



In the Name of God, the Compassionate, the Merciful

Message from

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to the

**WORKSHOP ON IMPLEMENTATION OF VACCINE LOT RELEASE
AND INFORMAL CONSULTATION ON THE ESTABLISHMENT OF A REGIONAL
VACCINE LOT RELEASE NETWORK**

Amman, Jordan, 2–5 November 2010

Distinguished Participants, Dear Colleagues, Ladies and Gentlemen,

It is my pleasure to welcome you to Amman to participate in the workshop on implementation of vaccine lot release and informal consultation on the establishment of regional vaccine lot release network. I wish to thank your respective countries for your nomination to attend this meeting. I wish also to welcome our guests from the national regulatory authorities of Australia, Islamic Republic of Iran, France and Thailand, as well as colleagues from WHO headquarters.

Ladies and Gentlemen,

The use of assured quality vaccines against common communicable diseases is one of WHO's core strategies to ensure the highest possible level of health for all people. In this regard, Member States at the 51st session of the Regional Committee for the Eastern Mediterranean in 2004, agreed to establish a regional programme on self-sufficiency and self-reliance in vaccines, focusing firstly and particularly on strengthening national regulatory capabilities.

Indeed, the national health authorities of Member States have the duty to ensure the quality, safety and efficacy of all vaccines, both imported and locally produced. To accomplish this, national health authorities need to establish and maintain an independent, competent and functional national regulatory authority that is responsible for overseeing the entire production process and providing continuing evidence on the quality, safety and efficacy of the vaccines produced in or imported into the country, for use in either the public or private sector.

For the time being, only two countries from the Eastern Mediterranean Region notably Egypt and the Islamic Republic of Iran, have established a functional national regulatory authority, that has been assessed by WHO against a set of standard indicators.

Ladies and Gentlemen,

Vaccines are complex biological molecules and due to their inherent variability, national vaccine regulatory authorities in all countries, whether self-procuring or vaccine-producing countries, are mandated to evaluate properly and release the vaccines lot by lot before their use in the post-marketing phase.

Due to the complexity of the antigens and their formulations, particularly in the case of new vaccines, the establishment of networking for lot release and control, as a part of the regional programme to achieve vaccine self-sufficiency and self-reliance, can provide critical support for national regulatory authorities and national control laboratories to improve the lot release process and strengthen their capacity to regulate vaccines.

In fact, a fully functional regional network is a long term goal. In the meantime, collaboration among national regulatory authorities and national control laboratories can be initiated in the short term, through sharing scientific information and exchanging experience on technical issues as well as on methodologies for the evaluation and release of vaccines. The development of such a network will certainly expand the capacity of individual regulatory bodies and will progressively build confidence and mutual recognition among them.

In addition, some countries of the Region have expressed the need for more guidance on the vaccine lot release process as well as for the establishment of a regional network for lot release in order to strengthen the performance of the regulatory function related to vaccine lot release.

Since 2007, WHO, through a consultative process, has been developing guidelines for independent lot release of vaccines by regulatory authorities. These guidelines were recently approved by the Expert Committee on Biological Standardization in its annual meeting in October 2010.

Ladies and Gentlemen,

The overall objective of this meeting is to strengthen the capacity of national regulatory authorities for releasing the vaccines lot by lot. As you may see on the programme, the meeting is divided into two parts. The first part will focus on the implementation of the lot release process through the implementation of the newly developed guidelines for independent lot release of vaccines by regulatory authorities in order to assist countries to establish and maintain a vaccine lot release system for ensuring the accessibility and availability of safe and effective vaccines. The second part will aim to explore the feasibility, evaluate the advantages and benefits and agree on the methodology for establishing a vaccine lot release network in the Region.

Dear Colleagues,

I am sure that with your active participation, the objectives of this workshop will be met. I can assure you that WHO will continue to support Member States and undertake the efforts necessary in establishing and strengthening national regulatory authorities to be recognized as functional for ensuring the quality, safety and efficacy of vaccines.

Once again I would like to express my sincere thanks to all of you for your efforts and for participating in this meeting. I wish you a successful meeting and a pleasant stay in this beautiful city.