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Ref. No.:- F.02(164)/RMSC/PROCUREMENT/DRUG/NIB-12/2015/1712_

Dated: 3-11-15

Corrigendum - 2

Subject:- Amended technical specifications and other conditions of bid document

For the NIB Ref. No. F.02(164)/RMSC/PROCUREMENT/DRUG/NIB-12/2015/1600

Dated:12.10.2015 (Technical bid opening due on dated - 17.11.2015)

Ref. - Pre bid meeting dated 26.10.2015

| S. No | : | eificatio | sting condition / technical n/Packing Unit/Quantity (clause no.) | Amended condition / technical specification/ Packing Unit/Quantity. | |
|----------|---|-------------|--|---|--|
| 1. | Annexure VIII and BoQ | | | Annexure VIII and BoQ | |
| , | S. No | Code No. | Name of item with specification | Drug with code no 31 is deleted. | |
| 1 | 1. | 31 | Pethidine Hydrochloride Injection | | |
| | | | IP 50mg/ml (IM/IV use) | | |
| 2. | Clause 2(c) ELIGIBILITY CRITERIA | | | Clause 2(c) ELIGIBILITY CRITERIA | |
| | Clause 5 (i) (j) TECHNICAL BID | | | Clause 5 (i) (j) TECHNICAL BID | |
| | Annexure XV Ref. Clause No. 2(c) | | | Annexure XV Ref. Clause No. 2(c) | |
| | S. No | Code No. | Name of item with specification | In the existing condition in the clause, it is | |
| | | 642 | Oseltamivir Phosphate for Oral Suspension IP 12 mg/ml. [Each ml contains 12 mg Oseltamivir base after reconstitution] | relaxed as per following:- A. For Item code 642 - Market Standing Certificate of two year acceptable. B. For Item code 642 - | |
| | | | | In performance statement (Annexure XV) the bidder should have manufactured at least total 3 commercial batches of the quoted drug in the last 3 years. [2011-2012, 2012-13, 2013-14 or 2012-13, 2013-14, 2014-15] | |
| 3. | Clause 5 (I) TECHNICAL BID | | | Clause 5 (I) TECHNICAL BID | |
| | WHO | O-GMP | (WHO - Good manufacturing | For item code 642 - Oseltamivir | |
| | practices Certificate) Certificate issued by the | | | Phosphate for Oral Suspension IP 12 | |
| | Licensing Authority. The WHO-GMP | | | mg/ml. | |
| | certificate must not be older than one | | | GMP (Good manufacturing practices | |
| | the due date of Bid submission in the case where | | | Certificate) Certificate issued by the | |
| | validity is not mentioned in the certificate. The | | | Licensing Authority. The GMP certificate | |
| | WHO-GMP certificate of all the manufacturing | | | must not be older than one year from the due | |
| | 1. | | which products have been quoted, | date of Bid submission in the case where | |
| | should be submitted. The Bidder shall also | | | validity is not mentioned in the certificate. | |
| | furni | sh an t | indertaking in the format given in | | |

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Annexure-VII point no.8 declaring that the Bidder complies with the requirements of WHO-GMP. The Importer should produce WHO-GMP /COPP of the manufacturing firm or a certificate which is at par with WHO-GMP issued by exporting countries like US-FDA approval, etc. In the case of imported drugs, labels and product literature of all quoted products must be submitted.

The GMP certificate of all the manufacturing plants, of which products have been quoted, should be submitted. The Bidder shall also furnish an undertaking in the format given in Annexure-VII point no.8 declaring that the Bidder complies with the requirements of GMP. The Importer should produce WHO-GMP /COPP of the manufacturing firm or a certificate which is at par with WHO-GMP issued by exporting countries like US-FDA approval, etc. In the case of imported drugs, labels and product literature of all quoted products must be submitted.

It bears approval of Purchase Committee dated 03.11.2015.

Rest terms and conditions will remain the same.

Executive Director (Proc.)

№ RMSC

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