

IN THE PUBLIC CONTRACTS REVIEW BOARD

5th October 2026



Re: 706 - Call for Remedies - CT2364/2026 - Framework Contract for the Supply of Nirsevimab Solution for Injection in Pre-filled Syringe/Pen

Reply of the **Central Procurement and Supplies Unit (CPSU)** on behalf of the Department of Health to the reasoned application lodged by **Associated Drug Company Limited** (the applicant) in terms of regulation 262 of the Public Procurement regulations (PPR) in relation to a number of specifications of the call for tenders in caption.

On the 10th of September 2026 a call for tenders for the Supply of Nirsevimab Solution for Injection in Pre-filled Syringe/Pen was published with a number of specifications.

The applicant felt aggrieved by a number of specifications, which it insists that are not required, and filed the present appeal.

CPSU humbly disagree with the application and are filing the below submissions in reply, in the same order of the issues raised by the applicant:

Submissions:

1. The objector cites the Public Procurement Regulations (SL.601.03), the Directive 2014/24EU, and numerous judgments of the Court of Justice of the European Union to highlight the general principle of Public Procurement Legislation that Contracting Authorities when issuing a tender should not in any way with the intention of artificially narrow competition, and that as much as possible the specification shall be open so as to allow more economic operators to participate;
2. CPSU agrees with these principles, however CPSU argues, that the very fact of imposing a specification, limits competition and excludes those who do not satisfy the particular specification. This is not inherently contrary to the applicable laws, as long as such specifications and requirements are justified;
3. The Court of Appeal in its Judgment of the 24th June 2024 in the names **Medina Healthcare Limited v. Central Procurement and Supplies Unit**, highlighted this when it stated that:

7. Ir-reg. 39(3) tal-L.S. 601.03 iġid hekk:

39. (3) Id-disinn tal-akkwist pubbliku ma għandux isir bl-intenzjoni li jeskludi mill-kamp tiegħu ta' applikazzjoni dawn ir-Regolamenti jew li b'mod artifiċjali jnaqqas il-kompetizzjoni. Il-kompetizzjoni titqies li għet imnaqqa b'mod artifiċjali meta d-disinn tal-akkwist pubbliku jsir bl-intenzjoni li jiffavorixxi b'mod ingustifikat jew ikun ta' żvantaġġ għal ċerti operaturi ekonomiċi.

8. Darbtejn tisemma l-intenzjoni, li jfisser li d-"disinn tal-akkwist" irid ikun sar bil-finalità speċifika ta' tnaqqis ta' kompetizzjoni. Kif sewwa jingħad fil-każ ta' Krypton, mhux mehtieg l-prova tad-disonestà jew tal-qerq, għax il-fatt li l-kondizzjonijiet tas-sejha ma jservu għal xejn iżjed hlief illi jagħtu vantaġġ lil parti u żvantaġġ lil parti oħra jkun prova biżżejjed tal-intenzjoni anti-kompetitiva. Din

tkun prova oggettiva li ma teħtiegħ ukoll prova ta' diżonestà sogġettiva jew ta' qerq. Kif sewwa jingħad ukoll fi Krypton, din il-prova biżżejjed isir jekk, "meta wieħed janalizza l-kriterji tas-sejha wieħed isib li dawn il-kriterji jkunu ġew introdotti fis-sejha mhux biex ikun hemm kompetizzjoni miftuħa li tithalla tiegħu l-kors naturali tagħha, iżda dawn il-kriterji jkunu ġew introdotti biex il-kompetizzjoni tiġi mnaqqsa b'mod ingiustifikat halli b'hekk ikun hemm inqas operaturi ekonomiċi li jieħdu sehem fis-sejha".

9. Fi kliem ieħor, il-fatt waħdu li l-kondizzjonijiet tas-sejha jistgħu jnaqqsu l-kompetizzjoni mhux biżżejjed biex il-kondizzjoniet tas-sejha jitqiesu bi ksur tar-reg. 39(3). Kondizzjoni f'sejha li trid li oblatur ikollu ċerta jew li jkollu ċerta saħħa finanzjarja jnaqqsu l-kompetizzjoni għax jeskludu oblaturi mingħajr l-esperjenza jew is-saħħa finanzjarja meħtieġa; ma jfissirx iżda illi huma ipso facto bi ksur tar-regolament, sakemm ma jintweriex illi dik il-kondizzjoni ddaħħlet b'dak il-ħsieb.

10. Dan jidher aktar ċar fir-reg. 53(6):

53. (6) L-ispeċifikazzjonijiet tekniċi għandhom joffru aċċess ugwali tal-operaturi ekonomiċi għall-proċedura ta' akkwist u ma għandux ikollhom l-effett li jgħolqu xkiel mingħajr ġustifikazzjoni għall-ftuħ tal-akkwist pubbliku għall-kompetizzjoni.

11. Il-fatt li jista' jkun hemm "ġustifikazzjoni" għax-xkiel għal aċċess ugwali jkompli juri illi l-effett anti-kompetitiv ma huwiex ipso facto illeċitu; huwa illeċitu meta ma huwiex "ġustifikat" b'għanijiet leġittimi.

12. Għalhekk, għalkemm huwa minnu illi l-prova tal-intenzjoni sogġettivament diżonesta mhix meħtieġa, għax jista' jirriżulta ogġettivament illi l-kondizzjonijiet tas-sejha ma seta' kellhom ebda għan ieħor, madankollu l-effett anti-kompetitiv, għalkemm jista' jgħolq prova prima facie ta' intenzjoni projbita, madankollu huwa biss wieħed mill-fatturi li għandhom jitqiesu, u prova tal-intenzjoni anti-kompetitiva tixxejjen jekk jintwera illi l-kondizzjoni daħħlet b'għan leġittimu.

13. Fil-każ tal-lum, għalkem forsi l-Bord ta' Reviżjoni esprima ruħu b'termini usa' milli kellu jkun, madankollu korrettement osserva illi ntweri illi l-ħsieb wara l-kondizzjoni kien wieħed leġittimu, viz. "to keep the safety of all workers as a paramount priority", u mhux li jnaqqas il-kompetizzjoni, għalkem seta' jkollu wkoll dak l-effett li, iżda, ma kienx l-effett mixtieq.

14. L-ewwel aggravju huwa għalhekk miċħud.

4. The tender under review is for the supply of Nirsevimab Solution, which is active Ingredient (not a brand) intended for the prevention of Respiratory syncytial virus (RSV).
5. This tender under review was published on the 10th of September 2026 and its specifications were being drafted in the preceding months from the Directorate of Pharmaceutical Affairs (DPA) in consultation with the practising clinicians.
6. The active ingredient Clesrovimab, which the objector is arguing that is being left out, was only approved to be used and distributed in Europe on the 15th of April of the current year, 2026 and thus has been approved, less than 5 months of the publishing of the tender;

7. The clinicians that have been consulted by the Directorate for Pharmaceutical Affairs have till now only recommended the use of Nirsevimab for the prevention of RSV in paediatrics and neonates and since Clesrovimab, they will necessarily have to study how this will work, and the results it will give, before possibly opening the specifications so as to include this medicine;
8. CPSU emphasizes that this vaccine is given to less than 100 newborn babies in Malta which are in high risk of contracting RSV, and thus strong confidence in the active ingredient being prescribed is necessary.
9. It is thus in CPSU's humble view that the novelty of Clesrovimab is a justifiable reason for its exclusion at the moment from the scope of the tender;
10. Moreover, and without prejudice to the above, CPSU refer to the Availability of Medicinal Products within Government Health Services Regulations, Subsidiary legislation 458.31 which provides inter alia that:

6.(1) An applicant may request that a medicinal product be included in the Government Formulary List. In such cases the applicant shall forward a separate application to the Superintendent of Public Health in accordance with the requirements laid down by the said Superintendent, as specified in the application form in Schedule I to these regulations.
11. The applicant did not make any such request for the medicines to be included on the formulary list, and thus this is an added reason why the applicant should not expect CPSU to issue a tender for this newly approved medicine;

For the above reasons and submissions which will be further explained and evidenced during the sitting, CPSU humbly requests that the application ought to be rejected and the tender document confirmed as published.

CPSU reserves the right to present evidence and to make additional submissions, orally or in writing and to present evidence to sustain its position.

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