QUESTIONS
APS SOL-OAA-13-000024
UNMET NEEDS

[ANSWERS ARE INDENTED AND IN ITALICS]

1. With regard to Aims 1 and 2, do "existing methods" include only products already approved or available in the market? If so, where do the "existing" products need to be approved or available?

   Yes, "existing" methods are those that are approved by a Stringent Regulatory Authority (SRA) and/or have WHO prequalification (PQ), and are available in any market.

2. Aim 2 calls for a response to product-related issues about currently available methods, but Priority A includes new or existing methods. Are new methods/products (not yet approved or available in the market) actually included in Aim 2?

   Any method addressed under Aim 2 has to be SRA approved and/or have WHO PQ, and currently available in some market. Given that, a method that is new to a particular country market can be included under Priority A.

3. Should the budget for this proposal cover the period of performance from 2015 to 2023?

   Yes. (See pg. 7 of the solicitation.)

4. Is this concept paper to be submitted via email to Mr. Terry Ellis (tellis@usaid.gov)? Who else should we copy (Cc line)?

   All future correspondence should be submitted to Ms. Jacquelin Bell (jacbell@usaid.gov).

5. Under Aim 1, does USAID view "refine existing FP methods" as limited to biomedical technology solutions?

   Yes – all approaches should address refinements to the physical properties of the product in order to reduce side effects and/or enhance provision.

6. Under Aim 1, would socio-behavioral research be considered within the scope of this call?

   No – socio-behavioral research is the mandate of USAID's Evidence project. Also see the answer to #5.

7. Since fertility awareness methods and vaginal rings were targeted under Objective 4 of Round 1 of this APS and this round (Round 2) focuses on Objectives 1 – 3, should we exclude these methods from our proposal?

   Any currently available method could be considered as illustrative examples of capacity in responding to either Aim 1 or 2.

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8. Since MPTs were targeted under Objective 5 of Round 1 of this APS and this round focuses on Objectives 1 – 3, should we exclude MPT research ideas from our proposal?
   MPTs are excluded from Round Two.

9. Would operations research that addresses improvements to service delivery options be considered within the scope of this call?
   No – please see the answers to #5 and 6.

10. Given the cost of contraceptive development, how early in the product development process is USAID willing to fund research proposed under Aim 3 of this APS?
    The innovative nature of the proposed research is more important than its stage of product development. (Please be mindful of the budget information for Aim 3, as provided in the solicitation on pg. 6; this level is intended for the duration of the project.)

11. Is this APS intended to support only products that are in later stages of development (i.e. products that will be available on the market during the timeframe of this APS)? Will preclinical activities be supported?
    Please see the answer to #10.

12. Will this APS support clinical trials?
    Yes, to the extent that available funding allows. (Please see the anticipated budget information provided on pg. 7 of the solicitation.)

13. Will this APS support development of MPT products combining contraception with HIV and/or STI prevention?
    Please see the answer to #8.

14. Is the use of a new molecule in an existing device (i.e. a vaginal ring or IUS) considered responsive to Aim 1 (refining existing methods)? Or would that be considered developing new methods (Aim 3)?
    If the use of a new molecule in an existing device were specifically to address method-related reasons for non-use, then that would respond to Aim 1. Otherwise, it should be considered under Aim 3.

15. If a nonprofit organization leads a bid with a for-profit partner, will the for-profit entity be expected to forego profit beyond the duration of the award (i.e. in perpetuity for as long as the product is available)?
    No – USAID cannot restrict profit beyond the duration of the award. However, preferential pricing for the public sector would be an expectation of any award, and would be part of the final negotiation with the Agreement Officer.

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16. Please clarify the duration of the award.
    As stated on pg. 7 of the solicitation, the potential maximum period of performance is from October 1, 2015 to September 30, 2023.

17. Please clarify submission process (i.e. email contact(s) and closing date/time) for the concept paper.
    As stated on pg. 6 of the solicitation, the deadline for submission of Round Two concept papers is February 27, 2015. Specifically, the deadline is 5:00pm ET on that date. All concept papers should be submitted via email to Ms. Jacquelin Bell (jacbell@usaid.gov).

18. Would USAID consider concept notes that include Sayana Press or does USAID consider this product to be sufficiently covered under other projects/funding mechanisms?
    Sayana Press can be included as an illustrative example of capacity.

19. Would USAID consider concept notes that include the SILCS Diaphragm, the Woman's Condom and vaginal rings or does USAID consider these products to be sufficiently covered under awards issued in Round 1 of this APS?
    These products can be included as illustrative examples of capacity.

20. The general APS objectives include development of multipurpose prevention technologies; however the specific objectives for Round Two make no mention of MPTs. Would USAID consider concept notes for Round 2 that include one or more MPTs?
    Please see the answer to #8.

21. Under Aim 1, the APS highlights as a priority *research addressing current and future method-related reasons for non-use or discontinuation.* Could USAID advise as to whether there is any similar or related research planned under the Evidence project?
    Please see the answer to #6.

22. The APS lists four research priorities under Aim 3. Are applicants required to address all 4 priorities?
    No; applicants can address any priority, or others not listed.

23. In instances where a product or device does not yet have stringent regulatory authority approval, will USAID cover commodity costs associated with acceptability or other small scale research along the R&D pathway?
    Yes, so long as the procurement of commodities is for research purposes only, and not for introduction.

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24. Under measurement and evaluation, the APS lists "the number of new products approved by the US Food and Drug Administration or other stringent regulatory authority". Could USAID confirm that applicants can budget/plan for costs and activities associated with FDA or other SRA approval?
    Yes -- confirmed.

25. Is USAID open to inclusion of new female and/or male condoms in concept notes responding to this APS?
    Yes – they can be included as illustrative examples of capacity.