SPEECH BY DR SHIN YOUNG-SOO
REGIONAL DIRECTOR, WHO WPRO
AT THE OPENING CEREMONY OF THE 14TH INTERNATIONAL CONFERENCE OF DRUG REGULATORY AUTHORITIES
TUESDAY, 30 NOVEMBER 2010, 9.45AM
AT THE RAFFLES CITY CONVENTION CENTRE

Mr Khaw Boon Wan, Distinguished Minister of Health of Singapore,

Dr John Lim, Chief Executive Officer of the Health Sciences Authority of Singapore,

Dr Jürg Schentzer, Executive Director, Swissmedic,

Distinguished Delegates,

Colleagues,

Ladies and gentlemen.

It is a great pleasure to welcome you to the 14th International Conference of Drug Regulatory Authorities.

I would like to thank the Government of Singapore and the Minister of Health for hosting this important event.

I am also grateful to the Health Sciences Authority for its generous and efficient support in organizing the conference.

Over the years, the International Conference of Drug Regulatory Authorities has proven to be an important event, as it provides a unique forum where issues related to medicines regulation can be discussed from a public health perspective.

Globalization and the expansion of international trade in recent years have more closely connected once a far and remote countries.

This, of course, affects the supply of medicines.

It has had positive implications, making medicines more widely available.

But it also has brought greater risks.

As supply chains become longer and more complex, there are greater possibilities for substandard and counterfeit medicines to penetrate supply systems.

As a result, the role of regulators is now more important than ever.

We all know that the primary role of regulators is to protect the public by ensuring the quality, safety and efficacy of pharmaceuticals and other medical products.

But there is more that regulators can and should do to support public health goals.

The Director-General of WHO, Dr Margaret Chan, has repeatedly stressed the need to reduce maternal and child mortality, which has been given high priority in the Millennium Development Goals.

At the same time, there is increasing attention to the need to tackle noncommunicable diseases in developing countries. Neither of these can be addressed effectively unless people have access to medicines whose quality, safety and efficacy are assured.

We all know that ensuring affordability and containing the costs of medicines are not your primary tasks.

But we also know that your decisions can indirectly affect both affordability and access.

And I am asking you to bear that in mind when executing your primary task as regulators.

In deciding to allow a medicine into your national market, you are guided by science and evidence.

And you operate within a framework of rules and regulations.

But there is likely to be a moment when you have to make a judgement call.

Obviously, you cannot – and should not – accept a product that is not safe or not effective.

In your decisions, you always have to balance risks and the benefits.

And that is where there may be room to take into account the impact of your decisions on access.

Of course, there are other challenges.

Despite increasing demands for specific expertise in drug regulation, we are often confronted with issues related to human and financial resources, especially in developing countries.

This will inevitably hinder the effective functioning of drug regulatory institutions.

That is why intercountry collaboration and an exchange of information among regulatory authorities can be beneficial to all parties.

I am thinking, for example, of the need to share best practices, and the need to share experiences about what works and what does not work.

I am very happy to see that this issue will be discussed during this conference.

Strengthening drug regulatory authorities is one of the priority issues on the WHO agenda.

Certainly, the task of ensuring the quality, safety and efficacy of pharmaceutical products means that drug regulatory agencies must be independent in their decision-making.

Drug regulatory agencies must demonstrate the highest level of professional conduct, using the best possible expertise and all available knowledge and evidence.

Good governance and transparency in drug regulatory institutions are crucial in ensuring professional conduct and in inspiring confidence in your work.

Your recommendations will shape WHO's work in strengthening medicines regulatory systems throughout the world.

I wish you every success in your deliberations.

Thank you.