Request for Proposal

Supply of Elastomeric Closures and Aluminum Overseals for the COVID-19 vaccines

The Coalition for Epidemic Preparedness Innovations (CEPI) is an international coalition of governments, academic, philanthropic, private, public, and intergovernmental institutions whose aim is to prevent outbreaks of emerging infectious diseases from becoming humanitarian crises.

Our mission is to accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for affected populations during outbreaks. We identify priority threats and act when market forces fail to drive needed development.

Based on its mission CEPI is promoting the development of new vaccines against the emerging threat of COVID-19. CEPI has funded several COVID-19 vaccine development projects and intends to support their manufacturing as well as the procurement of primary packaging components (e.g. vials, stoppers and aluminium flip-offs) that are fungible across CEPI’s COVID-19 portfolio. For this reason, CEPI is launching a Request for Proposals (RfP) to identify rubber stopper manufacturers and suppliers with the capacity and willingness to support delivery of COVID-19 vaccines.

CEPI operates under the laws of Norway as a non-profit international association and has offices in Oslo (HQ), London, and Washington, DC.

More details about CEPI and our mission can be found on our website: http://cepi.net

Scope of Tender

The objective of this request for proposal is to secure access to elastomeric closures and aluminium flip-offs to be used for the manufacture of Sars-Cov-2 vaccines.

The request for proposal will aim to achieve the following outcomes:

- secure the capacity with the manufacturer(s) so that:
  - 100,000,000 20 mm elastomeric closures ready to use (RTU) are delivered in monthly instalments in the period November 2020 – December 2021
  - 100,000,000 20 mm Aluminium flip-offs ready to use (RTU) are delivered in monthly instalments in the period November 2020 – December 2021
  - stoppers and flip offs should be suitable for ISO 20R vials whose dimensional specifications are attached below.
  - additional access to capacity may be secured should more doses of vaccines become available

- achieve maximum flexibility of use of the capacity over the period of time mentioned above
• the price per item is in line with value expectations: paying a price that covers manufacturers costs plus a reasonable mark-up
• ensure that the materials are ready to be shipped to designated locations within an agreed period of time

As a result of the RfP CEPI will work with the selected manufacturer(s) to establish contractual arrangements that best meet the objectives of this solicitation. These CAs will provide the framework on which Purchase Orders (PO) are made for specific deliveries throughout the period.

VIAL SPECIFICATIONS

Please see this PDF, for information on vial specifications.

Successful Proposals

We are seeking to engage with suppliers that have:
• infrastructure and expertise to serve the pharmaceutical industry
• high quality and technologically advanced manufacturing processes

Proposal are sought independently for elastomeric closures and aluminium flip-offs.

It is important that the supply forecasts made by each manufacturer are as accurate and realistic as possible. Inaccurate and unrealistic forecasts will jeopardize CEPI’s ability to meet the objectives of the RfP.

Applicants must be willing to work with CEPI to collaboratively manage the components supply chain.

Bidder Qualification

Applicants must meet the following minimum eligibility criteria:
• the applicant will demonstrate proven experience and qualification in the supply and delivery of the components proposed to the pharmaceutical industry by providing the following information:
  o Company general information (Structure, Turnover, N° of employees ….)
  o Site(s) of manufacturing
  o Customer references
  o Names of the regulatory bodies where products are registered
• The applicant may also supply other information as it considers appropriate in order to demonstrate proven experience and qualification in the supply and delivery of the components being proposed.
• Applicants must demonstrate appropriate customer service and project management capabilities.

Tentative Time Plan

The following is the expected time scale for the procurement process. However, CEPI reserves the right to change the time schedule at any time.

<table>
<thead>
<tr>
<th>Activity</th>
<th>End Date</th>
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<tbody>
<tr>
<td>Request for proposals advertised</td>
<td>Weds June 10, 2020</td>
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<tr>
<td>Deadline for submission of written proposal</td>
<td>Mon June 15, 2020</td>
</tr>
<tr>
<td>Selection process completed</td>
<td>Fri June 19, 2020</td>
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</tbody>
</table>
**Tender Instructions**

To be considered for a contract award under this request for proposals, please submit the written proposal (not exceeding 5 pages + applicable resumes and annexes) in English.

The proposal must include the following information:

- Formulation chemical and physical characterisation (applicable only to elastomeric closures)
- Drawings
- Offered price and associated payment schedule
- Quantity offered and monthly tentative delivery schedule
- Order fulfilment lead time
- Offered delivery terms including INCO terms
- Storage and transport conditions
- Agreement to store or procure storage of the components
- Agreement to provide samples to perform compatibility and stability tests
- Validity of offer
- Quality systems in place
- Name of the person who will be the primary contact for CEPI
- Completed tender declaration form and Supplier Details form (appendix 1 and 2 below)

Deadline for submission is **Midnight (23:59:59 GMT) on the date shown in the time plan above.** Proposals received after the deadline will not be considered. Costs for the preparation of proposals will not be refunded.

Electronic copies of your proposals should be sent to: tenders@cepi.net in PDF format.

**Evaluation Criteria**

We will assess the proposals against the information presented in the Scope detailed above. The contract will be awarded to the tenderer(s) who: have demonstrated that they can meet the technical capabilities and qualifications detailed in the scope (70%) and provided an economically competitive offer (30%).

**Confidentiality**

By accepting to take part in this RFP process, your firm agrees to keep in confidence all information imparted to you by CEPI during the period of consultancy, not to disclose it to third parties, and not to use it for any other purpose than for participation in the RFP process.

**Cancellation**

CEPI reserves the right to change the time plan or cancel the competition without any obligation to cover any cost associated with the tender process.

**Duration**

The expected duration for any contract awarded under this Request for Proposals will relate to the work specified in the contract with a maximum time period defined and a periodic evaluation and the option to renew, replace or terminate, based on an evaluation process.

**Additional Information**

If you have any questions, please contact mauro.bernuzzi@cepi.net
Appendix I – Tender Declaration Form

Before awarding any contract, and as part of the procurement procedure, CEPI, its Partners, representatives and Awardees will need to ensure that the candidates comply with the Labour, Environmental, Transport and Cargo, standards detailed below and has appropriate Whistleblowing and Duty to Inform policies and procedures in place. Written confirmation in the form of this signed document should be provided to confirm this.

CEPI, its Partners and Awardees reserves the right, even if such confirmation is given, to investigate / audit any of the situations listed if it has reasonable grounds to doubt the contents of such confirmation. This right to audit is applicable for CEPI’s supplier/contractor and its supply chain.

For the purpose of the declaration signed below, the term “the Tenderer” refers to the following:

Name of Tenderer:

Registered Office Address:

Registration Number (as appropriate):

ELIGIBILITY

The Tenderer hereby declare that I/we agree(s) to participate in the procurement procedure in adherence to the principles stated in CEPI’s Procurement Policy and Procedure and are fully aware that any failure to comply could lead to our exclusion from the tender process and to the rejection of our bid.

The Tenderer agrees to carry out our duties to the highest professional standards, with no consideration linked to possibilities for future contracts. The Tenderer commits to adhere to CEPI’s Procurement principles and minimum standards throughout our commercial and procurement activities and have procedures in place to ensure that respect for these principles and standards is upheld by our staff and contractors.

I/we hereby furthermore declare that the Tenderer:

(a) is not subject to any conflict of interest in the ongoing procurement procedure for this contract and there has not been any misrepresentation in the information supplied along the process;

(b) is not bankrupt or being wound up or having its affairs administered by the courts. It has not entered into an arrangement with creditors or suspended business activities and is not the subject of proceedings concerning those matters;

(c) we or persons having powers of representation, decision-making or control over them have not been convicted of an offence concerning their professional conduct by a final judgment;

(d) has never been proven guilty of any grave professional misconduct;

(e) has not failed to fulfil their obligations relating to the payment of social security contributions or taxes in accordance with the legal provisions of the country in which they are established, or with those of the country where the contract is to be performed;

(f) has never been convicted for fraud, corruption, illegal activity, involvement in a criminal organisation or money laundering by a final judgment.

(g) does not make use of child labour or forced labour and/or practise discrimination, and/or disrespect the right to freedom of association and the right to organise and engage in collective bargaining pursuant to the core conventions of the International Labour Organization (ILO).

I/we agree to hold in trust and confidence any information or documents disclosed to us, discovered by us or prepared by us during the course of the tender and agree that it shall be used only for the purposes of this process and shall not be disclosed to any third party. I/we understand that any unauthorized disclosure by us may render the Tenderer liable to legal action.
LABOUR STANDARDS

Employment is freely chosen.

a. There is no forced, bonded or involuntary prison labour.

b. Workers are not required to lodge 'deposits' or their identity papers with the employer and are free to leave their employer after reasonable notice.

Freedom of association and the right to collective bargaining are respected.

a. All workers have the right to join or form trade unions of their own choosing and to bargain collectively.

b. Where the right to freedom of association and collective bargaining is restricted under law, the employer facilitates, and does not hinder, the development of parallel means for independent and free association and bargaining.

Working conditions are safe and hygienic.

a. A safe and hygienic working environment shall be provided. Adequate steps shall be taken to prevent accidents and injury to health arising out of, associated with, or occurring in the course of work.

b. Access to clean toilet facilities and potable water, and, if appropriate, sanitary facilities for food storage shall be provided.

c. Accommodation, where provided, shall be clean, safe, and meet the basic needs of the workers.

Child Labour shall not be used.

a. The International Labor Organization ("ILO") defines “child labour” as work that deprives children of their childhood, their potential and their dignity, and that is harmful to physical and mental development. It refers to work that:
   - Is mentally, physically, socially or morally dangerous and harmful to children; and
   - Interferes with their schooling by depriving them of the opportunity to attend school; obliging them to leave school prematurely; or requiring them to attempt to combine school attendance with excessively long and heavy work.

b. There shall be no recruitment of children and children under 18 years of age shall not be employed at night or in hazardous conditions, including any work which is likely to jeopardize children’s physical, mental or moral health, safety or morals.

Living wages are paid.

a. Wages and benefits paid for a standard working week meet, at a minimum, national legal standards or industry benchmarks, whichever is higher.

b. In any event wages should always be high enough to meet basic needs and to provide some discretionary income.

Working hours are not excessive.

a. Working hours comply with national laws and benchmark industry standards.

b. In any event, workers shall not on a regular basis be required to work in excess of 48 hours per week and shall be provided with at least one day off for every 7–day period on average.

c. Overtime shall be voluntary, shall not exceed 12 hours per week, shall not be demanded on a regular basis and shall always be compensated at a premium rate.

No discrimination is practiced.

There is no discrimination in hiring, compensation, access to training, promotion, termination or retirement based on race, caste, national origin, religion, age, disability, gender, marital status, sexual orientation, union membership or political affiliation.

Regular employment is provided.

To every extent possible work performed must be on the basis of a recognized employment relationship established through national law and practice.

No harsh or inhumane treatment is allowed.
Physical abuse or discipline, the threat of physical abuse, sexual or other harassment and verbal abuse or other forms of intimidation shall be prohibited.

ENVIRONMENTAL STANDARDS

Suppliers should as a minimum comply with all statutory and other legal requirements relating to the environmental impacts of their business and should aim to address at least the following:

- **Waste Management.** Waste is minimised and items recycled whenever this is practicable. Effective controls of waste in respect of ground, air, and water pollution are adopted. In the case of hazardous materials, emergency response plans are in place.
- **Packaging and Paper.** Undue and unnecessary use of materials is avoided, and recycled materials used whenever appropriate.
- **Conservation.** Processes and activities are monitored and modified as necessary to ensure that conservation of scarce resources, including water, flora and fauna and productive land in certain situations.
- **Energy Use.** All production and delivery processes, including the use of heating, ventilation, lighting, IT systems and transportation, are based on the need to maximize efficient energy use and to minimize harmful emissions.

TRANSPORT & CARGO STANDARDS

Any transport services shall be provided by a company which adheres to the highest possible safety and employment standards and which commits to respect human rights and observe international humanitarian law. It is preferred that the company can demonstrate it has an effective ethical policy in place, particularly if the company is a broker or freight-forwarder, to ensure that standards are met. If the supplier of the goods is arranging transport, then the supplier should ensure that transport services also meet these standards.

Where air transport is required, preference shall be given to providers who are not on the EU Safety Ban List and whose aircraft are registered in countries which meet the International Civil Aviation Organization’s standards.

The supplier shall not engage the services of a transport provider known to also transport illicit or illegal goods such as narcotics or to transport arms, ammunition or other conflict-sensitive materials to or from territories subject to a UN or EU embargo.

The supplier shall not engage in the sale or transport of arms or conflict-sensitive supplies to governments which systematically violate the human rights of their citizens; or where there is internal armed conflict or major tensions; or where the sale of arms may jeopardize regional peace and security.

AVAILABILITY OF WHISTLEBLOWING CHANNEL

It is everyone’s responsibility to ensure that CEPI and its partners remain in compliance with these Principles. You are strongly encouraged to report any intentional or unintentional non-compliance with these Principles to CEPI Governance, Risk and Compliance Manager (GRC.Manager@cepi.net). If you are concerned about retaliation and prefer to report anonymously, you can do so through the implemented Whistleblowing Channels implemented at CEPI. Please see www.cepi.net for further information regarding the Whistleblowing Channel available. Rest assured, CEPI will not tolerate any retaliation against anyone who has reported an actual or suspected violation in good faith.
Appendix 2 – Supplier Details Form

CEPI, its Partners, Representatives and Awardees perform standard checks on all suppliers to ensure that we are engaging in accordance with good practice and relevant legislation.

Please provide the following information in order for CEPI to undertake standard procurement checks.

<table>
<thead>
<tr>
<th>Organisation name &amp; form:</th>
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<tbody>
<tr>
<td>Name of key contact:</td>
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<tr>
<td>Organisation registration number:</td>
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<td>Ultimate ownership:</td>
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<td>Email address:</td>
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<td>Website:</td>
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<td>Completed by:</td>
<td>Date:</td>
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Please ensure that you inform CEPI if any of the parameters above change.