# WHO Prequalification Fees

## Summary

A new fee schedule came into force on 1 January 2017 for active pharmaceutical ingredients (APIs), finished pharmaceutical products (FPPs) and vaccines. The fee structure for in vitro diagnostics (IVDs) is unaffected by this new schedule.

The introduction of the new fee schedule is intended to ensure the sustainability of WHO prequalification, while at the same time diversifying its funding (currently 100% donor-derived).

For further information relating to the introduction of a revised fee scheme, please refer to the document available at: http://who.int/medicines/news/finance-arrangements-prequal-med/en/

The introduction of the new fee schedule will be monitored, and a formal evaluation will be conducted in three-years' time. However, WHO is currently continuing consultation with manufacturers and partners about the impact of the fees on specific product groups and will be actively seeking further evidence and information to continually monitor the impact of the fees. WHO will also be consulting immediately with manufacturers and partners on the publication of details about waivers granted.

The applicable fees vary depending on the type of product for which prequalification is sought.

For medicines the fee is based upon:

- whether the product is an API or FPP
- the type of assessment to be undertaken: full or abridged assessment of a new application, or assessment of a major variation.

The annual fee is determined on whether the initial assessment was full or abridged.

For vaccines the fee is based upon:

- the type of service provided: screening, evaluation, site audit
- the complexity of the product: simple or complex vaccine.

The annual fee for vaccines is determined by the income tier of the manufacturer, based upon the level of income generated by prequalification-enabled sales (sales to UN agencies and GAVI, only).

For in vitro diagnostics (IVDs) the fee is based upon the type of service provided: screening or assessment. Currently, there is no annual fee, however, fees will be levied for certain reportable changes to a prequalified IVD.

For immunization devices (IMDs) the fee is based upon the type of product.

Applicants whose product(s) generate only a low level of profit, who may therefore be discouraged from applying or maintaining their product(s) on the list(s) of prequalified products, should contact the Prequalification Team (PQT) for advice. In particular, manufacturers of the products identified in the attached annex may apply for a waiver of the annual fees with justification indicating, for each product, the sales and net profit in the last year. This annex will be updated as more information becomes available.

## What are the prequalification fees?

### Medicines and active pharmaceutical ingredients

For an FPP a single product is defined as:

- a medicine of a unique strength and single dose form, but that may include multiple presentations, or
- a combination of medicines co-packed together.

For an API, a single product is defined as an API that is supported by a single active pharmaceutical ingredient master file (APIMF).

**Table 1: Fees for FPP and API prequalification applications (effective 1 January 2017)**

| | Single registration fee per product | Annual fee per product | Post-prequalification changes |
|---|---|---|---|
| | Application Fee | Annual Fee | Major variation |
| **FPP – full assessment** | $25,000 | $20,000 | $3,000 |
| **FPP – abridged assessment[1]** | $6,000 | $5,000 | NA |
| **API – full assessment** | $20,000 | $8,000 | |
| **API – abridged assessment[2]** | $10,000 | $4,000 | |
| **APIMF[3]** | | | $3,000 |

[1] Refer to procedure for SRA-approved multisource (generic) or innovator FPPs:- https://extranet.who.int/prequal/content/abbreviated-assessment-multisource-generic-or-innovator-product-0

[2] Refer to procedure for abridged assessment: https://extranet.who.int/prequal/content/abbreviated-assessment-api-already-accepted-stringent-regulatory-authority-0. The fee reflects the need to establish compliance with Good Manufacturing Practices.

[3] The APIMF post-PQ change fee applies to APIMF used in both the API-PQ procedure and APIMF procedure

## Vaccines

For a vaccine, a single product is defined as a vaccine of a unique strength and dose form. However, a single vaccine product may have several presentations (1 dose, 2 doses,...20 doses). Typically, a single product would be associated with a single entry in the WHO List of Prequalified Vaccines.

Vaccines are classified as simple / traditional, combination or novel as described in Table on the following link: http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_types_categorisation_for_fees_asat_dec_2015.pdf?ua=1. This annex will be updated to include all vaccines invited for prequalification. In case of doubt, manufacturers should contact PQT before submitting an application for prequalification.

**Table 2: Fees for vaccine prequalification applications (effective 1 January 2017)**

| | Single registration fee per product | | | Annual fee per product[2] | | | | Site audit |
|---|---|---|---|---|---|---|---|---|
| | **Screening fee** | **Reduced assessment fee[1]** | **Assessment fee** | **Tier 1** | **Tier 2** | **Tier 3** | **Tier 4** | **Site audit fee** |
| Simple / traditional vaccines | $2,500 | $25,000 | $100,000 | $4,800 | $19,200 | $41,500 | $140,000 | $30,000 |
| Combination or novel vaccines | $5,000 | $66,500 | $232,750 | $8,400 | $33,600 | $72,500 | $250,000 | $30,000 |

[1] For products for which there is urgent public health need but no (or very small) commercial market.

[2] See Table 5: Vaccine manufacturer-tiers for the purposes of annual fee calculations. .

## In vitro diagnostics

An IVD application may consist of one or more products provided they: detect the same analyte, are of the same design, contain the same reactive components (source, concentration, etc.), and have the same intended use. A single application may include different packaging configurations (number of tests, accessories, size of additional components such as buffer).

**Table 4: Fees for IVD prequalification applications**

| | Single registration fee | | Post-prequalification changes |
|---|---|---|---|
| | Application screening fee | Application assessment fee | Major change to a prequalified IVD |
| **IVD – full assessment** | $4,000 | $8,000 | $3000 |
| **IVD – abridged assessment[1]** | NA | $12,000 | $3000 |

[1] Refer to abbreviated process http://www.who.int/diagnostics_laboratory/evaluations/170224_pqdx_007_overview_document_v6.pdf?ua=1

## Immunization Devices

In general for immunization devices, a single application fee is applied to each device with a unique manufacturer's product reference number. The fee applicable to an IMD application depends on the type of product as outlined in table 5 below.

**Table 6: Fees for Prequalified IMDs**

| Category codes | Item descriptions | Application Assessment Fee | Annual fees |
|---|---|---|---|
| E001 | Cold rooms, Freezer rooms | $2400 | $1400 |
| E003 | Refrigerators/freezers | $2400 | $1300 |
| E004 | Cold boxes/Vaccine carriers | $2000 | $1200 |
| E005 | Coolant-packs | $600 | $300 |
| E006 | Temperature monitoring devices | $2400 | $1200 |
| E008 | Injection devices for immunization | $3000 | $1600 |
| E010 | Waste management, safety boxes | $2400 | $1200 |
| E013 | Injection devices for therapeutic use | $3200 | $1600 |

## When are the fees payable?

### Medicines

An invoice for the application fee will be issued after the application has been screened and accepted for assessment. Similarly, an invoice for the fee associated with a major variation will be issued following screening and acceptance of the variation application. Payment should be made within 15 days of receipt of the invoice from WHO.

An invoice for the annual fee will be issued by PQT on or before 1 October each year. The annual fee will be applied to all FPPs or APIs that, by 1 September of that year, have been prequalified for 12 months or more.

Payment of the annual fee should be made before 30 November of the calendar year in which the invoice was issued.

### Vaccines

Upon receipt of an application to prequalify a vaccine, an invoice for the applicable screening fee will be issued. Applications that pass screening and are accepted for assessment will then be invoiced for the application fee. In both cases, payment should be made within 15 days of receipt of the invoice from WHO.

If it is necessary during the evaluation of a vaccine to undertake an on-site audit of the manufacturer's facilities, an invoice for the site audit will also be issued. Payment should be made within 15 days of receipt of the invoice from WHO.

Determination of the annual fee payable for vaccines is a two-step process. Vaccine manufacturers are required to submit, by 30 June each year, a declaration of their manufacturer tier: I, II, III, or IV. Determination of manufacturer-tier should be based on the manufacturer's average, annual prequalification-enabled sales (of all prequalified vaccines), over the three previous completed calendar years. The manufacturer tiers, according to average yearly total sales value, are given in Table 5.

**Table 5: Vaccine manufacturer-tiers for the purpose of annual fee calculations**

| Tier | Average annual prequalification-enabled sales over the last completed three-year period (US$) |
|---|---|
| **1** | US$ 0 to US$ 1 million |
| **2** | >US$ 1 million to US$ 20 million |
| **3** | >US$ 20 million to US$ 300 million |
| **4** | >US$ 300 million |

Based on the manufacturer's declared tier, PQT will then invoice the manufacturer for each eligible prequalified vaccine, in accordance with the announced fee schedule. The annual fee will be applied to all vaccines that, on 1 September each year, have been prequalified for 12 months or more.

Payment of the annual fee should be made before 30 November of the calendar year in which the invoice was issued.

## In vitro diagnostics

Following submission of an application for evaluation of an IVD via the full assessment procedure, an invoice for the screening fee will be issued. If the application is accepted for assessment, the manufacturer will be invoiced for the assessment fee.

For IVD applications accepted for an abridged assessment, a single fee will be invoiced at the time of acceptance for assessment.

Payment should be made within 15 days of receipt of the invoice from WHO.

## Immunization Devices

The application assessment fee for an IMD is issued once the application has been accepted for assessment following screening.

The annual fee is invoiced in April of each year for all Prequalified IMDs.

Payment should be made within 15 days of receipt of the invoice from WHO.

## Whom can I contact?

Enquiries regarding the fees schedule are welcome; please email prequalfees@who.int