Emergency

WHO panels advise on medical interventions in Ebola outbreak

Geneva – A WHO-convened panel has reached consensus that in the particular circumstances of the severe Ebola outbreak in West Africa, with no treatment or vaccine yet having been evaluated in human beings, it is ethical to offer unproven interventions with as yet unknown efficacy and adverse effects to save the lives of patients and to curb the epidemic. The panel agreed that ethical criteria – including transparency, informed consent, freedom of choice, confidentiality, respect for the person, preservation of dignity and community involvement – must guide such interventions, and that there is a moral obligation to collect and share all data generated, and to evaluate these interventions in the best possible clinical trials under the circumstances.

At the margins of the 16th WHO International Conference of Drug Regulatory Authorities (ICDRA) held in August 2014, members of an interim International Coalition of Medicines Regulatory Authorities (ICMRA)¹ pledged to cooperate among themselves and with WHO on fast access to investigational treatments for patients most in need, and on access to safe and efficacious medicines in the future so that public health authorities in affected countries can respond effectively to outbreaks.

On 4–5 September, WHO brought together technical experts to discuss potential Ebola therapies and vaccines. The group identified some promising investigational treatments (although supplies will be limited for some time to come) and identified two advanced vaccines for accelerated development. If proven safe, a vaccine could be available in November 2014 for priority use in health-care workers. The group stressed that effective clinical care, rigorous infection prevention and control, careful contact tracing and follow-up, effective risk communication and social mobilization remain crucial to end the outbreaks.

On 18 September, in its first emergency meeting on a public health crisis, the UN Security Council declared the outbreak a threat to peace and security. The UN Secretary-General announced the deployment of a new emergency health mission to be known as the UN Mission for Ebola Emergency Response (UNMEER). The Ebola outbreak confirmed in West Africa in March 2014 is the largest, most severe and most complex in history.

¹ Members of the interim ICMRA Management Committee include: Therapeutic Goods Administration (TGA), Australia; National Health Surveillance (ANVISA), Brazil; Health Products and Food Branch, Health Canada (HPFB-HC), Canada; China Food and Drug Administration (CFDA), China; European Medicines Agency (EMA); European Commission - Directorate General for Health and Consumers (DG - SANCO); Health Product Regulatory Authority (HPRA), Ireland; Italian Medicines Agency (AIFA), Italy; Ministry of Health, Labour and Welfare (MHLW), and the Pharmaceuticals and Medical Devices Agency (PMDA), Japan; Medicines Evaluation Board (MEB), Netherlands; Health Sciences Authority (HSA), Singapore; Medicines Control Council (MCC), South Africa; Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom; Food and Drug Administration (FDA), United States.
Public health

UNAIDS report on HIV treatment coverage
Geneva – The newly published UNAIDS “Gap report” highlights the need for a smart scale-up to bring antiretroviral treatment to all who need it.

According to the report, 19 million of the 35 million people living with HIV today do not know that they have the virus. An estimated 14 million people were on ARV treatment at the end of July 2014, and new analyses show that the rate of new infections slows down with increasing treatment coverage. If the scale-up can be accelerated to reach all people in need of ARVs by 2020, the world could be on track to end the epidemic by 2030.

Closing the gap will require research and innovation, combined with protective laws that promote freedom and equality for all people. This will create space for tailored solutions to address the complex, varied epidemics and prevailing stigma within countries and communities.


Access to antiretroviral medicines in low- and middle-income countries
Geneva – WHO has released a report that examines global trends in antiretroviral (ARV) prices and assesses how WHO treatment guidelines have influenced the uptake of different ARV formulations. It describes constraints limiting the use of second-line, third-line and paediatric treatments, and explores how ARV quality can be secured and in-country distribution can be improved.

This publication complements an earlier WHO report, published in May 2014, on access to ARVs in middle-income countries in light of regulatory, pricing and intellectual property information.


UK studies show safety and effectiveness of whooping cough vaccination in pregnant women
United Kingdom – Young infants are at the highest risk of severe complications and death from whooping cough, as babies do not complete vaccination until they are four months old. The UK Department of Health had announced a temporary vaccination programme for pregnant women in October 2012 in response to a national whooping cough outbreak that had led to several infant deaths.

New research has shown that vaccinating pregnant women against whooping cough has been highly effective in protecting young infants from this potentially fatal disease. These findings are supplemented by the first large study of the whooping cough vaccine safety in pregnancy, conducted by the MHRA. The programme will now be continued for a further five years.


Swissmedic and Health Canada join ICH Steering Committee

Minneapolis – The International Conference on Harmonisation (ICH) Steering Committee and its Expert Working Groups met in Minneapolis, USA on 31 May – 5 June 2014. At the meeting the ICH Steering Committee decided to include the Swiss Agency for Therapeutic Products Swissmedic and the Canadian Health Authority Health Canada as ICH Steering Committee members.

The membership was granted in recognition of the two organizations' historical involvement and commitment to ICH, and started with immediate effect. The new roles of Swissmedic and Health Canada conform to a broader range of evolving ICH membership and governance reforms.

► ICH Press release, 8 July 2014.

Novartis transfers tuberculosis drug development to Global TB Alliance

Basel – Novartis has signed an exclusive worldwide licensing agreement with the Global Alliance for TB Drug Development (TB Alliance) for new anti-tuberculosis compounds discovered at the Novartis Institutes for Tropical Diseases (NITD). TB Alliance will take financial and operational responsibility for continued research, development, approval and distribution of the compounds, including a novel class of drugs called indolcarboxamides that are active against drug-sensitive and multi-resistant strains of tuberculosis.

TB Alliance is a not-for-profit organization with the mission of developing better, faster and affordable treatments for tuberculosis. It was launched in October 2000 at the International Conference on Health Research for Development in Thailand.

► TB Alliance News release, 19 August 2014.

WHO matters

Why we need an independent, impartial WHO

An article in the BMJ warns that WHO’s stewardship to protect the health of all is weakened as the Organization lacks a guaranteed budget to perform its vital normative functions.

WHO’s core budget has dwindled as the US and other countries have adopted zero nominal growth policies for their UN agencies core contributions – a decline in real terms – and many Member States are in arrears with payments. Today, 80% of WHO’s total budget are voluntary contributions from the public and private sector, meaning that the donor has control on how the funds are spent. Often this funding is given to disease-specific causes, and often these are disconnected from the global burden of diseases.

The authors emphasize that WHO is the only international agency that can broker global rules in the interest of public health. As new challenges arise that threaten health security across the world, assured funding to preserve the independence and neutrality of WHO becomes even more important.

**The International Pharmacopoeia – Fourth Supplement published**

WHO has published the Fourth Supplement of *The International Pharmacopoeia*, which provides specifications and test methods for reference or adaptation by any WHO Member State.

The Fourth Supplement introduces new or revised texts for eight monographs on active pharmaceutical ingredients, 15 finished product monographs, one general monograph, three methods of analysis and three supplementary information texts. WHO gratefully acknowledges the support from a wide range of experts and institutions in developing these texts.

Some highlights in this supplement include: (1) a new monograph on capreomycin sulfate with related substances test methods and limits that will help manufacturers to limit the toxicity of their capreomycin-containing products; (2) A revised monograph on artemisinin, enabling manufacturers to evaluate its quality using the same analytical methods as for artemisinin when used as a starting material; (3) a clarification note on dissolution test requirements for chewable tablets, considering that these may be swallowed whole; and (4) a new chapter on reference substances and reference spectra, with explanations of concepts and hands-on advice.


**WHO-ISoP core elements of teaching pharmacovigilance**

Pharmacovigilance experts from WHO Member States, the International Society of Pharmacovigilance (ISoP) and its Education and Training Project (ETP), have jointly developed a comprehensive and balanced pharmacovigilance curriculum.

The importance of pharmacovigilance for safe medicines and their safe use are gaining recognition, particularly in countries where highly effective but potentially harmful chemical medicines have come to replace traditional treatments.

To help orientate pharmacovigilance education and training amidst an abundance of guidelines and publications, the curriculum provides an inventory and overview of the scope of pharmacovigilance, including relatively new topics such as pharmacogenomics, consumer reporting of adverse drug reactions, risk management and WHO-led international projects. While it is not intended as ready-for-use teaching material or a course description, it reflects the current status of the rapidly evolving science of pharmacovigilance and provides a rich and valuable bibliography.