

File No.:Z.28015/43/2023-Proc.I(EPW)

Government of India
Ministry of Health & Family Welfare
Department of Health & Family Welfare
[Procurement-I (EPW) Section]

Nirman Bhawan, New Delhi
Dated: 14th September. 2023

OFFICE MEMORANDUM

Subject: Request for issuing advisory to the procuring entities under Department of Health & Family Welfare in respect of tender document for procurement of medical devices to contain specifications about the licenses issued by CDSCO / SLA as mandatory requirement instead of foreign standards - reg.

The undersigned is directed to refer to Department of Pharmaceuticals O.M. No.35017/2/2010- Policy dated 31.8.2023 (copy enclosed) on the subject mentioned above.

2. The Department of Health & Family Welfare had earlier issued an O.M.No.Z.17018/67/2017-EPW dated 05-11-2019 (copy enclosed) advising all the procuring entities under the Department to comply with the provisions of the Public Procurement (Preference to Make in India) Order, 2017 and desist from inclusion of the restrictive and discriminatory clauses i.e. insisting for USFDA/CE standards in their procurement of medical devices. All procuring entities under the Department of Health & Family Welfare are once again requested to ensure strict compliance to provisions of the Public Procurement (Preference to Make in India) Order, 2017 and desist from including the USFDA/CE standards as mandatory in their tender documents for procurement of medical devices.

(Encl: As above)



(Lavkesh Sehgal)

Under Secretary to the Govt. of India

Tel: 23061875

To,

All procuring entities under the Department of Health & Family Welfare (as per list attached-61 entities).

F. No. Z.28018/67/2017-EPW
Government of India
Ministry of Health & Family Welfare
(EPW Division)

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Nirman Bhawan, New Delhi
Dated: 05.11.2019

OFFICE MEMORANDUM

Sub: Implementation of Public Procurement (Preference to Make In India) Order, 2017 issued by DPIIT -reg.

The undersigned is directed to refer to minutes of 8th Standing Committee meeting of DPIIT held on 10.10.2019 to review the implementation of Public Procurement (Preference to Make In India) Order, 2017 (PPP-MII). It is observed that In-spite of this office OMs dated 14.01.2018, 23.02.2018, 26.02.2018, 02.11.2018 & 25.10.2019, procuring entities are still incorporating restrictive and discriminatory clause of mandatory USFDA/European CE certification in procurement of health sector goods.

Standing Committee has directed that stipulation of mandatory exclusion clause like USFDA/European CE certified products is restrictive and discriminatory for local manufacturers and hence policy should be discontinued forthwith.

All the procuring entities under MoHFW are requested to strictly comply with the provisions of PPP-MII Order, 2017 and desist from such restrictive and discriminatory clauses.


(Rajendran Nair M.B.)
Under Secretary (EPW)
Tel:-23061436

To:

1. PPS to DGHS, Nirman Bhawan, New Delhi
2. PPS to AS&FA, AS&MD, AS(H), AS&DG, MoHFW, Nirman Bhawan, New Delhi.
3. JS(SP)/ JS(LA)/ JS(SK)/ JS(MA)/ JS(RS)/ JS(SS)/ JS(VG)/ JS(MKB)/JS(NACO)/ JS(PP)/ JS(GM)/JS(RS)/ EA (PN)/EA(NS).
4. The Director, AIIMS, New Delhi/ Patna/ Bhubaneshwar/ Raipur/ Bhopal/ Jodhpur/ Rishikesh.

सं० / No. 35017/2/2010-Policy
भारत सरकार / Government of India
रसायन एवं उर्वरक मंत्रालय / Ministry of Chemicals and Fertilizers
औषध विभाग / Department of Pharmaceuticals

शास्त्री भवन, नई दिल्ली
Shastri Bhawan, New Delhi
Dated the 31st August, 2023

कार्यालय ज्ञापन / OFFICE MEMORANDUM

Subject: Request to issue an advisory to the State and Central procurement agencies of medical devices - tender documents to contain specifications about the licenses issued by CDSCO / SLA as mandatory requirement instead of foreign standards - regarding.

The undersigned is directed to refer to OM of even number dated 22.06.2023 requesting CDSCO and DoHFW to consider issuing an advisory to the State and Central procurement agencies of medical devices - tender documents may contain the specifications about the licenses issued by CDSCO / SLA for medical devices as mandatory requirement instead selectively mandating regulatory requirement such as US-FDA and CE certification.

2. In this regard, CDSCO vide email dated 13.07.2023 had shared the following:

(i) **MoHFW OM no.X.11035/379/2015-DFQC (Pt) dated 20.02.2018** wherein in all cases of procurement of medical devices / equipment, the following shall be complied with:

- Wherever Indian standards are available, these would be sufficient and USFDA/CE may not be insisted
- Wherever standards are not available, indenting organization would be free to lay down standards of ISO/USFDA/CE

(ii) **MoHFW OM no.Z017018/67/2017-EPW dated 05.11.2019** wherein all procuring entities under MoHFW were communicated about the direction of the 8th Standing Committee meeting of DPIIT held on 10.10.2019 that stipulation of mandatory clause like USFDA/European CE is restrictive and discriminatory for local manufacturers and hence policy should be discontinued forthwith. Further stated that all the procuring entities under MoHFW requested to comply with the provisions of PPP-MII order 2017 and desist from such restrictive and discriminatory clauses.

3. Here, it is conveyed that notwithstanding the above, Japan has stated the procurement in favour of US and EU certification seems to persist. Domestic manufacturers like AiMed have also raised that clauses in tender insisting on USFDA and CE standards place domestic manufacturers at a disadvantage. The matter was also discussed with the Japanese side on 18.08.2023 during the meeting

between Health Ministers of India and Japan on the sidelines of the Ministerial Health Working Group under Indian G20 Presidency.

4. In view of above, DoHFW is requested to reiterate the guidelines / directive effectively to procurement agencies in Central and State Governments to enable non-discriminatory approach.

5. This issues with the approval of the Secretary, Pharmaceuticals.


(Sanjay Meena)

Under Secretary to Govt. of India

Email: sanjay.m74@nic.in

Tel. 23385765

To

Secretary
Department of Health and Family Welfare
Nirman Bhawan
New Delhi

Copy to:

- (i) Sr. PPS to Secretary, DoP / Secretary, DoHFW
- (ii) Shri. Rajiv Wadhawan, Advisor, Procurement, DoHFW
- (iii) PS to HMCF