



30 September 2026

The Secretary
Public Contracts Review Board
Notre Dame Ditch
Floriana

Remedies Before Closing Date of a Call for Competition

Re: CT2364/2026

SUPPLIES – FRAMEWORK CONTRACT FOR THE SUPPLY OF NIRSEVIMAB SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE/PEN (the “Tender Procedure”)

Dear Sir, Madam,

1. Introduction

- 1.1 We are instructed by Associated Drug Company Limited (C 409) (hereinafter referred to as the “**Applicant**”) in connection with the Tender Procedure published by the Department of Contracts with the final beneficiary being the Central Procurement and Supplies Unit (the “**Contracting Authority**”).
- 1.2 In accordance with the Public Procurement Regulations, 2016 (S.L.174.04) (the “**PPR**”), our client hereby submits this reasoned application in terms of Regulation 262 (Remedies before Closing Date of a Call for Competition) for the reasons set out hereunder (this “**Application**”).
- 1.3 Enclosed with this Application is evidence of payment of the deposit, as required to be paid in terms of Regulation 262(2) of the PPR, to the Public Contracts Review Board (the “**Board**”).

2. Facts

- 2.1 The tender document governing the Tender Procedure (the “**Tender Document**”) was published by the Central Procurement and Supplies Unit (the “**Contracting Authority**”) on 10 September 2026, with the closing date being 12 October 2026.
- 2.2 The Estimated Procurement Value for this Tender Procedure as set out in article 1.3 of the Tender Document is that of €278,040 excluding VAT, split between Lot 1 – Nirsevimab 50mg Solution for Injection in Pre-filled Syringe/Pen with a value of €29,010 and Lot 2 – Nirsevimab 100mg Solution for Injection in Pre-filled Syringe/Pen with a value of €249,030.
- 2.3 The supply of the products is for a period of thirty-six (36) months, with an option for a further extension of six (6) months. The estimated quantity is 30 units under Lot 1 (Nirsevimab 50mg) and 225 units under Lot 2 (Nirsevimab 100mg).
- 2.4 In terms of article 3 of the Tender Document, the Tender Procedure is divided into two (2) lots, differentiated only by the strength/pack size of the same single named product: Lot 1

(Nirsevimab 50mg) and Lot 2 (Nirsevimab 100mg). The Tender Procedure is not divided, and does not in any manner allow, for the supply of any other product having the same or an equivalent therapeutic indication.

- 2.5 The Tender Document requested the supply of a single, named monoclonal antibody product for both lots (see Section 3 – Specifications, paragraph 1.1, item 2.0 “Technical specifications”), as follows:

“Nirsevimab 50mg solution for injection in pre-filled syringe/pen containing 0.5mL of solution” – mandatory for Lot 1.

“Nirsevimab 100mg solution for injection in pre-filled syringe/pen containing 1mL of solution” – mandatory for Lot 2.

- 2.6 Nirsevimab is a long-acting monoclonal antibody licensed for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants. It is not, however, the only monoclonal antibody licensed and available on the market for this purpose: Clesrovimab is a second long-acting monoclonal antibody, centrally authorised by the European Medicines Agency and available on the EU and Maltese market, licensed for the same therapeutic purpose of RSV prophylaxis in neonates and infants.
- 2.7 The requirements set out above were marked as “Mandatory” – that is, *“Economic operators who do not adhere to the mandatory requirements established herein will be disqualified”*. By naming “Nirsevimab” as the active ingredient/product in the mandatory technical specifications for both Lot 1 and Lot 2, the Contracting Authority has excluded Clesrovimab, and any other product having the same or an equivalent therapeutic effect, from being offered under this Tender Procedure.

3. Public Procurement Regulations

Artificially narrowing down competition

- 3.1 The Tender Procedure is governed by the PPR. The PPR is the national law which transposes Directive 2014/24/EU (the “**Directive**”).

- 3.2 Regulation 39(1) of the PPR provides that:

“Contracting authorities shall treat economic operators equally and without discrimination and shall act in a transparent and proportionate manner.”

- 3.3 Regulation 39(3) of the PPR provides that:

“The design of the procurement shall not be made with the intention of excluding it from the scope of these regulations or of artificially narrowing competition. Competition shall be considered to be artificially narrowed where the design of the procurement is made with the intention of unduly favouring or disadvantaging certain economic operators.” [emphasis added]



- 3.4 The requirement that contracting authorities are to treat each economic operator equally and without discrimination constitutes a central and fundamental principle of procurement law; in fact, Regulation 39 is included in the section entitled ‘*Principles Underlying the Procurement Process*’ in the PPR. In addition, Regulation 53(6) of the PPR provides that “*technical specifications shall afford equal access of economic operators to the procurement procedure and shall not have the effect of creating unjustified obstacles to the opening up of public procurement to competition*”.
- 3.5 The Contracting Authority has an obligation to promote competition for the supply of products required and to ensure that competition in the market is not distorted, and to also ensure that doctors can prescribe and patients are able to receive the most effective treatment.
- 3.6 In fact, preamble 74 of the Directive provides:

“.....

Consequently, technical specifications should be drafted in such a way as to avoid artificially narrowing down competition through requirements that favour a specific economic operator by mirroring key characteristics of the supplies, services or works habitually offered by that economic operator. Drawing up the technical specifications in terms of functional and performance requirements generally allows that objective to be achieved in the best way possible. Functional and performance-related requirements are also appropriate means to favour innovation in public procurement and should be used as widely as possible.

..... [emphasis added]

- 3.7 The Court of Justice of the European Union (the “CJEU”) stated in Case C-368/10¹ that:

“It must be recalled that under Article 2 of Directive 2004/18, which lays down the principles of awarding contracts, contracting authorities are to treat economic operators equally and non-discriminatorily and are to act in a transparent way. Those principles are of crucial importance with regard to the technical specifications, in the light of the risks of discrimination linked to the choice of those specifications or the manner in which they are formulated. Thus, Article 23(2) and (3)(b) and the last sentence of recital 29 in the preamble to Directive 2004/18 state that the technical specifications must afford equal access for tenderers and not have the effect of creating unjustified obstacles to the opening up of public procurement to competition and be sufficiently precise to allow tenderers to determine the subject-matter of the contract and to allow contracting authorities to award the contracts, being clearly indicated, so that all tenderers know what the requirements established by the contracting authority cover. It is therefore in the light of those considerations that Article 23(6) of Directive 2004/18 must be interpreted.” [emphasis added]

¹ Para. 62. The case in question related to Directive 2004/18 which preceded the Directive. However, the same principles are applicable to the Directive.



3.8 As confirmed by the CJEU in Case C-368/10, there is a considerable risk of discrimination linked to the choice of those specifications, or the way they are formulated. It is for this reason that the Directive and the PPR impose stringent conditions in relation to how these are formulated.

3.9 Article 42 of the Directive headed 'Technical specifications', gives specific expression to this prohibition. Article 42(2) provides that *"technical specifications shall afford equal access of economic operators to the procurement procedure and shall not have the effect of creating unjustified obstacles to the opening up of public procurement to competition"*. Article 42(4) further provides:

"Unless justified by the subject-matter of the contract, technical specifications shall not refer to a specific make or source, or a particular process which characterises the products or services provided by a specific economic operator, or to trade marks, patents, types or a specific origin or production with the effect of favouring or eliminating certain undertakings or certain products. Such reference shall be permitted on an exceptional basis, where a sufficiently precise and intelligible description of the subject-matter of the contract pursuant to paragraph 3 is not possible. Such reference shall be accompanied by the words 'or equivalent'."

3.10 The CJEU has repeatedly confirmed that a technical specification naming a single product or source, to the exclusion of an equivalent, infringes this obligation. In *Roche Lietuva* (Case C-413/17)², the Court held that Article 42(4) is a derogation *"to be strictly interpreted"*, and that *"the more detailed the technical specifications, the higher the risk of favouring the products of a given manufacturer will be"*, so that the failure to add the words *"or equivalent"* after designating a particular product *"may not only deter economic operators using systems similar to that product from taking part in the procurement procedure, but may also impede the flow of imports in intra-Union trade, by reserving the contract exclusively to suppliers intending to use the product specifically indicated"*.

3.11 In *DYKA Plastics* (Case C-424/23; judgment of 16 January 2025, *DYKA Plastics NV v Fluvius System Operator CV*), the Court went further and held:

"Where the use of a material does not follow inevitably from the subject matter of the contract, the contracting authority may not, without adding the words 'or equivalent', require a particular material to be used. It must then, in the context of technical specifications, refrain from requiring a particular material to be used, either by avoiding referring to such a material in the procurement documents or by referring to one or a number of materials while adding the words 'or equivalent'. Thus, in accordance with the objective of opening up to competition pursued by Directive 2014/24, the contracting authority will need to apply the award criteria to a variety of tenders, which may include both those proposing products made of materials which are commonly used in the sector concerned and those proposing products made of materials which are less usual, or which

² Paras. 37-39 and



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are innovative. The contracting authority thereby provides interested economic operators with the opportunity to demonstrate that such materials are equivalent.”³

And:

“Consequently, the answer to the fourth question referred is that Article 42(2) of Directive 2014/24, read in conjunction with Article 18(1) of that directive, must be interpreted as meaning that the obligation to afford economic operators equal access to public procurement procedures and the prohibition on creating unjustified obstacles to the opening up of public procurement to competition, set out in the latter provision, are necessarily infringed where a contracting authority eliminates certain undertakings or certain products by means of a technical specification which is incompatible with the rules set out in Article 42(3) and (4) of that directive.”⁴

And:

“Article 42(4) of Directive 2014/24 must be interpreted as meaning that contracting authorities may not, without adding the words ‘or equivalent’, state, in the technical specifications of a public works contract, the materials of which the products proposed by the tenderers must be made, unless the use of a particular material follows inevitably from the subject matter of the contract, it not being possible to contemplate an alternative based on a different technical solution.”⁵

- 3.12 This principle applies with particular force in the context of medicinal products. In *Medisanus* (Case C-296/15), concerning a hospital requirement that plasma-derived medicinal products (albumin and immunoglobulin) be obtained from Slovenian plasma, the Court held that, by not adding the words “or equivalent”, the hospital may “have deterred economic operators with analogous medicinal products from taking part in the tendering procedure”.⁶
- 3.13 In this case, the Contracting Authority required – as a mandatory requirement – that the product supplied under both Lot 1 and Lot 2 be Nirsevimab specifically, by naming that molecule in the mandatory technical specifications.
- 3.14 We further submit that Section 3 of the Tender Document demonstrates that a functional description of the subject matter was possible. For both Lot 1 and Lot 2, “*Monoclonal antibody*” is listed as a functional specification and marked “*Optional*”, while the named product, Nirsevimab, is marked “*Mandatory*”. Accordingly, the exception in Regulation 53(8) of the PPR, which applies only where a sufficiently precise and intelligible description of the subject matter is not possible, cannot apply. In any event, the Tender Document does not add the words “or equivalent”.

³ Pra. 61.

⁴ Para. 67.

⁵ Para. 68.

⁶ Para. 77.



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- 3.15 The Contracting Authority, by doing so, has limited the Tender Procedure to one particular branded/named product, to the exclusion of Clesrovimab, another monoclonal antibody which is licensed and available on the market for the same therapeutic purpose of RSV prophylaxis in neonates and infants.
- 3.16 The manner in which the Contracting Authority has formulated the technical specifications favours the specific economic operator(s)/manufacturer able to supply Nirsevimab, and at the same time prejudices other economic operators/manufacturers – including the Applicant – who are precluded from competing in this Tender Procedure by offering Clesrovimab or any other product having an equivalent therapeutic effect.
- 3.17 In addition, by requiring the product supplied to be Nirsevimab specifically, the Contracting Authority is restricting the products available to clinicians which could be prescribed for the prevention of RSV lower respiratory tract disease in neonates and infants, and at the same time not obtaining best value for money due to the fact that only the supplier(s)/manufacturer of Nirsevimab could compete for this Tender Procedure.
- 3.18 Indeed, naming a specific branded molecule as a mandatory technical requirement, when at least one other product with an equivalent therapeutic effect is available on the market, has no basis in any medical, clinical or technical justification put forward by the Contracting Authority in the Tender Document.
- 3.19 The UK Health Security Agency considers the two products to be equivalent, as is evident from the Guidance “*Why is my baby being offered an RSV immunisation Clesrovimab or Nirsevimab?*”⁷, updated on 5 August 2026, wherein it is stated:

“No immunisation gives complete protection but having clesrovimab or nirsevimab reduces the risk of needing hospital admission for RSV by at least 80% or more.”

- 3.20 In the Green Book RSV Chapter published on the UK Government website⁸, it was stated:

“For a universal programme for infant protection, JCVI has advised (June 2023) maternal vaccination with Pfizer pre-F vaccine (Abrysvo®) or infant immunisation with nirsevimab (Beyfortus®) would be suitable for a national programme.

JCVI subsequently advised that clesrovimab (Enflonsia™) be considered equally suitable for universal infant immunisation (October 2025). JCVI has advised that high risk infants and young children (see later) receive either nirsevimab (February 2023 advice) or clesrovimab (October 2025 advice), or palivizumab if neither first line monoclonal antibody immunisation is available.

JCVI has advised (2024 and 2025) that in a universal programme of maternal vaccination, clesrovimab or nirsevimab immunisation should be



considered for very and extremely preterm infants (born before 32 weeks), who are unlikely to benefit from maternal vaccination, to be offered in or immediately preceding their first RSV season."

- 3.21 Similarly, the CDC published an article on 18 August 2025, "RSV Immunization Guidance for Infants and Young Children", which provided as follows:

"Nirsevimab and clesrovimab are monoclonal antibodies that prevent severe RSV disease and are recommended for infants. Nirsevimab is also recommended for some young children.

Monoclonal antibodies are not vaccines. They do not activate the immune system. Rather, the antibodies themselves protect against disease.

Healthcare providers should discuss both the RSV maternal vaccine (Pfizer's Abrysvo) and infant RSV antibodies with parents and consider patient preferences when deciding which product is best for their patient's family."

- 3.22 In this respect, reference is made to the decision of the Board in Case 1397 – Request for Participation for the supply of Dabrafenib 75mg capsules and Trametinib 2mg tablets, in which the Board held that specifications naming a single branded product, obtainable from one manufacturer only, *"limits the scope of open competition"* and cannot be justified by reference to a restrictive formulary list, since *"the formulary list should not override a main principle in Public Procurement"*.
- 3.23 Reference is also made to Case 1361 – Request for Participation for the Supply of Enzalutamide 40mg capsules, in which the Board held that *"technical specifications should not be limited or inclined towards a particular product"* and that *"whenever a particular product is indicated, directly or indirectly, the word 'Or Equivalent' has to be incorporated, so that open competition is preserved"*, notwithstanding that the two products under consideration in that case, like Nirsevimab and Clesrovimab in the present case, were clinically distinct molecules addressing the same therapeutic need.
- 3.24 Reference is further made to PCRB Case 1157 (RFP 021/60011/2018 – Supply of Treatment Service of PD1 Inhibitors, decided 3 May 2018), a remedy filed by the Applicant itself against the CPSU, in which the Board held that *"under no circumstances, technical specifications or conditions should be stipulated which limit or precludes similar equivalent products to participate in an offer ..."*, that the tender needed to be amended *"to accommodate similar or equivalent products which render the same objective ..."*, and that the determination of equivalence should rest on the medical expertise of clinicians. In PCRB Case 1337 (CT 2379/2018 – Supply of Various Vaccines, 30 August 2019), the Board, having heard evidence that products of two different manufacturers were equivalent in their effectiveness, cancelled the award because the Contracting Authority produced no evidence of the alleged risk.
- 3.25 This artificial narrowing of competition is unlawful, and the Applicant is not required to prove any subjective bad faith or dishonest intent on the part of the Contracting Authority. As the Court of Appeal held in *Krypton Chemists Limited v CPSU* (15 February 2024, App. No. 538/23) and *Medina Healthcare Limited v CPSU* (24 June 2024, App. No. 86/2024/1), no proof of



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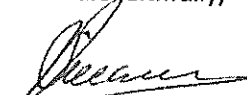
dishonesty or collusion is required: it suffices to show, objectively, that the conditions serve no purpose other than to advantage one party and disadvantage others, or that the criteria were introduced not to allow open competition to take its natural course but in a manner which unjustifiably reduces the number of economic operators able to participate. In Medina Case, the Court further held that the anti-competitive effect constitutes prima facie proof of the prohibited intention, which is displaced only where the Contracting Authority shows that the condition was introduced for a legitimate aim. Under Regulation 53(6), an obstacle is unlawful where it is not "justified". Here, we submit that the Tender Document puts forward no clinical, medical or technical justification for naming Nirsevimab.

- 3.26 In terms of Regulation 262(1)(c), an application before the Board may be made to remove discriminatory technical, economic or financial specifications which are present in the call for competition, in the contract documents, in clarifications notes or in any other document relating to the contract award procedure.
- 3.27 In view of the above, the Applicant was left with no alternative but to file this application to seek to rectify the unlawful way the Tender Document was published.

4. Conclusion

- 4.1 In view of the above, the Applicant respectfully requests the Board to:
- 4.1.1 order that the Contracting Authority amend the Tender Document in such a manner which allows economic operators to offer Clesrovimab, or any other product having the same or an equivalent therapeutic effect to Nirsevimab, for RSV prophylaxis in neonates and infants under Lot 1 and Lot 2; and
 - 4.1.2 in its decision stipulate a new closing date for the Tender Document which allows interested economic operators sufficient time to prepare their offer following the publication of the revised Tender Document.
- 4.2 In the event that it is not possible to revise the Tender Document as aforesaid, the Applicant respectfully requests the Board to order the cancellation of the Tender Procedure and re-issuance of a procurement process which allows economic operators to offer Clesrovimab, or any other product having an equivalent therapeutic effect to Nirsevimab, for the prevention of RSV lower respiratory tract disease in neonates and infants.
- 4.3 In addition, the Applicant respectfully requests the Board to reimburse the deposit paid by the Applicant, irrespective of the outcome of this Application.
- 4.4 The Applicant reserves the right to make other submissions, summon witnesses and submit other evidence during the proceedings relating to this Application before the Board.

Yours faithfully,


Steve Decesare


Stefan Cutajar



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List of Witnesses

- Person(s) responsible for and, or involved in the preparation of the Tender Document
- Person(s) responsible for determining the technical specifications
- Person(s) from the Contracting Authority responsible for this procurement process
- Person(s) from the Applicant and, or its suppliers
- Experts and medical professionals, including on the clinical and therapeutic equivalence of Nirsevimab and Clesrovimab for the prevention of RSV lower respiratory tract disease in neonates and infants

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