Opening address by His Excellency Maurice Peter Kagimu Kiwanuka
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Permanent Mission of Uganda

UN Prequalification of Diagnostics, Medicines and Vaccines, 6th Consultative Stakeholder Meeting and Meeting with Manufacturers
Geneva, Switzerland | 4–5 April 2011

- The moderator of this meeting, from Bill & Melinda Gates Foundation,
- The directors, coordinators, managers and staff of the WHO departments and units responsible for prequalifying diagnostics, medicines and vaccines,
- Manufacturers participating in the WHO Prequalification Programmes,
- Delegates from WHO Member States and other United Nations Organizations,
- Other stakeholders,
- Ladies and gentlemen,

Allow me to thank the Director-General and WHO in general for having given me, and particularly Uganda, the honour of presiding over the opening of this auspicious occasion.

This shows the great confidence WHO has in our country and in Africa at large. It should be noted that most of the modern pioneer work by WHO, like prequalification of drugs, to fight the deadly diseases has been done in Africa. We thank the world body very much for this.

It should be remembered that Uganda's beloved President Yoweri Museveni spearheaded the fight against AIDS by bringing it to the awareness of not only his country people, but to the world at large. This was during the early days of the scourge when others were afraid of treading the same line for fear of jeopardizing their tourism industry.

I am proud to say, that this is not the first time that the world has shown confidence in my country, its remote global positioning in the high-tech world notwithstanding. I will mention just a few conspicuous incidents. Recently, we were elected to the Human Rights Council, among the 40 voting members. Two years ago, we were elected to the Security Council in New York, a responsibility we feel we have met to the satisfaction of the world. Also recently, we were among the 6 African countries appointed by the African Union to mediate in the Libyan conflict.

And I can safely say with great hope that more show of confidence is yet to come. Allow me now to turn to today's event.

The Government of Uganda and those developing countries who have benefitted greatly from WHO's prequalification programmes, are who now better able to meet the health needs of their people with only scarce health budgets, are honoured to have been invited here.

In Uganda in 1990s, diseases like HIV/AIDS, Malaria, Tuberculosis, polio, whooping cough, measles, diphtheria and tetanus were responsible for the deaths of many men, women and children. The Government felt powerless: because of the high costs of diagnosis and treatment.

But WHO prequalification programmes are enabling countries like Uganda to access quality-assured medicines and vaccines. We have been able to expand our treatment and vaccination programmes.
We can now see the light at the end of the tunnel. The Millennium Development Goals (MDGs) can be reached.

It has been brought to my attention that the WHO prequalification programmes have two noble objectives.

- To ensure that patients in need have access to diagnostics, medicines and vaccines of assured quality.
- To enable countries to develop the capacity to regulate diagnostics, medicines and vaccines entering their markets, and to ensure that manufacturers in their countries produce good-quality products.

Let me share with you some examples that demonstrate the impact of the WHO prequalification programmes.

- In Uganda, 10 years ago, 1 month of 1st-line antiretroviral drugs (ARVs) treatment for HIV/AIDS cost US$ 1000. Today, it costs less than US$ 50. This is because good-quality generic antiretroviral drugs (ARVs) and especially fixed-dose combinations (FDCs) became available. They became available because WHO established the first international guidelines for producing quality-assured FDCs. Using these guidelines, it evaluated and approved the first generic ARVs and FDC products. The resultant price decreases meant that many more patients could be treated. In 2003, only 17,000 patients received ARV therapy. By September 2010, this number had soared to 248,222. What's more, availability of rapid diagnostic kits is helping to ensure early diagnostic and appropriate treatment.

- During the same period, Uganda has been able to scale up its vaccination programme. Based on the 3rd vaccination injection for Diphtheria-Pertussis and Tetanus (DPT3), an indicator used by our ministry of health, vaccinations coverage increased from approximately 58% in 2000 to 82% in 2010. All the vaccines we use in our immunization programmes have been prequalified by WHO.

Initially, India produced most of the generics assessed by WHO. We salute the Indian manufacturers for their contribution. Their efforts underpin the massive scale up of treatment programmes that we have witnessed across Africa.

But African countries themselves are increasingly submitting products to WHO for evaluation.

South Africa was the first country in sub-Saharan Africa to have some of its medicines prequalified by WHO.

Last year, products produced by a Zimbabwean company were prequalified. Also last year, a manufacturing plant in Uganda passed WHO inspection. The plant, which forms part of an Indian joint venture company, manufactures two prequalified medicines: one for malaria treatment and another for HIV/AIDS.

Products produced by a Kenyan company and a Tanzanian company are in the process of being assessed.
I have come to know that a similar trend is being observed for manufacturers in Latin America, the Middle East and China.

The newly introduced WHO prequalification of active pharmaceutical ingredients (APIs) will further support efforts to ensure that vulnerable populations have access not just to medicines, but to medicines of assured quality.

Prequalification of APIs will help manufacturers identify sources of good quality raw materials. Using a WHO-prequalified API will mean that a manufacturer has a head start in manufacturing good-quality medicines.

WHO-prequalified quality control medicines laboratories enable countries to verify the quality of medicines close to the treatment programmes that are administering them. Africa has more prequalified medicines quality control laboratories than any other WHO region: in Algeria, South Africa, Kenya and Tanzania. The national medicines quality control laboratory in Uganda, as well as many other laboratories in Africa and beyond, are at various stages of evaluation for prequalification.

African regulators not only benefit, but also actively contribute, to WHO prequalification activities. Many African regulators participate in medicines dossier assessments. African inspectors join WHO inspection teams to manufacturing sites.

This collaboration promotes harmonization in regulatory requirements and procedures among participating countries. For example, I was delighted to learn that regulators from the East African Community worked with WHO on a pilot joint assessment of two product dossiers. The products were prequalified by WHO. At the same time they were granted immediate marketing authorization by the East African countries (Kenya, Tanzania and Uganda) involved.

A similar exercise has been used under the African Vaccine Regulators Forum (AVAREF) where new vaccines have been jointly assessed, under WHO's coordination, for registration in several African countries.

These harmonization efforts make optimal use of scarce expertise, cut costs and speed up market access to diagnostics, medicines and vaccines of assured quality. Many more lives are being saved. Many more patients survive their illness. Many more patients enjoy a vastly improved quality of life.

All countries and organizations face enormous financial challenges. In times like these, the innovative approaches demonstrated by the WHO Prequalification Programmes are more needed than ever if we are to continue to improve our capacity to meet the public health needs of our citizens.

The targeted, inclusive and revolutionary approach of WHO's Prequalification Programmes has achieved the following:

- It has increased access to quality-assured and affordable medicines and vaccines which has in turn enabled countries to scale up treatment and immunization programmes.
- It has enhanced the capacity of manufacturers to produce quality-assured medicines and the capacity of countries to control and monitor the quality of these medicines in a more sustained way.
• Availability of quality assured medicines and vaccines has improved the reputation of health care systems which influences the health seeking behaviour of the people.

This stakeholders' meeting could not be more timely: to discuss how the WHO Prequalification Programmes, and their partners, can sustain their achievements.

I wish you success in your deliberations.