

**THE AUTHORITY ON ADVANCE RULINGS
IN KARNATAKA
GOODS AND SERVICES TAX
VANIJYA THERIGE KARYALAYA, KALIDASA ROAD
GANDHINAGAR, BENGALURU - 560 009**

Advance Ruling No. KAR ADRG 18/ 2019

Date : 07-08-2019

Present:

1. **Sri. Harish Dharnia,**
Additional Commissioner of Central Tax, Member (Central Tax)
2. **Dr. Ravi Prasad M.P.**
Joint Commissioner of Commercial Taxes Member (State Tax)

1.	Name and address of the applicant	M/s Strides Emerging Markets Limited, Strides house, Bilekanahally, Bannerghatta road, Bengaluru-560076
2.	GSTIN or User ID	29AARCS5667D1ZQ
3.	Date of filing of Form GST ARA-01	16.05.2018
4.	Represented by	Sri Abhi Paresh, Chartered Accountant
5.	Jurisdictional Authority - Centre	The Commissioner of Central Tax, South Commissionerate, Bengaluru
6.	Jurisdictional Authority - State	LGSTO-25 A, Bengaluru
7.	Whether the payment of fees discharged and if yes, the amount and CIN	Yes, discharged fee of Rs.5,000-00 under CGST Act and Rs 5,000-00 under SGST Act vide CIN HDFC 18052900083690 dated 16.05.2018

ORDER UNDER SUB-SECTION (4) OF SECTION 98 OF CENTRAL GOODS AND SERVICE TAX ACT, 2017 AND UNDER SUB-SECTION (4) OF SECTION 98 OF KARNATAKA GOODS AND SERVICES TAX ACT, 2017

1. M/s Strides Emerging Markets Limited, (called as the 'Applicant' hereinafter), Strides house, Bilekanahally, Bannerghatta road, Bengaluru-560076 having GSTIN number 29AARCS5667D1ZQ, have filed an application for Advance Ruling under Section 97 of CGST Act' 2017, KGST Act' 2017 & IGST Act' 2017 read with Rule 104 of CGST Rules 2017 & KGST Rules 2017, in form GST ARA-01 discharging the fee of Rs.5,000/- each under the CGST Act and the KGST Act.




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2. The Applicant, a Private Limited Company, registered under the Goods and Services Act, 2017, is a pharmaceutical company, engaged in the development and manufacture of generic and IP led niche pharmaceutical products. Also it is registered as a 100% Export Oriented Unit ("EOU") in Karnataka.

3. The Applicant has developed a new product "Narcotic Chewing Tablet" (NCT) which is used to wean off the withdrawal symptoms associated from the narcotic consumption cessation. The applicant further requested, vide their letter dated 28.05.2018, to consider "Narcotic Chewable Tablet" as "Nicotine Polacriliex Lozenge" in their application. In view of the above, the applicant has sought advance ruling in respect of the following question:

What is the appropriate classification of Nicotine Polacriliex Lozenge (hereinafter referred to as "NCT") manufactured by the Company and rate of tax applicable thereupon under Notification 01/2017-Central Tax (Rate), dated 28-06-2017

FACTS OF THE CASE:

4.1 The applicant, vide their application dated 28.04.2018, received in this office on 16.05.2018, submitted that they manufacture and sell a new product Nicotine Polacriliex Lozenge (herein after referred to as "NCT") which is used to wean off the withdrawal symptoms associated from the nicotine consumption cessation if taken in a prescribed manner; the manner of intake of NCTs is mentioned on a usage manual which is kept inside the NCT packets & the said product is available in dosages of 2 mg and 4 mg depending on the power of the medicine.

4.2 They further stated that the primary ingredient in NCT is nicotine which is mixed with various other ingredients to add color, flavor etc., and the target customer base of NCT is addicted smokers who wish to give up or reduce smoking habit. When a person intakes tobacco products, there are various harmful chemicals which go inside the human body in addition to nicotine which cause life threatening diseases.

4.3 The primary usage of nicotine in tobacco products is its stimulant effect which acts a contributing factor to the addictive properties of tobacco smoking. In other words, presence of nicotine in tobacco contributes towards addiction of a particular person to smoke tobacco. However in NCT, the primary ingredient nicotine is present in a non-harmful quantity.

4.4 They also stated that the NCT when taken in prescribed quantum, provides the body with adequate nicotine intake; however there is a gradual

decline in the dependency of the body on Nicotine. Given this, the harmful effects of smoking tobacco are nullified by taking NCT. The NCT of 2 mg dosage is available as an over the counter product, whereas NCT of 4 mg dosage would be available only pursuant to a prescription from a medical practitioner.

4.5. The applicant submits that their product is classifiable under chapter heading 3004 and claims the applicable rate of 12% GST in terms of entry no.63 of schedule-II of Notification 01/2017-Central Tax (Rate) dated 28-06-2017, effective from 01.07.2017. The applicant also submits that the competing entry is under Chapter 30, which attracts 18% of GST, under Sl.No.41 of Schedule-III of the Notification supra. The relevant extracts of said entries of relevant schedules are appended below:

S.No.	Chapter Heading/ Sub Heading/ Tariff Item	Description of goods	Rate
Schedule-II			
63	3004	Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) 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, including Ayurvedic, Unani, homoeopathic siddha or Bio-chemic systems medicaments, put up for retail sale	12%
Schedule III			
41	30	Nicotine polacrilex gum	18%

4.6 The Applicant submits that their product is rightly classifiable under the chapter heading 3004, on the basis of the following reasons:

1. The chapter heading 3004 covers all medicaments which consists of mixed or unmixed products for therapeutic or prophylactic use, put up in measured doses. In the instant case, Nicotine is put up in measured dosage of 2mg / 4mg and results in

- a. providing relief to the patient against tobacco abuse
 - b. safeguard the patient against life harming diseases such as chronic obstructive pulmonary disease, heart disease, diabetes, harms the reproductive system in woman, cancers etc.
2. The product in question, NCT, is a medicament in true sense which has therapeutic uses.
 3. The competing entry under chapter heading 30 specifically covers Nicotene Polacrilex gum and in the instant case the product NCT is in the form of "tablet" or "Lozenge" and not in the form of gum. Further the said entry under Chapter 30 is exhaustive and covers only a specific product i.e "Nicotene Polacrilex gum".

**PERSONAL HEARING: / PROCEEDINGS HELD
ON 21.05.2018 & 18.07.2018.**

5. The Applicant authorized Sri Abhi Parakh, Chartered Accountant and the said authorized representative appeared for personal hearing proceedings on 21.05.2018. The representative explained the nature and use of their product (NCT) and stressed that their product is a tablet and not gum; it merits classification under heading 3004 and hence attracts 12% GST, in terms of Notification 01/2017 supra; it does not fall under Serial No. 41 Schedule III of the said notification which attracts 18% GST. The applicant also requested time for submission of additional documents.

5.1 Further, the authorized representative, during the next personal hearing held on 18.07.2018 submitted the following additional documents, while reiterating their earlier submissions.

- Under taking statement of correction in the words of ARA-01 application ie "Narcotic chewing Tablets" to be read as " Nicotine Polacrilex Lozenge" (NPL)
- Screen shot of payment of balance of INR 50 though cash balance available in electronic cash ledger.
- Sample copy of the invoice raised by the company
- Drug approval license

FINDINGS & DISCUSSION:

6. The application for Advance Ruling, as submitted by the applicant, was duly forwarded to the jurisdictional office with a request to offer their

response. However no response has been received by this office in the matter nor was any appearance made during personal hearing. Consequently, the Authority proceeds to examine the issue and issue suitable orders on the basis of the documents and arguments preferred by the applicant.

6.1 We have considered the submissions made by the Applicant in their application for advance ruling as well as the submissions made by Sri. Abhi Parakh, Chartered Accountant, the authorized representative, during the personal hearings. We have also considered the issues involved on which advance ruling is sought by the applicant and relevant facts of the issue involved.

6.2 The Applicant, filed the instant application seeking advance ruling, on the following question:

What is the appropriate classification of Nicotine Polacriliex Lozenge (hereinafter referred to as "NCT") manufactured by the Company and rate of tax applicable thereupon under Notification 01/2017-Central Tax (Rate), dated 28-06-2017 ?

6.3 The Applicant seeks appropriate classification of their product "NPL" and thereby the applicable rate of GST thereon. Therefore the main issue before us to decide is the classification of the said product. Once the classification is determined, the applicable GST rate shall follow suit. We, therefore proceed to examine the issue of classification of the impugned product.

6.4 The product NPL, in terms of the applicant's submissions, consists of Nicotine as primary ingredient and is mixed with various other ingredients to add color, flavor etc.; Nicotine is put up in measured dosage of 2mg/4mg in NPL; it provides relief to the patient against tobacco abuse; it safeguards the patient against life harming diseases such as chronic obstructive pulmonary disease, heart disease, diabetes etc., and therefore it is a medicament in true sense having therapeutic uses; it is not a gum as it does not leave any residue when consumed and also it is in the form of tablet or lozenge.

6.5 The Applicant submitted that the Department of Drugs and Control Authority ,Karnataka vide their letter dated DCD/MFG/CR-770/16-17 dated 22-02-2017 has permitted them to manufacture Nicotine Polacrilex Lozenge 2 mg and 4 mg (frost mint), Tartrazine and brilliant Blue FCF colours and also 2 mg and 4 mg(rip cherry), colour being Ponceau 4R.



6.6 We find that Nicotine is an alkaloid present in tobacco leaves and it can also be obtained by synthesis. It is a colourless liquid, which turns brown when exposed to air, having a characteristic penetrating odour. It is a strong base, toxic, forms crystalline salts and can be used as a fungicide and insecticide for plants, as per the Explanatory Notes to the heading 29.39 at Sr. (G) of the Harmonised Commodity Description and Coding System. Further, the instant product is a chemical preparation made out from Nicotene and poly acrilix acid (carboxylic acid) having IUPAC name of Poly 1-Carboxyethelene.

6.7 The Applicant claims the classification of their product under heading 30.04 and the resultant benefit of entry No.63 of Schedule-II of Notification No.01/2017-Central Tax (Rate) dated 28.06.2017, effective from 01.07.2017. However, the Explanatory Notes, of the Harmonised Commodity Description and Coding System, to the heading 30.04 also specifies the products which are excluded from the heading 30.04. Among these exclusions the last sl.no.(f) specifies that the **Preparations, such as tablets, chewing gum or patches (transdermal systems), intended to assist smokers to stop smoking** are excluded from the heading 30.04 and also suggests alternate headings of 21.06 / 38.24. In view of the above, it is clearly evident that the impugned product does not fall under the heading 30.04. Therefore, we proceed to determine the right classification of the impugned product.

7. Definition of lozenge

7.1 A lozenge is a medicated tablet held in the mouth until it has dissolved, slowly providing the desired effect to the person who has consumed it. It is delivered to the bloodstream via absorption by the tissues of the mouth.

Working of Nicotine Polacrilex Lozenge:

7.2 Nicotine Polacrilex Lozenges deliver nicotine to the body, temporarily relieving craving and nicotine withdrawal symptoms when the smoking is intended to be stopped / quit. But unlike cigarettes, Nicotine Polacrilex Lozenges deliver a lower, steady level of nicotine to the blood of the consumer. When used as directed, Nicotine Polacrilex Lozenges help to regulate, control, and gradually reduce the body's craving for nicotine. The Nicotine Polacrilex Lozenges contain no tar or carbon monoxide, and therefore doesn't present the same medical risks as cigarettes. However, the lozenges still deliver nicotine, the addictive ingredient in cigarettes.

7.3 It could be seen from above that the instant product supplies only nicotine, when administered. The said product is manufactured out of the

chemical combination of nicotine and poly acrylic acid. Both the ingredients are organic chemicals. Therefore the product is an organic chemical, which is used to supply the nicotine. In effect the product being administered is nothing but nicotine in measured doses.

7.4 Explanation (iii) and (iv) appended to the Notification No. 01/2017-Central Tax (Rate), dated 28.06.2017 are relevant to classification of goods. The said explanations are reproduced below for ease of reference.

(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.

Accordingly we make a reference to the Section Notes and Chapter Notes of the relevant Chapters of the Customs Tariff and also the corresponding Explanatory Notes.

7.5 The applicant contends that their product is a medicament and hence is covered under Chapter Heading 3004. We find that Chapter 30 is titled 'Pharmaceutical Products'. We have further gone through the Chapter Notes. Chapter Note 1 lists out products not covered under Chapter 30 of the Tariff. There are eight categories of products listed therein which are not covered under Chapter 30. We find that entry no. (b) in this list reads as follows:

(b) Preparations, such as tablets, chewing gums or patches (transdermal systems), intended to assist smokers to stop smoking (heading 2106 or 3824);

7.6 Now we also go to the Explanatory Notes to the Harmonised Commodity Description and Coding System. The explanatory notes have two sets of notes. One is the Chapter Notes mentioned at the beginning of the Chapter. The second set of explanations is detailed in each of the sub-headings of the Chapter as well. The Chapter Notes in the Explanatory Notes are identical to those given in the Chapter Notes in the Customs Tariff. Accordingly preparations, such as tablets, chewing gums or patches (transdermal systems), intended to assist smokers to stop smoking are not

covered under Chapter 30, as claimed by the applicant. However we visit the exact Chapter Heading, 3004, as claimed by the applicant, in the Explanatory Notes. We find that towards the end of the discussion on Heading 3004, the Explanatory Notes provide for exclusions from the Heading 3004. The same are reproduced below for quick reference:

The heading also excludes:

- (a) *Snake or bee venom, not put up as medicaments(heading 30.01)*
- (b) *Goods of heading 30.02, 30.05, or 30.06, however they are put up*
- (c) *Aqueous distillates or aqueous solutions of essential oils and preparations of headings 33.03 to 33.07, even if they have therapeutic or prophylactic properties(Chapter 33)*
- (d) *Medicated soaps however they are put up (heading 34.01)*
- (e) *Insecticides, disinfectants, etc, of heading 38.08, not put up for internal or external use as medicines*
- (f) ***Preparations, such as tablets, chewing gum or patches (transdermal systems), intended to assist smokers to stop smoking (heading 21.06 or 38.24)*** (emphasis supplied by Authority)

7.7 The aforesaid exclusions, whether in the form of Chapter Notes at the beginning of Chapter 30 or exclusions specifically mentioned in the Explanatory Notes to Heading 3004, provide that any preparation intended to assist smokers to stop smoking shall not be covered under the Heading 3004. The use of the words 'such as' indicates that the preparation may be in any form, whether tablets, gums, lozenges or any other form, thereby meaning that if the preparations intend to wean off smokers from smoking then the preparations are either covered under heading 21.06 or 38.24.

7.8 We are also drawn to the exclusion mentioned at serial number (c) in Para 7.6. This exclusion shows that even if certain preparations have therapeutic or prophylactic properties still they can be excluded from the scope of the Heading 30.04, as in the case of the said Aqueous distillates or aqueous solutions of essential oils and preparations. Therefore, the applicant's contention on this ground is not maintainable.

7.9 The aforesaid analysis enables us to effectively answer the question raised by the applicant. The answer is that the said item does not fall under the Heading 3004. Accordingly it is not covered under Serial number 63 of Schedule II of Notification No.01/2017-Central Tax (Rate) dated 28.06.2017.

7.10 The Chapter Notes and Explanatory Notes provide that preparation intended to assist smokers to stop smoking shall be covered by heading 21.06 or 38.24. We find that Chapter 21 deals with Miscellaneous edible preparations and heading 21.06 deals with food preparations not elsewhere specified or included. The instant product basically consists of nicotine which is not an edible / food preparation. Therefore the only alternative left for the classification of the instant product is chapter heading 38.24.

8. In view of the foregoing, we pass the following

RULING

The instant product, Nicotine Polacriliex Lozenge, is rightly classifiable under the heading 38.24. Accordingly the product is covered under Serial number 97 of Schedule III to Notification No. 01/2017-Central Tax (Rate) dated 28.06.2017 and attracts GST at the rate of 18% (9% CGST, 9% SGST).


07-08-2019

(Harish Dharnia)
Member



(Dr. Ravi Prasad M.P.)
Member

Place : Bengaluru,
Date : 07-08-2019

To,

The Applicant

Copy to :

The Principal Chief Commissioner of Central Tax, Bangalore Zone, Karnataka.

The Commissioner of Commercial Taxes, Karnataka, Bengaluru.

The Commissioner of Central Tax, Bangalore South Commissionerate, Bengaluru.

The Asst. Commissioner, LGSTO-25 A ,Bengaluru.

Office Folder.

