medicines patent pool

BUILDING PARTNERSHIPS ACCELERATING ACCESS

ANNUAL REPORT 2013

CONTENTS

ACRONYMS

AIDS Acquired Immune Deficiency Syndrome

ARV Antiretroviral

FDC Fixed-dose combination

EOI Expression of Interest

HIV Human Immunodeficiency Virus

MPP Medicines Patent Pool

NIH United States National Institutes of Health

PLHIV People living with HIV

TRIPS Trade-Related Aspects of Intellectual Property Rights Agreement

UNAIDS Joint United Nations Programme on HIV/AIDS

UNICEF United Nations Children's Fund

US FDA United States Food and Drug Administration

WHO World Health Organization

WIPO World Intellectual Property Organization

WTO World Trade Organization

For a list of ARV names, see page 17.

LETTER FROM THE EXECUTIVE DIRECTOR

DURING MY FIRST YEAR AT THE MEDICINES PATENT POOL (MPP),

I have been pleased to work closely with all of our key stakeholders to move forward our collective mission of expanding access to new HIV medicines.

Twenty thirteen was an extraordinary year for the organisation. The MPP solidified its strong ties with people living with HIV, treatment providers, governments, international organisations and, importantly, originator and generic pharmaceutical companies. We signed three key agreements with multinational companies to ensure innovative and affordable HIV medicines reach those most in need in countries hardest hit by the epidemic. These new agreements build on our long-term discussions with civil society on the best approaches and priority medicines necessary for their constituencies.

In 2013, we also noted the progress of our earlier agreements. International organisations and governments are reaping the benefit of price cuts on key first-line combinations such as generic tenofovir disoproxil fumarate now available in many more countries than was the case just three short years ago. The MPP has forged sub-licences with six generic manufacturers and is currently managing 26 projects. Post-licensing work is crucial to our mandate. We continue to work closely with our sub-licensees to ensure the manufacture and registration of quality generic products.

There is much more work to be done this year and next to meet the rising demand for HIV medicines. The MPP continues negotiations with ViiV Healthcare on the crucial new ARV, dolutegravir, with Gilead on investigational drug, tenofovir alafenamide fumarate, and with AbbVie on paediatric formulations incorporating lopinavir and ritonavir. We continue to build on our work with ViiV Healthcare and with our founder UNITAID to ensure the development of fixed-dose combinations suitable for hundreds of thousands of young children living with HIV.

Our business model is providing an impact across countries that require the right HIV treatments at the right price. I look forward to the challenges ahead and am confident that with our strong ties with the major players in the HIV arena, the MPP can and will make a valuable contribution.

Greg Perry
Executive Director, MPP

LETTER FROM THE CHAIR OF THE GOVERNANCE BOARD

TWENTY THIRTEEN WAS A PIVOTAL YEAR for the Medicines Patent Pool. Under the leadership of its new Executive Director, Greg Perry, the MPP made strong headway in signing new agreements, strengthening its relationships with partners and in bringing key patent holders to the negotiating table.

The organisation kicked off the year in February by forging a strong collaboration with ViiV Healthcare (a joint venture among GlaxoSmithKline, Pfizer and Shionogi). The new MPP-ViiV licence increases access to a key paediatric HIV medicine, abacavir, in the 118 countries that are home to 99% of children living with HIV in the developing world. This agreement is crucial for meeting the needs of children under the age of 10 and set the bar for future licences with multinational companies. In August 2013, the MPP signed its first "hybrid" agreement with F. Hoffmann La-Roche securing an up to 90% price cut on valganciclovir, an important easy-to-take oral medicine to treat cytomegalovirus, an infection that can lead to blindness in people with compromised immune systems as a result of HIV infection.

In its agreement for a WHO preferred second-line therapy, the MPP's deal with Bristol-Myers Squibb for atazanavir at year's end covers 110 countries and includes provisions that may allow many more to benefit.

Six generic manufacturers—Aurobindo Pharma, Shasun Pharma Solutions, Laurus Labs, Hetero Labs, Emcure and Shilpa Medicare—have now licensed from the MPP as a first step in the global effort to scale-up treatment in low- and middle-income countries.

This was also a year when the MPP began negotiations with AbbVie on paediatric treatments, and with ViiV Healthcare and Gilead on dolutegravir and tenofovir alafenamide fumarate, respectively. To date, the organisation holds licensing agreements for almost half of the priority ARVs identified on the basis of WHO guidelines, patent status and information on clinical trials.

The MPP's reputation for high quality analytical work has been enhanced by the expanded coverage of its patent database that now includes information on 25 ARVs in 83 countries. In addition, its annual updating of the publication 'Priority Antiretrovirals for the Medicines Patent Pool' has become an essential sourcebook both for its own strategy and for others interested in expanding access to HIV medicines.

We have every confidence that this year will see further success, and that its licensing activities will be demonstrated to be having a real impact in improving access to antiretrovirals needed by adults and children. The MPP has turned a corner, growing from a fledgling organisation in 2010 to a valued part of the international mechanisms for improving access to medicines in 2014. As Chair of the Governance Board, I congratulate the MPP team and their stakeholders' efforts to ensure continued success in improving the lives of so many living with HIV.

Charles Clift
Chair of the Governance Board, MPP

LETTER FROM THE CHAIR OF THE EXECUTIVE BOARD AT UNITAID

AS CHAIR OF UNITAID, I WAS THRILLED TO SEE THE MEDICINES PATENT POOL'S PROGRESS in 2013 to help meet our objective of expanding access to priority HIV medicines for adults and children living with HIV. UNITAID and MPP's work is historic and is ushering in a new era in global public health policy.

To be successful, we need the participation of a wide range of stakeholders—not only governments and civil society but the pharmaceutical industry as well.

When UNITAID, an innovative financing and purchasing organisation, launched the MPP in 2010, the concept of voluntary licensing and patent pooling for HIV medicines was an untested and novel approach. Twenty thirteen, however, clearly demonstrated that the MPP business model is working. The geographical scope of all three agreements signed last year was unprecedented and went beyond the norm of past bilateral originator to generic agreements. The MPP focused on those medicines that are the most important in improving and prolonging life and for which patent pooling can help speed widespread rollout. Moreover, the quality of transparent, flexible and far-reaching licences will go a long way in sparking generic competition and in lowering prices for ARVs in the developing world. Although these may be small steps today, they could represent significant leaps for humanity tomorrow.

As MPP's founder, we look forward to a continued close collaboration, especially as the MPP solidifies its role as a "dealmaker" for licences on new HIV technologies and paediatric fixed-dose combinations. Last year's MPP-Bristol-Myers Squibb licence on atazanavir strongly complements UNITAID's work to reach more and more countries with second-line treatment options, for example.

Building on UNITAID and MPP's goal of improving HIV paediatric care, this year we expect to band together with other organisations to raise as a public health priority the development of appropriate HIV medicines for children. While the international community has made significant strides in scaling-up programmes for adults, only 647,000 children receive antiretroviral therapy, approximately a quarter of those in need of treatment.

I would like to express my gratitude to all who have agreed to join us in tackling these challenges. Working with UNITAID, we believe that the MPP can make a significant difference in the global fight against HIV. We are proud of MPP's accomplishments to date and to the promise of continued achievement in future years.

Philippe Douste-Blazy
Chair of the Executive Board at UNITAID and UN Under-Secretary General for Innovative Financing for Development

HOW WE **WORK**

1 PRIORITISE **HIV MEDICINES**

based on analysis of medical needs and existing patents

2 INVITE RELEVANT **PATENT HOLDERS**

to negotiate licences allowing others to develop adapted formulations or sell generic versions of patented medicines in developing countries

3 NEGOTIATE PUBLIC HEALTH-ORIENTED **LICENCES**

with the goal of increasing access to medicines for people living with HIV in developing countries

4 SIGN **AGREEMENTS**

for licences

5 SUB-LICENSE TO **GENERICS**

and other HIV medicines manufacturers to develop, produce and sell medicines in agreed-upon countries under strict quality assurance. MPP staff work with sub-licensees on product development and regulatory approval

6 BRING DOWN PRICES TO **INCREASE ACCESS**

Once manufacture has begun, robust competition ensures lower prices and increases supply of available medicines. Patent holders may receive a small royalty on medicines sales and people living with HIV can access the appropriate treatment they need at affordable prices

THE PATH OF PROGRESS

2010

JULY 16
The MPP was established with the support of UNITAID.

SEPTEMBER 30
The US National Institutes of Health (NIH) becomes the first patent holder to share its intellectual property with MPP.

DECEMBER 1
On the occasion of World AIDS Day, MPP invites patent holders to join its efforts.

2011

APRIL 4
MPP launches patent status database resource.

JULY 11
MPP signs its first agreement with a pharmaceutical company, Gilead Sciences, to increase access to HIV and Hepatitis B treatment in developing countries.

2012

JANUARY 5
Generic manufacturer Emcure licenses from the MPP.

JULY 19
Hetero Labs joins the patent pool as a sub-licensee.

SEPTEMBER 26
Laurus Labs, a manufacturer of active pharmaceutical ingredients, becomes the fourth generic manufacturer to sign an MPP licence.

OCTOBER 17
Licensing Executives Society awards MPP and partners its annual "Deals of Distinction" award.

OCTOBER 7
Aurobindo Pharma, a key producer of generic medicines, signs agreement to manufacture several ARVs.

2013

JANUARY 7
MPP appoints Greg Perry as its new Executive Director.

FEBRUARY 13
MPP and ViiV Healthcare announce broad collaboration and a licence agreement on abacavir.

FEBRUARY-JUNE
MPP signs sub-licences with Shasun Pharma Solutions, Aurobindo Pharma and Shipla Medicare.

AUGUST 5
MPP and F. Hoffmann-La Roche sign agreement on key HIV medicine valganciclovir.

DECEMBER 4
MPP begins negotiations with AbbVie on paediatric medicines.

DECEMBER 11
MPP and Bristol-Myers Squibb sign licensing agreement for atazanavir.

medicines patent pool

THE MEDICINES PATENT POOL (MPP) is a United Nations-backed organisation that aims to improve access to appropriate, affordable HIV medicines and technologies for people living with HIV in developing countries. Working in partnership with a range of stakeholders, the MPP opens the door to generic low-cost production of key HIV therapies as well as fixed-dose combinations and paediatric formulations by creating a pool of relevant patents for sub-licensing and product development.

IN 2013, THE MPP:

SIGNED TWO ARV LICENSING AGREEMENTS
with multinational companies, ViiV Healthcare and Bristol-Myers Squibb for WHO recommended paediatric antiretroviral abacavir (ABC) and preferred second-line treatment atazanavir (ATV).

FORGED ITS FIRST "HYBRID" AGREEMENT
with F. Hoffmann-La Roche to improve access to valganciclovir for people living with HIV in 138 developing countries. The deal's up to 90% cut in the price of the drug will help significantly expand treatment for cytomegalovirus (CMV), an infection that can lead to blindness in people with compromised immune systems. The parties agreed to enter into licensing negotiations in July 2014.

ENTERED INTO NEGOTIATIONS
with AbbVie on paediatric formulations incorporating lopinavir/ritonavir (LPV/r) and with ViiV Healthcare and Gilead Sciences on dolutegravir (DTG) and tenofovir alafenamide fumarate (TAF), respectively.

BROKERED THREE NEW SUB-LICENCES
with generic manufacturers– Aurobindo Pharma, for the manufacture of generic abacavir signed just months after an agreement with the patent originator, and with Shilpa Medicare and Shasun Pharma Solutions for tenofovir disoproxil fumarate (TDF), emtricitabine (FTC), elvitegravir (EVG) and cobicistat (COBI).

FURTHER DEVELOPED ITS PATENT STATUS DATABASE

a now essential information resource for HIV treatment–to cover 25 ARVs in 83 countries and updated its priority list of target HIV medicines.

STRENGTHENED STRATEGIC COLLABORATIONS

with many international partners such as UNITAID, Drugs for Neglected Diseases *initiative* (DND*i*), UNAIDS and the WHO Prequalification Programme on access to HIV medicines in middle-income countries and country readiness to meet the demand for new HIV medicines.

ENHANCED TIES WITH COMMUNITIES

of people living with HIV through consultations at various regional HIV meetings and other venues.

WORKED WITH SUB-LICENSEES

towards the development of an innovative new fixed-dose combination (FDC) known as the Quad (a combination product of TDF, FTC, COBI and EVG).

WORKING WITH UNITAID

UNITAID helped establish the MPP in July 2010 and remains an important partner. UNITAID is an innovative body led by governments, foundations, civil society, and representatives of communities living with the three diseases. UNITAID focuses on: HIV, tuberculosis and malaria.

Raising money primarily through a small tax on flights in participating countries, UNITAID funds strategic market interventions to increase access to medicines for the three diseases in developing countries. UNITAID is supporting the MPP through a five-year Memorandum of Understanding.

Lab clerk Violet Jombo at Namitambo Health Centre in Malawi, a point-of-care facility supported by UNITAID, MPP's founder. ›

THE NEED FOR THE MPP

IN JUNE 2013, the World Health Organization updated its guidelines for HIV treatment making the MPP's work to increase access to lower-cost, new HIV medicines even more crucial.

The guidelines call for an immediate increase in the number of people needing treatment—from 17 million to 26 million—given WHO's recommendation to start HIV treatment earlier.

MPP licences have focused on the treatment regimens now recommended as preferred treatments by the WHO:

- Regimens containing TDF—licensed in 2011 from Gilead Sciences—are now the preferred first-line treatment for adults and teenagers
- ATV—licensed from Bristol-Myers Squibb—continues to be one of two preferred protease inhibitors recommended for second-line treatment
- ABC—licensed from ViiV Healthcare—is part of the preferred first-line treatments for children up to the age of 10
- Paediatric formulations of LPV/r—currently under negotiation with AbbVie—are recommended as first-line treatment for children under three and second-line for older children

The MPP is also focusing on new, patented ARVs that will likely represent the future of HIV treatment. The emphasis is on ensuring they are widely available at affordable prices through generic licensees and promoting their development as fixed-dose combinations that simplify and improve treatment options for people living with HIV.

LICENSING **AGREEMENTS**

TO DATE, THE MPP HAS SECURED LICENCES for seven priority antiretrovirals: atazanavir (ATV), tenofovir disoproxil fumarate (TDF), emtricitabine (FTC), elvitegravir (EVG), cobicistat (COBI), abacavir (ABC) for paediatric use and darunavir (DRV).

The MPP signed three agreements in 2013 on ABC for paediatric use, valganciclovir for HIV-related cytomegalovirus and for ATV.

VIIV HEALTHCARE AGREEMENT

"ViiV Healthcare is proud to be a partner of the Medicine Patent Pool in seeking to improve access to existing and new ARVs. The abacavir licence agreement we signed in February 2013 was a major milestone in our collaboration with the MPP. We are confident that the MPP will be able to make a significant contribution in providing affordable, high quality abacavir and abacavir-containing products and formulations for children."

– **Dr. Scott Purdon**
Director, Government Affairs and Access, ViiV Healthcare

"The World AIDS Campaign (WAC) and the Pan-African Treatment Access Movement (PATAM) welcome the deal as an exciting development ... The two organisations particularly welcome the deal for its potential impact on the sub-Saharan Africa region which hosts the majority of children living with HIV."

– **WAC and PATAM**
Joint Statement

The Medicines Patent Pool launched a broad collaboration on paediatric HIV medicines with ViiV Healthcare in February 2013 at a crucial time. Although the world has made significant strides to improving universal access to HIV medicines worldwide, only 647,000 children received antiretroviral therapy in 2012, approximately a quarter of those in need.

As part of the collaboration, MPP and ViiV Healthcare signed a licence for a preferred treatment for children, ABC, for use in 118 countries where 98.7% of children living with HIV in the developing world reside. Under the terms of the new partnership, MPP and ViiV will also negotiate further licences that will allow the manufacture of low-cost versions of promising new, better adapted paediatric medicines currently in ViiV Healthcare's pipeline. These could then be sold in the 118 countries once the medicines receive quality and safety approval from drug regulators. ViiV Healthcare and MPP have also agreed to work together on various other fronts, including with other stakeholders, to explore the development of additional paediatric medicines that are easy-to-administer, palatable and appropriate for children.

F. HOFFMANN-LA ROCHE AGREEMENT

"The International Community of Women Living with HIV/AIDS is glad to see this excellent first step by Roche to deal with this badly neglected treatable illness. Since half of the people living with HIV globally are women, and in some countries even more, this could save the sight of many women living with HIV around the world."

– **Jessica Whitbread**
Chair of ICW Global

In August 2013, the MPP announced an agreement with Swiss pharmaceutical company F. Hoffmann-La Roche to increase access to valganciclovir, an important, easy-to-take, oral medicine to treat cytomegalovirus (CMV). CMV is a viral infection that can cause blindness in people living with HIV, and was one of the three unusual infections in the US Centers for Disease Control and Prevention report that marked the official start of the AIDS epidemic in June 1981. CMV continues to affect people living with HIV in low- and middle-income countries. Many are left permanently blind from undiagnosed or inadequately treated CMV.

The MPP/F. Hoffmann-La Roche agreement has a two-phased approach to increase access to valganciclovir—first an up to 90% price reduction that will significantly improve access to Roche's drug for people living with HIV in 138 countries. Then, the MPP and F. Hoffmann-La Roche will also negotiate licensing and technology transfer agreements to further the availability of quality generic versions of valganciclovir.

BRISTOL-MYERS SQUIBB AGREEMENT

In December 2013, the MPP and biopharmaceutical company Bristol-Myers Squibb signed a licensing agreement to increase access to a key HIV medicine, ATV, in 110 countries where 88.5% of people living with HIV in the developing world reside. The agreement also includes provisions to allow many more countries to potentially benefit. Atazanavir is a WHO preferred second-line therapy and a crucial option for the million people estimated to need second-line treatment in the coming two years.

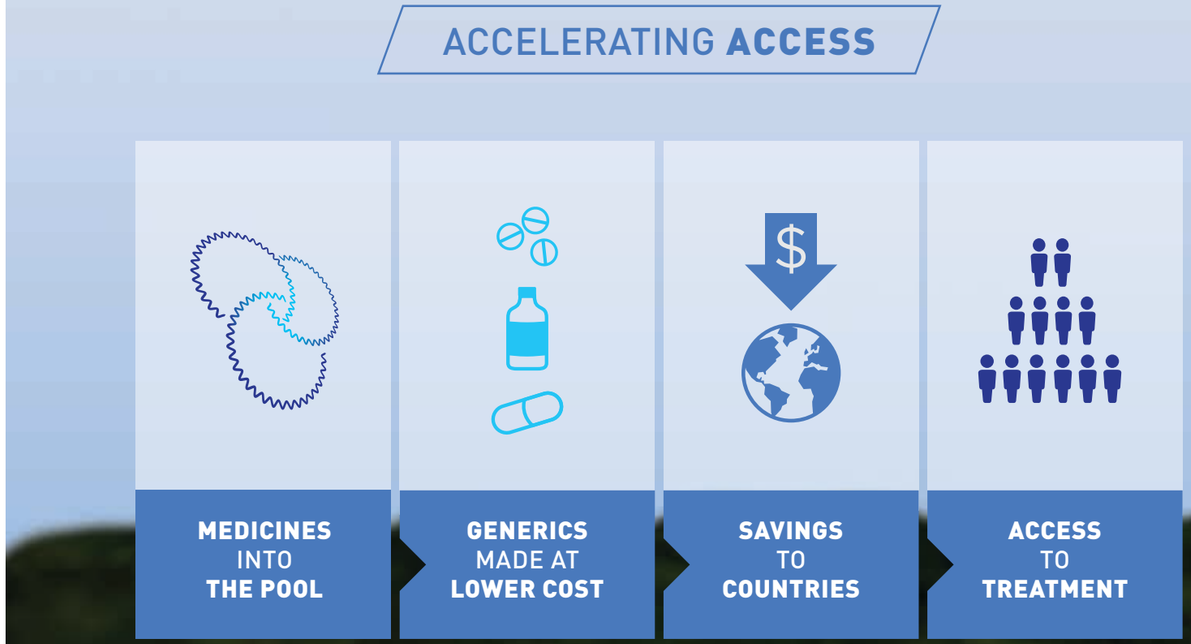
Under the terms of the agreement, a technology transfer package will be provided to sub-licensees to facilitate the manufacture of atazanavir. While royalties are not applicable in the vast majority of the countries and are waived for all paediatric products, any royalties that are collected under this licence agreement will be reinvested in local HIV groups in those countries.

"Second-line treatment is increasingly important as people living with HIV around the world develop resistance to their current regimens. I welcome this move to help ensure urgently needed medicines are more widely available at affordable prices."

– **Dr. Margaret Chan**
Director General, WHO

"This new agreement between the MPP and BMS on ATV is a breakthrough. It will enable generic competition for atazanavir, effectively increasing its availability and affordability for the growing number of people who need second-line treatment."

– **David Deakin**
Chair of the Ecumenical Advocacy Alliance's working group on access to treatment



PARTNERSHIPS **FOR ACCESS**

DEEPENING NEGOTIATIONS WITH OTHER PATENT HOLDERS

"Shareholders consider the MPP to be an important program to help address the access to medicines issues thus facilitating efforts of pharmaceutical companies to meet their moral obligation to the health needs of the world's most vulnerable."

THE INTERFAITH COUNCIL ON CORPORATE RESPONSIBILITY

The MPP's work depends on partnerships with stakeholders in the HIV field and its partnerships with originator companies are critical to its success. MPP has signed agreements with Bristol-Myers Squibb, F. Hoffmann-La Roche, Gilead Sciences, ViiV Healthcare and the US National Institutes of Health.

In December 2013, the MPP began negotiations with AbbVie on its ARVs, LPV/r for paediatric use. LPV/r is a part of the WHO preferred first-line and second-line treatment regimen for children. Talks also continue with ViiV Healthcare on additional paediatric and adult licences for DTG, a recently approved ARV considered a significant advancement in HIV therapy, and with Gilead on investigational drug TAF.

CONSULTING WITH PEOPLE LIVING WITH HIV, CIVIL SOCIETY, GOVERNMENTS AND INTERNATIONAL ORGANISATIONS

MPP spearheaded and participated in a series of key meetings in 2013 to strengthen its engagement with stakeholders. For example, at the International AIDS Society conference in Kuala Lumpur in July, UNITAID, DNDi and the MPP held a satellite meeting, "Closing the Treatment Gap for Children Living with HIV," to focus increased attention on the challenges of developing appropriate paediatric medicines.

In May, the MPP collaborated with UNAIDS, WHO, UNITAID and the Government of Brazil in the organisation of an event aimed at discussing access to HIV medicines in middle-income countries. The MPP also held a joint satellite with WHO at the WHO-UNICEF-UNFPA meeting in Copenhagen, Denmark in September to discuss the implications of increased demand for treatment as result of revised WHO guidelines.

At a World Trade Organization Public Forum in October, an MPP panel debated various ways for addressing deficits in both innovation and access—through non-profit development of medicines for neglected diseases, innovative licensing models such as the MPP and WIPO Re:Search, as well as through various proposals to delink the costs of research and development from the cost of goods sold.

The ICASA conference in Cape Town in December 2013 offered an opportunity for a joint MPP-IAS hosted event to discuss ways to increase access to HIV medicines in low- and middle-income countries. Finally, the MPP continued its close consultation with communities of people living with HIV on the margins of three regional conferences in 2013—ICAAP, REDCA and ICASA—as well as through participation in the Eastern European and Central Asian Community Advisory Board (EECA CAB).

INITIAL **RESULTS**

MPP'S 2011 LICENCE AGREEMENTS with patent holder Gilead have contributed to the prices of TDF dropping by 45-87% over the past two years, and the number of countries eligible for low cost generic competition increasing by more than 30%.

The difference in this price cut is specifically significant for countries that are now able to purchase first-line TDF from generic sources. One example is El Salvador. Before the MPP-Gilead licence, UNICEF secured TDF at a price of US$630 per patient per year. Price drops through the purchase from MPP licensees have allowed El Salvador 's national treatment programme to save approximately $916,000, essentially covering an extra year of treatment for all people currently taking the medicine.

Almost three million people have received TDF-containing formulations through MPP's generic partners.

SUB-LICENSING **AGREEMENTS**

SUB-LICENSING

In 2013, the MPP signed three sub-licences—first with Shilpa Medicare and Gilead Sciences to allow Shilpa to produce five key HIV medicines (TDF, FTC, COBI, EVG and the Quad, an innovative new FDC comprising all four ARVs) for sale in 100-112 countries. Secondly, MPP and Shasun Pharma Solutions forged agreements for the same five products covered under the 2011 Gilead licence.

Just four months after ViiV Healthcare and MPP signed an agreement for ABC, the MPP signed a deal with Aurobindo Pharma for the manufacturing of paediatric ABC to accelerate the distribution of generic ABC-containing medicines to children throughout the developing world. The MPP also facilitated a technology transfer between Gilead and MPP sub-licensees for an improved process of FTC that Gilead has developed to help reduce costs, and with Shasun and Shilpa for the full range of licensed Gilead products. The MPP provides on-going support after the technology transfer by facilitating dialogue between MPP sub-licensees and Gilead, an unprecedented way of doing business that helps speed the manufacturing process of medicines. With the MPP's hands-on approach, generic versions of the Quad could be developed as early as 2015.

TECHNICAL **EXPERTISE**

PATENT DATABASE

Since its launch in April 2011, the MPP Patent Status Database for Selected HIV Medicines (Patent Status Database) has provided a comprehensive review of the patent status of important HIV medicines throughout the developing world. The free-to-use database is the most complete single source of such information in the world, and was compiled with the help of national patent offices and the World Intellectual Property Organization (WIPO). Today it covers 25 ARVs in 83 countries and has become an important resource for international purchasing organisations and national treatment programmes globally.

PRIORITISED MEDICINE

Working closely with the WHO and in consultations with HIV and patent experts, the MPP updates its Antiretroviral Priority List annually based on recent clinical data and updated patent information. The report guides the MPP in its strategy of targeting the most appropriate ARVs with the highest probability of improving public health in developing world settings. The MPP released its updated priority list in December 2013. Its results are listed on the following page.

MEDICINES PATENT POOL PRIORITY ANTIRETROVIRALS

Compound	Clinical Priority	Market/IP Priority
Atazanavir (ATV)*	High	High
Dolutegravir (DTG)**	High	High
Lopinavir (LPV)***	High	High
Ritonavir (RTV or r)***	High	High
Tenofovir Alafenamide Fumarate (TAF)**	High	High
Cobicistat (COBI)*	High	High
Elvitegravir (EVG)*	High	High
Abacavir (ABC) (paediatrics)*	High	Medium
Emtricitabine (FTC)*	High	Medium
Efavirenz (EFV)	High	Medium
Tenofovir Disoproxil Fumarate (TDF)*	High	Medium
Darunavir (DRV)*°	Medium /High	Medium
Nevirapine (NVP)**	Medium /High	Medium
Etravirine (ETV)	Medium	High
Raltegravir (RAL)	Medium	High
Rilpivirine (RPV)	Medium	High

* ARVs already licensed to the MPP.

**ARVs for which the MPP is in negotiations.

***ARVs for which the MPP is in negotiations for paediatric formulations.

° The MPP has concluded a licence agreement for patents related to DRV with the US National Institutes of Health, but additional licences are needed to allow for generic manufacture.

FINANCIAL STATEMENTS

MEDICINES PATENT POOL FOUNDATION, GENEVA

Report of the Statutory Auditors to the Board
on the Financial Statements 2013

Report of the statutory auditor
to the Board of
Medicines Patent Pool Foundation
Geneva

Report of the statutory auditor on the financial statements

As statutory auditor, we have audited the financial statements of Medicines Patent Pool Foundation, which comprise the balance sheet, statement of operations and statement of changes in equity and notes (pages 22 to 29), for the year ended December 31, 2013. As permitted by Swiss GAAP FER 21, the information in the performance report (pages 30 to 31) is not required to be subject to audit.

Board's Responsibility

The Board is responsible for the preparation and fair presentation of the financial statements in accordance with the requirements of Swiss GAAP FER 21, Swiss law and the foundation's deed and internal regulations. This responsibility includes designing, implementing and maintaining an internal control system relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error. The Board 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 and fair presentation 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, 2013 give a true and fair view of the financial position, the results of operations and the cash flows in accordance with Swiss GAAP FER 21 and comply with Swiss law and the foundation's deed and internal regulations.

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 paragraph 3 CC in connection with article 728 CO) and that there are no circumstances incompatible with our independence.

In accordance with article 83b paragraph 3 CC in connection with article 728a paragraph 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 Foundation.

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

PricewaterhouseCoopers AG

Marcel Aeberhard	Reto Tognina
Audit expert Auditor in charge	Audit expert

Zürich, April 2, 2014

Enclosure:

- Financial statements (balance sheet, statement of operations, statement of changes in equity and notes)

PricewaterhouseCoopers AG, Birchstrasse 160, Postfach, 8050 Zürich
Telefon: +41 58 792 44 00, Telefax: +41 58 792 44 10, www.pwc.ch

BALANCE SHEET

AS OF DECEMBER 31ST, 2013
(with December 31st, 2012 comparative figures)

	NOTES	2013 CHF	2012 CHF
ASSETS			
CURRENT ASSETS			
Cash and bank		1'266'311	2'218'032
Prepaid expenses		51'305	29'049
Debtors		0	3'098
Other receivables		2'411	2'670
Total current assets		**1'320'027**	**2'252'849**
NON-CURRENT ASSETS			
Fixed assets			
Tangible fixed assets (net)	3b / 4 / 5	120'093	145'642
Total fixed assets		**120'093**	**145'642**
Other longterm receivables		39'280	0
Total non-current assets		**159'373**	**145'642**
TOTAL ASSETS		**1'479'400**	**2'398'491**
LIABILITIES, FUNDS AND CAPITAL			
LIABILITIES			
Current liabilities			
Creditors		220'529	267'056
Salaries and social charges	3d	159'620	34'001
Accrued liabilities	3c	130'290	102'232
Other liabilities		44'439	35'722
Total current liabilities		**554'878**	**439'010**
Total liabilities		**554'878**	**439'010**
RESTRICTED FUNDS			
Restricted Fund UNITAID	3a	874'522	1'909'481
Total restricted funds		**874'522**	**1'909'481**
CAPITAL			
Paid-in capital	3a	50'000	50'000
Total Capital		**50'000**	**50'000**
TOTAL LIABILITIES, FUNDS AND CAPITAL		**1'479'400**	**2'398'491**

STATEMENT OF OPERATIONS

FOR THE PERIOD FROM JANUARY 1ST, 2013 TO DECEMBER 31ST, 2013
(with December 31st, 2012 comparative figures)

	NOTES	2013 CHF	2012 CHF
INCOME			
DONATIONS			
Donations	3a	3'218'433	5'598'040
Total Donations		**3'218'433**	**5'598'040**
OTHER INCOMES			
Revenue on IP advise		0	3'098
Other incomes		18'075	8'389
Total Other Incomes		**18'075**	**11'487**
TOTAL INCOME		**3'236'508**	**5'609'527**
EXPENSES			
PERSONNEL COSTS			
Personnel costs and social charges		2'366'625	1'689'025
Other personnel costs		40'430	273'333
Total personnel costs		**2'407'055**	**1'962'358**
ADMINISTRATIVE EXPENDITURE			
Professional fees		686'442	896'326
Rent		185'260	194'817
Taxes		44'439	35'722
General and administrative expenses		225'483	214'837
IT services and maintenance		100'203	107'978
Marketing and Advertising		31'166	56'524
Travel and representation costs		531'683	569'476
Depreciation of tangible assets		40'461	25'806
Total administrative expenditure		**1'845'137**	**2'101'486**
Net financial loss	7	-19'275	-22'207
OPERATING (DEFICIT)/SURPLUS		**-1'034'959**	**1'523'476**
Net deficit/surplus for the year prior to allocations		**-1'034'959**	**1'523'476**
Withdrawal/(Allocation to) from restricted capital funds		1'034'959	-1'523'476
Total withdrawal/(allocations)		**1'034'959**	**-1'523'476**
Net surplus/deficit for the year after allocations		**0**	**0**

STATEMENT OF CHANGES IN CAPITAL

FOR THE PERIOD ENDING DECEMBER 31, 2012

2012

RESTRICTED FUNDS UNITAID	Beginning of the period 01.01.2012	Allocation of the funds	Use of the Funds	Revaluation	End of the period 31.12.2012
	386'006	5'609'527	-4'086'052	0	1'909'481

INTERNALLY GENERATED FUNDS	Beginning of the period 01.01.2012	External withdrawal	Internal fund transfers	Allocation to capital	End of the period 31.12.2012
Paid-In-Capital	50'000	0	0	0	50'000
Internally Generated Unrestricted Capital Surplus/(deficit) for the Year	0	0	0		
Capital of the organisation	**50'000**	**0**	**0**	**0**	**50'000**
TOTAL RESTRICTED FUNDS AND INTERNALLY GENERATED FUNDS	**436'006**	**5'609'527**	**-4'086'052**	**0**	**1'959'481**

STATEMENT OF CHANGES IN CAPITAL

FOR THE PERIOD ENDING DECEMBER 31, 2013

2013

RESTRICTED FUNDS UNITAID	Beginning of the period 01.01.2013	Allocation of the funds	Use of the Funds	Revaluation	End of the period 31.12.2013
	1'909'481	3'236'508	-4'271'467	0	874'522

INTERNALLY GENERATED FUNDS	Beginning of the period 01.01.2013	External withdrawal	Internal fund transfers	Allocation to capital	End of the period 31.12.2013
Paid-In-Capital	50'000	0	0	0	50'000
Internally Generated Unrestricted Capital Surplus/(deficit) for the Year	0	0	0	0	0
Capital of the organisation	**50'000**	**0**	**0**	**0**	**50'000**
TOTAL RESTRICTED FUNDS AND INTERNALLY GENERATED FUNDS	**1'959'481**	**3'236'508**	**-4'271'467**	**0**	**924'522**

NOTES TO THE FINANCIAL STATEMENTS

AT 31.12.2013

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 CHF are converted as follows:

Assets and liablities : Closing rates

Incomes and expenses : Average monthly rates.

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

A - 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 sole 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.

B- 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

C- ACCRUED LIABILITIES

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

D- PENSION FUND

As of December 31, 2013, the Company has a liabilitie due to the pension fund amounting of CHF 56'215 (2012 : no debt)

E- TAXES

The Foundation is not subject to taxes.

NOTES TO THE FINANCIAL STATEMENTS

AT 31.12.2012

APPENDIX 4 : Fixed assets

	OFFICE EQUIPMENT	IT INFRASTRUCTURE	TOTAL
NET CARRYING AMOUNT 01.01.2012			**72'522**
ACCUMULATED GROSS VALUES OF COST			
Beginning of the period 01.01.2012	53'158	39'655	92'813
Additions	50'795	51'906	102'701
Change in the actual values	0	0	0
Disposals (stolen assets)	-937	-5'178	-6'116
Reclassifications	0	0	0
End of the period 31.12.2012	**103'016**	**86'382**	**189'399**
ACCUMULATED DEPRECIATION			
Beginning of the period 01.01.2012	-7'060	-13'231	-20'290
Systematic depreciation	-9'964	-15'842	-25'807
Impairment	0	0	0
Disposals (stolen assets)	98	2'243	2'340
Reclassifications	0	0	0
End of the period 31.12.2012	**-16'926**	**-26'830**	**-43'757**
NET CARRYING AMOUNTS 31.12.2012	**86'090**	**59'552**	**145'642**

NOTES TO THE FINANCIAL STATEMENTS

AT 31.12.2013

APPENDIX 5 : Fixed assets

	OFFICE EQUIPMENT	IT INFRASTRUCTURE	TOTAL
NET CARRYING AMOUNT 01.01.2013			**145'642**
ACCUMULATED GROSS VALUES OF COST			
Beginning of the period 01.01.2013	**103'016**	**86'382**	**189'398**
Additions	**3'361**	**16'152**	**19'513**
Change in the actual values	**0**	**0**	**0**
Disposals (stolen and destroyed assets)	**0**	**-6'383**	**-6'383**
Reclassifications	**0**	**0**	**0**
End of the period 31.12.2013	**106'377**	**96'151**	**202'528**
ACCUMULATED DEPRECIATION			
Beginning of the period 01.01.2013	**-16'926**	**-26'830**	**-43'757**
Systematic depreciation	**-13'131**	**-27'330**	**-40'461**
Impairment	**0**	**0**	**0**
Disposals (stolen assets)	**0**	**1'782**	**1'782**
Reclassifications	**0**	**0**	**0**
End of the period 31.12.2013	**-30'057**	**-52'378**	**-82'435**
NET CARRYING AMOUNTS 31.12.2013	**76'320**	**43'773**	**120'093**

NOTES TO THE FINANCIAL STATEMENTS

AT 31.12.2013

APPENDIX 6 : Net financial result

The financial income and costs are the following :

	2013 CHF	2012 CHF
Exchange (loss)/gain, net	-12'711	-18'949
Bank interest income/(loss)	533	1'157
Others, net	-7'097	-4'416
TOTAL	**-19'275**	**-22'207**

APPENDIX 7 : Pro-Bono Agreements

In the collection of patent information, the MPP benefitted from in-kind contributions from a large number of national and regional patent offices.

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

The valuation of such donated services for the period from January 1, 2013 to December 31, 2013 amounts to CHF 55,419 (CHF 32,426 in 2012). This figure is a composite of the actual market value of pro bono legal services received, as well as an estimate of the value of the collection of patent information from national and regional patent offices.

The latter represents a conservative estimate of the value of such data if it had had to obtain it.

APPENDIX 8 : Other disclosures

Remuneration of the Governing Bodies of the Foundation

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.

PERFORMANCE **REPORT**

FOUNDATION

The "Medicines Patent Pool Foundation, Geneva" has been registered at the Commercial Register of Geneva on the 16th of July 2010.

PURPOSE OF THE FOUNDATION

Article 3 of the Statutes states that: The purpose of the Foundation is to improve health by providing patients in low- and middle-income countries with increased access to quality, safe, efficacious, more appropriate and more affordable health products, including through a voluntary patent pool mechanism, as described further in Article 4 below, initially in the area of antiretroviral pharmaceutical products, paediatric antiretroviral products and new fixed dose combinations (hereinafter referred to as the "Patent Pool").

The Foundation has no profit motive.

MEANS OF THE FOUNDATION

The Foundation may pursue all such lawful activities as may be appropriate to attain its purpose. The Foundation shall operate a patent pool through which intellectual property is made available, in order to reduce prices, improve access and facilitate the development and production of quality, safe and efficacious health products for use in low- and middle-income countries, considering the importance of technology transfer mechanisms, capacity building and local manufacturing in developing countries.

ADDRESS OF THE FOUNDATION

Chemin Louis-Dunant 17
CH-1202 Geneva
Switzerland

PHONE : +41 (0) 22 533 5050
E-MAIL : office@medicinespatentpool.org
WEB SITE : www.medicinespatentpool.org

MEMBERS OF THE GOVERNANCE BOARD

CHAIRMAN	ELECTED TERM
Dr. Charles Clift	2010-2015
MEMBERS	
Dr. Sigrun Møgedal	2011-2015
Dr. Bernard Pécoul	2010-2014
Dr. Anban Pillay	2012-2015
Dr. Paulo Teixeira	2010-2014
Ms. Anna Žakowicz	2012-2014

EXPERT ADVISORY GROUP

CHAIR	
Mr. Maximilliano Santa Cruz	2011-2014
MEMBERS	
Mr. Labeeb Abboud	2011-2014
Mr. Jonathan Berger	2011-2014
Dr. Alexandra Calmy	2011-2014
Dr. Shing Chang	2011-2016
Mr. Carlos Correa	2011-2016
Mr. Nelson Juma Otwoma	2011-2016
Ms. Eun-Joo Min	2011-2014
Ms. Lita Nelsen	2011-2014
Mr. Achal Prabhala	2011-2014
Ms. Gracia Violeta Ross Quiroga	2012-2015
Mr. Wim Vandevelde	2012-2015

MANAGEMENT

Mr. Greg Perry	Executive Director
Ms. Shamsa Abdulrasak	Executive Assistant
Mr. Esteban Burrone	Head of Policy
Ms. Erika Dueñas	Advocacy Officer
Ms. Aastha Gupta	Business Development Manager
Ms. Robyn Harshaw	Strategy and Operations Manager
Mr. José Imbernón	Finance and Resources Manager
Mr. Sandeep Juneja	Business Development Director
Ms. Kaitlin Mara	Communications Manager
Mr. Chan Park	General Counsel
Ms. Esperanza Suárez	Finance and Administration Officer
Ms. Maica Trabanco	Legal Officer
Mr. Richard Warren	Communications Officer

TRAINEES

Ms. Noreen Lala	Business Development Intern
Ms. Elizabeth Plumb	Operations Intern
Ms. Claire Willmington	Policy Intern

ACCOUNTING SERVICES PROVIDED

Accounting & Management Services SA

AUDITORS

PricewaterhouseCoopers

ACCOMPLISHMENTS

The MPP developed and implemented a new strategy in 2013 under the direction of its new Executive Director. The MPP continues to negotiate public health-oriented licences on HIV medicines and to sub-license these medicines to promote generic competition and ultimately the reduction of price and expansion of access.

BUSINESS ACCOMPLISHMENTS

The core work of the MPP is concerned with negotiating for public health-oriented licences on key HIV medicines.

The MPP signed three agreements this year with: ViiV Healthcare (a joint venture between GlaxoSmithKline, Pfizer and Shionogi) on abacavir for paediatric use; with Bristol-Myers Squibb on atazanavir, a key 2nd line drug; and with F. Hoffman-LaRoche for the price reduction and eventual licensing of valganciclovir, a treatment for an AIDS-related opportunistic infection, cytomegalovirus retinitis, which can cause irreversible blindness.

AbbVie entered into negotiations for lopinavir and ritonavir (LPV/r) for paediatric use. LPV/r is part of the WHO's preferred first-line treatment regimen for children. MPP advanced negotiations with Gilead and ViiV on the licensing of tenofovir alafenamide fumarate and dolutegravir, respectively.

The MPP updated its "Antiretroviral Priority List" based on the most recent medical evidence and patent data. The Antiretroviral Priority List prioritises antiretrovirals (ARVs) based on two criteria—(1) the most recent assessment of the medicine's medical importance from clinical experts; and (2) the extent to which the medicine is patented in developing countries. The Antiretroviral Priority List guides the licensing work of the MPP for the year. As part of this work, the patent data collected is published online in the MPP's Patent Status Database. The Database was expanded to 83 countries this year.

By the end of 2013, seven patent holders (of a total of 9 identified) remained in formal negotiations with the MPP: AbbVie, Boehringer-Ingelheim, Bristol-Myers Squibb, F. Hoffman-LaRoche, Gilead Sciences, the United States National Institutes of Health and ViiV Healthcare [a GlaxoSmithKline, Shionogi and Pfizer joint venture].

The MPP concluded sub-licence agreements with three generics manufactuers - Shasun and Shilpa for tenofovir disoproxil fumarate, emtricitabine, elvitegravir and cobicistat; and Aurobindo for abacavir.

The MPP continues to gather data relating to the price savings of TDF in developing countries as a result of its work. As a result of one of the terms in the MPP-Gilead licence agreement, sub-licensees have the flexibility to sell TDF in a large number of developing countries to which they were previously unable to sell.

The MPP held formal consultations with civil society at the IAS conference in Kuala Lumpur, Malaysia in July; the ICAAP conference in Bangkok, Thailand in November; the REDCA confernece in San Salvador, El Salvador in November; and at the ICASA conference in Cape Town, South Africa in December.

Additional relationships with intergovernmental and non-governmental organizations were built and maintained throughout the year. For example, the MPP held a consultation in Geneva on how to improve the Patent Status Database, collaborated with UNAIDS and UNITAID on a middle-income country incentives meeting and held formal consultations with civil society at the sidelines of major conferences, as per the MPP's consultative process approved by the Board in 2011.

OPERATIONAL ACCOMPLISHMENTS

The MPP launched its French and Spanish websites in 2013. It has also continued to expand the website as the business demands, such as with the introduction of an online Expression of Interest system, which enables interested parties to apply for a sub-licence from the MPP.

The Governance Board re-appointed Dr. Charles Clift as Chair, Dr. Sigrun Mogedal and Dr. Anban Pillay to the Governance Board. The Governance Board also re-appointed Dr.Shing Chang, Mr. Carlos Correa and Mr. Nelson Juma Otwoma to the Expert Advisory Group.

The MPP continued to submit the requisite reports to UNITAID as per the Memorandum of Understanding.

As per the Four-Year Business Plan, the MPP expanded its staff in 2013. Mr. Greg Perry joined the staff as Executive Director in January.

The MPP had three trainees in 2013—Ms. Elizabeth Plumb, Ms. Noreen Lala and Ms. Claire Wilmington. While the MPP does not have a formal internship programme, interns are recruited through university placement programmes or directly, depending upon the MPP's need.

The MPP reviewed and made minor revisions, as suggested by its auditors, to its internal control system in 2013.

www.medicinespatentpool.org