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## **Ayurvedic Medicine : Classifications**

Controversy regarding classification of Ayurvedic Medicine product was raised from time to time, because in case product is an Ayurvedic Medicine, it attracted lower rate of State Sales Tax as well as Central Excise. Therefore, both the departments attempted to classify the product as Cosmetics, in borderline cases.

It will be interesting to note that medicines and cosmetics both are defined under Drugs & Cosmetics Act, 1940. Therefore, their production including sale is governed by the Drug and Cosmetic Act, 1940.

As we know there are many varieties of treatment in India such as *Allopathic, Homeopathic, Ayurvedic, Siddha, Unani and Tibb*. Therefore, the said Act provides an inclusive definition, kindly see -

**Section 3.** Definitions:- In this Act, unless there is anything repugnant in the subject or context,— 7 [(a) “8 [Ayurvedic, Siddha or Unani] drug” includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of 8 [disease or disorder in human beings or animals, and manufactured] exclusively in accordance with the formulae described in, the authoritative books of 9 [Ayurvedic, Siddha and Unani Tibb systems of medicine], specified in the First Schedule;]

From the above, it may be noted that above definition is *inclusive* and describes the following properties of a medicine in general: -

diagnosis, treatment, mitigation or prevention

However, for a medicine to be treated as Ayurvedic systems of medicine, it is necessary that it should be manufactured exclusively in accordance with the formulae described in, the Authoritative Books mentioned in Annexure-1 appended to the Drugs Act . At this stage let us acquaint/know what is cosmetics: -

**Section-3(aaa)** “cosmetic” means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic.

There is another class of medicine -

**Sec. 3 [(h)]** “patent or proprietary medicine” means -

(i) in relation to Ayurvedic, Siddha or Unani Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani Tibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause (a).

**(A) Initial law of land (Classification by Hon'ble Supreme Court) :**

Hon'ble Apex Court held in **M/s. Ram Avtar Budhai Prasad vs. S.T.O., Akola [(1961) 12 STC 286]**, is still being followed and therefore, it is the law of land :-

*“It has not been defined in the Act and being a word of everyday use it must be construed in its popular sense meaning “that sense which people conversant with the subject-matter with which the statute is dealing would attribute to it.”*

**(B) Final Verdict :**

The controversy for classification of a product as claimed versus as alleged by the department, whether Central or State was finally settled at rest by Hon'ble Supreme Court in the case reported as **Commissioner, Central Excise vs. Richardson Hindustan 1989, (42) ELT 100 S.C.**

“We are also of the opinion that when there is no definition of any kind in the relevant taxing statute, the articles enumerated in the tariff schedules must be construed as far as possible in their ordinary or popular sense, that is how the common man and persons dealing with it understand it. If the customers and the practitioners in ayurvedic medicine, the dealers and the licensing officials treat the products in question as ayurvedic medicines and not as allopathic medicines that fact gives an indication that they are exclusively ayurvedic medicines or that they are used in ayurvedic system of medicine though it is a patented medicine.

But later on, in the case reported as **M/s. Puma Ayurvedic Herbal (P) Ltd. Vs. Commissioner, Central Excise (2006) 145 STC 200**; Principles for classification laid down in Richardson's case were expended and now they are commonly known as Twin Test in the judicial language, kindly peruse:-

I. *Whether the item is commonly understood as a medicament which is called the common parlance test. For this test it will have to be seen whether in common parlance the item is accepted as a medicament. If a product falls in the category of medicament it will not be an item of common use. A user will use it only for treating a particular ailment and will stop its use after the ailment is cured. The approach of the consumer towards the product is very material? One may buy any of the ordinary soaps available in the market. But if one has a skin problem, he may have to buy a medicated soap. Such a soap will not be an ordinary cosmetic. It will be medicament falling in chapter 30 of the Tariff Act.*

II. *Are the Ingredients used in the product mentioned in the authoritative text books on Ayurveda?*

### **(1) Ayurvedic Medicine may contain Products of I.P./B.P. grade :**

In Indian Pharmacopeia or British Pharmacopeia still it will be an Ayurvedic Medicine As held in *Amruthnajan case*, the mere fact that the ingredient are purified or added with some preservatives does not really alter their character/: In *Amritajan vs. C.C.E. 1995 (77) ELT 500 (SC)*

### **(2) Quantity of medicament not material :**

*Normally, the extent of use of medical ingredients is very low because a larger use may be harmful for the human body. The medicinal ingredients are mixed with what is in the trade parlance called fillers or vehicles in order to make the medicament useful. To illustrate an example of Vicks Vaporub is given in which 98% is said to be paraffin wax, while the medicinal part i.e. Menthol is only 2% Vicks Vaporub has been held to be medicament by the Court in *C C E vs. Richardson Hindustan Ltd. 1989 (42) ELT A 100.**

### **(3) Doctor's Prescription not necessary :**

In order to be a medicinal preparation or a medicament it is not necessary that the item must be sold under a doctor's prescription. Similarly, availability of the products across the counter in shops is not relevant as it makes no difference either way.

### **(4) Consumers opinion is important:**

What is important to be seen is how the consumer looks at a product and what is his perception in respect of such product. The user's understanding is a strong factor in determination of classification of the products.

**Commissioner of Central Excise vs. Baidyanath Ayurved Bhawan Ltd. [2010 NTN (Vol. 42) 63]**

**(5) Ayurvedic Medicine GST Act:**

It may be noted that Chapter 30 deals with Ayurvedic Medicine and Chapter 33 with cosmetics. They are as under :-

*Chapter 30*  
*Pharmaceutical products*

**3004-** MEDICAMENTS (EXCLUDING GOODS OF HEADING 3002, 3005 OR 3006) CONSISTING OF MIXED OR UNMIXED PRODUCTS FOR THERAPEUTIC OR PROPHYLACTIC USES, PUT UP IN MEASURED DOSES (INCLUDING THOSE IN THE FORM OF TRANSDERMAL ADMINISTRATION SYSTEMS) OR IN FORMS OR PACKINGS FOR RETAIL SALE.

*Chapter 33*  
*Essential oils and retinoids, perfumery, cosmetic or toilet preparations*

**(6) After consistently holding medicine department cannot change opinion without cogent reason:**

Hon'ble High court quoted its earlier judgment in **Bharat Sanchar Nigam Ltd. and Another vs. Union of India and Others [(2006) 3 SCC]** in the case of **M/s. Ponds India Ltd. Vs. Commissioner of Trade Tax (2008) 15 VST 256 (S.C.)**, and **Ponds India Ltd. Vs. C.T.T. [2008 (Vol. 2) UPTC 773]**.

If an entry had been interpreted consistently in a particular manner for several assessment years, ordinarily it would not be permissible for the Revenue to depart therefrom, unless there is any material change. {See **Bharat Sanchar Nigam Ltd. and Another Vs. Union of India and Others [(2006) 3 SCC 1]**}

**(7) Burden to prove that product is medicine lies on the department :**

- (i) In **Union of India and Others Vs. Garware Nylon Ltd. and Others (1996) 10, SCC 413**, this Court opined: (Date of Judgement: 09-09-1996: Supreme Court)

“The burden of proof is on the taxing authorities to show that the particular case or items in question is taxable in the manner claimed by them. Mere assertion in that regard is no avail...”

- (ii) In **Hindustan Ferodo Ltd. Vs. Collector of Central Excise, Bombay (1997) 2 S.C.C. 677**, this court held : (Date of Judgement : 4-12-1996 Supreme Court)

4. “It is not in dispute before us, as it cannot be, that the onus of establishing that the said rings fell within item 22F lay upon the Revenue. The Revenue led no evidence. The onus was not discharged. Assuming therefore, that the Tribunal was right in rejecting the evidence that was produced on behalf of the appellants, the appeal should, nonetheless, have been allowed.
5. It is not the function of the Tribunal to enter into the arena and make suppositions that are tantamount to the evidence that the party before it has failed to lead. Other than supposition, there is no material on record that suggests that a small-scale or medium scale manufacturer of brake linings and clutch facings ‘would be interested in buying’ averment in this behalf was incorrect and not for the Tribunal to assess their brittleness for itself. Articles in question in an appeal are shown to the Tribunal to enable the Tribunal to comprehend what it is that is dealing with. It is not an invitation to the Tribunal to give its opinion thereon, brushing aside the evidence before it. The technical knowledge of members of the Tribunal makes for better appreciation of the record, but not its substitution.”

Yet again in *Union of India Vs. Garware Nylons Ltd. [1996] 10 SCC 413*, this opined:

“... The burden of proof is on the taxing authorities to show that the particular case or item in question is taxable in the manner claimed by them. Mere assertion in that regard is of no avail. ...”

#### **(8) Doctor’s Prescription not necessary:**

*In order to be a medical preparation or a medicament it is not necessary that the item must be sold under a doctor’s prescription. Similarly, availability of the products across the counter in shops is not relevant as it makes no difference either way.*

#### **(9) Medicinal ingredients very low, fillers or vehicles major constituent still**

##### **Medicine :**

*To illustrate an example of Vicks Vaporub is given in which 98% is said to be paraffin wax, while the medicinal part, i.e., Menthol is only 2%. Vicks Vaporub has been held to be medicament by this Court in CCE vs. Richardson Hindustan Ltd. 1989 (42) ELT 100. Therefore, the fact that use of medicinal element in a product was minimal does not detract from it being classified as a medicament.*

## **(10) Pharmacopoeia of India:**

The manufacture and sale of any medicine is governed by the central enactment known as the Drugs & Cosmetics Act, 1940. For regulation of manufacture and production substance to be added known as filter or vehicle are standard products mentioned in Pharmacopoeia of India, Government of India, Ministry of Health & Family Welfare. To understand it, it will be useful to quote.

### ◆ **Introduction**

As the Indian Pharmacopoeia is the statutory books of standards under the Drug & Cosmetics Act, 1940 and the pharmaceutical manufacturers have to conform to these standards.

## **(11) Added Substances :**

An official drug substance, as distinguished from a dosage form, contain no added substances except where specifically permitted in the individual monograph. Where such addition is permitted, the label indicates the name(s) and amount (s) of any added substance(s).

Unless otherwise specified in the individual monograph, or elsewhere in the General Notices, suitable substances, such as bases, carrier's coatings, preservatives, stabilizers, vehicles and other pharmaceutical aids may be added to a Pharmacopoeia dosage form or finished device to enhance its stability, usefulness or elegance, or to facilitate its preparation. Such substances shall be harmless in the amounts used, shall not exceed the minimum quantity required to provide their intended effect, shall; not impair the therapeutic efficacy of the dosage form, and shall not interfere with the tests and assays prescribed for determining compliance with the official standards.

## **(12) User's test not permitted :**

The petitioner's case for **Balaji Agency 1994 UPTC 184** was rejected by this Hon'ble Court in Ponds' case (supra) being based on user test (kindly see paras 72,73 and 91) (The judgement of Balaji Agency enclosed as **Annexure 6** (P 100-102)

Singhal Brothers case is not based on any analogy but wholly following the law laid down in Balaji's case.

## **(13) Cosmetics definition:**

In the context of Ayurvedic Products, vis-a-vis their medicinal value came up for consideration in **Puma Ayurvedic Herbal (P) Ltd. Vs. Commissioner, Central Excise, Nagpur [(2006) 3 SCC 266]**, wherein it was stated:

- "20. It will be seen from the above definition of "cosmetic" that the cosmetic products are meant to improve appearance of a person, that is, they enhance beauty, whereas a medicinal product or a medicament is meant to treat some medical condition. It may happen that while treating a particular medical problem, after the problem is cured, the appearance of the person concerned may improve. What is to be seen is the primary use of the product. To illustrate, a particular Ayurvedic product may be used for treating baldness. Baldness is a medical problem. By use of the product if a person is able to grow hair on his head, his ailment of baldness is cured and the person's appearance may improve. The product used for the purpose cannot be described as cosmetic simply because it has ultimately led to improvement in the appearance of the person. **The primary role of the product was to grow hair on his head and cure his baldness.**"

Definition of Cosmetics is restrictive vis-a-vis definition of Medicine in Drugs and Cosmetic Act. 1944, was also observed by the Hon'ble Apex Court in **M/s.Ponds India Ltd. Vs. C.T.T. [(2008) (Vol. 2) UPTC 773]** :

27. We may furthermore notice that Parliament consciously used a restrictive meaning while defining the term "cosmetic" but an extensive meaning has been given to the word "drug".
- 46 Whether a product would be a drug or a cosmetic sometimes poses a difficult question and, thus, answer thereto may not be easy. For the said purpose, the Court may not only be required to consider the contents thereof, but also the (i) **history of the entry**, (ii) **the purpose for which the product is used**, (iii) **the manner in which it has been dealt with under the relevant statute** (iv) **as also the interpretation thereof by the implementing authorities.**

#### **Medicine Vs. Cosmetics :**

The difficulty in classification of medicine versus cosmetics was very well pointed out by the Hon'ble Supreme Court in **M/s. Puma Ayurvedic Herbal (P) Ltd. Vs. Commissioner, Central Excise, Nagpur [(2006) 3 SCC 266]** :

medicine as 'the science and art concerned with the cure, alleviation, and prevention of disease, and with the restoration and preservation of health'. In line with the learned Judge I think that a fair approach is **to regard a medicine as a medicament which is used to cure or to alleviate or to prevent disease or to restore health or to preserve health.**"

We may furthermore notice that Parliament consciously used a restrictive meaning while defining the term "cosmetic" but an extensive meaning has been given to the word "drug".

#### **(14) Medicament :**

##### **Commissioner of Central Excise, Nagpur vs. Shree Baidyanath Ayurved Bhawan Ltd. 2010 NTN (Vol. 42) - 63 (S.C.)**

The term “ayurvedic medicament” in the tariff will have the same meaning as the meaning in the Drugs and Cosmetics Act. Therefore, if the product under consideration conforms to the requirements specified in that Act and the tariff, it will be entitled to be so classified. There would be no requirement that the Central Excise authorities must independently test it for its efficacy as medicament by apply the provisions of Note (2) to the Chapter.

This maxim is based on public policy. **In our opinion, these maxims cannot be applied as a rule of thumb in the taxation matters. In the matters of classification of goods, the principles that have been followed by the courts – which we endorse – are that there may not be justification for changing the classification without a change in the nature or a change in the use of the product; something more is required for changing the classification especially when the product remains the same.**

‘Medicament’, Inter alia as a product comprising two or more constituents which have been mixed or compounded together for therapeutic or prophylactic use. [Sujanil Chemo Industries vs. CCE & Customs, (2005) 4 SCC 189, 190, para 5] [Central Excise Tariff Act, 1985 (5 of 1986), Ch. 30 Heading 2 (i)].

Johnson’s Prickly Heat Powder and Phipps Processed Talk Products are medicaments and not cosmetics. Muller & Phipps (India) Ltd. Vs. C.C.E., 2004 (4) SCC 787. [Central Excise Tariff Act 1985 (5 of 1986), Items 30.03 and 30.04].

Bhringraj Tail, Trifla, Brahmi Tail, Neem Harbal Sat, Sat Reetha, Meghdoot Harbal Sat, Meghdoot Harbal Powder, Ayurvedic Products come within the ambit of medicaments under heading 3003.30. They cannot be termed as cosmetics. Meghdoot Gramodyog Sewa Sansthan vs. C.C.E., 2004 (174) ELT [Central Excise Tariff Act 1985, (5 of 1986), Heading 3003.30]

Product of for killing of lice due to its therapeutic or prophylactic use comes within the expression medicaments, under Chapter 30, Heading 2(i). [Sujanil Chemo Industries Vs. C.C.E. (2005) 4 SCC 189] [Central Excise Tariff Act 1985 (5 of 1986), Chapter 30, Heading 2 (i).

#### **(15) Advertisement :**

Advertisement is not deceiving in classification of a medicine.



In the case of **M/s. Blue Star Ltd. Vs. Union of India [1980 (6) ELT Page 280) Hon'ble Bombay High Court** held as below :

“... In any event, what the petitioner may advertise by way of attracting customers, can be no criterion for adjudication upon the issue whether duty is payable under a particular tariff item. In other words, payment of duty under a particular tariff item must depend upon the fact of the case and not on the advertisement gimmick of the advertiser. Thus, it is not the basis of those facts and circumstances as disclosed by the record, the case would fall within the provisions of Tarff item No. 29A (1) or not”..”

**Customs, Excise & Gold, Tribunal Bombay in the case of Hindustan Lever Ltd. vs. Collector of Central Excise 2000 (121) ELT page 451. The Hon'ble high court gave no weightage to advertisement, kindly see.**

Advertising is a potent weapon in the manufacturer's armory, in the present days of consumerism, a wit has defined advertising as the craft of selling product (1) which is not worth buying, (2) which the consumer does not want and (3) which he cannot afford to buy, ...”

Thus we have seen that in about 5 decades the meaning and scope of Ayurvedic Medicine remained same with more classification of Twin Test and now the whole picture is much clear in comparison to past.

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