January 6, 2021

Call for tenders SANTE/2020/C3/091

DOCUMENT containing sensitive commercial information

Roche list of comments to the proposed Framework Contract (FWC)

Pursuant to the Call for tenders SANTE/2020/C3/091 for the supply of a combination COVID-19 medicinal product consisting of casirivimab and imdevimab, the negotiated procedure applies. For convenience and in the interest of time, Roche has provided further comments to individual sections of the contractual documents proposed which are listed below. Roche reserves the right to negotiate any additional items that are not explicitly mentioned below:

A. General	Comment
1. **Clarity regarding contracting parties**	• The FWC presupposes that the contractor for the FWC and the specific contracts are the same. The operating mother company F. Hoffmann-La Roche Ltd (FHLR) 5.1.2a will be the contracting party for the FWC. We assume this is compliant with the requirements as set forth in Section 2.2. of the tender specifications part I, administrative part (p.8). • The FHLR affiliates will be the contracting parties for the specific contracts with the national contracting authorities. We suggest to include a list of the FHLR affiliates once the country list is finalized. Accordingly, the proposed FWC will need to take into account that the Roche legal entities for implementation will vary according to the country in question.
2. **Missing: time frame for finalizing FWC**	• Given the dynamics of the current pandemic situation, a six month binding period during which Roche is bound by the offer may have the effect of reserving quantities during the peak time of the pandemic depriving patients of the product elsewhere. This causes significant concerns, in particular given the fact that global supply capacities are currently extremely limited.
3. **Missing: time frame for contracting authorities to sign binding specific contracts**	• Section II.4.1 does indicate that the FWC does not guarantee any actual purchase. Given the comments under A.2 above, contracting authorities must indicate by January 31, 2021 whether they wish to be bound by specific contracts (which enter into effect after marketing authorisation has been granted).

	• Ground for termination (k) in II.17 (k) particularly problematic against the background of the overall circumstances.
4. Missing: allocation management	• The FWC addresses in I.10.1 the allocation criteria (with reference to Annex I, i.e. technical tender specifications). However, this does not address the question of allocation management both on the level of all contracting authorities (i.e. participating countries) and on national level. Roche requests allocation to be handled by the EU Commission or steering committee as appropriate. • once Roche delivers the Product to the agreed point of delivery in the respective country, national distribution is either conducted by the local authorities or by Roche upon instruction of the national authorities, i.e. Roche does not handle allocation on national level. • Any re-allocation among contracting authorities shall be exclusively handled by the respective countries and/or the European Commission, i.e. Roche does not handle re-allocation among contracting authorities and Roche cannot shift the Product from one country to the other after delivery, see also our comment regarding Sections I.4 and I. 15.3 of the FWC. The financial reconciliation will be managed directly by the member states. • in this context it is important to clarify that Roche has fulfilled its obligations once the Product is delivered to the agreed upon point of delivery, no GDP responsibilities can apply to Roche thereafter
5. Missing: exclusivity	• Roche agrees to negotiate exclusively with the European Commission (on behalf of the interested countries) regarding the purchase of the Product until January 31, 2021 • thereafter, Roche is not able to commit to provide Product supplies to countries that do not join the FWC.
Retesting	• Requesting retesting following import via 5.1.2a despite existing Mutual Recognition Agreements between the EU and 5.1.2e and the EU and US has the potential to delay our delivery times. We expect an interpretation of Article 51(2) of Directive 2001/83/EC in an appropriate spirit to contribute to the management of this wider health crisis.
B. Referenced Sections of the FWC	
I. Special Conditions	

I.1 Order of priority of provisions	• The approach with various sets of (likely) conflicting rules is confusing and may lead to misunderstandings and implementation issues • It is strongly recommended to simplify and align on one set of coherent rules governing the purchase of the Product
I.2 Subject matter	• Subject matter of the offer must be specified as follows: ○ it is related to the Product with one common make-up (labelling on outer and immediate packaging and package leaflet) in the English language for pandemic purposes; ○ the quantity offered varies according to the number and population size of countries participating in the framework contract – 5.1.2c treatment courses being the maximum quantity Roche is able to offer in 2021 if all Joint Procurement Agreement signatory states (as of January 6, 2021) participate in the framework contract; ○ given the rapid clinical development that has been undertaken to address the pandemic, different doses of the Product are still being studied; the price for a treatment course will be 5.1.2b EUR (two thousand and sixty-five Euros) per treatment course for any dose up to 2.4g. • Labelling: Preference would be that all Contracting authorities shall apply full exemptions based on Art. 63(3) of Directive 2001/83/EC and that this is confirmed on the level of the FWC
I.3. Entry into Force and Duration of the FWC	• The signatory party to the FWC shall be F. Hoffmann-La Roche Ltd. (I.3.1). • Inconsistency of I.3.3 and I.3.1. • The specific contracts will be signed by Roche's affiliates and the national contracting authorities • the countries must indicate their binding commitment to purchase the allocated quantity of the Product by January 31, 2021 - this commitment enters into force on the day after marketing authorization is granted (I.3.4, see also comment above in A.3)
I.4 Appointment of the Contractor and Implementation of the FWC (including order management with scheme set forth in technical specifications, p.7)	• The specific contracts will be signed by Roche's affiliates and the national contracting authorities • the contracts between Roche affiliates and the national contracting authorities must be fit-for-purpose arrangements and we request that reliance is made on Roche's antibody supply chain expertise

	• To speed up delivery as much as possible, the following procedure should be envisaged:
	  ○ Commission informs the local contracting authorities (cc. FHLR) about the allocated quantities out of the total monthly available quantity (see financial offer) in due time (considering next bullet point below)
	  ○ Local contracting authority sends to local Roche affiliate/local contractor a written (or electronic) order for Product (as per requirements below) seven calendar days before the end of a calendar month
	• Terminology: What is a single FWC?
	• shipment within 2-5 working days after placement of order impossible (cf. scheme), relevant are the timelines of the financial offer
	• Minimum requirements for purchase orders:
	  ○ Name of contracting authority and name of supplier
	  ○ Specific contract number,
	  ○ Order reference,
	  ○ Product ordered
	  ○ FWC number: SANTE/2020/C3/091
	  ○ Quantity ordered (in units)
	  ○ Ordering date
	  ○ shipment address
	  ○ price per unit (excl. VAT) (as per FWC)
	  ○ Incoterms and payment terms (as per FWC)
	• Roche will return order confirmation (within 10 business days) confirming delivery date (within agreed time frame) in line with local regulations to local ordering authority (cc: European Commission or steering committee as appropriate)
	• orders cannot be changed or redirected once Roche has confirmed the purchase order
	• 1.4.4.: Incoterms: (a) for EU: DAP (place of delivery to be defined in country of ordering country) or FCA (Roche storage location in the respective country (b) for non-EU: DAP (place of delivery to be defined in country of ordering country)
	• 1.4.4.: notification of exact delivery date within one business day in advance
	• the termination ground of "refusal to sign" would comes at odds (see comment to II.17.1) if the procedure outlined above is respected

I.5. Prices	• 1..5.1: We refer to our comments under A.3
I.6. Payment Arrangements	• Full payment to be received by respective Roche affiliate 30 days from date of invoice • 1.6.2, I.6.3 and II.20.6 to be deleted
I.7. Bank Account	• Payments are made to Roche affiliates, not F. Hoffmann-La Roche Ltd - bank accounts in the countries may vary, separate list will be provided after finalization of participating countries
I.9. Processing of Personal Data	• Roche is committed to comply with any and all applicable data protection laws, including without limitation to EU-GDPR • We would ask to add to I.9.2(b) (i): "...or a country with adequate protection standards in accordance with a decision by the EU Commission or a third countries provided another mechanism in accordance with Chapter V of Regulation EU 2018/1725 is effectively in place."
I.10 Allocation, Importation, Distribution and Quality	• The Product will be delivered by Roche's affiliates • Allocation, see comments under A.4 and I.4 • I.10.3: Please note that also the national contracting authority's point of delivery will need to be in possession of the necessary authorisations
I.11 Scientific Information to Healthcare Professionals and Pharmacovigilance	• Reporting obligations are clearly defined for authorised medicines in the Pharma Acquis without the need for further clarifications in the FWC. • As with any other authorised medicine, FHLR's affiliates will communicate with Health Care Professionals regarding scientific information about safe and effective use of the product as appropriate and established by law.
I.12. Invoices and Value Added Tax	• Add: the contracting authority must provide all information required to complete the required formalities and to support FHLR or its affiliates in completing all necessary formalities
I.13. Termination by Either Party	• Due to the defined agreement term that ends on 31 December 2020 (*recte: likely 2021*) (I.3.3.) termination is not appropriate/comes at odds with the needs under the specific circumstances. • Clarification of language needed. Neither party is entitled to compensation except for (b) (I.13.(a)) • Clarification of the relation between the termination Sections in I and II needed (see also comment to I.1).
I.14. Applicable Law and Settlement of Disputes	• Clarification needed between applicable and governing law

	• For reasons of practicality in case of disputes the same law and jurisdiction shall be applicable for the FWC between FHLR and the EU-Commission as the signatories of the FWC and the specific contracts between Roche's affiliates and the national contracting authorities of the participating countries.
I.15.3. Joint Procurement FWC	• The specific contracts will be signed by Roche's affiliates and the national contracting authorities • A quantity delivered to an affiliate can not be redirected by Roche to another country and shall be supplied to the concerned national contracting authorities in the same country as the affiliate. Quantities produced and held at FHLR can be delivered to another affiliate than originally planned (if there is only one product label) pursuant to comments in I.4 • see also our comment in A.4
• **General Conditions (referenced Sections)**	
II.I Definitions	• to be reviewed after alignment on other terms
II.4.9 Delivery	• II.4.1: see comments under A.2/A.3 • II.4.9 (a): see comments under I.4 • II.4.9 (b): cost/risk governed by the agreed incoterm, last sentence to be deleted.re
II.4.10 Certificate of Conformity	• first sentence: Likely not compliant with international standards, obvious defects should be notified immediately (e.g. temperature) • Roche suggests to set up a control checklist for immediate checking requirements (for obvious defects) • second and last sentence: one month period too long, suggest to cut down to 7 calendar days
II.4.11 Conformity of the supplies delivered with the FWC	• I.4.11 (b) other than what is set forth in the Marketing Authorisation, Roche cannot imagine which specific fitness for purpose can be required by the contracting authority
II.4.12. Remedy	• Combination of remedy, liquidated damages and liability for consequential damages not acceptable, Section II.21 (Recovery) to be revisited once this item has been clarified • Roche can accept the following principles: ○ Roche warrants that the Product has been manufactured, sold and packaged and distributed in accordance with provisions on Good Manufacturing and Good Distribution Practice for medicinal products pursuant to applicable laws and

	guidances. Except for the foregoing warranties, Roche expressly excludes all other warranties, expressed or implied, statutory or otherwise (Section II.4.11 to be aligned with this principle). ○ Complaints due to incomplete, incorrect or defective deliveries of the Products must be notified in writing to Roche immediately (i.e. no later than within seven [7] calendar days upon receipt of the Products). If Roche is responsible for a Product defect as warranted and notified pursuant to this Section, Roche would (a) depending on quantity, replace the Products delivered assuming supply allowed for such replacement within 2 weeks or (b) if (a) is not feasible, the impacted Products are not charged or already completed payments reimbursed ○ Generally, in case of quality defects, Roche will act according to existing provisions of the EU Pharma acquis (in particular GMP provisions, Rapid Alert System) to remedy the situation in a standard procedure
II.4.13/14 Assembly/Services	Not applicable
II.4.15 General Provisions concerning Supplies	• (a) shipping boxes will be labelled with field tested Roche standard labels • (b)to be deleted, sufficiently covered by other specific provisions
II.5. Communication between the Parties	tbd
II.6 Liability	• In the event of liability obligations towards third parties (including pursuant to applicable product liability laws), the contracting authorities shall not treat Roche less favourably than other suppliers under comparable contracts • II.6.4 and II.6.5 to contain mutual support activities in case of third party liability actions.
II.7.2 Conflict of Interest and Professional Conflicting Interests	• FWC not implemented by FHLR, but by affiliates, contracting authorities likely may not conduct any sovereign activities on 5.1.2a territory without agreement with 5.1.2a
II.9 Processing of Personal Data	• see comments under I.9.
II.10.Subcontracting	• II.10.1 to clarify that Roche affiliates are not subcontractors and that Roche affiliates may involve local distributors if needed
II.13.1. Force Majeure	• It shall be clarified that pandemic related supply disruptions or denial of export/import clearance might constitute force majeure, also confiscation of relevant production sites, closed borders, export bans or other governmental measures capable of disrupting supply chains of the Product

	• See comment under II.17.1.(j) (Grounds for Termination by the Contracting Authority) below
II.14. Liquidated damages	• not acceptable, see also comment regarding II.4.12
II.15 Reduction in price	• see comments regarding II.4.12
II.16.2 Suspension by the contracting authority	• implementation of FWC conducted by Roche affiliates • It shall be clarified that in case of a suspension Roche does not have, during the suspension period, any supply obligations (impact on availability of quantities tbd) • suspension shall not be used by contracting authorities as means to circumvent own obligations • suspension based on "breach of obligations" to be further discussed - currently rather one-sided; multiple remedies not acceptable
II.17.1. Grounds for Termination by the Contracting Authority	• termination at odds with specific limited duration and to be discussed in the context of the binding effect of the FWC (see comments under A.3. above) • (b) what scenario would concretely be envisaged here as it may be expected that given the general urgency, contracting authorities do not impose additional administrative hurdles to obtain any such license? • (c) clarification needed that the contracts between Roche affiliates and the contracting authorities must be fit-for-purpose arrangements. Otherwise the termination ground of "refusal to sign" would come at odds (see also comments under I.4) • Force majeure shall not constitute a breach of contract (j) • termination ground (k) major concern as explained under A.3 • grounds for termination in (m) and (n) tbd, also questionable why one-sided as 2018/1725 essentially applies to institutions • List of ground for termination by the contracting authority to be deleted and replaced by an equivalent termination ground as per II.17.2 (Grounds for Termination by the Contractor)
II.17.4. Effects of termination	• Not acceptable. • Termination (if any) according to the terms of the contract shall not lead to any additional liability of Roche other than the one that is explicitly stated in the FWC

II.18 Invoices, Value added Tax and e-invoicing	• II.18.1
	  ○ general: invoice to mirror confirmed purchase order (see comments under I.4.)
	  ○ sentence: clarify date in line with comments under I.4.

	○ sentence 2: what is meant with place of taxation? This is only mentioned implicitly on the invoice. ○ sentence 4: see comment regarding I.12 • II. 18.2: to be handled in specific contracts according to local needs, regulations and needs
II. 19 Price revision	• Rightly so, Art. I.5.2 states that price revision does not apply, accordingly this Article must be deleted
II. 20 Payments and guarantees	• Payment to be received by respective Roche affiliate 30 days post delivery of goods where goods get allocated first. • II.20.1: very unusual, usual term: "when the contractor's account (i.e. of the respective Roche affiliate) is credited". • II.20.3 Conversion: If other, convertible, local currency is used, the EURO price is converted by the European Commission's official monthly accounting rates (INFOREURO https://ec.europa.eu/info/funding-tenders/how-eu-funding-works/information-contractors-and-beneficiaries/exchange-rate-inforeuro_en) for the respective currency at the date of the firm order. • II.20.5 /20.6: to be deleted • as from issuance of certificate of conformity, invoice issued on basis thereof is payable, suspension at any time not acceptable
II. 21 Recovery	• see comment regarding II.4.12
II.22 Checks and audits	• inspections/audits by OLAF on 5.1.2a territory may not be possible without agreement with 5.1.2a • Roche employees in 5.1.2a cooperating in any OLAF audit may be exposed to criminal liability under 5.1.2a Criminal law, see Art. 271[1]1. Felonies and misdemeanours against the state / Unlawful activities on behalf of a foreign state