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DELHI HIGH COURT PROMOTES INDIGENOUS R&D IN THE PHARMACEUTICAL INDUSTRY: NOVEL DRUG DELIVERY SYSTEMS ARE NOT IMPLICITLY INCLUDED UNDER THE DRUGS (PRICE CONTROL) ORDER, 2013

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In the recent case of Modi-Mundipharma Private Limited v Union of India & Ors., (Writ Petition (Civil) No. 11802 of 2016), the High Court of Delhi (Court) has clarified that incremental innovation or novel drug delivery systems like lipid / liposomal formulations, sustained release, controlled release, etc. should be treated as scheduled formulations under Drugs (Price Control) Order, 2013 (2013 DPCO) only if specifically specified in the list. The Court held that such differential forms should be considered different for the purposes of procurement, pricing, policy.

Background

Modi-Mundipharma Private Limited (Petitioner) challenged the standing order dated 9 May 2016 (Standing Order) passed by the National Pharmaceutical Pricing Authority (NPPA) as it sought to include TRD Contin 100mg tablet CR 10 (Subject Formulation), within the scope of the ceiling price fixed for Tramadol tablet. The Petitioner being aggrieved by the Standing Order preferred a review under paragraph 31 of the 2013 DPCO, which was dismissed. The NPPA held that ceiling price of Tramadol 100mg tablet was fixed under Section 2.2.3 of the National List of Essential Medicines, 2015 (NLEM), which included all variants, including the Controlled Release (CR) and Sustained Release (SR) delivery systems.

Issue

Whether a formulation developed through incremental innovations like the CR / SR delivery systems will be included in Schedule I of the 2013 DPCO only if it is specified in the list against a medicine?

Submissions of the Petitioner

The Petitioner contended that the Subject Formulation is not included in the NLEM. As per Explanation (2) to Schedule I of the 2013 DPCO, formulations developed through incremental innovations like the SR / CR release systems are included in the NLEM only if specifically mentioned. The Subject Formulation uses a 'Continuous Controlled Release Dual Mechanism Drug Delivery System', which is an innovative drug delivery system and is not specifically mentioned in the NLEM. As a result, the Subject Formulation cannot be read as included in the NLEM. Consequently, it was submitted that the Subject Formulation

is not a "scheduled formulation" within the meaning of the 2013 DPCO and is not subject to price fixation under the 2013 DPCO.

Respondent's Contention

The Respondent contended that the CR delivery system merely relates to strength and dosage and the non-inclusion of such strength and dosage would not mean that the Subject Formulation is outside the ambit of the 2013 DPCO. 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 2013 DPCO. The Respondent further submitted that in matters concerning procurement and availability of essential medicines, the public interest is paramount and hence, the provisions of the 2013 DPCO must be interpreted in a manner which furthers public interest.

Observations and findings of the Court

The Court clarified that an explanation is an integral part of the statute and therefore in certain circumstances, the legislature explains the true purpose of a statute through an explanation. Similarly, in the present case the strength which is not specified in Schedule I of the 2013 DPCO, is to be considered as 'non-scheduled formulation' and must be understood in the basis of Explanation (1) and Explanation (2) of the 2013 DPCO. Accordingly, the Court made the following observations:

- The true purpose of Explanation (1) to Schedule I of the 2013 DPCO is to extend the scope of Schedule I of the 2013 DPCO to include formulations with dosage forms different from those listed in Schedule I.

- Explanation (2) of the 2013 DPCO clarifies that those formulations which are developed through incremental innovation or involve novel drug delivery systems such as the CR / SR delivery systems would not be included in the list unless specifically mentioned.

- The Report of the Core Committee for Revision of National List of Essential Medicines 2015 (Core Committee Report) also elucidates that the Core Committee deliberated on dosage forms and formulations such as the SR delivery system, modified release and extended release and observed that 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 should be considered as included in Schedule I of the 2013 DPCO.

- In view of Explanation (2) to Schedule I of the 2013 DPCO, formulations developed through incremental innovation or involving a novel drug delivery system would be considered materially different and cannot be read as to be included in the said Schedule unless the same are specified in the list.

The Court accordingly rejected the Respondent's contention that only new drugs, which fall within the scope of paragraph 32 of the 2013 DPCO are excluded from the ambit of price control, while the remaining medicines must be read as included in Schedule I of the 2013 DPCO irrespective of their dosage or delivery systems. In paragraph 32 of the 2013

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DPCO, only new drugs which are developed by indigenous research and those which fall within the scope of paragraph 32 of the 2013 DPCO are excluded. The Court observed that a formulation which is excluded from the NLEM does not escape the rigour of the 2013 DPCO. However, if the formulations fall within the scope of paragraph 32 of the 2013 DPCO, the 2013 DPCO would have no application to such drugs.

Since, in the present case, it was not disputed whether the formulation manufactured by the Petitioner incorporates the CR delivery system, the Court held that the Subject Formulation manufactured by the Petitioner is not covered within the ambit of Schedule I of the 2013 DPCO and would not be subject to price fixation.

Comment

This judgement will be greatly welcomed by the pharmaceutical industry, which has of late being suffering from increasing costs, a regime seeking to control the price of innovative drug delivery systems, and the non-recognition of enhancements in therapeutic value under the guise of price fixation of scheduled drugs. By interpreting the true purpose of the 2013 DPCO through the observations made in the Core Committee Report, and differentiating the 2013 DPCO from the Drugs (Price Control) Order, 1995, the Court noted that the new regime now focusses on regulating the price of formulations, instead of regulating the price of bulk drugs. This observation ensures that a systematic approach is followed while adjudicating upon areas, which may prima facie appear to be ambiguous. The Court by ensuring careful monitoring and differential pricing for different products has promoted indigenous research in the pharmaceutical industry, which otherwise may have reached a standstill, in wake of the strict price fixation norms. The Court has interpreted the provisions of the 2013 DPCO in a manner which will enhance the opportunities for innovation, enhancement of therapeutic value and further promote the growth of the pharmaceutical industry. The Court recognised that medicines developed through incremental innovation cannot be treated at par with other medicines because of the method of manufacture, the technology involved, the advanced benefits to patients and the advanced research and development preceding the manufacture of such medicines.

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