IN THE PUBLIC CONTRACTS REVIEW BOARD

27th November 2023

Re: Call for Remedies - CT2333/2023 Supplies - Pneumococcal Polysaccharide Conjugate Vaccines Lot1

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

On the 25th of October 2023 a call for tenders for the Supply of Pneumococcal Polysaccharide Conjugate Vaccines, was published in 2 lots, with a number of technical specifications.

During the clarification period the applicant submitted a clarification note with 6 questions which were all duly answered, defending the specifications as published.

CPSU still attests to the reply to the clarification and submits that there are clinical reasons for the specificatons for Lo1, particulatly the requirement for a minimum 10 valent for the following reasons:

1. Pneumococcal vaccination policy is a dynamic field in constant evolution. To ensure the optimal level of disease prevention while streamlining budget allocations, national stakeholders periodically assess their strategies and adapt their recommendations to cater to the needs of each population. This results in the creation of various vaccination strategies according to each country's needs. The Maltese Advisory Committee for Immunisation Policy (ACIP) had recommended the introduction of pneumococcal conjugate vaccine into the National Immunisation Schedule following extensive studies on the local burden of disease and cost-effectiveness of vaccination. The vaccine was introduced on the Schedule in May 2020 for infants at 2, 4 and 12 months.

2. At the time of the initial recommendation there were only two types of pneumococcal vaccination available for use in children, the 10-valent and 13-valent vaccines. Since there was no policy of universal pneumococcal vaccination in Malta as yet, ACIP considered that the use of the 10-valent vaccine would already provide benefit to the prevention of pneumococcal disease in the Maltese Islands. Furthermore, comparison was made with other European countries using this type of vaccine successfully.

3. A recent comparative analysis of European and US National Immunisation Advisory Bodies' evolution of pneumococcal vaccine recommendations and criteria for decision making (Noharet-Koenig et al, May 2023) shows that the development of newer high valency pneumococcal vaccines has instigated some countries with a high burden of pneumococcal disease to recommend the use of these vaccines in lieu of lower valency ones. This is particularly the case for the United States where the 10-valent pneumococcal vaccine was never registered or licensed. On June 22, 2023, the American Advisory Committee on Immunization Practices (ACIP) convened and approved recommendations for the use of 20-valent pneumococcal conjugate vaccine in U.S. children. The ACIP recommendations were adopted by the CDC Director on June 27, 2023, and are now official.

4. **This is definitely not the case in Europe where despite the EMA licensing of 15-valent pneumococcal vaccine for use in children in June 2023, European ACIPs and the European Centre for Disease Prevention and Control still hold that there is enough health benefit provided by the 10-valent and 13-valent vaccines in their National Immunisation Schedules for children.** In fact, France and Belgium still use the 10-valent vaccine exclusively in their Schedule whereas Germany, Netherlands and Spain have both the 10-valent and the 13-valent vaccines in theirs.

5. The Maltese ACIP has reviewed its recommendations for universal pneumococcal vaccination in infants and concluded that it is still too early to recommend the exclusive use of the highest valency PCV vaccine currently licensed for children, thus excluding the 10-valent and the 13 valent. The Committee maintains that its recommendation to include **at least a 10-valent pneumococcal vaccine** in the National Immunisation Schedule three years ago is still relevant in the current local pneumococcal disease burden scenario, **and this does not exclude the 15-valent vaccine.**

6. CPSU submits that there is nothing contradictory in its replies to the clarification question. Although it does acknowledge that a 15-valent pneumococcal vaccine for children exists, on the basis of the ACIP's recommendations it decided to procure at least 10-valent for Lot 1, thus leaving competition open for the 10, 13 and 15 valent.

7. The contracting authority retains the discretion to purchase what it needs, without discriminating and this is what was done in this case. The approval of a new medicine, dose or indication does not mean that the contracting authority is bound to purchase exclusively products according to the latest international approval. This would run contrary to the basic principles of procurement and open competition when a less recent approval is still considered as effective.

8. The 15-valent pneumococcal vaccine is thus eligible to compete for lot 1 which requests at least 10-valent. This requirement is therefore open, transparent and

competitive and it is the applicant's action which is not and which is the contrary to what is usually expected from an application in terms of regulations 262 of the PPR!

9. Moreover and with reference to the remedy sought, CPSU strongly submits that there are no inconsistencies or clauses which are impossible to perform, and there are neither any errors. The CDC guidelines were consulted by the tender drafters but is not the tender document. As the applicant is well aware, ultimately it is the tender document and its conditions which determine the parameters of the call, and no other document. The tender document does not contain inconsistencies, clauses which are impossible to perform, and neither any errors.

10. It is the contracting authority on the basis of the advice given shall determine its needs, and since these needs and conditions are well founded, legitimate and are made in order to maintain competition in line with regulation 39 of the PPR, the tender conditions should be confirmed by this Honourable Board as published.

For the above cited reasons CPSU reiterates that the application of Associated Drug Co. Ltd shall be rejected and requests that the specifications are confirmed as published.

CPSU also requests that the deposit is forfeited, however if the applicant decides to withdraw its application before the hearing, CPSU does not object to the refund of the deposit.

With Respect.

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