ANNUAL REPORT 2016

EXPANDING FOR BETTER TREATMENT OPTIONS

medicines patent pool

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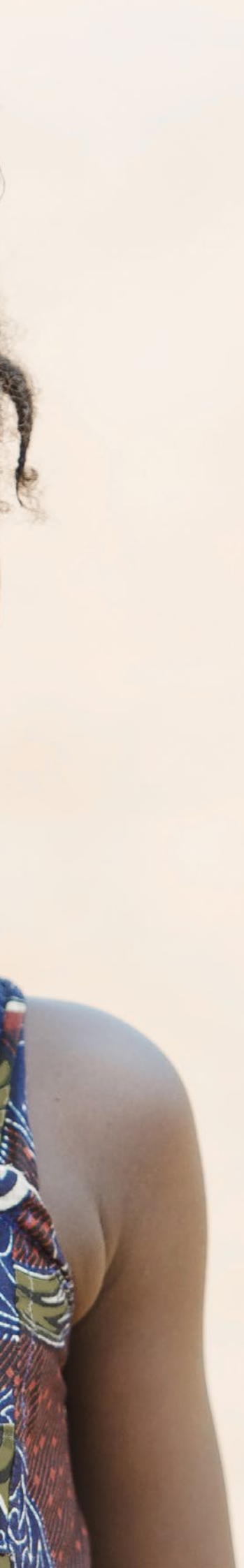


medicines patent pool

Vision

The vision of the MPP is a world in which people in low- and middle-income countries have rapid access to affordable and appropriate HIV, hepatitis C and tuberculosis treatments.

Mission

Our mission is to increase access and promote innovation in the fields of HIV, hepatitis C and tuberculosis treatment through voluntary licensing and patent pooling. Founded in 2010 by Unitaid, the MPP works with a range of partners – industry, civil society, international organisations, patient groups and governments – to prioritise and license new and existing medicines for low- and middle-income countries.

Message from the Chair of the Governance Board and the Executive Director

We are pleased to present our 2016 Annual Report to all stakeholders and supporters. Twenty sixteen was a dynamic year for the Medicines Patent Pool (MPP) and for the access to medicines field. With MPP funder Unitaid's approval for our expansion into hepatitis C and tuberculosis (TB) in late 2015, we made quick headway in these new disease areas. The MPP signed its first sublicensing agreements for a hepatitis C antiviral and our first memorandum of understanding to promote TB drug development in the early part of the year.

The organisation also made strides in ensuring access to MPP-licensed HIV medicines. Our network of generic pharmaceutical companies – 15 licensees strong – distributed 4.7 billion doses of low-cost antiretrovirals as of December 2016 and had moved several MPP-licensed products to registration. With this progress, the patent pooling model as an effective intervention gained ground in public health debates.

Sigrun Møgedal
Chair of the Governance Board, MPP

Greg Perry
Executive Director, MPP

The United Nations General Assembly's Political Declaration on HIV and AIDS, for example, welcomed the "broadening of the scope of [our] work to promote voluntary partnerships to address hepatitis C and TB" in June. The Lancet Commission on Essential Medicines Policies recognised that the MPP model could support widespread availability of medicines on the World Health Organization (WHO)'s Model Lists of Essential Medicines as well. At year's end, the MPP secured support from the Swiss government to explore our approach to tackling access issues for these medicines.

Importantly, last year we had an opportunity to expand our partnerships, drawing in experts and disease organisations as well as private sector and civil society leaders interested in bettering the lives of tuberculosis and hepatitis C patients. Together with our strong relationships in the HIV community, we are confident that we can play a role in international efforts to meet treatment goals in coming years.

Sigrun Møgedal and Greg Perry

Governance

Governance Board

Sigrun Møgedal
Chair

Charles Clift
Vice-Chair

Claudia Chamas
Member

Michel Manon
Member

Bernard Pécoul
Member

Anban Pillay
Member

Brian Tempest
Member

Jayashree Watal
Member

Anna Zakowicz
Member

Our funder, Unitaid

Unitaid founded the Medicines Patent Pool in 2010 and serves as the MPP's sole funder for HIV, hepatitis C and tuberculosis activities.

An innovative financing mechanism, Unitaid is engaged in finding new ways to prevent, treat and diagnose HIV/AIDS, tuberculosis and malaria more quickly, more affordably and more effectively. It takes game-changing ideas and turns them into practical solutions that can help accelerate the end of the three diseases. The MPP serves as an important implementer of Unitaid's objectives through its engagement with a range of stakeholders to license key medicines for generic manufacture.

Since 2010, Unitaid's investments in the MPP have yielded 10.9 times the value of its initial funding through expansion of generic access in countries and subsequent price reductions of licensed products. Savings are projected to reach $2.3 billion by 2028 for HIV medicines alone.

"The MPP model supports a collaborative approach among producers, universities, laboratories and others and this makes it possible for many countries to have access to medicines at affordable prices."

Celso Amorim, Chair of the Executive Board at Unitaid

"The MPP is a cornerstone of Unitaid's efforts to transform the HIV and hepatitis C market and rapidly scale up treatment in low- and middle-income countries. Unitaid is also working closely with the MPP and other partners to encourage the development of better treatment options for tuberculosis as a global health priority."

Lelio Marmora, Unitaid's Executive Director

Expert Advisory Group

Chair:
Maximiliano Santa Cruz

Vice-Chair:
Kees de Joncheere

HIV Sub-Group:
Jonathan Berger
Alexandra Calmy
Carlos Correa
Nathan Ford
Nelson Juma Otwoma
Achal Prabhala
Gracia Violeta Ross

Viral Hepatitis C Sub-Group:
Labeeb Abboud
Isabelle Andrieux-Meyer
Philippa Easterbrook
Ellen 't Hoen
Ludmila Maistat
Raquel Peck

Tuberculosis / Antimicrobial Resistance Sub-Group:
Jennifer Cohn
Jan Gheuens
Mayowa Joel
Christian Lienhardt
Eun-Joo Min
Lita Nelsen
Wim Vandevelde

MPP Team Members

Greg Perry
Executive Director

Chan Park
General Counsel

Maica Trabanco
Associate Counsel

Sandeep Juneja
Business Development Director

Aastha Gupta
Business Development Manager

Yao Cheng
Scientific Manager

Esteban Burrone
Head of Policy

Erika Dueñas
Advocacy Officer

Katherine Moore
Head of Communications

Sophie Thievenaz
Communications Officer

Alnaaze Nathoo
Strategy and Operations Manager

Asma Rehan
Operations Officer

Vincent Chauvin
Finance and Resources Manager

Esperanza Suarez
Finance and Administrative Officer

Sophie Naeye
Office Assistant

2016 Achievements

Extended the HIV licence for ViiV Healthcare's dolutegravir to all lower middle-income countries allowing sublicensees to sell in nations that are home to 94% of people living with HIV in the developing world. Announced the first World Health Organization prequalification submissions for generic dolutegravir less than three years after the drug's approval in Europe. Signed sublicensing agreements for AbbVie's lopinavir and ritonavir for Africa.

Signed first round of sublicences to improve access to Bristol-Myers Squibb's hepatitis C treatment daclatasvir in 112 low- and middle-income countries. Announced negotiations with the Egyptian drug manufacturer Pharco Pharmaceuticals for the hepatitis C drug candidate ravidasvir.

Finalised a memorandum of understanding with the Global Alliance for TB Drug Development (TB Alliance) to promote the development of new, faster-acting tuberculosis regimens and ensure their availability in developing countries. Opened negotiations to license sutezolid, a promising investigational treatment for both drug-susceptible and drug-resistant TB.

IMPACT 2010-2016

1 hepatitis C direct-acting antiviral

100+ ongoing pharmaceutical development projects

12 HIV medicines and an HIV technology platform licensed

312 million US dollars saved

12.9 million patient-years and 4.7 billion doses of HIV treatments delivered through MPP's generic partners

Launched MedsPaL, the Medicines Patents and Licences Database, with information on the intellectual property status of priority HIV, hepatitis C and tuberculosis medicines in developing countries. Brokered memoranda of understandings with three national patent offices to augment MedsPaL's content.

Strengthened collaborations with experts, civil society, patient groups and industry in the HIV, hepatitis C and TB fields. Extended MPP's Expert Advisory Group to 11 new members with hepatitis C and tuberculosis expertise. Added four new generic manufacturing partners, broadening the network to include companies from Bangladesh and Germany.

PRODUCTS LICENSED TO THE MPP (2010-2016)

abacavir (ABC) paediatrics
atazanavir (ATV)
cobicistat (COBI)
daclatasvir (DCV)*
darunavir (DRV)
dolutegravir (DTG)
elvitegravir (EVG)
emtricitabine (FTC)
lopinavir (LPV)
raltegravir (RAL) paediatrics
ritonavir (RTV or /r)
solid drug nanoparticle technology**
tenofovir alafenamide (TAF)
tenofovir disoproxil fumarate (TDF)

** Hepatitis C ** HIV technology platform*

How We Work

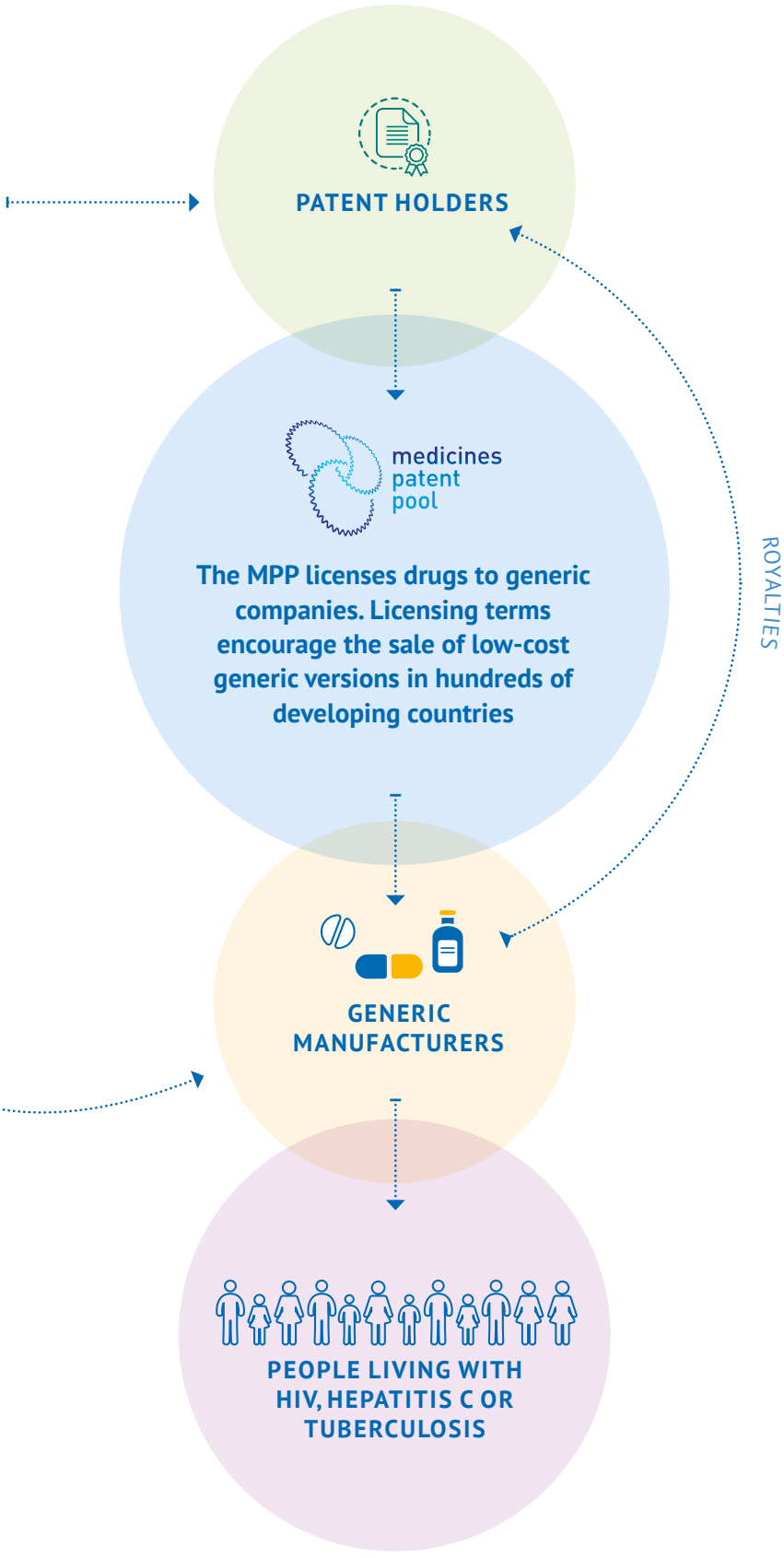
ORIGINATOR PARTNERS/PATENT HOLDERS

AbbVie
Bristol-Myers Squibb
Boehringer Ingelheim*
F. Hoffmann-La Roche**
Gilead Sciences
Janssen*
Merck Sharp & Dohme
University of Liverpool
ViiV Healthcare
United States National Institutes of Health

** Extension of non-enforcement policy*
*** Access agreement*

GENERIC MANUFACTURING PARTNERS

Aurobindo
Beximco
Cipla
Desano
Emcure
Hetero
Huahai
Laurus Labs
Lupin
Micro Labs
Mylan
Natco
Sandoz
Strides Shasun
Zydus Cadila



In 2016, the MPP moved to expand existing HIV licensing agreements and ramp up its work with generic manufacturing partners to bring MPP-licensed antiretrovirals to market.

As of December 2016, generic companies working with the MPP had delivered close to five billion doses of HIV medicines to 131 countries. This included 4.5 billion doses of tenofovir disoproxil fumarate combinations, 98 million of atazanavir, 47 million of paediatric abacavir and 50 million of lopinavir.

The MPP worked with long-standing partner ViiV Healthcare to extend their licence for dolutegravir (DTG) to all remaining lower middle-income countries, potentially benefiting a quarter of a million people in four countries — Armenia, Moldova, Morocco and Ukraine — with patents, that were not covered in the initial agreement.

KEY FEATURES OF MPP LICENCES

- **Non-exclusive, non-restrictive to encourage competition**
- **Wide geographical scope, to include countries home to up to 94% of people living with HIV and up to 99% of children living with HIV in low- and middle-income countries**
- **Waivers for data exclusivity**
- **Provisions to allow generics to sell outside agreed territory if there is no patent infringement***
- **Flexibility to combine different medicines and to develop appropriate fixed-dose combinations**
- **Compatible with the use of Trade-Related Aspects of Intellectual Property Rights Agreement flexibilities**
- **Public disclosure of company patent information**
- **Unprecedented full transparency of terms**

** In most agreements*

Alexandr Curasov
Executive Director of the Positive Initiative in Moldova and Communities Delegation Board Member at the Global Fund to Fight AIDS, Tuberculosis and Malaria

"This is very good news for Moldova.
New medicines with high efficacy and low side effects like dolutegravir can contribute to improving living conditions for people living with HIV. We look forward to working with all stakeholders in Moldova to make sure new and improved treatments become accessible to all people in need as soon as possible."

Dimytro Sherembey
Head of Coordination Council of the All-Ukrainian Network of People Living With HIV/AIDS (PLWHA)

"The Network is very supportive of the efforts of the Ukrainian Public Health Center, Ministry of Health (MoH) Ukraine ***and its partners in optimising and standardising treatment regimens. One of the core elements of such optimization is DTG, as it became available in generic version for Ukraine thanks to the ViiV and Medicines Patent Pool licence. The TDF/FTC/DTG treatment regimen is proposed as one of two main first-line treatment regimens in Ukraine in the new version of national treatment guidelines, which is to be approved soon. This opportunity motivated us to search for additional funding and we will be able to supply 1200 treatment courses of generic DTG to Ukraine with support of philantropic donors."***

As a result, the MPP-ViiV licence now includes 92 developing countries, including 59 middle-income nations. In addition, countries without patents in force can procure generic products from MPP's sublicensing partners, broadening access to many more countries. In 2016, three MPP sublicensees, Cipla, Hetero and Mylan, became the first companies to submit dossiers to the World Health Organization's prequalification programme for single-dose dolutegravir, while Mylan became the first company to submit a dossier for the triple drug combination dolutegravir/lamivudine/tenofovir to the prequalification programme.

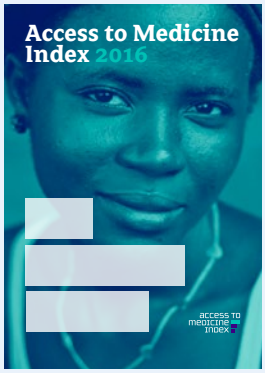
> ***"ViiV Healthcare has worked with the Medicines Patent Pool for many years and we are pleased to continue our work with the organisation to further improve access to innovative medicines to address the burden of HIV."***
> **Dominique Limet,** Chief Executive Officer of ViiV Healthcare

Second Annual Industry Meeting, March

As part of its industry collaboration, the MPP convened its second annual industry meeting on 7 March. The MPP showcased and analysed the progress of projects undertaken by MPP partners using the MPP's innovative model which helps bring generic medicines to market faster. The event introduced the detailed methodology of the antiretroviral (ARV) forecasts which MPP and the World Health Organization jointly undertake, and the resulting expected use of ARVs in the future. Experts from Unitaid, the Global Fund, the WHO, industry and the MPP discussed how the MPP model bridges the gap between innovation and subsequent access to drugs in developing countries. **The participants lauded the MPP for its approach to access-oriented licensing and encouraged its expansion to other disease areas**. Possible future collaborations between organisations were also discussed in the panel, while Philippe Duneton, Deputy Executive Director of Unitaid, recognised the potential need for Unitaid and the MPP to explore emerging threats in the public health sphere.

▲ *Industry meeting's panel discussion on "Shared Goals of Innovation and Access – Continuing to Build the Bridge"*

▲ *Unitaid's former Chair and Ministers of Health from France and South Africa address the MPP's ministerial breakfast*



The Access to Medicine (ATM) Index issued its biennial report in November 2016, giving high marks to companies that negotiated licences for antiretrovirals and hepatitis C medicines through the Medicines Patent Pool. The report acknowledged that since signing its first licence with an industry partner "[…] the MPP has been the central independent driver of access-oriented licensing in the pharmaceutical industry."

United Nations High-Level Meeting on HIV/AIDS, June

The MPP, Unitaid, UNAIDS and the French and South African governments held a side event on the margins of the United Nations High-Level Meeting on HIV/AIDS in New York on 9 June to discuss the patent pooling model. The ministerial breakfast featured Philippe Douste-Blazy, then Chair of Unitaid, French Minister of Social Affairs and Health Marisol Touraine, South African Minister of Health Aaron Motsoaledi and Luiz Loures, Deputy Executive Director of UNAIDS, as keynote speakers.

A panel presentation moderated by Sigrun Møgedal, Chair of the Medicines Patent Pool Governance Board followed.

Speakers agreed that the MPP model and voluntary licensing could be important enablers of expanding access to key medicines and ensuring sustainable supply in low- and middle-income nations.

▲ *MPP's International AIDS Conference civil society briefing*

International AIDS Conference, July

The Medicines Patent Pool attended the 21st Annual *International AIDS Conference* in Durban, South Africa from 18-22 July. The conference *Access and Equity Rights Now* focused on providing comprehensive services to all people living with HIV. **The MPP's programme included a consultation with civil society and community groups to discuss how best to accelerate access to the new HIV/hepatitis C treatments in low- and middle-income countries**. Senior staff participated in forums on a number of topics, including development and financing of paediatric HIV medicines, the challenge of addressing HIV/viral hepatitis co-infection, and the scale-up of hepatitis C treatments.

International Conference of Drug Regulatory Authorities, November

The MPP team attended the 17th International Conference of Drug Regulatory Authorities (ICDRA) pre-conference on 27-28 November in Cape Town, South Africa. Greg Perry, Executive Director, moderated a workshop session, *Shortages of Medicines: What Regulators Can Do to Help*, to review challenges of securing a sustainable supply of medicines globally.

Perry urged regulators to consider fast-tracking urgently needed new HIV and hepatitis C treatments.

▲ *Greg Perry explains the MPP model at MPP ICDRA booth*

PATENT POOLING IN THE INTERNATIONAL PUBLIC HEALTH DEBATE

The subject of patent pooling mechanisms to improve access to medicines was front and centre in global health debates in 2016. Recognising the crucial importance of scaling up treatment to meet the UN Sustainable Development Goals, **the United Nations General Assembly's Political Declaration on HIV and AIDS** welcomed the "broadening of the scope of the [MPP's] work to promote voluntary partnerships to address hepatitis C and tuberculosis."

The Lancet Commission on Essential Medicines Policies recognised that the MPP model could support the international public health commitment to access to essential medicines. The Lancet Commission, a group of 21 independent experts, noted that "there is great potential for expanding access to […] new essential medicines through licensing of patents through patent pooling."

Other public health leaders have raised the possibility of an MPP-like approach in tackling health crises, such as antimicrobial resistance (AMR), or have proposed patent pooling for oncology compounds. **The 2016 Review on Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations**, chaired by Lord Jim O'Neill, acknowledged the importance of ensuring broad access to future products through licensing approaches.

Ten companies are now licensed to produce daclatasvir, with the MPP adding three new licensees in 2016, Beximco, Sandoz and Zydus Cadila, to manufacture the treatment.

The MPP signed a licence and technology transfer agreement with patent holder Bristol-Myers Squibb (BMS) for the direct-acting antiviral daclatasvir in 2015 and added three new licensees in 2016. The foundation opened negotiations with Egyptian firm Pharco Pharmaceuticals for a licence on ravidasvir, a drug candidate for the genotype-4 chronic hepatitis C virus (HCV).

> ***"As part of our commitment to broadening access to medicines in developing countries, BMS has been proud to work with the Medicines Patent Pool on supporting the distribution of daclatasvir through its voluntary licensing programme.***
>
> **Amadou Diarra,** Head, Global Policy, Advocacy & Government Affairs at BMS

CONTRIBUTING TO INTERNATIONAL STRATEGIES FOR HIV AND VIRAL HEPATITIS C

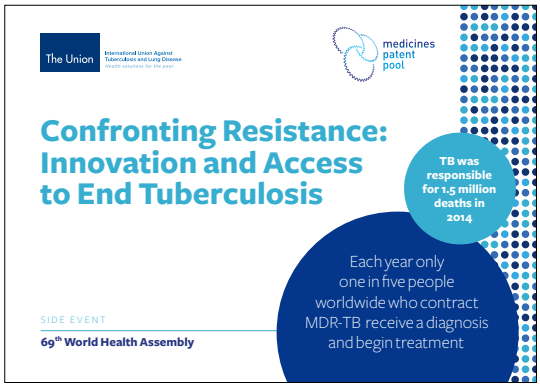
The MPP welcomed the new World Health Organization strategies for HIV and viral hepatitis in spring 2016. The strategies identified voluntary licensing as a path toward increased competition among manufacturers and reduced prices. The WHO issued revised guidelines for combatting hepatitis C in April and its first global report on treatment access in October.

The latter confirmed [that] *"to allow a competitive market, license agreements need to cover a broad territory, be non-exclusive, and include a number of generics-producing companies. They should be made public and ideally be negotiated through the Medicines Patent Pool to ensure transparency, and include pro-competitive, public health-friendly terms and conditions."*

TB Alliance and the MPP signed a Memorandum of Understanding in April outlining a collaboration to encourage the development of new TB regimens.

Under the terms of the agreement, the two organisations will work together on a range of initiatives, including a comprehensive review of promising TB compounds in development and joint programmes to improve access to correctly dosed, properly formulated TB medicines for children. In addition, TB Alliance and the MPP will share patent status, sales data, epidemiological and other information as well as work in consultation with other public health organisations to develop TB drug market forecasts and intelligence.

> ***"With its strong track record in negotiating voluntary licences for HIV treatments, we believe the MPP can contribute significantly toward improving the international response to combatting TB in low- and middle-income countries."***
>
> **Mel Spigelman,** Chief Executive Officer of TB Alliance



World Health Assembly, May

At the World Health Assembly in Geneva in May, the MPP joined the International Union Against Tuberculosis and Lung Disease in co-chairing a panel discussion on combatting growing resistance to TB treatment. The side event, co-organised by Unitaid, the Stop TB Partnership and the governments of France, the United States, Vietnam, the Republic of Korea and Zimbabwe, brought together leading voices in TB to discuss better approaches to developing shorter, more effective regimens. **Participants encouraged new approaches to incentivising industry to develop new tuberculosis interventions**. In the summer of 2016, the MPP opened negotiations with The Johns Hopkins University to license a promising new drug candidate for both drug-susceptible and drug-resistant TB.

THE MPP'S TUBERCULOSIS STEWARDSHIP STUDY

In 2016, the MPP conducted a study to examine how MPP licences could contribute to addressing some of the challenges in ensuring sustainable access to new TB drugs, specifically for multi-resistant TB. The report, based on input from private sector leaders, civil society, community-based organisations, product developers, academics and other experts, sought to inform the foundation's approach to negotiating licences for the manufacturing of TB compounds.

Findings acknowledged that the proper stewardship of new drugs must meet the twin public health goals of ensuring broad availability of new therapies while promoting their proper use to counter further resistance.

Recommendations included:

- Promoting quality standards by continuing to require that licensees comply with Good Manufacturing Practice as well as compliance with all applicable national laws and regulations;
- Retaining flexibility to permit incorporation of new learnings from the evolving field of antimicrobial stewardship;
- Refraining from overly-prescriptive requirements to ensure interest among sublicensees in developing TB compounds;
- Monitoring best practices in marketing and promotion through the MPP's Expression of Interest (EoI) process, requesting potential licensees to submit binding marketing plans in line with the WHO's Ethical Criteria for Medicinal Drug Promotion and with national laws;
- Collaborating closely with the Global Drug Facility (GDF) to ensure that the GDF's stewardship-related safeguards are adapted, as appropriate, for use in MPP licences;
- Working closely with National Treatment Programmes to ensure that licensed TB drugs are available in the private sector.

The report of this study can be downloaded from www.medicinespatentpool.org

Product Development

With its manufacturing partners, the MPP continued to intensify its efforts to expedite the development of generic versions of hepatitis C and HIV medicines in 2016. The MPP worked closely with its industry partners and provided early licences and support such as technical/commercial advice, forecasts, project management and market intelligence to accelerate development of active pharmaceutical ingredients (APIs) and formulations.

The MPP also identified and engaged with new players in 2016, including Beximco and Sandoz, two generic manufacturing partners from Bangladesh and Germany respectively.

In total, the organisation signed 12 new sublicensing agreements in 2016 for three antiretrovirals and one direct-acting antiviral. As of December 2016, the MPP's 15 manufacturing partners were working on more than 100 projects to develop APIs for more than 14 formulations and seven compounds.

Paediatric HIV Treatment Initiative (PHTI)

The Medicines Patent Pool is a key partner in the Paediatric HIV Treatment Initiative (PHTI), established in 2014 by Unitaid, the Drugs for Neglected Diseases *initiative* (DND*i*), the Clinton Health Access Initiative (CHAI) and the MPP to deliver six WHO-priority formulations for children. Although the latest figures from UNAIDS suggest that treatment coverage has risen among children living with HIV (CLHIV) over the past several years, less than half of children in need receive therapy. The dearth of paediatric formulations continues to block progress in HIV treatment access.

The MPP is currently leading two important PHTI projects to improve treatment options for children and their caregivers. In collaboration with its generic partners, the organisation is spearheading the development of the WHO-recommended first-line treatment for children from three to 10 years of age, ABC/3TC/EFV, as well as the development of paediatric raltegravir, a suitable treatment for infants and young children.

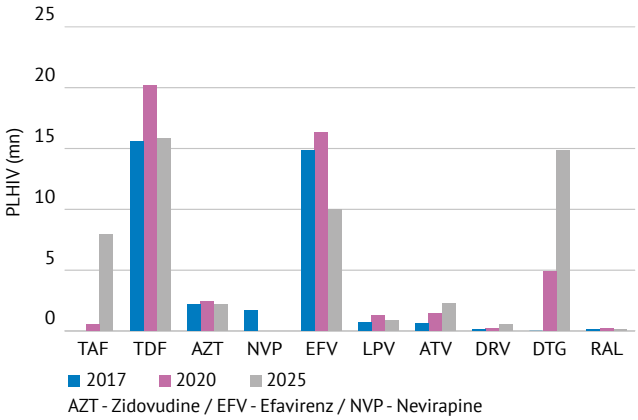
Technical Expertise

Forecasting

The MPP and the World Health Organization jointly prepare forecasts on the use of antiretroviral medicines in low- and middle-income countries. Among other analyses, these forecasts provide broad support to the HIV community and help guide MPP industry partners on access strategies, prioritisation and capacity-building. Forecasts also assist policymakers, procurement agencies, regulatory agencies and other public health stakeholders in planning policies and preparing for market uptake.

Recent forecasts published in PLOS One in 2016 concluded that DTG, licensed to the MPP from ViiV Healthcare, will likely be a major player among antiretroviral treatment regimens through 2025. TAF, licensed to the MPP from Gilead Sciences, will likely witness an increasing market share. Other currently used ARVs are expected to also play a crucial role, and their continued supply will be key to sustaining international scale-up targets. With increased access to viral load testing, substantially more people living with HIV could be using protease inhibitor-containing regimens as second-line treatment by 2025, mainly lopinavir/ritonavir and atazanavir/ritonavir. Both of these treatments are licensed to the MPP for generic manufacture and supply.

Number of People Living With HIV Using Each Antiretroviral



AZT - Zidovudine / EFV - Efavirenz / NVP - Nevirapine

Target Medicines

Over the past several years, the MPP has worked closely with the public health community to update its Antiretroviral Priority List based on recent clinical data and updated patent information. The list has sought to inform the organisation's in-licensing activities, identifying the most appropriate ARVs with the highest probability of improving public health in developing world settings. In 2016, the MPP expanded this process to include intense work on hepatitis C treatments. Among other activities, the team held consultations with civil society and disease experts at the European Association for the Study of the Liver conference in Barcelona and with HIV advocates at the International AIDS Conference in Durban. The final prioritization report will be published in 2017 and will serve as a roadmap for MPP's in-licensing strategies over the coming years.

MedsPaL
THE MEDICINES PATENTS & LICENCES DATABASE

MedsPaL - The Medicines Patents and Licences Database

On 5 October, the Medicines Patent Pool launched MedsPaL, its Medicines Patents and Licences Database, a new resource for information on the intellectual property status of priority medicines in developing countries. Introduced at the World Intellectual Property Organization (WIPO) General Assemblies, MedsPaL replaced MPP's HIV patent status database and includes patent and licensing data on HIV, hepatitis C and tuberculosis treatments covering more than 4,000 national patent applications in more than 100 low- and middle-income countries.

MedsPaL has searchable information on 35 patented medicines and more than 100 formulations for the treatment of HIV, hepatitis C and tuberculosis included in WHO guidelines or in its Essential Medicines List. The database also includes data on more than 30 licences to enable competitive manufacturing or supply of these medicines in low- and middle-income countries and on data exclusivity for 11 countries.

To support the MedsPaL initiative, the MPP signed collaborative agreements with the European Patent Office (EPO), Chile's National Institute of Industrial Property (INAPI), and the Dominican Republic's National Office of Industrial Property (ONAPI), and will be pursuing further arrangements with other patent offices in order to receive data on a regular basis for inclusion in the database.

▲ *Maximiliano Santa Cruz, the Executive Director of INAPI and Greg Perry, the Executive Director of the MPP sign a new cooperative agreement to share patent and licensing information*

▲ *From left: Pascale Boulet, MPP consultant, Esteban Burrone, MPP Head of Policy, Maximiliano Santa Cruz and Greg Perry at the WIPO General Assembly side event for the launch of MedsPaL.*

Photo: Thiru Balasubramaniam, KEI

LAUNCH OF MEDSPAL, OCTOBER

MPP, Unitaid and INAPI hosted a side event during the WIPO General Assembly to launch the MedsPaL database. The WIPO event featured an introduction from Maximiliano Santa Cruz and presentations from the MPP Executive Director and MPP staff. Wilbert Bannenberg, IDA Foundation; Peter Beyer, WHO; Rajesh Dixit, Office of the Controller General of Patents, Designs and Trademarks of India; Alejandro Roca Campañá, WIPO; Karin Timmermans, Unitaid; and Alessia Volpe, EPO, all served as panelists. The event underscored the importance of enhancing transparency of the intellectual property status of treatments for diseases that disproportionately affect developing countries.

> ***Access to comprehensive, updated patent information is essential for supplying customers worldwide and particularly those in middle-income countries. IDA Foundation has long relied on the Medicines Patent Pool for data related to HIV drugs. We welcome the launch of MedsPaL and the inclusion of hepatitis C and tuberculosis medicines in this new database.***
>
> **Edwin de Voogd,** Chief Executive Officer of the IDA Foundation, a leading not-for-profit supplier of essential, quality-assured medicines and medical supplies to low- and middle-income countries.

MEDICINES PATENT POOL FOUNDATION, GENEVA

FINANCIAL STATEMENTS

for the year ended December 31, 2016
and Report of the Statutory Auditor

Deloitte.

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Report of the Statutory Auditor

To the Board of the Foundation of
Medicines Patent Pool Foundation, Geneva

Report of the Statutory Auditor on the Financial Statements

As statutory auditor, we have audited the accompanying financial statements of Medicines Patent Pool Foundation, which comprise the balance sheet as at December 31, 2016, the statement of operations, the statement of changes in capital, the statement of cash flow and notes (pages 23 to 31) for the year then ended.

Board of the Foundation's Responsibility
The Board of the Foundation is responsible for the preparation of these financial statements in accordance with the requirements of Swiss GAAP FER (core FER), Swiss law and the Foundation's statutes. This responsibility includes designing, implementing and maintaining an internal control system relevant to the preparation of financial statements that are free from material misstatement, whether due to fraud or error. The Board of the Foundation is further responsible for selecting and applying appropriate accounting policies and making accounting estimates that are reasonable in the circumstances.

Auditor's Responsibility
Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with Swiss law and Swiss Auditing Standards. Those standards require that we plan and perform the audit to obtain reasonable assurance whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers the internal control system relevant to the entity's preparation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control system. An audit also includes evaluating the appropriateness of the accounting policies used and the reasonableness of accounting estimates made, as well as evaluating the overall presentation of the financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion
In our opinion, the financial statements for the year ended December 31, 2016 give a true and fair view of the financial position and the results of operations in accordance with Swiss GAAP FER (core FER) and comply with Swiss law and the Foundation's statutes.

Deloitte.

Medicines Patent Pool Foundation
Report of the statutory auditor
for the year ended
December 31, 2016

Other Matter
The financial statements of the Foundation for the year ended December 31, 2015 were audited by another auditor whose report, dated April 4, 2016, expressed an unqualified opinion on those financial statements.

Report on Other Legal Requirements

We confirm that we meet the legal requirements on licensing according to the Auditor Oversight Act (AOA) and independence (article 83b Civil Code (CC) in connection with article 728 Code of Obligations (CO)) and that there are no circumstances incompatible with our independence.

In accordance with article 728a para. 1 item 3 CO and Swiss Auditing Standard 890, we confirm that an internal control system exists, which has been designed for the preparation of financial statements according to the instructions of the Board of the Foundation.

We recommend that the financial statements submitted to you be approved.

Deloitte SA

Jürg Gehring
Licensed Audit Expert
Auditor in Charge

Aurore De San Nicolas

Geneva, March 16, 2017

Enclosures
- Financial statements (balance sheet, statement of operations, statement of changes in capital, statement of cash flow and notes)

MEDICINES PATENT POOL FOUNDATION, GENEVA

Balance Sheet as of December 31st, 2016

(with December 31st, 2015 comparative figures)

(Expressed in Swiss francs)	NOTES	2016	2015
Assets			
CURRENT ASSETS			
Cash and bank		**3'025'390**	1'377'460
Other receivables		**44'214**	19'909
Prepaid expenses		**104'533**	26'720
Total current assets		**3'174'137**	**1'424'089**
NON-CURRENT ASSETS			
Long term receivables		**100'448**	40'285
Tangible fixed assets (net)	3e / 4 / 5	**78'582**	77'030
Total non-current assets		**179'030**	**117'315**
Total ASSETS		**3'353'167**	**1'541'404**
Liabilities, funds and capital			
LIABILITIES			
Current liabilities			
Accounts payable		**361'780**	376'271
Salaries and social charges	3g	**68'664**	91'098
Other liabilities		**35'173**	57'302
Accrued liabilities	3f	**94'155**	39'000
Total current liabilities		**559'772**	**563'671**
Total liabilities		**559'772**	**563'671**
RESTRICTED FUNDS			
Restricted Fund	3c	**2'743'395**	927'733
Total restricted funds		**2'743'395**	**927'733**
CAPITAL			
Paid-in capital		**50'000**	50'000
Total Capital		**50'000**	**50'000**
Total LIABILITIES, FUNDS AND CAPITAL		**3'353'167**	**1'541'404**

MEDICINES PATENT POOL FOUNDATION, GENEVA

Statement of operations

for the period from January 1st to December 31st, 2016

(with December 31st, 2015 comparative figures)

(Expressed in Swiss francs)	NOTES	2016	2015
Income			
CURRENT ASSETS			
Donations			
Donations	3c	**6'375'433**	4'072'874
Total donations		**6'375'433**	**4'072'874**
OTHER INCOME			
Other income		**8'624**	14'332
Total other incomes		**8'624**	**14'332**
Total INCOME		**6'384'057**	**4'087'206**
Expenses			
PERSONNEL COSTS			
Personnel costs and social charges		**2'672'840**	2'653'523
Other personnel costs		**133'609**	82'144
Total personnel costs		**2'806'449**	**2'735'667**
ADMINISTRATIVE EXPENDITURE			
Professional fees		**623'930**	830'941
Rent		**236'980**	212'060
Other taxes (VAT)		**35'173**	57'302
General and administrative expenses		**252'783**	274'854
IT services and maintenance		**114'283**	96'089
Marketing and Advertising		**28'925**	57'106
Travel and representation costs		**432'264**	443'192
Depreciation of tangible assets		**27'865**	39'026
Total administrative expenditure		**1'752'203**	**2'010'570**
Non-Operating Expenses		-	(5'575)
Operating surplus/(deficit)		**1'825'405**	(664'606)
Net financial gain/(loss)	6	**(9'743)**	(7'260)
Net surplus/(deficit) for the year prior to allocations		**1'815'662**	**(671'866)**
(Allocation to)/use from restricted capital funds		**(1'815'662)**	671'866
Total (allocation)/use restricted capital funds		**-1'815'662**	**671'866**
Net surplus/deficit for the year after allocations		-	-

MEDICINES PATENT POOL FOUNDATION, GENEVA

Statement of operations

for the period from January 1st to December 31st, 2016

(with December 31st, 2015 comparative figures)

(Expressed in Swiss francs)	**2016**	2015
Cash flows from operating activities		
Net surplus / (deficit)	**1'815'662**	(671'866)
Depreciation and amortization	**27'865**	39'026
(Increase) decrease of other account receivable	**(24'306)**	3'981
Increase of prepaid expenses	**(77'812)**	(5'214)
Increase (decrease) of account payable from purchase of goods and services	**(14'491)**	167'608
Decrease of other accounts payable	**(44'563)**	(28'473)
Increase (decrease) of accrued expenses	**55'156**	(24'593)
Net cash provided by operating activities	**1'737'510**	**(519'531)**
Cash flow from investing activities		
Increase of long-term receivables	**(60'163)**	(980)
Increase of tangible fixed assets	**(29'417)**	(13'608)
Net cash used in investing activities	**(89'580)**	**(14'588)**
Cash flow from financing activites	**-**	-
Net cash from financing activities	**-**	-
NET CHANGE IN CASH	**1'647'930**	**(534'119)**
Cash and cash equivalents		
At the beginning of the fiscal year	**1'377'460**	1'911'579
At the end of the fiscal year	**3'025'390**	1'377'460
NET CHANGE IN CASH	**1'647'930**	**(534'119)**

MEDICINES PATENT POOL FOUNDATION, GENEVA

Statement of changes in Capital

for the period ending December 31st, 2016

(Expressed in Swiss francs)	Beginning of the period 01.01.2016	Allocation of the funds	Use of the Funds	Revaluation	End of the period 31.12.2016
Restricted funds Unitaid	927'733	6'184'057	(4'568'395)	-	2'543'395
Restricted funds Swiss Agency for Cooperation and Development	-	200'000			200'000

	Beginning of the period 01.01.2016	External withdrawal	Internal fund transfers	Allocation to capital	End of the period 31.12.2016
Internally generated funds					
Paid-in capital	50'000	-	-	-	50'000
Internally generated unrestricted capital					
Surplus/(deficit) for the year	-	-	-		
Capital of the organisation	**50'000**	**-**	**-**		**50'000**
Total restricted funds and internally generated funds	**977'733**	**6'384'057**	**(4'568'395)**	**-**	**2'793'395**

MEDICINES PATENT POOL FOUNDATION, GENEVA

Statement of changes in Capital

for the period ending December 31st, 2015

(Expressed in Swiss francs)	Beginning of the period 01.01.2015	Allocation of the funds	Use of the Funds	Revaluation	End of the period 31.12.2015
Restricted funds Unitaid	1'599'600	4'087'206	(4'759'073)	-	927'733

	Beginning of the period 01.01.2015	External withdrawal	Internal fund transfers	Allocation to capital	End of the period 31.12.2015
Internally generated funds					
Paid-in capital	50'000	-	-	-	50'000
Internally generated unrestricted capital		-	-	-	
Surplus/(deficit) for the year	-	-	-	-	-
Capital of the organisation	50'000	-	-	-	50'000
Total restricted funds and internally generated funds	**1'649'600**	**4'087'206**	**(4'759'073)**	**-**	**977'733**

MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements

as of December 31st, 2016

(with December 31st, 2015 comparative figures)

Appendix 1: Presentation

The financial statements are in compliance with Swiss GAAP FER 21 and the Swiss Law.

The Balance Sheet positions are valued at historical cost of acquisition.

The financial statements are based on the assumptions that the going concern is possible for the foreseeable future. They comply with the criterias of reliability and true and fair view.

Appendix 2: Accounting principles and allowed valuation principles for assets and liabilities

Translation of operations in foreign currency

Transactions in currencies other than Swiss francs are converted as follows:

– Assets and liabilities: Closing rates

– Incomes and expenses: Average monthly rates.

Appendix 3: Accounting principles and allowed valuation principles for assets and liabilities

a - Statement of compliance - The MPP financial statement includes:

– The balance sheet;
– The statement of operations;
– The cash flow statement;
– The statement of changes in capital 2015;
– The statement of changes in capital 2016.

The financial statements present all activities of the Foundation.

Accounting basis - the financial statements of the Foundation have been prepared in accordance with the provisions of the Swiss Code of Obligations and in accordance with Swiss GAAP FER (core FER), in particular Swiss GAAP FER 21 "Accounting for charitable non-profit organisations".

The recommendations have been established for entities seeking to present their financial statements to reflect a true and fair view of the financial situation.

All amounts are rounded to the nearest Swiss Franc with the consequence that the rounded amounts may not add to the rounded total in all cases.

b - Principle of recognition revenue

Revenue is recognised in the financial statements as it becomes earned and not when cash or cash equivalents are received.

For multi-year contracts, the revenue is allocated over the contract period based on the donor-approved annual budget.

c - Unitaid

The Medicines Patent Pool Foundation ("the MPP") was established as an independent legal entity on 16 July 2010 with the support of Unitaid, which remains the MPP's main donor.

Unitaid and the MPP have maintained a close working relationship since the MPP was established as an independent entity.

Per the MPP's statutes the majority of the MPP's third party funding (excluding royalty payments, if any) shall come from sources of public and/or non-profit nature.

d - Swiss Agency for Cooperation and Development

A grant agreement was signed in December 2016 with the Swiss Agency for Development and Cooperation SDC / Federal Department of Foreign Affairs FDFA.

This grant of 200'000 CHF (received in 2016) aims to finance a feasibility study of MPP's business model expansion to the Essential Medicines List set by the World Health Organization.

e - Fixed assets

The tangible fixed assets are valued at historical cost of acquisition, less the accumulated depreciation. The depreciation is recognised on the straight-line method over the useful life, as follows:

Category of fixed assets	*Useful life (years)*
Office equipment	8 years
IT infrastructure	3 years
Leasehold improvement	5 years

f - Accrued liabilities

This position includes the charges related to the current exercise that will be paid the following exercise.

g - Pension Fund

As of December 31, 2016, the Company has a liability due to the pension fund amounting of CHF 3'330 (2015: CHF 66'269).

h - Taxes

The Foundation is not subject to taxes.

MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements
as of December 31st, 2016

Appendix 4: Fixed assets

(Expressed in Swiss francs)	Office Equipment	IT Infrastructure	Leasehold Improvement	Total
Net carrying amount 01.01.2016				**77'031**
Accumulated gross values of cost				
Beginning of the period 01.01.2016	114'173	114'943	0	**229'116**
Additions	0	21'663	7'754	**29'417**
Change in the actual values	0	0	0	**0**
Disposals (stolen assets)	0	0	0	**0**
Reclassifications	0	6'502	0	**6'502**
End of the period 31.12.2016	114'173	143'108	7'754	**265'035**
Accumulated depreciation				
Beginning of the period 01.01.2016	-57'213	-94'873	0	**-152'085**
Systematic depreciation	-14'272	-13'594	0	**-27'865**
Impairment		0	0	**0**
Disposals (stolen assets)		0	0	**0**
Reclassifications		-6'502	0	**0**
End of the period 31.12.2016	-71'485	-114'969	0	**-186'453**
Net carrying amounts 31.12.2016	**42'688**	**28'139**	**7'754**	**78'582**

MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements
as of December 31st, 2015

Appendix 5: Fixed assets

(Expressed in Swiss francs)	Office Equipment	IT Infrastructure	Total
Net carrying amount 01.01.2015			**102'449**
Accumulated gross values of cost			
Beginning of the period 01.01.2015	109'746	112'998	**222'744**
Additions	4'427	9'181	**13'608**
Change in the actual values	0	0	**0**
Disposals (stolen assets)	0	-7'236	**-7'236**
Reclassifications	0	0	**0**
End of the period 31.12.2015	114'173	114'943	**229'116**
Accumulated depreciation			
Beginning of the period 01.01.2015	-43'495	-76'801	**-120'295**
Systematic depreciation	-13'718	-25'308	**-39'026**
Impairment	0	0	**0**
Disposals (stolen assets)	0	7'236	**7'236**
Reclassifications	0	0	**0**
End of the period 31.12.2015	-57'213	-94'873	**-152'086**
Net carrying amounts 31.12.2015	**56'960**	**20'070**	**77'030**

MEDICINES PATENT POOL FOUNDATION, GENEVA

Notes to the financial statements

as of December 31st, 2016

(with December 31st, 2015 comparative figures)

Appendix 6: Net financial result

The financial income and costs are the following:

(Expressed in Swiss francs)	**2016**	2015
Exchange gain/(loss), net	(4'238)	(2'665)
Bank interest income	4	552
Others, net	(5'509)	(5'147)
TOTAL	**(9'743)**	**(7'260)**

Appendix 7: Pro-Bono Agreements

The MPP received significant pro bono legal services from a number of law firms.

The valuation of such donated services for the period from January 1, 2016 to December 31, 2016 amounts to CHF 61'338 (CHF 268'740 in 2015). This figure represents the actual market value of pro bono legal services received.

Appendix 8: Other disclosures

Remuneration of the Governing Bodies of the Foundation and management

The members of the Governing Bodies of the Foundation - the Governance Board and the Expert Advisory Group do not receive any remuneration in respect of their activities within the Foundation.

The management of the Foundation is handled by one person. As permitted by Swiss GAAP FER 21.45, the disclosure of the compensation has been waived.

Date of approval of the Foundation's accounts

The Foundation council has validated the financial statement 2015 on May 19, 2016.

Appendix 9: Number of employees

The Foundation had an average of about 15 employees in 2016 (15 employees - 2015).

Appendix 10: Liabilities from leasing contracts

(Expressed in Swiss francs)	**2016**	2015
Liabilities from leasing agreement up to one year	279'749	170'541
Liabilities from leasing agreement from one year to five years	1'045'869	396'691

Appendix 11: Subsequent events

No subsequent event appeared after the preparation of the 2016 financial statements.

Acronyms

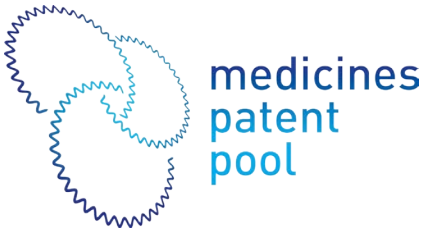
AIDS	acquired immune deficiency syndrome
API(s)	active pharmaceutical ingredient(s)
AMR	antimicrobial resistance
ARV(s)	antiretroviral(s)
DAA(s)	direct-acting antiviral(s)
EPO	European Patent Office
FDC(s)	fixed-dose combination(s)
HCV	hepatitis C virus
HIV	human immunodeficiency virus
INAPI	National Institute of Industrial Property of Chile
MPP	Medicines Patent Pool
MedsPaL	Medicines Patents and Licences Database
ONAPI	National Office of Industrial Property (Dominican Republic)
PHTI	Paediatric HIV Treatment Initiative
TB	Tuberculosis
WHO	World Health Organization
WIPO	World Intellectual Property Organization

For a list of medicines licensed to the MPP, see page 6

Graphic design: BRIEF

Photo credits: Zellweger/Unitaid; Shutterstock; DR.

The Medicines Patent Pool was founded and remains funded by Unitaid



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