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THE PHARMAPHOBIA



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Guess the place, having the highest real estate value in India? The Defence Colony of New Delhi? The Nariman Point of Mumbai? The MG Road of Bangalore? Or The Boat Club of Chennai? In the days to come, none of them will be. Instead, it could possibly be, Tanda Mallu of Uttaranchal, Banikhet of Himachal Pradesh, Wazeho of Nagaland and Dalgaon of Assam and the major reasons for this, could well be the advent of Notification 2/2005 - Central Excise (N.T.), dated 07.01.05.

Notification No 2/2005 - Central Excise (N.T.)., dated 07.01.05 is nothing but a Tsunami for the Pharma Sector. After years of speculation, the Pharma Industry has been brought under MRP based Levy under Section 4A of the Central Excise Act 1944. Even though, MRP based levy was in the offing for the Pharma sector over years, its present introduction has been so untimely, that too, when the Budget is round the corner.

Interestingly, while bringing the drug industry under Section 4A, the Government has consciously made some deviations, which are distinct from the earlier Notifications. Since the introduction of Section 4A, till date, there are around 92 Chapter headings/subheadings, which have been brought under the assessment based on the MRP. Even though Section 4A contemplates for levy of duty based on the MRP required to be fixed under the provisions of Standard of Weights and Measures Act 1976 and the Rules made there under or under any other law for the time being in force, so far, all the notified commodities have been assessed under the provisions of Standard Weights and Measures (Packaged Commodities) Rules. In other words, for all the notified goods under Section 4A, the assessment was made based on the MRP, only if such commodities and their packages are required to be affixed with MRP under the provisions of Standard Weights and Measures (Packaged Commodities) Rules. But on a conspicuous deviation, the present Notification 2/2005, has brought the Pharma products under Section 4A of the Central Excise Act, with the distinct explanation that, the retail sale price for the said Notification means the retail price required to be displayed by the manufacturers under the provisions of the Drugs (Price Control) Order, 1995. In other words, the Pharma products are assessed under Section 4A of the Central Excise Act on the basis of retail sale price required to be displayed under provisions of Drugs (Price Control) Order, 1995 and **NOT** under the provisions of Standard Weights and Measures Act 1976. The basic reason for the same could well be that, as per Rule 34 (c) of the Standard Weights and Measures (Packaged Commodities) Rules, the drugs covered under the Drugs (Price Control) Order, 1995 are excluded from the purview of the Standard Weights and Measures (Packaged Commodities) Rules.

Let us now delve into the provisions of Drugs Price Control Order, 1995 in comparison with the provisions of the Standard of Weights and Measures (Packaged Commodities) Rules, which would reveal that there is a Silver Line distinction between both the provisions, which is the subject matter of this article.

Earlier, we have all witnessed varied disputes arising under the Section 4A of the Central Excise Act, on account of the variety of interpretations including the types of Packages viz., Combination Package, Multipiece Package, Wholesale Package etc. There were also disputes about the exemption from marking of MRP on certain packages. For example, there is an exemption from marking the MRP on packages containing a quantity of less than 10 ml or 10 grams under Rule 34 (b) of Standard Weights and Measures (Packaged Commodities) Rules. In other words, even if the goods are notified under Section 4 A of the Central Excise Act, if the pack size is less than 10 ml or 10 grams, then such goods are not assessed under Section 4A but are assessed only based on the transaction value under Section 4 of the Act. Shampoo sachets of 8 ml would be a classic example. Now with the present Notification having reliance to the Drugs (Price Control) Order, 1995, there could not be any similar disputes. No such exemptions are not provided for under the Drugs Price Control Order, 1995 and hence there could be no exemption from Section 4A on this count.

Secondly, the abatement percentage given to the pharma sector. With the paltry 35% as abatement, the entire drug industry, feels totally being let down. But the fixation of the abatement @ 35 %, is not



thoroughly unjustified. As it could be seen from the definitions, there is a basic and vital difference between Retail Sale Price as defined under the Standards of Weights and Measures (Packaged Commodities) Rules and the Drugs (Price Control) order, 1995. Whereas the Standards of Weights and Measures (Packaged Commodities) Rules define "Retail Sale Price" under Rule 2 (r) of the said Rules as the maximum price which is "inclusive of all taxes", the Drugs (Price Control) order, 1995 define the "Retail Sale Price" shall be exclusive of local taxes, as per Rule 15(1) of the said Rules. In other words, the Retail Sale Price (RSP), required to be affixed under the Drugs (Price Control) order, 1995 does not include the local levies such as sales tax, etc. As per section 4A(3), of the central Excise Act,1944, the Central Government arrives at the abatement, taking into account the amount of duty of Excise, Sales Tax and other taxes, if any, payable on such goods. Hence, this 35% abatement should have been arrived taking into consideration that the RSP under the Drugs (Price Control) order, 1995 is exclusive of local levies.

Thirdly, there is a confusion prevalent among the trade that, as the explanation to the said notification defines RSP as the retail price required to be affixed under the provisions of Drugs (Price Control) order, 1995, whether the drugs / formulations scheduled under the said order alone, would be under the RSP or all the drugs would fall into the ambit. In this connection, we wish to point out that, as per Rule 15 of the Drugs (Price Control) order, 1995, even all the non-scheduled formulations, which are intended for sale, are required to be affixed with the RSP.. Thus all scheduled and non-scheduled formulations would be covered under the provisions of Section 4A, for assessment based on RSP.

Fourthly, there is a concept of "Physician's Samples", prevalent in the drug industry. Drugs of lesser denominations will be packed in cache covers, which will be distributed to the various Doctors/ Medical Practitioners/ Hospitals, free of cost, as a measure of demonstration/promotion. This is a very common trade practice in drug industry. There is a possible confusion about the valuation of such physician's sample. As per Rule 15(1) of the Drugs (Price Control) order, 1995, the retail price has to be affixed only if the drug is **offered for retail sale**. There is no requirement, whatsoever, to mention a RSP on the Physician's sample, because of the fact that they are for free distribution and not for any retail sale. Hence, valuation of the Physician's sample shall be based on the basis of Section 4 of the Central Excise Act, and not under Section 4A of the said Act.

There is also another mode of transaction, called "Institutional Sales". For example, drug manufacturers get orders form various institutions/ State Governments for supply of their drugs/formulations. Such drugs would be further distributed to public by such Institutions/ State Governments through their Hospitals/ Health Centers, etc, free of cost and are not offered for retail sale. It shall also not to be mistaken that, any bulk supply to a private hospital or a private institution, would be exempted from the payment of duty based on RSP. Even if the drugs are supplied directly to the private institution/ hospital and which are subsequently sold in retail by such private institution / hospital, then such drugs shall remain to be assessed under Section 4A of the Central Excise Act. To sum up, the essential determining factor for assessment under Section 4A would be that, ultimately, whether such goods are offered for retail sale or not.

Last but not the least, there is another major grievance to the drug industry which is in the form of "Discount". Discount is a buzzword of the drug industry. All drug manufacturers , be it a tiny manufacturer or a global giant, have to provide discount. These discounts are of various forms and of various proportions depending on their market strength. Discounts ranging from 10% to 100% is very common in the industry. For example, for 10 boxes of Paracetamol, the manufacturers may have to give a discount of 12 boxes, due to commercial compulsions. Earlier, when the assessment was under Section 4 of the Central Excise Act,(Transaction Value), the manufacturers were not paying duty on the drugs cleared as such discounts. But with the advent of the present notification, there is no provision for such discounts to get abated. In other words, the manufacturers will be constrained to pay Excise duty on the RSP for such drugs cleared as discounts also, which we fear, will take a toll on industry.

Already the drug industry is facing a severe blow, owing to the compliance of Schedule M of the Drugs and Cosmetics Act. Now with this present RSP Tsunami, the drug industry needs nothing short of a "Life Saving Drug".



Before parting:

Most of the MNCs were manufacturing their drugs from small Indian manufacturers on job work basis and were paying duty on the cost construction method based on the ratio laid down in the case of Ujagar Prints. With this present levy based on RSP, all the equations are on a roller coaster, whereby, the duty component has increased on a geometrical progression. This shall make the entire drug community to rush to excise exempted areas, thus justifying the opening paragraph of this article.