

**(T5)**

**Tender Specifications / Part 1: Administrative specifications / 3. Evaluation and Award / 3.4. Award criteria / Section 1.1 in table of criteria**

**Technical offer demonstrating that the tenderer has engaged in and is keeping dialogue with EU regulators to complete the modification of an EU wide marketing authorisation for Aflunov, according to as specified in the Technical Specifications, with the purpose to update Aflunov** [REDACTED]

[REDACTED]

[REDACTED]

No.	Criterion	Documents to be submitted regarding criterion. (for details, see point 3.1, Annex 1)	Criterion	Max points (/100)
1.1	Plan and proposed timeline for the modification of the EU marketing authorisation	Technical offer demonstrating that the tenderer has engaged in and is keeping dialogue with EU regulators to complete the modification of an EU wide marketing authorisation for Aflunov, according to as specified in the Technical Specifications, with the purpose to update Aflunov with the A/Astrakhan/3212/2020 (H5N8) virus strain. The target date to complete the modification of the marketing authorisation is 31/12/2023.	<ul style="list-style-type: none"> <li>- ■ points will be scored: If the tenderer demonstrates, by the deadline for the submission of the tender, keeping a dialogue with EU regulators to complete the process of the modification of the EU-level marketing authorisation for Aflunov by the target date, including thorough references to related scientific data and processes (to) present(ed) to the regulators, with a detailed timeline and steps completed and steps still to complete, in order to achieve the target date.</li> <li>- ■ points will be scored: If the tenderer demonstrates, by the deadline for the submission of the tender, keeping a dialogue with EU regulators to complete the process of the modification of the EU-level marketing authorisation for Aflunov by the target date, however with some gaps and/or incompleteness related to the scientific data and/or processes (to) present(ed) to the regulators, and/or with the timeline and steps described, but mostly in a generic manner.</li> <li>- ■ points will be scored: If the tenderer that has not engaged, at the time of the deadline for the submission of the tender, in a dialogue with EU regulators to complete the process of the modification of the EU-level marketing authorisation for Aflunov.</li> </ul>	■

**(T5) CSL Seqirus response incorporating appendices (T5a) to (T5g) as supporting documents.**

[Redacted content consisting of multiple lines of blacked-out text, likely representing the supporting documents mentioned in the header above.]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

**Table 1. Key dialogue and documents to date, supporting the regulatory procedure for A/Astrakhan H5N8 strain change**

Date	Activity	Appendix
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]

