Appendix No. 2 to the Request for Quotation No. 1.3
Consulting services for regulatory support in the registration of the medicinal product Insulin M30 in EMA

Scope of work with expected completion date

Below we present the scope of work that will be commissioned to the Tenderer by the Contracting Authority under **RFQ 1.3 - Consulting services for regulatory support in the registration of the medicinal product Insulin M30 in EMA**

Expected completion date:

Advisory services on EMA registration	**Expected completion date**
Stage I	
CMC Gap Analysis	from the date of conclusion of the contract within 2 months
Regulatory Action Plan	from the date of conclusion of the agreement within 1 month
Ad hoc consulting - service fee	from the date of conclusion of the contract within 2 months
Meetings and strategic project oversight	from the date of conclusion of the contract within 2 months
Stage II	
Non-Clinical Development Strategy/Plan	from the date of completion of Stage I within 1 month
Confirmation of the clinical trial protocol	from the date of completion of Stage I within 1 month
Scientific advice from EMA	from the date of completion of Stage I within 4 months
Ad hoc consulting - service fee	from the date of completion of Stage I within 4 months
Meetings and strategic project oversight	from the date of completion of Stage I within 4 months
Stage III (deadline for implementation by March 31, 2026)	
Preparation of immunogenicity biorelease	from the date of completion of Stage II within 1 month
Initial review of the registration dossier	from the date of completion of Stage II within 3 months
Ad hoc consulting - service fee	from the date of completion of Stage II within 3 months
Meetings and strategic project oversight	from the date of completion of Stage II within 3 months
Stage IV (stage planned to be implemented with own funds)	
Final Review of Registration Dossier	from the date of completion of Stage III within 2 months
Support in case of deficiencies during the central procedure (CP) (service fee)	from the date of completion of Stage III within 17 months or until the end of the EMA registration process
Ad hoc consulting - service fee	from the date of completion of Stage III within 17 months or until the end of the EMA registration process
Meetings and strategic project oversight	from the date of completion of Stage III within 17 months or until the end of the EMA registration process

Detailed scope of work:

Stage I

Task	Tenderer support	Support Description
CMC Gap Analysis	Leading	1. Expert review of CMC data to gain a complete understanding of product development history, challenges, and potential opportunities for streamlined development. 2. Scientific evaluation of available data, evaluation of data against relevant EMA requirements and linking to the SME assessment of existing precedents. 3. Discussing identified problems or threats with the Contracting Authority and developing recommendations for their mitigation. 4. Identify relevant, relevant questions for the EMA, if necessary. 5. Preparation of the final report, which includes: • Summary of the reviewed documentation • Summary of assessment and findings • Specific comments, impact assessment and recommended actions *As part of the task, the Tenderer will submit a maximum of two designs for verification by the Contracting Authority and one final version of the document approved by the Contracting Authority.*
Regulatory Action Plan	Preparation	1. The Tenderer will conduct a regulatory intelligence review to determine the minimum development requirements, which include the regulatory / product licensing strategy 2. The Tenderer will prepare a summary report outlining the relevant regulatory requirements and/or guidelines for each target country and the recommended order of interactions and regulatory submissions in that country/region *As part of the task, the Tenderer will submit one project for verification by the Contracting Authority and one final version of the document approved by the Contracting Authority.*

Stage II

Task	Tenderer support	Support Description
Non-Clinical Development Strategy/Plan	Preparation	The Tenderer will prepare a non-clinical plan containing an outline of recommended non-clinical studies, which will be carried out on the basis of data and documentation provided by the Contracting Authority and the objectives of the program and the Contracting Authority portfolio. *As part of the task, the Tenderer will submit one project for verification by the Contracting Authority and one final version of the document approved by the Contracting Authority.*
Confirmation of the clinical trial protocol	Confirmation	The Tenderer's medical, statistical and pharmacokinetic SME will carry out an independent quality review based on the Tenderer's standard SOP procedures and applicable guidelines of the provided Clinical Trial Protocol and prepare a report on the suitability of the provided protocol for the requested clinical trial. *As part of the task, the Tenderer will submit one report on the compliance of the Clinical Trial Protocol*
Scientific advice from EMA	Preparation	Drafting and writing a letter requesting scientific advice and submitting it to the EMA. *As part of the task, the Tenderer will submit a maximum of two designs for verification by the Contracting Authority and one final version of the document approved by the Contracting Authority*
Scientific advice from EMA	Preparation	Preparation and writing of the Information Package of Scientific Advice based on Contracting Authority summary documents. Expert Scientific Review (CMC, Non-Clinical, PK/PD, Clinical, Regulatory). *As part of the task, the Tenderer will submit a maximum of two designs for verification by the Contracting Authority and one final version of the document approved by the Contracting Authority*
Scientific advice from EMA	Review and discussion of implications	Facilitate discussion of EMA feedback to rationalise implications for further development

Stage III

Task	Tenderer support	Support Description
Preparation of immunogenicity biorelease	Preparation	SME Tenderers will prepare an immunogenicity biowaiver based on current EU guidelines for the nonclinical and clinical development of recombinant insulin products, which provide guidance on exemptions from safety/immunogenicity testing requirements prior to registration under certain conditions. *As part of the task, the Tenderer will submit one project for verification by the Contracting Authority and one final version of the document approved by the Contracting Authority*
Initial review of the registration dossier	Review	The Tenderer's SME will carry out an independent quality check of the registration dossier based on the Tenderer's standard SOPs and the applicable guidelines of the delivered design of the CTD modules and provide feedback to help finalise the modules. The budget will include full modules 1, 2, 3, 4 and 5. *As part of the task, the Tenderer will provide one module review project prepared by the Contracting Authority.*

Stage IV

Task	Tenderer support	Support Description
Final Review of Registration Dossier	Review	The Tenderer's SME will carry out an independent quality check of the registration dossier based on the Tenderer's standard SOPs and applicable guidelines for the final eCTD Modules delivered, as well as provide feedback to assist in the final update of the modules and their preparation for publication by the Contracting Authority and submission for registration with the EMA. *The budget will include full modules 1, 2, 3, 4 and 5.*