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PROCEEDINGS

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World Health Organization

Proceedings of the Eleventh International Conference of Drug Regulatory Authorities (ICDRA)

16–19 February 2004
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Spanish Agency for Medicines and Health Products

World Health Organization

Objectives of the International Conference of Drug Regulatory Authorities (ICDRA)

- to promote collaboration between drug regulatory authorities
- to reach a consensus on matters of interest
- to facilitate timely and adequate exchange of information
- to discuss issues of international relevance

Contents

Page

Recommendations

Presentations made during the conference can be found on the attached CD-ROM

Opening Ceremony

Dr Ana Pastor
Minister of Health, Spain

Allow me to welcome participants to this Eleventh International Conference of Drug Regulatory Authorities (ICDRA) and to inaugurate this important meeting which once again convenes all the world's countries, as represented by their drug regulatory agencies.

Before we begin our work, I should once again like to draw attention to the heavy responsibility we bear. Our countries' citizens trust that we are here to safeguard the use and availability of medicines and to enhance the unique opportunity for health that they represent. This makes it incumbent upon us to devote our best endeavours to drug regulation; these meetings sponsored by WHO are an exceptional opportunity to learn from each other and to return home with renewed ideas and enthusiasm.

I am convinced that meetings between people of different backgrounds, cultures and races are a valuable and hugely enriching opportunity which we must not neglect. We have enthusiastically drawn up a conference programme which we believe will help to cement many bonds. Also, a visit to Toledo, just over 100 kilometres from Madrid, is planned. Toledo is a thousand-year old city brimming with history and artistic treasures. It is also a city that for many years was a land of tolerance and diversity, and where different cultures engaged in peaceful dialogue and prospered together.

This is also an ideal moment to congratulate participants of the pre-ICDRA meeting which focused on the very serious problem of counterfeit drugs and the ever-more-important task of coordinating inspection activities. I am confident that the conclusions reached will help to improve the situation and to provide the most appropriate response.

Drug regulatory agencies have become a vital tool for public health. We are dealing with one of the most tightly controlled consumer goods of our time, in whatever part of the world. This is due to the nature of medicines themselves which, alongside their huge potential benefits, carry risks – even when they are properly manufactured and used. Reducing these risks as much as possible is a hugely complex and demanding task to which your agencies are devoting their efforts.

The international conferences of drug regulatory authorities demonstrate a fine example of cooperation. We enthusiastically welcome the efforts of the World Health Organization as a coordinator of efforts to achieve an ever-healthier world. There is no doubt that we all face ever more demanding challenges but the means of meeting these are constantly improving. One of the fundamental features of our time is the close connection between scientific considerations and political decisions. We need to be capable of putting into practice and focusing scientific and political considerations within a capacity to anticipate the future. This is becoming indispensable for regulatory authorities in the light of the challenges which the future is sure to bring. If we wish to successfully perform our task, we need to keep close track of scientific progress.

The conference programme will include many major issues with which we are concerned: these range from the specialized topic of fixed dose combinations of drugs to the general and vital issue of drug monitoring. From pharmacopoeias to herbal medicines, from drugs derived from blood to new frontiers.

Undoubtedly, one of the main problems we shall address is that of access to drugs. It is an unfortunate fact of our world that there are unacceptable differences preventing those in greatest need of essential medicines from obtaining them. However, the developed world can-