

ESPAÑA SPAIN

11th ICDRA

MADRID MADRID

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PROCEEDINGS



MINISTERIO
DE SANIDAD
Y CONSUMO



agencia española de
medicamentos y
productos sanitarios

World Health
Organization



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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

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**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 cannot turn its back on whole regions in which living conditions are precarious and we must strive to achieve the ultimate objective of allowing all to benefit from the advantages of progress.

There are some countries in which 40% of young adults are infected with the human immunodeficiency virus and in which the number of orphans, now and in the future, is enormous. We can no longer disregard this problem. I call on a collective sense of humanitarian responsibility to fulfil the obligations of our common human destiny. Should we fail to do this, suffering will continue to spread throughout the world and we shall have failed in our task.

It is impossible to guide health organizations towards new areas of concern without coordination or on the basis of only short-term policies. The need is for a firm commitment by all the specialists and officials concerned. This is a journey that we all have to make. The topics mentioned above are a clear demonstration of this need. It is pointless to address them in disarray, and without the active involvement of our countries' health professionals we shall undoubtedly fail. Ours is a time of enormous hope and potential. Thanks to the media and technical progress, we are all able to keep abreast, almost in real time, of the advances being made by science, and on many occasions it is possible for us to make use of those advances, or at least to take them into account when making decisions.

There are many of us who feel overwhelmed by the volume of information available to us. However, because we live in a world in which we will face an ever-growing volume of instantly-processed information, we are obliged to seek ways of accessing, analysing and applying it. Striving to keep up with progress being made in each field is a demanding task for any specialist, and it is even more so for health professionals. However, in order to overcome widespread prejudice against new technology, we need to strengthen those features which help to make health care more humane. There are excellent support groups for the chronically ill on the Internet together with information and medical consultation pages; at the same time, the new technologies are helping to link specialists at the different levels of care. Perhaps we, as regulatory authorities, should also develop a tool to enable us to keep regularly in touch with our specialists.

For this reason, meetings between agencies are essential. Far from the indifference of the computer or the office desk, these meetings give us an opportunity not only to formally examine the issues at hand, but also to meet those who have to deal with the same problems. All of us have something to learn and something to teach .

This Conference will undoubtedly enable us to improve our knowledge and help to improve the health of our populations. By working diligently and rigorously in our specialized field – in this case the complex and fascinating world of medicines – we help to ensure that future generations will enjoy a better world.

To achieve this, we need a world of peace. Without the right to peace, all other rights disappear and our achievements collapse. Development is impossible when violence prevails so that we must vigilantly maintain our daily commitment to building culture and peace. I hope that our conference proves to be a valuable opportunity for us and a success for all.

Dr LEE Jong-wook, Director-General World Health Organization

It is a pleasure to be here today for this important conference. Drug regulatory authorities around the world play a vitally important role in ensuring the safety, quality and efficacy of medicines, blood products, vaccines and biologicals. The greatest public health achievements of our time have involved wide and effective coverage of immunization and treatment. They would not have been possible without your efforts, and the world will need those efforts even more to meet the challenges that lie ahead.

The increase in volume and complexity of trade in pharmaceutical products continues to accelerate. Not only the products but the starting and intermediate materials used for making them are traded internationally. Finished products, in their turn, are often repackaged and re-traded several times before they reach their end users. Because speed can make the difference between success and failure in trade and in applying medicine, there is pressure to make regulatory procedures quick and minimal. Especially where there are demands for medicines on a large scale, at short notice, to fight an epidemic or support a campaign, manufacturers can find themselves under intense pressure to skip some of the mechanisms designed to ensure safety and quality. In addition, patients and their carers are increasingly turning to the Internet for alternative treatments, lifestyle drugs or just cheaper medicines. This exposes them to products that may not have been subjected to national regulatory control. This trend combines to help substandard or counterfeit medicines circulate more and more easily, presenting a growing threat to public health. Regulatory authorities increasingly find themselves in difficult situations, with strong but conflicting demands coming from government, business and the public. All stakeholders need to make a full review of this situation and find new ways to tackle it. Your discussions here this week can make a valuable contribution to this process.

An initial step towards making drug regulation manageable internationally is to enable more countries to have effective regulatory authorities. At present, only half of them do, and almost a third of the countries in the world have no regulatory system at all. It is in those countries most in need of safe and affordable medicines that this lack of regulatory facilities is most apparent. The gap can be bridged in part by making all existing regulatory information publicly available

and easily accessible. This can save time and avoid duplication of effort for regulators, prescribers, pharmacists, health workers and consumer groups.

Especially where medicines are being used to fight diseases that are killing thousands, regulatory activities have to be made as cost-effective as possible. In many cases, assessments made in other countries can be valid where there is harmonization of regulatory requirements. Harmonization can facilitate access and lower prices, and is developing rapidly in some parts of the world. But, harmonization lags far behind for multi-source generic drugs and these include many of the affordable essential medicines.

In all countries, adverse drug reactions are a major concern. They are the fifth leading cause of death in the USA, and elsewhere up to 17% of the health care budget is spent on dealing with them. A good pharmacovigilance system costs only about one dollar for every thousand dollars spent on the purchase of medicines. The challenges here include preventing the adverse reactions that can be caused by unsafe herbal medicines, ensuring the safety of products derived from blood and plasma and making an ever-expanding array of vaccines available to those who need them. Regulation, in these and other areas you will be discussing, requires the development of special expertise.

International negotiations, though slow and unpredictable, can present new opportunities to make safe and effective medicines more accessible. The World Trade Organization's decision last August, on Paragraph 6 of the Doha Declaration on TRIPS and Public Health, has the potential to facilitate the export of affordable medicines to the countries that need them most. Much depends on how this decision is implemented in countries without their own pharmaceutical production facilities. They need all the support we can give them, both through WHO and through your own agencies.

A catalyst and focus for many of the activities needed in this field is our current campaign to get three million people living with HIV in developing countries onto antiretroviral treatment by the end of 2005. To assist countries in obtaining the products they need for this, we have established an AIDS Medicines and Diagnostics Service (AMDS). It builds on work carried out over a number of years by WHO, UNAIDS, UNICEF, the World Bank, and the Global Fund. Its aim is to bridge the treatment gap in developing countries. The AMDS is based at WHO in Geneva and is run jointly with our UN partners.

The AMDS will provide buyers with up-to-date information on the sources, prices and regulatory status of antiretrovirals. It will continue to purchase diagnostic tests as part of its bulk procurement scheme and will be keeping manufacturers informed of anticipated needs. It will also be working with you and your colleagues to support product specification and registration, prequalification of antiretrovirals and diagnostics, and quality assurance methods for local production. The same partnership also provides a mechanism to ensure safety, efficacy and quality through the prequalification of products for HIV, malaria and tuberculosis. It has already helped to make nearly 100 reliable products available worldwide. Thanks to the support and expertise of many regulatory authorities around the world, this has become a highly effective and technically robust service.

During the twentieth century, technical innovation made an enormous contribution to improving the world's health status. Progress has continued for some tropical diseases such as African trypanosomiasis and visceral leishmaniasis, but for malaria and tuberculosis innovation has fallen well behind current needs. The older medicines are failing either because they encounter resistance or because they do not meet present-day standards of safety. In many countries, even where there are potential new products, regulators do not have the capacity to assess their safety and efficacy.

Slow progress in developing malaria and tuberculosis medicines is a major problem, and one that will benefit from your particular attention during this week. Recently, the European Medicines Evaluation Agency has been authorized to advise on products for use outside Europe. This is but one example of how regulators globally can help countries most in need.

To establish new drug regulatory authorities and strengthen those that are not yet working properly will require more of this kind of solidarity, as well as innovative thinking and a realistic investment. Your discussions during the next three days provide a valuable opportunity for sharing ideas and information on what works.

In conclusion, it is in the interests of everyone to have reliable national and international drug regulatory systems. The health authorities, the health workers and the public cannot do without this assurance, nor can the pharmaceutical companies.

Your work can rightfully claim the wholehearted support of all concerned. You certainly have that of WHO and I wish you every success in your discussions here this week.

**Dr Zheng Xiaou,
Commissioner, State Food and Drug Administration,
People's Republic of China**

As the representative of the host country which organized the Tenth International Conference of Drug Regulatory Authorities in Hong Kong, SAR, China in June 2002, please allow me to express my thanks to the organizers of this Eleventh ICDRA — the Spanish Ministry of Health and World Health Organization — for inviting me to say a few words on behalf of the People's Republic of China.

With the dramatic changes in our environment and the development of science and technology, drug regulatory authorities encounter many new issues and challenges. For twenty years now, the ICDRAs have served as a forum for senior drug regulators to discuss regulatory affairs, exchange views and identify the direction of future developments.

We appreciate the efforts that the Spanish Agency for Medicines and Healthcare Products and WHO have made in the preparation of this conference and the careful selection of various topics for discussion. We are very glad to participate in the ICDRA in Spain – a country with a long-standing history and splendid culture.

We look forward to fruitful discussion and dynamic exchange of views during the conference with an opportunity to clarify issues and challenges that drug regulatory authorities are now facing. This will provide us with ways to explore and improve harmonization, cooperation and communication among different authorities. It is also our wish to strengthen administration of drug regulation through effective measures that ensure the safety, efficacy and quality of medicines while improving access and rational use of drugs.

Eleventh ICDRA Programme Overview

MONDAY 16 FEBRUARY	Opening session	Plenary 1 Progress report on Tenth ICDRA
TUESDAY 17 FEBRUARY	Plenary 2. Regulatory aspects of access to medicines	Workshop 5-A Safety of herbal medicines Workshop 6-B Assuring quality and safety of blood products
WEDNESDAY 18 FEBRUARY	Plenary 3 Strengthening of regulatory frameworks for medicinal products	Workshop 7-C Human tissue: problems & challenges for regulators Workshop 8-D Regulatory tools for providing drug information
THURSDAY 19 FEBRUARY	Plenary 4 Pharmacovigilance practices	Plenary 5 Current topics

	<p>Workshop 1-E Pharmacopoeias in a changing regulatory environment</p> <p>Workshop 2-F Regulatory assessment of combination products</p>	<p>Workshop 3-I Regulators, GCP and Ethics</p> <p>Workshop 4-J Public health needs vs the marketplace</p>
	<p>—————</p>	<p>—————</p>
	<p>Workshop 9-G Harmonization updates</p> <p>Workshop 10-H Promoting good regulatory practices</p>	<p>Workshop 11-K Regulatory aspects of supply of quality medicines</p> <p>Workshop 12-L Implications of regulatory decisions for pharmacoeconomics</p>
	<p>Keynote presentation: Regulatory challenges of pharmacogenetics and pharmacogenomics</p>	<p>Recommendations and Closing remarks</p>

Eleventh ICDRA Programme

MONDAY 16 FEBRUARY

(Presentations made during the conference are provided on the attached CD-ROM)

Opening session

09.00 - 10.30 at Hospital San Carlos

Dr Ana Pastor, Minister of Health, Spain

Dr LEE Jong-wook, Director-General, World Health Organization

Dr Carlos Lens, Director, Spanish Agency for Medicines and Health Products, Spain

Mr X. Zheng, Commissioner, State Food and Drug Administration, People's Republic of China

Plenary 1. Progress report on Tenth ICDRA

11.00-12.30 at Hospital San Carlos

Introduction and overview of Tenth ICDRA : Dr Lam, Director, Department of Health, Hong Kong SAR, China

International implementation : Dr V. Lepakhin, Assistant Director-General, Health Technology and Pharmaceuticals, WHO

Country implementation : WHO Regional Advisers

Workshop 1-E

Pharmacopoeias in a changing regulatory environment

14.30-16.00 at Hotel M. Angel

Moderators: Dr Ashwini Kumar, India and Dr Chiale, Argentina

Pharmacopoeial monographs vs. manufacturers' specifications : Dr Vardulaki, Spain

Impurity profile specifications: repercussion of the new ICH guidance text : Dr Wang Guorong, China

International harmonization : Need for international reference substances, PDG, regional harmonization efforts : Dr Gugu Mahlangu, Zimbabwe

Workshop 2-F.

Regulatory assessment of combination products

14.30-16.00 at Hotel M. Angel

Moderators: Dr K. Woods, United Kingdom and Ms Maryam Hinds, Barbados

Regulatory approach to the fixed-dose combination products: new challenges : Dr L. Slamet, Indonesia

BfArm thinking about fixed-dose combinations : Dr Christian Behles, Germany

Need for new clinical studies and fixed-dose combinations :
Dr J. Molzon, USA

Combination drugs for public health needs – regulatory viewpoint :
Dr Shabir Banoo, South Africa

Workshop 3-I. Regulators, GCP and Ethics

16.30-18.00 at Hotel M. Angel

Moderators: Teresa Milan, Spain and Dr Y. Sohn, Republic of Korea

Role of regulators in improving the quality of ethical outcomes :
Dr Chor Hiang Tan, Singapore

Vaccine Development, GCP & the Global Challenge :
Dr Jesse Goodman, USA

GCP in Clinical Gene Therapy: the Role of the CPMP/Gene Therapy
Expert Group : Dr Cichutek, EMEA

The need for informed consent in research : Dr P. Saidon, Argentina

Workshop 4-J. Public health needs vs the marketplace

16.00 - 18.00 at Hotel M. Angel

Moderators: Mr Ben Botwe, Ghana, and Dr J. Lynnvig, Denmark

Orphan drugs legislation in the EU: lessons learned :
Mr P. Weissenberg, T. Lonngren EMEA

The role of regulators in improving access to drugs for neglected
diseases : Dr Ashwini Kumar, India

The challenges and implications of limited regulatory capacity :
Dr Kristin Raudsepp, Estonia

How to get necessary public health products developed and
authorized : Mr J. Lisman, Netherlands

Medicines regulation in tourism-driven economies : Mr G. Requin,
Mauritius

TUESDAY 17 FEBRUARY

Plenary 2. Regulatory aspects of access to medicines

09.00 - 10.30 at Hotel Miguel Angel

Moderators : Dr Rodrigo Salinas, Chile and Dr. Jose Félix Olalla, Spain

Fast track, orphan drugs, public health needs, distribution, supply :

Dr Supachai Kunaratanapruk, Thailand

Innovation, patents : Dr R. Peterson, Canada

Distribution, supply and availability : Dr Per Roksvaag, Norway

Spanish experience in facilitating access to public health priority

drugs : Dr. Jose Félix Olalla, Spain

Workshop 5-A. Safety of herbal medicines

11.00 - 12.30 at Hotel Miguel Angel

Moderators : Dr K. Keller, Germany, and Dr Ashwini Kumar, India

Safety monitoring : Dr Duc Vu, Canada

Quality issues contributing to safety : Dr R. Lin, China

Regulatory aspects of herbal medicines : Dr Dora Akunyili, Nigeria

Customer education and herbal medicines : Dr Rolf Spang,

Switzerland

Workshop 6-B. Assuring quality and safety of blood products

11.00 - 12.30 at Hotel Miguel Angel

Moderators : Dr J. Lower, Germany and Dr Hong-Ki Min,

Republic of Korea

Plasma fractionation in Canada : Ms Julia Hill, Canada

Issues related to GMP : Dr C. Schaerer, Switzerland

Country Experience : Dr Beatriz MacDowell Soares, Brazil

Round table discussion – Problems encountered in practice

WEDNESDAY 18 FEBRUARY

Plenary 3. Strengthening of regulatory frameworks for medicinal products

09.00 - 10.30 at Hotel Miguel Angel

Moderator : Dr M. Limeres, Argentina

Regional initiatives, ASEAN : Dr Dato Che Zin, Malaysia

Regional initiatives, EU : Mr P. Weissenberg, EU

Global Training Network : Dr H.K. Min, Republic of Korea

Workshop 7-C.

Human tissue: problems and challenges for regulators

11.00 - 12.30 at Hotel Miguel Angel

Moderators : Dr Davi Rumel, Brazil, and Dr Pierrette Zorzi, France

US Approach to the Regulation of Human Cell and Tissue-Based Products : Jill Warner, USA

Development of a comprehensive regulatory framework for the safety of cells, tissues and organs for transplantation in Canada : Ms Julia Hill, Canada

FACT Creditation as a model of the Surveillance and Standard for the Canadian System : Dr Tony Giulvi, Canada

Issues in cells and tissues regulatory oversight in Brazil : Dr De Faria Vilaca, Brazil

The development of cell & tissue based products, a regulatory perspective : Dr Yeowon Sohn, Korea

Surveillance following cell and tissue transplantation in Spain : Dr Blanca Miranda, Spain

Workshop 8-D. Regulatory tools for providing drug information

11.00 - 12.30 at Hotel Miguel Angel

Moderators: Dr J. Molzon, USA and Dr F. Garcia Alonso, Spain

Developing SPCs, the experience of a small authority : Pr A. Toumi, Tunisia

The Europharm project : Dr R. Santos Ivo, Portugal

EMA: transparency, information and communication : Ms Arielle North, EMA

Publication Bias, Dr B. Beermann, Sweden

Workshop 9-G. Harmonization updates

14.30 - 16.00 at Hotel Miguel Angel

Moderators : Mr T. Lonngren, EMEA, and Dr John Lim, Singapore

New Horizons in Harmonization: report from ICH6 : Mr Shuichi Kishida, Japan

Impact of ICH to non-ICH countries. Global Cooperation Group : Mr Mike Ward, Canada

Regional harmonization initiatives. SADAC countries experience : Dr Gugu Mahlangu, Zimbabwe

Role of WHO in regional harmonization initiatives. PANDRH : Ms Rosario D'Alessio, PAHO/AMRO

Workshop 10-H. Promoting good regulatory practices

14.30 - 16.00 at Hotel M. Angel

Moderators : Dr Zheng Xiaoyu, China, and Dr R. Palop, Spain

Country experience : Dr Celeste Sanchez, Cuba

Country experience: Mr B.K. Botwe, Ghana

Country experience: Ms Eishah Abdul Rahman, Malaysia

Workshop 11-K. Regulatory aspects of supply of quality medicines

16.30 - 18.00 at Hotel Miguel Angel

Moderators : Dr J. Molzon, USA and Dr J. Lim, Singapore

Quality considerations in bulk purchase: challenges for internationally valid specifications – stability data : Mr Rutendo Kuwana, Zimbabwe

GMP and inspection: future approaches and challenges : Dr T. Paal, Hungary

Supply of quality pharmaceutical starting materials : Dr J. Lisman, Netherlands

Workshop 12-L. Implications of regulatory decisions for pharmacoconomics

16.30 - 18.00 at Hotel Miguel Angel

Moderator : Pr A. Toumi, Tunisia

Lessons from pharmaco-economic evaluations : Dr Carlos Lens, Spain

The role of regulators in reimbursement decisions : Dr A. Addis, Italy

Regulatory decisions and pharmacoconomics : Dr S. Tarragona, Argentina

THURSDAY 19 FEBRUARY

Plenary 4. Pharmacovigilance practices

09.00 - 10.30 at Hospital San Carlos

Moderators : Dr S. Jessamine, New Zealand, and Dr Gugu Mahlangu, Zimbabwe

Factors for success in national pharmacovigilance programmes :
Abida Haq, Malaysia

How pharmacoepidemiology and other methods of intensive monitoring post approval can supplement spontaneous reporting:
Francisco de Abajo, Spain

A model for introducing pharmacovigilance for new therapies for neglected diseases in developing countries- example of artemisinin derivatives : Mr. Henry Irunde, United Republic of Tanzania

The burden of assessing PSURS : Milan Smid, Czech Republic

Plenary 5. Current topics

11.00 - 12.00 at Hospital San Carlos

Moderators : Professor A. Toumi, Tunisia and Dr T. Paal, Hungary

Keynote presentations and panel discussion

14.00-15.00 at Hotel Miguel Angel

Moderator : Dr Carlos Lens

Regulatory challenges of pharmacogenetics and pharmacogenomics: impact for new and existing therapies

- Dr G. Kreutz, Germany
- Dr Jesse Goodman, USA
- Dr R. Peterson, Canada

Recommendations and closing remarks

15.00 - 16.00 at Hotel Miguel Angel

Presented by Dr Carlos Lens, Spanish Agency
for Medicines and Health Products, Spain

Selected presentations*

Challenges to regulators in establishing efficacy

In recent years, there has been a substantial increase in the number of clinical trials for biomedical research conducted in both developed and developing countries. As a result of sequencing of the genome, clinical research in potential therapies is likely to increase, while even the best-proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged by research. Despite this situation and introduction of new clinical trial management processes and methods, there is currently a lack of regulation of clinical trials in many countries and non-medicinal product trials are rarely subject to regulatory oversight.

The abundance of alliances and partnerships between academia and the pharmaceutical and biotechnology industries has also given rise to concern over the application of ethical and scientific principles and the following issues are subject to current debate:

- the potential for conflict of interest;
- unethical patient recruitment practices;
- inadequacy of informed consent;
- lack of capacity to ensure ongoing monitoring of clinical trials and adherence to principles of sound and ethical clinical practice; and
- poor reporting and management of adverse events.

For drug regulators, such trends in the conduct of clinical trials present special and urgent challenges, particularly in ensuring that the rights and health of patients and their communities are protected. In their approval of clinical trials, regulatory bodies should look not only at safety and efficacy of new products under investigation but they must also pay attention to the general standards of care

* Slide-show presentations made during the conference are available on the attached CD-ROM.

and safety of study subjects, in close collaboration with the appropriate ethical review committees and institutional review boards.

The increasing complexity of clinical trials presents further challenges to regulators. Study design often requires large cohorts of participants. In many instances trials are carried out at various sites in several countries and local ethics committees and drug regulators are not always aware of patient or investigator experiences at other international sites. Clinical trials are increasingly contracted to clinical research organizations and patient recruitment agencies, which act as intermediaries between the sponsors of the study, the investigators and the patients, and these escape appropriate monitoring.

Regulatory authorities have a responsibility for all clinical trials carried out in their country and they need to protect the safety, well-being and rights of the subjects participating in trials by ensuring that trials are adequately designed to meet scientifically sound objectives. They should also create legal structures and systems to support the development of norms and standards for clinical research, their implementation and oversight, and ensure that all trials are conducted according to the ethical and quality standards of good clinical practices.

WHO is currently developing a manual that clearly articulates the roles and responsibilities of various stakeholders (e.g., sponsors, investigators, regulatory authorities and ethics committees) involved in the conduct of health and clinical research studies, including any study that may have an impact on the safety and well-being of human subjects.

Role of regulators in improving the quality of ethical outcomes

Dr TAN Chor Hiang, Health Sciences Authority , Singapore

Clinical research is rapidly evolving. During the 1990s, industry-sponsored research moved rapidly beyond the familiar territory of the United States, the European Union, and Japan into large parts of Central and Eastern Europe, South America, Asia, and Africa (1). Clinical research is now increasingly complex and there is a greater involvement of vulnerable populations in research. The United States National Institutes of Health Revitalization Act of 1993 includes guidelines that require inclusion of women & minorities in clinical studies.

Invariably and unfortunately, mishaps in research are also encountered. Some commonly encountered and debated ethical issues in biomedical research include use of control arms (placebo), data protection, monitoring, role and responsibilities of institutional review boards, compensation for trial injury, patient confidentiality and privacy, stem cell research, gene therapy, tissue banking and the informed consent process.

The ethical review committee or institutional review board (IRB) plays a critical role in ensuring human subject protection by having effective and functioning systems for initial review and approval of trials, review of methods and materials to be used in obtaining and documenting informed consent, ongoing trial review and safety monitoring. The most fundamental role of ethical review is to ensure the application of basic ethical principles: respect for persons, beneficence and distributive justice, as articulated in such documents as the Nuremberg Code and Declaration of Helsinki.

Compliance oversight findings have shown that there are weaknesses in ethical review systems, particularly the lack of written procedures for reviewing protocols and informed consent forms, failure to minute convened meetings, inadequate training of IRB members, insufficient resources, conflict of interest, lack of monitoring systems (*Quis custodiet*), composition and quorum requirements (2).

International focus

On 2 October 2001, the US Department of Health and Human Services released a report entitled *The Globalization of Clinical Trials: A Growing Challenge in Protecting Human Subjects* (3). This report marks a significant point in US policy toward the protection of human subjects in foreign clinical trials, and provides an impetus, along with clear direction, for a framework to ensure protection for clinical trial participants abroad. It recommends that regulatory bodies increase the information they have on non-US IRBs and contribute to capacity building. The US Department of Health and Human Services Office for Human Research Protections encourages a system of accreditation for such IRBs.

An article entitled *Ethical review and globalization of clinical trials* (4) recognized that international guidance and national legislation are essential to developing well-functioning ethical review systems. However, international guidelines and national law alone will not suffice. Without a systematic approach to information gathering and capacity building, standards alone will not achieve greater protection for research.

In the broadest sense, the human research protections programme approach is intended to address both accountability (compliance) and assurance — the accountability of all individuals involved in clinical research (not only the researchers), and the assurance of all entities involved in clinical research (spanning administrative, legal, and regulatory compliance, biosafety, pharmacy, nursing, quality and risk management, among others). A culture of compliance is regulation-driven; one of conscience is driven by professional responsibility taking and sharing (5).

The situation in Singapore

In October 2003, a draft bill to regulate research on human stem cells and tissue was introduced in Singapore. The Regulation of Biomedical Research Act provides clear and stringent regulations for research using human stem cells and tissues carried out in Singapore and will ensure that all the work being done is ethically sound.

The Health Sciences Authority of Singapore is a one-stop regulatory agency, administering a seamless regulatory process for all therapeutic products. Our vision is to be world class for scientific and regulatory expertise in health sciences and our mission is to excel in applying science to support healthcare services and regulation, serve the administration of justice, and enhance safety in our community.

A formal regulatory framework for the governance of clinical research is limited to clinical drug trials. It is a shared responsibility by the IRB and the Health Sciences Authority. The conduct of clinical drug trials in Singapore is regulated by the Medicines Act 1975 and the Medicines (Clinical Trials) (Amendment) Regulations 1998, and the Singapore Guideline for Good Clinical Practice. The clinical drug trials regulatory framework is being reviewed and some of the initiatives in the revised framework include improved agency oversight through GCP inspections, IRB verification, and trial centre licensing.

All other forms of biomedical sciences research in Singapore require IRB approval at this point in time. Guidelines and position papers have been published to address ethical issues arising from biomedical research, viz. the National Medical Ethics Committee's guidelines, and position papers from the Bioethics Advisory Committee. A Bill to regulate research on human stem cells and tissue — The Regulation of Biomedical Research Act — is also currently being drafted.

The US Department of Health and Human Services commissioned a report following the death of 18-year-old Jesse Gelsinger during a

1999 clinical study at the University of Pennsylvania. In October 2002, the Institute of Medicine produced a report on Responsible Research: A Systems Approach to Protecting Research Participants (6). One of the recommendations reads: “Broader federal oversight is needed to ensure that the health and well-being of people who are enrolled in research studies, whether publicly or privately funded, are better-protected. Congress should require every organization conducting research with human subjects to do so under the authority of a research participant protection programme, which would be subject to federal oversight. However, ultimate responsibility for ensuring that the essential protections are in place and followed must rest with the highest levels of the research organization’s leadership.”

In conclusion, this statement from the WHO Operational Guidelines for Ethics Committees that Review Biomedical Research (2000) (7) aptly summarises the shared responsibility for ethical outcomes in research: “Countries, institutions, and communities should strive to develop ECs and ethical review systems that ensure the broadest possible coverage of protection for potential research participants and contribute to the highest attainable quality in the science and ethics of biomedical research. States should promote, as appropriate, the establishment of ECs at the national, institutional, and local levels that are independent, multi-disciplinary, multi-sectorial, and pluralistic in nature.”

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Regulatory aspects of gene transfer medicinal products

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Gene transfer medicinal products (GT-MP) are medicinal products which are either used with the aim of genetically modifying human somatic cells in vivo and which consist of or contain ex vivo genetically modified autologous, allogeneic or xenogeneic cells, or which consist of recombinant microbes used for other indications than the infectious disease caused by the microbe used.

Genetic modification of cells, either ex vivo or in vivo, involves the use of replication-incompetent viral vectors, non-viral vectors or naked nucleic acid. In some cases, replication-competent microbes, such as replicating adenovirus, are being used. Viral vectors commonly used include retroviral, adenoviral, AAV and pox virus vectors — the safety and efficacy profile of which are different. Therefore, each vector is commonly used in specific settings. The modified cells used in vivo include autologous or allogeneic cells, whereas xenogeneic cells or organs planned to be used in humans are considered xenogeneic cell therapy medicinal products. European definitions and technical requirements can be found in Part IV of the new Annex I of Directive 2001/83/EC as amended by Directive 2003/63/EC and in the relevant European Notes for guidance or Points to consider documents (www.emea.int.org).

To date, a marketing authorization of a GT-MP has been granted in China, a number of scientific advice procedures with a view to marketing authorization in the European Union have been completed and some gene therapy products have obtained orphan drug status. Marketing authorization for industrially produced non-finished medicinal products may be obtained via the centralized procedure of the European Medicines Agency, EMA. Starting from May 2004, clinical trials in the EU using somatic cell and gene therapy medicinal products will be approved by the national regulatory authority, and the local ethics committees will give a positive appraisal. Clinical trials, so far mainly carried out in Europe and North America, have been phase I/II trials with emphasis on analysing safety and obtaining first evidence for possible efficacy. Disease targets include monogenic diseases, cancer, infectious, neurological and cardiovascular disease. With an increasing understanding of the underlying molecular biology, first evidence of possible efficacy has been obtained in a number of clinical trials including those targeting ischaemia, head-and-neck

cancer, haemophilia and monogenic disease. With the improvement of gene transfer efficiency, serious adverse reactions are also being observed and will have to be addressed through improvement of vectors and strategies.

In general, clinical gene transfer medicinal products have presented acceptable risk-benefit ratios. Clinically successful therapies have been noted for the treatment of monogenic diseases such as SCID-X1 or ADA-SCID. First evidence of successful therapy has also been obtained in the treatment of graft-versus host disease following donor lymphocyte infusion during bone marrow transplantation or cardiovascular disease. However, development of gene therapy products has to be accompanied by the establishment of adequate regulations including technical requirements. The EMEA Gene Therapy Expert Group is involved in harmonizing regulatory needs by reviewing important clinical developments and highlighting the necessity of a regulatory framework.

The need for informed consent in clinical research

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Informed consent is the process by which a person voluntarily confirms his or her willingness to participate in a particular research trial or study after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and personally dated informed consent form.

Informed consent is a process, and should be understood essentially as a documented procedure to ensure that (i) the subject controls the decision on whether to participate in clinical research and (ii) that such participation only occurs when the research is consistent with the subject's values, interest and preferences. Informed consent thus allows individuals to decide for themselves whether to participate in research. It is based in the principle of respect for persons and it protects individual freedom of choice.

The most important goal of informed consent is that the patient has an opportunity to be an informed participant in health care decisions. The following elements should be addressed or described in the informed consent process:

1. An explanation of the study purpose and duration, including an approximate number of subjects involved in the study.
2. A statement that the individual is free to refuse participation and may withdraw from the trial at any time. Subjects should never be obliged to participate and investigators and trial staff should not coerce or unduly influence a subject to participate or continue to participate in a trial.
3. A statement that the study involves research with a description of procedures and their probable effect on the subject. This includes (i) foreseeable harms, discomforts, inconvenience and risk, and (ii) benefits to subjects or the community. Unverified efficacy or safety claims should not be made. An explanation should be provided of all known alternatives to the research project objectives, e.g. other treatments or interventions currently available.
4. Explanation of the extent of compensation and treatment to be provided both within the trial and afterwards, including declarations concerning the subject's legal rights, responsibilities of the investigator, institution or sponsors in the event of liability or negligence. A declaration of liability for trial costs and information on conflict of interest of the investigators.
5. Clearance from the ethical review committee or institutional review board that has reviewed the research trial. Identification of independent persons able to answer questions about the research, rights of research subjects and research related injuries.
6. A statement that treatment or procedures may involve currently unforeseeable risk to the subject (or the embryo or fetus, if the subject is or may become pregnant). A statement that any significant new findings developed during the trial will be transmitted to the subject, especially if these may relate to the subject's willingness to continue to participate.
7. Particular attention should be paid to the circumstances involving subjects unable to consent or vulnerable populations (children, illiterate, physical incapacity, dementia, in emergency situations, populations with limited resources, individuals whose willingness to volunteer in a trial may be

unduly influenced by expectations, persons kept in detention, armed forces, medical personnel, students, employees of the pharmaceutical industry, incurable patients, persons in nursing homes and ethnic minorities). An independent witness should always be present in such a situation.

The consent process

The language used in informing subjects about the trial, including the informed consent form, should be at a level of complexity which is understandable to the subject, the subject's legal representative, or impartial witness.

The investigator should ensure that the subject has adequately understood the information and should give each participant full opportunity to ask questions. These should be answered honestly and completely and, wherever there is doubt of comprehension, an oral or written test may determine whether the information has been adequately understood.

Before informed consent may be obtained, the investigator or a person designated by the investigator should provide the subject or the subject's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. Where appropriate and feasible, potential trial subjects should also have access to independent expertise to answer their questions. All questions about the trial should be answered to the satisfaction of the subject or the legally acceptable representative.

The principal or designated investigator is responsible for obtaining and documenting informed consent. The investigator should comply with applicable regulatory requirements and adhere to GCP and to ethical principles that have their origin in the Declaration of Helsinki and the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects. Prior to the beginning of the trial, the investigator must obtain approval of the trial and consent process from the ethical review committee or institutional review board and any other legally required clearances. During the trial, any change in the informed consent process should be subject to ethical approval in advance of use. In many countries, the regulatory authority should also approve the Informed consent procedure.

Prior to participation, the informed consent form should be signed and dated by the subject (or under special circumstances by the sub-

ject's legal representative) by the person who conducted the informed consent discussion, and by an independent witness. A copy of the signed consent should be given to the subject.

Challenges to regulators: safety monitoring

By the time a medicinal product is marketed, it has been tested in trials involving only 2000 to 3000 subjects. The results of these trials will subsequently be used as evidence to determine safety prior to marketing in large populations. It is accepted that any medicine carries some risk, so that it is important to monitor the effects, both intended and unwanted, to gain reliable evidence upon which to base a risk/benefit assessment. As with all new medicines, the early identification of unexpected adverse reactions and their risk factors is essential for the rational use of medicines and to maintain public confidence in their use. This is the role of pharmacovigilance, a process of information gathering on adverse reactions which may assist in identifying the most appropriate medicine for each patient.

Pharmacoeconomic studies suggest that governments pay unnecessary amounts from health budgets to counter the costs caused by adverse reactions. In the USA, adverse drug reactions are the fifth leading cause of death. Other countries spend up to 17% of their healthcare budget dealing with ADRs. Meanwhile, a pharmacovigilance system would not cost more than 1 dollar for every 850 – 1000 dollars of medicines purchased.

Furthermore, current post-marketing surveillance systems may not be adequate for ensuring the safety of medicinal products, particularly in developing countries. Present systems rely heavily on spontaneous reporting, yet under-reporting and inadequate provision of data are common and drug safety monitoring is established in only 70 countries. Often, ADRs may be country-specific – since medical practice, ethnic and racial factors may affect the response to drugs. The WHO Programme on International Drug Monitoring maintains a global database of more than 3 million reports of adverse reactions to drugs. However, other tools need to be developed and linked to the current system to promote better transmission of data and more complete reporting.

No medicines regulatory authority, however competent and sophisticated it may be, can fully anticipate and meet the need to address the safety and rational use of new medicines prior to their introduction

for general use. Regulatory authorities have come to depend increasingly on their national pharmacovigilance centres for the ongoing review of the safety of medicines that they approve and particularly those medicines used in the public sector.

Success factors in national pharmacovigilance programmes

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The word pharmacovigilance often conjures up the idea of spontaneous adverse drug reaction (ADR) reporting. But pharmacovigilance extends beyond this activity — it is also about the re-evaluation of marketed drugs, risk management, communicating drug information, promoting rational drug use and crisis preparedness. The success of a national pharmacovigilance programme will depend on many of the following suggestions:

- Programme managers should tailor the pharmacovigilance system according to the capacity and capability of existing resources within the national context.
- Developing nations should utilize work already carried out by other centres, adapt and adopt systems practised elsewhere, and identify and focus on issues which are of importance and relevant.
- Creating awareness and training within the system is important. Health professionals should be trained in pharmacovigilance and this should be incorporated into continuing medical education programmes.
- The pharmaceutical industry should also play an active role in monitoring, including of newly marketed drugs. Mechanisms should also be developed to include information from consumers on adverse reactions encountered with the use of over-the counter and traditional medicines.
- Guidelines should be made available for health professionals and the industry on how and to whom to report ADRs.

- Information sharing through effective networking between regulatory agencies and the WHO is imperative and information should be utilized optimally to help identify signals and make judgments based on good science.
- An objective of pharmacovigilance is to ensure rational utilization of drugs. Dissemination of information to stakeholders and prescribers should be effective and efficient to avoid delay and ensure that risks to consumers are minimized.
- The decision making process should be credible, transparent and free of external pressure. As far as possible, decisions should be made based on input from the relevant stakeholders taking into account the effect of these decisions on the health system.
- Crisis preparedness and crisis management should be planned.

Until now, pharmacovigilance has concentrated on the safety of individual drugs. However, to be successful it should also be patient-oriented, and seen as a clinical and public health issue and not just a regulatory function.

How pharmacoepidemiology can improve pharmacovigilance practice

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Pharmacovigilance is a public health practice aimed at analysing and managing the risks of medicinal products once they have been marketed. According to this definition, pharmacovigilance can be divided in two distinct phases (i) risk analysis and (ii) risk management. Risk analysis concerns identification, quantification (or estimation) and evaluation of emerging risks in a stepwise manner, while risk management concerns the implementation and follow-up of adopted regulatory measures, communication of risks to health professionals and/or the population at large, and the setting up of specific preven-

tive strategies (1, 2). Risk analysis is data-driven whereas risk management is action-driven, and the decisions taken constitute the bridge between these two areas.

In the realm of pharmacovigilance, the identification of risks is normally achieved by spontaneous reporting schemes, the bedrock of any drug surveillance strategy. However, according to the above mentioned scheme the identification of a risk should be followed by its proper quantification, which means (i) the measurement of the strength of the association between the drug and the suspected ADR (as a way to confirm or refute the causal relationship); (ii) the estimation of the impact of such a risk in the exposed population; and (iii) the identification of effect modification factors (risk factors). Although spontaneous reports compared with consumption or sales data may provide a first estimation of the risk (e.g. reporting rates), the limitations of such a simple approach are well-known (e.g. variable under-reporting, selective reporting, lack of adjustment for confounding factors, difficulty in assuming a daily dose etc.), in particular for comparison between different drugs. An appropriate quantification will normally require the implementation of appropriate epidemiological studies.

Experience shows, however, that too often regulatory authorities pass directly from risk identification to risk evaluation and take important decisions solely on the grounds of spontaneous reports. Although this may sometimes be warranted, for instance when the causal relationship can be easily established by individual case reports e.g. anaphylactic shock, or the suspected ADR is reasonably linked to the drug and represents a very serious issue prompting application of the precautionary principle, it is not frequently the case. A good number of pharmacovigilance signals cannot be properly assessed without the help of pharmacoepidemiologic studies: Do highly active antiretroviral drugs increase the risk of myocardial infarction (3)? Does the use of SSRIs increase the risk of serious bleeding disorders (upper gastrointestinal or intracranial haemorrhages) (4, 5)? Is the use of dinoprostone (PGE₂) as a labour inducer associated with the increased risk of postpartum disseminated intravascular coagulation (6)? Spontaneous reports have raised a signal in all these examples, but a rational decision was not possible because of the presence of major uncertainties.

A prevailing fact that regulatory authorities have to face is that the practice of pharmacovigilance is not optimal because risk quantification is rarely achieved through appropriate epidemiological studies. The reason for this shortcoming is probably twofold: the prevailing

conception that pharmacovigilance is just monitoring individual case reports; and the lack of efficient data sources to perform the studies in the timeframe required by a risk analysis process in pharmacovigilance, where units are normally months, not years.

Regulatory authorities are not comfortable with this status quo and may need to progress in two directions in order to improve pharmacovigilance practice by providing or reinforcing training in epidemiological methods among pharmacovigilance teams, and supporting the development of permanent and efficient data sources in respective countries that may allow performance of epidemiological studies to assess signals raised by spontaneous reports or any other source. Efficient data sources could be automated healthcare databases (either requiring record-linkage or stand-alone databases), but may also be permanent registries for specific diseases potentially associated with drugs (ideally with a case-control scheme), or product-specific or patient-specific large and long-term cohorts. Although some progress has been made in the past, a greater and generalized impulse is needed for the proliferation of these efficient data sources. Multi-site database studies would be necessary in the future to face risks emerging in the early postmarketing phase, where even the largest databases are underpowered. Health authorities have much to say in this development.

In line with this idea, the Spanish Agency for Medicines and Health Products has set out a programme of funding aimed at supporting some private initiatives such as case-control surveillance of blood dyscrasias in the Barcelona area, a register of serious liver injuries provided by a nationwide network of 37 hepatology units coordinated by the University of Malaga, or the long-term follow-up of rheumatologic patients treated with anti-TNF products managed by the Spanish Society for Rheumatology. In addition, the Spanish Agency has assumed the challenge of setting up a database (called BIFAP) using clinical records from general practitioners (7). Up to now, this database includes information from around half a million patients provided by more than 400 general practitioners, and it is currently in the clinical validation phase. One of the important advantages of this database is that health data are anonymous, guaranteeing the confidentiality of patient identity.

Sometimes, the study we need is not an etiology-oriented one but merely a drug utilization enquiry. In a good number of pharmacovigilance crises, the misuse component plays a fundamental role (for instance, the cerivastatin case with the highly prevalent concomitant use of gemfibrozil and the habit of using high doses from the very be-

ginning of treatment). Early detection of such misuse problems (or off-label use) may help to prevent risk situations. Yet, efficient and valid data sources that complement spontaneous reporting are necessary as well. To this aim, this year, the Spanish Agency is planning the establishment of a network of community pharmacies to provide our agency with information about drug utilization.

Pharmacovigilance is a cooperative and worldwide effort. Although it is clear that developed countries have a greater responsibility in setting up the newer data sources, we need better pharmacovigilance practices. The developing countries should also be prepared for progress by acquiring at least the necessary training in order to keep up with the pace of modern pharmacovigilance.

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Assuring the safety and quality control of traditional medicines

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With its centuries-old history in research, production and application, China is the home of traditional Chinese medicine (TCM). Guaranteeing the safety of TCM requires the establishment and perfection of quality assurance and control systems based on scientific methods. The State Food & Drug Administration (SFDA) implements quality

control and management of all TCM in accordance with the requirements of the Chinese Law on Drug Management.

Fundamental principles of Good Agricultural Practice for Chinese Crude Drugs (GAP), Good Laboratory Practice (GLP), Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP) are the prevailing references in the safety evaluation of medicines worldwide. Guaranteeing the safety and efficacy of medicines to its people is a sacred responsibility of SFDA.

Quality assurance provides a technical guarantee of the safety, efficacy and quality control of a drug. Ten years ago, SFDA issued a Revision and Supplement to the New Drug Examination and Approval Measures Related to TCM in accordance with the Law on Drug Management, requiring rigorous monitoring of contamination caused by externally harmful substances. China began specialized research of heavy metal and pesticide residue in crude drugs in the late 1980s and has established quality criteria for TCM. Toxic ingredients have always been defined as a key focus for quality control, with content rigidly controlled within defined limits.

The principles of safety, efficacy and quality are also applicable to TCM. However, processing of TCM is complex and differs from medicinal drugs. A major feature of quality control is the need for procedures which are specific to TCM preparations and which can be handled within clearly defined quality criteria for Chinese crude drugs. At present, quality control of TCM has surpassed conventional identification methods and experience so that development of TCM safety requirements must adhere to scientific criteria. Quality control and management of TCM is a significant task, with many hurdles to overcome. Through common efforts, good quality, safe TCM products will continue to benefit patients.

Regulation of herbal medicines in Nigeria

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Due to increased interest in the use of herbal medicines in Nigeria and the need for regulation of herbal medicines, the Government has established various committees and boards and approved a National Policy on Traditional Medicine.

Until 2001, there was little or no regulation of herbal medicine by the National Agency for Food and Drug Administration (NAFDAC). This led

to herbal practitioners producing, packaging, advertising and selling herbal products without any control. However, in 2001, NAFDAC requested all herbal medicine practitioners to have their products screened prior to registration. The herbal medicine practitioners were also invited to a workshop to participate in drafting guidelines for the registration of herbal products. This action has led to increased public confidence in the use of herbal medicines. NAFDAC acknowledges WHO's contribution to progress, and is now seeking support from the International community for staff training, establishment of a herbal control laboratory and collaborative studies.

Safety surveillance system for natural health products

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As with all health products, the benefit/risk ratio of natural health products (NHP) licensed for sale in Canada should be favourable. In Canada, the effective safety surveillance of health products relies on two components: A pre-market assessment system that requires evidence to support the quality, safety and efficacy of products; and a post-market surveillance system that efficiently and effectively collects data, makes it easy to access reported information and includes an effective risk communication strategy.

In January 2004, the Natural Health Products Directorate within Health Canada has implemented Natural Health Product Regulations. Requirements under the new Regulations include product licensing, good manufacturing practices in licensed facilities, standards of evidence to support the health claims made on the product label, and mandatory reporting of adverse reactions by market authorization holders. In addition, the post-market surveillance Directorate of the Marketed Health Products Directorate coordinates post-market monitoring activities, and collects and assesses safety information related to licensed NHPs. The post-market Directorate also develops communication strategies to increase awareness of potential safety issues and stimulate adverse reaction reporting from health care providers, and enhance safe and rational use of NHPs.

Consumer/patient information on safe use of herbals

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Development of patient information (PI) began in Switzerland in 1983 with a 5-year experimental phase, leading to mandatory use for all products on the market as of 1 January 1989. In 1994, PI requirements were extended to cover all products (in line with introduction of a PI by the European Union). PI complements product information, and both are published in the Swiss Kompendium. The PI, in the three Swiss languages, must contain all relevant patient information in a simple, intelligible language without use of scientific expressions with a view to ensuring the correct and safe use of medicines without compromising compliance.

Since introduction of the PI in Switzerland, some minor modifications have been made. Different types of PI are used for synthetic pharmaceutical substances, herbals and homoeopathics. For herbals, the words “herbal medicine” has to be attached to the brand name. Therapeutic properties are differentiated depending on presence or lack of clinically tested efficacy, so that different PI formulations include “traditionally attributed properties such as ...” or “acts against ...”. Contraindications and precautions are merged to improve clarity of information.

Keeping a balance between information and advertising is not an easy task. The PI is enclosed as a printed leaflet in all product packages. It is also available on the internet and company website. Advertising to the public is allowed for herbals and there is no pre-vetting of the advertisements, except for advertising on television, radio or cinema, and for a few product groups.

Herbals are rarely perceived as medicinal products by the general public, but are considered natural and safe. However, many reports show that this may not be the case and there may be important quality and safety issues involving toxicity and adverse drug reactions.

In conclusion, it is important to make the public and health care professionals aware that herbals are also medicines and to watch for adverse drug reactions.

Recommendations

Recommendations from the Eleventh ICDRA aim to provide the means for future collaboration among Member States, drug regulatory authorities, WHO, interested agencies and institutions, and will set priorities for WHO action and support.

Progress report on Tenth ICDRA

Participants recognized the progress made in many areas of medicines regulation since the Tenth ICDRA in Hong Kong in 2002. As globalization continues and has a profound impact on the development and marketing of medicines, strong international collaboration between regulatory authorities is needed to safeguard public health interests.

In view of continued regulatory problems and new challenges, participants stressed the importance of government commitment to strengthening national regulatory systems and policies and the need to intensify international collaboration to improve access to safe and effective medicines of good quality.

Regulatory aspects of access to medicines

The mission of regulatory authorities is to promote and protect public health. The lack of access to medicines remains a huge concern, whether these are essential medicines, vaccines, orphan drugs or drugs for tropical diseases. To facilitate access, regulators and all other stakeholders need to be actively involved in identifying difficulties and seeking solutions leading to balanced approaches to access which do not compromise public health safeguards.

Recommendations

- Regulators have a role and responsibility to facilitate access to drugs of public health importance including proposing changes to the respective regulations in order to facilitate access without compromising quality, safety and efficacy.

- When considering marketing authorization (registration) applications, regulators should give priority to medicines of high public health importance in their countries. Regulators should consider mechanisms to facilitate registration, such as reducing fees or other related costs.
 - As part of the medicines approval process, regulators should carry out an appropriate risk benefit assessment to allow for adjustment to the needs and profile of the anticipated patient populations.
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Strengthening of regulatory frameworks for medicinal products

The establishment of a well-functioning national regulatory system as an integral component of effective public health leads to better patient protection through provision of medicines which are safe, efficacious and of good quality. Cooperation, communication and trust between national regulatory authorities based on common principles and harmonized approaches will strengthen the effectiveness of national regulation and international collaboration. Transparency is an important aspect of regulatory systems and helps to build public confidence, while facilitating cooperation and information exchange among regulators.

- Member States should strengthen their efforts to increase transparency of the work of national regulatory authorities. Regulatory guidelines, procedures and criteria as well as data about registered medicines should be made publicly available to all stakeholders.
 - National regulatory authorities should make available to the public, in understandable language, negative and positive assessment reports (including pharmacovigilance reports).
 - National regulatory authorities should provide applicants for a marketing authorization with full information on regulatory decisions and an explanation of the reason for such decisions.
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Pharmacovigilance practices

Spontaneous reporting is the mechanism used for compiling adverse drug reaction reports and regulatory authorities take important decisions based on these data. Pharmacovigilance is a broad concept, and

also includes the re-evaluation of marketed drugs, risk management, communicating drug information, promoting rational drug use and crisis preparedness. It is becoming increasingly important to provide training in all of these activity areas and to carry out intensive monitoring of new drugs in order to evaluate the risk/benefit. Increasingly, medicines are being donated for off-label indications for specific public health needs and it is important that sufficient data is available to the national regulatory authority on safety, efficacy and quality.

Recommendations

- Member States should be encouraged to involve pharmacovigilance staff in public health risk assessment, management and communication for medicines safety activities including adverse reactions monitoring, medicines re-evaluation, drug information, rational drug use, lack of efficacy and crisis preparedness.
- Increasingly, certain medicines are approved based on special conditions, such as finalization and reporting of Phase IV studies. National regulatory authorities should collaborate on harmonizing the terms of conditional approval, and develop systems to allow sharing of information on medicines in this category.
- All sponsors and donors of medicines should provide sufficient data to allow the national drug regulatory authority to be assured that the product being donated, or recommended for use, meets appropriate standards of safety, quality and efficacy. Obligations to conduct post-marketing surveillance as a public health protection measure should also lie with sponsors and donors, as appropriate. International agencies and aid programmes should make every effort to comply with these requirements and provide the necessary data.
- Member States should be encouraged to establish databases of clinical information suitable for epidemiological studies to examine and quantify signals of possible emerging risk.
- WHO should coordinate and develop training resources in pharmacovigilance and pharmaco-epidemiology and expand its commitment to include training programmes in each of its regions.
- WHO should provide, upon request, technical advice and support to Member States on the appropriateness of post-

marketing surveillance plans submitted by sponsors when a medicine is being introduced to manage a specific public health campaign in that country.

- WHO should investigate the feasibility and potential utility of creating a database of “recommendations for action” arising from evaluations made by national regulatory authorities of the periodic safety update reports (PSURs) in order to improve the usefulness of such information by making this generally available.

Pharmacopoeias in a changing regulatory environment

Pharmacopoeial standard-setting for starting materials and finished dosage forms underpins the work of drug regulatory authorities by providing the means of ensuring the quality of medicines, particularly multisource (generic) products.

Increased collaboration and coordination at international level of pharmacopoeial bodies and all related parties is needed: (i) for the development and analysis of quality control specifications; (ii) to speed up development of pharmacopoeial specifications; (iii) to address the increasing diversity and complexity of impurity profiles and limits set at international level, especially for pharmaceutical starting materials; and (iv) to promote independent and worldwide validation of analytical methods to ensure the quality of traded and sourced products internationally.

The promotion of good quality pharmaceutical products, and the development of quality control methods — in particular to detect counterfeit drugs — is important for public health. Participants agreed on the need for international harmonization of quality control specifications, and recognized WHO’s leadership role in providing normative guidance for quality control and quality assurance of medicines, particularly in the development and international harmonization of pharmacopoeial specifications for new drug entities, including antiretrovirals, anti-tuberculosis and antimalarial medicines.

Recommendations

- Member States should encourage close collaboration between regulatory authorities and pharmacopoeial secretariats/commissions.

- In collaboration with those concerned, WHO should organize an international conference on pharmacopoeial issues to exchange views and experiences among pharmacopoeial bodies and regulators.
 - In collaboration with parties concerned, WHO should develop a harmonized approach to providing internationally validated specifications for medicines for neglected and emerging diseases with high public health risk.
 - WHO should continue to support the establishment of international chemical reference substances (ICRS) and assist in their supply, particularly for medicines used in the treatment of diseases with high public health impact.
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Regulatory assessment of combination products

Combination products for various diseases have always been used in medical practice. Today, HIV/AIDS, tuberculosis and malaria are the major infectious diseases threatening public health and the focus of many national, regional and global initiatives. Combination therapy is considered essential for their treatment as well as for the prevention of drug resistance. Attempts to manage these diseases include the development of fixed dose combinations (FDC) of individual drugs to be administered together in one finished dosage form. Well documented clinical evidence of the efficacy and safety of the loose combination is a key entry point for development of any FDC drug. Currently, there are no uniform principles, guidelines or international standards addressing the development and regulatory assessment of FDCs. Only a few countries have specific FDC regulatory guidelines available and irrational combinations are still common in several markets.

Recommendations

- In countries where specific guidelines do not exist, regulators need to establish clear quality, safety and efficacy requirements for registering fixed dose combination medicines, particularly prescription-only drugs. Regulators should critically review the existing fixed dose combination drugs on the market and withdraw those which do not meet these requirements.
- WHO is urged to create, as a matter of urgency, model guidelines for regulatory approval of prescription-only fixed dose combination drugs with special emphasis on drugs for communicable diseases with high public health impact.

Regulators, good clinical practice and ethics

Application of good clinical practice (GCP) guidelines assures that clinical studies on medicinal products meet scientific and ethical requirements. However, recent advances in medicine may encompass areas of clinical research not covered by existing GCP guidelines and this gap should be filled since all clinical research, including research on gene therapy and biotechnology products, should be conducted under rigorously implemented GCP. Since data on the safety and efficacy of innovative products may be limited, it is important that national regulatory authorities strengthen mechanisms to share knowledge and experience. Given the increasing tendency to involve vulnerable subjects in research, there is a special need to strengthen the application of ethical principles in research carried out in these populations.

Recommendations

- Member States should implement good clinical practice (GCP) guidelines to assure that clinical studies follow scientific and ethical requirements. All clinical research, not only for medicinal products, needs to be regulated.
- Member States should ensure that informed consent processes, particularly for vulnerable populations and for obtaining biological samples for genetic studies, meet all GCP, national and ethical requirements.
- Member States should recognize that gene therapy is a new complex area of medicine needing rigorously implemented GCP and ethical oversight.
- WHO is requested to gather existing knowledge and experience of safety, efficacy and quality of innovative biotechnology products and share this information with Member States.
- WHO is requested to accelerate its work in regulatory capacity building for assessment of vaccines and medicines of public health importance and to explore options for providing external regulatory expert support for assessment of clinical trial applications in countries with limited resources.

Public health needs vs. the marketplace

Development of new drugs is often driven by market forces. Some medicines for priority disease of public health impact are commercially unattractive, and this is often because they are unaffordable by poor populations. Effective mechanisms compensating for this mar-

ket failure are needed to bridge the gap. Regulators, together with other stakeholders, can play an important role in supporting initiatives aimed at creating new drugs for diseases where there is no market attractiveness by motivating investment into research and development. However, there is also a regulatory capacity gap to overcome, as regulators from developing countries have limited capacity to advise on drug development or assess the safety, efficacy and quality of new drugs created for diseases exclusively prevalent in those settings.

Recommendations

- WHO is encouraged to continue cooperation with Member States, industry and other stakeholders in order to promote and facilitate development of new treatments for diseases that have little market potential, in particular for diseases prevalent in developing countries (neglected diseases). Mechanisms and incentives should be created for more proactive involvement of national regulatory authorities in all stages of research and development of these products.
- WHO should continue facilitating regulatory capacity building and networking among regulators of different countries in order to empower regulators in countries with limited resources to take informed and evidence-based decisions.
- WHO should explore the potential of creating distance learning courses for regulators.

Safety of herbal medicines

The use of herbal medicines is increasing rapidly worldwide. Although the reasons for this may vary in different settings, the safety of herbal medicines is a common global concern. Both public and national health authorities are committed to making progress in ensuring the safe use of herbal medicines. This is a very complicated and complex issue because of differing regulatory requirements, availability and suitability of technical methods for quality control, post-marketing quality surveillance, and safety monitoring, the presence or absence of qualified practitioners and consumer education. Major issues concerning the safe use of herbal medicines are set out below.

Recommendations

- The safe use of herbal medicines requires adequate regulation. Member States should continue to adapt their national

and/or regional regulatory framework, including pharmacovigilance, to the specific requirements of herbal medicines. WHO should continue to provide support including guidance and training programmes.

- Quality assurance and quality control of herbal medicines presents specific challenges. WHO should continue to provide technical guidelines, particularly for the quality control of combination products and criteria for reference substances and materials.
- Awareness amongst consumers on the benefits and limitations of herbal medicines needs to be strengthened. Member States should consider preparing a policy on consumer information and guidelines on the advertising of herbal medicines. WHO should provide general guidance to support these activities.
- Providers of traditional/complementary health care play an important role in the safe use of herbal medicines. Member States should explore appropriate mechanisms to ensure adequate training and education of these health care providers. WHO should provide policy and technical guidance.
- Regulatory agencies should work together to make the best use of scientific resources related to herbal medicines. Sharing national experience and information is crucial. WHO should facilitate these activities e.g. by providing updated monographs on medicinal plants and technical/regulatory guidance.

Assuring quality and safety of blood products

Blood and blood products are essential for the treatment of a number of life-threatening conditions. However, because blood may transmit infectious agents this can also cause severe harm to the recipients. During the Ninth and Tenth ICDRAs, emphasis was therefore given to procedures aimed at inactivating and removing infectious agents. In order to avoid transmission of infectious agents in a reliable manner, good manufacturing practice (GMP) has to be implemented as an essential tool of quality assurance. In addition, adherence to GMP at all levels of the process, from donor to recipient, is a prerequisite for consistent quality in the preparation of blood and blood products.

Recommendations

- WHO's policy to give high priority to the implementation of GMP in blood and plasma collection establishments is welcomed. Educational programmes and training opportunities should be continued and strengthened. Guidance documents should be developed and/or updated.
 - In order to facilitate the enforcement of GMP in both blood/plasma collection and fractionation facilities, WHO should promote joint inspections between several countries under the guidance of experienced inspectors.
 - WHO should promote cooperation between regulatory authorities with regard to GMP compliance aimed at mutual agreements among Member States.
 - WHO should contribute to advancing the technical expertise of regulatory authorities by enabling the creation of regional networks to facilitate their regulatory role in the area of blood and blood products.
 - WHO should facilitate the formation of a global network of regulatory authorities for blood and blood products.
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Human tissue: problems and challenges for regulators

The transplantation of human cells, tissues and organs has become the treatment of choice for a wide range of both fatal and non-fatal diseases. The volume and complexity of activities relating to transplantation is growing rapidly. The ethical and safety risks of transplantation require effective regulatory oversight at national level, and international cooperation.

Given the rapid global increase in the allogenic transplantation of cells, tissues and organs, and the associated ethical and safety risks this entails, Member States should develop and implement effective national regulation of procurement, processing and transplantation of human cells, tissues and organs.

Recommendations

- To facilitate this process, WHO is requested to develop clear guidelines for the quality, safety and efficacy of human cell, tissue and organ transplantation.

- To complement the regulation of human cell, tissue and organ transplantation, Member States should develop and implement effective surveillance after cell, tissue and organ transplantation.
 - WHO should facilitate these surveillance activities by development of appropriate written standards and reference materials
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Regulatory tools for providing drug information

Accurate drug information is essential for the rational use of medicines. Assessment of safety, efficacy and quality of products includes also assessment of product information provided by the applicant of the marketing authorization. Although national regulatory authorities have the responsibility of validating the correctness and appropriateness of the product information, resource constraints may limit the capacity of small regulatory authorities to be able to verify the quality of information provided by the manufacturers.

Recommendations

- National regulatory authorities should establish and implement requirements for product information in line with the information provided in the summary of product characteristics (SPC) as part of their national drug registration process.
 - At national level, product information should be harmonized for all products having the same active ingredient.
 - WHO should develop guidance and new tools to control promotion and drug information.
 - National regulatory authority-approved information should be the reference for providing independent information and the benchmark for controlling promotion. Approved information should be made available on the regulatory agency website.
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Harmonization updates

Harmonization of technical requirements for the registration of medicines can contribute to public health by improving access to safe, effective and good quality medicines. It can also facilitate development of a fair and transparent regulatory process, improve international collaboration, reduce duplication of work by different regulatory authorities. [Eleventh International Conference of Drug Regulatory Authorities \(ICDRA\)](#)

tory agencies and facilitate trade and competition. Harmonization initiatives are ongoing in all WHO regions. The major focus of many of those initiatives is to first harmonize basic regulatory requirements for generic drugs. In contrast, the International Conference of Harmonization (ICH), an initiative set up between the European Union, Japan and USA, has been focusing on requirements to evaluate the quality, safety and efficacy of new innovative drugs, thus avoiding the necessity to duplicate many time-consuming and expensive test procedures. ICH has established a Global Cooperation Group for non-ICH harmonization initiatives to learn from ICH experience.

Recommendations

- WHO should continue to support regional and sub-regional harmonization initiatives that contribute to public health priorities. WHO should facilitate information exchange between different harmonization initiatives and report on progress made in these initiatives through its website.
- Regional harmonization initiatives should have clear public health priorities according to local needs, clear milestones to measure progress, and appropriate resources to make progress possible. Member states are encouraged to facilitate harmonization which will increase availability and accessibility of medicines.
- The ICH Global Cooperation Group should continue to serve as a forum of discussion and dialogue between ICH and non-ICH harmonization initiatives recognizing different regional needs, priorities and capacity.

Promoting good regulatory practices

To meet the objectives of promoting and protecting public health, national regulatory authorities need to carry out their functions effectively and efficiently within a set of principles based on transparency and good governance. The issues that are necessary to promote good regulatory practices nationally and internationally include sustainability of resources, optimal structure, effective cooperation within the agency and with other agencies, transparency and accountability, competence in evaluating efficacy, safety, and quality, timeliness, independence, collaboration as a service provider, sharing information, harmonization, and mutual recognition. In many cases, regulatory authorities do not have sufficient resources to carry out these activities. Most importantly, regulatory agencies must be ac-

countable and decision-making processes must be transparent but this needs to be balanced against the need for protecting the confidentiality of the data that has been submitted by the manufacturer. Sources of information and the decision process should be made publicly available whenever possible.

Good regulatory practices thus cover an evolutionary process, with good practices built into the systems which continuously reinforce collaboration and trust. Regulatory authorities should establish mechanisms to ensure the quality of the procedures they operate to.

Recommendations

- WHO should develop the tools and guidelines needed to help national regulatory authorities effectively implement the principles of good regulatory practices.
- Member States should encourage interagency cooperation for effective implementation of drug regulation involving national regulatory authorities, customs, judiciary, police, civil society and other relevant bodies set up to protect public health.
- National regulatory authorities should formulate a clear mission statement to reinforce effective and efficient drug regulation and customer satisfaction and make use of benchmarking to improve their performance.
- National regulatory authorities should nurture good regulatory governance (integrity, transparency, accountability, public service ethics) to establish credibility and gain confidence. The political governance responsible for national regulatory authorities should promote teamwork, overcome bureaucracy and streamline work.
- WHO should promote and provide technical assistance for the evaluation of regulatory capacity of national regulatory authorities in order to analyse the situation and to undertake necessary corrective measures.

Regulatory aspects of supply of quality medicines

Access to quality medicines contributes to improving human health and promoting well-being. Rigorous implementation of good manufacturing practices in the production of medicines will ensure that only safe, quality products are allowed on the market.

The importance of quality has been repeatedly underlined by the occurrence in various countries of counterfeit and substandard drugs. Evidence shows an increase in production, distribution and sale worldwide of counterfeit, spurious and substandard medicines which do not comply with any quality standards. Such products are a waste of money for the people who buy them, prolong treatment periods, exacerbate the conditions being treated, increase the emergence of drug resistance and can even cause death.

Special efforts have been undertaken to raise awareness of the importance of regulatory measures covering trade in products and starting materials, including active pharmaceutical ingredients and excipients, and implementation of good manufacturing practices.

Recommendations

- Countries are encouraged to implement the new WHO good trade and distribution practices, intended to improve safety in the trade of starting materials for pharmaceutical use.
- Member States are encouraged to implement a pilot phase of the new WHO certification scheme for pharmaceutical starting materials which will give additional information on the quality assurance system used in the production of starting materials.
- WHO should continue the Prequalification Project of medicines for priority diseases, particularly HIV, malaria and tuberculosis.
- WHO should foster collaboration between manufacturers and regulators in the implementation of GMP and provide training.
- WHO should continue to develop international guidelines for registration of multisource (generic) products.

Implications of regulatory decisions for pharmacoeconomics

The mandate of regulatory agencies is to promote and protect public health by ensuring that all medicines entering the market meet quality criteria, are safe and effective. The particular expertise of national regulatory authorities may make a valuable contribution to decisions

on the cost effectiveness and rational use of medicines with regard to pharmaco-economics and pricing. In countries with limited resources it is difficult to avoid direct involvement of national regulatory authorities in pharmaco-economics due to their unique knowledge base.

Recommendations

- Where national regulatory agencies do not have pricing responsibilities, they should ensure that all information about safety and efficacy needed to conduct economic evaluation is made available to public bodies charged with reimbursement or pricing responsibilities.
- WHO should further support national regulatory authorities in introducing, wherever needed, elements which will contribute to pharmaco-economic evaluation.
- WHO should carry out an analysis on the affordability of medicines, particularly in developing countries experiencing such problems. WHO should collect and make available to Member States information on various pricing options and mechanisms, examples of impact of inadvertent marketing strategies to medicines expenditure and potential public health implications of implementation of the TRIPS agreement.
- WHO should support pharmaco-economic studies based on scientific methodology in countries and regions. Countries undertaking pharmaco-economic studies are encouraged to present outcomes during the next ICDRA.
- Member States should study the potential of using objective measurement units such as defined daily doses (DDD) for monitoring drug utilization and using these data for developing rational national policies for pricing and increased access to essential medicines.

Current topics

The current topics session provides an opportunity to all regulators at the ICDRA to express their views on the newly-emerging topics which have not been reflected in the conference programme. Often, the topics raised in this session lead to substantial discussion during subsequent ICDRAs.

Recommendations

- The full flexibility of the TRIPS agreement to improve access to medicines should be explored by countries. Countries should not voluntarily exceed TRIPS obligations which could limit flexibility and utility in protection of national public health interests.
 - Member States should consider the potential impact of usage patents on access and affordability of medicines.
 - Countries should adopt the WHO Guidelines on Developing Measures for Combating Counterfeit Drugs, raise public and political awareness of the problem of counterfeiting, increase national and international cooperation, data exchange between all stakeholders, including national regulatory authorities, interested nongovernmental organizations, law enforcement agencies, industries, and relevant international organizations.
 - WHO, in collaboration with other stakeholders, should develop a draft concept paper for an international convention on counterfeit drugs. WHO should convene a meeting of national regulatory authorities to discuss further the concept paper and related issues before the next ICDRA.
 - The comparator product for a multisource (generic) medicine should be the first product registered in the market with a complete data file available. In case the originator is not available on the market and there is no multisource (generic) market leader, then other appropriate solutions should be considered on case by case basis.
 - Doping in sports is a serious health problem and is within the remit of drug regulation. National regulatory authorities should remain vigilant and provide the necessary resources to combat such practices.
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