**UNITED NATIONS CHILDREN'S FUND (UNICEF)**

**REQUEST FOR EXPRESSION OF INTEREST**

Date of Request for Expression of Interest (REoI): 27th of Nov. 2020

Closing date for receipt of Expression of Interest (EoI)**:** 11th of Dec. 2020

**Reference: REoI – *Hearing Aids***

**Description of requirements:**

900 million people around the globe is in need of one or more assistive technologies, this is an area which UNICEF has committed to do as part of the AT2030 programme. In collaboration with WHO, UNICEF will add different assistive technology product ranges into our global supply catalogue, one of the first of which is hearing aids. The goal of this project is to increase availability and affordability to optimal hearing aids and services in low and mid resource countries.

UNICEF and WHO are requesting Expressions of Interest from eligible suppliers in preparation for a solicitation exercise for hearing aids. The aim of the solicitation exercise is to establish Long Term Arrangements (LTAs) with relevant, qualified suppliers for delivery of hearing aids and accessories for UNICEF and WHO programmes and partners over the coming years.

The products identified fall under the following categories:

Category 1: Programmable Behind-the-Ear Hearing Aids for Adults

Category 2: Pre-programmed Behind-the-Ear Hearing Aids for Adults

Category 3: Programmable Behind-the-Ear Hearing Aids for Pediatrics

Category 4: Earmolds

Category 5: Hearing Aid Batteries

For an itemised list of products per category, please refer to Annex A.

**Potential suppliers:**

This REoI is addressed to manufacturer products of these categories as well as wholesalers with experience in the sourcing and supply of hearing aids.

UNICEF and WHO are particularly interested in identifying competitive suppliers that can offer all items within 1 category, or within several selected categories, or possibly, the full range (all 5 categories).

Only suppliers with proof of conformity to Quality Management System standards are invited to express interest as follows:

1. **Supplier: Valid ISO 13485 or ISO 9001 certificate (as applicable) including scope.**

**Copy in English.**

1. **Manufacturer: Valid ISO 13485 certificate. Copy in English**

To be considered for the planned tender it is preferable, but not a requirement for potential suppliers to have a website providing access to the product information (e.g., manufacturer specifications).

Only products with at least one of the following pre-market approvals / market clearances will be considered in the planned solicitation exercise:

**(a) Australia: TGA Device Licence;**

**(b) Canada: Device Licence;**

**(c) European Union: CE 93/42 Medical Device Directive (MDD) Mark;**

**(d) Japan: Device Licence;**

**(e) USA: 510k market clearance**

**(f) Other regional market clearance (please submit paperwork)**

Only products with at least one of the following current product standards will be considered in the planned solicitation exercise:

**(a) IEC 60118-0: 2015**

**(b) ANSI S3.22-2014**

**Procedure for submission of EoI:**

Interested suppliers are encouraged to complete **the attached EoI form** and return it to UNICEF by email to: **Annie Wang** ([anwang@unicef.org](mailto:anwang@unicef.org)) with **Dan Ilie** ([dilie@unicef.org](mailto:dilie@unicef.org)) in copy on or before 11th of December 2020.

**Please note:**

1. Prices are not required at this stage;
2. Questions about e.g. conformity of the supplier’s products will not be entertained;
3. This REoI does not constitute a solicitation. Submitting an EoI does not automatically guarantee receipt of the solicitation document when issued;
4. UNICEF reserves the right to require compliance with additional conditions as and when issuing the final solicitation document.
5. UNICEF reserves the right to change or cancel the requirement at any time during the REoI and/or solicitation process.
6. The *WHO Preferred Profile for hearing-aid technology suitable for low- and middle-income countries* document should be considered for all five categories.
7. The *WHO Assistive Product Specification for Procurement – Hearing aids* document should be considered for all given categories. For more information on the APS please see: <https://www.unicef.org/innovation/disability-friendly-supplies>

Thank you.

|  |  |
| --- | --- |
| **ANNEX A: Itemised list of products per category** | |
| **CATEGORY 1: Programmable Behind-the-Ear Hearing Aids for Adults** | |
| BTE Power Levels | Medium power: Adults with mild-to-moderate hearing loss |
| Multiple power: Adults with mild to moderately-severe hearing loss |
| Super power: Adults with moderately-severe to profound hearing loss |
| Spare parts | Slim tubes (multiple sizes available), domes (multiple sizes available), spare hooks, hearing aid cases, user manual, hearing aid cleaning tools and other necessary parts. |
| **CATEGORY 2: Pre-programmed Behind-the-Ear Hearing Aids for Adults with a mild-to- moderately severe hearing loss** | |
| Fitting range: Mild-to-moderately severe hearing loss | At least 3 different pre-set configurations for common hearing loss shapes in adults with a mild-to-moderately severe hearing loss with different volume settings available. |
| Spare parts | Slim tubes (multiple sizes available), domes (multiple sizes available), spare hooks, hearing aid cases, user manual, hearing aid cleaning tools and other necessary parts. |
| **CATEGORY 3: Programmable Behind-the-Ear Hearing Aids for Pediatrics** | |
| BTE Power Levels | Medium power: Children with mild-to-moderate hearing loss |
| Multiple power: Children with mild to moderately-severe hearing loss |
| Super Power: Children with moderately-severe to profound hearing loss |
| Accompanying Products | Pediatric care kits, pediatric sized earhooks, hearing aid cases, drying capsules and other necessary parts |
| **CATEGORY 4: Earmolds** | |
| Tubing | Different sizes available (standard, dry-wall, heavy-wall, reverse horn, etc). |
| Earmold material | Different materials are available (silicone, acrylic, etc). |
| Earmold style | Different styles are available (full shell, half shell, skeleton, etc). |

|  |  |  |
| --- | --- | --- |
| **CATEGORY 5: Hearing Aid Batteries** | | |
| Zinc air battery size | IEC code | ANSI code |
| 10 | PR70 | 7005ZD |
| 312 | PR41 | 7002ZD |
| 13 | PR48 | 7000ZD |
| 675 | PR44 | 7003ZD |

**EXPRESSION of INTEREST (EoI) – Hearing Aids**

**Closing date of EoI: 11th of Dec. 2020**

***(Please check the appropriate boxes and return to UNICEF)***

**A - GENERAL INFORMATION**

|  |  |  |  |
| --- | --- | --- | --- |
| Supplier’s full name: |  | | |
| Type of company | Manufacturer | Trader | Other |
| Address: |  | | |
| Country: |  | | |
| Email address (company): |  | | |
| Website address: |  | | |
| Telephone: |  | | |
| Fax: |  | | |
| Contact person: |  | | |
| E-mail address (personal): |  | | |

**B – INTEREST / CAPACITY TO SUPPLY THE FOLLOWING CATEGORIES**

|  |  |  |
| --- | --- | --- |
| **Categories – Hearing Aids** | **Yes** | **No** |
| Category 1: Programmable Hearing Aids for Adults (18+years) |  |  |
| Category 2: Pre-programmed Hearing Aids for Adults (18+ years) |  |  |
| Category 3: Programmable Hearing Aids for Pediatrics |  |  |
| Category 4: Earmolds |  |  |
| Category 5: Hearing Aid Batteries |  |  |

**C – INTERNATIONAL COVERAGE**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** |  |
| Ability to supply UNICEF worldwide |  |  | If No, elaborate on geographical limitations: |
| Ability to provide worldwide technical support |  |  | If No, elaborate on geographical limitations: |

**D - COMPLIANCE WITH INTERNATIONAL QUALITY STANDARDS**

|  |  |  |
| --- | --- | --- |
| **Quality Management System (company):** | **Yes** | **No** |
| ISO 9001 |  |  |
| ISO 13485 |  |  |

|  |  |  |
| --- | --- | --- |
| **Market Clearance(s) (product):** | **Yes** | **No** |
| Australia: TGA Device Licence |  |  |
| Canada: Device Licence |  |  |
| European Union: CE 93/42 Medical Device Directive (MDD) Mark |  |  |
| Japan: Device Licence |  |  |
| USA: 510k market clearance |  |  |
| ***If others, please specify:*** | | |

**E - COMPLIANCE WITH PRODUCT STANDARDS**

|  |  |  |
| --- | --- | --- |
| **Current product standards for hearing aids:** | **Yes** | **No** |
| IEC 60118-0: 2015 |  |  |
| ANSI S3.22: 2014 |  |  |

**F – ACCESS TO PRODUCT INFORMATION**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** |  |
| Product information available on-line |  |  | If Yes, specify web address: |
| Product catalogue available on-line |  |  | If Yes, specify web address: |
| Product technical specifications available on-line |  |  | If Yes, specify web address: |
| Please include a PDF copy product information and technical specifications if it is not accessible online |  |  | If Yes, please send PDF attachments. |
| Other ways of providing access to product information |  |  | If Yes, specify which way(s): |

**G- ADDITIONAL INFORMATION**

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| Registered with UNGM ([www.ungm.org](https://www.ungm.org/))? |  |  |
| Please provide UNGM reference if available |  | |
| Additional comments: | | |

**On completion, please return this form to UNICEF by email to:**

**Annie Wang** **(**[**anwang@unicef.org**](mailto:anwang@unicef.org)**) with Dan Ilie (**[**dilie@unicef.org**](mailto:dilie@unicef.org)**) in copy on or before 11th of December 2020.**