REQUEST FOR PROPOSAL (RFP)

Title: Request for manufacturing of affordably priced, quality-assured ferric carboxymaltose (FCM) for use in low- and middle-income countries (LMICs)

RFP Number: RFP-MA001-SECURE

Issue Date: Wednesday 24 June

Deadline for Questions: Friday 10 July

Closing Date: Friday 31 July (Midnight UTC)

Section 1: Background and Context

1.1 About the SUPREME-SECURE Project

SUPREME (Sustained Uptake of Products for Pre-Eclampsia and Maternal Anemia) is a Unitaid-funded initiative designed to catalyze equitable access to quality-assured diagnostics and therapeutics for the prevention, diagnosis, and management of preeclampsia/eclampsia and maternal anemia across sub-Saharan Africa. The program operates across two complementary projects: SUPREME-SECURE and SUPREME-LIFELINES.

SUPREME-SECURE (Sustainable Equitable Care and Universal Resources for Eclampsia and Anemia) is a four-year project (2026–2029) implemented by a consortium led by the Clinton Health Access Initiative (CHAI), in partnership with Aurum Institute, Burnet Institute, Concept Foundation, and WACI Health. The project addresses a critical unmet need: despite the existence of effective, low-cost interventions, preeclampsia and maternal anemia remain leading drivers of maternal and neonatal mortality in low- and middle-income countries (LMICs), largely due to fragmented markets, weak regulatory systems, poor quality assurance, and insufficient supply chain integration. This RFP is part of a broader global initiative involving various donors and partners, including Gates Foundation and Unitaid's Regional Manufacturing Initiative implemented by USP, to increase access to maternal health products.

SUPREME-SECURE operates across four strategic outputs:

- Evidence generation: verification and validation of new diagnostic products, and operational research to inform deployment.
- Demand generation, advocacy, and community and civil society engagement: multi-level stakeholder engagement to build awareness and drive product uptake.
- Product access: market assessments, manufacturer engagement, technical assistance, market shaping, and regulatory support to improve the availability of quality-assured products.
- Country adoption and scale-up: country-level market intelligence, product introduction planning, registration support, and catalytic procurement in full and selective implementation countries.

Manufacturers selected through this process may be eligible to receive technical and/or financial support.

1.2 About CHAI and Unitaid

The Clinton Health Access Initiative (CHAI) is a global health organization committed to catalyzing access to high-quality, low-cost drugs and diagnostics and strengthening integrated health systems in resource-limited settings.

Unitaid is a global health agency hosted by the World Health Organization. Unitaid invests in finding innovative solutions to prevent, diagnose, and treat diseases more quickly, cheaply, and effectively in LMICs. Unitaid's work includes funding initiatives to address major diseases including HIV/AIDS, malaria, tuberculosis, as well as co-infections and co-morbidities. SUPREME-SECURE is funded by Unitaid under its portfolio on improving access to lifesaving tools for the prevention, diagnosis, and management of preeclampsia and maternal anemia. For more information, please visit www.unitaid.org.

1.3 Implementation Countries

SUPREME-SECURE operates in several sub-Saharan African countries, with specific implementation varying by product. For this RFP, the target countries are:

- Ghana

- Kenya
- Malawi
- Senegal
- Tanzania
- Nigeria

In addition to these primary implementation countries, SUPREME-SECURE's market shaping activities are designed to generate access commitments and regulatory filings that benefit LMICs globally. Bidders are therefore encouraged to consider access pricing, registration strategies, and supply commitments that extend beyond the immediate project countries.

Section 2: Product Scope and Market Context

2.1 Target Product

Product Name/ International Nonproprietary Names (INN)	Ferric carboxymaltose (FCM)
Target Indication[1]	Moderate to severe iron-deficiency anemia in pregnant women (second and third trimester) and postpartum women
Formulation(s) of Interest	500 mg/10 mL vials 1000 mg/20 mL vials
Patent Status	Originator patent expired

2.2 Market Overview

Ferric carboxymaltose (FCM) is an intravenous iron product with a growing body of clinical evidence supporting its use in the treatment of moderate-to-severe iron deficiency anemia in pregnant and postpartum women, including in sub-Saharan Africa. Despite its demonstrated clinical value, access across sub-Saharan Africa remains constrained by the following key barriers:

- *High commodity price*
- *Lack of inclusion in guidelines/EML*
- *Limited product registration*
- *Weak delivery infrastructure and supply chains*
- *Low clinical awareness and limited IV iron training*

Section 3: Objective and Scope of the RFP

3.1 Objective

Under SUPREME-SECURE, CHAI is issuing this open Request for Proposals (RFP) to identify and select one or more manufacturers to receive technical assistance and/or financial incentives to accelerate the development, registration, and market access of quality-assured, affordable FCM in LMICs. This RFP is part of a broader global initiative involving various donors and partners, including Gates Foundation and

[1] Per WHO context specific recommendation: https://www.who.int/publications/i/item/9789240115637

Unitaid's Regional Manufacturing Initiative implemented by USP, to increase access to ferric carboxymaltose and other maternal health products.

This RFP is open to all eligible manufacturers as defined in Section 4. It is posted publicly on the CHAI website (www.clintonhealthaccess.org) and the websites of relevant SUPREME-SECURE consortium partners to ensure equitable access. Manufacturers meeting the eligibility criteria are actively encouraged to apply.

The product-specific goals of the SUPREME program include:

- Increase access to quality-assured supply (e.g., WHO Prequalification, SRA approval, WLA approval[2], or WHO Expert Review Panel) of 500 mg / 10 mL and/or 1000 mg / 20 mL FCM injectable.
- Reduce the price of the product in LMIC markets.
- Accelerate registration of the product in all six SECURE implementation countries.
- Ensure the sustainable supply of quality-assured product.

3.2 Scope of Work

The Successful Bidder(s) will be required to perform the following activities, in an accelerated manner and in accordance with the timelines agreed during the program support contracting process:

Product Development

- If supplier does not have SRA or WLA approval for their FCM injectable, conduct necessary activities to develop or strengthen current manufacture of FCM API (i.e., the iron carboxymaltose complex). Activities may include but are not limited to: API development, formulation development, analytical method development and validation, stability studies, and/or other studies, such as those required by the US FDA Draft Product Specific Guidance on FCM.[3]

Quality & Regulatory

- Host and pass a quality site inspection of applicable manufacturing sites if selected for the award.
- Prepare and submit regulatory dossiers for FCM 500 mg / 10 mL and/or 1000mg / 20 mL injectable to WHO Prequalification (if available), the WHO-coordinated Expert Review Panel (ERP) (if available), a Stringent Regulatory Authority (SRA) or a WHO Listed Authority (WLA) in accordance with timelines agreed during contracting.
- Undertake product registration in the following countries, in accordance with agreed timelines: Ghana, Kenya, Malawi, Senegal, Tanzania, and Nigeria
- Maintain valid product registrations in target countries for the duration of the program support agreement.

Commercialization and Supply

- Host and pass a financial forensics audit, potentially to be conducted by an independent third-party, if selected for award.
- Supply FCM to eligible procurement entities at or below an agreed access price for a period and under terms to be specified in the program support contract.

[2] https://www.who.int/initiatives/who-listed-authority-reg-authorities
[3] https://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_203565.pdf

- Prepare a production and supply plan demonstrating the capacity to supply qualified orders, with a standard manufacturing lead time not to exceed 120 days and demonstrating scale-up capacity in line with projected demand.
- Engage with relevant global and regional procurement platforms (including but not limited to APPM, AxMed, UNFPA, Medipool, WAHO, and EAC) to list the product and enable broad procurement access.

Collaboration and Reporting

- Establish a joint project team structure with CHAI and participate in regular project meetings (in person and/or via videoconference) as required.
- Submit regular progress reports to CHAI as defined in the program support contract, covering development milestones, regulatory activities, and commercialization plans.
- Provide transparency on funding received or pending from other donors or stakeholders for overlapping activities related to this product.
- Acknowledge Unitaid's funding support in public communications related to activities conducted under this program, as required under the terms of the program support contract.

Section 4: Eligibility Criteria

The RFP is open to companies that meet all the following minimum eligibility criteria. Proposals from manufacturers that do not satisfy all eligibility criteria will not be considered for further evaluation.

- Manufacturer produces a commercialized 500 mg / 10 mL and/or 1000 mg / 20 mL FCM injectable product.
- The manufacturer has:
    - SRA or WLA approval for their 500 mg / 10 mL and/or 1000 mg / 20 mL FCM injectable product

    OR

    - Received SRA approval, WLA approval, WHO PQ, or a positive opinion from the WHO ERP for a sterile injectable product and is interested in submitting their 500 mg / 10 mL and/or 1000 mg / 20 mL FCM injectable for SRA approval, WLA approval, WHO Prequalification (if available), or the WHO-coordinated Expert Review Panel (ERP) (if available).
- The manufacturer demonstrates financial stability and commits to hosting a financial forensics audit.
- Manufacturer must agree to host a quality site inspection of applicable manufacturing sites if selected for award.
- Manufacturers must agree to establish a project team structure that includes CHAI membership as well as host regular meetings (in person or via telecom) as/when required.
- The manufacturer has sufficient production capacity to supply qualified orders in target countries. Initial landscaping conducted by CHAI provides a high-level indication of potential demand for FCM across a subset of LMIC markets; this work is publicly available here.

Section 5: Instructions to Bidders

5.1 What to Submit

Bidders are required to submit a complete proposal package consisting of the following components:

1. **Annex I - Declaration (Form A):** Completed, signed, and dated declaration confirming the accuracy of information submitted and the Bidder's agreement to the terms of the RFP.
2. **Annex II - Quality Audit Agreement (Form B):** Completed and signed agreement confirming the Bidder's willingness to host a quality audit of applicable manufacturing sites.
3. **Annex III - Financial Forensics Audit Agreement (Form C):** Completed and signed agreement confirming the Bidder's willingness to host a financial forensics audit.
4. **Annex IV - RFP Excel Questionnaire:** Fully completed RFP response questionnaire (Excel format, attached separately). Please include any supporting documents as separate attachments rather than embedded within the Excel file.

All proposals must be submitted in English and must be signed by a duly authorized representative of the Bidder. Proposals received after the submission deadline will not be considered. No fee is required to submit a proposal.

Bidders are also required to disclose, in their technical and commercial narrative, any funding received from or pending with other donors or stakeholders for activities that overlap with the scope of work described in Section 3.2.

5.2 How to Submit

Proposals must be submitted in electronic format by email to: securerfp@clintonhealthaccess.org.

The subject line of the submission email must read: RFP-MA001-SECURE - [Bidder Organization Name]

Files should be submitted as PDF or Excel, as appropriate. Where supporting documents (e.g. certificates, audit reports) are included, these should be provided as separate attachments rather than embedded in the Excel questionnaire.

5.3 Enquiries and Q&A Process

All enquiries regarding this RFP must be directed to CHAI by email (securerfp@clintonhealthaccess.org). Unitaid and other consortium partners will not respond to RFP-related enquiries.

Following the release of this RFP, an informational session will be held (details in Section 6). After the informational session, a formal question period will be open to all potential Bidders. All questions must be submitted via email. Telephone enquiries will not be accepted.

All questions received by the deadline (details in Section 6) will be compiled into a single Q&A document, which will be published on the CHAI website and shared with all registered interested parties. This ensures that all potential Bidders have equal access to the same information. The Q&A document will be the sole mechanism for responding to queries after the information session; individual responses will not be provided.

5.4 Changes in Circumstances

Bidders must promptly notify CHAI in writing of any change in circumstances that may affect their eligibility or their capacity to perform the activities described in this RFP.

5.5 Costs of Preparing a Proposal

All costs associated with preparing and submitting a proposal are the sole responsibility of the Bidder. CHAI and Unitaid will not reimburse any such costs regardless of the outcome of the evaluation process.

5.6 Bid Validity

Proposals remain valid for a minimum of 120 days from the submission deadline. Proposals with a shorter validity period will be deemed non-responsive and will not be considered.

Section 6: Process and Timeline

6.1 Overview

The SUPREME-SECURE supplier selection process is subject to independent oversight by the Independent Review Panel (IRP). The process is designed to be transparent, competitive, and fair. The following dates are indicative and are subject to change. Bidders will be notified of any timeline changes.

Activity	**Indicative Date/Deadlines**
RFP posted publicly and released to potential Bidders	Wednesday 24 June
Informational session for potential Bidders	Thursday 02 July
Deadline for Bidder questions (email only)	Friday 10 July
Q&A document published on CHAI website	Friday 17 July
Proposal submission deadline	Friday 31 July
Shortlisted manufacturers notified	Friday 21 August
One-to-one manufacturer meetings	Monday 24 August – Friday 04 September
Shortlisted manufacturers submit revised RFP responses	Friday 11 September
Selected manufacturer (s) notified	Mid-October (TBC)

6.2 Informational Session [TBC]

An informational session will be held on Thursday 02 July via videoconference. All interested manufacturers are invited to attend. Details for joining the session will be posted on the CHAI website (www.clintonhealthaccess.org) and on relevant SUPREME-SECURE consortium partner websites.

Following the informational session, all further enquiries must be submitted in writing via the Q&A process described in Section 5.3.

Section 7: Evaluation Process and Criteria

7.1 Evaluation Criteria

CHAI will form an evaluation committee to review the bids. To be successful, the Bidder must demonstrate the availability of the required production and distribution structures to meet the demands of major donors and governments and have demonstrated experience registering and supplying products to the focal countries indicated by the project.

The Evaluation Committee will assess each eligible proposal based on technical and financial criteria. The technical assessment includes manufacturing capability and capacity, proposed API, product development plans, bioequivalence and regulatory strategy, prior experience, quality track record and proposed overall timelines. The financial criteria will focus on access price proposed by manufacturers, along with associated terms and supply conditions. Supply conditions may include, among other things, conditions on minimum order size and lead times. Beyond the initial access price, manufacturers may also provide a pricing schedule related to procurement volumes and terms which may attract a lower price and better value for money or incentives award and other support to be provided; price reductions due to economies of scale through procurement would be given consideration.

In addition to the criteria above, the evaluation team will consider environmental and climate-smart manufacturing practices, including energy efficiency, sustainable packaging, and regional production, as a secondary consideration in the evaluation. Gender-related organizational policies (e.g. female leadership and workforce representation) will also be noted. These considerations will not constitute primary selection criteria but will be factored into the overall assessment where proposals are otherwise comparable.

Section 8: Nature and Conditions of Program Support

8.1 Types of Support Available

SUPREME-SECURE may provide the following types of program support to Successful Bidders, subject to IRP verification and Unitaid approval:

- **Technical Assistance:** Subject matter expertise provided directly by CHAI or through third-party consultants in areas including product development, formulation optimization, analytical method development, regulatory strategy, dossier preparation, and quality management systems. Assistance with preparation and submission of regulatory dossiers is also included; specifically, to WHO Prequalification, the WHO-coordinated ERP (if available), SRAs, WLAs, and national regulatory authorities in SUPREME-SECURE implementation countries.
- **Financial Incentives:** Milestone-linked financial grants to offset late-stage development costs, regulatory filing fees, or capital expenditure, as justified by the Bidder and approved by the IRP and Unitaid. The availability and quantum of financial incentives is subject to the outcome of the evaluation and due diligence process of selected manufacturer(s).

8.2 Conditions of Program Support

Program support will be subject to the following conditions, to be formalized in a program support contract between CHAI and the Successful Bidder:

- Development and commercialization timelines agreed during the contracting process, including key milestone dates.
- Milestone-linked disbursement of financial incentives, where applicable. Incentive payments will generally be linked to late-stage activities (e.g. WHO PQ submission, country registration, first

supply to eligible procurement entities) to ensure the manufacturer receives funding only upon meeting agreed targets.
- Agreed access price for eligible procurement entities for the duration of the grant period and beyond, with associated terms and supply conditions.
- Country registration commitments in SUPREME-SECURE implementation countries, in accordance with agreed timelines.
- Transparency on progress, including regular reporting to CHAI and openness to quality audits and financial forensics audit.
- Acknowledgement of Unitaid's funding support in relevant public communications.
- Termination clause: failure to achieve a minimum set of agreed milestones may result in termination of the program support contract and forfeiture of any remaining incentive payments.

Program support contracts are subject to Unitaid's review and approval prior to execution.

Section 9: Reservation of Rights and Legal Disclaimer

This RFP must not be construed as a recommendation, offer, or invitation to enter into a contract, agreement, or any other arrangement. It is an invitation for the submission of proposals only and does not legally oblige CHAI to accept any proposal in whole or in part. The issuance of this RFP does not create any contractual obligations or binding legal relationship between any Bidder and CHAI until and unless CHAI issues a formal Letter of Acceptance and a program support contract is signed by duly authorized representatives of both parties.
CHAI and Unitaid make no representation or warranty, and shall incur no liability, as to the accuracy, reliability, or completeness of the information contained in this RFP.

CHAI and Unitaid will not reimburse or otherwise bear any costs associated with the preparation and submission of a proposal in response to this RFP. No fee is required to submit a proposal.

Information submitted in response to this RFP that the Bidder considers to be commercially confidential or proprietary should be clearly marked as such. CHAI and Unitaid will take all reasonable measures to protect such information and will not share it with any entity or individual outside the evaluation process without the Bidder’s prior written authorization, except where such information: (a) was already known to CHAI or Unitaid prior to disclosure; (b) was in the public domain at the time of disclosure; (c) subsequently enters the public domain through no fault of CHAI or Unitaid; or (d) becomes available from a third party not in breach of any obligation of confidentiality to the Bidder. Information not marked as confidential will not be shared in a manner that identifies individual manufacturers without their authorization, but may be used in anonymized or aggregated form.

All enquiries regarding this RFP must be directed to CHAI the contact details set out in Section 5.3. Neither Unitaid nor any other consortium member will respond to RFP-related enquiries.

CHAI and the evaluation committee reserve the right to:
- Accept or reject any or all proposals, in whole or in part, without assigning reasons and without incurring any liability to any Bidder.
- Annul the RFP process, in whole or in part, at any time without prior notice.
- Add, modify, alter, or revoke the RFP and any of its terms and conditions, with notification to Bidders who have already registered their interest or submitted proposals.
- Extend any deadline set out in this RFP.
- Request additional information, arrange interviews or presentations, visit facilities, or conduct audits to verify information provided by Bidders.

- Shortlist more or fewer Bidders than indicated in this RFP if, in the evaluation committee's judgement, this is warranted by the quality of proposals received.
- Award program support to more than one manufacturer for a given product, where this is consistent with the project goals and the approved product support justification.

Please review and sign the following pages.

Annex I: Declaration (Form A)

This form must be completed, signed, and returned to CHAI.

DECLARATION

I, the undersigned, having read the RFP for Ferric Carboxymaltose (FCM) 500 mg / 1000 mg our proposal, which includes the information requested in Section 5. We confirm that all the information provided is correct.

We confirm that we are interested in entering discussions for a possible collaboration with CHAI on the development, manufacture, filing to WHO PQ, the WHO-coordinated ERP, SRAs, WLAs, and national regulatory authorities in SUPREME-SECURE implementation countries, and commercialization of FCM 500 mg / 1000 mg according to the terms of this RFP.

We understand that CHAI's issue of the RFP and the proposal we submit is not a commitment by either party to enter into such discussions or collaboration. We further understand that CHAI reserves the right to discuss and collaborate with one or multiple parties, no parties, or to cancel this RFP at its sole discretion.

This RFP and any proposals thereto shall be the property of CHAI.

I, who am duly authorized to act on behalf of the above-named organization, hereby certify that:

- The information provided in this proposal, including all annexures and supporting documents, is accurate, complete, and not misleading.
- The organization I represent is eligible to participate in this RFP and meets all eligibility criteria set out in Section 4.
- The organization I represent agrees to comply with the Compliance with WHO Code of Ethics; the WHO Policy on Preventing and Addressing Sexual Misconduct; the WHO Policy on Preventing and Addressing Abusive Conduct; the WHO Code of Conduct for Responsible Research; the WHO Policy on Preventing and Addressing Retaliation; the WHO Policy on Prevention, Detection and Response to Fraud and Corruption; and the UN Supplier Code of Conduct, in each case as amended from time to time, and which are publicly available on the WHO website at the following links: http://www.who.int/about/finances-accountability/procurement/en/ for the UN Supplier Code of Conduct and http://www.who.int/about/ethics/en/ for the other WHO Policies.
- No official, employee, or officer of CHAI, Unitaid, or any consortium partner has received or has been offered any individual benefit in connection with the preparation or submission of this proposal.

Name of authorized representative:	_____
Title:	_____

Signature:	_____
Date:	_____
Company name:	_____
Postal address:	_____
Telephone number:	_____
Email address	_____

Annex II: Quality Audit Agreement (Form B)

This form must be completed, signed, and returned to CHAI.

QUALITY AUDIT AGREEMENT

The organization named below (the "Bidder") hereby agrees that, in the event it is selected as a Successful Bidder under this RFP, it will provide permission for CHAI and/or its designated representative to conduct a quality assurance and cGMP audit of all applicable manufacturing sites (including API and FDF manufacturing, as relevant), in order to verify compliance with cGMP standards as per WHO Prequalification requirements or equivalent SRA or WLA standards.

Such audits may be conducted by an independent third-party consultant appointed by CHAI. Audits will be scheduled directly with the Bidder following the award of program support. The Bidder agrees to provide reasonable access to relevant personnel, documentation, and facilities during the audit.

This agreement does not constitute a commitment by CHAI to award program support to the Bidder.

Organization / Company	_____
Name of authorized representative	_____
Title	_____
Signature	_____
Date	_____

Annex III: Financial Forensics Audit Agreement (Form C)

This form must be completed, signed, and returned to CHAI.

FINANCIAL FORENSICS AUDIT AGREEMENT

The organization named below (the "Bidder") hereby agrees that, in the event it is selected as a Successful Bidder under this RFP, it will provide permission for CHAI and/or its designated representative to conduct a financial forensics audit of the Bidder's relevant financial records and accounts, in order to assess the Bidder's financial capacity to perform the activities outlined in this RFP.

Such audits may be conducted by an independent third-party consultant appointed by CHAI. Audits will be scheduled directly with the Bidder prior to or following the award of program support. The Bidder agrees to provide reasonable access to relevant personnel, documentation, and facilities during the audit.

This agreement does not constitute a commitment by CHAI to award program support to the Bidder.

Organization / Company	_____
Name of authorized representative	_____
Title	_____
Signature	_____
Date	_____

Annex IV: RFP Questionnaire

The RFP Excel Questionnaire is provided as a separate attachment to this document and must be completed and submitted as part of the proposal package.

The Questionnaire is structured in the following sections:

Tab	Section Title	Content
A	**Instructions**	Legal name, registered address, key contact details, company overview, and authorized signatory.
B	**General**	Legal name, registered address, key contact details, company overview, and authorized signatory.
C	**API Info**	Current product development status, manufacturing site details, API sourcing, FDF manufacturing capacity, quality certifications, and cGMP compliance.
D	**FDF**	
E	**Regulatory Approvals**	Current regulatory approvals (WHO PQ, SRA, national) and target country registration plan.
F	**Regulatory Strategy**	If product does not have SRA or WLA approval, Proposed activities, timelines, and risks for regulatory filing.
G	**Costs**	Estimated capital expenditure and regulatory filing fees required to achieve WHO Prequalification or equivalent quality-assured regulatory approval.
H	**Pricing**	Dosage form, final packaging, and pack size details; API and FDF pricing (ex-works, USD) across volume tiers; minimum order quantity; and any other supply conditions.
I	**Gender & Climate**	Organizational policies and practices relating to gender equity in the workplace and environmental sustainability.
J	**Additional Information**	Questions that are optional to answer and will not be used for evaluation.

Supporting documents (e.g. cGMP certificates, audit reports, prior regulatory approvals) should be submitted as separate file attachments. Please do not embed documents within the Excel file.

Bidders should not alter the structure of the tabs or the questions. Where a question is not applicable, please indicate N/A and provide a brief explanation.