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F. No. 6/46/2020-DGTR
GOVERNMENT OF INDIA
MINISTRY OF COMMERCE & INDUSTRY
DEPARTMENT OF COMMERCE
(DIRECTORATE GENERAL OF TRADE REMEDIES)
JEEVAN TARA BUILDING, 4TH FLOOR
5, PARLIAMENT STREET, NEW DELHI-110001

Dated: 23rd September, 2021

Final Findings
NOTIFICATION
Case No. (ADD-OI -39/2020)

Subject: Anti-Dumping investigation concerning imports of "Ceftriaxone Sodium Sterile" originating in or exported from China PR-reg.

06/46/2020-DGTR: Having regards to the Customs Tariff Act 1975, as amended from time to time and the Customs Tariff (Identification, Assessment and Collection of Anti-Dumping Duty on Dumped Articles and for Determination of Injury) Rules 1995, as amended from time to time thereof:

A. BACKGROUND OF THE CASE

2. M/s. Nectar Life Sciences and M/s. Sterile India (hereinafter also referred to as the applicants or the petitioners or the domestic industry) had filed an application before the Designated Authority (hereinafter also referred to as the Authority) on behalf of the domestic industry, in accordance with the Customs Tariff Act, 1975 as amended from time to time (hereinafter also referred to as the Act) and the Customs Tariff (Identification, Assessment and Collection of Anti-dumping Duty on Dumped Articles and for Determination of Injury) Rules, 1995, as amended from time to time (hereinafter also referred to as the Rules or AD Rules), for initiation of anti-dumping investigation on the imports of "Ceftriaxone Sodium Sterile" (hereinafter also referred as the subject goods or the product under consideration or the PUC) originating in or exported from China PR (hereinafter also referred to as the subject country). M/s Aurobindo Pharma Ltd. is the other domestic producer of the subject goods supporting the application filed by the applicants.

3. The product under consideration was earlier subjected to anti-dumping duty. The duty was first imposed in 2007. An anti-dumping investigation was initiated on imports of

Ceftriaxone Sodium Sterile from China PR and Japan on 04th April, 2007. Anti-dumping duty (ADD) was imposed on imports of the PUC from China PR vide Custom Notification No.117/2007-Customs dated 30th November, 2007. The Authority conducted sunset review investigation and notified the final findings on 20th May, 2014 vide Notification No. 15/12/2012-DGAD and definitive anti-dumping duty was continued by the Ministry of Finance vide Customs Notification No. 39/2014 dated 14th August, 2014. The duty on the subject goods expired on 13th August, 2019.

4. The domestic industry filed a fresh application seeking imposition of antidumping duty contending that the producers in China are dumping the product and the same is causing injury to the domestic industry. The Authority, on the basis of a duly documented petition and after sufficient prima-facie examination of the evidence submitted by the Applicants, issued a public notice vide Notification No. 6/46/2020-DGTR dated 24th September, 2020, published in the Gazette of India, initiating the investigation in accordance with Rule 5 of the Rules to determine existence, degree and effect of the alleged dumping of the subject goods, originating in or exported from China PR, and to recommend the amount of anti-dumping duty, which, if levied, would be adequate to remove the alleged injury to the domestic industry.

B. PROCEDURE

5. The procedure described herein below has been followed by the Authority with regard to the subject investigation:

   a. The Authority notified the embassy of the subject country in India about the receipt of the present anti-dumping application before proceeding to initiate the investigation in accordance with Sub-Rule (5) of Rule 5 supra.

   b. The Authority issued a public notice No. 6/46/2020-DGTR dated 24th September, 2020, published in the Gazette of India Extraordinary, initiating the anti-dumping investigation concerning imports of the subject goods from the subject country.

   c. The Embassy of the subject country in India was informed about the initiation of the investigation in accordance with Rule 6(2) of the Rules. The Authority sent a copy of the initiation notification to the Government of the subject country, through its Embassy in India, known producers/exporters from the subject country, known importers/users and the domestic industry as well as other domestic producers as per the addresses made available by the applicants and requested them to make their views known in writing within the prescribed time limit.

   d. The Authority provided a copy of the non-confidential version of the application to the known producers/exporters and to the Government of the subject country, through its Embassy in India in accordance with Rule 6(3) of the Rules supra. A copy of the non-confidential version of the application was also made available in

the public file and provided to the other interested parties, wherever requested.

e. The Authority also forwarded a copy of the notice to the known producers/ exporters from the subject country, known importers/users in India, other Indian producers and the domestic industry as per the addresses made available by the applicants and requested them to make their views known in writing within 30 days of the initiation notification.

f. The Authority sent exporter's questionnaire to the following known producers/exporters to elicit relevant information in accordance with Rule 6(4) of the Rules:

i. M/s Qilu Antibiotics Pharmaceutical Co. Ltd
ii. M/s Zhuhai United Laboratories Trading Company Limited
iii. M/s Lizhu Pharmaceutical Trading Co. Ltd.
iv. M/s Sinopharm Weiqida Pharmaceutical Co Ltd
v. M/s Fujian Fukang Pharmaceutical Co.
vi. M/s Suzhou Dawnrays Pharmaceutical Co. Limited
vii. M/s Shijiazhuang Pharm Group
viii. M/s Livzon Syntpharm Co. Limited
ix. M/s Harbin Pharmaceutical Group Co. Limited
x. M/s Shenzhen Salubris Pharmaceuticals Limited
xi. M/s Shandong Lukang Record Pharmaceutical Co. Limited
xii. M/s Shanxi Weiqida Pharmaceutical Co. Limited
xiii. M/s Hebei Zhongrun Pharmaceutical Co. Ltd
xiv. M/s Shandong Ruiying Pioneer Pharmaceutical Co. Ltd
xv. M/s Shandong Jincheng Pharmaceuticals & Chemicals Co. Ltd.
xvi. M/s Shandong Haibang pharmaceutical co., Ltd.

g. In response to the initiation of the subject investigation, only M/s Shahdong Ruiying Pioneer Pharmaceutical Co., Ltd., a producer of the subject goods in China PR, filed a questionnaire response.

h. The Embassy of the subject country in India was also requested to advise the exporters/producers from China PR to respond to the questionnaire within the prescribed time limit. A copy of the letter and questionnaire sent to the producers/exporters was also sent to them along with the names and addresses of the known producers/exporters from the subject country.

i. The Authority sent Questionnaire to the following known importers/users of subject goods in India calling for necessary information in accordance with Rule 6(4) of the Rules:

i. M/s Aurobindo Pharma Limited,
ii. M/s Lupin Limited India
iii. M/s Concept Pharmaceuticals Ltd
iv. M/s Covalent Laboratories Private Limited

v. M/s G C Chemie Pharmie Ltd
vi. M/s Global Trotters Pvt Ltd
vii. M/s Kopran research laboratories pvt ltd
viii. M/s Flamingo Pharmaceuticals Ltd
ix. M/s Rajasthan Antibiotics Ltd.
x. M/s Strides Arcolab Ltd
xi. M/s Biochem Pharmaceutical industries
xii. M/s Lyka Labs Ltd
xiii. M/s Maruti Pharma Chem Pvt Ltd
xiv. M/s Merpro Pharmaceuticals Pvt Ltd.
xv. M/s Orchid Pharma Ltd.
xvi. M/s Orchid Chemicals and Pharmaceuticals
xvii. M/s Parabolic drugs Ltd
xviii. M/s Wexford Labs Ltd
xix. M/s Wockhardt from India

j. In response to the initiation of the subject investigation, only Shah TC Global Exim LLP filed a questionnaire response.

k. The Authority sent notice of initiation to the following other domestic producers, intimating them of the initiation of the investigation with a request to provide the relevant information to the Authority in the form and manner prescribed:

i. M/s Concept Pharmaceuticals Ltd
ii. M/s Covalent Laboratories Private Limited
iii. M/s Kopran research laboratories Pvt ltd
iv. M/s Orchid Pharma Ltd.
v. M/s Rajasthan Antibiotics Ltd.

l. None of the other domestic producers have responded or participated in the present investigation.

m. The Authority made available non-confidential version of the evidence presented/ submissions made by the various interested parties in the form of a public file kept open for inspection by the interested parties. Later on, due to inaccessibility of the public file in the wake of global pandemic of COVID-19, all interested parties were asked to share the non-confidential versions of all their submissions with all other interested parties via emails. Submissions made by all the interested parties to the extent considered relevant at this stage have been taken into account in this final findings notification.

n. Request was made to the Directorate General of Commercial Intelligence and Statistics (DGCI&S) to provide the transaction-wise details of imports of subject goods for the past three years and the period of investigation which was received by

the Authority. The Authority has relied upon the DGCI&S data for computation of the volume of imports and its analysis after due examination of the transactions.

o. The Non-injurious Price (NIP) based on the optimum cost of production and cost to make and sell the subject goods in India based on the information furnished by the domestic industry on the basis of Generally Accepted Accounting Principles (GAAP) and Annexure III to the Rules has been worked out so as to ascertain whether anti-dumping duty lower than the dumping margin would be sufficient to remove injury to the domestic industry.

p. Due to the worldwide outbreak of COVID-19 and consequent restrictions imposed by different countries, including India, the physical inspection through on-spot verification of the information was not carried out by the Authority. Desk Verification of the information provided by the Applicants/producers/ exporters, to the extent deemed necessary, was carried out by the Authority. Only such verified information with necessary rectification, to the extent deemed necessary, has been relied upon for the purpose of this final findings notification.

q. Other submissions made by the interested parties during the course of this investigation, to the extent supported with evidence and considered relevant to the present investigation, have been appropriately considered by the Authority, in this final findings notification.

r. The Period of Investigation (POI) for the purpose of the present anti-dumping investigation is from April, 2019 – March, 2020 (12 months). The examination of trends in the context of injury analysis covered the periods April 2016-March 2017, April 2017-March 2018, April 2018-March 2019 and the POI.

s. The Authority in accordance with the Rules and due to the worldwide outbreak of COVID-19 and consequent restrictions imposed by different countries, including India, conducted oral hearing through video conferencing on 03rd June, 2021 to provide an opportunity to the interested parties to present relevant information orally before the Designated Authority.

t. All the parties who had attended the above-mentioned oral hearings were advised to file written submissions of the views expressed orally, followed by rejoinders, if any. The arguments made in such written submissions and rejoinders received from the interested parties have been considered, to the extent deemed necessary, for the purpose of this final findings notification.

u. The information provided by the interested parties on confidential basis was examined with regard to sufficiency of the confidentiality claim. On being satisfied, the Authority has accepted the confidentiality claims wherever warranted and such information has been considered as confidential and not disclosed to the other

interested parties. Wherever possible, parties providing information on confidential basis were directed to provide sufficient non-confidential version of the information filed on confidential basis.

v. The Authority has considered the arguments raised and the information provided by all the interested parties till this stage, to the extent the same are supported with evidence and considered relevant to the present investigation.

w. Wherever an interested party has refused access to, or has otherwise not provided the necessary information during the course of the present investigation, or has significantly impeded the investigation, the Authority has considered such parties as non-cooperative and recorded the final findings on the basis of the facts available.

x. A disclosure statement containing the essential facts in this investigation which would have been formed the basis of the final findings was issued to the interested parties on 08.09.2021 and the interested parties were allowed time to comment on the same. The comments on the disclosure statement received from the interested parties have been considered, to the extent found relevant, in this final findings notification.

y. '***' in this final findings notification represents information furnished by an interested party on confidential basis and so considered by the Authority under the Rules.

z. The exchange rate for the POI has been taken by the Authority as US$1 = Rs. 71.65.

C. PRODUCT UNDER CONSIDERATION AND LIKE ARTICLE

6. At the stage of initiation, the product under consideration was defined as:

3."The product under consideration in the present investigation is "Ceftriaxone Sodium Sterile" also known as Ceftriaxone Disodium Hemiheptahydrate-Sterile. This is a third- generation parenteral Cephalosporin Antibiotic.

4. Ceftriaxone Sodium Sterile is an Active Pharmaceutical Ingredient (API) used for formulation for treating disease like lower respiratory tract infection, skin & skin structure infection, pelvic inflammatory disease, intra-abdominal infection, uncomplicated gonorrhoea infection, and surgical prophylaxis.

5. Ceftriaxone Sodium Sterile does not have dedicated classification and is being imported into India under different HS codes as under subheading 2941.1090, 2941.9090 & 2942.0090 of Chapter 29 of Schedule 1 of the Act. Customs

classification is only indicative in nature and not binding on the scope of the investigation."

C.1 Views of the domestic industry

7. The following are the submissions made by the domestic industry with regard to the product under consideration and like article:

a. The product under consideration for the present investigation is "Ceftriaxone Sodium Sterile", originating in or exported from China PR.
b. The product is an Active Pharmaceutical Ingredient (API) used for the formulation of filling the injection for intravenous or intramuscular administration, mainly used for the diseases like lower respiratory infection tract infection, skin & skin structure infection, pelvic inflammatory disease, intra-abdominal infection, uncomplicated gonorrhea infection and surgical prophylaxis.
c. The prescribed unit of measurement for the product under consideration is the weight in Kgs.
d. Ceftriaxone Sodium Sterile does not have dedicated classification and is being imported into India under different HS codes under subheadings 2941.1090, 2941.9090 & 2942.0090 of Chapter 29 of Schedule 1 of the Act. Customs classification is only indicative in nature and not binding on the scope of the investigation.
e. The goods produced by the applicants are like article to the imported goods as they are comparable in terms of chemical & technical characteristics, manufacturing process & technology, functions & uses, product specifications, pricing, distribution & marketing and tariff classification of the goods and are technically & commercially substitutable.
f. There is no known significant difference in the technology employed by the domestic industry and the producers in the subject country.
g. There is no use of Ceftriaxone Sodium Non-Sterile, neither in oral form nor in injection form. It is just a chemical and not for human consumption. After sterilization or further processing, it is converted into Ceftriaxone Sodium Sterile which is used in the form of dry powder injection/Ceftriaxone injection.
h. As per Indian pharmacopoeia, additional tests and precautions are required to manufacture human consumable Ceftriaxone Sodium Sterile like Particulate Matter, Bacterial Endotoxin Test and Sterility test which is a process of 14 days. The same is not done for non-Sterile product. The domestic producers do follow the standards as per IP as Ceftriaxone Sodium Sterile is a lifesaving drug. None of the domestic producers are modifying the basic properties of the product.
i. The responding exporter has mentioned both Ceftriaxone Sodium Sterile and Non-Sterile in separate product category in its product brochure. Ceftriaxone Sodium Sterile is categorized under APIs of Cephalosporin series whereas Ceftriaxone Sodium Non-Sterile is mentioned under Medicines intermediates of Cephalosporin series.

j. The value addition from Ceftriaxone Sodium Non-Sterile to Sterile is much higher.

k. The product under consideration can be manufactured from the stage of 7-ACA (7-Amino Cephalosporinic Acid), which is the major raw material produced by fermentation of Cephalosporin-C and from the intermediate stage by using and purifying Ceftriaxone non-sterile through a process of filtration. Some Indian producers have the capacity to manufacture the product under consideration from both '7- ACA' as well as 'Ceftriaxone Non-sterile' stages.

l. Ceftriaxone Sodium Non-Sterile is supplied in plastic or fiber or HDPE drum whereas Ceftriaxone Sodium sterile is supplied in sterile aluminium drum.

m. Ceftriaxone Sodium Non-Sterile was never a part of the application or the present investigation and was never a part of the antidumping duty in the previous investigations.

n. The Designated Authority has always considered Ceftriaxone Sodium Non-Sterile as a raw material.

o. The Applicants have identified production of PUC and N-PUC and considered information for product under consideration for the purpose of the present investigation.

p. The Authority has already dealt that Ceftriaxone Sodium Sterile and Ceftriaxone Sodium Non-sterile were two different products in the previous investigations. No response or submission has been filed by any of the producers/exporters from the subject country in the previous sunset review investigation.

q. Designated Authority is the quasi-judicial Authority. Once the Designated Authority makes a determination, the same becomes binding on the interested parties. The views of the interested parties lose their meaning once the Designated Authority makes a determination.

r. The responding exporter is not even aware of the raw materials involved in producing the product under consideration and "purification" is not a process. The Authority needs to impose a ban on exports by such exporters who are unable to even distinguish and differentiate between nonsterile and sterile as goods supplied by such producers can be a huge health hazard for the country leading to large scale deaths in hospitals.

C.2. Views of the other interested parties

8. The following are the submissions made by the other interested parties with regard to the product under consideration and like article:

   a. The PUC as defined by the petitioner is misleading and does not cover all forms of Ceftriaxone Sodium which is the real product. Such a division of the product has been adopted only to cover up petitioner's own imports of Ceftriaxone Sodium (CS) from China PR.

   b. The petitioners have been importing CS from China PR which is nothing but the penultimate stage of Ceftriaxone Sodium Sterile (CSS).

   c. The PUC should cover Ceftriaxone Sodium in sterile and non-sterile forms as these are basically same products in two different forms and not two different

products. The petitioner should manufacture from 7ACA stage and both CS and CSS should be covered in the PUC if the protection sought has to be meaningful. The PUC should be defined to include the basic product which is Ceftriaxone Sodium in its scope irrespective of the forms such as Sterile and Nonsterile as claimed by the petitioners. Non-sterile form is nothing but Ceftriaxone Sodium only.

d. Indian Pharmacopoeia (IP) identifies and describes Ceftriaxone Sodium as a drug and it does not separately provide for its forms such as Sterile and Non-sterile as claimed.
e. A manufacturer of Ceftriaxone Sodium is mandated to follow the IP and it is not a case that the sterile manufacturer can modify the basic properties of Ceftriaxone Sodium while undertaking the sterilization or the purifying process.
f. It is irrational that Ceftriaxone Sodium is the raw material for Ceftriaxone Sodium Sterile whereas the key product itself is Ceftriaxone Sodium as per IP which is manufactured from 7ACA (7- Amino Cephalosporinic Acid).
g. Only few other chemicals like Acetone are used in the process of sterilization which is focused on purification and does not involve any manufacturing to alter the product properties in any manner.
h. The petitioners have not explained any differences between Ceftriaxone Sodium Sterile (CSS) and Ceftriaxone Sodium (CS) in terms of CAS number, HS code, Pharmacopeia, molecular formula, molecular weight, chemical structure, basic raw material etc. The Molecular Formula of Ceftriaxone Sodium as per the IP and the molecular details of Ceftriaxone Sodium Sterile given in the petition along with other basic product details are the same and it cannot be said that Ceftriaxone Sodium and Ceftriaxone Sodium Sterile are two different products based on such details
i. It is not clear whether all the equipment and premises of the petitioners pertain only to Ceftriaxone Sodium Sterile or some other products also because the website of the petitioners shows many sterile products.
j. No significant issues have been raised by any interested party regarding the scope of the product under consideration and like article in the previous cases. (Relied upon SSR anti-dumping investigation of Ceftriaxone Sodium Sterile No.15/12/2012-DGAD dated 20.5.2014).
k. The petitioner in the original matter requested the Authority to consider import of sterile and nonsterile items as one and the same thing.
l. Annual Report of the Nectar Life Sciences Ltd says that the product being produced by them is Ceftriaxone Sodium. But in the petition, it is stated that they produce Ceftriaxone Sodium Sterile, which is different from Ceftriaxone Sodium (relied upon Section A of the Annual Report). Now the claim is that Ceftriaxone Sodium and Ceftriaxone Sodium Sterile are different products.
m. Petitioners are not engaged in the manufacturing of CS which is the key product and are only engaged in the business of sterilising the CS imported from China PR. A process of sterilization does not render CS and CSS as two different products. Sterilization process does not alter the basic product properties and

molecules it only changes the form to sterilized as the sterilized form is practically used in humans.

C.3 Examination by the Authority

9. The product under consideration, as defined in the notice of initiation, is "Ceftriaxone Sodium Sterile", also known as "Ceftriaxone Disodium Hemiheptahydrate-Sterile". This is a third- generation parenteral Cephalosporin Antibiotic.

10. Ceftriaxone Sodium Sterile is an Active Pharmaceutical Ingredient (API) used for formulation for treating diseases like lower respiratory tract infection, skin & skin structure infection, pelvic inflammatory disease, intra-abdominal infection, uncomplicated gonorrhoea infection and surgical prophylaxis. It is a lifesaving drug.

11. Ceftriaxone Sodium Sterile does not have a dedicated classification and is being imported into India under different HS codes as under subheadings 2941.1090, 2941.9090 & 2942.0090 of Chapter 29 of Schedule 1 of the Act. Customs classification is only indicative in nature and not binding on the scope of the investigation.

12. As regards to the forms of the product under consideration, the Authority notes that the scope of the product under consideration is only "Ceftriaxone Sodium Sterile" also known as "Ceftriaxone Disodium Hemiheptahydrate-Sterile". "Ceftriaxone Sodium Non-Sterile" was neither the part of the application nor is considered in the present investigation.

13. As regards to the difference in Ceftriaxone Sodium Sterile and Ceftriaxone Sodium Non-sterile, the Authority notes that "Ceftriaxone Sodium" is a general term, which denotes both "Ceftriaxone Sodium Sterile" and "Ceftriaxone Sodium Non-Sterile". However, "Ceftriaxone Sodium Non-Sterile" is a chemical and cannot be used for human consumption. "Ceftriaxone Sodium Non-Sterile" is first run through a process of sterilization and additional testing to make "Ceftriaxone Sodium Non-Sterile" which is humanly consumable.

14. The sale of the product in the Indian market either through domestic manufacturers or the imports has to comply as per Indian Pharmacopoeia (IP) and, therefore, the product sold by the parties should have comparable chemical and physical properties.

15. Major raw material for production of Ceftriaxone Sodium Sterile is 7-ACA (7-Amino Cephalosporinic Acid), which is produced by fermentation of Cephalosporin-C. Ceftriaxone Sodium (Non-Sterile) is the intermediate product which requires further processing and sterilization operation to be converted into Ceftriaxone Sodium Sterile, which is the product under consideration.

16. The Authority notes that the product under consideration can be manufactured from the stage of 7-ACA (7-Amino Cephalosporinic Acid), which is the major raw material

produced by fermentation of Cephalosporin-C. However, the product under consideration can also be manufactured from the intermediate stage by using and purifying Ceftriaxone non-sterile through a process of filtration. Out of the applicants, M/s Nectar life Sciences has the capacity to manufacture the product under consideration from both '7-ACA' as well as 'Ceftriaxone Non-sterile' stages. The domestic producers are producing product under consideration from Ceftriaxone Non-sterile' stage. However, producing from non-sterile to sterile does not make the producers ineligible.

17. With regard to the annual report of M/s. Nectar Life Sciences, the Authority notes that the Annual Report mentions Ceftriaxone Sodium as a generic term as the company produces both Ceftriaxone Sodium Non-sterile and Sterile.

18. The applicants claimed that the Ceftriaxone Sodium Sterile produced by them and that imported from the subject country are produced using the same basic raw materials having broadly similar manufacturing process & technology, functions & uses, product specifications, pricing, distribution & marketing and tariff classification. The contention of the applicants has not been disputed by the other interested parties. The product was subject to antidumping duty in the past and there was no established difference between the domestic and imported product. The Authority holds that the subject goods produced by the domestic industry are like article to the product imported from the subject country in terms of Rule 2(d) of the Rules.

D. SCOPE OF DOMESTIC INDUSTRY AND STANDING

D.1 Views of the domestic industry

19. Following are the submissions made by the domestic industry with regard to the scope of the domestic industry and the standing:

a. The application has been filed by M/s. Nectar Life Sciences and M/s. Sterile India Co. Ltd. and supported by M/s. Aurobindo Pharma Ltd.
b. Apart from the applicants and the supporter, following are the other Indian producers of the subject goods in India:
    i. M/s Concept Pharmaceuticals Ltd
    ii. M/s Covalent Laboratories Private Limited
    iii. M/s Kopran research laboratories Pvt ltd
    iv. M/s Orchid Pharma Ltd.
    v. M/s Rajasthan Antibiotics Ltd.

c. The applicants are neither related to an importer in India nor to an exporter from the subject country and have not imported the product under consideration from the subject country.
d. The standing of the domestic industry has been determined with regard to the product under consideration, which is Ceftriaxone Sodium Sterile. The applicants hold a

major proportion of total domestic production of the subject goods in India and thus, constitute the domestic industry.

D.2. Views of the other interested parties

20. Following are the submissions made by the other interested parties with regard to the scope of the domestic industry and the standing:

    a. The standing of the petitioners as domestic industry producing like article should be determined after defining the PUC properly.
    b. If the PUC include non-sterile form of Ceftriaxone Sodium also, then the petitioners will become importers of the PUC from the subject country leading to the disqualification of the petitioners.

D.3. Examination by the Authority

21. Rule 2(b) of the Rules defines the domestic industry as under:

> *"domestic industry" means the domestic producers as a whole engaged in the manufacture of the like article and any activity connected therewith or those whose collective output of the said article constitutes a major proportion of the total domestic production of that article except when such producers are related to the exporters or importers of the alleged dumped article or are themselves importers thereof; in such case the term 'domestic industry' may be construed as referring to the rest of the producers".*

22. The application has been filed by M/s. Nectar Life Sciences and M/s. Sterile India Co. Ltd. The applicants are not related to any importer or exporter of subject goods in the subject country, nor have they imported subject goods from subject country.

23. Further, the application filed by the applicants is supported by M/s Aurobindo Pharma Limited, another domestic producer of the product under consideration.

24. Apart from the applicants and supporter, following are the other Indian producers of the subject goods in India:
    i. M/s Concept Pharmaceuticals Ltd
    ii. M/s Covalent Laboratories Private Limited
    iii. M/s Kopran research laboratories Pvt ltd
    iv. M/s Orchid Pharma Ltd.
    v. M/s Rajasthan Antibiotics Ltd.

25. At the stage of initiation and thereafter, the Authority sent a communication to other domestic producers advising them to file the information in the form and manner

prescribed with regard to injury determination. However, none of other domestic producers have filed complete injury information in the prescribed format.

26. With regard to the contention that if the product under consideration includes non-sterile form of Ceftriaxone Sodium, then the applicants will become importers of the product under consideration from the subject country, the Authority notes that the product under consideration only consists of Ceftriaxone Sodium Sterile and standing of the domestic industry has been determined with regard to the product under consideration.

27. The evidence on record shows that the applicants command a major proportion (49%) in the total domestic production in India. Further, the applicants, along with the supporter, account for more than 50% of the total production of the subject goods in India. Accordingly, the Authority holds that the applicants constitute the domestic industry within the meaning of Rule 2(b) of the Rules and considers that the application satisfied the criteria of standing in terms of Rule 5(3) of the Rules.

E. CONFIDENTIALITY

E.1 Views of the domestic industry

28. The following submissions have been made by the domestic industry with regard to confidentiality:

a. The interested parties have filed grossly deficient response in non-confidential version even after being given an extension to file sufficient and complete information. The same is purely with the intent to prevent the domestic industry from defending its legitimate interests. The questionnaire responses are required to be rejected.
b. The foreign producer and the importer have claimed excessive confidentiality with regard to business licenses, manufacturing license, shareholding structure, production process, procurement of raw materials, channel of marketing in the home market and exports to India, Annual Reports, import data and resale data are claimed as confidential.
c. The exporters have failed even to specify the raw material used for manufacturing the subject goods.
d. The applicants have been denied sufficient details to permit a reasonable understanding of the substance of the response submitted to the Authority. The applicants cannot even determine the extent to which information has been provided and whether any reliance can be placed on the same. As a result, the applicants are severely handicapped and unable to comment on the responses filed by the exporters.

E.2 Views of the other interested parties

29. The following submissions have been made by the other interested parties with regard to confidentiality:
    a. The petitioners have resorted to excessive confidentiality relating to PUC in their submission.

E.3 Examination by the Authority

30. Various submissions made by the Applicants as well as other interested parties during the course of the investigation with regard to confidentiality, to the extent considered relevant by the Authority, have been examined and addressed as follows.

31. The Authority made available non-confidential version of the information provided by various interested parties to all interested parties as per the Rules.

32. With regard to confidentiality of information, Rule 7 of the Rules provides as follows:

> *"Confidential information: (1) Notwithstanding anything contained in sub-rules (2), (3) and (7) of rule 6, sub-rule(2) of rule12,sub-rule(4) of rule 15 and sub-rule (4) of rule 17, the copies of applications received under sub-rule (1) of rule 5, or any other information provided to the designated authority on a confidential basis by any party in the course of investigation, shall, upon the designated authority being satisfied as to its confidentiality, be treated as such by it and no such information shall be disclosed to any other party without specific authorization of the party providing such information.*
>
> *(2) The designated authority may require the parties providing information on confidential basis to furnish non-confidential summary thereof and if, in the opinion of a party providing such information, such information is not susceptible of summary, such party may submit to the designated authority a statement of reasons why summarization is not possible.*
>
> *(3) Notwithstanding anything contained in sub-rule (2), if the designated authority is satisfied that the request for confidentiality is not warranted or the supplier of the information is either unwilling to make the information public or to authorise its disclosure in a generalized or summary form, it may disregard such information."*

33. As regards the contentions with regard to confidentiality of the information, the information provided by the interested parties on confidential basis was examined with regard to sufficiency of the confidentiality claim. On being satisfied, the Authority has accepted the confidentiality claims, wherever warranted, and such information has been

considered confidential and not disclosed to other interested parties. Wherever possible, parties providing information on confidential basis were directed to provide sufficient non confidential version of the information filed on confidential basis. The Authority made available the non-confidential version of the evidence submitted by various interested. Business sensitive information has been kept confidential as per practice.

F. MISCELLANEOUS SUBMISSIONS

F.1 Views of the domestic industry

34. The following submissions have been made by the applicants with respect to miscellaneous submissions:

    a. The application has been filed as per the Indian Rules laid down and the Authority has initiated the investigation in accordance with the same.

F.2 Views of the other interested parties

35. The following submissions have been made by the other interested parties with respect to miscellaneous issues:

    a. The Authority may subject dumping claims by the petitioners to strict scrutiny and the same should be determined based on the Rules and as per the practice of the Authority.

F.3 Examination by the Authority

36. With regard to the contention that dumping claims may be under strict scrutiny, the Authority notes that the present investigation has been initiated and conducted in accordance with the Act and the Rules, 1995 as amended from time to time.

G. MARKET ECONOMY TREATMENT (MET), NORMAL VALUE, EXPORT PRICE & DETERMINATION OF DUMPING MARGIN

37. Under Section 9A(l)(c) of the Act, normal value in relation to an article means:

> *(i) the comparable price, in the ordinary course of trade, for the like article when meant for consumption in the exporting country or territory as determined in accordance with the rules made under sub-section (6); or*
> *(ii) when there are no sales of the like article in the ordinary course of trade in the domestic market of the exporting country or territory, or when because of the particular market situation or low volume of the sales in the domestic market of the exporting country or territory, such sales do not permit a proper comparison, the normal value shall be either-*

(a) comparable representative price of the like article when exported from the exporting country or territory or an appropriate third country as determined in accordance with the rules made under sub-section (6); or the cost of production of the said article in the country of origin along with reasonable addition for administrative, selling and general costs, and for profits, as determined in accordance with the rules made under sub-section (6):

(b) Provided that in the case of import of the article from a country other than the country of origin and where the article has been merely transshipped through the country of export or such article is not produced in the country of export or there is no comparable price in the country of export, the normal value shall be determined with reference to its price in the country of origin.

G.1 Views of the domestic industry

38. The following submissions have been made by the applicants with respect to determination of the normal value, the export price and the dumping margin:

a. China PR should be considered as a non-market economy, in line with the position taken by the Authority in previous cases, and by the investigating authorities in other countries.
b. The cost and price of the Chinese producers cannot be relied upon for determination of normal value, and accordingly, the normal value should be determined in accordance with the provisions of para 7 of Annexure I of the Rules.
c. The applicants have determined the normal value of subject goods based on international prices of the raw materials as per DGCI&S transaction wise data and considering the conversion cost of the domestic industry duly adjusted with selling, general and administrative expenses and a reasonable amount of profit.
d. The export price is based on transaction wise import data provided by DGCI&S. With the export prices being CIF value while the normal values being at ex-factory level, the export prices have been adjusted for, ocean freight, marine insurance, commission, inland freight expenses, port expenses, bank charges and VAT.
e. The responding producer is from China PR and normal value cannot be determined based on his own data. The producer had to identify a trader in the USA for exporting the product to India. The export price cannot be precisely determined as the exporter has not participated. Unless the Authority can verify CIF export price, the Authority cannot establish export price.
f. The dumping margin of the imports from the subject country is not only above de-minimis levels but also significant.

G.2 Views of the other interested parties

39. The following submissions have been made by other interested parties with respect to determination of the normal value, the export price and the dumping margin:

a. The petitioners have claimed dumping margin on the basis of constructed normal value and export price as per DGCI&S. The dumping margin claims appears exaggerated.
b. Indian producer themselves are importers of CS/Non-Sterile from China PR to make their final API which is Ceftriaxone Sodium Sterile. It is impossible that such huge dumping as claimed by the petitioners is taking place in the Sterile product but non-sterile is exported at un-dumped rates to India.
c. The Authority should determine individual margin for Shandong Ruiying Pioneer Pharmaceutical Co., Ltd.
d. Anti-dumping duty, if required, should be imposed on Ceftriaxone Sodium in all its forms and Ceftriaxone Sodium Sterile alone should not be accepted by the Authority.

G.3 Examination by the Authority

G.3.1 Determination of normal value and export price

Market economy status for Chinese producers

40. Article 15 of China's Accession Protocol in WTO provides as follows: "Article VI of the GATT 1994, the Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994 ("Anti-Dumping Agreement") and the SCM Agreement shall apply in proceedings involving imports of Chinese origin into a WTO Member consistent with the following:

> *"(a) In determining price comparability under Article VI of the GATT 1994 and the Anti-Dumping Agreement, the importing WTO Member shall use either Chinese prices or costs for the industry under investigation or a methodology that is not based on a strict comparison with domestic prices or costs in China based on the following rules:*
>
> *(i) If the producers under investigation can clearly show that market economy conditions prevail in the industry producing the like product with regard to the manufacture, production and sale of that product, the importing WTO Member shall use Chinese prices or costs for the industry under investigation in determining price comparability;*
>
> *(ii) The importing WTO Member may use a methodology that is not based on a strict comparison with domestic prices or costs in China if the producers under investigation cannot clearly show that market economy conditions prevail in the industry producing the like product with regard to manufacture, production and sale of that product.*
>
> *(b) In proceedings under Parts II, III and V of the SCM Agreement, when*

addressing subsidies described in Articles 14(a), 14(b), 14(c) and 14(d), relevant provisions of the SCM Agreement shall apply; however, if there are special difficulties in that application, the importing WTO Member may then methodologies for identifying and measuring the subsidy benefit which take into account the possibility that prevailing terms and conditions in China may not always be available as appropriate benchmarks. In applying such methodologies, where practicable, the importing WTO Member should adjust such prevailing terms and conditions before considering the use of terms and conditions prevailing outside China.

(c) The importing WTO Member shall notify methodologies used in accordance with subparagraph (a) to the Committee on Anti-Dumping Practices and shall notify methodologies used in accordance with subparagraph (b) to the Committee on Subsidies and Countervailing Measures.

(d) Once China has established, under the national law of the importing WTO Member, that it is a market economy, the provisions of subparagraph (a) shall be terminated provided that the importing Member's national law contains market economy criteria as of the date of accession. In any event; the provisions of subparagraph (a)(ii) shall expire 15 years after the date of accession. In addition, should China establish, pursuant to the national law of the importing WTO Member, that market economy conditions prevail in a particular industry or sector, the non-market economy provisions of subparagraph (a) shall no longer apply to that industry or sector."

41. It is noted that while the provision contained in Article 15 (a) (ii) have expired on 11.12.2016, the provision under Article 2.2.1.1 of WTO read with obligation under 15 (a) (i) of the Accession Protocol require criterion stipulated in para 8 of the Annexure I of the Rules to be satisfied through the information/data to be provided in the supplementary questionnaire on claiming the market economy status. It is noted that since the responding producer from China PR has not submitted relevant questionnaire response, the normal value computation is required to be determined as per provisions of para 7 of Annexure I of the Rules. Accordingly, the normal value and export price for the producers/exporters from the subject country have been determined as below.

G.3.2 <u>Determination of Normal Value for China PR</u>

42. M/s Shandong Ruiying Pioneer Pharmaceutical Co., Ltd., a producer of the subject goods in China PR, has filed exporter questionnaire response but not claimed the market economy status. Further, the Authority notes that M/s Shandong Ruiying Pioneer Pharmaceutical Co., Ltd. has exported the subject goods to India through unrelated exporter named M/s Asian Pioneer Group, USA, who exported the goods to M/s Shah TC Global Exim LLP, an unrelated importer in India. M/s Asian Pioneer Group, USA has not filed exporter's questionnaire response in the present investigation. The Authority notes

that in the absence of exporter's questionnaire response by M/s Asian Pioneer Group, USA, the complete value chain in respect of the exports of subject goods made by Shandong Ruiying Pioneer Pharmaceutical Co., Ltd. cannot be established. Under the above stated circumstances, the Authority cannot determine the individual normal value for M/s Shandong Ruiying Pioneer Pharmaceutical Co., Ltd. based on the information provided by the said producer.

43. In the absence of sufficient information on record regarding the other methods as enshrined in Para 7 of Annexure I of the Rules, the Authority has determined the normal value by considering the method on "any other reasonable basis, including the price actually paid or payable in India for the like product, duly adjusted, if necessary, to include a reasonable profit margin".

44. The Authority, therefore, constructs the normal value for all producers/exporters from China PR on the basis of international prices of the raw materials as available in the public domain and considering the conversion cost of the domestic industry duly adjusted with selling, general and administrative expenses and addition of reasonable profits. Accordingly, the constructed normal value so determined for all producers/exporters from China PR is mentioned in the dumping margin table below.

G.3.3 Determination of Export Price for China PR

45. Since M/s Shandong Ruiying Pioneer Pharmaceutical Co., Ltd., a producer of the subject goods in China PR, has exported the subject goods to India through an unrelated exporter named M/s Asian Pioneer Group, USA and this exporter has not filed exporter's questionnaire response in the present investigation, the Authority is of the view that complete value chain in respect of the exports of the subject goods made by Shandong Ruiying Pioneer Pharmaceutical Co., Ltd. cannot be established. Under the above stated circumstances, the Authority cannot determine the individual net export price for M/s Shandong Ruiying Pioneer Pharmaceutical Co., Ltd. The Authority, therefore, determines the net export price for all producers/exporters from China PR as per facts available, taking into account the DGCI&S import data. The same is mentioned in the dumping margin table below.

G.3.4 Dumping Margin

46. On the basis of normal value and export price, as determined above, the dumping margin for producers/exporters from China PR has been determined and the same is provided in the table below:

Dumping Margin Table

Particulars	Constructed Normal Value (US$/Kg)	Export Price (US$/Kg)	Dumping Margin (US$/Kg)	Dumping Margin %	Dumping Margin % Range
All Producers/Exporters from China PR	***	***	***	***	25-35

H. INJURY AND CAUSAL LINK

H.1 Views of the domestic industry

47. The submissions made by the domestic industry with regard to injury and causal link are summarized as follows:
    a. Imports from the subject country had increased over the injury period in absolute terms.
    b. The imports in relation to the production had increased over the injury period.
    c. The demand for the subject goods had continuously increased over the injury period.
    d. The market share of the domestic industry had declined from the base year in 2017-18, increased in 2018-19 and declined once again in the POI.
    e. The landed price of imports is significantly below the selling price of the domestic industry. The imports are undercutting the prices of the domestic industry.
    f. The imports are significantly depressing the prices of the product in the market.
    g. The production of the domestic industry increased till 2017-18, increased in 2018-19 and declined in the POI.
    h. The domestic sales declined in 2017-18 and increased in the POI.
    i. The capacity utilization increased in 2017-18 but declined in the POI.
    j. The domestic industry has suffered losses throughout the injury period. The losses have increased sharply in the POI.
    k. Inventories with the domestic industry increased by 20 times in the POI when compared to the base year.
    l. Productivity per day of the domestic industry has increased throughout the injury period.
    m. Employment and wages increased from the base year to 2017-18, declined in 2018-19 and increased in the POI.
    n. The performance of the domestic industry has deteriorated over the period. While some of the volume parameters have shown growth, with a decline in market share during the period of investigation; the profitability parameters have shown a negative trend throughout the injury period.
    o. The domestic industry has recently increased its production capacities.

p. Difference between landed price of major raw material ceftriaxone sodium nonsterile and landed price of the PUC continues to decline which was the reason of continued losses.
q. The Injury analysis has been determined for the product under consideration which is Ceftriaxone Sodium Sterile.
r. The investments of 7ACA stage have been not included.

H.2 Views of the other interested parties

48. The submissions made by the other interested parties with regard to injury and causal link are summarized as follows:
    a. The petition does not show any material injury on account of imports of the subject goods and the breach of causal link is very apparent as the petitioners have been suffering losses even when ADD was in place. The volume and price of imports cannot be linked to the injury claimed.
    b. 95% of the domestic demand is met by the petitioners and imports were not more than 5% of the total Indian demand.
    c. The increase in imports is for exports and such imports did not reach the local market evidently. Out of the 4 to 5 MT imported, barely 500Kg went into the local market and the rest were supplied for export manufacturing. Only very negligible volume of imports from China PR reached the Indian market during the POI.
    d. The petitioners suffered losses due to their imports of Ceftriaxone Sodium from China PR and later they could not realize any margin as expected from the sterilization process.
    e. Situation of injury would look entirely different if the domestic industry is considered for all forms of Ceftriaxone Sodium while examining the injury.
    f. Investments for production from 7ACA stage must be excluded for all practical purposes and the proper allocation should be made considering the fact that the sterilisation plant is used for many products other than the PUC.
    g. The petitioners have been making losses in the entire injury period even when they were having the protection of ADD till almost half part of the POI.
    h. The data regarding the price difference between Sterile and Non-Sterile provided by the petitioners has no volume details and price alone is not sufficient for any analysis as price is a factor of demand for the product.
    i. Increase in price of CS imported into India signifies the fact the Indian sterile manufacturers are now largely importing CS from China PR and are merely converting it into CSS.
    j. About 65% gap in price of CS and CSS prevailed in the year 2016-17 due to such demand aspect and as the demand for CS increased, the gap between CS and CSS also narrowed and the same was only about 21% in the POI.
    k. The value addition is not more than 20-25% which is much lower than the 35% minimum threshold considered under the circumvention provision.
    l. It is very clear from the facts now that the petitioners are not engaged in the manufacturing of CS which is the key product and are only engaged in the

business of sterilising the CS imported from China PR. The business model of importing the substantial product which is CS from China PR and then doing a value addition of not more than 15-25% and anticipating profits as a producer of CS is suspectable to failures and the losses, any, of the petitioners are their own creation in such a scenario and import of CSS cannot be blamed for that.

m. The whole claims of injury and causal link is vitiated and distorted as the PUC is not defined properly

n. The petitioners must share the capital investment when the factory was designed to produce Ceftriaxone 7ACA stage and what is now considered for the production from non-sterile stage.

o. Volume and price of imports cannot be linked to the injury claimed by the petitioners in any manner.

p. It is a fact that about 95% of the domestic demand is met by the petitioners and imports were not more than 5% of the total Indian demand as shown in the petition. Such limited imports causing any injury as claimed by the petitioner is completely illogical and unsubstantiated.

q. The contention of price injury from imports even under Advance Licence has no basis in truth. Such imports shall not be impacted even if ADD is imposed and the whole claim of injury by the petitioners on account of such imports is completely unexplained.

r. The petitioners did not suffer any injury on account of import of CSS into India and the cause of injury claimed are other issues including a business model dependent on the imports of Ceftriaxone Sodium from China PR to make the sterilized form of it.

H.3 Examination of the Authority

49. Rule 11 of Antidumping Rules read with Annexure II provides that an injury determination shall involve examination of factors that may indicate injury to the domestic industry, "... *taking into account all relevant facts, including the volume of dumped imports, their effect on prices in the domestic market for like articles and the consequent effect of such imports on domestic producers of such articles...*". In considering the effect of the dumped imports on prices, it is considered necessary to examine whether there has been a significant price undercutting by the dumped imports as compared with the price of the like article in India, or whether the effect of such imports is otherwise to depress prices to a significant degree or prevent price increases, which otherwise would have occurred, to a significant degree. For the examination of the impact of the dumped imports on the domestic industry in India, indices having a bearing on the state of the industry such as production, capacity utilization, sales volume, inventory, profitability, net sales realization, the magnitude and margin of dumping, etc. have been considered in accordance with Annexure II of the Rules.

50. The Authority has taken note of various submissions made by the domestic industry and the other interested parties on injury and causal link and has analyzed the same

considering the facts available on record and the applicable laws. The injury analysis undertaken ipso facto addresses submissions made by the domestic industry and the other interested parties.

H.3.1 Volume effect of the dumped imports

a. Assessment of demand/apparent consumption

51. For the purpose of the present investigation, the Authority has taken into consideration the demand or apparent consumption of the product in India as the sum of domestic sales of the Indian Producers and imports from all sources.

Particulars	UoM	2016-17	2017-18	2018-19	POI
Domestic Industry Sales	MT	***	***	***	***
Trend	Index	100	99	107	135
Sales of Other Producers	MT	***	***	***	***
Trend	Index	100	101	92	133
Total imports from the subject country	MT	7,340	20,540	68,800	73,570
Imports from other countries	MT	2,750	-	-	2,500
Total Demand/Consumption	MT	***	***	***	***
Trend	Index	100	101	105	141

52. It is seen that the demand of the product under consideration had continuously increased over the injury period.

b. Import volumes from subject country

53. With regard to the volume of the dumped imports, the Authority is required to consider whether there has been a significant increase in dumped imports from the subject country, either in absolute terms or relative to production or consumption in India. For the purpose of injury analysis, the Authority has relied on the transaction-wise import data procured from DGCI&S. The volume of imports of the subject goods from the subject country has been analysed as under:

Particulars	UoM	2016-17	2017-18	2018-19	POI
Subject Country-China	MT	7,340	20,540	68,800	73,570
Other Countries	MT	2,750	-	-	2,500
Total Imports	MT	10,090	20,540	68,800	76,070
Imports of subject goods from subject country in relation to					
Total Indian Production	%	***	***	***	***
Demand/Consumption	%	***	***	***	***
Total imports	%	72.75	100.00	100.00	96.71

54. It is noted that:
    a. The volume of imports increased significantly over the injury period.
    b. The imports in relation to domestic production and consumption have shown the similar trends. Whereas the imports increased till 2018-19 in relation to production and consumption in India, they declined thereafter in the period of investigation.

H.3.2 Price effect of the dumped imports

55. In terms of Annexure II (ii) of the Rules, with regard to the effect of the dumped imports on prices, the Authority is required to consider whether there has been a significant price undercutting by the dumped imports as compared with the price of the like product in India, or whether the effect of such imports is otherwise to depress prices to a significant degree or prevent price increases, which otherwise would have occurred, to a significant degree.

a. Price undercutting

56. For the purpose of price undercutting analysis, the net selling price of the domestic industry has been compared with the landed value of imports from the subject country. While computing the net selling price of the domestic industry, all taxes, rebates, discounts and commissions have been deducted and sales realization at ex-works level has been considered for comparison with the landed value of the dumped imports. Accordingly, the undercutting effects of the dumped imports from the subject country work out as follows:

Price Undercutting

Particulars	Units	China PR			
		2016-17	2017-18	2018-19	POI
Landed price of imports	Rs/Kg	6,021	6,182	6,563	5,799
Trend	Index	100	103	109	96
Net Selling Price	Rs/Kg	***	***	***	***
Trend	Index	100	106	136	117
Price Undercutting	Rs/Kg	***	***	***	***
	%	***	***	***	***
	Range	(10-20)	(10-20)	0-10	0-10

57. It is seen that the landed price of the subject goods is slightly below the selling price of the domestic industry. Further the selling price increased till 2018-19, with the increase in the landed price of imports. However, the selling price declined in the period of investigation along with the decline in the landed price of imports. Further, marginal price undercutting is indicative of stiff competition between the foreign producers and domestic industry.

b. Price suppression and depression

58. In order to determine whether the dumped imports are depressing the domestic prices and whether the effect of such imports is to suppress prices to a significant degree or prevent price increases which otherwise would have occurred in normal course, the changes in the costs and prices over the injury period, were compared as below:

Parameters	Unit	2016-17	2017-18	2018-19	POI
Cost of Sales	Rs/Kg	***	***	***	***
Trend	Indexed	100	110	136	123
Selling Price	Rs/Kg	***	***	***	***
Trend	Indexed	100	106	136	117
Landed Price-China	Rs/Kg	6,021	6,182	6,563	5,799
Trend	Indexed	100	103	109	96

59. It is seen that while the landed price of imports from the subject country were above the cost of sales of domestic industry in the year 2016-17 and 2017-18, it declined thereafter to a level lower than the cost of sales. During the period of investigation, the landed price of imports is below the cost of sales. The selling price of the domestic industry also increased till 2018-19 but declined in the POI even below the cost of sales.

H.3.3 <u>Economic parameters of the domestic industry</u>

60. Annexure II to the Rules requires that the determination of injury shall involve an objective examination of the consequent impact of dumped imports on domestic producers of such products. With regard to consequent impact of dumped imports on domestic producers of such products, the Rules further provide that the examination of the impact of the dumped imports on the domestic industry should include an objective and unbiased evaluation of all relevant economic factors and indices having a bearing on the state of the industry, including actual and potential decline in sales, profits, output, market share, productivity, return on investments or utilization of capacity; factors affecting domestic prices, the magnitude of the margin of dumping; actual and potential negative effects on cash flow, inventories, employment, wages, growth, ability to raise capital investments. The various injury parameters relating to the domestic industry are discussed herein below.

a. Production, capacity, sales and capacity utilization

61. Capacity, production, sales and capacity utilization of the domestic industry over the injury period is as follows:

Particulars	UOM	2016-17	2017-18	2018-19	POI
Capacity	Kgs	***	***	***	***

Trend	Indexed	100	100	111	122
Total Production	Kgs	***	***	***	***
Trend	Indexed	100	123	130	127
Capacity Utilization	%	***	***	***	***
Trend	Indexed	100	123	117	104
Domestic Sales	Kgs	***	***	***	***
Trend	Indexed	100	99	107	135
Export Sales	Kgs	***	***	***	***
Trend	Indexed	100	247	118	54
Total Sales	Kgs	***	***	***	***
Trend	Indexed	100	120	108	124

62. It is seen that:

a. Domestic industry increased its capacities in the year 2018-19 and then again in POI considering the increase in demand of the product under consideration in the country. Though the demand increased in the POI, the capacity utilization declined in the POI due to increase in capacity.
b. The production of the domestic industry increased till 2018-19 but declined in the POI despite increase in capacity.
c. The domestic sales declined in 2017-18 and thereafter increased till POI.

b. Market Share in Demand

63. Market share of the domestic industry and of imports was as shown in table below:

Particulars	UoM	2016-17	2017-18	2018-19	POI
Domestic Industry Sales	%	***	***	***	***
Sales of Other Producers	%	***	***	***	***
Imports from the subject country	%	***	***	***	***
Other countries	%	***	***	***	***
Total	Indexed	100	100	100	100

64. It is seen that while the market share of subject imports has increased till 2018-19, it declined in the period of investigation. The share of the domestic industry has declined in 2017-18 but increased in 2018-19 and thereafter again declined in the POI. The imports were subjected to anti-dumping duty till August, 2019.

c. Inventories

65. Inventory position with the domestic industry over the injury period is given in the table below:

Parameters	Unit	2016-17	2017-18	2018-19	POI

Opening Stock	Kgs	***	***	***	***
Trend	Index	100	157	328	2147
Closing Stock	Kgs	***	***	***	***
Trend	Index	100	209	1367	1589
Inventory	Kgs	***	***	***	***
Trend	Index	100	189	963	1806

66. It is seen that the stocks with the domestic industry have increased significantly over the injury period.

d. Profitability, return on investment and cash profits

67. Profitability, return on investment and cash profits of the domestic industry over the injury period is given in the table below:

Particulars	Unit	2016-17	2017-18	2018-19	POI
Selling price	Rs/Kg	***	***	***	***
Trend	Indexed	100	106	136	117
Cost	Rs/Kg	***	***	***	***
Trend	Indexed	100	110	136	123
Profit/ loss	Rs/Kg	***	***	***	***
Trend	Indexed	(100)	(191)	(133)	(252)
Profit/ loss	Rs Lacs	***	***	***	***
Trend	Indexed	(100)	(188)	(142)	(342)
Profit/ loss before Interest and Tax	Rs Lacs	***	***	***	***
Trend	Indexed	(100)	(564)	(508)	(1,297)
Cash Profit	Rs. Lacs	***	***	***	***
Trend	Indexed	(100)	(332)	(271)	(777)
ROCE	%	***	***	***	***
Trend	Indexed	100	586	714	1,108

68. It is seen that
    a. The domestic industry has incurred losses throughout the injury period. The losses have increased sharply in the POI.
    b. Return on investment and cash profits have followed the same trend as that of profitability.

e. Employment, productivity and wages

69. Performance of the domestic industry with regard to employment, productivity and wages over the injury period was as follows:

Particulars	UoM	2016-17	2017-18	2018-19	POI
Employee	Nos.	***	***	***	***
Trend	Index	100	113	108	113
Productivity per employee	MT/Nos	***	***	***	***
Trend	Index	100	106	108	111
Wages	₹ Lacs	***	***	***	***
Trend	Index	100	109	91	145

70. It is seen that:
    a. Employment and wages increased from the base year to 2017-18, declined in 2018-19 and increased in the POI.
    b. Productivity has increased over the injury period.

f. Growth

Growth	Unit	2016-17	2017-18	2018-19	POI
Production (MT)	%		19.97	(3.25)	7.82
Domestic Sales Volume (MT)	%		(1.43)	8.14	27.09
Cost of Sales (Rs/Kg)	%		9.83	23.44	(9.31)
Selling Price (Rs/Kg)	%		5.98	28.04	(13.91)
Cash Profit	%		(232.45)	18.58	(186.90)
ROI	%		-6.48%	-1.70%	-5.25%

71. Growth of the domestic industry with regard to production was negative during 2018-19, though it improved to some extent in the period of investigation. Whereas the domestic sales were negative in the 2017-18 but the same improved till the POI. However, the cost of sales and selling price improved till 2018-19 but became negative in the POI. However, profits, return on capital employed and cash profits showed negative growth throughout the injury period, especially during the period of investigation.

g. Ability to raise capital investments

72. The Authority notes that domestic industry is suffering low-capacity utilization and losses. Further, the return on capital employed of the domestic industry has become negative.

h. Magnitude of dumping

73. It is noted that the subject goods are being dumped into India and the dumping margin is above de-minimis and significant.

i. Factors affecting domestic prices

74. The examination of the import prices from the subject country, change in the cost structure, competition in the domestic market, factors other than dumped imports that might be affecting the prices of the domestic industry in the domestic market shows that the landed value of imported subject goods from the subject country is the benchmark for the selling price of the domestic industry. In fact, the domestic industry is matching the price of imports, and has not increased its prices in proportion to the increase in costs. This shows that the landed prices of subject goods from subject country are affecting the prices of the domestic industry.

j. Injury margin

75. The Authority has determined Non-Injurious Price (NIP) for the domestic industry on the basis of principles laid down in the Rules read with Annexure III, as amended. The non-injurious price of the product under consideration has been determined by adopting the information/data relating to the cost of production provided by the domestic industry and duly certified by the practicing cost accountant for the period of investigation. The non-injurious price has been considered for comparing the landed price from the subject country for calculating injury margin. For determining the non-injurious price, the best utilisation of the raw materials by the domestic industry over the injury period has been considered. The same treatment has been carried out with the utilities. The best utilisation of production capacity over the injury period has been considered. It is ensured that no extraordinary or non-recurring expenses were charged to the cost of production. A reasonable return (pre-tax @ 22%) on average capital employed (i.e., average net fixed assets plus average working capital) for the product under consideration was allowed as pre-tax profit to arrive at the non-injurious price as prescribed in Annexure III of the Rules and being followed as per consistent practice of the Authority.

76. For all the non-cooperative producers/exporters from the subject country, the Authority has determined the landed price based on facts available.

77. Based on the landed price and the non-injurious price determined as above, the Authority, determines the injury margin for all producers/exporters from China PR and the same is provided in the injury margin table below:

Injury Margin Table

Particulars	Non-Injurious Price (US$/kg)	Landed Value (US$/kg)	Injury Margin US$/kg	Injury Margin (%)	Injury Margin % (Range)
All Producers/Exporters from China PR	***	80.93	***	***	10-20

78. It is noted that the landed value of the subject imports was below the non-injurious price of the domestic industry.

I. Non-attribution analysis

79. Having examined the existence of injury, volume and price effects of dumped imports on the prices of the domestic industry, the Authority has examined whether injury to the domestic industry can be attributed to any factor, other than the dumped imports, as listed under the Rules.

a. Imports from other sources

80. Imports from other countries are either at de-minimus levels or the import prices are higher. It is, therefore, seen that the imports from other countries have not caused injury to the domestic industry.

b. Increase in demand

81. The demand of the product under consideration has increased over the injury period. Further, the domestic industry has lost market share to the subject imports in the present demand. Thus, the injury to the domestic industry is not on account of any contraction in demand.

c. Changes in the pattern of consumption

82. There is no evidence of any change in the pattern of consumption with regard to the product under consideration. Therefore, changes in the pattern of consumption cannot be considered to have caused injury to the domestic industry.

d. Trade restrictive practices of and competition between the foreign and domestic producers

83. The import of the subject goods is not restricted in any manner and the same are freely importable in the country. No evidence has been submitted by any interested party to suggest that the conditions of competition between the foreign and the domestic producers have undergone any change.

e. Developments in technology

84. None of the interested parties have furnished any evidence to demonstrate significant changes in the technology that could have caused injury to the domestic industry.

f. Export performance

85. The injury information examined hereinabove relates only to the performance of the domestic industry in terms of its domestic market. Thus, the injury suffered cannot be

attributed to the export performance of the domestic industry.

g. Performance of other products being produced and sold by the domestic industry

86. The Authority has only considered data relating to the performance of the subject goods. Therefore, performance of other products produced and sold are not a possible cause of the injury to the domestic industry.

h. Examination of causal link

87. It is noted that other known factors listed under the Rules do not show that the domestic industry could have suffered injury due to these other factors.

J. POST DISCLOSURE COMMENTS

88. The Authority issued a disclosure statement disclosing the essential facts of the case and inviting the comments from all the interested parties. The post-disclosure submissions have been received from the interested parties. The majority of the issues raised in the post disclosure comments have already been raised earlier and also addressed appropriately. Additional submissions to the extent deemed relevant have been examined as under:

J.1 Views of the domestic industry

89. The following are the post-disclosure submissions made by the domestic industry:

a. The imposition of the anti-dumping measure on the imports of the product under consideration would be in the interest of the domestic manufacturers. The imposition of duty is in the consumers' interest to have a competitive domestic industry capable of supplying the product to the consumers in competition to fair priced imports and in the interest of the public at large to have a strong, competitive domestic production of the product.
b. The objective of imposition of the anti-dumping duty is to establish a level playing field by removing any trade distortion by the producers in the subject country and allowing the Indian industry an opportunity for fair competition.
c. The impact of the duty on the eventual end products are miniscule.
d. The domestic producers are sensitive towards the importance of the PUC and cannot leave the country in the hands of China PR in this time of the pandemic.
e. If the domestic industry is shut down, then it will not be able to cater to the demand and it will lead to acute shortages of the PUC which is a lifesaving drug.
f. The majority of the subject goods are entering under the advance licence. The prices of the subject goods imported under advance licenses are working as referral price for the domestic industry. The imports made under advance licenses have the effect of benchmarking the prices in the domestic market.

g. While the DGTR can ascertain the volume and price of the imports after excluding duty free imports, there shall be no mechanism to exclude the same from the domestic industry's sales. The WTO has held in "Argentina – definitive anti-dumping duties on poultry from Brazil" that the injury analysis must necessarily exclude un-dumped imports. The volume and price effect may be just the opposite based on the gross dumped imports and the dumped imports excluding duty free imports.
h. The duty should be imposed as fixed amount, expressed in terms of US$.

J.2 Views of the other interested parties

90. The following post-disclosure submissions have been made by the other interested parties:

a. The definition of the PUC goes against the standards and requirements as per IP (Indian Pharmacopoeia) and also standards put in place by the competent Drug Controller as the product in question is a drug and cannot be produced and sold as one wishes. Some sample certificate of registration and related documents concerning non-sterile product are provided for the information of the Authority.
b. The Authority ought to have taken the views of competent authorities under D&C Rules, as it is absurd to say that non-sterile is only an intermediate and not a drug.
c. The Central Drugs Standard Control Organisation (CDSCO) has not considered sterile and non-sterile as two different products as is being erroneously treated by the Authority. CDSCO has clearly identified non-sterile as a drug,
d. The disclosure statement shows that the total imports of the PUC into India have been 73 MT in the POI which is again very misleading as only about 500 kgs of the material has come to India for the domestic use and the rest were imported for export manufacturing under advance license, etc.
e. The landed price data has been presented by the domestic industry to mislead the Authority and the fact is that the domestic prices were not governed by the landed price of the imports.
f. The disclosure statement also fails to bring on record the analyses or the technical documents and the facts which show that chemical structure, CAS, ICUI, molecular weight etc. of Non-Sterile & Sodium Sterile are different to treat them as two different products.

J.3 Examination by the Authority

91. The Authority has examined the post disclosure submissions made by the other interested parties and notes that some of the comments are reiterations which have already been examined suitably and addressed adequately in the relevant paras of the findings. The issues raised for the first time in the post-disclosure comments/submissions by the interested parties and considered relevant by the Authority are examined below.

92. With regard to the contention that the definition of the PUC goes against the standards

and requirements as per IP and standards placed by Drug Controller, the Authority notes that the product under consideration is Ceftriaxone Sodium Sterile, also known as Ceftriaxone Disodium Hemiheptahydrate-Sterile (C18H16N8Na2O7S331/2H2O). It is a third generation parenteral Cephalosporin Antibiotic which is an active pharmaceutical ingredient (API) used for the formulation of filling the injection for intravenous or intramuscular administration. As per pharmacopoeia there is no use of Ceftriaxone Sodium (Non-Sterile) as such, neither in oral form nor in injection form. After Sterilization/further processing, it is used to make the dry powder injection/Ceftriaxone Injection (ready to fill material).

93. The Authority has taken cognizance of the standards laid down under the Indian Pharmacopeia. The IP monograph of Ceftriaxone Sodium Non-Sterile and Ceftriaxone Injection were compared. The Authority notes that neither the dosage of Ceftriaxone Sodium (Non-Sterile) is prescribed in IP nor it is sold in the retail market for human consumption. IP clearly mentions *"Ceftriaxone Injection is a sterile material consisting of Ceftriaxone Sodium with or without excipients. It is filled in a sealed container. The injection is constituted by dissolving the contents of the sealed container in a requisite amount of the sterile water for injections immediately before use."* Further, the product patent shows that Ceftriaxone Sodium being an injectable has to be made sterile for its therapeutic use. This conclusively proves that the Ceftriaxone Sodium Nonsterile cannot be used as a final drug for any human application.

94. The Authority, based on the submissions and evidence advanced, has found that Ceftriaxone Sodium Non-Sterile and Ceftriaxone Sodium Sterile are not the same products. The Authority noted as follow-

    a. Ceftriaxone Sodium Non-Sterile as such is not for human application either in oral form or in injection form. Ceftriaxone Sodium Non-Sterile is just a chemical and is not for human consumption.
    b. After sterilization or further processing non-sterile is converted in Ceftriaxone Sodium Sterile which is used in the form of dry powder injection/Ceftriaxone Injection.
    c. As per the pharmacopoeia, additional tests and precautions are required to manufacture humanly consumable Ceftriaxone Sodium Sterile like particulate matter, BET and sterility test which is a process of 14 days. The same is not done for the non-Sterile product.
    d. Ceftriaxone Sodium Sterile is categorized under APIs of Cephalosporin series whereas Ceftriaxone Sodium Non-Sterile is mentioned under Medicines intermediates of Cephalosporin series.
    e. The value addition from Ceftriaxone Sodium Non-Sterile to Ceftriaxone Sodium Sterile is much higher.
    f. Ceftriaxone Sodium non-sterile is supplied in plastic or Fibre or HDPE drum whereas Ceftriaxone Sodium sterile is supplied in sterile aluminium drum.

95. With regard to the import of the subject goods made under the advance authorisation, the Authority notes that the imports made under the advance authorisations have the effect of benchmarking the prices in the domestic market, while they may not have an adverse effect on the volumes sold by the domestic industry. In certain situations, the domestic industry may even be catering to the requirement of this segment by undertaking deemed exports sales. Further, these are clearly indicative of the prices at which the material is likely to be imported in the absence of the measures. An advance authorization holder has a choice either to import the inputs on a duty-free basis or procure the same from indigenous sources by using the mechanism of Advance Release Order/Invalidation Letter. Further, the imports under advance authorisation are a benchmark for the price at which the goods can be imported by a consumer after payment of taxes and duties. It would not be appropriate to consider that the imports made under advance authorisation do not impact the prices of the domestic industry. In fact, the exporters and the importers should not worry if their claim is that the imports take place only under duty free scheme because in that case the imposition of duty will not impact them at all.

96. With regard to the contention that the domestic prices were not governed by the landed price of the imports, the Authority notes that the same has been verified by the Authority and the injury margin is not only above de-minimis but also substantial.

K. INDIAN INDUSTRY INTERESTS AND OTHER ISSUES

97. The Authority recognizes that the imposition of anti-dumping duties might affect the price levels of the product in India. However, fair competition in the Indian market will not be reduced by the imposition of the anti-dumping measures. On the contrary, the imposition of the anti-dumping measures would remove the unfair advantages gained by the dumping practice, prevent the decline of the domestic industry and help maintain availability of wider choice to the consumers of the subject goods. The purpose of anti-dumping duties, in general, is to eliminate injury caused to the domestic industry by the unfair trade practices of dumping so as to re-establish a situation of open and fair competition in the Indian market, which is in the general interest of the country. The imposition of the anti-dumping duties, therefore, would not affect the availability of the product to the consumers. The Authority notes that the imposition of the anti-dumping measures would not restrict the imports from the subject country in any way and, therefore, would not affect the availability of the product to the consumers.

98. The Authority considered whether the imposition of ADD shall have adverse public interest. For the same, the Authority examined whether the imposition of the anti-dumping duty on the imports of the product under investigation would be against the larger public interest. This determination is based on the consideration of the information on record and interests of various parties, including the domestic industry, the importers and the consumers of the product.

99. The Authority issued gazette notification inviting views from all the interested parties,

including the importers, the consumers and other interested parties. The Authority also prescribed a questionnaire for the consumers to provide relevant information with regard to the present investigations, including possible effect of the ADD on their operations. The Authority sought information on, inter-alia, interchange ability of the product supplied by various suppliers from different countries, ability of the domestic industry to switch sources, effect of the ADD on the consumers, the factors that are likely to accelerate or delay the adjustment to the new situation caused by the imposition of the ADD.

100. Only one importer, namely, M/s Shah TC Global Exim LLP, has filed the questionnaire response in the manner prescribed by the Authority. The Authority has considered the arguments of all interested party in the present findings and questionnaire response filed by these parties. None of the users or user associations have opposed to the present investigation. Though the parties have contended that there shall be adverse effect of the proposed ADD on the public at large but the importer has not provided any verifiable information to demonstrate the effect of the anti-dumping duty on the consumers. Further, in this regard, the Authority reiterates that the imposition of the anti-dumping measures would not restrict the imports from the subject country in any way and, therefore, would not affect the availability of the product to the consumers.

101. Even though the Authority has prescribed formats for the users to quantify the impact of the ADD and elaborate how the imposition of the ADD shall adversely impact them, it is noted that none of the interested parties have provided any relevant information. It is, thus, noted that the interested parties have not established the impact of the ADD on the user industry with verifiable information. Further, the domestic industry has quantified the impact of the recommended anti-dumping duty on the consumer industry and submitted that the impact is meagre.

102. The product is under free import category and, therefore, can be freely imported from the various countries. The imposition of the anti-dumping measures would not restrict the imports from the subject country in any way and, therefore, would not affect the availability of the product to the consumers. The imposition of the anti-dumping duties, therefore, would neither affect the availability of the product to the consumers nor create the monopoly.

103. Further, the capacity utilization of the domestic industry is low in the period of investigation and declined as compared to the preceding year. The domestic industry had the potential to cater to the much higher degree of demand in India. However, due to the dumping of the product under consideration, the domestic industry was faced with unutilized capacity and had a lesser share in the domestic market as compared to the subject imports.

104. It is noted that the interested parties have not demonstrated how the prices of the subject goods have adversely impacted the consumers. On the other hand, the domestic industry

has submitted quantified information showing that the impact of the proposed antidumping duty on a patient consuming the product would be miniscule. The product is mainly used to treat the patients of lower respiratory tract infection, skin & skin structure infection, pelvic inflammatory disease, intra-abdominal infection, uncomplicated gonorrhoea infection and surgical prophylaxis. The Authority notes that the impact analysis of anti-dumping duty on per patient is not even 0.1%. From the information on record, it is also noted that the impact of anti-dumping duty is miniscule to the consumers of the product under consideration, and the Authority is of the view that the imposition of the anti-dumping duty will be in the public interest.

105. It is, thus, noted that the interested parties have not established the possible adverse impact of the proposed ADD on the user industry with verifiable information. Thus, even if it is considered that the imposition of the ADD might affect the price levels of the product manufactured using the subject goods, the impact of the antidumping duty on the eventual product would be grossly insignificant. Further, the fair competition in the Indian market will not be reduced by the anti-dumping measure, particularly if the levy of the ADD is restricted to an amount necessary to redress the injury to the domestic industry. The objective of the imposition of the anti-dumping measure is to remove the unfair advantages gained by the dumping practices, to prevent the injury to the domestic industry and help maintain the availability of a wider choice to the consumers of the subject goods.

L. CONCLUSION & RECOMMENDATIONS

106. After examining the submissions made by the interested parties, the domestic industry, the issues raised therein and considering the facts available on record, the Authority concludes that:
    a. The product produced by the domestic industry is the like article to the product under consideration imported from the subject country.
    b. The application contained all the information relevant for the purpose of initiation of investigation and the application contained sufficient evidence to justify initiation of the investigation.
    c. Considering the normal value and the export price for the subject goods, the dumping margin for the subject goods from the subject country has been determined, and the margin is significant.
    d. The domestic industry has suffered material injury. The examination of the imports of the subject goods and the performance of the domestic industry clearly shows that the volume of the dumped imports from the subject country has increased significantly in absolute terms, relative terms and remained significant despite the capacity addition by the domestic industry and increase in its production. The imports from the subject country are marginally undercutting the prices of the domestic industry, indicating stiff competition between the foreign producers and the domestic industry. The

capacity utilization of the domestic industry has declined and its inventories have increased in the period of investigation.

e. The material injury suffered by the domestic industry has been caused by the dumped imports.

f. Despite providing sufficient opportunity to the interested parties to quantify the impact of ADD and elaborate on how the imposition of ADD will adversely impact them, the responding importer has not demonstrated possible adverse effect. The information on record shows that the non-imposition of the anti-dumping duty will adversely and materially impact the indigenous production, while the imposition of the duty will not materially impact the consumer or the downstream industry or the public at large. On the basis of the information provided by the interested parties and the investigation conducted, the Authority is of the considered view that the imposition of anti-dumping duty will not be against the public interest.

107. The Authority notes that the investigation was initiated and notified to all interested parties and adequate opportunity was given to the domestic industry, the exporters, the importers and the other interested parties to provide positive information on the aspect of dumping, injury and the causal link. Having initiated and conducted the investigation into dumping, injury and the causal link in terms of the provisions laid down under the Anti-Dumping Rules and having quantified the impact of the non-imposition and the imposition of the ADD, the Authority is of the view that imposition of the anti-dumping duty is required to offset the dumping and the consequent injury to the domestic industry. The Authority considers it necessary and recommends the imposition of the anti-dumping duty on the imports of the subject goods originating in or exported from the subject country.

108. Having regard to the lesser duty rule followed by the Authority, the Authority recommends imposition of the anti-dumping duty equal to the lesser of the margin of dumping and the margin of injury, so as to remove the injury to the domestic industry. Accordingly, the Authority recommends the imposition of the antidumping duty on the imports of subject goods, originating in or exported from subject country, from the date of notification to be issued in this regard by the Central Government, equal to the amount mentioned in Col. 7 of the duty table appended below. The landed value of the imports for this purpose shall be the assessable value as determined by the Customs under Customs Act, 1962 and applicable level of custom duties except duties levied under Section 3, 3A, 8B, 9, 9A of the Customs Tariff Act, 1975.

Duty Table

SN	Heading	Description	Country of Origin	Country of Export	Producer	Amount	Unit	Currency
1	2	3	4	5	6	7	8	9
1.	2941.1090, 2941.9090 & 2942.0090	Ceftriaxone Sodium Sterile	China PR	Any country including China PR	Any	12.91	Kg	US$
2.	2941.1090, 2941.9090 & 2942.0090	Ceftriaxone Sodium Sterile	Any country including China PR	China PR	Any	12.91	Kg	US$

M. FURTHER PROCEDURE

109. An appeal against the order of the Central Government that may arise out of this recommendation shall lie before the appropriate forum.

(Anant Swarup)
Designated Authority