Part I: Target Product Profile (TPP) for the Advance Market Commitment (AMC) for Pneumococcal Conjugate Vaccines

Master Table

The product specifications tabled below are called the target product profile (TPP). The specifications relate to the public health impact and suitability of the product, covering measures of vaccine efficacy, safety, dose-scheduling, presentation and packaging, and represent the minimally acceptable standard a vaccine needs to meet in order to be eligible for AMC support. This table must be read in conjunction with the accompanying Part II TPP Supplementary Information that provides the rationale for the selected criteria, and proposes more advanced product characteristics, that are desirable but not essential. For other pneumococcal vaccine types, such as protein-based vaccines, several attributes will require adaptation.

Attribute	**Minimally Acceptable Profile**
A. Vaccine serotypes	The serotypes in the vaccine formulation must cover at least 60% of the invasive disease isolates in the target region, and must include serotypes 1, 5 and 14 which are the most frequent isolates in GAVI eligible countries.
B. Immunogenicity	Immunogenicity should be demonstrated in accordance with WHO criteria, which are based on non-inferiority to a licensed pneumococcal vaccine as outlined in WHO *Recommendations for the production and control of pneumococcal conjugate vaccines.* (WHO Technical Report Series, No 927, 2005 and any subsequent published guidance).
C. Target population/ target age groups	The vaccine must be designed to prevent disease among children <5 years of age and in particularly be effective in those < 2 years of age.
D. Safety, reactogenicity and contra-indications	The safety and reactogenicity profile should be comparable to, or better than that of the currently licensed pneumococcal conjugate vaccine. Contra-indications should be restricted to known hypersensitivity to any of the vaccine components.
E. Dosage schedule	Vaccine scheduling must be compatible with national infant immunization programmes and consist of not more than 3 doses in the first year of life. The first dose must be shown to be administrable at 6 weeks of life or earlier.

F. Interference and co-administration with other vaccines	There should be no clinically significant interaction or interference in relation to safety and immunogenicity with concurrently administered vaccines.
G. Route of administration	Intramuscular or subcutaneous.
H. Product presentation	The vaccine must be available in mono-dose or low multi-dose presentations. Mono-doses must be either a single dose vial or a auto-disable compact pre-filled device. Low multi-dose presentations must be formulated and labeled in compliance with WHO policy or guidance.
I. Product formulation	Liquid formulation with a standard volume of 0.5 ml/dose.
J. Storage and cold chain requirements	The product must be stable at 2-8 °C with a shelf-life of at least 24 months and a vaccine vial monitor should be attached as outlined in *Making use of vaccine vial monitors. Flexible vaccine management for polio* (WHO/V&B/00.14).
K. Packaging and labeling	Name and labelling must be in accordance with WHO *Recommendations for the production and control of pneumococcal conjugate vaccines.* (WHO Technical Report Series, No 927, 2005). Packaging must ensure minimal storage space requirements as set out in *Guidelines on the international packaging and shipping of vaccines* (WHO/IVB/05.23).
L. Product registration and prequalification	The product must be WHO pre-qualified in accordance with *Procedures for assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies* (WHO/IVB/05.19).
M. Post marketing surveillance	Post-marketing surveillance should be conducted in accordance with national regulatory authorities and WHO prequalification requirements as set out in *Guideline for preparation of the product summary file for vaccine prequalification* (WHO/IVB/06.16) , *Guidelines on clinical evaluation of vaccines: regulatory expectations* (WHO Technical Report Series, No 924, 2004) and any relevant published guidance.