

GST issues in Pharmaceutical sector

A photograph of two business professionals in white shirts sitting at a desk. One person is holding a red pen and pointing at a document with a complex flowchart or diagram. The other person is holding a yellow pen. A laptop keyboard is visible in the foreground. The image is partially covered by a blue diagonal overlay on the left side.

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Coverage

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Introduction

- Medicines-Nutraceuticals-Cosmetics
- Medicines: Allopathic, Ayurvedic, Homeopathic
- Highly regulated (D&C Act, DPCO, FDA etc)
- Indirect selling (mainly sold through prescription)
- Distribution channel: Super Stockists, Stockists, Chemists, End user.
- No MRP based valuation in GST

Manufacturing

- Own Manufacturing: Own brand, own manufacturing facility.
- Third party: Own brand, Manufacturing facility of others, Principal to Principal basis, Inputs by Mfgr, Valuation.
- Only Marketing: Brand and Manufactured by others.
- Loan Licensing (Job work): Own brand, Manufacturing facility of others, APIs supplied, excipients by job worker, Valuation, direct supply of inputs, clearance from the place of the job worker, Job work procedure.

Classification

Why Classification?: Rate of tax, exemption, conditions and procedural compliance

Medicine~P or P Medicine~Formulations~Drugs~Generic

Factors for classification;

- End use (Therapeutic or prophylactic)
- FDA license
- Prescription by doctors
- Period of use
- Trade parlance

Classification

- The *High Court of Madhya Pradesh* in the case of *Global Tele Mall* 2018 (18) G.S.T.L. 227 (M.P.). held that hair Wash/Shampoo prepared from Ayurvedic ingredients and having therapeutic quality was classifiable as Ayurvedic Medicine
- Swad having therapeutic value is medicine though it is sold in tea stall or betel shop *Khandelwal Drug Agencies* 2017 (5) G.S.T.L.242 (Raj.).
- If a product's primary function is "care" and not "cure", it is not a medicament. Cosmetic products are used in enhancing or improving a person's appearance or beauty, whereas medicinal products are used to treat or cure some medical conditions. *Ciens Laboratories* 2013 (295) E.L.T. 3 (S.C.).
- when a product has effects of both medicine and tonic, and the classification becomes doubtful, the matter has to be referred to the Drug Controller. *Dabur India Ltd.* 2016 (337) E.L.T. 80 (Tri. Kolkata).

Classification

- Whenever a product has curative or prophylactic value as well, but the Department still wants the said product to be brought under sub-heading 3304 00, the onus is on the Department to show that it is not a medicament. Hindustan Lever Ltd 2015 (323) E.L.T. 209 (S.C.).
- The Hon'ble Supreme Court in the case of Amrutanjan Ltd 1995 (177) E.L.T. 500 (S.C.) held that use of letter IP after the article concerned only demonstrates that it is of pharmaceutical quality and is usable in a medicinal preparation
- The Hon'ble Supreme Court in the case of Ponds India Ltd 2008 (227) E.L.T. 0497 (S.C.). held that Wikipedia, like all other external aids to construction, like dictionaries, etc. is not an authentic source, although the same may be looked at for the purpose of gathering information. Petroleum jelly has curative value hence covered under the meaning of drug.

Classification

- **The Trade Parlance or Common Parlance or Commercial Parlance theory** means making a classification based on how the said product is known in the market. It is based on the perception of the consumers, its primary functions, and utility. This theory is used when the words are not defined under the Act and words used in the tariff are not used in a scientific or technical sense.
- Vitamins are commonly understood to be medicaments required to be taken under advise of a Medical Practitioner. A common man does not understand them to be ‘food supplements/part of food’ like ‘Bournvita’ or like products. Therefore, classifiable as medicine.
- In classification primary use of the product is relevant. The extent or quantity of medicament used in a particular product is not a relevant factor. The fact that the use of the medicinal element in a product was minimal does not detract from it being classified as a medicament. The item need not be sold under a doctor’s prescription. The availability of products across the counter in shops is also not relevant as it makes no difference either way

Classification

Factors to be considered in classification of pharma products:

- (a) Curative effect of the product (therapeutic use)
- (b) Preventive effect of the product (prophylactic use)
- (c) Period of usage i.e., to be used for a limited period or regularly
- (d) Prescription by a medical practitioner
- (e) License to manufacture, store and sell by FDA
- (f) Reference to Pharmacopoeia or authoritative books
- (g) Trade parlance, i.e., how it is known in the market
- (h) Certificate by the technical experts or authorities.
- (i) Whether put up in measured doses or not?

Classification

GST Rate Notification No. 1/2017-Central Tax

(iii) “Tariff item”, “sub-heading” “heading” and “Chapter” shall mean respectively a tariff item, sub-heading, heading and chapter as specified in the First Schedule to the Customs Tariff Act, 1975 (51 of 1975).

(iv) The rules for the interpretation of the First Schedule to the Customs Tariff Act, 1975 (51 of 1975), including the Section and Chapter Notes and the General Explanatory Notes of the First Schedule shall, so far as may be, apply to the interpretation of this notification.

Classification

Rate Notifications 1/2017-CGST (R),

Tax invoice to contain 2/4 digit HSN Code based on turnover 12/2017-CT

4 digit code – Heading

6 digit code – Sub Heading

8 digit code – Tariff Item

Unit of measure lost its relevance in GST ???

Classification

Rate Notifications 1/2017-CGST (R),

CH	CTA	GST Notification
3822	DIAGNOSTIC OR LABORATORY REAGENTS ON A BACKING, PREPARED DIAGNOSTIC OR LABORATORY REAGENTS WHETHER OR NOT ON A BACKING, OTHER THAN THOSE OF HEADING 3002 OR 3006	All diagnostic kits and reagents

Classification

Rate Notifications 1/2017-CGST (R),

The Karnataka AAR in the case of Chromachemie Laboratory Pvt Ltd held that on the principle of *ejusdem generis* the word “diagnostic” is not just applicable to “kits” but also “reagents”. The word “and” is a word of conjunction and it joins two goods “kits” and “reagents” and they are with the common adjective of being “diagnostic” and hence joins two classes of goods “diagnostic kits” and “diagnostic reagents”.

Classification

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Subsequently Appellate AAR reversed the above decision and held that all reagents (diagnostic reagents and laboratory reagents) are covered under S.No 80 of Sch II.

Physician's Samples

- Physician's sample-Not to be sold
- No consideration, hence not a supply, distributed through DC.
- Eligible for input?
 - Own manufactured PS
 - Bought out PS – covered u/s 175(h), disposed by way of free samples?

CBIC Sectoral FAQ on Drgs & Pharmaceuticals

Replacements

Replacements for:

- Near expiry goods
- Expired/damaged goods. Circular No. 726/46/2018-GST dt. 26.10.2018.
- Issue credit note and make a fresh supply.
- Return under tax invoice.
- Expired goods must be destroyed as per D&C Act and Rules made thereunder.
- ITC (returned under tax invoice) or reduction in liability (returned under GST CR)??

Promotional items

Promotional items to doctors, distributors/retailers, not to end users.

- No supply since no consideration

Input tax credit??

- Whether it is in the nature of gift?
- Commercial consideration Vs. consideration for supply.

Schemes

- Additional quantity of the same product
- Product A given free with certain quantity of Product B

Valuation: Section 15(3)-Discount:

- Discount may be by way of reduction in the value or by way of additional goods/ quantity.
- Should be mentioned in the tax invoice, or
- Through credit note where it is linked to the tax invoice and known at the time or before the supply by way of agreement (the event when the discount shall be given and the method of quantification should be mentioned in the agreement). In case of credit notes, the recipient would reduce the ITC.

Research & Development

- R&D on behalf of someone else-service –Issue of place of supply (Notification No. 4/2019-IT dated 30.09.2019).
- Outcome of R&D transferred to others – Service
- R&D for own-part of business activity.
- Input tax credit shall be available on the goods and services used.

Analytical Testing

- In house – for self or service to others Issue of place of supply (Notification No. 4/2019-IT, dated 30.09.2019)
- External agency
- Part of manufacturing activity, hence business eligible for ITC
- ITC on goods lost/destroyed in testing???

Material Handling loss

- Manufacture or any activity incidental to manufacture is included in the definition of business.
- Goods or services used in the course or furtherance of the business is eligible for ITC.
- Material handling loss whether covered u/s 17(5)(h)..goods lost, destroyed??
- Recent Madras HC decision in case of ARS Steels & Alloy International Pvt. Ltd

Quality Control

- QC samples are maintained for each batch for certain specified period.
- To be destroyed after expiry period.
- May get destroyed while checking the quality.
- May be required to be given to regulatory authorities.
- It is mandatory under D&C Act and Rules made thereunder.
- QC is part of manufacturing activity hence used in business.
- The Hon'ble Supreme Court held in the case of Rajasthan State Chemical Works that the process of handling, lifting, pumping, transfer, transportation of raw materials is also a process in or in relation to manufacture, if integrally connected with further operations leading to manufacture of goods. 1991 (55) E.L.T. 444 (S.C.)

Batch Failure

- Batch failure- cannot be sold, need to be destroyed as per the provisions of the D&C Act and the Rules made thereunder.
- What about ITC?

The Chennai High Court, in the case of Rupa & Co. Ltd. 2015 (324) E.L.T. 295 (Mad.), it was held that the expression 'inputs of such finished product', 'contained in finished products' cannot be looked at theoretically with its semantics. It has to be understood in the context of what a manufacturing process is. If there is no dispute about the fact that every manufacturing process would automatically result in some kind of a loss such as evaporation, creation of by-products, etc., the total quantity of inputs that went into the making of the finished product represents the inputs of such products in entirety.

Batch Failure

- The Hon'ble Supreme Court in the case of Multimetals Ltd 1992 (57) E.L.T. 209 (S.C.) observed that manufacturing loss forms part of the raw material “used” in the manufacture though not reflected in the final product.
- Further, the Hon Supreme Court in the case of Indechem Electronics 2003 (157) E.L.T. A206 (S.C.) held that Modvat/Cenvat credit is not deniable on inputs destroyed in fire accident when the fact that inputs were actually issued and thereafter destroyed in fire accident.

Destruction of goods due to natural calamity

- The goods may get destroyed due to any natural calamity, fire etc.
- Hon Supreme Court in the case of Chandigarh Petro Foam P. Ltd 2017 (350) E.L.T. 075 (S.C.) held that cenvat credit on inputs issued and destroyed thereafter by fire at factory is available. The cenvat credit is not deniable.
- Hon'ble Supreme Court in the case of Indchem Electronics 2003 (157) E.L.T. A206 (S.C.) held that cenvat credit is not deniable on inputs destroyed in fire accident when the fact that inputs were actually issued and thereafter destroyed in fire accident.

Destruction of goods due to natural calamity

- a. Where the inputs are destroyed after the same being put to use in the business, then there is no need to reverse the input tax credit.
- b. Where the finished goods are destroyed, then also there is no need to reverse the input tax credit on inputs used in the manufacture of the finished goods as the input has already been put into business use.
- c. Where the inputs are destroyed before the same is being put to use, in the absence of any provision ITC may not be required to be reversed relying on the decision of the Apex Court in the case of Dai Ichi Karkaria Ltd (*Supra*). Section 17(1) of the CGST Act read with rule 42 provides for reversal of input tax credit where the inputs are partly used for business and partly used for other purpose. The inputs as such destroyed cannot be said to be used for other than business purpose.

ITC on special constructions

- State of the art pharma manufacturing is mostly unmanned.
- Some special civil construction may act as a plant.
- Recently, Gujarat State AAR in the case of Satyesh Brinechem Pvt. Ltd 2020(4) TMI631-AAR held that input tax credit of GST paid on goods and services used to construct the “bunds” is admissible provided that the bunds are used for making zero rated supplies and fulfill the conditions which are necessary for treating the bunds as “plant and machinery.”
- The Allahabad High Court in the case of Kanodia Cold Storage (1975) 100 ITR 155 held that where a building with insulated walls is used as a freezing chamber, though it is not machinery or part thereof, it is part of the air conditioning plant of the cold storage of the assessee and will be entitled to special depreciation at 15% on its written down value. Similarly, the Hon’ble Punjab & Haryana High Court in the case of Yamuna Cold Storage (1981) 129 ITR 728 held that the building with insulated walls of the cold storage was a plant and was entitled to depreciation at 15%.

Accumulation of ITC

- The accumulation of ITC which was there in excise regime continues in GST regime also.
- Most of the inputs and input services are attracting 18% GST.
- The finished product may attract 5% or 12%.
- Refund under inverted rate structure on inputs.

THANK YOU



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