

Information brief to applicants/manufacturers of immunization-related devices and products: Revisions to the administration of payment of prequalification fees.

Since 2017, WHO levies fees for dossier evaluation and the annual product review for each prequalified product <https://extranet.who.int/prequal/immunization-devices/prequalification-procedures-and-fees-immunization-devices#collapse92> . The dossier evaluation and annual fees are set per category of products or devices. The fees are administered to applicants or manufacturers at specific time points as per applicable amount for each product or device as stipulated in the terms and conditions.

This brief is to inform applicants and manufacturers about an update on procedures for handling of prequalification (PQ) fees for immunization-related products or devices that has been made as part of our quality management system. The update was to strengthen the alignment and consistency of internal procedures and practices in handling PQ fees for various products. It is important to note that the **applicable fees per category of products or devices remain the same and are not affected by this revision** of internal quality procedures. The following changes have been implemented:

- **Dossier evaluation fee:** The dossier evaluation fees must be paid in full once the dossier has been accepted for evaluation. Payment should be made within 30 days of receipt of the invoice from WHO. The commencement of dossier evaluation will be triggered by a confirmation of payment of the invoiced fees.
- **Annual review fee:** WHO will invoice the annual product review fees to the applicant or manufacturer by 31 March for each prequalified immunization-related product or device that was on the prequalification catalogue (list) up to the 31 December of the previous year. Payment should be made within 30 days of receipt of the invoice from WHO. The annual product review will not commence unless payment of the invoiced annual fees has been confirmed.

WHO takes this opportunity to inform applicants and manufacturers that the above outlined changes to the administration of PQ fees will **be effective from 1st January 2024**. Any feedback and queries for further clarifications on these changes can be sent by email to pqsinfo@who.int with a copy to prequalfees@who.int.