1. Representations for clarifying that distribution of free medical samples does not attract TDS u/s. 194R

1.1. This has reference to guidelines/clarifications to be issued by the Central Board of Direct Taxes (CBDT) for removal of difficulties in application of new withholding provision section 194R which comes into effect from 1 July 2022. This also has reference to recent press reports which suggest that CBDT officials are of the view that distribution of free medical samples to doctors will be liable to TDS under the new section[1].

1.2. This representation seeks to put forth industry views why it may not be correct to clarify that distribution of free medical samples results in 'benefit' or 'perquisite' to doctors requiring TDS u/s. 194R and also bring forth practical challenges that the industry and doctors will face if any such clarification is issued.

2. Object of TDS u/s. 194R – to capture incomes u/s. 28(iv) hitherto unreported by recipients

2.1. The new TDS provision u/s. 194R requires the payer to deduct tax @ 10% on provision of 'benefit' or 'perquisite', whether convertible into money or not, arising from business or exercise of profession, to a resident. The section provides a de-minimus threshold of Rs. 20,000 for applicability of TDS such that no TDS is required if the aggregate value of benefits or perquisites provided to a single person during a financial year does not exceed Rs. 20,000.

2.2. As per Explanatory Memorandum to Finance Bill 2022, the object of the new TDS provision is explained as follows which makes it clear that the intention is to capture those benefits which are admittedly taxable u/s. 28(iv) but were escaping assessment in absence of reporting framework :-

> *"As per clause (iv) of section 28 of the Act, the value of any benefit or perquisite, whether convertible into money or not, arising from business or exercise of profession is to be charged as business income in the hands of the recipient of such benefit or perquisite.* ***However, in many cases, such recipient does not report the receipt of benefits in their return of income, leading to furnishing of incorrect particulars of income. Accordingly, in order to widen and deepen the tax base, it is proposed to insert a new section 194R*** *to the Act to provide that the person responsible for providing to a resident, any benefit or perquisite, whether convertible into money or not, arising from carrying out of a business or exercising of a profession by such resident, shall, before providing such benefit or perquisite, as the case may be, to such resident, ensure that tax has been deducted in respect of such benefit or perquisite at the rate of ten per cent of the value or aggregate of value of such benefit or perquisite."*

3. Free medical samples are not 'benefits' or 'perquisites' in the hands of doctors

3.1. It may be recollected that CBDT Circular No. 20D dated 7 July 1964 had explained the effect of s.28(iv) by providing illustration of "*the value of rent-free residential accommodation secured by an assessee from a company in consideration of the professional services as a lawyer rendered by him to that company".* This itself suggests that s.28(iv) is intended to cover an item which results in personal benefit or enrichment to the taxpayer. It cannot cover free medical samples which doctors are statutorily required to use strictly for clinical evaluation purposes by giving them to patients and cannot be sold or monetised by them.

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[1] TDS: Finance Ministry to clarify doubts on applicability of TDS on perks received in business, profession - The Economic Times (indiatimes.com)
https://www.zeebiz.com/india/news-budget-2022-finance-ministry-to-clarify-doubts-on-applicability-of-tds-on-perks-received-in-business-profession-new-rule-effective-from-1-july-185065

3.2. The Hon'ble Supreme Court ruling in the case of Eskayef v. CIT (245 ITR 116) supports that expenditure incurred on physician's samples are for the purposes of advertisement, publicity or sales promotion – regardless of whether they are for the purposes of testing efficacy of new medicine or for promoting an established medicine.

3.3. FAQ 64 in CBDT Circular No. 8/2005 in context of erstwhile Fringe Benefits Tax (FBT) clarified that they are in the nature of 'sales promotion and publicity' and hence liable to FBT. But subsequently, S.115WB was amended firstly to exclude distribution of free samples of medicines or medical equipment to doctors by Finance Act 2006, and subsequently by Finance Act 2007 to distribution of samples either free of cost or at concessional rate of any products (not necessarily pharma products), from scope of FBT on the ground of being an ordinary selling expenditure which does not result in any fringe benefit for the employees.

3.4. The above judicial and legislative development shows that distribution of free physician samples is an ordinary/bonafide selling expenditure which cannot be regarded as resulting in benefit or perquisite to the doctors.

4. Distribution of free samples is regulated by law to ensure it is strictly for clinical evaluation – no personal benefit or perquisite can arise

4.1. Providing samples of pharmaceutical products is not prohibited under either the Indian Medical Council (Professional Conduct, Etiquette and Ethics), Regulations 2002 ("MCI Code") or the Uniform Code of Pharmaceutical Marketing Practices by the Department of Pharmaceuticals ("UCPMP"). The UCPMP prescribes guidelines under which medical samples should be dispensed which ensure that they are used strictly for clinical evaluation purposes. Even the draft Uniform Code for Medical Device Marketing Practices ("UCMDMP") published for stakeholder consultation on 16 March 2022 lays down guidelines to ensure that medical devices are distributed as samples for evaluation purposes only.

4.2. The Drugs and Cosmetics Rules, 1945 also recognizes the practice of providing drugs for distribution to medical professionals as a free sample by providing specific labelling requirements, requiring such sample to be labelled with the words 'Physician's Sample – Not to be sold'.[2]

4.3. The above referred guidelines illustratively require following compliances by the pharma/medical devices industry

(a) Samples to be provided only to Health Care Professionals (HCP) or their authorised representatives

(b) Quantity of samples should be very nominal – for medicines, it is restricted to prescribed dosage for 3 patients.

(c) It should be accompanied by latest product information

(d) The pharma/medical device company must maintain record of the quantities of samples distributed, details of the HCP to whom they were supplied and date of supply

Relevant extracts from UCPMP and draft UCMDMP are provided in Annexure A

4.4. Considering the above referred strict conditions under which product samples are distributed to doctors, it is humbly submitted that distribution of free samples cannot be regarded as benefit or perquisite for the doctors. The doctors are required to administer them to patients. They cannot monetise them or personally enjoy them like other gift items like television, gold coins, free travel or hospitality, etc. Hence, it should be clarified that distribution of free samples is not covered within scope of TDS u/s. 194R at all. Alternatively, it may be clarified

[2] Drugs and Cosmetics Rules, 1945, rule 96 (ix)

that distribution of free samples in compliance with regulatory norms like Drugs and Cosmetic Act, UCPMP or UCMDMP are not covered within scope of s.194R.

5. Practical challenges which may arise for industry and doctors if free samples is subjected to TDS u/s. 194R

5.1. We may also highlight the practical challenges which pharma/medical device industry and doctors may face if TDS is made on value of free samples. In most cases, the free samples will either be dispensed to patients or scrapped by the doctors and hence, the doctors may not perceive it as their income. This is not comparable to other freebies prohibited by MCI Guidelines.

5.2. The pharma/medical device company will, therefore, find it difficult to recover the TDS from the doctors. In fact, the doctors may simply refuse to accept the free samples if pharma/medical device company requests for TDS amount and PAN/Aadhar. The issue of recovery of TDS will cause friction between the industry and doctors defeating the purpose of statutory guidelines on dispensation of free samples. Ultimately, due to business considerations, the pharma/medical device industry may need to bear the TDS liability themselves by suitably grossing up the value of free samples in terms of s.195A which will result in additional cost burden on the industry.

5.3. Since the free samples are either distributed to patients or scrapped, the doctors should be entitled to corresponding deduction, if the value of free samples is considered as taxable in their hands. However, in absence of clarity, the issue of allowability of corresponding deduction for such expense in the hands of the doctors will also pose challenges.

5.4. Some doctors may wish to take position that the free samples do not constitute their income and hence not offer anything in their return of income nor claim corresponding TDS credit. But their AIS/Form 26AS will reflect TDS u/s. 194R made by pharma/medical device companies on value of free samples. This will result in the doctors facing action by the CPC u/s. 143(1)(a)(vi) while processing their returns to add the value of income appearing in Form 26AS or Form 16A to their returned income.

5.5. All in all, if TDS is made by pharma/medical device industry on value of free samples distributed to doctors, it will cause immense practical difficulties for both industry and doctors.

5.6. TDS on free samples is not justified since it does not represent ‘benefit’ or ‘perquisite’ for the doctors. Hence, it is humbly requested that the CBDT should not impose such burden on the industry. Rather it should be clarified that TDS u/s. 194R will not apply on free samples distributed in compliance with statutory guidelines.

Annexure A

Extracts from Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) and draft Uniform Code for Medical Device Marketing Practices (UCMDMP) on distribution of free samples

From UCPMP

5. Samples

5.1 Free samples of drugs shall not be supplied to any person who is not qualified to prescribe such product.

5.2 Where samples of products are distributed by a medical representative, the

sample must be handed directly to a person qualified to prescribe such product or to a person authorized to receive the sample on their behalf.

5.3 The following conditions shall be observed in the provision of samples to a person qualified to prescribe such product:

(i) Such samples are provided on an exceptional basis only (see (ii) to (vii) below) and for the purpose of acquiring experience in dealing with such a product;
(ii) Such sample packs shall be limited to prescribed dosages for three patients for required course of treatment;
(iii) Any supply of such samples must be in response to a signed and dated request from the recipient;
(iv) An adequate system of control and accountability must be maintained in respect of the supply of such samples;
(v) Each sample pack shall not be larger than the smallest pack present in the market;
(vi) Each sample shall be marked “free medical sample - not for sale” or bear another legend of analogous meaning;
(vii) Each sample shall be accompanied by a copy of the most up-to-date version of the Product Information (As required in Drug and Cosmetic Act, 1940) relating to that product.

5.4 A pharmaceutical company shall not supply a sample of a drug which is an anti-depressant, hypnotic, sedative or tranquillizer.

5.5 The companies will maintain details, such as product name, doctor name Quantity of samples given, Date of supply of free samples distributed to Healthcare practitioners etc.

From draft UCMDMP

5. Evaluation Samples

5.1 Free evaluation samples of Medical Devices shall not be supplied to any person other than HCPs or as per hospital protocol to reach the HCPs.

5.2 Where evaluation samples of products are distributed by a medical representative, the sample must be handed directly to a person qualified to use & prescribe such product or to a person authorized to receive the sample on their behalf.

5.3 The following conditions shall be observed in the provision of evaluation samples to a person qualified to prescribe such product:

(i) Such samples are provided for the purpose of acquiring experience in using such a product, hands on experience and evaluation.
(ii) An adequate system of control and accountability must be maintained in respect of the supply of such samples by all Companies including maintaining proper documentation and rationale.
(iii) Each sample shall be accompanied by a copy of the most up-to-date version of the Product IFU/DFU/ e-IFU (link to the website/digital IFU), wherever applicable, relating to that product.
(iv) The number of evaluation samples (single use products) provided at no charge should not exceed the quantity reasonably necessary for the adequate evaluation of the products.

5.4 The Companies will maintain details, such as product name, HCP's name& contact information, Quantity of evaluation samples given, Date of supply of evaluation samples distributed to HCPs, relevant product traceability information.

5.5 Demonstration products: Company demonstration products are different from Evaluation Samples. Demonstration products can be either single use products, mock-ups, temporary software or equipment that are used for HCP and Patient awareness & education. Demonstration products are typically identified as not intended for patient use and demonstration equipment are taken back by Company after the demonstration period is over. However, consumables used in live procedural demonstration usually cannot be taken back. Clause 5 of this code does not apply to demonstration products and is limited to Evaluation Samples only. Demonstration products shall be specifically identified and tracked by the Company.

5.6 The documents/records required to be maintained under this Clause shall be maintained by Company for a period, as per applicable laws specific to category of document/record and in absence of such applicable laws as per Company's record management policy.