Recent Publications, Information and Events

WHO Good Governance for Medicines Model Framework

The World Health Report identifies ten leading causes of health system inefficiency, four of which are related to medicines: price, quality, use and waste.

In most countries, expenditure on pharmaceuticals comprises a large proportion of the health budget. Effective management and good governance in the pharmaceutical sector is therefore an essential element to improving efficiency and making a sustainable contribution to health systems strengthening and universal health coverage. Growing numbers of public health officials in ministries of health, medicines regulatory authorities and national procurement departments recognize the need for institutions and personnel to work in a more transparent and accountable environment in accordance with ethical professional practices.

Thirty-six countries are participating in the Good Governance for Medicines Programme (GGM) and are applying the principles of determining the strengths and weaknesses of a country’s pharmaceutical system and developing and applying appropriate interventions. A recent evaluation of the programme confirms the need for strong support to countries for strengthening governance in the pharmaceutical sector.

To further support country efforts, WHO has published the Good Governance for Medicines Model Framework. This guideline can be adapted according to country needs and proposes a combination of discipline-based and values-based strategies for effective, efficient, ethical, transparent and accountable management of pharmaceutical systems. The first edition of the framework was published in 2008 and since revised by experts and country representatives building on their experience of work already undertaken. The updated version is now available at www.who.int/medicines/areas/policy/goodgovernance/


Transparency of clinical trial data

In the context of on-going negotiations on the European Union Clinical Trials Regulation and the European Medicines Agency’s (EMA’s) work towards the proactive publication of clinical trial data, HAI Europe has published a policy paper Protecting citizens’ health: transparency of clinical trial data on medicines in the EU, with the objective of shaping the debate towards greater data transparency.

Many adverse drug reactions, including deaths, could have been avoided had the public known about the undisclosed effects of medicines. In addition, open access to trial data can facilitate independent re-analyses of claimed efficacy and comparison between therapies. The transparency of clinical trial data also responds to an ethical obligation. According to the Declaration of Helsinki, authors have the duty to make publicly available the results of their studies: whether positive, negative or inconclusive. The policy paper argues that increased public knowledge on the effects of medicines plays an
unquestionable role in the strengthening and protection of public health.


Drug-resistant TB treatments: more support needed

Médecins Sans Frontières (MSF) and the International Union Against Tuberculosis and Lung Disease have released the third edition of the drug-resistant TB drug report *DR-TB Drugs Under the Microscope*. The report covers the issues faced in accessing DR-TB drugs, including the high price of the new drug bedaquiline. A currently recommended DR-TB treatment regimen costs anywhere between US$ 3000 – 5000 per person per treatment. The treatment has awful side effects, is effective only half the time and lasts around two years — with people taking as many as 14 600 pills.

Also relaunched is the *Test me, treat me* DR-TB Manifesto which asks people to sign on to support people receiving treatment, better treatment options, and funding to scale up treatment. The manifesto can be accessed at http://www.msfaccess.org/TBmanifesto/.

MSF is one of the largest nongovernmental organizations providing DR-TB care. In 2012, MSF treated 29 000 patients for TB in 30 countries, and 1780 patients for DR-TB in 18 countries. The mission of the International Union Against Tuberculosis and Lung Disease is to bring innovation, expertise, solutions and support to address health challenges in low- and middle-income populations.


2013 WHO Global Tuberculosis Report

The World Health Organization has identified five priority action areas that could make a rapid difference between now and 2015 to strengthening the fight against tuberculosis (TB). The 2013 TB report calls for more attention to multidrug-resistant TB (MDR-TB) and better strategies to reach those who are being missed by the system.

The WHO-recommended actions are based on new data from almost 200 countries and territories. It documents how TB treatment has saved the lives of more than 22 million people, and how both the numbers of people ill with TB and those who died from the disease fell in 2012.

The report also identifies the challenges still ahead to help control the disease.


International Pharmacopoeia: fourth edition

*The International Pharmacopoeia* contains a collection of recommended procedures for the determination of pharmaceutical substances, excipients and dosage forms and is intended to serve as source material for reference or adaptation. The Third Supplement has now been added to the Fourth Edition of *The International Pharmacopoeia*.

New, revised and withdrawn texts

New and revised texts are introduced in the section on Supplementary information for ten monographs on pharmaceutical substances, thirty-one monographs on dosage forms, two general monographs, ten methods of analysis and six texts. A list of the new, revised and withdrawn texts is provided as an annex.
Artemisinin and its derivatives should no longer be used as monotherapy and fixed-dose combination formulations are now recommended. The 47th meeting of the Expert Committee on Specifications for Pharmaceutical Preparations therefore decided to withdraw these monographs.

Pharmacopoeial Discussion Group (PDG) harmonized general texts
A number of PDG texts have been adopted and include:

- Residue on ignition/sulphated ash
- Test for extractable volume for parenteral preparations
- Disintegration
- Test for particulate contamination: sub-visible particles
- Microbiological examination of non-sterile products: acceptance criteria for pharmaceutical preparations and substances for pharmaceutical use
- Microbiological examination of non-sterile products: tests for specified micro-organism
- Test for sterility
- Tablet friability
- Bulk and tapped density of powders
- Bacterial endotoxins test
- Microbial examination of non-sterile products: microbial enumeration tests

Reproductions from the European Pharmacopoeia
The following new tests have also been published in the European Pharmacopoeia:

- Measurement of consistency by penetrometry
- Resistance to crushing of tablets

Infrared Reference Spectra
Many monographs in The International Pharmacopoeia include an identification test using infrared spectroscopy. Such tests usually allow comparison either with a spectrum obtained from an International Chemical Reference Substance (ICRS) or with an International Infrared Reference Spectrum (IIRS). Nine additional spectra were added.

International Chemical Reference Spectra
The release procedure for ICRS was revised and is included in the Supplementary information.

Complete information on the texts and access to The International Pharmacopoeia is available online at the WHO Medicines web site.