Publications and events

**Development**

Sustainable development goals aim at health for all

Geneva – WHO has welcomed the launch of the 2030 Agenda for Sustainable Development and is committed to work with partners around the world to achieve the new Sustainable Development Goals (SDGs).

Building on the Millennium Development Goals (MDGs), the SDG agenda demonstrates unprecedented scope and ambition. Poverty eradication, health, education, and food security and nutrition remain priorities, but the 17 SDGs also encompass a broad range of economic, social and environmental objectives, as well as the promise of more peaceful and inclusive societies.

SDG 3, “Ensure healthy lives and promote well-being for all at all ages”, profiles health as a desirable outcome in its own right. However, health is also presented as an input to other goals, and a reliable measure of how well sustainable development is progressing in general. The health goal includes new targets for key issues such as the global HIV, tuberculosis and malaria epidemics as well as child mortality and maternal mortality, on which major progress has been made under the MDGs. It also covers non-communicable diseases; health security; reproductive, maternal, newborn, child and adolescent health and infectious diseases, as well as universal health coverage – a goal which WHO particularly welcomes as it expresses the very spirit of the new development agenda, with its emphasis on equity and social inclusion that leaves no one behind.


**Access to medicines**

WHO publishes updated essential medicines lists

Geneva – WHO has published its updated WHO Model Lists of Essential Medicines and Essential Medicines for Children (1). A range of direct-acting antiviral medicines for hepatitis C (sofosbuvir, simeprevir, daclatasvir, ledipasvir and ombitasvir) have been added, despite the high cost of some of these medicines. This inclusive approach aims to enable the selection of optimal treatment regimens and to promote competition. Four medicines for treatment of multi-drug resistant tuberculosis have also been added, including the first new medicines to be developed for this disease in decades (bedaquiline and delamanid). The list further includes 16 new and 30 existing cancer medicines that were found to be associated with substantial or highly relevant benefits. The report specifies the evidence upon which the decisions were taken.

The model list will influence the development of national Essential Medicines Lists worldwide. The authors of a comment published in The Lancet (2) have welcomed the report, noting that the concept of selecting a limited list of essential medicines is applicable across countries and settings as a means to implement the moral imperative of
assuring universal access to life-saving medicines. They further emphasized the importance of comprehensive essential medicine policies covering a wide range of aspects, such as appropriate research and development, financing mechanisms, generic policies including various measures to overcome patent barriers, quality assurance, supply systems, and safe and cost-effective use. The 2016 report of the Lancet Commission on Essential Medicines Policies (3) will recommend ways of implementing such policies through concrete actions at the national and global levels.


First patent pool licence for a hepatitis C medicine

Geneva – The Medicines Patent Pool (MPP) has signed a licence with Bristol-Myers Squibb for the hepatitis C medicine daclatasvir. The royalty-free agreement allows manufacturers to develop daclatasvir for sale in 112 low- and middle-income countries, 76 of which are classified as middle-income nations by the World Bank. Nearly two thirds of all patients living with hepatitis C in the LMICs reside in the territory covered by this agreement.

Importantly, the licence allows generic manufacturers to develop fixed-dose combinations with other direct-acting antivirals to create powerful pan-genotypic regimens that offer the potential to treat all of the six major genotypes of HCV. Pan-genotypic regimens are crucial in resource-limited countries where access to genotype testing is limited. Bristol-Myers Squibb will provide a technology
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Medicines Patent Pool expands mandate to hepatitis C and tuberculosis
Geneva – The Medicines Patent Pool (MPP), the world’s only voluntary licensing mechanism in public health, has announced an expansion of its mandate to hepatitis C and tuberculosis medicines.

Hepatitis C affects between 130 and 150 million people worldwide. Tuberculosis killed 1.5 million people globally in 2014 alone and has become a public health challenge particularly with the emergence of multidrug-resistant strains of Mycobacterium tuberculosis. New treatments have been developed for both diseases, but they are unaffordable for many health systems.

Since its creation in 2010, the MPP has signed agreements for 12 antiretrovirals with six patent holders for countries that are home to 87-93% of people living with HIV in the developing world, saving the international community an estimated $119.6 million from the procurement of low-cost HIV medicines. Building on its existing model, the MPP will seek to license for generic manufacture of new direct acting antivirals for hepatitis C as well as new and re-purposed medicines for tuberculosis.

► MPP Press release, 6 November 2015.

Genus – The Medicines Patent Pool (MPP) has announced an expansion of its mandate to hepatitis C and tuberculosis medicines. These new additions are crucial for resource-limited countries where access to effective treatment options is limited.

Hepatitis C affects an estimated 130 to 150 million people worldwide, while tuberculosis killed 1.5 million people globally in 2014 alone. The emergence of multidrug-resistant strains of Mycobacterium tuberculosis has made it even more challenging for healthcare providers.

New treatments for both diseases have been developed, but they are often unaffordable for many health systems. Building on its existing model, the Medicines Patent Pool (MPP) will seek to license for generic manufacture of new direct acting antivirals for hepatitis C as well as new and re-purposed medicines for tuberculosis.

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► MPP Press release, 6 November 2015.
transfer package and information needed for the manufacture and registration of the product. As all licences signed by the MPP, the full agreement is available on the MPP’s website.

MPP Press release, 23 November 2015.

Controlled substances not accessible to all in need
Kuala Lumpur – The Global Commission on Drug Policy (GCDP) has released a new report showing that 75% of the world’s population does not have access to pain-relieving medicines included in the WHO Model List of Essential Medicines, because of strict drug control policies. Ninety-two percent of the world’s supply of morphine is consumed by just 17% of the global population, with consumption primarily concentrated in North America and Europe.

The report notes that governments have an obligation under international law to ensure equitable access to controlled medicines for their populations, and that this obligation has equal importance as drug control measures to reduce illegal diversion. The upcoming UN General Assembly Special Session (UNGASS) on Drugs in New York in April 2016 will be an opportunity to address this major gap in access to controlled medicines. (1)

Aside from morphine and other opioid analgesics, ketamine – an anaesthetic – is one of the needed substances. In March 2015 a UN Commission vote on whether ketamine should be placed under international control had been postponed. The WHO Expert Committee on Drug Dependence (ECDD) has recommended against this measure on three separate occasions, in 2006, 2012 and 2014. In response to a request for more information from the UN Commission on Narcotic Drugs, the WHO Expert Committee considered updated evidence on the issue at its 37th meeting on 16-20 November 2015. The material presented to the Committee confirmed the importance of the medical use of ketamine, particularly for low and middle income countries, and highlighted the potential role of ketamine as a prototype for a completely new class of antidepressants. The report did not find any changes with regard to global ketamine use and related medical problems, or abuse liability or toxicity. (2)

► (1) 24th International harm reduction conference, 18-21 October 2015, Kuala Lumpur, Malaysia. Press release, 19 October 2015.


Inefficiencies in the global insulin market
Health Action International (HAI) has released its first fact sheet from the ACCISS (Addressing the Challenges and Constraints of Insulin Sources and Supply) Study, which shows that one in two people in need of insulin cannot reliably access this life-saving medication because it is unavailable, unaffordable or both. The fact sheet provides an overview of the increasing global need for insulin to treat type 1 and type 2 diabetes and describes some of the barriers at national and global level that prevent millions of people from accessing insulin.

The three-year study, which was launched in early 2015, aims to identify the causes of poor insulin availability and unaffordable prices as a basis for
developing policies and interventions to improve access, particularly in the world’s most under-served regions.


## Health and trade

### European Council resolution defends public health interests

**Strasbourg** – The Parliamentary Assembly of the Council of Europe has adopted a resolution titled “Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?”

The resolution recognizes the indisputable role that the pharmaceutical industry has played in medical advances. However, it notes that in recent years very few new medicines have been placed on the market which present “a real therapeutic benefit satisfying real health needs.” Prices for some medicines, such as cancer and hepatitis C treatments, have increased sharply placing a burden on public health systems. The resolution calls on member states to apply rules to limit rising prices and conflicts of interest. It also proposes to set up a public fund for independent research geared to address unmet health needs, and calls on the WHO to put forward alternatives to the current patent-based model for development of new medicines.


### HAI/MSF report on EU trade policies and public health

**Brussels** – Médecins sans Frontières (MSF) and Health Action International (HAI) have launched their new report reviewing the European trade and investment policies, and have urged the European Union (EU) to close the gap between its public position to support access to affordable medicines and the current reality of its trade policies. The report recommends that countries should be supported in making use of the public health related flexibilities of the TRIPS Agreement to promote access to medicines.

The report comes as the European Trade Commissioner has presented her future trade and investment strategy. The European Commission has recently decided to support the world’s poorest countries in their request for an indefinite exemption from implementing intellectual property rules on medicines until they are no longer classified as a least-developed country.

- HAI / MSF Press release, 14 October 2015.

### WTO extends drug patent exemption for least-developed countries

**Geneva** – The World Trade Organization (WTO)’s Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) has agreed to extend until 2033 the period during which key provisions of the WTO’s intellectual property agreement, the TRIPS Agreement, do not apply to pharmaceutical products in least-developed countries. The
decision also keeps open the option for further extensions beyond that date. The extension comes a month after the adoption of the new UN Sustainable Development Goals (SDGs), which affirm the right of developing countries to utilize TRIPS Agreement flexibilities to ensure access to medicines for all.

**New WHO publication about trade and health**

**Geneva** – A new WHO publication explores the linkages between trade and health in today’s globalized world, and the strategies that policy-makers can adopt in order to harness trade-related benefits and mitigate negative impacts in order to promote public health. It provides background information, makes recommendations for coherent policy-making on trade and health, reviews recent initiatives in trade and health capacity building and offers technical advice, from a public health perspective, on the implementation of trade treaties in national legislation. The book concludes with three chapters on sector-specific intersections between health and trade, including a chapter on trade in medicines, which examines the impact of trade-related mechanisms – especially aspects related to intellectual property protection – on medicines availability, and policy instruments used in different countries to strike a balance between public health and commercial interests.

**Hepatitis world summit adopts Declaration**

**Glasgow** - Over 400 global stakeholders representing over 90 countries gathered at the first-ever World Hepatitis Summit held in Glasgow on 2-4 October 2015 (1). Concluding the summit, the participants released the Glasgow Declaration on Hepatitis (2), which calls upon governments to develop and implement comprehensive, funded national plans and programmes for prevention, testing, diagnosis, care and treatment of hepatitis. Around 400 million people are currently living with viral hepatitis. Claiming an estimated 1.45 million lives each year, the disease is one of the world’s leading causes of death. The draft WHO Global Health Sector Strategy on Viral Hepatitis (3) proposes targets for reduction of incidence and mortality, and aims for treatment of 80% of eligible people with chronic hepatitis B and C infections. Medicinal treatments exist, but funding is the big question in view of their current high cost.

**Malaria death rates plunge but risk remains**

**London** – WHO and UNICEF have launched their joint report on achieving the malaria millennium development goals (MDGs) (1).

The report (2) summarizes the remarkable progress seen in reversing malaria mortality and incidence. Between
2000 and 2015, malaria incidence fell by 37% globally and death rates by 60%. New research from the Malaria Atlas Project – a WHO Collaborating Centre based at the University of Oxford – shows that insecticide-treated nets have been by far the most important intervention across Africa (3).

However, serious bottlenecks remain in providing full access to malaria prevention, diagnostic testing and treatment. Progress has been uneven: fifteen countries – mainly in sub-Saharan Africa – bear the burden of 80% of malaria cases globally. Children under five account for more than two thirds of all malaria-associated deaths.

The World Health Assembly’s 15-year road map for malaria control aims at a further 90% reduction in global malaria incidence and mortality by 2030. The WHO-UNICEF report notes that these targets can only be achieved with political will, country leadership and significantly increased investment. Annual funding will need to triple, from US$ 2.7 billion today to US$ 8.7 billion in 2030.


Tuberculosis remains a public health challenge
Geneva – The WHO has released its Global tuberculosis report 2015. The report shows a continuing decline in mortality, which has nearly halved since 1990. The number of new cases reported globally has fallen by 1.5% each year for a total decrease of 18% since the year 2000. The millennium development goal to halt and reverse tuberculosis incidence by 2015 has been achieved globally and in 16 of the 22 high-burden countries that collectively account for 80% of cases.

However, tuberculosis remains a public health challenge. Tuberculosis and HIV now rank alongside each other as the infectious diseases with the highest numbers of deaths in the world. Each accounted for 1.1–1.2 million deaths in 2014.

To reduce the global burden of tuberculosis, detection and treatment gaps need to be closed, funding shortfalls filled and new diagnostics, medicines and vaccines developed. Detection and treatment gaps are especially serious among people with multidrug-resistant tuberculosis. Only about a quarter of an estimated 480 000 cases worldwide were detected and reported to national authorities in 2014. The major reason for these gaps is a shortfall in funding.


Ebola still a public health emergency
Geneva – At its 7th meeting, the Emergency Committee convened by the WHO Director-General under the International Health Regulations has advised that the Ebola virus disease (EVD) outbreak continues to constitute a public health emergency of international concern. Two active chains of transmission continued in October 2015, one in Guinea and one in Sierra Leone. The Committee has updated its recommendation on measures to minimize the risk of international spread of EVD.
There should be no international travel of Ebola contacts or cases unless they are part of appropriate medical evacuation, and exit screening should be performed at the borders of States with Ebola transmission. On the other hand, there should be no general ban on international travel or trade, nor any restrictions on the travel of EVD survivors. (1)
On 7 November 2015 WHO declared that Ebola virus transmission in Sierra Leone had ended. Forty-two days after the last person confirmed to have Ebola virus disease had a second negative blood test, the country entered a 90-day period of enhanced surveillance. (2)
► (1) WHO Statement, 5 October 2015.
► (2) WHO News release, 7 November 2015.

Measles immunization gap persists
Geneva – WHO has reported that although an estimated 17.1 million lives have been saved since 2000 through measles vaccination, 2015 global milestones and measles elimination goals are off track. New published data shows that since 2010 overall progress towards increasing global immunization coverage has stagnated at 85% of children having received their first dose of measles vaccination, and only half of the world's children receiving the recommended second dose.

Despite successful implementation of vaccination campaigns in a number of countries, more than 100 000 children needlessly died from measles in 2014. Large outbreaks were reported from China, the Philippines, Viet Nam, Angola, Ethiopia, India, the Russian Federation and Somalia. Such outbreaks happen when there are gaps in vaccination programmes and continue to pose a serious challenge to meeting global targets.
► WHO News release, 12 November 2015.

Antiretroviral treatment
WHO recommends treatment for all people living with HIV
Geneva – WHO has published new guidelines recommending that anyone infected with HIV should begin antiretroviral therapy (ART) as soon after diagnosis as possible. The recommendations are supported by recent findings from clinical trials confirming that early use of ART keeps people living with HIV alive, healthier and reduces the risk of transmitting the virus to partners.

WHO now also recommends that people at “substantial” risk of HIV should be offered preventive antiretroviral treatment. This should be seen as an additional prevention choice based on a comprehensive package of services, including HIV testing, counselling and support, and access to condoms and safe injection equipment.

The new recommendations increase the number of people eligible for ART from 28 million to 37 million people globally. The recommendations were developed as part of a comprehensive update of WHO guidelines on ART. They were published ahead of the full guidelines because of their potential for public health impact.
► WHO News release, 30 September 2015.

Updated optimal list of ARVs for children
Geneva – The Inter-Agency Task Team (IATT) on the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Children and other groups is
focused on meeting the needs of children with HIV infection. The IATT has published an update to the Optimal and Limited-Use Paediatric ARV Formularies, for use by governments and implementing agencies. The lists provide guidance on optimal products that are most readily available on the market and comply with WHO treatment guidance. The IATT works with WHO and UNICEF to periodically review and update these formularies.

► IATT. Update to the Optimal List of Paediatric ARV Formulations. Policy brief.

Antibiotics

International summit on antibiotic resistance

Uppsala – Following the adoption of the global action plan on antimicrobial resistance by the World Health Assembly in May 2015, some 200 stakeholders and experts from all parts of the world met at the 2015 Uppsala Health Summit in October to engage in dialogue how to put this action plan into practice.

The discussions held at the summit are documented in a post-conference report, which calls for information and education, leadership from governments and international organizations, and delinking of peoples’ incomes from antibiotics sales. It was further stressed that rational use requires access to diagnostics and data on resistance, which is lacking particularly in developing countries, and that communication, coordination and more analyses on the consequences of antibiotics resistance are needed, including analyses on the cost of inaction.

Research efforts to develop new antibiotics need to be intensified. While academia and small and medium size enterprises were seen as the most appropriate place for the discovery of new antimicrobial compounds, the expertise and experience of the pharmaceutical industry will be important to increase the chance of success.

► Uppsala Health Summit. Conference report points the way in the fight against antibiotic resistance [web page], 9 October 2015.

Use of veterinary antibiotics in Europe

European Union – The EMA has released its fifth report on sales of antibiotics used in animals. According to this report, overall sales in the period 2011-2013 have decreased by approximately 8%, with 11 countries reporting decreases and six countries reporting increases.

Sales data on veterinary antibiotics are collected annually as part of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, which is a cooperation between the national authorities throughout the European Union (EU) and is coordinated by EMA. A total of 26 countries from the European Economic Area (EEA) contributed data for the fifth ESVAC report, which comes with an interactive database tool. (1)

In November 2015, the EMA released its new strategy on antimicrobials adopted by its Committee for Veterinary Medicinal Products for public consultation. The strategy recognizes that antimicrobial resistance affects both animal and human health and sets clear objectives to help combat the threat of resistance which may arise from the use of antimicrobials in animals. Comments are invited until 29 February 2016. (2)

► (1) EMA News, 15 October 2015.
(2) EMA News, 17 November 2015.
Multi-country survey reveals misconceptions on antibiotic resistance

Geneva – A multi-country survey shows that people are confused about antibiotic resistance. Three quarters (76%) of respondents think it happens when the body becomes resistant to antibiotics, 66% believe that they are not at risk if they personally take their antibiotics as prescribed, and 44% think that it is only a problem for people who take antibiotics regularly. In fact, anyone, of any age, in any country can get an infection with bacteria that are resistant to antibiotics.

What people can do to address antibiotic resistance is also not well understood. For example, 64% of respondents believe that antibiotics can be used to treat colds and flu, and 32% believe they do not need to complete the prescribed course of treatment if they feel better. More than half (57%) feel there is not much they can do to stop antibiotic resistance, while 64% believe medical experts will solve the problem before it becomes too serious.

Another key finding of the survey was that almost three quarters (73%) of respondents said farmers should give fewer antibiotics to food-producing animals.

The survey findings coincide with the launch of a new WHO campaign ‘Antibiotics: Handle with care’ – a global initiative to improve understanding of the problem. Antibiotic resistance is one of the biggest health challenges of the 21st century and will require global behaviour change by individuals and societies.

WHO News release, 16 November 2015.

Lists and manuals

Indicators to assess pharmacovigilance systems

Geneva – WHO has published a practical manual for assessment of pharmacovigilance systems, with indicators that can be understood by health care workers without formal training in monitoring and evaluation.

The proposed indicators are based on the expected functions of pharmacovigilance centres as described in the WHO’s Minimum Requirements for a Functional Pharmacovigilance System. They reflect the existing structures, the processes used, and the outcomes or impact achieved in pharmacovigilance systems.

Pharmacovigilance is critical to monitor the safety and safe use of medicines in public health programmes. The manual proposes a set of nine pharmacovigilance indicators for public health programmes. Pharmacovigilance is also a regulatory function. A subset of indicators from this manual has been included in the WHO harmonized tool for assessing a national regulatory agency (NRA).

The manual is published as version 1 (v1.0) to underscore its evolving nature. Feedback from user groups will be used in developing the subsequent versions.


Specifications for selected HIV diagnostics

Geneva – WHO, in collaboration with a wide range of institutions constituting the technical working group for procurement specifications of HIV diagnostics, has
Published its updated technical report to support efficient procurement of essential equipment and laboratory commodities for HIV. This procurement tool covers all laboratory items approved for procurement by WHO and the Global Fund.

The manual includes lists of laboratory items required to perform HIV-related tests on specific defined technology, specifications of the items to facilitate their procurement, examples of quantities of reagents required to perform 1000 tests, and price benchmarks that will continue to be updated based on procurement of the contributing partners. This information assists professionals in understanding the different technologies and their cost implications, and in ensuring that all items are ordered in adequate quantities.


WHO matters

WHO launches independent assessment of snake antivenoms

Geneva – In response to the current crisis in the supply of antivenoms, WHO has decided to offer an independent assessment of antivenoms. A call to manufacturers of antivenoms intended for use in sub-Saharan Africa was sent out in December 2015 (1).

About 5 million people are bitten by snakes every year, causing around 125 000 deaths and 400 000 people to be permanently disabled or disfigured. News that one of the most effective treatments for snake bite, Fav-Afrique, will run out in 2016 has caused dismay among public health experts and has spurred media interest in the subject. A prequalification scheme for antivenoms could incentivize manufacturers to develop and produce affordable, good quality antivenoms. Financial backing from donors will be needed to address this issue, on which WHO has attempted to raise the alarm for a number of years. WHO also encourages

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research to develop new therapeutic options for snakebites. (2)

WHO prequalification is open to a range of priority medical products by invitation for expression of interest (3). In November 2015 updated invitations were published for active pharmaceutical ingredients (API), for reproductive health medicines and for medicines to treat HIV infection and related diseases, including treatments for hepatitis B and C.

► (1) WHO Prequalification update, 4 December 2015.
► (2) WHO Prequalification update, 2 October 2015.
(3) WHO Prequalification. Invitations for Expressions of Interest (EOIs) [web page].

WHO Expert Committees on medicines meet in Geneva

Geneva – The WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) held its 50th meeting in Geneva on 12–16 October 2015. The experts adopted a number of monographs and texts for The International Pharmacopoeia as well as new and revised WHO guidelines.

Some important new guidance has been adopted. Good pharmacopoeial practices, as recommended by a group of world pharmacopoeias, will support convergence and could reduce the costs caused by differences among standards. In collaboration with the International Pharmaceutical Federation (FIP), guidance has been developed on points to consider in the preparation of children-specific medicines that are not available as authorized products. New guidance has also been adopted on regulatory control of variations and on conducting medicines quality surveys. The finalized guidelines will be published as annexes to the WHO Technical Report Series in 2016. The working versions are available on the WHO web site.

The WHO Expert Committees on Biological Standardization and on the Selection and Use of Essential Medicines, as well as the International Nonproprietary Names (INN) Expert Group, met concurrently with the ECSPP and provided their updates and input on some cross-cutting issues.

► WHO Essential medicines and health products. 50th Expert Committee on Specifications for Pharmaceutical Preparations [web page].

New web site on substandard and falsified medicines

Geneva – WHO has launched a new website on substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products, with answers to frequently asked questions and links to related information and WHO activities, such as the global WHO surveillance and monitoring system.

The existence of SSFFC products is an unacceptable risk to public health. They affect every region of the world, harm patients and undermine confidence in medical products, healthcare professionals and health systems. SSFFC products from every category have been reported. WHO is working with stakeholders to minimize the risks from SSFFC medical products by collecting data and transferring knowledge and good practices to countries.

► WHO Essential Medicines and health products. Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) Medical Products [web site].