

(2018) 07 DEL CK 0245

In the Delhi High Court

Case No : W.P.(C) 11802 OF 2016 and CM Nos. 8215, 8217, 19029 OF 2017

Modi-Mundipharma Pvt. Ltd

APPELLANT

Vs

Union Of India & Ors

RESPONDENT

Date of Decision : 17-07-2018

Acts Referred:

Drugs and Cosmetics Rules, 1945 — Section 122E
Essential Commodities Act, 1955 — Section 3

Citation : (2018) 07 DEL CK 0245

Hon'ble Judges : VIBHU BAKHRU, J

Bench : Single Bench

Final Decision : Allowed

Judgement

'''

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 â??the impugned notificationâ?) passed by the Assistant Director, National Pharmaceutical Pricing Authority (hereafter â??NPPAâ?) to",'''

the extent that it includes the formulation, TRD Contin 100 mg. tablet Â CR 10 (hereafter â??the Formulationâ?), within the scope of the â??ceiling",'''

price fixed for Tramadol tabletâ??.Â Â",'''

2. The petitioner also impugns the order dated 19.09.2016 (hereafter â??the impugned orderâ?) passed by the Deputy Secretary, NPPA whereby the",'''

petitionerâ??s review petition under paragraph 31 of the Drug (Price Control) Order, 2013 (hereafter ?DPCO-2013?), was rejected.Â Â",'''

3. In addition, the petitioner also impugns a communication dated 05.07.2016 (â??the impugned communicationâ?) 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).Â 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.Â,,,

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 â?? DPCO-1995â?), 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 â??scheduled formulationâ? 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.Â Â",,,

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 NLEM2015 only if specifically mentioned. The formulations manufactured by the petitioner uses a,,,

Continus Controlled Release Dual Mechanism Drug Delivery System (referred to as â??CR-Technologyâ?). 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.Â Â,,,

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 DPCO2013; 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 DPCO2013.

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.Â Â Â",,,

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.Â Â",,,

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.Â 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.Â Â",,,

Reasoning and ConclusionÂ",,,

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.Â 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",,,

,Medicine,"L e v e l 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,"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

included.Â To elaborate, if tablet is included, other dosage forms like conventional tablets and capsules are considered as included.Â 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.Â Â",,,

Biological Medicines",,,

Â *Â Â Â Â *Â Â Â Â Â *Â Â Â *,,,

Incremental Innovation",,,

The Committee deliberated in detail about the issue of inclusion of improved formulations of a medicine developed through incremental innovation",,,

involving technology.Â 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.Â",,,

Strength of a Medicine",,,

Formulations of a medicine are usually available in many strengths.Â 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.Â The committee recommends that such strengths may be examined by the regulators in consultation with experts for appropriateness of",,,

continuance of such strengths.Â 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.Â" ,,,

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.Â However, there is no significant difference in the above mentioned" ,,,

aspects, between the two salts.Â Hence only diclofenac is mentioned in the NLEM, which implies that both diclofenac sodium and diclofenac" ,,,

potassium are included in the NLEM.Â Â" ,,,

Isomer/Analogue/Derivative of a Medicine ,,,

In many cases, different isomers/analogs /derivatives of one active moiety are available as different medicines.Â" ,,,

Â TheyÂ mayÂ differÂ withÂ respectÂ to potency/pharmacokinetics/ pharmacodynamics/safety/efficacy profile. ,,,

For example, S-amlodipine is an optical isomer of amlodipine.Â These two forms have been considered as separate entities and approved as two" ,,,

different medicines.Â 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.Â Inclusion of carbamazepine in NLEM does not imply that oxcarbazepine is also included.Â Â" ,,,

Thus, wherever, such different forms exist, which have been considered as different entities 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 ,,,

* *Â Â Â Â Â *Â Â Â * ,,,

Issue of Pack Sizes ,,,

* *Â Â Â Â Â *Â Â Â * ,,,

Consideration of representationsÂ" ,,,

The Core-Committee received more than 50 representations from institutions, industry associations, pharmaceutical companies, NGOs, as well as",,,

individual experts.Â The committee considered these representations.Â Wherever considered appropriate, the view points have been included in the",,,

NLEM. ConclusionÂ,,,

* *Â Â Â Â Â * Â Â Â *Â Â Â Â Â Â,,,

Â Â Â Â Â Ââ??Â Â,,,

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.Â 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 NLEM2015, the same must be read to be included.Â Â",,,

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 â?" Explanation (1) and (2) to the Schedule-I to DPCO-2013 â?" must be given their full effect.Â,,,

26. The contention that once a medicine finds mention in any NLEM2015 it would necessarily fall within the scope of the expression",,,

â??scheduled formulationâ? as defined under Section 2(zb) of the DPCO2013 unless expressly excluded in terms of paragraph 32 of the DPCO2013,",,

is unpersuasive.Â In terms of paragraph 2(v) of the DPCO-2013, the term â?? non scheduled formulationâ? 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.Â 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.Â 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.Â 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.Â Â" ,,,

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.Â Paragraph 32 of the" ,,,

DPCO-2013 reads as under:- ,,,

â??32. Nonâ?"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.Â ,,,

(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:Â,,,

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.Â,,,

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.Â The import of,,,

paragraph 32 is that the DPCO-2013 does not apply to such new drugs.Â 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.Â 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.Â 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.Â 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.Â",,,

(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.Â??",,,

31. If the drug falls within the scope of paragraph 32 of the DPCO2013, then the same would be completely excluded for the purview of the DPCO-",,,

2013.Â This includes the application of paragraph 20 of the DPCO2013.,,,

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.Â 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.Â 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 â??CRâ? Technology.Â 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.Â",,,

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.Â The contention that an explanation can never be read to expand the scope of the statute is plainly unpersuasive.Â,,,

Explanation to a statute is an integral part of the statute and must be read according to its own tenor.Â The decision of the Supreme Court in S.,,,

Sundaram Pillai and Others v. V. R. Pattabiraman and Others: (1985) 1 SCC 591 does not support the proposition as sought to be advanced on behalf,,,

of the respondents.Â On the contrary, the Supreme Court had held that an explanation is added to a statutory provision to explain and clarify the main",,,

statute.Â Â 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:-,,,

Â â??25. On the basis of the language of the Explanation this Court held that it did not widen the scope of clause (c).Â 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.Â?,,,

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.Â 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.Â Similarly, an explanation may also restrict the applicability of the",,,

statute in order to express the legislative intent to do so.Â 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 â??non-scheduled formulationâ?.Â 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.Â 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.Â Explanation (2) to the,,,

Schedule-I to the DPCO2013 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 â??Scheduled Bulk Drugâ? within the meaning of paragraph 2(u) of theÂ DPCO-1995. Admittedly, Theophylline was one of the",,,

Scheduled bulk drugs.Â The term â??Bulk Drugâ? was defined under paragraph 2(a) of the DPCO-1995 to mean as under:-,,,

â??(a) â??bulk drugâ? 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;â?,,,

38. In the aforesaid context, the appellants claimed that Doxofylline was a derivative of Theophylline and was thus included in the definition to",,,

â??Scheduled bulk drugâ?.Â 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 â??Bulk Drugâ? as defined under paragraph 2(a) of DPCO-1995 and also a,,,

â??Scheduled Bulk Drugâ? within the meaning of Paragraph 2(u) of the DPCO-1995. The term â??scheduled formulationâ? was defined in,,,

paragraph 2(v) of DPCO-1995 as under:-Â,,,

â??2(v) â??Scheduled formulationâ? 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;â?,,,

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.Â,,,

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.Â 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.Â 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.Â,,,

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

own costs.,,,