In the Name of God, the Compassionate, the Merciful

Address by

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to the

CONSULTATIVE MEETING ON STRENGTHENING THE QUALITY MANAGEMENT SYSTEM IN NATIONAL CONTROL LABORATORIES FOR VACCINES

Cairo, Egypt, 23–25 April 2007

Distinguished Participants, Dear Colleagues, Ladies and Gentlemen,

It is my pleasure to welcome you to the consultative meeting on strengthening the quality management system in national control laboratories for vaccines. I wish to thank all the facilitators of this important meeting.

In line with the WHO health for all strategy, universal immunization against common communicable diseases using assured quality vaccines remains the main objective of all Member States. In 1992, the Regional Office developed a regional plan to promote vaccine production and quality assurance in order to support expanded programmes of immunization in all countries. In 1998, the Forty-fifth session of the Regional Committee for the Eastern Mediterranean passed resolution EM/RC45/R.5 on regional self-reliance in the production of essential drugs and vaccines. It urged the Member States to develop strategies to ensure the availability of drugs and vaccines of high quality through importation or high quality local production; to strengthen national capacities for the control of drugs and vaccines, to include establishing functional national control authorities where these have not yet been established; and to establish
coordination and collaboration in quality assurance, research and development, and in essential
drugs and vaccine production. In 2004, the Fifty-first session of the Regional Committee for the
Eastern Mediterranean adopted resolution EM/RC51/R.10 on vaccine development, accessibility
and availability: towards self-sufficiency in the Eastern Mediterranean Region. This resolution
reaffirmed the 1998 resolution and urged the vaccine-producing countries in the Region to take
necessary action to upgrade their national regulatory authorities in order to meet the WHO core
six functions required for prequalification and to strengthen their national production capabilities
to fully comply with the current good manufacturing practices (cGMP) for vaccine production.
The resolution also urged the non-vaccine producing Member States in the Region to
establish/strengthen a well functioning national regulatory authority to ensure the quality of
vaccines available in their countries, and, importantly, urged them to consider buying vaccines
from regional sources that comply with WHO prequalification requirements.

Since 1998, the Regional Office has supported Member States in planning, coordination
and provision of technical advice to help them to ensure that vaccines produced and supplied in
their countries are of internationally acceptable quality standards, and in establishing effective
national regulatory mechanisms for quality assurance. Within the framework of the regional
strategy for self-sufficiency in vaccines, the Regional Office will focus particularly on
strengthening national regulatory capabilities.

The process of building regulatory capacity is based on the implementation of an
independent national regulatory system. An effective vaccine regulatory system is based on the
principle that vaccine quality is primarily the responsibility of the manufacturer. However, it is
the responsibility of the government to oversee the entire production process and to provide the
continuing evidence for quality, safety and efficacy of the vaccine through a competent and
independent national regulatory authority. WHO considers the national regulatory authority to be
a national institutional basis for ensuring that what is produced in, or imported into, the country
as a health product is of reliable quality, safety and efficacy. The national regulatory system for
vaccines comprises the six critical control functions established by WHO to ensure that all
vaccines can be evaluated for quality and safety and released into the market for use by national
immunization programmes. One of the six critical functions is laboratory access. The main role
of the laboratory as a part of the national regulatory authority is to control the quality, efficacy
and safety of the vaccines.

Ladies and Gentlemen,

The present situation clearly indicates that none of the national regulatory authorities in the
Eastern Mediterranean Region satisfies all of the six functions, and particularly the function
related to the control of vaccines. The area that requires most attention is that of the laboratory
quality system and that is why this consultative meeting was planned.

The main purpose of the meeting is to describe the framework of a laboratory quality
system in the context of the vaccine regulatory system; to provide information on the key
elements of a quality system; to discuss how to identify and fill gaps and correct deviations in a
quality system; and to provide guidance on how to implement a quality management system in
order to ensure the quality, safety and efficacy of vaccines. The meeting will focus on important
areas where the majority of the national control laboratories for vaccines had shortcomings in
implementing a quality assurance mechanism. The WHO tools to assess the performance of the
national vaccine control laboratory will also be discussed. These include the documentation
system, qualification and validation processes, internal and external audit systems and biosafety
programme. All these are essential to achieving accurate and reliable results in the control of
vaccines and to ensuring the quality of vaccines.

Dear Colleagues,

I hope that this consultative meeting will come up with useful and feasible
recommendations to improve quality management of vaccines. WHO will continue to support
Member States in establishing quality management systems and in strengthening the national
regulatory authorities to ensure the quality, safety and efficacy of vaccines. I wish you a fruitful,
successful and enjoyable stay in the beautiful and historical city of Cairo.