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Physician samples – The LB twist



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“Physicians’ samples” are more often found in Court rooms than in Doctors’ tables, considering the complexity of their valuation. In its first birth in Section 4 era, it has lived a full circle, starting from CBEC Circular dated 01.07.2002 (clarifying that it has to be valued on the basis of cost plus 15 %), volte facie on 25.04.2005 (circular clarifying sale price of similar goods has to be adopted under Rule 4 of the Valuation Rules, 2000), Larger bench decision in Blue Cross Laboratories case {2006 (202) ELT 182 = 2006-TIOL-1142 – CESTAT LB} upholding application of Rule 4 ibid and Mumbai High Court ruling out valuation based on cost construction and upholding the circular dated 25.04.2005 in the case of Indian Drugs Manufacturers Association Vs UOI – 2008 (222) ELT 22 BOm = 2006 – TIOL – 292 HC Mum.

When valuation based on Maximum Retail Price (MRP), under section 4 A of the Central Excise Act, 1944 was introduced for pharma goods, with effect from 07.01.2005, the valuation of physicians’ samples, once again raised its ugly head.

Physicians’ samples, as the name suggests, are the medicines, distributed free of cost among the Doctors, as a sales promotion measure. The Doctors are supposed to administer the medicine on the patients and depending upon its effect, they may recommend the said medicine for wider use.

In order to appreciate the issue better, it is also necessary to understand the business practices of the pharma industry. In one business model, medicines are manufactured by the manufacturers themselves, who have their own manufacturing facilities as well as the drug licence for the product. Such medicines are marketed by them through various dealers / marketing companies. The manufacturer would sell the goods in wholesale to such dealers / marketing companies and ultimately the goods would be sold through retail outlets, at the MRP. In another business model, companies having established brand names and marketing network, would get the medicine manufactured by other manufacturers who have drug licence to manufacture such products, by utilizing the manufacturing facilities available with such persons. In the industry, such practice is known widely as “third party manufacture”, where the manufacture is done for a “third party”. The goods thus manufactured by a manufacturing unit, would be sold at a mutually agreed price to the “third party” who order the goods to be manufactured on his behalf. The goods would finally reach the market through the marketing network and ultimately be sold at the MRP in retail outlets.

Under the first business model, no sale price would be available for the physicians’ samples, as the manufacturer himself would distribute such samples to the doctors directly, to promote the sale of his product. But, the goods meant for retail market, though affixed with the MRP, would be sold at a wholesale price, to the first wholesale buyer in the marketing network. The goods thus meant for retail market, would be subjected to duty of excise, on the basis of MRP printed on such goods, minus the prescribed abatement. Under the second business model, both the goods, viz., the goods meant for retail market and affixed with the MRP and the goods bearing no MRP and marked as “Physicians’ sample – Not for Sale”, would be sold at a mutually agreed price, by the manufacturer to the third party, at whose instance the goods were manufactured. While the goods affixed with MRP would ultimately reach the retail market, the physicians’ samples, would be distributed free of cost, by such third party, who got the goods manufactured on his behalf. The difference between these two business models, as far as physicians’ samples are, that in the first case, the physicians’ samples do not at all have a selling price, whereas in the second case, the physicians’ samples are also sold by the manufacturer and the buyer alone would distribute such physicians’ samples, free of cost. So, the valuation of physicians’ samples shall also be dealt with for the above two types of cases. With this basic understanding about the business practices, let us now go back to the issue of their valuation.

Ever since the introduction of MRP based valuation for pharma goods, the valuation of physicians’ samples was a mind teaser. As the previous authorities on the subject in the form of Board circulars, judgements, etc were in the context of valuation under Section 4, they were of not much use. While the

department wanted to levy duty of excise on physicians' samples, on the basis of comparable MRP (minus abatement) of such goods, the trade wanted to value the physicians' samples for payment of excise duty, on the basis of the sale price of the physicians' samples itself (whenever they are actually sold by the manufacturer to the third party, for whom it was manufactured) or when the physicians' samples are not at all sold but are distributed free of cost by the manufacturer themselves, on the basis of the first sale price of such goods meant for retail market.

It is in this context, the recent decision of the Larger Bench of the Hon'ble Tribunal in the case of Cadila Pharmaceuticals Vs CCE – 2008 – TIOL – 1668 – CESTAT – AHM – LB has to be looked into. The Larger Bench was comprised of the Hon'ble President of the Tribunal, one Hon'ble Member (Judicial) and one Hon'ble Member (Technical) of the Tribunal.

In the said order, Hon'ble Member (Judicial) has come to the following conclusions.

- ⌚ Admittedly, there was no requirement to affix MRP on the physicians' samples.
- ⌚ As such, Section 4 A is not applicable and valuation has to be made only under Section 4 of the Act.
- ⌚ Recourse has to be made to the Central Excise (Determination of Price of Excisable Goods) Rules, 2000.
- ⌚ As none of the said rules specifically cover the situation, recourse has to be made to Rule 11 thereof, according to which the value has to be determined on the basis of best judgement, in consistent with the other rules.
- ⌚ The only probable rules which can be considered are Rule 4 (sale price of such goods sold) and Rule 8 (cost plus 15 %).
- ⌚ The value referred to Rule 4 *ibid*, is the value under Section 4 of the Act.
- ⌚ If value under section 4 of the Act is available for physicians' samples, the same has to be adopted for payment of duty of excise (where the physicians samples are sold at a particular price to the third party, by the manufacturer).
- ⌚ If no sale price is available for the physicians' samples, whether the value determined for regular packs under Section 4 A (MRP – Abatement) can be adopted as the value for physicians samples? Or, the Section 4 Value of such goods, which are actually subjected to duty of excise under Section 4 A, has to be ascertained and such value has to be adopted for the physicians' samples?
- ⌚ After raising the above two posers, the Hon'ble Member (Judicial) has answered both of them in negative. As the value contemplated in Rule 4 is only Section 4 value, the Hon'ble Member (Judicial) has ruled out the application of Section 4 A value for physicians' samples. Further, since there is no statutory basis for notionally arriving at the assessable value under section 4 of the Act, for the goods for which only section 4 A is applicable, she has ruled out the possibility of treating the first sale price of the goods, which are assessed under Section 4 A, as the assessable value of physicians' samples.
- ⌚ In view of the above decisions, the Member (Judicial) has concluded that the value of physicians' samples has to be determined only on the basis of Rule 8 *ibid*, i.e. cost plus 15 %.

The Hon'ble President of the Tribunal has chosen to differ from the above view of the Member (Judicial).

It may be noted carefully that the Hon'ble Member (Judicial)'s conclusion

"As such, it can be reasonably concluded that if the value of excisable goods under Section 4 of the Act is available, the same has to be picked up for arriving at the value of the physician's samples, in terms of Rule 4"

has not been differed with by the Hon'ble President, who also concurs with the view, by observing,

"She also observed that in view of the definition of 'value' under Rule 2(c) of the Valuation Rules - 'value' means "the value under Section 4 of the Act" - where the value of excisable goods under Section 4 is available, the same can be picked up for arriving at the value of the physician's free samples in terms of rule 4"

From the above, it may be observed that the Larger bench has held that in the second business model, where the manufacturer actually sells the physicians' samples to the third party, who, in turn would be distributing them free of cost, the valuation of physicians' samples shall only be on the basis of such sale price and not on the basis of Section 4 A value of similar goods.

The Hon'ble President has chosen to differ from the view of the Hon'ble Member (Judicial), only in case, where no sale price is available for the physicians' samples. According to the Hon'ble Member (Judicial), in such cases (i.e. in case of first business model, where the physicians' samples are directly distributed free of cost by the manufacturer), the value shall be cost plus 15 %. But, the Hon'ble President has held that according to Section 4 A, the value of the goods shall be **deemed to be** the MRP minus abatement and hence the reference to "value" under Rule 4 would refer only to such MRP minus abatement. In other words, the Hon'ble President has held that value of physicians' samples, which do not have their own sale price, shall be the MRP minus abatement of similar goods, which are subjected to duty of excise under section 4 A of the Act.

Hon'ble Member (Technical) has concurred with the views of the Hon'ble President.

To put it in a capsule, what the Larger Bench has prescribed,

- ⌚ When the physicians' samples are having their own sale price and when they are actually sold at the first instance – such sale price (section 4 value) has to be their assessable value. (Second business model)
- ⌚ When the physicians' samples are not having their own sale price, but are distributed free of cost by the manufacturers themselves, the first whole sale price of similar goods (on which duty is paid under section 4 A), cannot be adopted as the assessable value (First business model).
- ⌚ When the physicians' samples are not having their own sale price, but are distributed free of cost by the manufacturers themselves, the MRP minus abatement of similar goods (Section 4 A value), shall be the assessable value (First business model).

Before parting...

What if the same product has different MRPs? For example, when the same tablet is sold at a MRP Rs.25 for 10s strip and at a MRP of Rs.40 for 20s strip – which MRP shall be the basis of valuation of physicians' sample of the tablet strip containing 2 tablets?

