



WIPO Standing Committee of the Law of Patents Information Exchange Session:

Publicly accessible databases on patent information status and data on medicines and vaccines

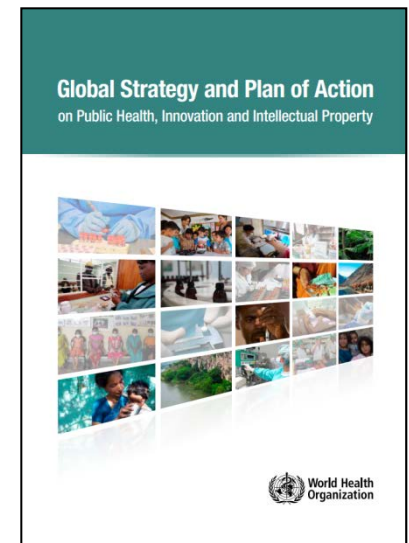
12 December 2017

Patent & Legal Status Information on Medicines and Vaccines

WHO's Mandate

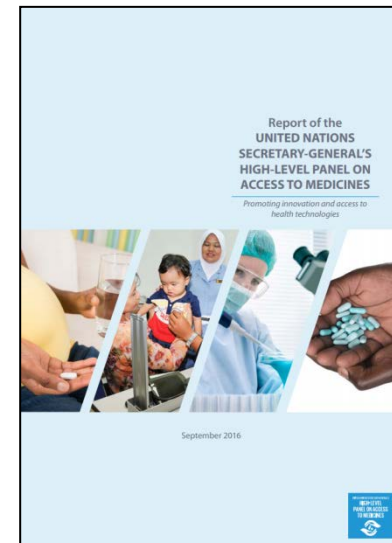
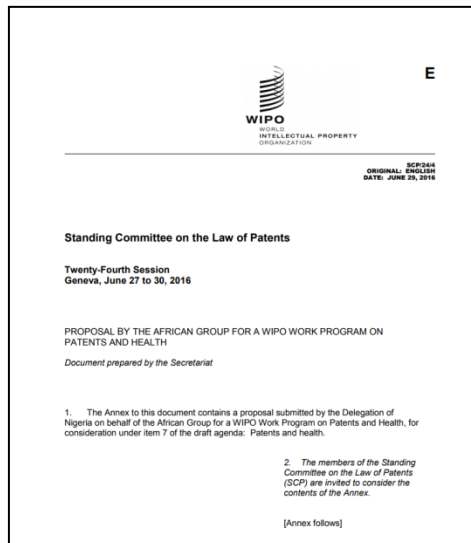
Element 5. Application and management of intellectual property to contribute to innovation and promote public health

5.1 (c) facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases that contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents



Patent & Legal Status Information on Medicines and Vaccines

Proposal: Element II-Information Exchange



18. WIPO development of an international patent register, in consultation with Member States and the support of WHO, for essential medicines to facilitate determination of the patent status of a medicine internationally, including those for communicable and non-communicable diseases. Currently, there is no efficient or accurate way to determine the patent status of medicines, including those on the WHO Model List of Essential Medicines. This lack of transparency in the patent status of essential medicines (and other medicines) negatively affects efforts of governments and procurement agencies to negotiate terms and conditions of access to medicines.

4.3 Recommendations

4.3.6 Patent information

(a) Governments should establish and maintain publicly accessible databases with patent information status and data on medicines and vaccines. This information should be periodically updated and consolidated by WIPO in collaboration with stakeholders to develop an international, easily searchable database which should include:

- standard international common names for biological products;
- international non-proprietary names for products, either as known at the time of application or after the granting of a patent; and
- dates of grant and expiry.

Sources: http://www.wipo.int/edocs/mdocs/scp/en/scp_24/scp_24_4.pdf

<https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>

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The Broader Context: Trilateral Cooperation

Examples:

- WIPO Patent Search Report on Pandemic Influenza Preparedness (PIP)-Related Patents and Patent Applications, 2011
- Patent Landscape Report on Vaccines for Selected Infectious Diseases, 2012
- Ad-hoc patent search requests processed through WIPO
- Access to Medicines, Patent Information and Freedom to Operate: Joint Technical Symposium, 2011



Sources: http://www.wipo.int/edocs/pubdocs/en/global_challenges/628/wipo_pub_628.pdf

http://www.who.int/phi/access_medicines_feb2011/en/

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Public Health Relevance

- Procurement of medicines
- Research and development, transfer of technology, production, and freedom to operate
- Analyzing innovation activity and tracking developments with regards to research and development
- WTO TRIPS Agreement flexibilities



Patent & Legal Status Information on Medicines and Vaccines

The Challenge

- Obtaining reliable, up-to-date patent & legal status information is difficult
- Health authorities and other stakeholders face difficulties
 - Matching relevant patents to particular products
 - Finding information in LMICs in particular
- Lack of available and easily accessible patent and legal status information
- Lack of communication between relevant authorities
- Language barriers



Patent & Legal Status Information on Medicines and Vaccines

Facilitating the Solution

- Freely-accessible patent databases/registers
 - US FDA *Orange Book*
 - Health Canada Patent Register
 - European Patent Office Espacenet
 - Medicines Patent Pool
 - WIPO Patentscope
 - Indian Patent Office
 - ...
- Commercial patent databases

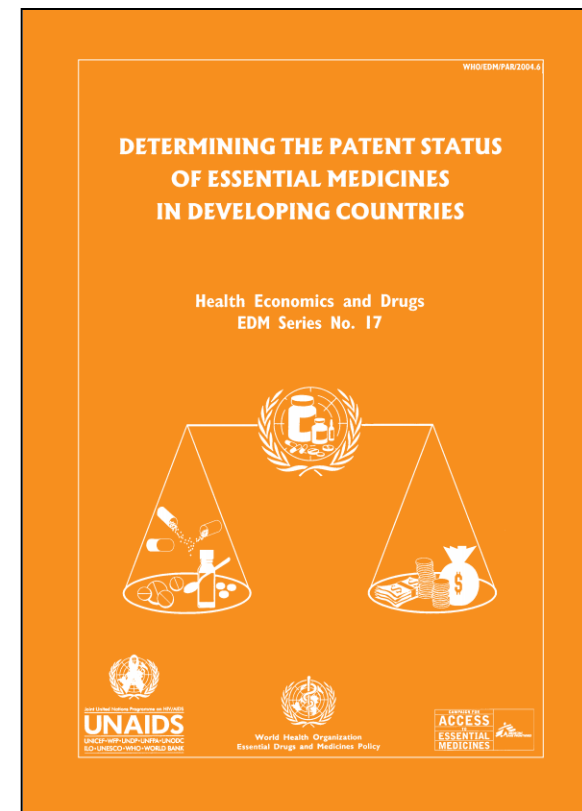


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WHO Activity: Determining the Patent Status of Essential Medicines in Developing Countries

As early as 2004, WHO publication on patent situation of HIV treatments:

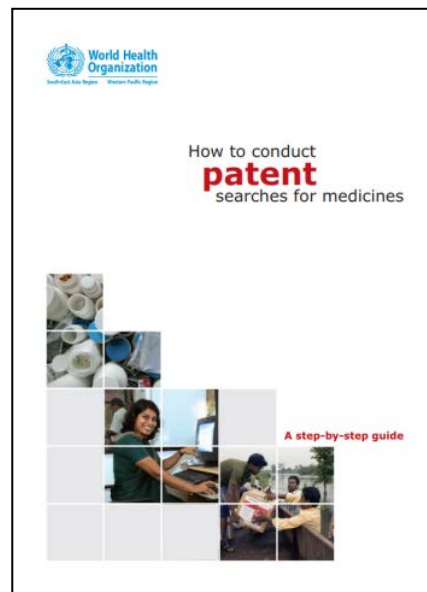
- There are a range of policy options for countries to ensure that patents do not constitute a barrier to access to medicines
- A crucial factor to ensure effective decision-making must be the availability of accurate and up-to-date information about patent status



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WHO Activity: How to conduct patent searches for medicines: A step-by-step guide

- Starting point for health authorities, procurement bodies and others to identify whether patents relating to a pharmaceutical product exist in the country of interest



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WHO Activity: Patent Report

New Hepatitis C medicines:

- Daclatasvir
- Ledipasvir
- Simeprevir
- Sofosbuvir
- Paritaprevir/Ombitasvir/Dasabuvir

WHO updates patent information on treatments for Hepatitis C



World Hepatitis Alliance

New medicines on the market have given hope to the millions of people who suffer from Hepatitis C, a liver disease that kills approximately 700,000 people annually.

In 2016, the World Health Assembly, WHO's policy-making body, endorsed the Global health sector strategy on viral hepatitis 2016-2021 that requests WHO to "advocate for comprehensive strategies to reduce prices of viral hepatitis vaccines, medicines, diagnostics and other commodities".

WHO works closely with Member States to assess and promote policy options for increasing access to these medicines, which remain unaffordable to many of those who need them and put an enormous financial strain even on the health systems of high-income countries.

Knowledge of the patent status of new medicines is important for governments who are trying to make those medicines available to their populations. To that end, WHO has carried out an analysis of the patent situation for seven of the new treatments, including sofosbuvir, ledipasvir and daclatasvir, all of which have been included in the WHO List of Essential Medicines in 2015. The reports provide clarity on whether the medicines are patent protected or not in individual countries.

The dataset was completed for more than 40 countries, territories and regions.

Download the reports here:

- ↓ Daclatasvir pdf, 496kb
- ↓ Ledipasvir pdf, 542kb
- ↓ Paritaprevir / Ombitasvir / Dasabuvir pdf, 577kb
- ↓ Simeprevir pdf, 517kb
- ↓ Sofosbuvir pdf, 594kb



Sources: <http://apps.who.int/iris/bitstream/10665/250625/1/WHO-HIV-2016.20-eng.pdf?ua=1>
http://www.who.int/phi/implementation/ip_trade/ip_patent_landscapes/en/

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WHO Activity: Report on the Role of IP in Local Production

- Highlights the importance of transparent and fair patent administration systems, including easy access to reliable patent information
- Contains analysis of patent landscape for
 - Annex 1. Atazanavir
 - Annex 2. Raltegravir
 - Annex 3. Imatinib
 - Annex 4. Sitagliptin
 - Annex 5. Pegylated interferon alfa-2a
 - Annex 6. Gardasil
(human papillomavirus vaccine)



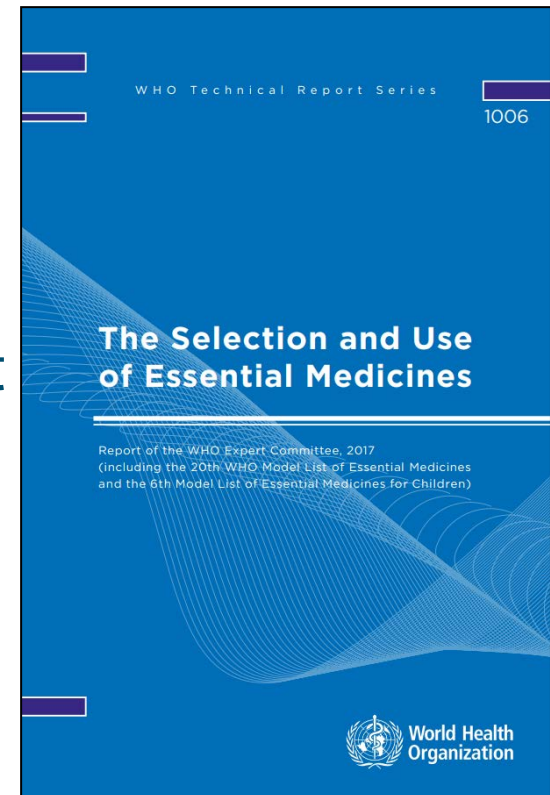
Source: http://www.who.int/phi/publications/int_prop_role_local_prod_opportunities-challenges.pdf?ua=1

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Model List of Essential Medicines (EML)

- Launched in 1977
- Updated and revised every 2 years
- Essential medicines are those that satisfy the priority health care needs of the population
- Serves as a guide for the development of national and institutional essential medicine lists
- Includes 433 essential medicines



Source: <http://apps.who.int/iris/bitstream/10665/259481/1/9789241210157-eng.pdf?ua=1>

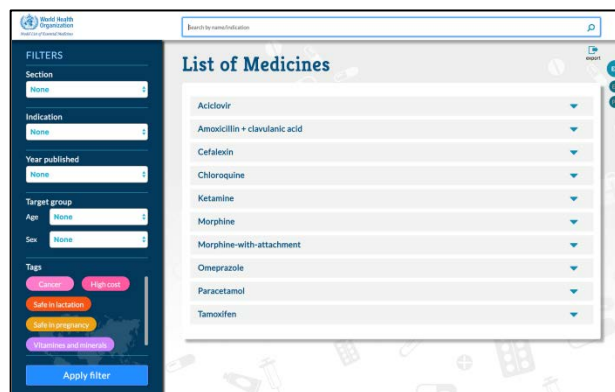
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Electronic Essential Medicines (E-EML)

- Anatomical Therapeutic Chemical (ATC)
- International Non-proprietary Names (INN)
- MedsPal

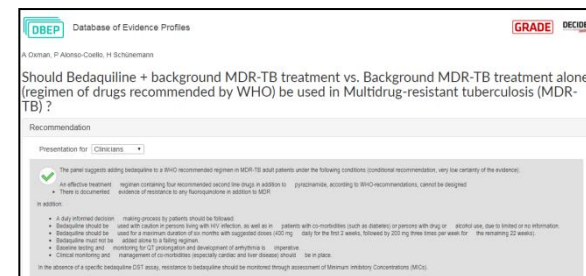
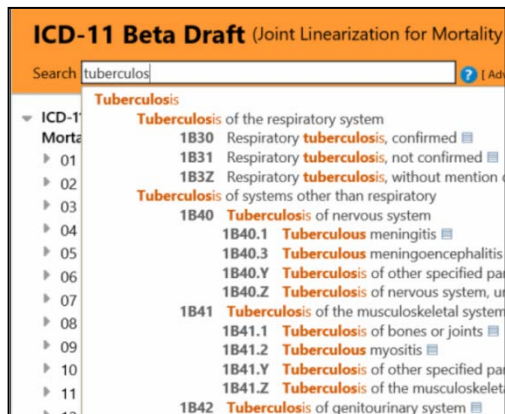
ONLINE SEARCH PLATFORM



LINKED TO

WHO DATABASES

ICD-11 UPDATE



WHO GUIDELINES

EXTERNAL PARTNERS



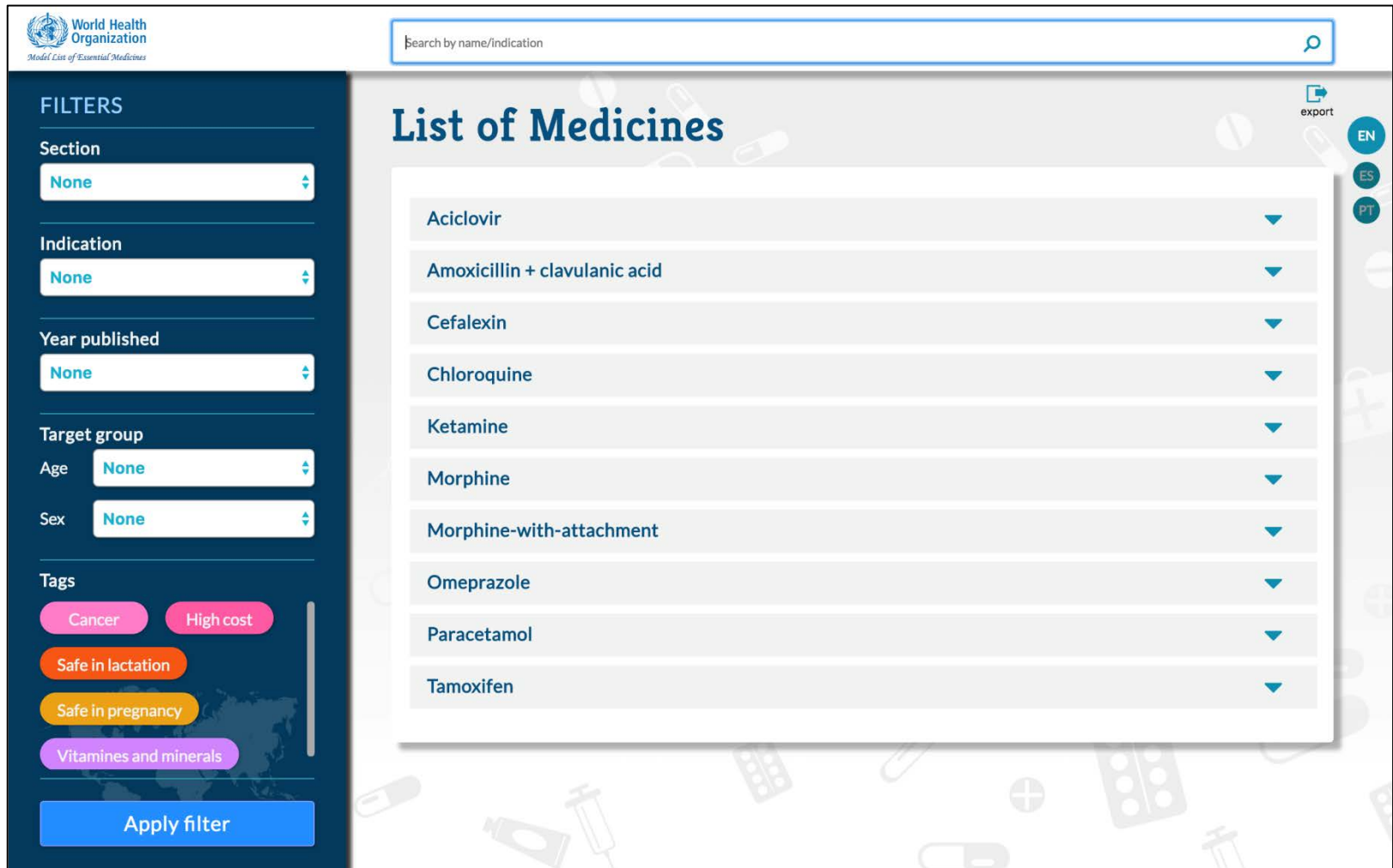
WIKIPEDIA
The Free Encyclopedia



The DrugBank database is a unique bioinformatics and cheminformatics resource that combines detailed drug data with comprehensive drug target information.

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E-EML Online Search Platform



The screenshot displays the E-EML Online Search Platform interface. At the top left is the World Health Organization logo and the text "World Health Organization Model List of Essential Medicines". A search bar at the top right contains the text "Search by name/indication". On the left side, there is a "FILTERS" panel with several dropdown menus: "Section" (None), "Indication" (None), "Year published" (None), "Target group" (None), "Age" (None), and "Sex" (None). Below these are "Tags" with buttons for "Cancer", "High cost", "Safe in lactation", "Safe in pregnancy", and "Vitamines and minerals". A blue "Apply filter" button is at the bottom of the filter panel. The main content area is titled "List of Medicines" and features an "export" icon and language selection buttons (EN, ES, PT). The list includes the following medicines with dropdown arrows to their right: Aciclovir, Amoxicillin + clavulanic acid, Cefalexin, Chloroquine, Ketamine, Morphine, Morphine-with-attachment, Omeprazole, Paracetamol, and Tamoxifen.

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Outlook

WHO will:

- continue to engage in facilitating access to patent information;
- link the EML with MedsPal and potentially other patent databases;
- undertake patent analysis where necessary to enhance access, facilitate local production; and
- work with WIPO in this context



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Thank you!