Q&A Document

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

RFP Closing Date: Friday 24 July (Midnight UTC)

Question ID	Question	Response
Q1	Is SRA/WLA Registration Approval for FCM mandatory to participate for the RFP?	As indicated in Section 4 (Eligibility Criteria) of the RFP document, the RFP is open to companies that meet all the minimum eligibility criteria. Proposals from manufacturers that do not satisfy all eligibility criteria will not be considered for further evaluation. This includes the requirement that 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-coordinated 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).
Q2	Please inform about the year wise volumes procurement plan	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. More detailed, country-specific volumes will be provided to manufacturers who progress through the RFP process.
Q3	If product is ready at R&D level and Manufacturing Site has FCM Manufacturing capability and EU-GMP Approval for the site in process, then is the above requirement relaxed?	As indicated in Section 4 (Eligibility Criteria) of the RFP document, the RFP is open to companies that meet all the minimum eligibility criteria. Proposals from manufacturers that do not satisfy all eligibility criteria will not be considered for further evaluation. This includes the requirement that the manufacturer produces a commercialised 500 mg / 10 mL and/or 1000 mg / 20 mL FCM injectable product.
Q4	How much funding value being granted	As indicated in Section 8 (Nature and Conditions of Program Support) of the RFP document, SUPREME-SECURE may provide the following types of program support to Successful Bidders, subject to IRP verification and Unitaid approval: 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).
Q5	Will multiple suppliers be selected?	The number of suppliers that will be selected through the RFP process will depend on the volume and quality of the submissions received, in addition to market alignment and demand. It is possible that more than one supplier will be selected. The RFP document is designed to allow for either a single or multiple manufacturers to be selected.
Q6	Are distributors allowed also to bid or fill the form on behalf of the manufacturer?	As indicated in Section 4 (Eligibility Criteria) of the RFP document, the RFP is open to companies that meet all the minimum eligibility criteria. Proposals from manufacturers that do not satisfy all eligibility criteria will not be considered for further evaluation. This includes the requirement that the manufacturer produces a commercialised 500 mg / 10 mL and/or 1000 mg / 20 mL FCM injectable product. As such, a distributor may submit a response if they are the Market Authorization Holder for the FCM injectable product. Otherwise, a distributor may not submit a response on behalf of the manufacturer. *This response is an update from the verbal response shared during the live RFP Information Session. We apologise for any confusion.*
Q7	The RFP requires applicants to manufacture a commercialized Ferric Carboxymaltose (FCM) injectable product. Is a commercialized product mandatory at the time of proposal submission, or are manufacturers with an FCM product currently under development also eligible to apply?	As indicated in Section 4 (Eligibility Criteria) of the RFP document, the RFP is open to companies that meet all the minimum eligibility criteria. Proposals from manufacturers that do not satisfy all eligibility criteria will not be considered for further evaluation. This includes the requirement that the manufacturer produces a commercialised 500 mg / 10 mL and/or 1000 mg / 20 mL FCM injectable product.
Q8	Is an operational sterile injectable manufacturing facility mandatory at the time of application, or can this	As indicated in Section 4 (Eligibility Criteria) of the RFP document, the RFP is open to companies that meet all the minimum eligibility criteria. Proposals from manufacturers that do not satisfy all eligibility criteria will not be considered for further evaluation.

	capability be established during the project period with support available through the program?	This includes the requirement that the manufacturer produces a commercialised 500 mg / 10 mL and/or 1000 mg / 20 mL FCM injectable product. As such, an operational sterile injectable manufacturing facility is mandatory at the time of application.
Q9	Can a manufacturer that does not currently meet the minimum eligibility criteria participate through a partnership model where manufacturing, regulatory, commercialization, or market access responsibilities are shared?	As indicated in Section 4 (Eligibility Criteria) of the RFP document, the RFP is open to companies that meet all the minimum eligibility criteria. Proposals from manufacturers that do not satisfy all eligibility criteria will not be considered for further evaluation.
Q10	Are technology transfer, licensing, or contract manufacturing (CMO) arrangements acceptable under this RFP? If yes, must the manufacturing partner be identified at the time of proposal submission?	Yes, these types of arrangements are acceptable if the RFP applicant is the Market Authorization Holder for the FCM injectable product. Yes, the manufacturing partner must be identified at the time of proposal submission.
Q11	Would manufacturers with established GMP-compliant pharmaceutical manufacturing operations and regulatory experience, but without current sterile injectable manufacturing capability, be considered under any implementation model supported by this RFP?	As indicated in Section 4 (Eligibility Criteria) of the RFP document, the RFP is open to companies that meet all the minimum eligibility criteria. Proposals from manufacturers that do not satisfy all eligibility criteria will not be considered for further evaluation. This includes the requirement that the manufacturer produces a commercialised 500 mg / 10 mL and/or 1000 mg / 20 mL FCM injectable product. As such, a manufacturer without sterile injectable manufacturing capability would not be considered eligible.
Q12	Is PICS / EU GMP considered SRA/WLA. In essence if the product are manufactured in an accredited GMP which has either certificate, would the GMP qualify for submission for bid?	Evidence of PICS / EU GMP is not equivalent to SRA / WLA approval. However, the manufacturer may still be eligible if they have received SRA approval, WLA approval, WHO Prequalification, or a positive opinion from the WHO-coordinated Expert Review Panel for a different sterile injectable product, and the manufacturer is interested in submitting its FCM injectable for one of these approval routes. All other eligibility criteria in Section 4 must also be met.
Q13	The bid requires pricing FOB / EX Works, thus will all the Logistics be covered by SECURE and Team?	As indicated in Section 8 (Nature and Conditions of Program Support) of the RFP document, SUPREME-SECURE may provide the following types of program support to Successful Bidders, subject to IRP verification and Unitaid approval: 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). Logistics and shipping costs associated with product supply are outside the scope of program support.
Q14	Is there a preferred strength of the FCM, either the 500 mg / 10 Ml or the 1000 mg / 20 mL?	The formulations of interest are 500 mg/10 mL vials and 1000 mg/20 mL vials. This RFP is open to manufacturers who produce a commercialised 500 mg / 10 mL and/or 1000 mg / 20 mL FCM injectable product. Successful RFP applicants will be expected to pursue both 500 mg/10 mL vial and 1000 mg/20 mL vial presentations if selected.
Q15	Please could you assist us with some information on yearly best estimates (Quantities) of 500 mg / 10 Ml and/or 1000 mg / 20 mL FCM injectable per African country, for the below: • Kenya • Malawi • Senegal	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. More detailed, country-specific volumes will be provided to manufacturers who progress through the RFP process.

	• Tanzania • Nigeria • Ghana	
Q16	What is the maximum funding available for FCM Product?	As indicated in Section 8 (Nature and Conditions of Program Support) of the RFP document, SUPREME-SECURE may provide the following types of program support to Successful Bidders, subject to IRP verification and Unitaid approval: 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).
Q17	What are the presentations CHAI is interested to source from the manufacturers? Can the applicant seek funding for any one of the presentations? If so what is the maximum funding for each of the SKU?	The formulations of interest are 500 mg/10 mL vials and 1000 mg/20 mL vials. This RFP is open to manufacturers who produce a commercialised 500 mg / 10 mL and/or 1000 mg / 20 mL FCM injectable product. Successful RFP applicants will be expected to pursue both 500 mg/10 mL vial and 1000 mg/20 mL vial presentations if selected. As indicated in Section 8 (Nature and Conditions of Program Support) of the RFP document, SUPREME-SECURE may provide the following types of program support to Successful Bidders, subject to IRP verification and Unitaid approval: 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).
Q18	Considering the FCM product will be manufactured in a facility approved by U.S and EU and quality of the product meets global regulatory standards, does CHAI still mandate SRA approval for this product?	SRA or WLA approval of the 500 mg / 10 mL and/or 1000 mg / 20 mL FCM injectable product is not required to apply for this RFP. As indicated in Section 4 (Eligibility Criteria) of the RFP document, the RFP is open to companies that meet all the minimum eligibility criteria. Proposals from manufacturers that do not satisfy all eligibility criteria will not be considered for further evaluation. This includes the requirement that 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-coordinated 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).
Q19	What is the expected volumes that CHAI will be sourcing from the manufacturer for each presentation during commercial manufacturing and supplies?	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. More detailed, country-specific volumes will be provided to manufacturers who progress through the RFP process.
Q20	Will CHAI work together with the manufacturer for expediting approvals from regulatory agencies in the markets of interest?	As indicated in Section 8 (Nature and Conditions of Program Support) of the RFP document, 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.
Q21	Will CHAI play the critical role for shaping the market for transitioning from current available products to	SUPREME 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

	FCM injection in the markets of interest?	operates across two complementary projects: SUPREME-SECURE and SUPREME-LIFELINES. SUPREME-SECURE is focused on the supply-side barriers to product access, operating 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. The product access strategic output includes market shaping work, that will be carried out by SECURE. SUPREME-SECURE works in close collaborate with SUPREME-LIFELINES, which is focused on the demand-side barriers to product access. More information about the SUPREME project is publicly available here.
Q22	What is the price expectations from CHAI for each of the presentations?	Access pricing will be jointly determined with the selected supplier, with critical consideration for the selected supplier's proposed access price, market demand, and the competitive landscape, among other factors. As part of SUPREME-SECURE it is expected that the selected supplier will collaborate with CHAI to both offer access pricing for FCM and demonstrate a commitment to sustainable supply to target markets.