

**DELHI HIGH COURT HOLDS THAT EXPLANATION (2) TO SCHEDULE - I TO THE DRUGS (PRICES CONTROL) ORDER, 2013 (“DPCO 2013”) RESTRICTS THE SWEEP OF EXPLANATION (1) AND CLARIFIES THAT THOSE FORMULATIONS DEVELOPED THROUGH INCREMENTAL INNOVATION OR/AND INVOLVING A NOVEL DRUG DELIVERY SYSTEM WOULD NOT BE INCLUDED IN THE LIST UNLESS SPECIFICALLY MENTIONED.**

**MODI-MUNDIPHARMA PVT. LTD. V. UOI & ORS.; W.P. (C) 11802/2016**  
**(JUDGMENT DELIVERED ON: JULY 17, 2018 BY HON’BLE MR. JUSTICE VIBHU BAKHRU)**

### **INTRODUCTION**

In a recent decision, the **Delhi High Court has removed ambiguity** around the treatment of formulations developed through incremental innovation and/or involving a novel drug delivery system, for the purpose of *inter-alia*, pricing. By differentiating between two seemingly overlapping explanations to **Schedule I** of the DPCO 2013, and holding that even though **Explanation I** expands the scope of Schedule I to include formulations with dosage forms different from those listed in the Schedule, **Explanation (2)** restricts the sweep of Explanation (1) and **excludes from the list** those formulations which are developed through **incremental innovation and/or involving a novel drug delivery system** unless specifically mentioned, the Delhi High Court has clarified a position which the industry has for long attempted to articulate before the **National Pharmaceutical Pricing Authority (“NPPA”)**.

### **THE CHALLENGE**

The Petitioner challenged the following orders/communication:

- i) Standing Order No. 1687 (E) dated 09.05.2016 passed by the Assistant Director, NPPA, including the formulation, **TRD Contin 100 mg. tablet CR 10 (“Formulation”)**, within the scope of the ceiling price fixed for **Tramadol** tablet.
- ii) Order dated 19.09.2016 passed by the Deputy Secretary, NPPA whereby the Petitioner’s review petition under paragraph 31 of the DPCO 2013 was rejected.
- iii) Communication dated 05.07.2016 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 challenged the above orders/communication on the ground that the Formulation having not been included in NLEM-2015 was not a “scheduled formulation” within the meaning of the DPCO-2013 and as such could not be subjected to price fixation under the DPCO-2013.

The Petitioner further relied upon Explanation (2) to NLEM-2015 in support of its claim that formulations developed through incremental innovations like SR/CR are included in NLEM-2015 only if specifically mentioned.

The Petitioner claimed that **Continus Controlled Release Dual Mechanism Drug Delivery System** (referred to as “**CR-Technology**”) used by the Petitioner in its Formulation, 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.

### **THE GOVERNMENT’S CASE:**

The Respondent disputed the Petitioner’s contentions and submitted as follows:

- i) That CR-Technology merely relates to the strength and dosage of the medicine Tramadol. 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.
- ii) 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.

- iii) That as long as the “Scheduled Formulation” was utilized for production or manufacture of a drug, it would fall within the scope of price control. If the manufacturer combined, tweaked or modified 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.
- iv) That the interpretation of a statute must depend on the context of the statute. DPCO-2013 was issued in the context of placing a price ceiling on certain essential drugs to ensure that the same were 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.
- v) 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. Explanation (2) to NLEM-2015 could not be read in a manner so as to exclude the Formulation from NLEM-2015.

#### **FINDINGS:**

The Hon’ble Court observed that most of the decisions referred to by Government counsel were rendered by Courts in the context of the DPCO-1995, and since the price control regime had undergone a paradigm shift after the replacement of the Drug Policy of 1994 (on which DPCO-1995 was based) by the National Pharmaceutical Pricing Policy 2012 (on which DPCO-2013) is based), such judgments were of little assistance to the Government.

The Hon’ble Court held as follows:

- i) On a plain reading of the description under “Dosage form and strength” against Tramadol in Serial No. 2.2.3 of NLEM-2015, CR Technology is not expressly mentioned.
- ii) 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 SR/CR should be considered as included only if specified in the list against any medicine.
- iii) The said 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.
- iv) It is apparent 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.
- v) Explanation (2) to the Schedule-I to the DPCO-2013 clarifies that 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.
- vi) Both the aforesaid explanations – Explanation (1) and (2) to the Schedule-I to DPCO-2013 – must be given their full effect.
- vii) Explanation to a statute is an integral part of the statute and must be read according to its own tenor.
- viii) 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.
- ix) **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. Whereas 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 SR/CR would not be**

included in the list unless specifically mentioned.

## CONCLUSION

The judgment recognises that incremental innovation or/and novel drug delivery systems deserve to be treated differently and cannot be painted with the same brush as conventional forms. The report submitted by the Core Committee in 2015 records that the while revising the NLEM it had deliberated and accepted that innovation in medicine must be encouraged and that formulations developed through incremental innovation/ novel drug delivery systems like *inter-alia*, lipid/liposomal, sustained release, controlled release formulations should be considered differently for purposes such as procurement policy, pricing etc. However the intent of the Core Committee even though it found a place in the explanations to the Schedule I remains inadequately reflected in legislation and government action. The judgment marks a welcome intervention in a domain which the Courts have of late shown reluctance to enter and have left to the discretion of the experts. As the Government expands the scope of price control to medical devices, it is hoped that more issues relating to the inadequacies and ambiguities inherent in the DPCO-2013 when applied especially to medical devices, will be discussed, paving the way for changes.

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