



**World Health
Organization**

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct:
Fax direct:
E-mail :

In reply please
refer to:

Your reference:

Dr Ananad Kumar Kanakasapapathy
Managing Director
Indian Immunologicals Limited
Road No. 44, Jubilee Hills
500 033 Hyderabad
Telangana
Inde

1 December 2023

Dear Dr Kanakasapapathy,

WHO Prequalification Unit (PQT) – Fees for the Prequalification of Vaccines

As you may know, pursuant to Section 14 of the procedure for WHO's prequalification of vaccines, the World Health Organization (WHO) charges fees in connection with its prequalification assessment of vaccines. These fees are composed of a screening fee, an initial evaluation fee, a site inspection fee, and annual maintenance fees, as further described below:

- **Screening fee (for screening of applications)** – US\$ 2 500 for simple or traditional vaccines and US\$ 5 000 for combination or novel vaccines. In this regard, a product is considered as the unique combination of manufacturer + vaccine + dosage. Thus, by way of example, a paediatric and an adult formulation of the same vaccine would be considered as different products, but a one-dose and a 10-dose presentation of the same vaccine would be considered as only one product.
- **Evaluation fee (for evaluation of dossiers)** – US\$ 100 000 for simple or traditional vaccines and US\$ 232 750 for combination or novel vaccines.
- **Reduced evaluation fee (for evaluation of dossiers)** – US\$ 25 000 for simple or traditional vaccines and US\$ 66 500 for combination or novel vaccines will be considered by WHO, in its discretion, for products for which there is urgent public health need but no (or a very small) commercial market.
- **Site inspection fee** – The site inspection fee for simple or traditional vaccines, as well as for combination or novel vaccines, is a flat fee of US\$ 30 000 per manufacturing site (even if an inspection of a manufacturing site involves multiple vaccines in a single inspection review).
- **Annual maintenance fee** – An annual maintenance fee is charged to each manufacturer each calendar year to cover the costs of activities required to keep updated the WHO prequalification list (i.e., review of annual reports, reassessments, handling of complaints and resolution of out-of-specification results). The annual maintenance fee is applied per prequalified vaccine (i.e., the unique combination of manufacturer + vaccine + dosage, including if the vaccine is manufactured at different sites). The annual maintenance fee is also tiered, and the Tier applicable to a particular prequalified vaccine will be determined each year in accordance with the following two-step process:

ENCL: (1)

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