).

Oral liquid dosage forms include syrup, suspension, elixirs etc.

Injectable dosage forms include conventional liquid injection or powder for injection, as well as delivery system like depot, liposomal/lipid complex etc.

Topical dosage forms include ointment, cream, lotion drops etc.

When the solid oral dosage form of the medicine is available both as tablet and capsule, the more commonly available dosage form (between tablet and capsule), is listed in NLEM.

If both the formulations i.e. tablet and capsule are available in almost equal proportions, the formulation as included in Indian Pharmacopoeia, has been listed in NLEM. For example, ibuprofen which is included in IP as tablet, is listed in NLEM as tablet though it is also available as capsule. Similarly, tramadol is mentioned in IP as capsule but is also available as tablet. In NLEM, it has been listed as capsule.

Where, more than one solid oral dosage form is mentioned in IP, the more commonly used form is listed in NLEM. However, in case the formulation is not mentioned in IP, the more commonly available dosage form is mentioned in NLEM.

Oral liquid formulation may be available as syrups, suspensions, solutions etc. In NLEM, all such formulations are listed as oral liquid dosage forms. Similarly, many medicines intended for topical use are available as cream, ointment, lotion etc. If the formulation is includes in Indian Pharmacopoeia, the same dosage form as mentioned in IP is listed in NLEM. For example, fusidic acid and silver sulfadiazine, are available as cream and ointment, but only cream is mentioned in IP. Hence, in NLEM they are listed as cream. Where, more than one dosage form is mentioned

in IP, the more commonly used form is listed in NLEM. However, in case the medicine is not included in IP, the more commonly available form is mentioned in NLEM.

For pricing and policy decisions, only the similar formulations of oral solid dosage forms should be grouped together. However, if different technology in involved, such different dosage forms may be considered separately by purposes such as pricing, procurement etc. Any dosage form of a medicine, other than the dosage form included in NLEM but in same strength and route of administration, which does not have significant difference in terms of pharmacokinetics/pharmacodynamics/efficacy-safety profile over the dosage form mentioned in the list, should be considered as included. To elaborate, if tablet is included, other dosage forms like conventional tablets and capsules are considered as included. However, such different dosage forms should be considered differently for purposes such as procurement policy, pricing etc. This principle also applies to all other dosage forms e.g. oral liquid dosage forms, injectables, topical dosage forms etc.

Biological Medicines

* * * *

Incremental Innovation

The Committee deliberated in detail about the issue of inclusion of improved formulations of a medicine developed through incremental innovation involving technology. The Committee considered that such formulations including novel drug delivery systems like lipid/liposomal formulations modified release formulations like sustained release, controlled release etc. of a medicine, which are developed to overcome certain disadvantages associated with the use of

conventional formulations, will be considered included **only if** specified in the list against any medicine.

Strength of a Medicine

Formulations of a medicine are usually available in many strengths. The Committee deliberated that where more than one strength(s) is/are available, the strength(s) which is/are appropriate and meet the need of most, have been considered for inclusion in the NLEM.

Some strengths of a particular formulation of some medicines, presently available in the market do not appear to be appropriate and are rarely required. The committee recommends that such strengths may be examined by the regulators in consultation with experts for appropriateness of continuance of such strengths.

Different salts of active moiety of a medicine

The Committee decided that in general, medicines should be mentioned in the NLEM in terms of their active moieties, without mentioning the salts. However, in case, where the different salts of a medicine have significant difference in potency/pharmacokinetics/pharmacodynamics/efficacy-safety profile, the medicines have been mentioned in the list with respect to its specific salt. The Committee also considered that in case a medicine is available in more than one salt without any significant difference in above aspects, it is implied that all salts of that medicine with specified dosage form and strength are considered included in NLEM, 2015.

For example, diclofenac is available as diclofenac sodium or diclofenac potassium. However, there is no significant different in the above mentioned aspects, between the two salts. Hence only diclofenac is mentioned in the NLEM, which implies that both diclofenac sodium and diclofenac potassium are included in the NLEM.

Isomer/Analogue/Derivative of a Medicine

In many cases, different isomers/analogues /derivatives of one active moiety are available as different medicines. They may differ with respect to potency/pharmacokinetics/pharmacodynamics/safety-efficacy profile.

For example, S-amlodipine is an optical isomer of amlodipine. These two forms have been considered as separate entities and approved as two different medicines. Therefore, inclusion of amlodipine in NLEM does not imply that S-amlodipine is also included in NLEM.

Similarly, oxcarbazepine is a derivative of carbamazepine and both oxcarbazepine and carbamazepine have been considered and licensed as different medicines. Inclusion of carbamazepine in NLEM does not imply that oxcarbazepine is also included.

Thus, wherever, such different forms exist, which have been considered as different entitles and licensed as different medicines, inclusion of one form of such medicines in NLEM will not automatically imply inclusion of other forms.

Medicines in Various National Health Programmes

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Issue of Pack Sizes

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Consideration of representations

The Core-Committee received more than 50 representations from institutions, industry associations, pharmaceutical companies, NGOs, as well as individual experts. The committee considered these

representations. Wherever considered appropriate, the view points have been included in the NLEM.

Conclusion

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23. It is apparent from the above that the Core Committee was of the view that once a formulation is listed; any dosage form of the medicine, which does not have any significant difference in terms of pharmacokinetics or pharmacodynamics or efficacy-safety profile over the dosage form, as mentioned in the list, should be considered as included. This view of the Core Committee finds expression in Explanation (1) to the Schedule-I to the DPCO-2013. Thus, if there is no innovation and the different dosage forms of medicine have the same efficacy then notwithstanding that the said dosage form is not mentioned in NLEM-2015, the same must be read to be included.

24. Explanation (2) to the Schedule-I to the DPCO-2013 clarifies if there is an improved formulation, which has been developed through incremental innovation involving technology, to overcome certain disadvantages associated with the use of conventional formulations, the same would not be read as included in NLEM-2015 unless specifically mentioned. The Core Committee has specifically referred to Sustained release and Controlled release formulations as an illustration remove any ambiguity.

25. Both the aforesaid explanations – Explanation (1) and (2) to the Schedule-I to DPCO-2013 – must be given their full effect.

26. The contention that once a medicine finds mention in any NLEM-2015 it would necessarily fall within the scope of the expression 'scheduled formulation' as defined under Section 2(zb) of the DPCO-2013 unless expressly excluded in terms of paragraph 32 of the DPCO-2013, is unpersuasive. In terms of paragraph 2(v) of the DPCO-2013, the term *'non scheduled formulation'* is defined to mean a formulation, the dosage and strengths of which are not specified in the Schedule-I to the DPCO-2013. Thus, even if a medicine is mentioned in Schedule-I (NLEM-2015); but the specific dosage and strength has not been specified, the same would fall within the definition of non scheduled formulation. However, Explanation (1) to the Schedule-I to the DPCO clarifies that if the dosage form does not have any significant difference in terms of pharmacokinetics or pharmacodynamics or efficacy-safety profile over the dosage form that is listed in NLEM-2015, the same should be read as included. The illustration provided is that if a tablet is included then other forms of conventional tablets such as capsules etc. would be deemed to be included in NLEM-2015.

27. Explanation (2) to the Schedule-I to the DPCO-2013 refers to a completely different situation. It refers to a situation where although the essential medicine is the same but the formulation is developed through incremental innovation or involves a novel drug delivery system such as lipid/liposomal formulations, Sustained release/controlled release etc. In such cases, the formulations developed would be considered materially

different and cannot be read as to be included in the Schedule unless the same are specified in the list.

28. As noticed above, there are a number of formulations listed in the First Schedule to the DPCO-2013, which specifically indicate the delivery system such as CR (Control Release) or ER (Extended Release) against such medicines. Thus, in cases where the intention was to include such formulations, the delivery systems were specifically mentioned.

29. The contention that only new drugs, which fall within the scope of paragraph 32 of the DPCO are excluded and all the remaining medicines must be read as included in the Schedule-I to the DPCO-2013 irrespective of their dosage or delivery systems, is plainly unmerited. Paragraph 32 of the DPCO-2013 reads as under:-

> "32. **Non–application of the provisions of this order in certain cases**.- The provisions of this order shall not apply to, -
>
> (i) a manufacturer producing a new drug patented under the Indian Patent Act, 1970 (39 of 1970) (product patent) and not produced elsewhere, if developed through indigenous Research and Development, for a period of five years from the date of commencement of its commercial production in the country.
>
> (ii) a manufacturer producing a new drug in the country by a new process developed through indigenous Research and Development and patented under the Indian Patent Act, 1970 (39 of 1970) (process patent) for a period of five years from the date of the commencement of its commercial production in the country.

(iii) a manufacturer producing a new drug involving a new delivery system developed through indigenous Research and Development for a period of five years from the date of its market approval in India:

Provided that the provision of this paragraph shall apply only when a document showing approval of such new drugs from Drugs Controller General (India) is produced before the Government.

Explanation.- Notwithstanding anything contained in this Order, for the purpose of this paragraph "new drug" shall have the same meaning as is assigned to under rule 122E of the Drugs and Cosmetics Rules, 1945."

30. As is clear from the plain language of paragraph 32 of the DPCO-2013, only new drugs which are developed by indigenous research and fall within the scope of the three sub-paragraphs of paragraph 32 of the DPCO-2013 are excluded from the scope of the DPCO-2013. The import of paragraph 32 is that the DPCO-2013 does not apply to such new drugs. At this stage, it is relevant to observe that the DPCO-2013 also contains provisions regarding "non scheduled formulations" and such formulations, even though not considered as a part of NLEM, are nonetheless subject to monitoring of prices by the Government. This is evident from paragraph 20 of the DPCO-2013, which provides that the Government would monitor the maximum retail prices of all drugs including the non scheduled formulations to ensure that no manufacture increases the maximum retail prices of a drug more than 10% of the maximum retail price during the preceding twelve months. In terms of sub paragraph (2) of paragraph 20 of the DPCO-2013, a manufacturer (including a manufacturer of the non-scheduled formulation) is required to deposit over charged amount along with interest thereon computed from

the date of such increase. Paragraph 20 of the DPCO-2013 is set out below:-

> "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."

31. If the drug falls within the scope of paragraph 32 of the DPCO-2013, then the same would be completely excluded for the purview of the DPCO-2013. This includes the application of paragraph 20 of the DPCO-2013.

32. Thus, merely because a formulation is excluded from NLEM-2015, does not mean that it escapes rigour of the DPCO-2013. However, if the formulations fall within the scope of paragraph 32 of the DPCO -2013, the DPCO-2013 would have no application to such drugs. A plain reading of paragraph 32 of the DPCO-2013 also indicates rationale for excluding new drugs, which are developed through indigenous research from the scope of the DPCO-2013 for a limited period. This is, plainly, to remunerate the innovation for indigenous research and development done to produce a new drug.

33. In the facts of the present case, it is not disputed that the formulation manufactured by the petitioner incorporates Continus Controlled Release Delivery System, which is referred to as "CR" Technology. The licence granted to the petitioner for manufacturing drugs also reflects the same. It is not disputed that the same is an innovation developed to overcome certain disadvantages associated with the conventional formulations.

34. It was also contended on behalf of the respondents that Explanation (2) to the Schedule-I to the DPCO-2013 should be read only to mean that such formulations shall be considered differently for purposes such as procurement policy, pricing and not that such formulations are excluded from the Schedule. This contention is also unpersuasive, principally for the reason that the express language of Explanation (2) to the Schedule-I to the DPCO-2013 indicates that such formulations are to be considered included in the Schedule only if specifically mentioned. Further, the respondents have, if fact, not considered the formulation differently for the purposes of pricing. Thus, this contention appears to be an afterthought.

35. The contention that an explanation ought not to be read to enlarge the scope of the original statute, is merited but the said proposition has little application in the present case. The contention that an explanation can never be read to expand the scope of the statute is plainly unpersuasive. Explanation to a statute is an integral part of the statute and must be read according to its own tenor. The decision of the Supreme Court in ***S. Sundaram Pillai and Others v. V. R. Pattabiraman and***

Others: (1985) 1 SCC 591does not support the proposition as sought to be advanced on behalf of the respondents. On the contrary, the Supreme Court had held that an explanation is added to a statutory provision to explain and clarify the main statute. The Court had also referred to an earlier decision in ***Hiralal Rattanlal v. State of Uttar Pradesh: 1973 (1) SCC 216***, wherein the Supreme Court had observed as under:-

> "25. On the basis of the language of the Explanation this Court held that it did not widen the scope of clause (c). But from what has been said in the case, it is clear that if on a true reading of an Explanation it appears that it has widened the scope of the main section, effect be given to legislative intent notwithstanding the fact that the Legislature named that provision as an Explanation."

36. Although the true purpose of an explanation is to explain the main proviso, the legislature is not impeded in any manner to express its intention by way of an explanation. Thus, an explanation indicating that a statute has to be read in an expansive manner would necessarily have to be given its full effect and the main statute would have to be read in an expansive manner. Similarly, an explanation may also restrict the applicability of the statute in order to express the legislative intent to do so. In the present case, on a plain reading of Section 2(v) of the DPCO-2013, a formulation of a dosage and strength which is not specified in the Schedule, is to be considered as 'non-scheduled formulation'. However, the width of this exclusion is restricted by Explanation (1) to the Schedule-I to the DPCO-2013, which provides that even though a dosage form is not mentioned in the Schedule, it would be read as included if it does not have any significant difference in terms of pharmacokinetics or

pharmacodynamics or efficacy-safety profile over the dosage form as mentioned in the list. Thus, the import of Explanation (1) to the Schedule-I to the DPCO is to expand the scope of the Schedule-I to the DPCO-2013 to include formulations with dosage forms different from those listed in the Schedule. Explanation (2) restricts the sweep of Explanation (1) and clarifies that those formulations which are developed through incremental innovation or/ and involve a novel drug delivery system such as Sustained release/Controlled release would not be included in the list unless specifically mentioned. Explanation (2) to the Schedule-I to the DPCO-2013 only clarifies the manner in which the Schedule-I to the DPCO-2013 is to be read.

37. The decision of the Supreme Court in the case of ***Union of India v. Swiss Garnier and Ors.*** (*supra*) is of little assistance to the respondents. The said decision was rendered in the context of DPCO-1995. The principal controversy involved in that case was whether Doxofylline should be included in the definition of 'Scheduled Bulk Drug' within the meaning of paragraph 2(u) of the DPCO-1995. Admittedly, Theophylline was one of the Scheduled bulk drugs. The term 'Bulk Drug' was defined under paragraph 2(a) of the DPCO-1995 to mean as under:-

> "(a) **"bulk drug"** means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940), and which is used as such or as an ingredient in any formulation;"

38. In the aforesaid context, the appellants claimed that Doxofylline was a derivative of Theophylline and was thus included in the definition to 'Scheduled bulk drug'. After examining various technical opinions, the Supreme Court held that Doxofylline was a derivative of Theophylline which was admittedly a bulk drug included in the First Schedule to the DPCO-1995. The Supreme Court proceeded to hold that Doxofylline being a derivative of Theophylline would also fall within the meaning of 'Bulk Drug' as defined under paragraph 2(a) of DPCO-1995 and also a 'Scheduled Bulk Drug' within the meaning of Paragraph 2(u) of the DPCO-1995. The term "scheduled formulation" was defined in paragraph 2(v) of DPCO-1995 as under:-

> "2(v) **"Scheduled formulation"** means a formulation containing any bulk drug specified in the First Schedule either individually or in combination with other drugs, including one or more than one drug or drugs not specified in the First Schedule except single ingredient formulation based on bulk drugs specified in the First Schedule and sold under the generic name;"

39. Since Doxofylline was held to be included in Scheduled Bulk Drug being a derivative of a Theophylline, any formulation which contained Doxofylline would consequently fall within the definition of the term scheduled formulation.

40. As noticed earlier, the price control regime has undergone a material change and instead of regulating the price of Bulk Drug, the focus is to regulate prices of formulations, which are included in the Schedule-I to the DPCO-2013. Thus, given the narrow definition of the

term 'scheduled formulation', the only question to be examined is whether the medicine is specified in the Schedule-I to the DPCO-2013. And, as discussed above, the Explanation (2) to the Schedule-I to the DPCO-2013 expressly provides that formulation developed through incremental innovation or novel drug delivery system such as sustain release/control release would be considered included only if specified in the list against any medicine. Since it is not disputed that CR-Technology is an innovative drug delivery system, the Formulation cannot be considered as included as it is not specifically mentioned.

41. The decision of the Allahabad High Court in the case of ***T. C. Healthcare Pvt. Ltd. v. Union of*** **India** (*supra*) is of a little assistance to the respondents. In that case, the innovation in question (Notification dated 11.07.2006) expressly mentioned *"SR/CR/DR/TR/ER"* against the description of the tablet. It was contended on behalf of the petitioner that "Continus Dual Mechanism" drug delivery system used by it was different from the controlled release system (referred to as CR) and, therefore, the drug in question was not within the scope of said price notification. However, this contention was not accepted, as the Court found that "Continus Dual Mechanism" fell within the scope of CR system. The issues before the court were materially different. Further, the decision was rendered in the context of the DPCO-1995 and as noticed above, the scheme of the DPCO-1995 is different from the scheme of the DPCO-2013.

42. In view of the above, the petition is allowed. The impugned notification cannot be extended to the Formulation –TRD Contin 100 mg.

tablet CR 10 manufactured by the petitioner. The impugned communication dated 05.07.2016 issued by NPPA is also set aside.

43. All pending applications are also disposed of. The parties are left to bear their own costs.

VIBHU BAKHRU, J

JULY 17, 2018
RK/MK