Generic medicines play a vital role in containing health care costs and extending access to treatment. The scaling up of treatment programmes for HIV/AIDS, following the availability of generic, quality-assured antiretroviral (ARVs), is a prime example. The WHO Prequalification of Medicines Programme, and its two major donor partners — UNITAID and the Bill & Melinda Gates Foundation — have played an important role in ensuring that generic medicines for treating HIV/AIDS, as well as for treating malaria and TB, meet international agreed quality standards, including demonstration of interchangeability with original medicines. Today, all medicines for treating HIV, TB and malaria that are procured with international funds must be prequalified or approved by a stringent regulatory authority. The result is a level playing field for manufacturers with respect to evaluation and procurement of these medicines.

POQ recently added products for reproductive health, zinc sulfate for the treatment of diarrhoea in children, and diethylcarbamazine and mebendazole for the treatment of lymphatic filariasis and soil-transmitted helminthiasis, to its portfolio of work. But the Programme’s impact is not limited to specific therapeutic areas. Rather, it has been instrumental in improving the quality of generic medicines internationally and has raised awareness of medicines quality issues globally.

Yet much more remains to be achieved. The burden of chronic noncommunicable diseases is shifting from wealthy populations to the poor and disadvantaged. Eighty per cent of the burden of diseases related to cardiovascular conditions, such as hypertension, and other diseases such as diabetes and cancer, is now borne largely by low- and middle-income countries. Many of those affected will require long-term, if not life-long, access to medicines. Cost containment and quality assurance will be vital if effective treatment is to be guaranteed for those in need.

In other therapeutic areas, both access to and quality of treatment are also of increasing concern. For example, ensuring regular availability of quality-assured miltefosine, paromomycin and antimonials for treating leishmaniasis is an ongoing challenge. Many medicines currently used for treating neglected tropical diseases are “old” medicines that have either not been evaluated according to current international standards of quality, safety and efficacy and/or are manufactured in countries that do not yet have stringent medicines regulation.

This briefing session will address:

- the role of generic medicines in increasing access to treatment
- the essential function of the WHO Prequalification of Medicines Programme in ensuring the quality of multisource medicines, in collaboration with national regulatory authorities
- the challenge of scaling up the availability of quality essential medicines to treat noncommunicable diseases and neglected tropical diseases.

1 WHO defines a “generic product” as a multisource pharmaceutical product that is intended to be interchangeable with the comparator product.
There will be ample time for questions and answers.

This session will be of interest to ministries of health seeking to optimize the impact of health care expenditure, to NGOs and civil society groups working on access to medicines issues, to donors who want to ensure a good return on their investment in pharmaceutical projects, and to WHO staff who would like to know more about how the WHO Prequalification of Medicines Programme works and with whom.

Participants can use reach WHO Headquarters by using the minibuses that will operate between Door 15 at the Palais des Nations and the main entrance to WHO Headquarters.

A simple sandwich lunch will be offered.

Space at the session will be limited and so we kindly ask you to register by sending your name and affiliation by email to: Ms Kai Kalmaru, WHO Medicines of Prequalification Programme: kalmaruk@who.int.

**Briefing session agenda**

**Moderators:** Philippe Duneton, Deputy Executive Director, UNITAID & Ellen ‘t Hoen, consultant

12:30  Welcome and introduction: The role of generic medicines in national medicines policy and introduction to WHO guidelines on medicines pricing policies.  
*Kees de Joncheere, Director, Department of Essential Medicines and Health Products (EMP)*

12:40  WHO Prequalification of Medicines Programme (WHO-PQP): Ensuring quality medicines  
*Lembit Rägo, Coordinator, Quality and Safety: Medicines, EMP*

12:50  The role of WHO-PQP in establishing markets for quality-assured generic medicines  
*Philippe Duneton, Deputy Executive Director, UNITAID*

13:00  The Medicines Patent Pool (MPP) and its collaboration with WHO-PQP in expanding access to quality generic antiretroviral medicines  
*Greg Perry, Executive Director, Medicines Patent Pool*

13:10  Challenges in national regulation of critically needed medicines  
*Hiiti B. Sillo, Director General, Tanzania Food and Drugs Authority*

13:20  Priority medicines and the role of generic medicines in scaling up treatment and prevention of noncommunicable diseases  
*Richard Laing, Coordinator, Medicine Information and Evidence for Policy, EMP*

13:30  Questions and discussion

13:50  Summarized discussion points and closure