

Madhya Pradesh Public Health Services Corporation Limited

**Minutes of Pre-bid Meeting of IOL (Foldable) Tender No. 07
held on 19-12-14 at 01:00 PM in the meeting hall Satpuda Bhawan,
Bhopal.**

The following were present in the meeting:-

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|---|------------------------------------|---|----------|
| 1 | Dr. Vinay Dubey | CGM (Technical) Madhya Pradesh public Health Services Corporation Ltd. | Chairman |
| 2 | Dr. Himanshu Jayswar | GM (Procurement) Madhya Pradesh public Health Services Corporation Ltd. | Member |
| 3 | Dr. M.A Khurram, Eye Specialist | Kamla Nehru Hospital, Bhopal | Member |
| 4 | Mr. R.D Gautam | Consultant-Procurement, NHM Bhopal | Member |
| 5 | Mr. Harish Gupta | Consultant-Procurement, Bhopal | Member |

Representatives of following firms were present:-

- (i) M/s Alcon India Pvt. Ltd., Indore.
- (ii) M/s Omni Lens Pvt. Ltd., Ahmedabad
- (iii) M/s Auro Lab Pvt. Ltd.
- (iv) M/s Biotech Vision Care.
- (v) M/s Bausch & Laumb, Valeant Pharmaceuticals Inc; Gurgaon.
- (vi) M/s Abbott Medical Optics Pvt. Ltd.
- (vii) M/s Polymer Technologies International.

The proceeds of Pre-bid meetings are as follows:-

- 1- The prospective bidders were asked to submit their queries.
- 2- It was decided to collect the technical specification queries and put before the Technical Committee for discussion:-
 - (a) 10 degree of angle to be removed as it is not available. **(M/s Alcon India Pvt. Ltd.)**
 - (b) Government of India is specification be read as "Govt. Of MP"
 - (c) Specification of Tender floated are very precise and closed to specific models of a particular company. Every company holds their own design and A-constant calculations open & reasonable specification be made. **(M/s Valeant Pharmaceuticals)**

(d) There is not a single Manufacturer of USFDA approved/certified intra ocular lens is range of Foldable or Non Foldable lens, CE , ISO & GMP certified are being used satisfactory without any complaint.

At present in state Govt. Of Gujarat Omni Lens pvt.ltd Hydrophobic IOL (Foldable) are being used under yearly rate contract continuously since last 2 years and with no complaints from state Authorities or from end users so far as quality is concerned. The party objected to USFDA CERTIFIED CLAUSE from tender to encourage Indian IOL Manufacturers party has also written about other manufacturers Bio-Tech Vision Care Pvt. Ltd, Ahmadabad, I.O care Pvt. Ltd. Vadodara & A.I Optics Ltd, Chennai as manufacturers of Indian IOL lenses while none of these have US FDA certification . Party has requested to accept CE, ISO & GMP certified IOL lenses instead of USFDA certified IOL lenses. **(M/s Omni Lens Pvt. Ltd.)**

(e) Section VIII Sr. No. 08 reads "Compliance of US FDA 21 CFR and IEC 60601" are not applicable to IOL. Since there is no plan to export to US, USFDA has not been obtained The Product is WHO-GMP certified for pharmaceuticals & ISO certified for entire range of items produced & also complies to USFDA quality standard for manufacturing & quality control persons. Although IOL comes under section C & C (i) the drugs rules 1945 put does not come under the perview of WHO-GMP in India. Raw materials, production and quality control equipments are sourced from US & Europe.

Only difference is IOL lens (Rigid & Foldable) are manufactured in India. Prospective bidders is asking for removing monopolistic situation giving no scope for competition by adding CE to USFDA **(M/S Auro Lab).**

(f) M/s Bio-Tech Vision Care has asked to amend to Technical Specifications. "The foldable IOL lenses required should be USFDA approved & also with 10 Degree angle & compressible 0.06 to 0.14" Party has informed that as per tender requirement, the IOL's with above specifications demanded would restrict for few companies based out of India only. No Indian IOL manufacturing companies process USFDA & they call above Indian FDA as well as comply to ISO, CE standards. All Indian IOL companies will be disqualified with these specifications and hence requested to change the specifications.

(M/s Biotech Vision Care Pvt. Ltd. Ahmadabad)

Query:-

- 1- USFDA not required.
- 2- 10 degree angulation in not required.

(g)


- 1- Production company & product should have at least 4 years experience in Indian IOL supply.
- 2- Hydrophobic material is mandatory because of features.
- 3- USFDA approval is mandatory for quality assurance.

(M/s Abbott Medical Optics Pvt. Ltd)

(h)

1- USFDA not required for IOL Govt. Tenders as USFDA. The specification are restrictive to participation. of Indian companies.(M/s **Polymer Technologies International**)

The member decided to present the queries before the technical committee final discussion will be put on website after technical meeting, Prebid meeting ended with a vote of thanks.


(Dr. Vinay Dubey)
CGM (Technical)
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