

Municipal Corporation of Greater Mumbai
Central Purchase Department
(Medicine Tender Section)

Gentleman,

Drugs have always remained and are likely to remain the core element in preventive as well as in curative healthcare.

An efficient procurement system is the only way to improve access to medicines for the majority of the population within the given budgetary provisions.

With a view to develop Quality Procurement System, MCGM has incorporated some changes in Procurement system so that Drugs made available should be of good Quality and should be safe.

Hence, MCGM has decided to accept the offers only from Direct Manufacturers / Importers.

Being the prospective bidder, you are requested to remain present for the meeting arranged by MCGM so as to understand and get familiar with the procurement System better.

Date, Time and Venue of Meeting :- **08/10/ 2015 at 3.00 p.m.**
Municipal Head Office,
Conference Hall, 3rd Floor,
Opp. to AMC (W.S.)'s Office,
Mahpalika Marg, Mumbai-400001.

Sd/-

Dy. Dean (CPD)

**MUNICIPAL CORPORATION OF GREATER MUMBAI
CENTRAL PURCHASE DEPARTMENT
MEDICINE TENDER SECTION**

Who can quote:-

- Only direct Manufacturers/Importers would be allowed to participate in the tender.
- A Manufacturer will be allowed to appoint his distributor if he wishes to do so for supply of the goods, however the said distributor will not be recognized as Agent of the Manufacturer / Importer.
- Manufacturer / Importer would be directly responsible for all the tender related issues including quality and quantity of the goods.
- Manufacturer / Importer shall supply the goods and raise the bills directly.
- So as to timely completion of tendering process, it is prerequisite to get Registered with Medicine Tender Section, MCGM.

Empanelment / Registration of Manufacturers / Importers :-

- The firms willing to participate in the tendering and rate contract process of MCGM for supply of Medicines / Medical Devices / Surgical items etc should note that it is a prerequisite to get Registered with Medicine Tender Section , MCGM.
- Manufacturers / Importers has to submit the Administrative documents in file 'A' and technical documents in file 'B' for registration.
- The tenderer fulfilling prequalification criteria would be registered with the MCGM.
- The Registration Fees of Rs. 10,000/= (Rs. Ten Thousand only) would be charged to each Manufacturer / Importer for the period of 5 (Five) years.
- The Registration will be renewed every 5 years after paying Registration Fees.
- The Registration will be awarded itemwise, Sectionwise / Schedulewise, Locationwise.
- In the event of final rate Contract been awarded to successful tenderer, he will have to supply awarded items only from the plant locations which are registered with MCGM.
- Registration certificate will be awarded to the Manufacturers/Importers after proper scrutiny of relevant documents which are submitted for Registration and payment of Registration Fees.
- The Registration Validity period will be for 5 Years subject to the validity of documents and terms, condition of tender.

- Manufacturers / Importers will be registered only for those items which are included in Schedule item list.
- Manufacturers / Importers are required to get registered new items whenever added in Schedule list.
- The Firms who are already registered with MCGM for a particular Section / Schedule, location or number of items, the firm can apply for inclusion of :-
 additional Location of factory by paying a fees of Rs. 2,000/- per plant location,
 additional Section / Schedule by paying of fees of Rs. 2,000/- per Section / Schedule,
 additional items by Paying a fees of Rs. 1000/- per item.
- The Registration Fee is Non – Refundable.
- Firms have to submit all relevant documents with respect to the product / New products, the final decision of addition of the Location, section and items in Registration and subsequently in rate contract shall be made only after proper scrutiny of the relevant documents.
- The Registration certificate is not a permission for supply.
- The Registration certificate along with registered product list issued by MCGM should be uploaded in systems during tender process till the due date and time of tender in respective Pkt A and B i.e. Administrative and technical Pkts.
- Those who have received product Registration certificate issued by MCGM are exempted from submission of those documents in system during tender mentioned in the said certificate / list of the documents for registration.
- However those who have not received product Registration certificate **on application** must upload all the relevant documents with respect to product / New Products as per tender condition in respective Pkt A and B in system till due date and time of tender.
- The process of Registration of firms would be ongoing process, however acceptance of file for Registration will be temporarily stopped after 15 days of advertisement of the tender(start date) so as to scrutinize documents and issue of the Registration certificates.
- Tenderer are requested to note that if the product Registration certificate is not issued by MCGM during further period, the tenderer has to upload all relevant documents as per tender terms and conditions in respective Pkt A and B till the due date and time of tender.

- The process of acceptance of the files for registration will again start after due date of the tender.
- The Registration automatically stands cancelled in case it is found that the documents submitted by the tenderer are forged / false / inaccurate etc.
- In the event of Registration being awarded / the firm is required to submit the updated, latest attested copies of certificates like Drug license / Import license / WHO – GMP certificate etc. during the validity of Registration period.
- In the event of Registration being awarded unit has to apply at least 3 months in advance for renewal of registration before the expiry of the last Registration date.
- **Turnover Criteria** :- The Manufacturer / Importer having average annual turnover of Rs. One Crore (Non- Drug items and medical devices) and Rs. Six crore for Drug items (Injections , Tablets and Capsules, Sutures , X- Ray firms etc.) for last three financial years will be only eligible for participation in the tender.
- Tablets, Capsules should be supplied in Blister / Strip Pkg. and Syrups, liquids should be supplied in packed Bottles.
- Manufacturers / Importers have to submit the production / Import and sale data (Quantity) for past 3 years on letter head of C.A. and certified by C.A. (As per Proforma 'C') to be submitted in packet 'B' in system till due date and time of tender.
- In case of new Drugs (New molecules) / New Medical devices two years Production / Import and sell (quantity) should be submitted in tender (Proforma 'C').
- Details of the item quoted must be submitted as per the completely filled format Annexure 'A' in respective packet A and B in the system till due date and time of the tender.
- Performance certificate as per Annexure 'D' format (DHS format) should be submitted for previous three financial years issued by FDA authority in tender till due date and time of tender in Packet 'B'.
- Manufacturer / Importer has to give the exact specification of the product which he has offered / quoted against Schedule item in proforma 'E'.
- Manufacturer / Importer has to submit the details of firm in Annexure 'B' format.
- You are requested to collect the 'Proforma for Enlistment' (Form of Registration) filled and submit along with all relevant documents to obtain Registration certificate.

MUNICIPAL CORPORATION OF GREATER MUMBAI
CENTRAL PURCHASE DEPARTMENT

566, N.M. Joshi Marg, Byculla, Mumbai – 400 011.

FORM OF REGISTRATION

उत्पादन नोंदणी अर्ज.

PROFORMA FOR ENLISTMENT

Form of application to be filled & submitted by the firm for enlistment with Central Purchase Department, Byculla, Mumbai.

मध्यवर्ती खरेदी खाते यांच्या मान्यता प्राप्त संस्थांच्या यादीत नाव नोंदणीसाठी करावयाच्या अर्जाचा नमुना.

१	बृहन्मुंबई महानगरपालिका वेंडर नोंदणी आणि ई-नोंदणी क्रमांक MCGM Vendor Registration & e-Registration Number	
२	कंपनीचे नाव व स्थापना झाल्याची तारीख Name of Firm & Date of Establishment	
३	पत्ता – Address - अ) मुख्य कार्यालय, शाखा कार्यालय व वितरकाचे कार्यालय. a) Head Office, Branch Office & Distributors's Office. आ) उत्पादन ठिकाण (एकापेक्षा जास्त उत्पादन ठिकाण असल्यास) b) Manufacturing Unit : If Manufacturing units are more than one, give. इ) सर्व उत्पादन ठिकाणांचे संपुर्ण पत्ते द्यावेत. c) Detail address of all the units.	
४	पत्रव्यवहाराचा पत्ता व दुरध्वनी क्रमांक /फॅक्स क्रमांक /ई – मेल. Telegraphic address & Telephone No. /Fax No. / E – mail Id. (Manufacturer and / or Importer)	
५	या कार्यालयाला तातडीच्या कामासाठी गरज पडल्यास ज्या व्यक्तीशी संपर्क साधावा लागेल त्या व्यक्तीचे नाव, हुद्दा, दुरध्वनी क्रमांक व फॅक्स क्रमांक / ई – मेल द्यावा. State the name, Designation, Address, Telephone Number & Fax Number / email id of the authority whom should be contacted by this office in case of any urgent official work.	
६	प्रपत्र 'ब' (विहित नमुन्यात) Annexure B (In Prescribed Format)	
७	ज्या औषधांसाठी / बाबींसाठी आपणास नाव नोंदणी करून पाहिजे आहे त्या औषधांची / बाबींची स्वतंत्र यादी सोबत दिलेल्या विहित नमुन्यात अर्जासोबत जोडावी. Furnish the Details of items (as per format attached) for which you wish to register with this Central Purchase Department, MCGM in Annexure.	

मी / आम्ही असे जाहीर करतो की या अर्जात दिलेली माहिती माझ्या/आमच्या माहितीप्रमाणे खरी आहे. यामध्ये देण्यात आलेली माहिती असत्य/वा दिशाभूल करणारी आढळून आल्यास माझी / आमची नोंदणी रद्द होण्यास पात्र ठरेल आणि मी / आम्ही कायदेशीर दंडात्मक कारवाईस पात्र ठरेन /ठरू.

I / We declare that the particulars furnished in this application are true to the best of my / our knowledge & belief & that any of the particulars is found to be materially incorrect, misleading, my / our registration shall be liable to be rejected & I / we are liable for penal action.

अर्जदाराची पुर्ण सही, शिक्का व पुर्ण पत्ता

Full signature of the Applicant with official seal & address

दिनांक –

ठिकाण –

ANNEXURE 'B'

(Particulars of the tenderer. Specimen Copy)

Following information to be submitted along with tenders (in envelope 'A') as detailed herein below. Put a tick mark where applicable. Write N.A. where not applicable.

1. Total annual turnover in the preceding 3 Financial Years.
2. Is the firm registered under the Indian Companies Act-1 of 1956 or any other Act, in force?
 - a. If so, furnish certified Photostat copy of Certificate of Registration.
 - b. In case of Limited Companies furnish a certified Photostat copy of the Memorandum Articles of Association alongwith the List of Directors, their addresses, Telephone Number, Fax Number, Mobile Number, & Email ID, if any.
 - c. In case of Proprietorship/Partnership firms, name of the Proprietor/Partners with complete Postal Residential & Business address, Telephone Number, Fax Number, Mobile Number, & Email ID, if any (in order of ----- % of shares) alongwith certified copy of registered documents of Partnership Deed.
 - d. Ownership status of the Firm. (Maharashtra Govt./Other State Govt. / Central Govt. / Joint Sector / Co-Operative / B.S.I. / Private / Foreign Company)
3. Whether tendering as Manufacturer/Importer. (State your category)
4. Name and Designation of the Officer/complete Postal Address, Phone Number Mobile Number, Fax Number, Email ID etc. who should be contacted by this office in case of urgent problem.
5. Location of other manufacturing works/factories owned by the firm (if any)
6. Specify how much quantity of products were supplied to the Govt. of Maharashtra / Brihanmumbai Mahanagarपालिका in the last four years as shown below. (Use separate sheet, if necessary)

Years	Quantity of Supply	Name of the stores Institute to whom supply is made
1	2	3

I/We have carefully gone through the tender documents & the terms & conditions mentioned therein & are all acceptable & agreeable in entirety to me/us.

**Full Signature of the Tenderer
With Official Seal and Address**

A) Proforma to be attached as Annexure:

List of the products to be “Registered list only those items” which are approved in MCGM schedule list. (To be submitted in Hard & Soft copy)

Provide separate schedule wise list.

SCHEDULE No. & NAME OF SCHEDULE:-

Manufacturer’s Name: - M/s.

Sr. No.	Item No.	Category of product	Name of the product to be Registered (Brand Name If any) <u>with pharmacopial standard</u> (if Drug item)	Mfg. License No. with product list & Validity (Pg. No.)	Location of the Factory where the product is manufactured (Pg. No.)	Item-wise WHO-GMP Ceft. / COPP. & its Validity (for Drug item) (Pg. No.)	FDA product permission Date (for Drug item) (Pg. No.)	Copy of ISI/ISO/CE/IEC cft. etc. & its validity (Criteria as per schedule copy / tender manual (For Non Drug) (Pg. No.)

I/We hereby undertake that all the information submitted above is correct and our registration will get automatically cancelled in case if it is found in future that the information provided is false.

Authorized Signatory of the Firm.

Date :

Seal of the Firm

B) Proforma to be attached as Annexure (Imported Items) :

List of the products to be “Registered list only those items” which are approved in MCGM schedule list. (To be submitted in Hard & Soft copy)

Provide separate schedule-wise product list.

SCHEDULE No. & NAME OF SCHEDULE :-

Manufacturer’s Name & Address :- M/s.

Importer’s Name & Address :- M/s.

Sr. No.	Item No.	Category of product	Name of the product to be Registered (Brand Name If any) <u>with pharmacopial standard</u> (if Drug item)	Manufacturer’s Name & Location of Factory	Country of Origin	Date of First Import	Date of recent Import	Drug Controller Import Lic. No. & Validity (Form 10 with product list) (Pg. No.)	WHO-GMP Ceft./ COPP. Issued date & Valid upto (Pg. No.)	IEC code No/ISO/CE Ceft. etc. & Date of Issue & its Validity (Criteria as per schedule copy / Tender Manual) (For Non Drug Items) (Pg. No.)

I/We hereby undertake that all the information submitted above is correct and our registration will get automatically cancelled in case if it is found in future that the information provided is false.

Authorized Signatory of the Firm.

Date :

Seal of the Firm

CHECK LIST FOR DOCUMENTS

ADMINISTRATIVE DOCUMENTS (PKT – A)

Tenderer should submit the attested / notarized copy of following Documents for Registration

Sr. No.	Document	Submitted in Page No.	Validity dates of Document for		Signature of the Tenderer
			From	To Date	
1	VAT and CST Registration Certificate as applicable.				
2	Pan Card with Photograph.				
3	Power of attorney in case of partnership Firms/ Public Ltd. Co./ Pvt. Ltd. Co./Societies/ Govt. Undertaking.				
4	Company Registration Certificate, Partnership deed, articles of association, society's registration certificate as the case may be.				
5	Valid Registration Certificate, under E.P.F. M. P. Act 1952 or Declaration for E.P.F. M. P. Act 1952				
6	Valid Registration Certificate, under ESIC Act 1948 or Declaration for ESIC				

Total number of pages submitted from..... to.....

**Full Signature of the Tenderer
With Official Seal and Address**

CHECK LIST FOR DOCUMENTS
TECHNICAL DOCUMENTS (PKT – B)

Tenderer should submit the attested / notarized copy of following
Documents for Registration

Sr. No.	Document	Submitted in Page No.	Validity dates of Document for		Signature of the Tenderer
			From	To Date	
1	Proforma for Enlistment				
2	Proforma to be attached as annexure (List of products to be Registered should be filled completely)				
3	Annexure 'B'				
4	Attested copy of valid Drug Mfg-Lic. / Import Lic.(Form 10) / re - packing Lic. etc. Issued by Drug authority.				
5	Approved Product list under Drug Mfg-Lic. / Import Lic. / re-packing Lic. Issued by Drug authority. <u>(Schedule item no. Should be highlight & marked in product list.)</u>				
6	Valid item-wise WHO-GMP cft. (with list approved under WHO-GMP cft.) / Certificate of Pharmaceutical product (COPP) / GMP cft. etc. Issued by Drug authority. As mentioned in prequalifying criteria of Schedule Copy / Tender Manual <u>(Schedule item no. Should be highlight & marked in product list.)</u>				
7	US FDA / IEC / ISI / ISO / CE CFT etc. (As mentioned in schedule copy / Tender Manual				
8	Quality Control Test Report. <u>Pls. mark Schedule Item No.</u>				
9	Copy of permission from the Drug Controller general of India, New Delhi for items coming under "New Drug & fixed dose combinations in Form 45 / 46				
10	Statement showing details of product offered with its composition (Proforma 'E')				

Total number of pages submitted from to

Full Signature of the Tenderer
With Official Seal and Address

PROFORMA 'C'

(Document of Technical Bid)

Statement showing item-wise total number of units manufactured / imported and sold during last three financial years.

Name of Manufacturer / Importer and Address _____

Sr. No	Tender Item No.	Tender Item Name with Description)	Total Number of units Manufactured / Imported in last 3 financial years.						
			Year 'A'		Year 'B'		Year 'C'		
			No. of units Manufactured / Imported	Sold	No. of units Manufactured / Imported	Sold	No. of units Manufactured / Imported	Sold	

“This annual sale is more than 20 percent of the quantity of total requirement specified in the tender”.

Note: In case of new drugs & new medical devices items wise quantity of Manufactured / Import & sales of previous 2 years.

Signature and Seal of Chartered Accountant

Date:

PROFORMA 'E'

Statement showing details of Product offered with its composition

(Product offered column should not simply repeat the tender specification rather it must give actual details of the product manufactured by the manufacturer.)

Name of Manufacturer/Importer and Address _____

Sr. No	Schedule Item No	Item Name & Description in Tender (Schedule Description)	Details of product offered with Composition by the tenderer (with pharmacopoeial grade IP/BP/USP/NF etc. if any)	F.D.A Product Permission Date (for Drug items)	DCGI Permission Date in case of New Drugs & FDCs	Certificates as per prequalifying criteria in Sch. Copy / tender manual With validity
1						
2						
3						

The products offered above are of the same compositions / specifications with the items in schedule copy. If not matches with schedule specification my offer will get rejected.

Signature and Seal of the Manufacturer/ Importer

Date:

Annexure 'D'

(Performance Certificate)

CAPACITY AND QUALITY CERTIFICATION FROM DRUG AUTHORITY

(To be submitted on official letter of drugs authority and stamped with Govt. Seal)

FDA Reference no.

Date-

1. Name of the firm:- M/s.
Address
Telephone
E-mail
Tele fax
Website

The firm is holding following valid and own manufacturing license / licenses (not on Loan Lic.) and have approved and valid manufacturing facilities at following location/s as per World Health Organization Good Manufacturing Practices (WHO-GMP Certification) at following locations/facilities and they are manufacturing the following products since the last 3 years under the license mentioned below. It is further certified that the following products are also being marketed for the last three years.

Name of Firm:

Sr. No. of the Item as in tender enquiry	Name & Specification of the Item	Date of issue of Mfg. license for the product	Date of marketing the 1 st batch	Actual production details (last three years)						Remarks
				201... -		201... -		201... -		
				Batch No.	Batch size / Quantity	Batch No.	Batch size / Quantity	Batch No.	Batch size / Quantity	

2. Drug license No. 1) Date of issue..... Valid till date.....
Location address.....
3. Drug license No. 2) Date of issue..... Valid till date.....
Location address.....
4. Drug license No. 3) Date of issue..... Valid till date.....
Location address
5. All the above licenses are valid, own licenses and not loan licences.
6. M/s. _____ (Name Of firm) is properly registered to supply Medicines / Medical devices and is in good legal and statutory standing and is licensed as a primary manufacturer of the range of Medicines / Medical devices to be offered. (The list of medicines/medical devices for which tenderer wishes to participate is attached herewith).
7. No product from this list attached herewith, manufactured by the firm had been declared of sub standard quality/ spurious / counterfeit as defined under prevailing Drug & Cosmetics Act and rules there under during last 3 years.

8. The firm have not been prosecuted or convicted and license of the firm had not been suspended even for one day under prevailing drug & Cosmetics Act and rules there under during last three years.
9. No administrative action or prosecution is contemplated or launched against the manufacturer under the Drugs & Cosmetics Act, 1940 & Rules there under in respect of any of the drugs, surgical items, medical device offered by him in the tender mentioned in the list attached herewith, during last three years.
10. During the preceding three (3) years there is no instance of suspension or cancellation of a part of license, issued to the manufacturer, in respect of any of the drugs, surgical items, medical device which are offered by the manufacturer in the tender mentioned in the list attached herewith, on account of Drugs & Cosmetic Act under tender being not of standard quality.
11. The department wise approved production capacities for _____ (Name of firm) are as follows:
The prequalified installed capacity for the firm is as follows:
Annual Capacity –
A. Non – Sterile Tab/Cap., Liquid orals etc.
B. Sterile – Injections / I.V. Fluids/Ophthalmic/External etc.
12. M/s. _____ (Name of firm) retains full records of production batches and quality control test results, and will exhibit these on request.
13. M/s. _____ (Name of firm) has at least three years experience in the manufacturing of specific dosage forms it will bid on, and has three years or more experience in producing any product covered by this Invitation for Bids.
14. M/s. _____ (Name of firm) has experience with the knowledge of modes of packing, distribution, and transportation of Medicines similar to that of the Purchaser in terms of level of development, climate, etc.

We hereby certify that the above information is true and accurate to the best of our knowledge. We understand that the provision of information that is later found to be false is sufficient justification for disqualification.

Signature of Officer

In relevant Drug Control Authority

Date: _____

Full Name (Printed)

Position of Officer

In relevant Authority

Signature of the Manufacturer

Signature of the State Drug Commissioner along with address And seal

Note: Firm will have to produce documentary evidence respect of production as and when asked for

TO BE AFFIXED WITH OFFICIAL GOVERNMENT FDA SEAL

Annexure 'L'

Dy. Dean / CPD/ of 201... - 201...

Bid No:

PRO-FORMA FOR "Declaration for E.P.F. & M. Act 1952 from Bidder" (To be uploaded in ENVELOPE 'A')

To,
Municipal Commissioner

M.C.G.M. Mumbai.

Dear Sir,

Reference: - E-Tender Document No. _____ dated _____.

1. We, M/s. _____ are authorized distributor/dealer/agent of M/s. _____ (name of manufacturer).
2. We hereby **declare that** E.P.F. & M.P. Act 1952 is not applicable to our firm as our firm has less than 20 employees/persons on our establishment up to date.
3. In future if nos. employees / persons on our establishment will increase equal to or more than 20 nos. the valid registration certificate under E.P.F. & M.P. Act 1952 will be submitted immediately.

Yours faithfully,

(Signature with Date, Name & Designation)

For and on behalf of M/s. _____

Note: 1) This letter should be on the letter head of the manufacturing firm and should be signed by a person competent and having the power of attorney to legally bind the manufacturer.

- 1) **Scanned copy of Original letter shall be uploaded.**
- 2) Tender No / Bid No should be written on this Declaration.
- 3) This Declaration should be given on Rs.200/- stamp paper duly notarized by Notary with red seal and registration Number.

Annexure 'M'

Dy. Dean / CPD/ of 201... - 201...

Bid No:

PRO-FORMA FOR "Declaration for ESIC from Bidder" (To be uploaded in ENVELOPE 'A')

To,
Municipal Commissioner
M.C.G.M. Mumbai.

Dear Sir,

Reference: - E-Tender Document No. _____ dated _____.

1. We, M/s. _____ are authorized distributor / dealer / agent of M/s. _____ (name of manufacturer).
2. We hereby **declare that ESIC 1948** is not applicable to our firm as our firm has less than 10 employees/persons on our establishment (In case of production by use of energy) and 20 employees / persons on our establishment (In case of production without use of energy) up to date.
3. In future if nos. employees/persons on our establishment will increase as stated above, the valid registration certificate under ESIC. Act 1948 will be submitted immediately.

Yours faithfully,

(Signature with Date, Name & Designation)

For and on behalf of M/s. _____

Note: 1) This letter should be on the letter head of the manufacturing firm and should be signed by a person competent and having the power of attorney to legally bind the manufacturer.

- 1) Scanned copy of Original letter shall be uploaded.**
- 2) Tender No / Bid No should be written on this Declaration.
- 3) This Declaration should be given on Rs.200/- stamp paper duly notarized by Notary with red seal and registration Number.