WHO hepatitis C guidelines published

London – WHO has published its first guidelines on hepatitis C screening, care and treatment. Complementing existing guidance on the prevention of transmission of blood-borne viruses, the guidelines give recommendations on how to manage infections with the hepatitis C virus in resource-limited settings.

Two new oral medicines, sofosbuvir and simeprevir, have recently been approved for chronic hepatitis C, and others are in the pipeline. The guidelines strongly recommend the use of sofosbuvir for most hepatitis C genotypes. Quality-assured products at affordable prices will be needed for countries to scale up treatment.


WHO report reveals worldwide antibiotic resistance

Geneva – A new WHO report reveals that antimicrobial resistance is now a major global threat to public health that can affect anyone, of any age, in any country.

This is the first report to provide a global picture of antimicrobial resistance, with data from 114 countries. The findings suggest that the world may be headed for a post-antibiotic era, in which common infections and minor injuries can once again kill.

Antibiotic resistance occurs when bacteria change so that antibiotics no longer work to treat infections. The results show that bacteria causing common, serious diseases such as bloodstream infections, diarrhoea, pneumonia, urinary tract infections and gonorrhoea have become resistant to antibiotics in all regions of the world.

While some important steps are being taken to address the problem, every country and individual needs to do more. Urgent, coordinated action by health care workers, patients, policy makers and industry is needed to prevent infections and to improve the ways in which antibiotics are produced, prescribed and used.

WHO News release, 30 April 2014.

EU and US continue joint battle against antimicrobial resistance

Atlanta – The Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) has presented its first progress report, highlighting some significant achievements.

TATFAR has identified 17 recommendations for collaborations between the US and the EU to combat antimicrobial resistance. Implementation of these recommendations has led to an increase in exchanging information, understanding of best approaches and practices, and developing peer relationships. It is hoped that the positive outcomes of this
partnership will serve as a global model for continued work on this critical issue.

Concern about antimicrobial resistance continues to grow. In 2013 the mandate of the taskforce was extended for two additional years until 2015.
► CDC Press Release, 13 May 2014.

WHO core functions need reliable funding
Financing of WHO’s work in support of essential medicines remains a cause for concern, according to a recent letter in The Lancet. In particular, reliable funding is still lacking to maintain the norms, standards, policy and pricing guidance and mechanisms that will support Member States in securing affordable supplies of appropriate, quality-assured medicines.

The authors emphasize that WHO’s work on medicines cuts across almost every component of health services in countries, and that many international organizations depend on this work. They call on WHO Member States to ensure that WHO has the necessary resources to effectively support universal health coverage at a time of complex and expanded global health needs.

WHO and Global Fund strengthen partnership
Geneva – The World Health Organization and the Global Fund have strengthened their long established partnership with a new technical agreement to support countries in developing more strategic investments in the fight against HIV, tuberculosis and malaria.

Under the agreement, WHO will provide technical assistance to Global Fund applicants under the new funding model ahead of the submission of their grant applications, or concept notes. The new funding model promotes opportunities for health interventions with a bigger impact.

WHO will provide assistance through its country or regional offices and with the Roll Back Malaria and STOP TB partnerships.

Sixty-seventh World Health Assembly held
Geneva – The Sixty-seventh World Health Assembly (WHA), attended by nearly 3500 registered delegates, has adopted more than 20 resolutions, many of which involve medicines and related products.

Some important topics included: access to essential medicines, access to biotherapeutic products; tuberculosis prevention, care and control; hepatitis; antimicrobial resistance; and regulatory systems strengthening. With regard to the latter the WHO Prequalification Programme was requested to continue its regulatory capacity-building activities, with future progressive transition to networks of strengthened regulatory authorities.

The WHA also gave the go-ahead for innovative health research and development demonstration projects for diseases that disproportionately affect developing countries, and WHO-supported capacity-building for countries to assess the value of new technologies for their health systems.
► WHO News release, 24 May 2014.
**Market and supply**

**ViiV and MPP sign licence agreement for dolutegravir**

**Geneva** – The Medicines Patent Pool (MPP) and ViiV Healthcare have signed a licence agreement for dolutegravir, an antiretroviral medicine approved by EMA and FDA in recent months. Access to dolutegravir could improve millions of lives in developing countries.

The agreement will enable generic manufacturers based anywhere in the world to supply low-priced products containing dolutegravir for adults and children also as fixed-dose combination with other medicines including abacavir. The countries covered by the agreement are home to over 93% of adults and 99% of children living with HIV in the developing world.


**Global Fund meets with Chinese pharmaceutical manufacturers**

**Shanghai** – The Global Fund to Fight AIDS, Tuberculosis and Malaria and the China Chamber of Commerce for Import and Export of Medicines and Health Products have held a conference with Chinese pharmaceutical manufacturers in Shanghai, with a view to source more quality-assured medicines from China.

China is the world’s leading source of active pharmaceutical ingredients. The country is currently taking steps to strengthen oversight and independence of the medicines approval process. WHO representatives attended the event to explain requirements for prequalification of medicines for procurement by international organizations.


**First WHO GMP-compliant Nigerian manufacturer**

**Lagos** – A WHO inspection and verification of follow-up action has confirmed that Swiss Pharma Nigeria Limited (Swipha) operates at an acceptable level of WHO good manufacturing practice (GMP) for the manufacture of oral solid dosage forms. A public inspection report is available on the WHO website.

Swipha is the first manufacturer in Sub-Saharan West Africa to pass a GMP inspection by the WHO Prequalification Team (PQT). The company is developing a product dossier for submission to WHO-PQT. WHO has provided technical assistance to Nigerian manufacturers since 2011, with active support from the Nigerian medicines regulatory authority.

► WHO Prequalification update, 4 April 2014.

**Snapshot of patents and licences on antiretrovirals**

**Geneva** – UNITAID and the Medicines Patent Pool (MPP) have jointly released a new report providing an overview of the patent and licensing status of selected antiretroviral (ARV) medicines in developing countries.

The document focuses on WHO-recommended ARVs, but also analyzes data on new ARVs that have either recently obtained regulatory approval or are in Phase III clinical trials. The main source of data for compiling this report is the MPP patent database.

► Medicines Patent Pool announcement, 8 May 2014.


Antiretroviral prices in middle-income countries

Geneva – The World Health Organization (WHO) has published an analysis of the prices paid by 20 middle-income countries for adult and paediatric formulations of WHO-recommended antiretroviral treatments, together with information on the patent status and license agreements of the products, their regulatory status as well as tariffs, markups and taxes.

The data show that procurement prices vary widely between the countries included in the analysis. While prices are low in India and middle-income countries in Africa for first-line and many second-line treatment regimens, they are higher in other middle-income countries, especially for newer second-line and third-line treatments sourced from originator producers.


WHO prequalifies first products manufactured in Egypt

Geneva – WHO has prequalified two products manufactured by the Egyptian Pharmaceutical Industry Co. (EIPICO): ceftriaxone, 1 gm/vial and ceftriaxone, 500 mg/vial powder for injection. These two products — antibiotics for use in treating HIV/AIDS-related conditions in adults, adolescents and children — are now eligible for procurement by international donors. They represent Egypt’s potential as a producer of quality-assured medicines for priority diseases.

WHO has been providing technical support to manufacturers and national regulatory authorities in the WHO Eastern Mediterranean region since 2008. Several other manufacturers in Egypt, Iran, Jordan, Pakistan and Oman are also actively pursuing prequalification of their products.

BRICS Ministers join forces for access to medicines

Geneva – At a side event to the opening of the 2014 World Health Assembly, strong statements were made by BRICS (Brazil, Russia, India, China and South Africa) country ministers and representatives to cooperate to tackle the issue of inaccessibility to affordable medicines in their countries and the developing world.

The Ministers shared national experiences and showed mutual support for the continued use of local production, compulsory licensing and parallel importations and other mechanisms to push down prices and increase access to medicines for all in need, including in middle-income countries that often do not classify for donations from health initiatives despite large parts of their populations still living in poverty.

Speaking at the event, WHO Director General Margaret Chan thanked the BRICS countries for their leadership. She referenced ongoing activities by international organizations to support quality-assured local production of medicines, the need to strengthen national regulatory capacity, and the importance of knowing the data to make the right investments in health.

Intellectual Property Watch reporting from the World Health Assembly, 20 May 2014.
Upcoming events

16th International Conference of Drug Regulatory Authorities (ICDRA)

The 16th ICDRA will be held in Rio de Janeiro, Brazil on 24-29 August 2014. This biennial conference provides a forum for medicines regulatory authorities of WHO Member States to meet and discuss ways to strengthen collaboration. This conference provides a strategic opportunity to drug regulatory authorities to share solutions found in different parts of the globe, and to determine priorities for action in national, regional and international regulation of medicinal products.

While the ICDRA conference itself is restricted to governmental officials and regulators, the Pre-ICDRA conference, to be held on 24-25 August 2014, is open to pharmaceutical industry, academia, non-governmental and international organizations.

Further information is found on the 16th ICDRA official website at http://www.icdra.com.br/

WHO-UNICEF-UNFPA meeting with manufacturers

This year’s joint WHO-UNICEF-UNFPA meeting with manufacturers and suppliers of diagnostic products, finished pharmaceutical products, active pharmaceutical ingredients and vaccines will take place on 22-25 September 2014 at UN City in Copenhagen, Denmark.

This meeting provides a forum at which diagnostic, pharmaceutical and vaccine manufacturers, together with quality, safety and efficacy experts, procurement agencies, and international donors working in public health, can come together to discuss issues around production and supply of quality products needed for treatment for vulnerable populations.

Further information will be posted closer to the event on the WHO Prequalification website at http://apps.who.int/prequal/info_press/press_and_media.htm.
## WHO working for you

### Online database of training activities

All WHO trainings on medical products in a single web database – focus on regulation

For the first time ever, training activities of an entire WHO department are publicly available in a consolidated database. The Essential Medicines and other Health Technologies (EMP) Department has created an online platform with updated information on all its past and coming training events.

WHO-EMP offers training on a wide range of topics related to the manufacture and use of medical products, including pharmaceuticals, vaccines, diagnostics and medical devices. The focus is on regulatory issues.

The training activities are grouped by organizing WHO units and by topics, including access; product efficacy / performance, good practice compliance; patents; policy; quality; regulatory practice; and safety and vigilance.

This powerful new tool enables WHO partners and stakeholders to stay informed, plan their own training schedules, access training materials of past events, or contact the organizer for further information.

► [Training activities offered by Department of Essential Medicines and other Health Technologies (EMP)](https://www.who.int/entity/medicines/training/emp_training_activities/en/index.html) [webpage - see below].

► Contact WHO at emp_training@who.int with any questions or comments.

---

### Online database of training activities

[www.who.int/entity/medicines/training/emp_training_activities/en/index.html](https://www.who.int/entity/medicines/training/emp_training_activities/en/index.html)

Training activities offered by Department of Essential Medicines and other Health Technologies (EMP)

**Link to activities table:**

[Training and capacity building activities organized and provided by Department of Essential Medicines and other Health Technologies (EMP)](https://www.who.int/entity/medicines/training/emp_training_activities/en/index.html)

<table>
<thead>
<tr>
<th>Area of work</th>
<th>Title of the training (click on title for full activity details)</th>
<th>Start date</th>
<th>Responsible technical staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access</td>
<td>Training on vaccine safety and pharmacovigilance for eight anglophone countries</td>
<td>28-04-14</td>
<td>BALAKRISHNAN, Doctor Madhava Ram</td>
</tr>
<tr>
<td>Quality</td>
<td>6th annual PQP quality assessment training</td>
<td>18-05-14</td>
<td>STAHL, Doctor Matthias Mario</td>
</tr>
<tr>
<td></td>
<td>Workshop on Blood Testing and Risk Assessment as part of GMP in Blood Establishments</td>
<td>09-06-14</td>
<td>PADILLA MARROQUIN, Doctor Ana Maria</td>
</tr>
<tr>
<td></td>
<td>Quality Assurance Systems for Blood Products</td>
<td>04-08-14</td>
<td>PADILLA MARROQUIN, Doctor Ana Maria</td>
</tr>
</tbody>
</table>