All India Institute of Medical Sciences, Bhubaneswar
At - Sijua (Patrapada), Post - Dumuduma, Bhubaneswar (Odisha) - 751 019

Reference No: AIIMS/BBSR/PROC/COVID-19 **Dated: 11 /08/2020**

Sub: Procurement of Tocilizumab Injection 400mg/20ml vials at AIIMS, BBSR on Proprietary basis - **Inviting Comments thereon.**

The Department of Pulmonary Medicine and Critical care of AIIMS, Bhubaneswar has requested for Procurement of Tocilizumab Injection 400mg/20ml vials from **M/s Cipla Ltd.**

The Notice is being uploaded for general information of prospective manufacturer/Authorized Distributor/Dealers to submit their objection/proposal/comments, if any, on proprietorship of the item.
In case the product of any manufacturer/Authorized distributor/Dealer conforms to the enclosed specifications, they may submit their proposal for the supply of the same along with the brochures, point by point compliance of the enclosed specifications along with all documentary evidence. One quotation of the product may also be submitted.

The objections/comments/proposal should be sent in sealed cover to the Office of Sr. Procurement Cum Stores Officer, AIIMS, Bhubaneswar (Odisha) – 751019 or through E-mail to aso.jkbiswal@aiimsbhubaneswar.edu.in & spo@aiimsbhubaneswar.edu.in, so as to reach on or before **date: 18/08/2020** failing which it will be presumed that no other firm is interested to offer comments/protest/object and case will be decided on its merits.

The ref. no. – **AIIMS/BBSR/PROC/COVID-19 dt: 11/08/2020, due on dated: 18/08/2020** should be superscripted on sealed envelope.

Enclosure:

1. Proprietary Article Certificate from Indenting Officer of Department of Pulmonary Medicine and Critical care of AIIMS, Bhubaneswar. **Annexure-I**
2. Manufacturer's PAC declaration. **Annexure-II**
3. Price Quotation for Tocilizumab Injection 400mg/20ml vials. **Annexure-III**

Copy to:

1. Indenting Officer, Department of Pulmonary Medicine and Critical care : for information please
2. Accounts Officer : for information please
3. IT Cell : for hoisting in the website.

Sr. Procurement-cum-Stores Officer

ANNEXURE-I

AIIMS, BHUBANESWAR

(463)

Proprietary Article Certificate
Valid for the Current Financial Year

File No. and Date Reference :		
1	Description of article	Tocilizumab Injection 400mg/20ml vial
2	Forecast of quantity /annual requirement	Approximately 100 vials (unpredictable requirement)
3	Approximate estimated value for above quantity	Rs. 30,00,000 /- (Rupees Thirty Lakh only)
4	Maker's name and address	M/s. : Chugai Pharma Manufacturing Co. Ltd.Utsunomiya,Japan, for M/s. F.Hoffmann-La Roche Ltd.,Grenzacherstrasse,124,CH-4070,Basel,Switzerland.The product is imported by Roche Products (India) Pvt. Ltd. And marketed by Cipla Ltd.
5	Name(s) of authorized dealers/ stockiest	M/s. Natraj Pharmaceuticals,Plot No.-1151/2232,Ground Floor,Basudev Nagar,Near Reliance Fresh,CGP Colony,Rasulgarh,Bhubaneswar-751025.
6	I approve the above purchase on PAC basis and certify that :- Note- Tick to retain only one out of (b), C-1) or (c-2) whichever is applicable and cross out others. Please do confirm (a) by ticking it - without which PAC certificate will be invalid.	
6 (a)	This is the only firm who is manufacturing / stocking this item. AND	Yes
6 (b)	A Similar article is not manufactured / sold by any other firm, which could be used in lieu OR	Yes
6 (c-1)	No other make/brand will be suitable for following tangible reasons (like OEM/ Warranty, spares.) : OR	
6 (c)	No other make/brand will be suitable for following intangible reasons (if PAC was also given in the last procurement cycle, please also bring out efforts made since then to locate more sources): OR	
7	Reference of concurrence of finance wing to the proposal :	To be obtained.

History of PAC Purchase of this item for past three years may be given below :

Name of the Supplier

Order/ Tender Reference & Date	Quantity Ordered	Basic Rate on Order (Rs.)	Adverse Performance Reported if Any
PO No.-304 dtd.24/07/2020	08	Rs.29,400.00	Nil

DIRECTOR.

Signature of the Indenting Officer.
03/08/2020

Manoj Kumar Panigrahi
Additional Professor
Department of Pulmonary Medicine & Critical Care
AIIMS, Bhubaneswar

ANNEXURE-II

Roche

To Whom It May Concern

Basel, 16 January 2020

Proprietary Article Certificate for Tocilizumab Injection 400mg/20ml (Actemra®)

This to certify and confirm that Tocilizumab Injection 400mg/20ml (Actemra®) is the proprietary product of F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, CH- 4070, Basel, Switzerland.
Chugai Pharma Manufacturing Co., Ltd, Utsunomiya, Japan is the sole manufacturer of Tocilizumab Injection 400mg/20ml (Actemra®) for F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, CH- 4070, Basel, Switzerland. This product is imported by Roche Products (India) Pvt. Ltd and marketed by Cipla Limited.

Yours sincerely,
F. Hoffmann - La Roche Ltd

Erika Hauck Eckel
International Regulatory Manager

Diogo Espanhol
International Regulatory Manager

F. Hoffmann-La Roche Ltd
Pharma Development
CH-4070 Basel

PDRAR
Drug Regulatory Affairs
Building 686/3 518

Tel. +41 61 688 2198
Fax. +41 61 688 1561
e-mail erika.eckel@roche.com

ANNEXURE-III

Cipla

Date: -16-07-2020

To,
The Director,
AIIMS, Sijua
Bhubaneshwar

Sub: Quotation for our Actemra 400mg (Tocilizumab Inj)

Dear Sir,

With Reference to above subject below is the quotation for our Actemra 400mg Tocilizumab Inj): -

Sr. No	SKU Name	Molecule Name	Pack Size	GST %	MRP	Rate Excluding Tax
1	Actemra Tocilizumab Injection 400 MG	Tocilizumab 400 mg	1 Inj	5%	40545	**29400**

Other terms & conditions are as under: -

1. GST: GST as applicable will be charged extra.
2. Please note that since there is sudden unforeseen demand for this product across the globe, we are having limited shelf life stocks and hence would be able to supply the stocks for Actemra Tocilizumab Injection 400 MG. (Declaration Enclosed)
3. This is 6 months shelf life stocks which is manufactured at M/s Roche's site at Genentech Inc. Hillsboro, United States, to meet the global demand of Pandemic Covid 19. We have enclosed import license duly mentioning the 6 months shelf life, approval of DCGI to import the global artwork pack along with our declaration for your perusal.
4. As you are aware Inj Tocilizumab 400mg (Actemra 400mg) is cold chain product (2-8 degree C) supply would be made on a non-returnable basis.
5. As the demand for drug is huge and is required to be supplied for emergency use. Cipla will not commit to supply any fixed quantities as per the purchase order and on or before the delivery dates. Cipla will endeavour to supply the drug 'as and when available basis'.
6. Cipla will not be liable for any delay or default in supplying the drugs.
7. This quotation is submitted on ad-hoc basis, hence other terms that are agreed for supplying other products shall not be applicable to the above products. Cipla will provide required undertaking as regards the quality of the Product but will not be liable or responsible for providing any additional information not required under law.
8. Supply would be done through our authorised distributor address as below:-

   NATRAJ PHARMACEUTICALS
   Plot no.1151/2232,Ground Floor,
   Basudev Nagar,Near Reliance Fresh,
   GGP Colony, Rasulgarh,Bhubaneswar-751025

Thanking You
Yours Faithfully,

CIPLA LIMITED MUMBAI

For Cipla Limited

Authorized Signatory
Vishwas Ahuja
Director Market Access & Public Health India Business

Cipla Ltd.
Mumbai Central, Mumbai - 400008, India.
P +91 22 2302 5555, 2308 2891, 2309 5621

Regd. Office - Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.
P +91 22 24826000 F +91 22 24826120. W www.cipla.com E-Mail contactus@cipla.com Corporate Identity Number L24239MH1935PLC002380

Cipla

DELCARATION

Actemra import and shelf-life as per India specific labelling on global packs

Subject: **Declaration regarding import of Actemra (Tocilizumab) 400mg/20ml at 6 months shelf life and adapting the expiry date as per India specific labeling requirements on the global make up packs**

This is regarding import of Actemra 400mg/20 ml from Roche's Hillsboro, US facility.

Following the outbreak and spread of COVID- 19, several countries have included Actemra on their national COVID-19 treatment guidelines. As a result of the Covid-19 pandemic, Roche has observed sudden increase in average demand for Tocilizumab globally as well as in India. In order to mitigate the stock out situation, Roche has set up additional emergency drug product manufacturing facility for Actemra IV 400mg/20ml at Genentech Inc. Hillsboro, USA (As per current set up and registered license, Actemra IV is manufactured by Chugai, Japan.). Further, the product is supplied in global make up (EFA-English, French, Arabic) packs to all the countries from this site instead of country specific makeup packs due to emergency situation and packaging facilities constraints.

Since Hillsboro, USA is emergency facility set up to cater sudden increased demand of the product, in accordance with the Roche's quality system and intended use, the shelf life for Product is set at 6 months. The stability study has been already initiated at Hillsboro, USA site. Potential shelf-life extension to longer expiry may be conducted with technical justification based on the results from these stability studies. Actemra 400mg/20 ml with 6 months shelf life is supplied to all the countries where this emergency facility is approved including USA.

Roche India had submitted applications to DCGI for registration of this additional emergency manufacturing site. We have received Import license approval wherein shelf life of 6 months has been approved by DCGI based on review of the data submitted. Import license (IL No. IL/BIO-000127 - RC/BIO-000125 dated 05 June 2020) is enclosed with this declaration.

We have informed the DCGI that in order to ensure the availability of the product to needy patients in India at the earliest possible, we will import this product in global make up packs in accordance with the multiple time import permission granted (vide File No. X-11026/82/2020-BD dated 01 June 2020) and will ensure to incorporate India specific labeling requirements on the packs before distribution in the India market. This labeling activity will be carried out at our licensed premises (Redressing site).

As you are aware, the shelf life of Tocilizumab Injection 400mg/20ml manufactured at Genentech Inc., Hillsboro, United States will be 6 months. We would like to inform you that as per the practice followed globally for assigning the expiry date, the month of manufacturing is not considered while calculating the expiry date.

For e.g. For the product having shelf life of 6 month and particular batch manufactured in Apr 2020, the expiry date will be Oct 2020 (Note: In this case, the shelf life is considered as 7 months as per the practice followed in India).

However, as per the local requirements in India, month of manufacturing is considered while calculating the expiry date of the product. Due to this reason, the expiry date in the above case should be assigned as Sep 2020 (i.e. globally assigned shelf life minus 1 month).

The upcoming lot from Hillsboro facility manufactured in April 2020 will have Mfg. Date: 04.2020 and Exp. Date: 10.2020 (as per globally followed calculation). Hence, we will require to correct the expiry date as 09.2020 on the packs. In order to fulfill the requirement, an additional flap sticker containing expiry date of 09.2020 will be applied on the bottom panel of the carton. There will be no such additional label will be required on the vial as the new vial label will have India style corrected shelf life i.e. 09.2020

Thanks and best regards,

CIPLA LIMITED MUMBAI

For Cipla Limited
Authorized Signatory
Vishwas Ahuja
Director Market Access & Public Health India Business

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Mumbai Central, Mumbai - 400008, India.
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