

ESPAÑA SPAIN

# 11<sup>th</sup> ICDRA

MADRID MADRID

16 - 19 febrero

16th - 19th February

2004

PROCEEDINGS



MINISTERIO  
DE SANIDAD  
Y CONSUMO



agencia española de  
medicamentos y  
productos sanitarios

World Health  
Organization



This document is not issued to the general public, and all rights are reserved by the World Health Organization (WHO). The document may not be reviewed, abstracted, quoted, reproduced or translated, in part or in whole, without the prior written permission of WHO. No part of this document may be stored in a retrieval system or transmitted in any form or by any means — electronic, mechanical or other — without the prior permission of WHO.

The views expressed by presenters/authors are solely the responsibility of those presenters/authors.

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

16–19 February 2004  
Madrid, Spain



**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
<b>Opening ceremony</b>	
Dr Ana Pastor, Minister of Health, Spain	1
Dr LEE Jong-wook, Director-General, World Health Organization	4
Dr Zheng Xiaou, Commissioner, State Food and Drug Administration, People's Republic of China	7
<hr/>	
<b>Programme</b>	
Eleventh ICDRA programme overview	8
Eleventh ICDRA Programme	10
<hr/>	
<b>Selected presentations</b>	
Challenges to regulators in establishing efficacy	16
Role of regulators in improving the quality of ethical outcomes	17
Regulatory aspects of gene transfer medicinal products	21
The need for informed consent in clinical research	22
Challenges to regulators in ensuring safety monitoring	25
Success factors in national pharmacovigilance programmes	26
How pharmacoepidemiology can improve pharmacovigilance practice	27
Assuring the safety and quality control of traditional medicines	30
Regulation of herbal medicines in Nigeria	31
Safety surveillance system for natural health products in Canada	32
Consumer/patient information on safe use of herbals	33
<hr/>	

	<b>Page</b>
<b>Recommendations</b>	
Progress report on Tenth ICDRA	34
Regulatory aspects of access to medicines	34
Strengthening of regulatory frameworks for medicinal products	35
Pharmacovigilance practices	35
Pharmacopoeias in a changing regulatory environment	37
Regulatory assessment of combination products	38
Regulators, good clinical practice and ethics	38
Public health vs. the marketplace	39
Safety of herbal medicines	40
Assuring quality and safety of blood products	41
Human tissue: problems and challenges for regulators	42
Regulatory tools for providing drug information	43
Harmonization updates	43
Promoting good regulatory practices	44
Regulatory aspects of supply of quality medicines	45
Implications of regulatory decisions for pharmacoeconomics	46
Current topics	47
<hr/>	
List of participants	49
<hr/>	
Presentations made during the conference can be found on the attached CD-ROM	
<hr/>	

---

## 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-

预览已结束，完整报告链接和二维码如下：

[https://www.yunbaogao.cn/report/index/report?reportId=5\\_30104](https://www.yunbaogao.cn/report/index/report?reportId=5_30104)

