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Plenary 1

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Mr Si-Min Rhyu, Minister,
Ministry of Health and Welfare, Republic of Korea (PL1-1)

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Korea Food and Drug Administration (PL1-2)

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Welcome address

Mr Si-Min Rhyu, Minister,
Ministry of Health and Welfare, Republic of Korea

On behalf of the Republic of Korea, I would like to extend our warmest welcome to participants of the 12th International Conference of Drug Regulatory Authorities.

Since 1980, the ICDRAs have played a critical role in international cooperation and in advancing global health under the leadership of officials of drug regulatory authorities. Building on past achievements, we are gathered here today to discuss ways to enhance safety and efficacy, and to improve the quality of pharmaceutical products.

I am particularly pleased that such a significant and meaningful international event is being held in Seoul, and would like to thank officials and staff of the World Health Organization and the Korean Food and Drug Administration for orchestrating and coordinating this conference.
Ladies and gentlemen, we all share one dream. The dream is to make a world where everyone can live a healthy life, both physically and mentally. We may have differences in nationality and culture but, in collaboration with WHO, we are united in our commitment to realize this dream. In particular, the universal dream of a long healthy life can be realized when countries work together through economic growth and scientific advancement to develop new pharmaceutical breakthroughs. In this respect, I believe ICDRA can play a key role.

Human history witnesses the never-ending fight against disease. At this very moment, there are so many young children suffering from diseases and hunger in the world. In particular, the new strain of avian influenza is posing a serious health threat. In order to address these health problems, international cooperation and coordination in technological and economic development are increasingly important.

The ICDRA is dedicated to the promotion of global health and has contributed considerably to making the world a healthier place where people can live in harmony and with hope. Let me take this opportunity to applaud WHO which has served as an invaluable catalyst in its alliance with the ICDRA member countries, and we look forward to its continued support in the future.

The Korean government is fully aware of the consequences associated with the current range of health threats. These include the emergence of new epidemics such as SARS and avian influenza, and the increase in cancers and chronic diseases caused by changes in life structure and population ageing. Health problems such as these lead to rising healthcare cost and could ultimately undermine the quality of life.

To resolve emerging and existing health problems, the Ministry of Health and Welfare in the Republic of Korea has implemented a range of policies on pharmaceutical products and epidemics. Under the Ministry, the Korean Food and Drug Administration is tasked with evaluating the safety and efficacy of drugs as well as conducting quality inspections. Also, the Korean Center for Disease Control is in charge of epidemic preparedness and response. In addition, fully recognizing the need for international cooperation in the surveillance against new epidemics and development and provision of new and innovative drugs, the Korean government is willing to take a proactive role in challenges to international society.

I sincerely hope the 12th ICDRA in Seoul will be a significant stepping stone to the goal of promoting global health and I would like to reiterate
Korea’s unequivocal commitment to attainment of this goal and close cooperation with the developed, developing, and least developed countries, as a part of international coordination efforts in the regulation of pharmaceutical products.

Once again, I welcome all of you to the 12th ICDRA in Seoul and hope you will have a rewarding and enjoyable stay in the Republic of Korea.

Opening remarks

Dr Chang-Jin Moon, Commissioner
Korea Food and Drug Administration

It is indeed an honor for me to present the opening remarks on behalf of the Korea Food and Drug Administration, and I welcome this opportunity to speak to you all on this beautiful Spring day, at the opening of the 12th International Conference of Drug Regulatory Authorities.

I do believe that among those many numerous inventions of the human race, drugs are a most valuable creation. Such developments as antibiotics and the synthesis of aspirin became beams of light rescuing mankind from the dark fears of diseases and promising hope for the future. The development of drugs has gained increasing speed and has led to today’s use of cutting edge technologies in manufacturing drugs such as antivirals and gene therapy products.

However, unresolved issues such as strengthening access to drugs in underdeveloped countries, continued circulation of substandard and low-quality drugs in countries, and ethical issues surrounding developmental processes have created shadows over such growth.

Furthermore, new diseases such as avian influenza are appearing around the world, translating into a need for countries across the globe to join hands in establishing a system to prevent new epidemics and better share technologies to accelerate the development and supply of treatments. Amidst such a period of change, the ICDRA has played a central role in improving the health of people around the world as a forum to discuss pending issues such as the harmonization of regulations to ensure the safety, efficacy and quality of drugs.

I hope that the 12th Conference will prove to be a venue for future-oriented discussions with the single goal of improving the health of people around the world, transcending political ideologies and serving the
interests of both advanced and developing countries.

I also hope that this conference will serve as an opportunity to bring the drug safety management of Member States to a new level through action plans derived from the ICDRA. As a member of the international community, the Republic of Korea will do its utmost to fulfill its given role and mission.

Korea boasts four distinct seasons, and I hope all our guests will be able to fully enjoy Korea’s Spring. Last but not least, I would like to pay my tribute to the cooperation of WHO officials and the efforts of the preparatory secretariat which have made this event possible.

**Opening remarks**

_Dr Howard Zucker, Assistant Director-General, Health Technology and Pharmaceuticals, World Health Organization_

This is now the Twelfth Conference in a series of events which have proven of immense international value both to drug regulatory officials worldwide and to the World Health Organization. The ICDRA provides a unique forum where issues of common concern can be debated. I am delighted to see so many officials from such a variety of countries representing near and far regions of the world, and I am confident that your expectations of this Conference will be fulfilled.

Our hosts at the Ministry of Health of the Republic of Korea and the Korea Food and Drug Administration have been more than generous in providing such an attractive venue. I appreciate the enormous task that organizing such an event represents. I would particularly like to extend my gratitude to all those involved in arranging the Conference, and transmit my thanks to the planning committee for proposing such an excellent and varied agenda which targets so well our immediate interests and concerns.

WHO attaches great importance to the links it has established with national and international bodies. Without intercommunication and teamwork, little can be achieved. WHO is particularly proud of the networks which it has created and built up over time between WHO and drug regulatory officials and experts in so many countries. These provide us with valuable feedback for our public health work and give important technical input for the recommendations and guidelines which WHO disseminates to health care professionals and interested parties worldwide.
Only with your valued support can WHO continue in its task of promoting the quality, safety, efficacy and rational use of medicines and vaccines as part of national health and drug policies. Let me address several areas of major importance to WHO in the programme proposed for the twelfth ICDRA.

WHO is particularly concerned about the increase of counterfeiting throughout the world. This is why we have taken action on the recommendations of the eleventh ICDRA that asked us to elaborate further on ways of strengthening international collaboration to fight this major public health threat. The workshop on counterfeit medicines will report back to the ICDRA what we have achieved during the recent international meeting of stakeholders in Rome.

As a result of the discussions which took place in Rome, and to demonstrate the importance which WHO places on the need for action to fight counterfeiting of medicines, I should like to inform you of the launch of the global task force, IMPACT. This task force will be based at WHO in Geneva, and will focus on creating partnerships and improving cooperation among stakeholders with specific action in the areas of legislation, law enforcement, trade, and risk communication. Additionally, IMPACT will seek innovative solutions, including technology transfer to developing countries, to improve the effectiveness and impact of global action.

Until recently, there were insufficient regulatory mechanisms to assess quality, safety and efficacy of medicines specifically meant for the diseases prevalent in the developing world. This concerns not only the major killer diseases such as HIV/AIDS, tuberculosis and malaria but also vaccines for prevention of many infectious diseases for which immunization is the most cost effective intervention. Without access to reliable medicines for treatment and prevention of devastating infectious diseases, it is not possible to achieve the Millenium Development Goals set by the United Nations. We are happy to note that due to excellent cooperation with Governments and regulators during recent years several new regulatory pathways have become available. These new regulatory pathways include the EU scientific opinions for WHO, also known as Article 58 of the EU pharmaceutical legislation, and they will be described in detail during Plenary Three. We also hope that this plenary will facilitate understanding of how regulators with limited resources can benefit from these new initiatives and avoid unnecessary duplicative efforts.
We believe that regulators have a clear role in helping to address the health care problems related to emerging new diseases, including a potential influenza pandemic. Regulators should not be part of the problem but rather be proactive in seeking solutions and taking the lead in those areas where their expertise can help. The role of regulators in addressing emerging diseases crisis management will be discussed during Plenary Four.

There are many challenges to regulating biological products and vaccines, which are particularly complicated innovative products. A pre-meeting on improving world health through regulation of biological products has just been held and the results of this very important gathering will be reported to participants in Workshop H dealing with the Global challenges for regulation of vaccines.

Blood and blood-derived products can save many lives, but they must be handled correctly due to a threat of transmitting killer infections; they must also be effective. We are concerned that this area of medicines regulation remains underdeveloped in many countries, or even worse, non-existent, and can pose substantive risks to patients. The regulatory situation of blood and blood derived products together with discussion on seeking workable solutions to improving the situation will take place in Workshop D. I hope that by the end of this conference we have a clear action plan on how to move forward.

Finally, I would like to mention safety. It is often perceived as a relative luxury and something that only well resourced regulatory agencies can manage to have. I wish to disagree. Safety is not a luxury, as deaths occurring due to adverse effects are mostly avoidable. Adequate feedback on safety issues is also a basic element of the rational use of medicines. Studies before the launch of a product may not necessarily reveal the true safety pattern. If feedback in terms of monitoring is lacking, we may not be able to take corrective measures; be it a safety concern, or lack of efficacy. The workshop on new challenges in safety of medicines will reflect the increasing interest and willingness of developing countries to set up functioning national pharmacovigilance centres. Figures show that during the last 10 years there have been more new national centres established than during the previous two decades together. I hope that this session will provide recommendations that are both pragmatic and to the point in addressing the specific needs of developing countries.

I have commented on only some of the important topics you will be addressing. This does not mean that the rest of the programme is not also
important. All topics suggested by the planning committee deserve serious attention, and we count on your valuable input throughout the conference.

While deliberating on the technical and scientific areas of this core work, we must not lose sight of the challenges that lie ahead. In parallel with its technical normative work, WHO is committed to strengthening all elements of national drug policies including national medicines regulatory agencies, promoting the concept of essential medicines, along with measures for prevention and immunization. In a rapidly globalizing world, we need to learn quickly from each other to avoid duplication of effort and benefit from each others’ work.

Together, we must strive for the full realization of scientific and technical advances to the betterment of all countries, developed and developing. We must define how technology can be delivered to those in need wherever they are, while ensuring that all populations are the recipients of safe quality medicines which are appropriately delivered. Our past successes have now become the building blocks of the new millennium, through which we can effectively contribute to achieving the Millennium Development Goals. Regulators have an important role to play and a responsibility in achieving the objectives which have been set. Let us continue to work together to achieve them.