

Procurement of Medical Devices for University Children Hospital “Tiršova”

IOP/11-2017/RD

Clarification no. 5

Issued on December 1, 2017

Question 1:

Concerning the licence for selling medicines and medical devices on the territory of the Republic of Serbia issued by Ministry of Health of the Rep. of Serbia, please clarify if an awarded foreign company based outside Serbia must apply for the registration in ALIMS-R.Serbia or if it is acceptable that it provides goods already registered, without applying for ALIMS (in other words: if it is acceptable that the awarded foreign company provides goods purchased from a Serbian company which is registered in ALIMS).

Answer 1:

Regarding the Postqualification requirements, (f) Certifications, standards and licences, Bidder is obliged to:

1. Have a professional certificate ISO 9001
2. Submit evidence (licence) that is registered for selling medicines and medical devices on the territory of the Republic of Serbia, issued by Ministry of Health of the Republic of Serbia. **This requirement applies to the bidder (legal entity, firm, company).** If a bid is submitted by a Joint Venture of two or more firms as members, this minimum qualification criterion can be fulfilled jointly, which means that the requirement is fulfilled if only one member of a Joint Venture is properly registered for selling medicines and medical devices on the territory of the Republic of Serbia.
3. For offered medical devices, it is necessary to submit documentation (licence) of current valid registration in ALIMS -R. Serbia or CE certificate, if the device is not registered with ALIMS at the time of the bids submission.
After the award decision is announced the successful Bidder is obliged to submit documentation of valid registration in ALIMS before signature of the contract. **This requirement applies to devices (goods). Each device/good in commercial transactions in the territory of the Republic of Serbia has to be registered with ALIMS. It is allowed to offer devices/goods already registered with ALIMS.** Successful Bidder is obliged, not later than at the time of signing the contract, to submit documentation (licence) of current valid registration in ALIMS -R of the goods/devices offered.
4. For equipment with ionizing radiation source Bidder is obliged to submit evidence (licence) that is registered for selling equipment which produce ionizing radiation on the territory of the Republic of Serbia, issued by Serbian Radiation Protection and Nuclear Safety Agency.

Furthermore, Note the Additional requirements for Lot 6 ICT, UPS and backup Infrastructure stipulated in the Tender Documents.

Question 2:

Please kindly explain the steps to apply for the licence for selling companies in the Republic of Serbia (licence issued by the Ministry of Health).

Please kindly explain the steps to apply for registration of medical devices in ALIMS – R. Serbia.

Answer 2:

Please contact Ministry of Health Republic of Serbia as well as the Medicines and Medical Devices Agency of Serbia in order to inform about the steps necessary for registration in question.

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Procurement Committee