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Improving the financial sustainability of the prequalification of medical products by the WHO

Overview

The World Health Organization (WHO) operates a prequalification (PQ) programme to assess the quality, safety and efficacy of products that address global public health priorities. Pre-qualified products are listed on the WHO website as eligible for procurement, giving purchasing agencies such as UNICEF a range of quality-assured diagnostics, medicines and vaccines from which to choose. The WHO was looking to introduce a new funding mechanism to generate at least 50% of the funds directly from user contributions in order to guarantee the financial sustainability and quality of the WHO's prequalification programme over the long term. Charles River Associates (CRA) was asked to support the development of a new financing arrangement that addressed the needs of all stakeholders, including industry groups, key partners and the WHO.

Approach

CRA consultants investigated how different stakeholders use the PQ programme and the benefit it delivers. We then conducted a series of interviews with industry representatives across all three sectors (vaccines, medicines and diagnostics) and end users of the PQ programme such as UNICEF, UNITAID and donors such as the Bill & Melinda Gates Foundation (BMGF) and GAVI, The Vaccine Alliance

Using the interview evidence, CRA considered alternative funding options that meet the guiding principles of predictability, fairness and equity underpinning the scheme, as well as the goals and objectives of the PQ programme today and in the future. A range of proposals were considered based on who should pay for the cost of PQ and what forms the fees could take. CRA also drew upon existing funding mechanisms that have been applied in the past, e.g., the funding mechanism proposed for the Pandemic Influenza Preparedness (PIP) Framework.

CRA consultants then developed recommendations regarding preferred mechanisms for funding the WHO prequalification system on a sustainable basis to meet the needs of all stakeholders.

Solution and outcomes

The result is an improved fee structure that reflects the relative value and needs of individual users and stakeholders and ensures the long term financing of the prequalification programme.

The new arrangement involves a mix of fixed contributions and variable user fees differentiated by type of product, its public health relevance and the current market. Manufacturers wishing to have their products prequalified by WHO to sell them through the United Nations and international supply systems will pay a set of fixed user fees adapted to the type of product being assessed (vaccines, medicines or diagnostics), as they would for major reference regulatory authorities, and an additional annual user contribution. The additional annual user contribution consists of a proportional contribution to an annual fixed sum weighted according to the nature and capacity of each company. These fees cover assessment services such as manufacturing site inspections and product assessments. The arrangement is projected to generate $20 million annually in cost recovery.

The improved fee structure creates a forward-looking, transparent system that can adapt to future system changes and lays the groundwork to strengthen and expand services and improve financial predictability. The new fee structure for vaccines and medicines will be launched in January 2017, and in early 2018 for diagnostics.

More details on the new financial arrangement for the WHO prequalification programme is available on the WHO website. Click **here** for more details.

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The Life Sciences Practice works with leading biotech, medical device, and pharmaceutical companies; law firms; regulatory agencies; and national and international industry associations. We provide the analytical expertise and industry experience needed to address the industry's toughest issues. We have a reputation for rigorous and innovative analysis, careful attention to detail, and the ability to work effectively as part of a wider team of advisers. To learn more, visit **www.crai.com/lifesciences**.

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