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WHO Prequalification Financing Model – Questions and Answers

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What is WHO prequalification?

Prequalification is a service provided by WHO to assess the quality, safety and efficacy of medical products for priority diseases and which are intended for UN and international procurement to developing countries. Currently, the programme evaluates in vitro diagnostics, medicines and vaccines. In 2017 it will introduce assessments of vector control products (insecticides).

Manufacturers Interested in entering the global procurement market apply to have their products assessed on the basis of expressions of interest WHO issues periodically. Once evaluated, if the products are deemed compliant with international standards they are listed as eligible for procurement on a public web platform. Large medical products suppliers, such as the Global Fund, GAVI, UNITAID and UNICEF, rely on the list when selecting products for procurement to countries. By guaranteeing acceptable standard levels for the products, WHO helps procurement agencies to buy quality-assured products and to save money on otherwise expensive evaluations they would have to contract to private companies.

The prequalification of vaccines began in 1987 in an effort to ensure that vaccines used in national immunisation programmes were of assured quality. Later, with the creation of the GAVI vaccine fund, WHO vaccine prequalification became even more relevant as GAVI mainly purchases products that have been vetted by WHO.

Medicines prequalification started in 2001, at the height of the AIDS epidemic and the beginning of major global efforts to tackle priority infectious diseases. Prequalification has been instrumental in broadening access to medicines for HIV/AIDS, malaria and tuberculosis by prequalifying a large number of the less expensive Indian generic medicines. The lower prices have allowed more people to be treated for the same money. In time,

medicines prequalification also began to include other products - some paediatric medicines, reproductive health products, treatments for neglected diseases and active pharmaceutical ingredients.

Diagnostics prequalification began with the assessment of in vitro HIV tests in 2008 and soon expanded to include malaria tests. Today, the diagnostics team also works on emergency-prone pathogens for which few or no medical products exist, such as Ebola and Zika.

Many low- and middle-income countries also use WHO's lists of prequalified products to guide national procurement of medical products.

What's changing?

WHO began to charge prequalification fees for vaccine prequalification in 1999, for diagnostics since the programme inception in 2008, and for medicines in 2013. The introduction of fees was motivated by the need for financial sustainability in order to continue to provide this vital service in the future. Before fees were introduced, the sole donor for vaccines prequalification was UNICEF, and medicines prequalification was reliant on only two donors – the Gates Foundation and UNITAID.

The new fee structure represents a fine-tuning of previous arrangements to take several variables into account:

For vaccines:

- type of service: screening, evaluation, site audit;
- complexity of the product: simple or complex vaccine;
- level of income generated by prequalification-enabled sales (sales to UN agencies and GAVI, only) to determine which tier (from four levels) will be used to calculate the annual maintenance fee, payable per product.

For medicines:

- product nature: active pharmaceutical ingredient (API) or finished pharmaceutical product (FPP);
- type of assessment: full or abridged assessment of new application, or assessment of major variation;
- an annual maintenance fee tailored to whether the initial assessment was full or abridged.

Based on the number of prequalification applications received by WHO between 2013 and 2015, the new fee model is expected to generate about US\$20 million annually in income for WHO, which will cover about half of the programme's annual operating costs. It is expected that this fee structure will secure the financial sustainability and quality of the programme.

Development of the model, which was funded by the Bill & Melinda Gates Foundation (BMGF), was guided by the following principles:

- it should not introduce inequity among manufacturers;
- should not represent a financial burden that restricts the ability of manufacturers to enter a market (and especially not those where public health need is critical);
- should be financially and administratively simple to execute and monitor.

What are the fees?

Medicines

	Single Registration Fee		Annual Fee Per Product			
	New application Full assessment	New application Abridged assessment	Annual fee Full assessment	Annual Fee Abridged assessment	Major variation	Minor variation or variation in an abridged assessment product
FPP (Rx)	\$25,000	\$6,000	\$20,000	\$5,000	\$3,000	
API	\$20,000		\$8,000		\$3,000	

Vaccines

	Screening Fee	Reduced Evaluation Fee	Maximum Evaluation Fee	Annual Fee Tier 1 (per product)	Annual Fee Tier 2 (per product)	Annual Fee Tier 3 (per product)	Annual Fee Tier 4 (per product)
Simple/Traditional Vaccines	\$2,500	\$25,000	\$ 100,000	\$ 4,800	\$ 19,200	\$41,500	\$ 140,000
Combinations or Novel Vaccines	\$ 5,000	\$ 66,500	\$ 232,750	\$ 8,400	\$ 33,600	\$ 72,500	\$ 250,000

When does the new financing model start?

The new fee structure will be applied to prequalification applications for medicines and vaccines from 1 January 2017, and for in-vitro diagnostics in early 2018.

How will the fees affect small manufacturers in low-income countries?

In order to mitigate the risk for small companies, the list of potentially affected manufacturers has been reviewed, along with their products. At most, there are currently 2-3 such manufacturers who have products on the prequalified product list – and most of these products are of public health importance so there may be scope to negotiate deferred fees.

What happens to products that generate only small profits – won't the manufacturers be discouraged from applying?

Medicines that generate only minimal profit for their manufacturers may be withdrawn from prequalification, potentially reducing the range of products from which procurers can select and the usefulness of the lists of prequalified products. However, most of these products are also registered by the United States Food and Drug Administration, and this provides an alternative pathway to procurement by the Global Fund and UNITAID.

Will these fees lead to increased prices?

Medicines prices may increase for some products to absorb the cost of the prequalification fees. However, major procurement agencies have accepted that ensuring quality products has a cost.

How will this new fee structure be evaluated?

Implementation of the new model is planned to start on 1 January 2017. As well as enabling many prequalification services to be continued, the fees will be used to further improve those services. This will include setting (and public disclosure) of quantitative performance targets. Indicators and performance targets will relate to: review time for full assessment, review time for abbreviated assessments and review time for assessment of major variations. Discussion with the industry associations about performance targets and indicators will be continuous.

It is intended that the impact of the model will undergo a review after three years of implementation. Prior to that regular assessment of model impact will be undertaken.

Who can I contact for more information?

prequal@who.int

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