KARNATAKA APPELLATE AUTHORITY FOR ADVANCE RULING
6TH FLOOR, VANIJYA THERIGE KARYALAYA, KALIDASA ROAD,
GANDHINAGAR, BANGALORE – 560009

(Constituted under section 99 of the Karnataka Goods and Services Tax Act, 2017 vide Government of Karnataka Order No FD 47 CSL 2017, Bangalore, Dated:25-04-2018)

BEFORE THE BENCH OF

SHRI. D.P.NAGENDRA KUMAR, MEMBER

SHRI. M.S.SRIKAR, MEMBER

ORDER NO.KAR/AAAR-06/2020-21 **DATE:21-10-2020**

Sl. No	Name and address of the appellant	M/s BIOCON Ltd, 20th KM, Hosur Road, Electronic City, Bangalore 560100
1	GSTIN or User ID	29AAACB7461R1ZZ
2	Advance Ruling Order against which appeal is filed	KAR/ADRG 31/2020 Dated: 4thMay2020
3	Date of filing appeal	23-07-2020
4	Represented by	Sri Harish Bindumadhavan and Ms Disha Gursahaney, Advocates
5	Jurisdictional Authority- Centre	Commissioner of Central Tax, Bangalore SouthCommissionarate
6	Jurisdictional Authority- State	ACCT,LGSTO- 25 Bangalore
7	Whether payment of fees for filing appeal is discharged. If yes, the amount and challan details	Yes. Payment of Rs. 20,000/- made vide CIN NO. HDFC20072900213139 Dated. 18-07-2020

PROCEEDINGS

(Under Section 101 of the CGST Act, 2017 and the KGST Act, 2017)

1. At the outset we would like to make it clear that the provisions of CGST, Act 2017 and SGST, Act 2017 are in *parimateria and have the same provisions* in like matter and differ from each other only on a few specific provisions. Therefore, unless a mention is particularly made to such dissimilar provisions, a reference to the CGST Act would also mean reference to the corresponding similar provisions in the KGST Act.

2. The present appeal has been filed under section 100 of the Central Goods and Service Tax Act 2017 and Karnataka Goods and Service Tax Act 2017 (herein after referred to as CGST Act, 2017 and SGST Act, 2017) by M/s BIOCON Ltd, 20th KM, Hosur Road, Electronic City, Bangalore 560100(herein after referred to as Appellant) against the advance Ruling No. KAR/ADRG 31/2020 Dated: 4thMay 2020.

Brief Facts of the case:

3. The Appellant is registered as a public company under the Companies Act, 1956. The Appellant has GST registrations for its SEZ unit bearing GSTIN 29AAGCB0811M2ZM for its office situated at Plot No 2 and 3, Phase IV BIA, Bommasandra Industrial Area, Jigani Link Road, Bangalore – 560100(hereinafter referred to as "Biocon SEZ" or "SEZ unit"). Further, the Appellant has a separate registration for its unit in the DTA bearing GSTIN 29AAACB7461R1ZZ located at 20th KM, Hosur Road, Electronic City, Bengaluru, Karnataka 560100 (hereinafter referred to as "Biocon DTA" or "DTA unit").

4. The Appellant is engaged in manufacturing of generic active pharmaceutical ingredients (APIs), novel biologics, biosimilar insulins and antibodies. In the present case, the SEZ unit of the Appellant manufactures "Micafungin Sodium" and sells the same as bulk drug to third party DTA units, who in turn use it for injections. Entry No. 180 of Schedule I of Rate Notification provides that Drugs or medicines covered under List 1 appended to the said schedule is leviable to GST at the rate of 5% (2.5% SGST and 2.5% CGST). Accordingly, the Appellant is discharging IGST at the rate of 5% on clearance of Micafungin Sodium from its SEZ unit. Thereafter, the said product is sold by the Appellant's DTA unit by charging GST at 5%, which is used by the Appellant's customers for injection.

5. The Appellant filed an application for Advance Ruling under section 98 of the CGST Act, 2017 and KGST Act, 2017 on the following questions:

"Whether the sale of Micafunign Sodium by the DTA unit of the applicant is covered under Serial No. 114 of Entry No. 180 of the Rate Notification No 01/2017 Central Tax (R) and therefore, is leviable to GST at the rate of 5%".

6. It was decided by the Karnataka Advance Ruling Authority vide Ruling No. KAR/ADRG 31/2020dated 4thMay2020 that:

"The sale of Micafungin sodium by the DTA unit of the applicant is not covered under SerialNo. 114 of Entry No. 180 of the Notification No. 1/2017-Central Tax (Rate) dated June 28, 2017, and therefore, is not entitled for concessional rate of GST at the rate of 5%".

7. Aggrieved by the said Ruling of the Authority (herein after referred to as 'impugned order'), the Appellant has filed an appeal under section 100 of the CGST Act, 2017 and KGST Act, 2017 on the following grounds.

7.1 The Appellant humbly submits that while Micafungin Sodium is cleared as bulk drugs, and the same is used by customers for an injection. The impugned order has erred in restricting the applicability of Rate Notification on the basis of clearance instead of product's usage. They submitted that Micafungin is an echinocandin antifungal drug used to treat and prevent invasive fungal infections including candidemia, abscesses and esophageal candidiasis; that Micafungin is a drug but has to be prepared for administration, for which it has to be made in salt form; that Micafungi sodium is a salt of drug Micafungin.

7.2. The Appellant supplies the said product "Micafungin sodium" as bulk drugs. The term "bulk drug" is not defined under the Goods and Services Tax Act or the Drugs and Cosmetics Act, 1940. However, commonly, a "bulk drug" means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient of the drug product. They submitted that the United States Food and Drug Administration Regulations defines "bulk drug" as any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

7.3. The Appellant relied on the case of **In Re: Laurus Labs Ltd. 2018 (13) GSTL 472 (AAR-GST)**, which has been passed in reference to Pharmaceuticals products in the form of bulk drug, held to be covered under List 1 under Sl. No. 180 of Schedule I to Notification No. 1/2017-C.T. (Rate) and taxable at 5% GST. They submitted that in the present case, it is clear that Micafungin Sodium cleared as bulk drugs by the Appellant to its customers, is still covered as a 'drug' under List 1 under Sl. No. 180 of Schedule I to Notification No. 1/2017-

C.T. (Rate) and thereby, taxable at 5% GST. They also relied on the Tribunal's decision in the case of Cipla Ltd vs Commissioner of Customs, Chennai (218 ELT 547 (Tri-Chennai) wherein it was held that bulk drugs are also drugs; that as per the Drugs (Prices Control) Order, 1995, 'drugs' includes bulk drugs and the same was reaffirmed by the Tribunal in the case of Astrix Laboratories Ltd vs CCE &Cus, Hyderabad-I (2009 (233) ELT 372 (Tri-Bang). They submitted that the decision of Astrix Laboratories Ltd (supra) was followed in the case of Aurobindo Pharma Ltd vs CCE, Hyderabad-I (2009 (247) ELT 206 (Tri-Bang) which held that the notification does not distinguish between bulk drugs and other drugs for the purpose of granting exemption. Therefore, the bulk drug supplied by the Appellant's DTA unit to its customers by charging GST at 5% under entry 180 of the rate notification is correct in law.

7.4. The Appellant submitted that any drug or medicine in its bulk form would be available either as acid, base or its salt/ester. It can be administered as such if the other parameters are met or in some cases, it needs to be converted as a salt or ester so that it will be ready for administering. However, the salts or esters of the drug or medicine needs to undergo some other additional processes, before it can be made in measured dosages for administering. They submitted that standalone Micafungin cannot be administered as Injection. Thereby, the Appellant manufacturesMicafungine and converts it into Micafingine Sodium, and supplies the same to its customers, in the form of lyophilised powder which is in the form of salt, which needs to be sterilised before making them into measured dosages to be filled in vials; that the form in which the product is sold is a salt and same can be administered in measured dosages as injection only. Therefore, they contended that Mcafungin sodium being a salt of Micafungin will then fall under "salts and esters" of drug category under Sl. No. 180 of the Rate Notification which reads as *'**Drugs** or medicines **including their salts** and esters and diagnostic test kits, specified in List 1 appended to this Schedule.'*. They relied on the clarification given by the CBEC in the earlier tax regime wherein vide**Circular No. 60/2003-Cus. dated July 16, 2003**, it was clarified that *the terms drugs and medicines, referred to in Sl. 80(A) of Notification No. 21/2002-Cus. include their salts & esters as well. Therefore, the Notification No. 21/2002-Cus., Sl. 80(A), covers not only drugs or medicines specified in list 3 but also their salts & esters.*

7.5. The Appellant also states that for sale of "Micafungin sodium" to be covered under Serial No. 114 of the list specified under Entry No. 180 of the Rate Notification

as "Micafungin Sodium for Injection", such bulk drugs should be utilized for injection; that in the present case, Micafungin Sodium supplied by the Appellant would be used by the recipient customers to manufacture formulations or vials of Micafungin Sodium; that these vials would be labelled as "Micafungin Sodium for Injection" as per the nomenclature requirement. They submitted a declaration given by their customer M/s Crenza Pharmaceuticals Pvt Ltd holding that the Micafungin Sodium procured from the Appellant will be used solely for Micafungin Injection. They also submitted that the U.S. Food & Drug Administration has also acknowledged that Micafungin Sodium is administered in the form of injection only and in no other form. They also drew attention to the approval provided for 'Micafungin Sodium for injection' by the Central Drugs Standard Control Organisation (CDSCO); that the CDSCO approval is only granted to Micafungin Sodium for injection and not as an ointment, tablets or any other formation. They contended that the product sold by the Appellant is the predominant and indispensable component of the formulation "Micafungin Sodium for Injection" and hence the same can be administered as injection only.

7.6. The Appellant also drew reference to the Nomenclature guidelines provided by the United States Pharmacopeia (USP) which states that the phrase "for injection" is a nomenclature requirement for dry solids that upon the addition of a suitable vehicle, yield solutions, conforming, in all respects to the requirements for injections. In view of the above, they submitted that any drug in the form of dry solids which conforms with the requirements of injection on addition of a suitable vehicle are covered under the category of "drug" for injection and the suffix "for injection" should be added to the drug name; that Micafungin Sodium supplied by the Appellant conforms to the requirements of injection on addition of a suitable vehicle called "Sodium Chloride" and thus is covered under the category of "Drug for injection". They also drew reference to the technical description of "Mycamine" which is the brand name for Micafungin Sodium for injection, wherein it states that Mycamine is a sterile, lyophilized product for intravenous infusion that contains micafungin sodium; that the term 'lyophilized' refers to a process of freeze drying for preparing dry solids that can be reconstituted for injections; that the word "for" is succeeded by the purpose for which it is meant to be used; that the use of the drug is the basis on which concessional rate must be given.

7.7. In addition to the above, the Appellant also submitted that the product "Micafungin sodium" supplied by it, is medical in nature, and it the intention of the government to tax

such products at a concessional rate of tax. Similar concessions have existed in tax laws since 2001. Therefore, they contended that there is no reason why a narrow view should be taken to hold that sale of Micafungin Sodium by Appellant's DTA unit is not covered under Sl.No 114 of entry No 180 of the notification No 01/2017 CT (R) dt 28.06.2017

7.8. In view of the aforesaid submissions, the Appellant pleaded that the impugned order deserves to be set aside.

PERSONAL HEARING

8. The appellant was called for a virtual personal hearing on 6th October 2020 but they sought an adjournment. Accordingly, the Appellants were called for another virtual hearing on 14th October 2020.

8.1. The hearing on 14th October 2020 was conducted on the Webex platform following the guidelines issued by the CBIC vide Instruction F.No 390/Misc/3/2019-JC dated 21st August 2020. The Appellant was represented by their Advocates Shri. Harish Bindumadhavan and Ms Disha Gursahaney who explained that the Appellant is engaged in the manufacture of active pharmaceutical ingredients in the form of bulk drugs. One such bulk drug is Micafungin Sodium which is manufactured at their SEZ unit. The same is cleared to the DTA unit and from the Appellant's DTA unit it is cleared to third party customers.

8.2. The Appellant explained that the drug, Micafugin Sodium is an antibiotic and is used for anti-fungal treatment. It is always used for invasive treatment and is administered intravenously in the form of an injection. The Appellant drew attention to the approval given by the CDSCO (Central Drug Standard Control Organisation) which is specifically granted for the use of the drug in the form of an injection. He also submitted that the US FDA also acknowledges that the drug Micafungin Sodium is used only for administering as injections.

8.3. The Appellant submitted that in the earlier Central Excise tax regime, the product Micafungin Sodium was being cleared by availing a concessional rate of duty in terms of a notification which was worded in the same manner as in the present GST rate Notification; that there was no dispute by the Department in the past that the product Micafungin Sodium

was not eligible for the concessional rate. He submitted that the entry sl.no 180 of the GST rate Notification applies to drugs, including their salts and esters which are specified in List I to the Schedule; that the product Micafungin Sodium is undoubtedly a salt. It is sold in a powder form in a vial and its sole purpose is for use as an injection. In order to administer the drug intravenously, the customer adds a soluble medium i.e Sodium Chloride to the Micafungin Sodium powder and administers it to the patient; that the Sodium Chloride is mixed only for the ease of administering intravenously. He emphasised that apart from the Sodium Chloride, no other fillers or other ingredients are added to the powder; that no further processing of any kind is undertaken by the customer before administering the drug as an injection. In this connection, he submitted that they have obtained declarations from third parties to substantiate that the drug procured from the Appellant is administered only in the form of an injection.

8.4. The Appellant also highlighted the fact that the CDSCO approval in India (which applies to all drug manufacturers) is only for using the Micafungin Sodium as an injection. The said drug cannot be used in any other form other than by way of an injection as it is statutorily not permitted by the Drug Control laws in India. The Appellant submitted that the lower Authority has erred in ruling that Micafungin Sodium is a raw material for the manufacture of the injection. He submitted that Micafungin Sodium is the only material in the injection which is sold in the form of a salt and that it is mixed with Sodium chloride, an electrolyte only in order to make is suitable for administering intravenously.

8.5. In view of the above submissions he pleaded that the product Micafungin Sodium is eligible for GST rate of 5% in terms of Sl.No 180 of Schedule I as the product supplied by the Appellant is listed at Sl.No 114 of List I to the Schedule I. Accordingly, he prayed that the appeal be allowed

DISCUSSIONS AND FINDINGS

9. We have gone through the records of the case and considered the submissions made by the Appellant in the grounds of appeal as well as at the time of the virtual personal hearing.

10. The short point for determination is whether the product "Micafungin Sodium" supplied by the Appellant is eligible for the benefit of GST rate of 5% in terms of entry No

180 of Schedule I to Rate Notification No 01/2017 IT (R) / CT (R) dated 28-06-2017. The relevant extract of the Notification is repro*duced below:*

Schedule I – 5%

S.No	***Chapter / Heading / Sub-heading / Tariff item***	***Description of goods***
180	*30 or any Chapter*	*Drugs or medicines including their salts and esters and diagnostic test kits, specified in List 1 appended to this Schedule*

List 1 appended to Schedule Imentions the following item at Sl.No 114

(114) Micafungin sodium for injection.

11. A reading of the above entry of the rate Notification indicates that drugs and medicines falling under Chapter 30 or any other Chapter and specified in List 1 are eligible for 5% GST under the entry Sl.No 180 of Schedule I. The said entry also covers the specified drugs and medicines which are in the form of their salts and esters and diagnostic test kits. It is the case of the Appellant that the product "Micafungin Sodium" supplied by them is solely for the purpose of injection and hence is covered under the item No 114 of List I. The lower Authority has taken a stand that the impugned product is supplied as a bulk drug and bulk drugs are not covered under the entry SL.No 180.

12. We observe from the invoice placed on record that the impugned product is classified by the Appellant under Chapter sub-heading 294190 90. We have also perused the technical write up of the product "Micafungin Sodium". The terms "bulk drug" and "drug" have not been defined either in the rate notifications or in the GST laws. However, the same havebeen defined in the Drugs (Price Control) Order, 1995 which is reproduced below:

> *2.* ***Definitions*** *: In this Order, unless the context otherwise requires, -*
>
> ***(a) "bulk drug"*** *means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940), and which is used as such or as an ingredient in any formulation;*
>
> ***(f) "drug"*** *Includes –*

(i) all medicines for internal or external use of 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, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(ii) such substances, intended to affect the structure or any function of the human or animal body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Government by notification in the official Gazette; and

(iii) bulk drugs and formulations; (Emphasis supplied)

13. It is seen from the above that the term 'drug' also includes 'bulk drug'. A common understanding of the term 'bulk drug' means a licenced product which is manufactured for use as an active pharmaceutical ingredient. In this case, Micafungin Sodium is the sodium salt form of the antifungal drug Micafungin which is used in the treatment of internal fungal infections. It is the active pharmaceutical ingredient in the manufacture of the drug "Mycamine" which is the brand name for the antifungal injection. We find that the Central Drugs Standards Control Organisation (CDSCO), the authority which approves new drugs in India, has granted approval for the drug "Micafungin Sodium for Injection" of strength 50mg and 100mg, for the treatment of patients with candidemia, acute disseminated candidiasis, abscess and esophageal candidiasis, etc. The approval given is for the drug which is to be administered only as an injection.Therefore, although Micafungin Sodium is a bulk drug, its use can be only by way of injection as there is no statutory approval given for using the drug in any other form.

14. We also take note of the U.S Pharmocopeia Nomenclature Guidelines which specifies how the established names for drugs are created. The relevant extract dealing with the nomenclature for injections is reproduced hereunder:

The USP currently recognizes seven categories of injections:

1. [DRUG] Injection – Liquid preparations that are drug substances or solutions thereof

2. [DRUG] for Injection – Dry solids that upon the addition of a suitable vehicle yield solutions conforming in all respects to the requirements for Injections.

3. [DRUG] Injectable Emulsion – Liquid preparations of drug substances dissolved or dispersed in a suitable emulsion medium.

4. [DRUG] Injectable Suspension – Liquid preparations of solids suspended in a suitable liquid medium.

5. [DRUG] for Injectable Suspension – Dry solids that upon the addition of a suitable vehicle yield preparations conforming in all respects to the requirements for injectable suspensions.

6. [DRUG] Extended-Release Injectable Suspension – Liquid preparations of solids suspended in a suitable liquid medium and formulated in a manner that allows the contained drug substance to be available over an extended period of time.

7 [DRUG] for Extended-Release Injectable Suspension – Dry solids that upon addition of a suitable vehicle yield preparations conforming in all respects to the requirements for Extended-Release Injectable Suspension.

15. It is evident from the above that, drug preparations which are used as injections carry a suffix to indicate the kind of preparation. This gives an indication regarding the route of administration i.e intravenous, intramuscular, subcutaneous or intrathecal. A drug which carries as a suffix the phrase "for injection" signifies that the drug is in the form of a dry solid and becomes suitable for use as an injection only upon addition of a suitable vehicle. On the other hand, a drug with a suffix "Injection" merely indicates that it is a liquid preparation which does not need any other medium to make it suitable for injection. In this case, the Micafungin Sodium supplied by the Appellant is in the form of a lyophilised powder. The term "lyophilized" refers to a process of freeze drying where a product becomes stable and absolutely free of moisture. The lyophilized powder gets reconstituted to its original form for injection with the addition of a suitable vehicle which in this case is Sodium Chloride. Therefore, the Micafungin Sodium supplied by the Appellant is the drug "Micafungin Sodium for Injection". As already stated, the phrase "for injection" used in the Notification is only an indication of the form in which the drug is supplied i.e in a dry solid form.

16. We also take note that the Customs Tariff provides a similar concessional rate of 5% for Micafungin Sodium for injection when imported in India in terms of Customs Notification No 12/2012 dated 17th March 2012. The relevant extract of the Notification is reproduced below:

S. No	*Chapter or Heading or sub-heading or tariff item*	*Description of goods*	*Standard rate*	*Additional duty rate*	*Condition No*
147	*28,29 or 30*	*The following goods, namely:-* *(A) Drugs, medicines, diagnostic kits or equipment specified in List 3* *(B) Bulk drugs used in the manufacture of drugs or medicines at (A)*	*5%* *5%*	*-* *-*	*-* *5*

List 3 appended to S.No 147 specifies the following item:

(174) Micafungin Sodium for Injection.

We find that the Customs Notification is worded in the same manner as the GST rate Notification. We therefore disagree with the findings of the lower Authority and hold that in this case, the usage of the drug is the basis on which the concession has to be given.

17. In view of the above discussion, we pass the following order

ORDER

We set aside the ruling no NO.KAR ADRG 31/2020 dated 4th May 2020 passed by the Advance Ruling Authority and answer the question of the Appellant as follows:

"The sale of Micafunign Sodium by the DTA unit of the Appellant is covered under Serial No. 114 of Entry No. 180 of the Rate Notification No 01/2017 IT (R) / CT (R) and therefore, is leviable to GST at the rate of 5%".

The appeal filed by M/s M/s BIOCON Ltd, 20th KM, Hosur Road, Electronic City, Bangalore 560100 is disposed off on the above terms.

(D.P.NAGENDRAKUMAR)
Member
Karnataka Appellate Authority
For Advance Ruling

Member
Appellate Authority for Advance Ruling

(M.S. SRIKAR)
Member
Karnataka Appellate Authority
For Advance Ruling

Member
Appellate Authority for Advance Ruling

To,

The Appellant

Copy to

1. The Member (Central), Advance Ruling Authority, Karnataka.
2. The Member (State), Advance Ruling Authority, Karnataka
3. The Commissioner of Central Tax, Bangalore South Commissionerate
4. The Assistant Commissioner, LGSTO-25-Bangalore
5. Office folder

APPELLATE AUTHORITY FOR ADVANCE RULING BANGALORE