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In the Name of God, the Compassionate, the Merciful

Opening remarks

to the

CONSULTATION ON SCALING UP THE UTILIZATION OF THE TUBERCULOSIS NEW DIAGNOSTICS IN THE EASTERN MEDITERRANEAN REGION INCLUDING XPERT MTB/RIF

EMRO, Cairo, Egypt, 29 November-1 December 2011

I would like here to welcome the members of the regional taskforce for implementation of the new diagnostics for tuberculosis control to the first consultation meeting of this taskforce. We highly appreciate the support from the senior consultants who are sharing their valuable experience with national tuberculosis programme managers and directors of tuberculosis laboratories in the Region through this taskforce.

Let me start by reminding all of us that in 2010, the world witnessed 8.8 million incident cases of tuberculosis, 1.1 million deaths from tuberculosis among HIV-negative people and an additional 350 thousand deaths from HIV-associated tuberculosis.

Therefore early detection of tuberculosis – including smear-negative disease, often associated with HIV co-infection – as well as multidrug-resistant tuberculosis (MDR-TB) are global priorities for tuberculosis control.

There are several challenges facing the scale up of early detection of tuberculosis and multidrug-resistance-tuberculosis. One of these relates to access to traditional diagnostic tools (that is, comprehensiveness of the laboratory network including culture and drug-susceptibility testing) and others relate to the diagnostic techniques themselves which are slow and burdensome. National tuberculosis programmes are looking for cheap, fast and feasible new

diagnostic tests that can be implemented anywhere, and this was the focus of the global efforts in tuberculosis research and development during the last decade.

WHO endorsed, on 8 December 2010, a new rapid technology called Xpert MTB/RIF. WHO's endorsement of this rapid test, follows 18 months of rigorous assessment of its field effectiveness in the early diagnosis of tuberculosis, as well as multidrug-resistant tuberculosis and tuberculosis complicated by HIV infection, which are more difficult to diagnose.

Xpert MTB/RIF is an automated, cartridge-based nucleic amplification assay for the simultaneous detection of tuberculosis and rifampicin resistance directly from sputum in less than two hours. The technology is based on the GeneXpert platform and was developed as a partnership between the Foundation for Innovative New Diagnostics (FIND), Cepheid Inc. and the University of Medicine and Dentistry of New Jersey, with support from the US National Institutes of Health.

This new and novel rapid test for tuberculosis is especially relevant in countries most affected by the disease. The test could revolutionize tuberculosis care and control by providing an accurate diagnosis for many patients in about 100 minutes, compared to current tests which can take up to three months to get results from.

WHO has developed policy statements and rapid implementation guidance to support implementation of the new technique and is monitoring the global roll-out of the technology. WHO Regional Office for the Eastern Mediterranean has established a regional taskforce comprising prominent laboratory consultants and national tuberculosis programme managers in the Region, supported by headquarters' colleagues and international tuberculosis experts who are familiar with the Region. The taskforce will undertake the following in close consultation with countries in the Region:

- study cost, cost-effectiveness and feasibility of implementation;
- adapt the global road map to the regional situation to enable proper advice and guidance to the countries; and
- develop a plan for implementation of the recommended global policy based on the results of consultations with countries.

This is the first meeting of the taskforce, the aim of which is to discuss countries' situations, identify the needs of the countries, adopt the global guidance to the regional context and draft regional/country operational plans to support countries.

The discussions will be based on the WHO policy statement and guidance for rapid implementation of the new technology. The operational considerations of implementation comprise five topics which will be considered in group work for adaptation to the regional context as follows:

- 1) positioning of the test (site selection)
- 2) selection of individuals to be tested (algorithms)
- 3) managerial aspects (revised case definition, monitoring of treatment)
- 4) monitoring of implementation and evidence for scaling up
- 5) practical considerations (planning, pricing, follow up and maintenance).

It is expected by the end of the meeting that the main points of adaptation of the global guidance to the regional context will have been agreed upon and draft country plans for implementation of the new technique will have been developed.

The timetable of the consultation is heavy but I hope this will not prevent you from some social activities and from enjoying winter in Cairo.

I wish you a fruitful consultation and productive results.