Critical Analysis: Judgments delivered in the Cases of

Modi-Mundipharma & Indoco Remedies

The Hon'ble High Court of Delhi recently passed very important judgments concerning the Drugs Prices Control Order, 2013 ("**DPCO 2013**") in the separate cases of Modi-Mundipharma Pvt. Ltd. Vs. Union of India ("**Modi-Mundipharma**") and Indoco Remedies vs. UoI ("**Indoco Remedies**"). These judgments are singularly significant as, apart from the judgment also passed by the Hon'ble Delhi High Court in the case of Reckitt Benkiser, these are the first judgments to deal with the nuances of the provisions of 'price control' under DPCO 2013.

MODI-MUNDIPHARMA ("MM") CASE:

Facts:

The petitioner in MM case inter alia impugned the Standing Order dated 09.05.2016 passed by the National Pharmaceutical Pricing Authority ('NPPA') to the extent that it included the formulation, TRD Contin 100 mg. tablet CR 10 ('the subject Formulation'), within the scope of the 'ceiling price fixed for Tramadol tablet'. The petitioner also impugned a communication dated 05.07.2016 issued by the 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).

Petitioner's Contention:

NLEM-2015 included formulations of Tramadol Tablet and injection, having strength of 50 mg, 100 mg and 50 mg/ml respectively; however, it did not include CR/SR dosage forms of Tramadol. As the subject Formulation was not included in the list of NLEM-2015 and, therefore, was not a 'scheduled formulation' within the meaning of the DPCO-2013, it cannot be subjected to price fixation under DPCO-2013.

Respondents' Contention:

The respondents contended that since Tramadol was included in the NLEM-2015, therefore, the said drug in all forms of dosage or strength would be subject to price fixation under the DPCO-2013.

Issue for consideration:

When only Capsules (50 mg and 100 mg) and Injection of 50 mg/ml of Tramadol are specified in NLEM and the CR dosage form of Tramadol was not expressly mentioned, whether the latter should be read as impliedly included in NLEM/First Schedule to DPCO 2013?

Hon'ble High Court's Opinion:

The Ld. Judge, while deciding the issue, placed overwhelming reliance upon Explanations (1) and (2) to Schedule-I to the DPCO-2013 and upon the Report of the Core Committee formed for revision of NLEM 2011.

The Hon'ble High Court concluded 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".***

"However, 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".

The Hon'ble High Court opined: ***"Both the aforesaid explanations-Explanation (1) and (2) to the Schedule-I to DPCO-2013 - must be given their full effect".*** Further, ***"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".***

Further, relying upon paragraph 2(v) of the DPCO-2013, which defines the term **'non-scheduled formulation"** to mean a formulation, the dosage and strengths of which are not specified in the Schedule-I to the DPCO-2013, the Hon'ble High Court concluded that even if a medicine is mentioned in Schedule-I 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.

Conclusive finding in the facts of MM case: Since it is not disputed that the subject formulation manufactured by the petitioner incorporates Continus Controlled Release Delivery System, which is referred to as "CR" Technology and, hence, the same is an innovation developed to overcome certain disadvantages associated with the conventional formulations, the subject formulation cannot be read as included in NLEM 2015. Hence, NPPA cannot fix ceiling price for the subject formulation.

My Analysis:

The conclusion of the Hon'ble High Court is absolutely correct but, unfortunately, wholly inadequate to give a complete picture of the scheme of price control under DPCO 2013. The Hon'ble High Court seems to grapple with the issue at hand and comprehend the situation on the basis of only the tip of the iceberg and not the entire iceberg itself. The reason for the inadequacy stems from the fact that the Hon'ble High Court and the lawyers who appeared before it seemed to ferret all answers to the burning issue from only the provisions of DPCO 2013 and, consequently, missed the wood for the trees.

The Missing Background & Link:

DPCO is not a complete code in itself and it needs to be read and construed in conjunction with NPPP 2012 and the Reports of the Committees that framed the NLEM 2011 and 2015. Furthermore, recourse to the Science of Pharmacology is imperative to actually understand some of the pharmacological concepts, which even if defined in DPCO 2013, fails to provide complete understanding thereof.

The superstructure of DPCO 2013 is erected in the pillars of NPPP 2012 and NLEM (as revised, from time to time). DPCO 2013 is only an **Implementing Document** issued to implement the **National Pharmaceutical Pricing Policy, 2012 ('NPPP 2012')**. NPPP 2012 is **implemented** through notification of DPCO 2013 by the Ministry of Chemicals & Fertilizers (MoC&F). The broad objective of NPPP 2012 is to *put in place a regulatory framework for pricing of drugs so as to ensure availability of "essential medicines" – at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry.*

Thus, the foundation stone of DPCO 2013 is laid down by NPPP 2012. The key principles for regulation of prices under NPPP 2012 are: (1) Essentiality of drugs, (2) **Control of formulations prices only** and (3) Market-based pricing.

The NPPP 2012 mandates that the **Essentiality Criterion** is met by the **National List of Essential Medicines** ("NLEM") published by the Ministry of Health & Family Welfare ("MoH&FW"). Hence, NLEM is the second pillar on which the superstructure of DPCO 2013 is erected.

NLEM 2011 defines "essential medicine" as those medicines that "**satisfy the priority healthcare needs of the majority of the population",** which is achieved by "careful selection of a limited range of essential medicines".

The term **"Formulation" i**s defined in DPCO 2013 but the definition doesn't really make one understand the concept. In layman's language, a formulation is the final form of a drug in which it is consumed by the patients. A bare perusal of the List in the NLEM helps us understand what are the ingredients of a formulation. The List specifies **"API/Medicine", "strength of medicine," "route of administration (RoA) & dosage form**" of the drugs included in the List. These are the 4 vital attributes or ingredients of a Formulation, implying clearly that any change in any of the foregoing attributes or ingredients results in the creation of a different formulation.

API is not to be confused with "formulation". The Hon'ble High Court in the judgments under review gives some indication of such confusion still persisting in the mind of the Ld. Judge. In fact, even the definition of "API or Bulk Drug" in DPCO 2013 clarifies that it is an ingredient in any formulation.

However, it is noteworthy that not all formulations can be brought under the ambit of "ceiling price" under DPCO 2013 but only those formulations that are considered "essential" under the NLEM and which, by incorporation in the Schedule to DPCO 2013, are called "Scheduled Formulations".

It is, thus, apparent that in pursuance to the key principles of NPPP 2012, NPPA can fix ceiling price for formulations only AND only for those formulations, whose API, RoA, strength and dosage are all specified in NLEM, and thereby, in the First Schedule to DPCO 2013.

In the case under consideration, the burning question was whether a "controlled release" dosage form of a medicine is a "scheduled formulation" if the API is included in the NLEM but not its Controlled Release (CR) dosage form.

The basic shortcoming in the MM Judgment is that it has failed to comprehend the term "Dosage Forms" but still, fortunately, arrived at the right conclusion solely on the basis of Explanation 2 to the First Schedule to DPCO 2013 (inserted on 10.3.2016) and relying upon the definition of "Non-scheduled formulation", which had already been amended on 9.3.2015.

It is on account of the inadequate understanding of the scheme of DPCO 2013, and its underlying vital concepts, that the MM Judgment, although absolutely correct, stands on marshy terrain and on tenuous grounds.

As stated earlier, first, the concept of **"formulation"**, in particular contradistinction to the term 'API or Bulk Drugs' need to be understood clearly and the paradigm shift in the policy principles of 2012 from the earlier policy and its implication requires adequate emphasis.

Next, the concept of **"dosage forms",** which are of paramount significance, needs complete and thorough elaboration. The biggest shortcoming of the MM Judgment rendered by the Hon'ble High Court is that it has missed the opportunity of such elaboration entirely.

DOSAGE FORMS: This is a pharmacological concept and must be understood in pharmacological parlance. Mere reliance upon statutory definitions and provisions is bound to flounder. In *Biopharmaceutics, the term **"Dosage form"*** is defined as the **means or the form** by which the Drug Molecule is delivered to the sites of action within the body. Dosage Forms can be **classified** according to: (a) Physical Form, such as tablets, capsules, injections; (b) RoA and (c) most eminently, on the basis of **Drug Delivery System ('DDS').**

Dosage Forms, when classified or perceived in terms of DDS, can further be classified into: (a) conventional dosage forms or, (b) modified dosage forms. In **conventional dosage form**, the API of the drug is released immediately **(IR)**. *Eg. Normal tablets, capsules, ointments.* In **modified dosage form (MR) of a formulation,** the drug release characteristic of time course and/or location is altered and chosen to accomplish *therapeutic objective* not offered by conventional dosage forms**.** Types of MR drug products include **Sustained Release, Controlled Release,** Delayed Release, Extended Release, Targeted release and Orally Disintegrating tablets.

Indian Pharmacopeia (IP) 2014 has specified different types of dosage forms in which Tablets could be further categorized.

Even DPCO 2013 itself considers ***"dosage forms"*** as crucial for the purpose of bringing a particular drug within the folds of price control. **Paragraph 14 of DPCO 2013** provides for Fixation of Ceiling Price of **Scheduled formulations.** Scheduled Formulations are formulations that are included in the First Schedule to DPCO 2013. Ceiling Price is fixed under para 14 of DPCO 2013 in accordance with the provisions of para 4 and 6 of DPCO 2013. Notably, **Para 4** of the DPCO 2013 provides for calculation of Ceiling Price of Scheduled formulation of '***specified strength and dosage*** **as specified under the First Schedule'.** The First Schedule to DPCO 2013 is simply the List of Essential Medicines published in the NLEM 2011/NLEM 2015, which is incorporated in DPCO 2013 as its First Schedule.

The definition of "Non-scheduled formulation" (*as it stood prior to its amendment on 9.3.2015*) made it amply clear that if the dosage and strength of a formulation was not specified in the First Schedule, it would be a non-scheduled formulation. The MoC&F amended the definition but the said amendment was not in consonance with the principles of the NPPP 2012 and the concept of "essentiality" developed under NLEM and the said amendment was challenged as ultra vires by way of a writ petition, which is pending adjudication before the Hon'ble Division Bench of the Delhi High Court.

Amendment in the definition of "non-scheduled formulation" was the first malafide step by the MoC&F in its endeavour to revert to the principles of DPCO 1995 and the next step in that direction was the proposed amendment to para 4 of DPCO 2013. However, since para 4 stands unamended as of now, the impact of amendment in the definition of "non-scheduled

formulation" is cushioned by para 4, whereby, a formulation whose strength or dosage form is not specified in NLEM/First Schedule, cannot still be brought under ceiling price fixed by NPPA. Thus, the force of the said amendment is blunted fully and is inconsequential.

Therefore, the aforesaid amendment made on 9.3.2015, although malafide, malicious and ultra vires, has not succeeded in entirely damaging or distorting the scheme of DPCO 2013 and cannot do so till para 4 is retained unamended in DPCO 2013. While the Ld. Judge in MM case failed to notice the said amendment but, moreover, has not been able to construe the position correctly and, in the subsequent matters, found to be placing undue reliance upon the said definition of "non-scheduled formulation" and the date of its amendment.

More perturbing shortcoming in the understanding of the scheme of DPCO in the mind of the Ld. Judge emanates from the fact that he places undue emphasis on Explanations added to the First Schedule to DPCO 2013 on 10.3.2016. Explanation 2 only explains and clarifies the situation that prevailed since inception of DPCO 2013. Explanation is not to be confused with amendment. Irrefutably, Explanation 1 adds a new concept and it restricts the ambit and operation of Explanation 2.

Unfortunately, the Ld. Judge did not receive full assistance by placing before him the following **Inter-Ministerial Deliberations and the Opinion formulated and disseminated** by the DoP and the Ministry of Health and Family Welfare, which is briefly narrated below:

- On 1st August, 2013, NPPA sought the advice of DoP on the issue of treatment of modified dosage forms under DOCO 2013;
- DoP constituted a **Committee** on the above issue. The Committee observed that while *all forms and strengths of formulation related to drugs were included in the First Schedule of **DPCO, 1995***, and were brought under the ambit of price control; **in DPCO, 2013, only the dosage forms and strengths of drugs/formulations, as specified under NLEM 2011, have been brought under the ambit of price control;** wherever only conventional forms of a drug were specifically mentioned under NLEM 2011, the **modified dosage forms** like modified release forms, dispersible, effervescent, soluble, enteric coated, lipid suspension/liposomal forms of that drug **may not be part of NLEM, 2011**.
- Vide Letter dated **6th September, 2013,** DoP requested the MoH&FW to get the issue clarified at the earliest so that the prices could be notified accordingly.
- Vide Letter dated **19th September, 2013**, DoP informed the OPPI that innovative dosage forms have been opined not to be kept under price control as per DPCO 2013.
- MoH&FW got the matter examined by **CDSCO** in consultation with the Head of Department of Pharmacology, AIIMS, who was also the Chairman of the Core Committee constituted to prepare the NLEM 2011.
- Vide **Office Memorandum dated 6th December, 2013**, the Ministry of Health and Family Welfare informed the DoP and NPPA that *in the opinion of CDSCO,* conventional forms of a drug like tablet/capsule/injection would be considered as

a part of NLEM 2011 and ***not the dosage forms*****,** like modified release forms, dispersible, effervescent, soluble, enteric coated, lipid suspension/liposome of that drug, **unless these drugs are specified in non-conventional dosage forms in NLEM 2011 itself.**

Thus, neither the recommendation of the Core Committee in its Report of December 2015 for Revision of NLEM nor the Explanation 2 inserted in the First Schedule to DPCO 2013 in pursuance to the former, adds anything new but merely reaffirms the existing position and gives a statutory flavour thereto.

Even the earlier Core Committee set up for preparing ***NLEM 2011*** took the considered view that **strength and dosage forms** of the medicine should be mentioned in the NLEM. The NLEM 2011 consciously **distinguished** between conventional and modified dosage forms of formulations and, *whenever the domain experts deemed it fit,* the modified dosage form of the formulation(s) was also included in the NLEM. For instance, **Nifedipine Tablets and Capsules** alongwith its **'sustained release' dosage form**, were included in NLEM 2011. Pertinent to note is that, in accordance with NLEM 2011, when NPPA fixed the ceiling price of *Nifedipine tablet, Nifedipine capsules, Nifedipine sustained release tablet and Nifedipine sustained release capsules*, such ceiling prices were fixed separately and differently by NPPA. Nifedipine Tablet's ceiling price was fixed at Rs. 1.20 per unit as against Rs. 1.51 per unit for Nifedipine Sustained Release Tablets. The percentage difference in price works out to **more than 25%**.

The conclusion that **Conventional and Modified dosage forms of any formulation** processed out of the same drug, and even though having the same "Active Pharmaceutical Ingredient" (API), strength and route of administration, are **separate formulations, if arrived at by the Court, would set to rest the entire controversy and herald a quietus to all such disputes**. Alas, the judgment rendered in the MM case by the Hon'ble High Court is, thus, a case of "Missed Opportunities". It leaves us not only confused but many pertinent questions remain unanswered.

Furthermore, the construction of paragraph 32 of the DPCO-2013 in MM case, whereby 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, is not wholly correct. The Judgment holds that if the drug falls within the scope of paragraph 32 of the DPCO-2013, then the same would be completely excluded from the purview of the DPCO-2013.

The correct construction of Para 32 of DPCO 2013 is that this provision can be taken recourse to in respect of such new drugs, which are developed through indigenous research from the scope of the DPCO-2013 but are otherwise, "scheduled formulation" and further that in the foregoing circumstances, the exemption is only for a limited period of 5 years.

INDOCO REMEDIES LIMITED ('IR') CASE:

Facts:

The petitioner in IR case impugned the demand notice dated 20.11.2017 issued by NPPA towards overcharged amount plus towards interest on the ground that IR had not complied with the ceiling price fixed under DPCO-2013.

Here, the subject formulation was TRIZ Syrup 60 ml containing CETIRIZINE 5mg/5ml. NLEM-2011 included CETIRIZINE with the following strengths: -

- CETIRIZINE Tablets 10 mg and
- CETIRIZINE Syrup 5 mg/ ml.

By issuing Price Notification Order(s), NPPA fixed the ceiling price of CETIRIZINE syrup with strength 5mg/ml. Thereafter, upon coming into effect of NLEM 2015, which included CETIRIZINE syrup with strength 5mg/5ml, NPPA issued a Price Notification Order inter alia for CETIRIZINE Oral liquid of strength 5mg/5ml.

Petitioner's Submissions:

Schedule I to the DPCO-2013 included CETIRIZINE in only two dosage forms and strength, namely, Tablets of 10 mg and Syrup of 5 mg/ml. Since the dosage and strength of the subject Formulation was different from the one as listed in Schedule I to the DPCO-2013, the Formulation, was covered within the scope of "non-scheduled formulation" as defined in paragraph 2(v) of the DPCO-2013. Reliance was placed on the recent judgment in Modi-Mundipharma case (supra).

The next contention was that even if it is assumed that the subject Formulation was included under DPCO-2013, the ceiling price as fixed under Price Notification Orders issued on 28.04.2014, 26.02.2015 and 02.03.2016 could not be applied as the said Price Notification Orders did not provide any ceiling price for CETRIZINE with the dosage and strength manufactured/sold by IR. The subject Formulation was included under ceiling price for the first time by virtue of Price Notification Order dated 09.05.2016. Hence, the demand was unsustainable.

Courts' Discussion and Conclusion (as extracted):

A plain reading of paragraph 8(1) of DPCO-2013 read with the definition of the expression "scheduled formulation", clearly indicates that the formulation CITRIZINE would fall within the scope of DPCO-2013.

A conjoint reading of the definitions of 'scheduled formulation' and 'non-scheduled formulation' indicates that those drugs, which are not mentioned in Schedule I of DPCO-2013 clearly fall outside the scope of price ceiling under paragraph 8(1) of DPCO-2013. They would undisputedly fall outside the purview of the definition of the term 'scheduled formulation' and squarely fall within the definition of the expression 'non-scheduled formulation'. However, there is another set of drugs which on a plain reading of paragraph 2(1)(zb) of DPCO-2013 fall within the scope of the term 'scheduled formulation' but would stand excluded on account of the specific dosages and strengths not being specified in the said schedule. In respect of such medicines, paragraph 2(1)(v) of DPCO-2013 (which defines the term "non-scheduled formulation") would work as an exclusionary clause.

The interpretation of provisions of DPCO-2013 must lean towards including essential medicines within the scope of DPCO-2013 rather excluding them. Accordingly, clause (v) of paragraph 2(1) of DPCO-2013 must be read in a restrictive and not an expansive manner.

It is trite law that exclusionary clauses of a beneficial legislation are to be read narrowly. This is so to ensure that the beneficent impact of the Act is not diluted. It is also well settled canon of statutory interpretation that such statutes must be interpreted, in so far as possible, to further public interest.

The reference to dosage and strengths as used in clause (v) of paragraph 2(1) DPCO-2013 as it existed prior to 09.03.2015 cannot be read in a literal sense and must be interpreted in a meaningful manner to further the purpose of DPCO-2013.

In the aforesaid view, the expression "non-scheduled formulation" in the context of excluding medicines that are specified in Schedule-I but not of the specified strengths and dosages, must be read in the manner to exclude only those medicines where unspecified **dosage/strength result in a qualitative difference to the formulation.** In other words, the dosage and strength on the basis of which the medicines specified in Schedule I are sought to be excluded, must necessarily mean dosages and strength which have an effect of resulting in a different product. Mere quantitative differences would be insufficient to establish any material difference from the scheduled formulation. Plainly, dilution in the strength of a medicine or increasing the concentration would have little effect on the product. For example, a tablet of the strength of 250 mg and a tablet of 500 mg would have little difference in the product. A patient, who has been prescribed to take two such tablets of 250 mg, could take one tablet of 500 mg strength. In such cases, there would be little added advantage or disadvantage in using one or the other. Similarly, a medicine may be given in the form of a tablet or a capsule, the dosages and strengths of the medicines in this respect may differ but the essential product remains the same. In these cases, it would be difficult to accept that although the drug falls within the expression 'scheduled formulation' as defined in Paragraph 2(1)(zb) of DPCO-2013, the same should, nonetheless, be excluded merely because the dosage or strength-which has no material effect on the Formulation in question-is not specified. However, there are formulations, which use innovative forms or route of administration that render the formulations materially different from the one listed in Schedule-I of DPCO-2013 even though the medicine remains the same. Such formulations would qualify to be non-scheduled formulations if not specifically included.

Conclusion: There is no material difference between the subject Formulation and the CETRIZINE as included in NLEM-2011. The Formulation manufactured by IR is only a dilution of the strength of CETRIZINE, as specified in Schedule I. Clearly, such variation in the strength of the medicines would be wholly insufficient to exclude the same from Schedule I of the DPCO-2013.

Surely, accepting a mere dilution in the strength of medicine is insufficient to exclude the same Schedule-I of the DPCO-2103. Such interpretation would be an open invitation for all drug manufacturers to tweak the strength of their formulations so as to escape the price control regime under the DPCO-2013. Plainly, this would frustrate the object of the legislation. More importantly, it is impossible to accept that legislative intent was to exclude formulations from Schedule I merely on the basis of dilution or concentration in the strength of the medicines as specified.

Clause (v) of paragraph 2(1) of DPCO 2013 was substituted with effect from 09.03.2015 to read as under:-

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

The words 'dosages and strengths' were deleted from the definition of the term 'non-scheduled formulation'. With the aforesaid amendment, the provisions of paragraph 2(1)(zb) and 2(1)(v) of DPCO-2013 have been harmonised. Thus, any medicine which is included in Schedule I of DPCO-2013 would be a scheduled formulation and any medicine which is not, would be a non-scheduled formulation.

Explanation 1 now expressly provides that any dosage form, which is not included in Schedule I, but in same strength which does not have any significant difference in terms of pharmacokinetics/pharmacodynamics/efficacy-safety profile over the dosage form mentioned in the list, should be considered as included in Schedule I.

By virtue of Explanation 2, the formulations that were developed through incremental innovation or novel drug delivery system such as Sustained release or Controlled release were unless specified in Schedule I, expressly to be excluded from Schedule I. Plainly, medicines with such added qualities or attributes that are substantial enough to render the product itself dissimilar to the one entered in Schedule-I, cannot be assumed as covered by an entry in Schedule-I, which does not specifically indicate so. This is also the substratal rationale of clause (v) of paragraph 2(1) of DPCO-2013 as it existed prior to 09.03.2015.

The reliance placed on the decision in the case of Modi-Mundipharma Pvt. Ltd. v. Union of India and Ors. (supra) is misplaced.

In the present case, it is, ex facie, clear that there is no material difference in the medicine as specified in Schedule I-CETRIZINE Syrup 5mg/ml and oral syrup 5mg/5ml and the latter would only be a diluted version of the former.

In view of the above, the Court formed the view that the Formulation in question was included in Schedule I and was fully covered within the scope of DPCO-2013.

The next question to be considered is whether the Formulation in question was covered within the Price Notification Orders issued under DPCO-2013. The first such order was issued on 28.06.2013 where the selling price was fixed at ` 0.54/-. The same would, plainly, be applicable and would not exclude the formulation in question merely because it was a diluted version of the scheduled formulation-CETRIZINE Syrup.

My Analysis:

I am afraid to say that this Judgment is wholly incorrect and unsustainable for myriad reasons.

The Court holds that *"A plain reading of paragraph 8(1) of DPCO-2013 read with the definition of the expression "scheduled formulation", clearly indicates that the formulation CITRIZINE would fall within the scope of DPCO-2013"*.

First, the Hon'ble Court fails to understand that CITRIZINE is not a "formulation" but an "API" and that DPCO 2013 is concerned with formulations and price control of formulations only. The key principles of NPPP 2012, read in conjunction with NLEM, has been lost sight of.

Secondly, the Hon'ble Court errs in construing the original definition of "non-scheduled formulation" as an exclusionary clause only. The Court fails to comprehend that a formulation becomes a "scheduled formulation" only when all the ingredients, namely, API, RoA, Strength and Dosage Forms are specified in NLEM and, thereby, in the First Schedule to DPCO 2013. The fallacy in the reasoning of the Hon'ble Court arises on account of relying entirely upon the literal interpretation of the terms defined in DPCO 2013 and not broadening the understanding by also taking the aid of the principles of NPPP 2012 and the NLEM. This blunder is understandably bound to happen if the course adopted is to restrict oneself only to a plain reading of the provisions of DPCO 2013. I reiterate that DPCO 2013 is not a complete code but rather an implementing document that stands on the twin pillars of NPPP 2012 and NLEM 2011/2015 and without the aid of the said twin pillars, the superstructure of DPCO 2013 would inevitably collapse like a house of cards. And, unfortunately, this is what has

happened in the case of IR. The conceptual understanding of the pharmacological terms is glaring.

What the Hon'ble Court has failed miserably to appreciate is that unlike other Price Control Orders issued under Section 3 of the Essential Commodities Act. 1955, the Drugs Prices Control Order is propelled and governed by the National Pharmaceutical Pricing Policy which, read conjointly with the List in the NLEM in force, would determine what are "essential medicines" that can be brought under the ambit of price control. If we read the Schedule to the Essential Commodities Act, then all "drugs" are essential commodities. But, the delegated legislations, in the form of NPPP, which in turn allows the MOH&FW to decide what are "essential medicines" by preparing and publishing the NLEM, filter what actually are the essential medicines/commodities for price control under DPCO 2013. Hence, not all drugs or medicines can be brought under price control. Till NPPP 2012 was framed and DPCO 2013 issued to implement the former, all formulations of a bulk drug could be brought under ceiling price if the said API or "Bulk drug" was specified in the Schedule to the then DPCO 1995.

Actually speaking, the position while fixing Ceiling Price of a formulation, is very simple. You only have to look at the First Schedule/NLEM (as revised, from time to time) and look at all the 4 parameters/ingredients, viz. the API, RoA, Strength and Dosage Form, and is all the 4 aforesaid parameters are specified therein, the said formulation can be brought under price control and if any of these 4 parameters are not specified, it becomes a "non-scheduled formulation" and, hence, it cannot be brought under the ambit of price control under DPCO 2013.

The Hon'ble High Court failed to appreciate the above position. In light of the foregoing, the proposition that exclusionary clause must be construed narrowly is utterly misconceived. The concept of "public interest" cannot be artificially imported to dislodge the scheme. Public interest is fully subserved by fixing the Ceiling Price of "scheduled formulation". Fixing the ceiling price of non-scheduled formulation is alien to the scheme of price control under DPCO 2013.

Having made the above fundamental error, the Hon'ble High Court fallaciously treats "strength" and "dosage forms" alike in IR case.

In the IR case, the question was not of "dosage forms" but of "strength" of the subject formulation. In fact, this case was easier to comprehend than MM case but the Ld. Judge falters conspicuously while deciding this case. In MM case, it was quite fortuitous for the petitioner that Explanation 2 came to its rescue but in IR case, Explanation 1 was misread to dismiss the petition.

The Ld. Judge commits a grave error when it goes on to say that the subject formulation was only a diluted version of the scheduled formulation, which made no difference. The reasoning reflects a complete lack of understanding of the scheme of DPCO 2013.

Whereas, Explanation 1, which was added on 10.3.2016, is actually an aberration to the entire scheme and tries to incorporate the concepts of Patents Act, particularly that of 'enhanced therapeutic efficacy" under Section 3 (d) of the Patents Act, 1970 and of "evergreening", the restriction brought into effect applies solely to "dosage forms" and not at all to "strength" of a formulation. In fact, contrary to its fallacious application by the Hon'ble Court in the IR case, Explanation 1 refers to different dosage forms but "in same strength".

Hence, the IR judgment suffers from the grave malady of not only miscomprehending the scheme of DPCO 2013 but also from misconstruing the import and scope of Explnation1 to the First Schedule to DPCO 2013.

Even after a discordant note added by way of Explanation1 to the First Schedule to DPCO 2013, it is wholly incorrect for the Ld. Judge to dismiss the petition filed by IR on the ground that *"There is no material difference between the Formulation and the CETRIZINE as included in NLEM-2011"* and further to observe that ***"accepting a mere dilution in the strength of medicine is insufficient to exclude the same Schedule-I of the DPCO-2103. Such interpretation would be an open invitation for all drug manufacturers to tweak the strength of their formulations so as to escape the price control regime under the DPCO-2013. Plainly, this would frustrate the object of the legislation. More importantly, it is impossible to accept that legislative intent was to exclude formulations from Schedule I merely on the basis of dilution or concentration in the strength of the medicines as specified".***

The Hon'ble Court failed to appreciate that Formulations of a medicine are usually available in many strengths. It further failed to take note of the Report of the Core Committee set up for the purpose of Revision of NLEM 2011. The Core 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"**.

Thus, the Committee has considered what strengths of a formulation are to be considered essential and it is not open to the Courts to tinker with it. It is trite law that the opinion of Experts is not subject to judicial review.

Another grave mistake in IR judgment is that it considers the Price Notification Orders issued under DPCO-2013 for a different strength of Cetirizine to be applicable to the subject formulation because, according to the Ld. Judge, *"it cannot exclude the subject formulation merely because it was a diluted version of the scheduled formulation-CETRIZINE Syrup"*.

The Ld. Judge falters again in holding that with the aforesaid amendment in the definition of "non-scheduled formulation", the provisions of paragraph 2(1)(zb) and 2(1)(v) of DPCO-2013 have been harmonised. Actually, as stated earlier, the said amendment is the first step taken by the MoC&F in overturning the meaning and applicability of NPPP 2012 and what was explicit under the original definition of "non scheduled formulation" has been obfuscated for achieve the foregoing purpose. The MoC&F proposed to amend para 4 of DPCO 2013 as well and, subsequently, inserted para 11(3) to DPCO 2013. All these amendments have been brought about with the objective to widen the ambit of price control beyond permissible limits. Apparently, the MoC&F is guilty of doing something indirectly, i.e overturning the NPPP 2012, which, it cannot do directly. Moreover, it tantamounts to blunting the edge of NLEM, which falls squarely in the domain of MoH&FW.

In recapitulation, I would humbly submit that while the judgment in MM case is correct in its final conclusion, it manifestly falls short in dealing with the scheme of price control under DPCO 2013 and, irrefutably, the judgment in IR case is a horrendous blunder.

Manoj

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