WEST BENGAL APPELLATE AUTHORITY FOR ADVANCE RULING
AT 14, BELIAGHATA ROAD, KOLKATA-700015

Before:
Mr. A.P.S Suri, Member
Ms. Smaraki Mahapatra, Member

In the matter of

Appeal Case No. 08 /WBAAAR/Appeal/2019 dated 29.04.2019

- And -

In the matter of:

An Appeal filed under Section 100(1) of the West Bengal Goods and Services Tax Act, 2017/ Central Goods and Services Tax Act, 2017, by Eskag Pharma Pvt. Ltd., AG-112, 8th Floor, Suite No. 804, Baishakhi, Salt Lake , Sector-II, Kolkata- 700 091

Present for the Appellant: Sri Dipankar Majumdar, Advocate &
Ms Riya Bhattacharjee, Advocate

Present for the Respondent: None

Matter heard on: 03.07.2019
Date of Order: 23.07.2019

1. This Appeal has been filed by Eskag Pharma Pvt. Ltd. (hereinafter referred to as "the Appellant") on 29.04.2019 against Advance Ruling No. 46/WBAAR/2018-19 dated 26.03.2019, pronounced by the West Bengal Authority for Advance Ruling (hereinafter referred to as the WBAAR) in the matter of Eskag Pharma Pvt. Ltd.

2. Eskag Pharma Pvt. Ltd located at AG-112, 8th Floor, Suite No. 804, Baishakhi, Salt Lake Sector-II, Kolkata- 700 091 holding GSTIN 19AAACE5646H1ZJ and is stated to be a manufacturer of pharmaceuticals, active pharmaceutical ingredients (APIs), medicaments, etc.

3. The Appellant sought an advance ruling under section 97 of the West Bengal Goods and Services Tax Act, 2017/ the Central Goods and Services Tax Act, 2017, (hereinafter

collectively referred to as "the GST Act") on classification of 15 products manufactured by the Appellant which are as follows:

Sl. No.	Name of the product	Composition
1	Biogut capsule	Streptocuccus faecalis 30 million Clostridium Butyricum 2 million Mesentericus 1 million Lactic Acid Bacillus 50 million
2	Folcovit capsule	Lactoferrin 20mg Bacillus coagulans 2.0 billion spores Saccharomyces boulardii 0.25 billion cells Folic acid 1.5 mg Vitamin B12 15 mg Sodium selenite equ to elemental selenium 40 mcg Zinc ascorbate equ to elemental Zinc 12 mg
3	Folcovit Distab	Bacillus Coagulans1.25 billion spores Folic acid 1.5 mg Vitamin B12 15 mcg
4	Myova/Myowin tablet	Myo -Inositol 550 mg D-chiro-Inositol 13.8 mg L-Methylfoate calcium 1.0 mg Chromium 100 mcg (As chromium picolinate) Vitamin D3 1000 IU
5	Candyflora Tablet	Lactobacillus reuteri 200 million CFU Lactobacillus rhamnosus 50 million CFU Bifidobacterium longum 50 Million CFU
6	Carisma Tablet	Carica Papaya Extract 1100 mg Excipients Q.S.
7	Lactolite syrap	Sodium chloride 520 mg Potassium Chloride 300 mg Sodium Citrate 580 mg Dextose (anhydrous) 2.7 mg Purified Water, Sucrose, Dextrose Preservative
8	Lacolite Z Sachet	Sodium chloride IP 0.52 gm Potassium Chloride IP 0.3 gm Sodium Citrate IP 0.58 gm Dextrose (anhydrous) IP 2.7 mg Zinc sulphate monohydrate 10.98 mg Eqv. to elemental zinc 4 mg Bacillus coagulans 0.5 billion spores Lactobacillus acidophilus 0.25 billion cells Lactobacillus rhamnosus 0.25 billion cells Excipients q.s.

9	Biogut Dry Syrup	Each 5 ml contais probiotics 1.25 bilion cells strains
10	Enterobiotic Dry Syrup	Lyophilizes saccaromyces Boulardii 2.5 billion cells
11	Gutclausy Dry Syrup	Each 5 ml contains Bacillus clausii 2 billion cells
12	Evaday Capsule	Evening primrose oil, Isoflavonoids, Vitamin E Acetate, Vitamin C, Vitamin B6, Cynocobalamide, Niacinamide, Folic acid, Dibasic Calcium Phosphate,Magnesium sulphate, Zinc Sulphate Monohydrate, biotin
13	Zink Ascorbate (Dry syrup)	Each 1ml contains Zinc Ascorbate Eqv. To elemental Zinc 20mg
14	Zink ascorbate (syrup)	Each 5ml contains Zinc Ascorbate Eqv. To elemental Zinc 20mg
15	Lactoin Drop	Each 1 ML contains Lactase Enzyme 600 units

4. The WBAAR, out of the above 15 products classified 12 products (Serial nos. 2 to 13 of the above table) under HSN 2106, and taxable under Sl. No. 23 of Schedule III of Notification no. 1/2017-C.T (Rate) dated 28-06-2017 under the Central Goods and Services Tax Act, 2017 & Notification No. 1125-FT dated 28-06-2017 under the West Bengal Goods and Services Tax Act, 2017, as amended vide Notification no. 41/2017-C.T (Rate) dated 14-11-2017 under the Central Goods and Services Tax Act, 2017 & Notification No. 2019-FT dated 14-11-2017 under the West Bengal Goods and Services Tax Act, 2017, (hereinafter referred to as "the Rate Notification as amended"). The WBAAR refrained from classifying the remaining 3 products in the light of the observation of the West Bengal Appellate Authority for Advance Ruling (hereinafter referred to as the WBAAAR) in the matter of Akansha Hair & Skin Care Herbal unit Pvt. Ltd. (Appeal Case No. 2/WBAAAR/Appeal/2018 dated 01-08-2018).

5. The Appellant has filed the instant Appeal against the above Advance Ruling with the prayer to set aside/modify the impugned Advance Ruling passed by the WBAAR or pass any such further or other orders as may be deemed fit and proper in the facts and circumstances of the case on the following grounds:

   (i) The WBAAR erred in law by accepting the Appellant's application partially. The issue of classification of products ; Biogut Capsule (Serial no. 2), Zinc Ascorbate - Syrup (Serial no. 14) and Lactoin Drop (Serial no. 15) have not been answered.

   (ii) The WBAAR while classifying the products relied solely on the details/ inscriptions mentioned on the packages of the products and has ignored the usage of the products. The affixation of label "Not for Medicinal Use" on packaging of the products in question is as per regulations issued by the Food Safety and Standards Authority of India (FSSAI) under the Food Safety and Standards Act,

2006. This is just a statutory regulation and has no bearing on the usage of the products. The products on which classification has been sought are not in the nature of fortified foods and are not health supplements.

(iii) The WBAAR relied on the judicial observation made on the meaning and scope of the term "Medicament" in the matter of Shree Baidyanath Ayurved Bhavan Ltd. v Collector of Central Excise, Nagpur [1996 (83) E.L.T. 492 (S.C.)] where the Apex Court laid down the "common parlance". The WBAAR erred in its judgment on this issue. The definition of "drugs" or referral of the products under the Drugs and Cosmetics Act is not applicable for determination of classification under the GST Act. In ordinary course, the test to identify whether a product is a medicament or not, is whether the said product:

(a) Is prescribed by a Medical Practitioner, and
(b) Is used for a limited period of time.

6. During the course of hearing the Appellant reiterated the points as stated in the Grounds of Appeal. The Appellant stressed on the description of goods in serial no. 63 of the Rate Notification where tariff item 3004 is "Medicaments" which consists of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including trans-dermal administration) and includes Ayurvedic, Unani, Homeopathy, Siddha or Bio-chemic systems of medicaments. The Appellant submitted relevant extracts of the Indian Pharmacopoeia, 2018, prescriptions issued by medical practitioners prescribing the products in question, invoices issued by various pharmacists, certificate issued by Dr. Agnik Pal of JNM Hospital, Kalyani, stating that the products in question are used as medicaments. Further the Appellant stressed on the judgement of the Apex Court in the matter of Kalyani Breweries Ltd. vs Assistant Collector of Customs, Calcutta [2001(134) ELT 12(SC)]. The Appellant also submitted that stickers on its products proclaiming Health/Dietary Supplements", "Health Drinks" and "Not for Medicinal Use" have been pasted to meet procedural requirements only and nothing else. The prescription and use of the products themselves are altogether different.

7. The matter is examined and written and oral submissions made before us are considered. The moot question is whether the products for which classification has been sought fall under the category of dietary/health supplement or they are drugs and medicines as claimed by the Appellant.

8. Central Drugs Standard Control Organisation (CDSCO) is a regulatory body for Indian pharmaceuticals and medical devices, set up under the Ministry of Health and Family Welfare and is responsible for approval of drugs, conduct of clinical trials and laying down the standards for drugs and overseer aspects of safety, rights and well being of

patients. As per provisions of sub-section (b) of section 3 of the Drugs and Cosmetics Act, 1940, "drug" includes *inter alia* all medicines for internal or external use in human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals. Further, sub-section (c) of section 18 of the said Act prohibits manufacture, stocking or sale of any drug without a license procured under the Act. In course of hearing the Appellant stated that he does not hold a drug license under the Drugs and Cosmetics Act, 1940. On being asked as to why the Appellant did not obtain drug license, Appellant's representative stated that obtaining the same is a lengthy and difficult process and it is easier to get license under Food Safety and Standards Authority of India (FSSAI).

9. FSSAI is an autonomous body also created under the Ministry of Health and Family Welfare and is responsible for protecting and promoting public health through the regulation and supervision of food safety. Notification No. 1-4/Nutraceutical/FSSAI-2013 dated 23.12.2016 (hereinafter referred to as "the Regulations") issued by FSSAI cover eight categories of functional food, namely:
   (i) Health Supplements,
   (ii) Nutraceuticals,
   (iii) Food for Special Dietary Use,
   (iv) Food for Special Medical Purpose,
   (v) Speciality Food containing Plant or Botanicals,
   (vi) Food containing Probiotics,
   (vii) Food containing Prebiotics, and
   (viii) Novel Food

10. The Appellant is a license holder under FSSAI and as per the Appellant's submission and observations of WBAAR, the products have stickers pasted on packaging proclaiming "Health/Dietary Supplements", "Health Drinks" and "Not for Medicinal Use". This is as per the Regulations set by FSSAI. It is noted that Food for Special Medical Purpose and Food for Special Dietary Use are intended to be used only under medical advice [Regulations 3 & 8]. The general requirement [Regulation 2(d)(ii)]of the Regulations specifies that the articles of food sold in capsules, tablets, syrups, hard or soft or vegetarian, shall comply with the general monograph and quality requirements specified for them in Indian Pharmacopoeia and also, the quantity of nutrients added to the articles of food shall not exceed the recommended daily allowance as specified by the Indian Council of Medical Research and in cases such standards are not specified the standards laid down by international food standards body, namely, Codex Alimentarius Commission, shall apply.

    Health supplements as per Regulation 6 of FSSAI, *shall contain concentrated source of one or more nutrients, namely amino acids, enzymes, minerals, proteins, vitamins, other*

dietary substances, plants or botanicals, prebiotics, probiotics and substances from animal origin or other similar substances with known and established nutritional or beneficial physiological effect, which are presented as such and are offered alone or in combination, but are not drugs as defined in the clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 and the rules made thereunder.

So being prescribed by medical practitioners for a limited period use or sold by pharmacists are not sufficient parameters for the products in question to be classified as medicaments as per HSN classification in the light of the current Regulations laid down by FSSAI. It is clear that products under the Drugs and Cosmetics Act, 1940, will not fall under those categories regulated by FSSAI and *vice versa*. These two categories, namely the products falling under the Drugs and Cosmetics Act, 1940, and those regulated by FSSAI are mutually exclusive. In fact the products in question are not eligible for drug license under the Drugs and Cosmetics Act, 1940 as these are mainly prebiotic and probiotic supplements, oral rehydration formulae and tonic. Chapter 30 of Customs Tariff Code on which classification under the GST Act is based, excludes food and beverages like fortified food, food supplements, tonics, etc., even if they have therapeutic and prophylactic properties.

In view of above discussion we find no infirmity in the ruling pronounced by the WBAAR. The products in question are classifiable under HSN 2106, and taxable under Sl. No. 23 of Schedule III of Notification No. 1/2017-C.T (Rate) dated 28-06-2017 under the Central Goods and Services Tax Act, 2017 and Notification No. 1125-FT dated 28-06-2017 under the West Bengal Goods and Services Tax Act, 2017, as amended vide Notification No. 41/2017-C.T (Rate) dated 14-11-2017 under the Central Goods and Services Tax Act, 2017 and Notification No. 2019-FT dated 14-11-2017 under the West Bengal Goods and Services Tax Act, 2017.

The appeal thus fails and stands disposed accordingly.

Send a copy of this order to the Appellant and the Respondent for information.

Sd/-

(Smaraki Mahapatra)
Member
West Bengal Appellate Authority
for Advance Ruling

Sd/-

(A.P.S Suri)
Member
West Bengal Appellate Authority
for Advance Ruling