

22nd November 2023

The Secretary
Public Contracts Review Board
info.pcrb@gov.mt

Dear Sir/ Madam,

Reference: CT2333/2023

Subject: Supplies- Pneumococcal Polysaccharide Conjugate Vaccines

We write on behalf of Associated Drug Co. Ltd. of Zone 1, Central Business District, Birkirkara CBD 1040, Malta in relation to the above-captioned call for tender proceedings (the "**Tender**"). By means of this application, which is being filed in terms of Article 262 of the Public Procurement Regulations ("**PPR**") (S.L. 601.03), our clients are respectfully seeking a suitable remedy before the closing date of the said Tender.

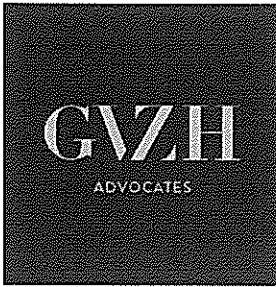
1. Facts

The subject of the Tender is the supply of Pneumococcal Polysaccharide Conjugate Vaccines As and is divided into two (2) distinct lots, designated in the Tender as "Lot 1" and "Lot 2", and detailed as follows:

Lot 1 - Pneumococcal Polysaccharide Conjugate Vaccine (adsorbed) at least 10-valent

Lot 2 - Pneumococcal Polysaccharide Conjugate Vaccine (adsorbed) at least 20-valent

In the course of the tender process, clarification was sought in relation to the age groups for which the vaccines are intended, specifically seeking to ensure that Lot 1 was intended for infants during the first two years of life (CT2333_2023 Clarification Note no.3 Question 1), attached as **Document AD1**. Clarification was also provided by the Department of Contracts that the guidelines which have been taken into account for the specifications of Lot 1 and Lot 2 of the tender are those set out by the Centers for Disease Control and Prevention (CDC) of the United States Department of Health and Human Services and by the European Medicines Agency (EMA).



In the CDC guidelines attached and marked as **Document AD2** the CDC recommends the administration of a vaccine of at least 15 valent for infants (highlighted text). In its response to question 2 (CT2333_2023 Clarification Note no.3 Question 2), the Department of Contracts also indicated that it is aware that there is a 15 valent PCV vaccine registered and EMA approved for use in infants, children, adolescents and adults.

However, in spite of the clear provision within the CDC Guidelines of a minimum 15-valent for infants, the Contracting Authority's Product Specifications under Lot 1 calls for a minimum 10-valent, which is contradictory.

2. Remedy Sought

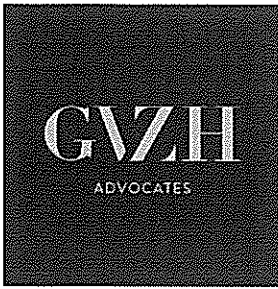
In the light of the facts set out above, and the conflict created between the Tender specifications set out under the heading "General Provisions" (paragraph 1.1) and the CDC guidelines which serve as the technical basis of the Tender, our client wishes to avail itself of the remedial procedure set out in Regulation 262(1) paragraphs (a) and/or (d) of the PPR, as the Board may consider appropriate, and this exclusively in relation to the specifications of Lot 1 of the Tender.

It is humbly submitted that any vaccines having a valency of less than 15 should not be invited to participate in the Tender for Lot 1 and the relevant Tender specifications for Lot 1 should read "a vaccine of at least 15-valent" to be consistent with CDC technical specification guidelines as clarified by the contracting authority in the clarification (CT2333_2023 Clarification Note no.3 Question 3), attached as **Document AD1**.

3. Remedy Sought

By virtue of this application, and on behalf of our clients, we respectfully request the Board to exercise its powers as set out in Regulation 262 (1) paragraphs (a) and/or (d) of the PPR, and proceed to:

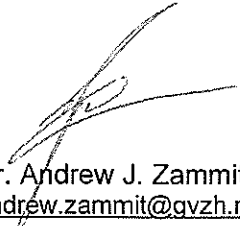
- (i) set aside or ensure the setting aside the technical specifications contained in the Tender document which are inconsistent with the CDC technical specification guidelines, which conflict could render the Tender difficult or impossible to perform; and/or
- (ii) to correct the errors in the technical specifications of the Tender to render them conformant with the relevant CDC technical specification guidelines which apply to the vaccine that forms the subject of the Tender.



We reiterate that this reasoned application is being filed specifically with reference to Lot 1 of the Tender and that the deposit accompanying this application in fulfillment of the obligation set out in regulation 262(2) of the PPR is calculated on the basis of the Estimated Procurement Value of €957,180 that applies to Lot 1, which value is set out in paragraph 1.2 of the Tender document.

Our client reserves the right to make further submissions during an eventual hearing. Proof of payment of deposit is attached hereto as **Document AD3**.

Yours sincerely,
For GVZH Advocates



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CT2333/2023

17th November 2023

Clarification Note No. 3

To all prospective bidders

CT2333/2023 – Supply of Pneumococcal Polysaccharide Conjugate Vaccines

Reference is made to the above-captioned tender for which the deadline for submission of offers is **07/12/2023 at 9.30am.**

Please find a set of clarifications, which are construed to form an integral part of the tender document.

Question No. 1 – *Can the contracting authority kindly clarify for which ages lot 1 and lot 2 are being issued?*

Answer No. 1 – Lot 1 will be used to satisfy the requirements of the National Immunisation Schedule for infants during the first two years of life. The vaccines specified in Lot 2 are intended for the vaccination of all adults 65 years and over, as approved by ACHCB and ACIP.

Question No. 2 - *Is the contracting authority aware that there is a 15 valent PCV vaccine registered and EMA approved for use in infants, children, adolescents and adults?*

Answer No. 2 – Yes.

Question No. 3 - *Can the contracting authority kindly specify which guidelines have been taken into consideration for the specifications of lot 1 and lot 2?*

Answer No. 3 – CDC and EMA were used for both lots.

Question No. 4 - Has the ACIP been consulted for the tender specifications for lot 1?

Answer No. 4 – Yes.

Question No. 5 - Has the ACIP been consulted for the tender specifications for lot 2?

Answer No. 5 – Yes.

Question No. 6 - For Lot 2: The specifications on page 19 point 1.1 state "Vaccine - without the indication for concomitant use of polysaccharide 23 valent vaccine as per CDC guidelines for adults 65 years and older"

- a) *Can the contracting authority please clarify what is meant by 'concomitant use'?*
- b) *Is a 15 valent vaccine followed by the 23valent polysaccharide vaccine (as indicated in the CDC guidelines) not eligible to participate?*

Answer No. 6 –

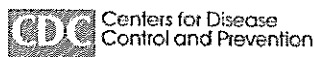
a) A – As per CDC guidelines, adults 65 years or older can either receive PCV20 only as a single dose or receive PCV15 followed by shots of PPSV23 every 5 years. A vaccine to be given to adults 65 years and older, without the requirement for it to be followed by PPSV23, as per CDC guidelines, is being requested.

b) As per answer 6(a), and as per specifications, a 15 valent vaccine followed by the 23 valent polysaccharide vaccine is not eligible to participate.

All other tender documents, conditions and requirements, which are not superseded by this clarification remain in place.

Adrian Dalli (signed)

Director General (Contracts)



Vaccines and Preventable Diseases

[Vaccines and Preventable Diseases Home](#)

Pneumococcal Vaccine Recommendations

Below are summaries of recommendations from CDC's Advisory Committee on Immunization Practices (ACIP). For the full text of the recommendations, see [Pneumococcal ACIP Vaccine Recommendations](#).



Download "PneumoRecs VaxAdvisor" App for Clinicians

This free mobile app gives clinicians patient-specific pneumococcal vaccination recommendations from anywhere at any time.




Routine Vaccination of Infants and Children

CDC recommends routine administration of pneumococcal conjugate vaccine (PCV15 or PCV20) for all children younger than 5 years of age:

- Give PCV15 or PCV20 to infants as a series of 4 doses, one dose at each of these ages: 2 months, 4 months, 6 months, and 12 through 15 months.
- Children younger than 5 years of age who miss their shots or start the series later should still get vaccinated. The number of doses recommended and the intervals between doses will depend on the child's age when vaccination begins.

Catch-Up Guidance Job Aid

[Pneumococcal Conjugate Vaccine Catch-Up Guidance for Healthy Children 4 Months through 4 Years of Age](#) 
This job aid should assist clinicians in interpreting table 2 of the child and adolescent immunization schedule.

Vaccination of Adults 65 Years or Older

Routine Recommendation

CDC recommends routine administration of pneumococcal conjugate vaccine (PCV15 or PCV20) for all adults 65 years or older who have never received any pneumococcal conjugate vaccine or whose previous vaccination history is unknown:

- If PCV15 is used, this should be followed by a dose of PPSV23 one year later. The minimum interval is 8 weeks and can be considered in adults with an immunocompromising condition[†], cochlear implant, or cerebrospinal fluid leak.
- If PCV20 is used, a dose of PPSV23 is NOT indicated.
- See [Pneumococcal Vaccination: Summary of Who and When to Vaccinate](#) for CDC guidance on vaccination options for adults who have previously received a pneumococcal conjugate vaccine.

Footnote

[†] Immunocompromising conditions include chronic renal failure or nephrotic syndrome; congenital or acquired asplenia or splenic dysfunction; congenital or acquired immunodeficiencies; diseases or conditions treated with immunosuppressive drugs or radiation therapy, including


generalized malignancy, Hodgkin disease, leukemia, lymphoma, multiple myeloma, and solid organ transplant; HIV infection; and sickle cell disease or other hemoglobinopathies.

Recommendation for Shared Clinical Decision-Making

Based on shared clinical decision-making, adults 65 years or older have the option to get PCV20 if they have received

- PCV13 (but not PCV15 or PCV20) at any age
AND
- PPSV23 at or after the age of 65 years old

Shared Clinical Decision-Making Job Aid

PCV20 Vaccination for Adults 65 Years or Older 


This job aid should assist clinicians in discussions with patients about this vaccine recommendation.

Vaccination of Older Children and Adults with Certain Indications

In certain situations, children 2 through 18 years of age may need additional pneumococcal vaccine doses. In addition, adults younger than age 65 years of age may be recommended to receive pneumococcal vaccines. See [Pneumococcal Vaccination: Summary of Who and When to Vaccinate for all pneumococcal vaccine recommendations by vaccine and age](#).

Vaccine Options for Adults Who Received an Earlier Conjugate Vaccine

PCV13: Adults who received PCV13 have options on how to complete their pneumococcal vaccine series.

- See [Pneumococcal Vaccination: Summary of Who and When to Vaccinate for CDC guidance on those vaccination options](#).
- See [Examples: Complete pneumococcal vaccine schedules for adults](#)  [4 pages] for a visual illustration of these vaccine options.

PCV7: Treat adults who received PCV7 the same as people who have never received any pneumococcal vaccines.

Contraindications and Precautions

Do not administer a pneumococcal conjugate vaccine to:

- A person who has ever had a severe allergic reaction (e.g., anaphylaxis) after a previous dose of PCV7, PCV13, PCV15, or PCV20, or to any vaccine containing diphtheria toxoid
- A person with a severe allergy to any component of these vaccines

Do not administer PPSV23 to:

- A person who has ever had a severe allergic reaction (e.g., anaphylaxis) after a previous dose
- A person with a severe allergy to any component of this vaccine

Clinicians may administer pneumococcal vaccines, if the provider and parent or patient deems the benefits of vaccination to outweigh the risks, to:

- A person who has a moderate or severe acute illness with or without fever

Related Pages

[ACIP—Vaccines for Children \(VFC\) Resolutions](#)

CDC Expert Commentary on Medscape: 5 Things to Know about Pneumococcal Disease and the New Adult Pneumococcal Vaccine Recommendations [↗](#)

Contraindications and Precautions

- General Best Practice Guidelines for Immunization
- To Pneumococcal Vaccination
From the Pink Book's "Pneumococcal Disease" chapter
- To Vaccination (General Information)
From the Pink Book's "General Recommendations on Immunization" chapter

Guidelines for Vaccinating Pregnant Women



PneumoRecs VaxAdvisor Mobile App

Pneumococcal Vaccine Information Statements

- PCV (English / Other Languages [↗](#))
- PPSV23 (English / Other Languages [↗](#))

Standing Orders

From the Immunization Action Coalition

- Pneumococcal Conjugate Vaccine to Children  [2 pages] [↗](#)
- Pneumococcal Polysaccharide Vaccine to Children and Teens  [1 page] [↗](#)

Use of Vaccines to Prevent Meningitis in Persons with Cochlear Implants

Last Reviewed: September 21, 2023

You have authorised this payment
The status for payment 38546QW01XZP is: Forward dated instruction received by bank

Payment summary - Eurozone payment

Pay from
ASSOCIATED DRUG CO LTD D
MT MTHBMTCA033-076613-001 EUR

Instruction reference number 38546QW01XZP
Transaction type Eurozone-SEPA payment

Total amount **EUR 4,785.90**

Expected value date **Thu 23 Nov 2023**
This is the date we expect to debit your account.
Please ensure that the debit account has enough funds, otherwise the payment will be rejected.

Your payment reference **CT2333/23**

Total entries **1**

Transactions

Entry	Beneficiary	Payment details	Amount (EUR)
1	Beneficiary name: CASHIER MALTA GOVERNMENT IBAN: MT55MALT011000040001EURCMG5001H SWIFT-BIC: MALTMTMT Reference: TENDER REF CT2333/23 OBJECTION	Purpose of payment: GOVT GovernmentPayment Transaction is a payment to or from a government department. Remittance information: OBJECTION RE TENDER REF CT2333/23 ASSOCIATED DRUG CO LTD - MSD	4,785.90