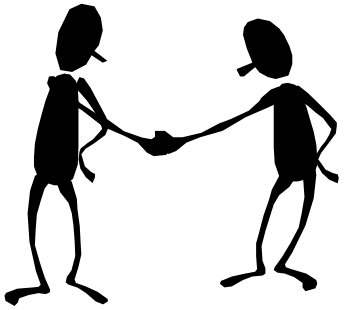
WHO Update on World Health Assembly and Executive Board + related important events

Sabine Kopp, PhD
Quality Assurance and Safety: Medicines

World Health Organization

Governing bodies meetings since May 2010



17-21 May 2010:

- **63rd World Health Assembly (WHA)**
  Delegations from 193 Member States

22 May 2010 + *17-25 January 2011:*

- ***126th + 127th Executive Board (EB)***
  Representatives from *34 Member States* +

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63rd World Health Assembly

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WHA63/2010/REC/1

WORLD HEALTH ORGANIZATION

SIXTY-THIRD WORLD HEALTH ASSEMBLY

GENEVA, 17–21 MAY 2010

RESOLUTIONS AND DECISIONS
ANNEXES

GENEVA
2010

2. REQUESTS the Director-General:

(1) to guide Member States to meet internationally recognized standards in updating their legislation, national standards and regulations for effective control of the quality and safety of blood products and associated medical devices, including in vitro diagnostics;

(2) to advise and build capacity in Member States on leadership and management of blood supply systems in order to strengthen national coordinated and sustainable blood and plasma programmes by sharing best practices about the organizational structure of blood supply systems in order to increase efficiency and minimize error;

(3) to augment the support offered to Member States for developing and strengthening their national regulatory authorities and control laboratories so as to increase their competence in the control of blood products and associated medical devices, including in vitro diagnostic devices, and to foster the creation of regional collaborative and regulatory networks where necessary and appropriate;

(4) to ensure sustainable development and provision of WHO International Biological Reference Preparations (International Standards) for use in the quality control and regulation of blood products and related in vitro diagnostic devices;

(5) to improve access by developing countries to WHO International Biological Reference Preparations and to the scientific information obtained in their validation in order to assure the appropriate use of these preparations;

(6) to develop, provide and disseminate guidance and technical support to strengthen national coordinated blood and plasma programmes and introduction of blood component separation and plasma fractionation technology, to meet local needs, and promote effective regulatory oversight of blood services and implementation of good manufacturing practices in plasma-fractionation programmes, under the responsibility of regulatory authorities;

(7) to provide guidance, training and support to Member States on safe and rational use of blood products and to support the introduction of transfusion alternatives including, where appropriate, autologous transfusion, safe transfusion practices and patient blood management;

(8) to encourage research into new technologies for producing safe and effective blood substitutes;

(9) to inform regularly, at least every four years, the Health Assembly, through the Executive Board, on actions taken by Member States and other partners to implement this resolution.

(Eighth plenary meeting, 21 May 2010 –
Committee B, second report)

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Resolution WHA 63.12: Availability, safety and quality of blood products - Overall Goals

- To make safe blood products available to patients
- To raise quality standards in blood establishments (BE)
- To reduce risk of transmission of infectious diseases
- To enforce implementation of blood products regulations

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WHA 63.12: Availability, safety and quality of blood products

2. REQUESTS the Director-General:

2. (1) to guide Member States to meet internationally recognized standards in updating their legislation, national standards and regulations for effective control of the quality and safety of blood products and associated medical devices, including in vitro diagnostics;

2. (3) to augment the support offered to Member States for developing and strengthening their national regulatory authorities and control laboratories so as to increase their competence in the control of blood products and associated medical devices, including in vitro diagnostic devices, and to foster the creation of regional collaborative and regulatory networks where necessary and appropriate;

WHA 63.12: Availability, safety and quality of blood products

2. REQUESTS the Director-General:

2. (4) to ensure sustainable development and provision of WHO International Biological Reference Preparations for use in the quality control and regulation of blood products and related in vitro diagnostic devices;

(5) to improve access by developing countries to WHO International Biological Reference Preparations and to the scientific information obtained in their validation in order to assure appropriate use of these preparations

→WHO is requested to report back in 4 years time to the WHA (through the Executive Board) on actions taken by Member States to implement this resolution

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..What needs to be done? The "Achilles" project

- To raise quality standards for production activities in BE
- To provide a framework to make use of, otherwise destroyed plasma, for the fractionation of plasma derivatives
- To build technical and regulatory capacity on quality assurance systems in blood establishments and NRAs
- To transfer knowledge & experience from developed countries

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The "Achilles" project
What do we already have?

- **The mandate**
  - WHA 63.12 on availability, quality and safety of blood products
- **The tools (internationally agreed standards)**
  - WHO Guidelines on GMP for blood establishments
  - WHO Guidelines on Production, control & regulation plasma for fractionation
  - WHO Guidelines on Viral Inactivation and Removal procedures
  - Biological reference materials: blood products and blood safety IVDs
  - Assessment criteria for national blood regulatory systems
- **Access to government organizations: national regulatory authorities and InspectorateTraining experience strengthening implementation of regulatory systems**
  - Coordination of international expertise: ECBS, BRN, WHOCC, ICDRA
  - Worldwide network of National Regulatory Authorities
  - Expertise from other quality assurance programs in WHO
  - Support from WHO Regional Offices and Country Offices

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What is "SSFFC"?

New terminology since World Health Assembly held in May 2010 to cover:

"Substandard/ Spurious/Falsely-labelled/Falsified/Counterfeit" medical products

For the purpose of this Working Group it was agreed that the term “medical products” refers to medicines, vaccines and in vitro diagnostics.[1]

[1] This may also include medical devices at an appropriate time in the future.

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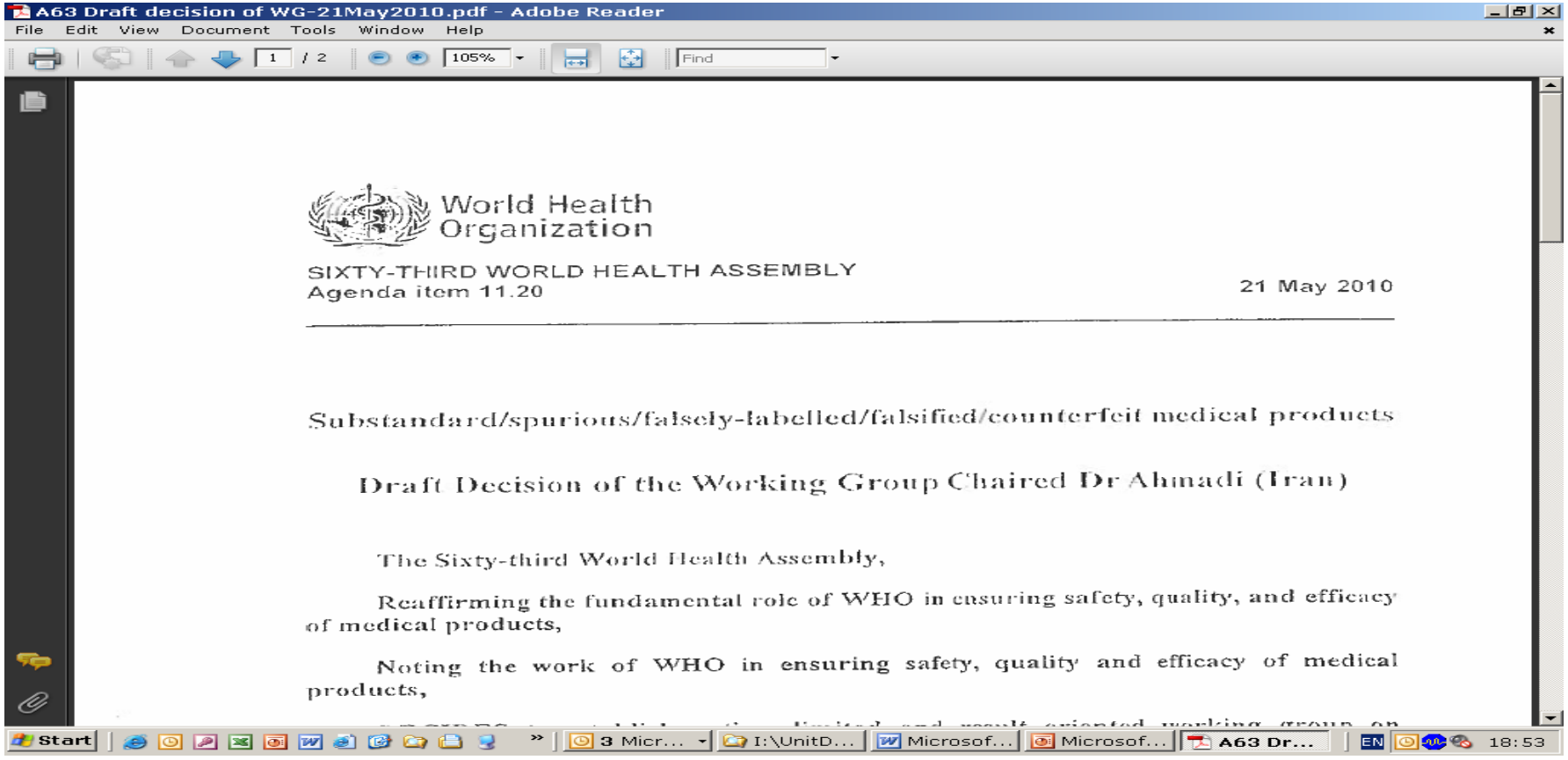
63rd World Health Assembly and "SSFFC"


A63 Draft decision of WG-21May2010.pdf - Adobe Reader

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SIXTY-THIRD WORLD HEALTH ASSEMBLY
Agenda item 11.20

21 May 2010

Substandard/spurious/falsely-labelled/falsified/counterfeit medical products

Draft Decision of the Working Group Chaired Dr Ahmadi (Iran)

The Sixty-third World Health Assembly,

Reaffirming the fundamental role of WHO in ensuring safety, quality, and efficacy of medical products,

Noting the work of WHO in ensuring safety, quality and efficacy of medical products,

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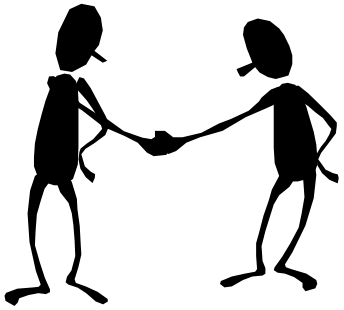
ICDRA



30 November - 3 December 2010:

- ***14th International Conference of Drug Regulatory Authorities (ICDRA)***
- ***→ Recommendations published in WHO Drug Information Vol. 25, No 1, 2011***

Ref: http://www.who.int/medicines/publications/druginformation/en/

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http://www.icdra2010.sg/
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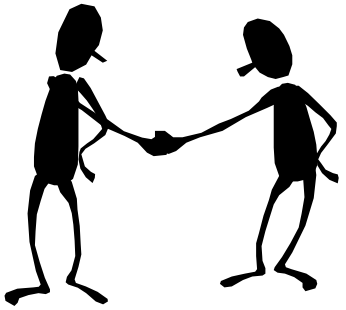
Conference Programme
Conference Information
Registration
Conference Venue
Hotel Accommodation
Social Programme
Newsletter
About Singapore
Getting around Singapore
Things to Do
Useful Links
Contact
ABOUT THE INTERNATIONAL CONFERENCE OF DRUG REGULATORY AUTHORITIES (ICDRA)
Since 1980, the ICDRA has been providing drug regulatory authorities of WHO Member States with a forum to meet and discuss ways to strengthen collaboration. It continues to be an important tool for WHO and drug regulators in their efforts to harmonize regulation and improve the safety, efficacy and quality of medicines globally.
Objectives
To promote collaboration between national drug regulatory authorities
To forge a consensus on matters of mutual interest
To facilitate timely and adequate exchange of technical information
To discuss contemporaneous issues of international relevance
Internet
100%

More governing bodies meetings …



28 February to 2 March 2011

- ***Working Group of Member States* on *Substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products***
- ***Delegations from 93 Member States participated***

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Working Group on SSFFC

- **Discussion during the Member States Working Group meeting on *Substandard/spurious/falsely-labelled/falsified/counterfeit medical products* (SSFFC) medicines:**
  - *- WHO's role in measures to ensure the availability of good-quality, safe, efficacious and affordable medical products;*
  - *- WHO's role in the prevention and control of medical products of compromised quality, safety and efficacy such as substandard/spurious/falsely-labelled/falsified/counterfeit medical products;*
  - *- WHO's relationship with the International Medical Products Anti-Counterfeiting Taskforce.*

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Outcome of the Working Group on SSFFC medical products

Future role of WHO in:

- **Information and awareness creation**
- **Norms and standards**
- **Technical support to countries**
- **…**addresses specifically perspectives of **surveillance of the market** and guidelines for good distribution practices for Internet sales, importers and brokers

…Report presented to 64th World Health Assembly in May 2011

World Health Organization

Dr Margaret Chan, Director-General, to the 64th World Health Assembly

..." I have been doing this job now for nearly five years. Sometimes during meetings, I have to interrupt and make a simple request: ***remember the people.*** *Never forget the people. All of our debates and discussions have meaning only when they improve the health of people and relieve their suffering.*

Personally, when I remember the people I have met during this job, two special encounters stand out…..I dedicate this speech to the memory of these women and children…."

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64th WHA: Some impressions

Floor of the Assembly

Dr Margaret Chan, WHO Director-General

Mr Bill Gates, Co-chair of the Bill & Melinda Gates Foundation

Her Excellency Sheikh Hasina, Prime Minister of Bangladesh

Dr Christos Patsalides, President of the Sixty-fourth World Health Assembly and Minister of Health of Cyprus, and

Dr Maria Teresa Valenzuela (Chile), Chair of Committee B .

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64th World Health Assembly - RESOLUTIONS

- WHA64.1 Implementation of the International Health Regulations
- WHA64.2 WHO reform
- WHA64.3 Appropriation resolution for the financial period 2012–2013
- WHA64.4 Health conditions in the occupied Palestinian territory, including east Jerusalem, and in the occupied Syrian Golan
- WHA64.5 Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits
- WHA64.6 Health workforce strengthening
- WHA64.7 Strengthening nursing and midwifery

64th World Health Assembly - RESOLUTIONS -2-

- WHA64.8 Strengthening national policy dialogue to build more robust health policies, strategies and plans
- WHA64.9 Sustainable health financing structures and universal coverage
- WHA64.10 Strengthening national health emergency and disaster management capacities and the resilience of health systems
- WHA64.11 Preparations for the high-level meeting of the United Nations General Assembly on the prevention and control of noncommunicable diseases, following the Moscow Conference
- WHA64.12 WHO's role in the follow-up to the United Nations High-level Plenary Meeting of the General Assembly on the Millennium Development Goals (New York, September 2010)

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64th World Health Assembly - RESOLUTIONS -3-

- WHA64.13 Working towards the reduction of perinatal and neonatal mortality
- WHA64.14 Global health sector strategy on HIV/AIDS, 2011–2015
- WHA64.15 Cholera: mechanisms for control and prevention
- WHA64.16 Eradication of dracunculiasis
- WHA64.17 Malaria
- WHA64.18 Unaudited interim financial report on the accounts of WHO for the year 2010
- WHA64.21 Scale of assessments for 2012–2013
- WHA64.22 Amendments to the Financial Regulations
- WHA64.23 Appointment of the External Auditor

64th World Health Assembly - RESOLUTIONS -4-

- WHA64.24 Drinking-water, sanitation and health
- WHA64.25 Salaries of staff in ungraded posts and of the Director-General
- WHA64.26 International Agency for Research on Cancer: amendments to Statute
- WHA64.27 Child injury prevention
- WHA64.28 Youth and health risks

Progress reports on

- A. Poliomyelitis
- B. Onchocerciasis control through ivermectin distribution ….
- I. Progress in the rational use of medicines (resolution WHA60.16) ..

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64th World Health Assembly -5 -

Saturday, 21 May 2011, Committee A

….. decision on

- ***Substandard/spurious/falsely-labelled/falsified/counterfeit medical products***

…"decided to extend the period set out in decision WHA63(10) in order to allow the working group to complete its work as soon as possible"…

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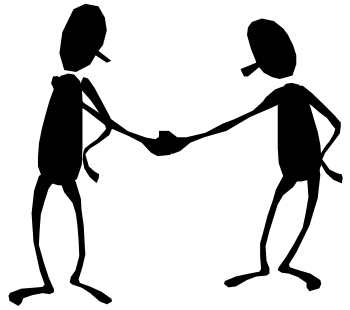
Related events



18-23 October 2010:

- ***WHO Expert Committees***
- ***… on Specification for Pharmaceutical Preparations (ECSPP), 45th* and**
- ***… on Biological Standardization (ECBS)***

21 to 25 March 2011:

- ***..on Selection and Use of Essential Medicines, 18th held in Accra, Ghana***

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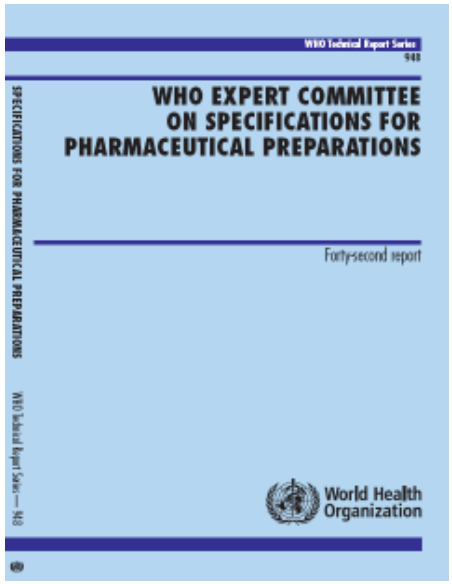
8th meeting of the WHO Advisory Committee on Safety of Medicinal Products

- **31 March - 1 April 2011**
- **Key topics included:**
  - Open access to WHO pharmacovigilance (PV) database,
  - WHO Pharmacovigilance strategy,
  - Pharmacovigilance (PV) tool kit,
  - New PV methods to support HIV and TB programmes,
  - PV in Chagas,
  - Technical support to The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM),
  - Vaccines blue print project, etc.

WHO Governing bodies …



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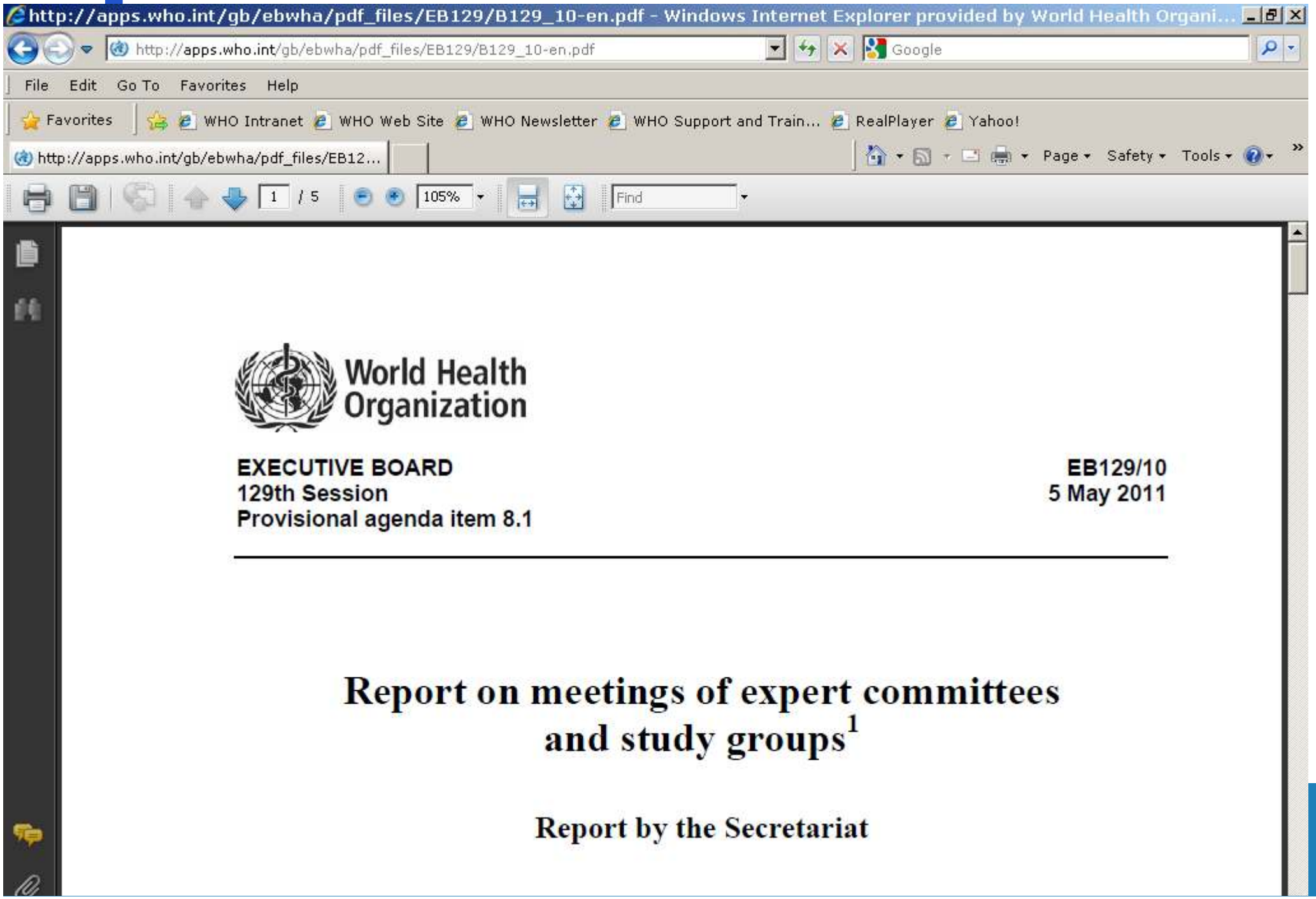
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EXECUTIVE BOARD
129th Session
Provisional agenda item 8.1
EB129/10
5 May 2011
Report on meetings of expert committees and study groups[1]
Report by the Secretariat

45th WHO Expert Committee on Specifications for Pharmaceutical Preparations – outcome - 1-

1. Texts for *The International Pharmacopoeia*

- Medicines for HIV and related conditions:

- **Didanosine capsules**
- **Efavirenz tablets**
- **Emtricitabine capsules**
- **Emtricitabine and tenofovir tablets**
- **Efavirenz, emtricitabine and tenofovir tablets**

45th WHO Expert Committee on Specifications for Pharmaceutical Preparations – outcome -2-

- Antimalarial medicines

- Artesunate
- Artesunate for injection
- Mefloquine tablets
- Sulfadoxine and pyrimethamine tablets

- Antituberculosis drugs

- Capreomycin sulfate
- Capreomycin for injection
- Ofloxacin

45th WHO Expert Committee on Specifications for Pharmaceutical Preparations – outcome -3-

- Antituberculosis drugs (ctd)

- Ofloxacin tablets
- Levofloxacin
- Levofloxacin tablets

- For anti-infectives:

- Amoxicillin oral suspension
- Levamisole tablets
- Metronidazole oral suspension
- Sulfamethoxazole and trimethoprim tablets

45th WHO Expert Committee on Specifications for Pharmaceutical Preparations – outcome -4-

- For other medicines

- **Oseltamivir phosphate**
- **Oseltamivir capsules**
- **Sodium bicarbonate intravenous infusion**
- **Paracetamol oral solution**
- **Paracetamol oral suspension**
- **Levonorgestrel tablets**
- **Retinol concentrate**

45th WHO Expert Committee on Specifications for Pharmaceutical Preparations – outcome -5-

2. Global quality assurance guidelines adopted:

- Procedure for adoption of International Chemical Reference Substances (ICRS) (updated)
- Good Practices for Pharmaceutical Microbiology Laboratories (new)
- GMP: main principles (updated)
- GMP for blood establishments (jointly with ECBS) (new)
- Supplementary GMP for HVAC (updated)
- GMP for sterile pharmaceutical products (updated)

45th WHO Expert Committee on Specifications for Pharmaceutical Preparations – outcome -6-

- Guiding principles on transfer of technology in pharmaceutical manufacturing (new)
- Good Pharmacy Practice: standards for quality of pharmacy services (joint FIP/WHO, updated)
- Model guidance for the storage and transport of time- and temperature sensitive pharmaceutical products (new jointly with ECBS)
- Procedure for prequalification of pharmaceutical products (updated)

45th WHO Expert Committee on Specifications for Pharmaceutical Preparations – outcome - 7 -

- Guidance on submission of documentation for prequalification of innovator FPPs approved by stringent regulatory authorities (new)
- Procedure for prequalification of laboratories (updated)
- WHO guidelines for preparing a laboratory information file (updated)
- Guidelines for preparing a Site Master File (new, PIC/S type)
- Guideline for submission of documentation for a multisource (generic) finished product (new, based on CTD)

In the pipeline - quality assurance for medicines..

- *Ph.Int.:* Harmonization with PDG general texts – for those evaluated by ICH Q4B
- External Quality Assessment Scheme for National Drug Quality Control Laboratories, 5th series, 3rd test in process, 4th in preparation
- Guidance on selection of *comparator products* for equivalence assessment of interchangeable generic products *(revision)*
- Paediatrics development – points to consider

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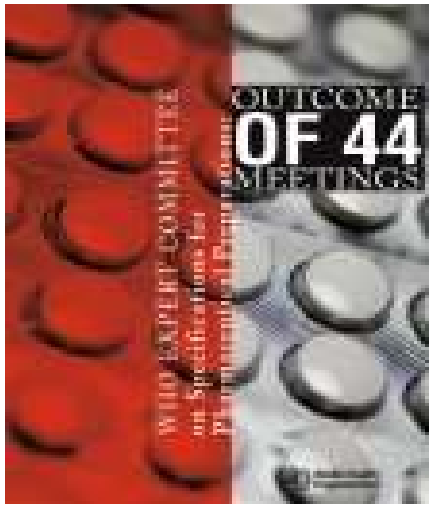
In the pipeline..

- Development of generics *- points to consider*
- Risk analysis based on *HACCP towards Quality Risk Management*
- Guideline on submission of documentation for a multisource (generic) product – quality part
- Tools and framework for monitoring of market situation

WHO Medicines and Biologicals websites:

http://www.who.int/medicines

http://www.who.int/biologicals



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