JOINT WHO/UNAIDS ANNUAL CONSULTATION WITH PHARMACEUTICAL COMPANIES AND STAKEHOLDERS

GLOBAL FORECASTS OF ANTIRETROVIRAL DEMAND 2012–2015

5–6 NOVEMBER 2012 GENEVA, SWITZERLAND

World Health Organization

UNAIDS

HIV/AIDS Programme

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WHO Library Cataloguing-in-Publication Data

Global forecasts of antiretroviral demand 2012–2015: joint WHO/UNAIDS annual consultation with pharmaceutical companies and stakeholders.

1.Anti-Retroviral agents – supply and distribution. 2.HIV infections – therapy. 3.Drug industry - trends. 4.Intersectoral cooperation. I.World Health Organization. II.UNAIDS.

ISBN 978 92 4 150507 9 (NLM classification: WC 503.2)

Layout L'IV Com Sàrl, Villars-sous-Yens, Switzerland.

Printed by the WHO Document Production Services, Geneva, Switzerland.

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ACRONYMS AND ABBREVIATIONS

ADG	Assistant Director General
AIDS	Acquired immunodeficiency syndrome
AMDS	AIDS Medicines and Diagnostics Service
API	Active pharmaceutical ingredient
ART	Antiretroviral therapy
ARV	Antiretroviral
AZT	Zidovudine
CHAI	Clinton Health Access Initiative
CL	Compulsory License
d4T	Stavudine
DFID	Department for International Development (United Kingdom)
EEP	Economics, Evaluation and Programme Effectiveness
EMP	Essential Medicines and Policies
FP	Finished product
FTT	Financial transaction tax
GPRM	Global Price Reporting Mechanism
HIS	Health Systems and Innovation (WHO Cluster)
HIV	Human immunodeficiency virus
HTM	HIV, TB, Malaria and Neglected Tropical Diseases (WHO Cluster)
ICDRA	International Conference of Drug Regulatory Authorities
IDA	International Dispensary Association
ITPC	International Treatment Preparedness Coalition
MPP	Medicines Patent Pool
MSF	Médecins Sans Frontières
NMRA	National Medicine Regulatory Authority
NRTI	Nucleoside Reverse Transcriptase Inhibitor
OGAC	Office of the Global AIDS Coordinator (United States)
PEPFAR	President's Emergency Plan for AIDS Relief
PfSCM	Partnership for Supply Chain Management
PHI	Public health intellectual property and innovation
PMTCT	Prevention of mother-to-child transmission (of HIV)
PSM	Procurement and supply management
R&D	Research and development
SCMS	Supply chain management system
SIP	Strategic Information and Planning (HIV Department Unit)
TAC	Treatment and Care (HIV Department Unit)
TAMs	Thymidine-analog mutations
TCO	Technologies and Commodities (HIV Department Unit)

TDF	Tenofovir
TWG	Technical working group
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VL	Viral load
VPP	Voluntary pooled procurement
WHO	World Health Organization
WG	Working group

I. INTRODUCTION

The World Health Organization (WHO) and the UNAIDS Secretariat jointly organized the annual consultation with pharmaceutical companies on 5–6 November 2012. The consultation gathered around 70 participants from the following institutions: innovator and generic ARV companies, active pharmaceutical ingredient (API) manufacturers, the Global Fund to Fight AIDS, Tuberculosis and Malaria, US Office of the Global AIDS Coordinator (OGAC), Unites States Agency for International Development (USAID), UNITAID, United Nations Development Programme (UNDP) representing as well United Nations Children's Fund (UNICEF), Partnership for Supply Chain Management (PfSCM), the Clinton Health Access Initiative (CHAI), International Dispensary Association (IDA) Foundation, i+Solutions, Futures Institute, relevant WHO departments and units, International AIDS Society (IAS), the Medicines Patent Pool, Médecins Sans Frontières (MSF) and International Treatment Preparedness Coalition (ITPC).

The opening remarks were respectively delivered by Dr Gottfried Hirnschall, Director of HIV Department on behalf of the Assistant Director General of HIV, TB, Malaria, and Neglected Tropical Diseases Research Cluster, Dr Hiroki Nakatani and by Dr Paul De Lay, Deputy Executive Director UNAIDS. In his opening remarks, Dr Hirnschall noted the importance of this meeting on global ARV demand forecasts to prevent stock-outs while the international community is scaling up access to antiretroviral treatment towards the objective of 15 million people on ART by 2015. He thanked the technical working group (CHAI, OGAC, SCMS, UNAIDS, Futures Institute and WHO) on ARV forecasting for coordinating their efforts to produce the global ARV demand forecast figures that were going to be discussed. He welcomed all participants and expressed his gratitude to UNAIDS for the effective collaboration on this project. Dr Paul De Lay welcomed the participants. He talked about the Treatment 2.0 Framework. UNAIDS and WHO are collaborating on the implementation of the Treatment 2.0 Framework to remove barriers to access care and treatment. The involvement of the international community and civil society is imbedded in the framework. The pillars on which UNAIDS is focused were elaborated in his speech. He noted that, with treatment optimization and better paediatric formulations, we will achieve the target of 15 million people on ART by 2015.

Joseph Perriëns, Coordinator HIV/TCO, introduced the following objectives and expected outputs of the meeting:

- Present global guidance for ARV innovation for advancing Treatment 2.0 Initiative: the 2013 consolidated guidelines;
- Present and discuss ARV market trends and global demand forecasts for 2012–2015;
- Present and discuss the situation on domestic and international financial resources for ARVs; and
- Report on ARV market and global supply constraints.

At the end of this consultation, four major outputs are expected:

- Update on the WHO 2013 Consolidated guidelines;
- Summary of the WHO 2012 ARV survey and GPRM procurement data;
- Summary of global ARV demand forecasts 2012–2015; and
- Update on current achievements and constraints in procurement and supplies.

The target is to publish by February 2013 the final global ARV demand forecasts after the forecasting working group will have incorporated participants' feedback and comments received during the consultation.

This report summarizes the main points discussed during the meeting. The agenda and list of participants are found in annexes I and II. The concept note and the presentations can be found on the WHO AMDS web site: http://www.who.int/hiv/amds/forecasting_meeting2012/en/.

II. MEETING SESSIONS

This report is focused on the discussions which followed the presentations. For details on each of the presentations we refer the reader to the link indicated above.

SESSION I: ACHIEVING UNIVERSAL ACCESS: GLOBAL GUIDANCE FOR INNOVATION

Chaired by Gottfried Hirnschall (Director, WHO/HIV Department), this session covered the state of the response towards 15 million by 2015, progress on the 2013 WHO consolidated guidelines for HIV treatment and prevention, d4T phase out and the civil society update on access to ART. In his presentation on progress towards 15 million by 2015, Yves Souteyrand (Coordinator, HIV/SIP/WHO) gave an overview of the epidemic, the achievements made on scaling up priority HIV/AIDS interventions particularly PMTCT and ART where we have over 8 million people on ART and highlighted the challenges as we need to continue to scale up. In her intervention, Meg Doherty (Coordinator Treatment & Care, WHO/HIV Department) described the major shifts in technical guidance 2011–2012, potential new game changers for 2013 WHO consolidated guidelines, and the timeline up to the end of the development process of the 2013 guidelines which will be published in June 2013. Nathan Ford (Treatment 2.0 Coordinator, WHO/HIV Department) gave an update on d4T phase out which is moving fast for some countries but slow for others due to programmatic and financial reasons.

Following these three interventions, civil society representatives made three presentations. They voiced the need to expand ART coverage faster than it is today: they noted that despite the progress of 8 million people on ART, the number of people who do not yet have access to ART is still high and access to laboratory tests such as CD4 and viral load is still low.

Patents are still challenging ART programme managers to ensure access to more affordable treatments particularly in Latin America. In view of the current gap towards the 15 by 15 target, civil society representatives suggested that WHO and its partners in the forecasting working group move from linear regression to a more ambitious projection scenario, because there is evidence that in some countries funds allocated to HIV programmes are under-utilized, prices of commodities are decreasing every year and innovative financing mechanisms are generating more resources.

Regarding d4T phase out, it was suggested that those moving from d4T based regimens switch to TDF based regimens in view of the risk of drug resistance which occurs when AZT based regimens are used for those patients. Recent studies indicate that d4T exposure (particularly in subtype C) can lead to the emergence of thymidine-analog mutations (TAMs) that lead to AZT resistance or K65R that leads to TDF resistance. K65R has been a relatively rare mutation. It is seen in less than 3% of treatment-experienced patients. In contrast, TAMs which are selected by AZT and d4T are seen more commonly. Therefore, in order to maximize long-term effectiveness of treatment response, in the absence of genotyping, it is preferred to replace d4T with TDF rather than AZT because replacing d4T with AZT would lead to a higher risk of treatment failure.

In the discussion, it was clarified at the request of Cipla that, WHO and its partners in the forecasting technical working group recommend that companies producing d4T containing formulations should maintain current registration of their d4T products to avoid disrupting the supply of ARVs for over 1.5 million people still using d4T containing regimens. Switching from d4T based regimens for all these people to TDF based regimens may take some time. Therefore, registration of d4T could be allowed to expire when it is clear that there is no longer demand for this product.

Suggestions from the discussion:

- Countries to accelerate scale up to ART in order to achieve 15 by 15 target.
- WHO and its partners in the forecasting working group to use more ambitious projection scenarios than the linear projection scenario which is too conservative to cover the unmet ART needs of about 50% people in need of ART.
- Countries to expand access to CD4 and VL monitoring services to ensure good quality ART services and timely switch to second line ART.
- Patients on d4T based regimens should be switched to TDF based regimens to minimize HIV drug resistance.
- Registration of d4T should be maintained until there is clarity that there is no demand for this product.
- International community to support countries in using effectively HIV allocated funds to reach the objective of 15 million people on ART by 2015.

SESSION II: FORECASTS OF ARV GLOBAL DEMAND 2012–2015

Chaired by Joel Kuritsky (Senior Medical Advisor, USAID), the second session was opened with three presentations: Vincent Habiyambere (HIV/TCO/WHO) presented the results of the 2012 WHO survey on ARV use and the distribution of various ARV in first- and second- line ART in adults and in children including the trends in consumption since 2006. Joseph Perriëns (HIV/TCO/WHO) presented the ARV sale trends since 2006. Using the information and trends from the two sources of data inputs from the Clinton Health Access Initiative (CHAI) and data from Partnership for Supply Chain Management (PfSCM), the Futures Institute developed global ARV demand forecasts 2012–2015. Using a linear regression scenario, it was projected that 13 million people will be on ART by 2015, and a country target scenario projected that 16 million people will be on ART by 2015. It is important to note that, historically since it was first used in 2006, the linear regression scenario has been underestimating the number of people who would be on ART two years later by 3% on average. The detailed projections and related volume of ARV demand by 2015 were presented by Adebiyi Adesina (Futures Institute) on behalf of the ARV forecast technical working group.

In the discussion, pharmaceutical companies mentioned that they would have no problem in meeting the projected global ARV demand forecasts. However, they voiced that pooled procurement for paediatric ARV formulations was needed to increase efficiency. The Global Fund and other funding partners were advised to increase their coordination for paediatric ARV procurement as it used to be when UNITAID and CHAI collaborated in supporting access to paediatric treatment. UNITAID, the Global Fund and CHAI and other partners are discussing ways and means to continue this cost-effective initiative.

Pooled procurement was suggested to the Global Fund and other partners to continue the good experience that UNITAID and CHAI had initiated. Furthermore, it was found that pooled procurement requires harmonization of policies in ART guidelines, ARV registration and language requirements of documents accompanying the ARV products. Also during the discussion, it was mentioned that the Paediatric ARV Procurement Working Group has been created to address these issues including those related to paediatric ARV market. At this stage the WG includes: UNITAID, The Global Fund, CHAI, MSF, UNICEF, PFSCM/VPP, and SCMS/President's Emergency Plan for AIDS Relief (PEPFAR). Soon more information about the WG will be disseminated among stakeholders.

In the next session, Robert Dintruff (Abbott) showed that access to laboratory services is important to ensure good quality ART care and treatment: it was evidenced that viral load (VL) testing leads to earlier detection of ART failure than CD4 count alone. This means that, when there is no VL test, ART may be administered to many patients without achieving the desired effect (virus suppression), which would explain partially why life expectancy in countries with near universal access to ART and a generalized epidemic has not recovered to levels seen prior to the HIV epidemic.

Michael Meynard (Quality Chemical Industries Ltd) made a presentation on local solutions to ARV access. He made a case for strengthening local production, stating that it contributes to strengthening supply chains of life-saving medicines in heavily affected areas. Besides promoting local self-reliance and socio-economic impact at country/regional levels, local production of quality approved medicines was mentioned to bolster the supply chain management system by availing products closer to patients, thus reducing the long lead time which often causes stock-outs.

Suggestions from the discussion:

- Relevant institutions to support the continued production of forecasts of global ARV demand.
- WHO and its partners to continue using several ARV forecasting scenarios.
- International community to support countries to reach their ART set targets.
- Access to laboratory services in particular CD4 and VL should be increased to ensure good quality ART care.

SESSION III: ENSURING FINANCIAL RESOURCES TO MEET DEMAND OF ARVS

Chaired by Joseph Perriëns (Coordinator, HIV/TCO/WHO), this session covered topics related to financing and resources available to meet the global ARV demand as presented in the previous session. Gulmira McHale (Head, Resource Mobilization, UNITAID) discussed the various innovative financing mechanisms used by UNITAID to raise funds required to support public health programmes. These mechanisms include notably the air ticket levy. Nine countries are contributing to UNITAID through this mechanism which has generated US$ 1.2 billion so far: Cameroon, Chile, the Republic of Congo, France, Madagascar, Mali, Mauritius, Niger, and the Republic of Korea. Norway, founding member of UNITAID, contributes from the carbon dioxide tax. UNITAID is also advocating for financial transaction tax (FTT) implementation, but we don't have yet commitments from the donors. Some countries, such as Kenya, Zambia and Zimbabwe are setting up resource mobilization of innovative financing for domestic funding to ensure ways to fund their national AIDS programmes. As a global leader on innovative financing, UNITAID has raised US$ 2 billion and has supported 94 countries worldwide, from 2006

to 2012. UNITAID also works with pharmaceutical producers to reduce drug and diagnostic prices for low-income and low-middle income countries.

Karl-Lorenz Dehne (UNAIDS) showed that ART needs are increasing but the cost per patient treated is decreasing while funds are increasing with a global target of reaching US$ 22–24 billion by 2015. With treatment optimization, it is expected that HIV programmes will be more efficient, evidence-based and deliver better value for money. The goal is to invest against agreed priorities, and implement at low cost (efficiently) with tangible results. WHO/UNAIDS will continue making the case to invest in ART, setting global targets, advocacy and clinical guidelines and providing technical support to countries for achieving their ART targets.

Lara Stabinski (OGAC) showed in her presentation how PEPFAR is committed to fight HIV/AIDS. The current annual budget for HIV programmes is over US$ 6 billion and a similar budget is requested for the next fiscal year. PEPFAR continues to have substantial resources and is working closely with national governments and donor partners such as the Global Fund to ensure coordination and maximum impact of collective investments. There is an increased focus on evidence-based interventions including treatment and PMTCT. PEPFAR plans to accelerate treatment to meet coverage gaps in higher burden/low resourced partner countries, and to maintain the scale-up in others in coordination with other donor partners. Continued attention to efficiency, as illustrated by the continued decline of costs per patient treated, will enable even greater health impacts in the future.

Ade Fakoya (Global Fund) presented the financial overview of current Global Fund investments in the HIV Portfolio. Over US$ 8 billion from the total life time budget of over US$ 13 billion has been approved by the board. The Global Fund has large investments in ARV therapy, but at the same time, the institution has encouraged domestic government contributions to ensure sustainability. Value for money, result-focused, transparency and efficiency continue to be the principles in Global Fund supported programmes.

Suggestions from the discussion:

- Adopt pooled procurement procedures for small ARV quantities to obtain more economies of scale on these small volume products, especially paediatric and second-line ARVs, and diagnostics.
- Support countries in their efforts towards domestic financing mechanisms to ensure sustainable national HIV programmes.
- Continue collaboration with manufacturers to obtain reduced prices on ARVs and diagnostics for low-income and low-middle income countries.

At the end of Day 1, it was clear that:

- The revised ART guidelines will recommend robust and easy to take ARV treatments to facilitate access to ART for at least 15 million people by 2015.
- Global ARV demand forecasts and projection scenario to 2015 show that it is possible to reach and even go beyond the 15 by 15 target if country ART targets become the focus for financial and technical support.
- UNITAID, UNAIDS, OGAC and the Global Fund agree that efficiency and the commitment of governments and the international community are showing positive results. This makes it plausible that the 15 million people on ART defined for 2015 will be met and might be exceeded.

SESSION IV: ADDRESSING REGULATORY, PATENT AND PSM CHALLENGES TO SCALE UP ACCESS TO ART

1. REGULATORY ISSUES

Moderated by Karl-Lorenz Dehne (Acting Chief EEP, UNAIDS), this session started on Day 2 and covered the following topics: drug registration, procurement policies and patent issues related to ARV procurement.

Boniface Dongmo-Nguimfack (HIV/TCO/WHO) presented the drug regulatory database. This database includes information provided by ARV, TB and ACT manufacturers on where their products have been registered. This database is useful for informing procurement agencies on where products have market authorization and can also show gaps on where some cost-effective products need to be registered to achieve efficiency in procurement.

Lembit Rägo (Coordinator, QSM/EMP/HIS) a presented activities that WHO is doing to facilitate that WHO prequalified medicines follow an accelerated registration procedure. This will reduce the current lengthy registration procedures, thus allowing accelerated access to good quality and sometimes lower price medicines. In addition, through the International Conference of Drug Regulatory Authorities (ICDRA) which is held biannually, WHO is encouraging networking, collaboration and harmonization between national drug regulatory authorities. The new procedure for accelerated registration of prequalified medicines has been developed in wide consultation and is available on the WHO website: http://www.who.int/entity/medicines/areas/quality_safety/quality_assurance/PQProcedure- A pilot project involving ten countries is now under way to support accelerated registration through increased regulatory cooperation.

2. PROCUREMENT ISSUES

Regarding the subject on procurement policies, Robert Staley (PFSCM) made an overview of the SCMS procurement procedures. He showed that their procurement is based on aggregated quantities forecasted in each country programme, which leads to bulk procurement and economies of scale. Regional stores assist in preventing stock-outs and ensure uninterrupted supply of ARVs. Renewal orders are allocated taking into account not price first, but other criteria, such as lead time. Consequently, orders are split between prequalified suppliers in the interest of supply continuity. Discussions to use the same approach to supply ARVs through the Global Fund voluntary pooled procurement (VPP) mechanism are on-going.

Sophie Logez (Global Fund) made an overview of policies and principles for the Global Fund procurement. The products should be recommended in the national treatment guidelines, should be registered in the country and should be WHO prequalified or approved by a stringent regulatory authority. A product recommended by an expert review panel is also acceptable if only two products which are WHO prequalified or authorized by a stringent regulatory authority are available. She also reported that the VPP was recommended by the Global Fund Board to promote value for money and to contribute to the ARV market shaping strategy, approved by the Global Fund in May 2011. VPP will achieve over US$ 100 million for ARVs in 2013. It is expected to achieve savings of over US$ 10 million through better unit prices and use of sea freight. Use of the latter as a means to achieve a lower cost of handled goods was also emphasized in the presentation by the Global Fund and by PfSCM.

In their comments, pharmaceutical companies appreciate the VPP as it encourages bulk procurement. However, they expressed concern about long delays in disbursement of funds even when products have been fully delivered.

3. INTELLECTUAL PROPERTY AND PUBLIC HEALTH

Regarding intellectual property, Peter Beyer (PHI/HIS/WHO), provided an update on recent developments in the area of intellectual property and public health: the Indonesian Government issued compulsory licenses for seven HIV/AIDS and hepatitis medicines at the beginning of September 2012 with a view to allow for generic competition and generate cost savings. Another major development was the first compulsory license (CL) issued in March 2012 by the Indian Controller of Patents under the Indian Patents Act for a treatment for liver and kidney cancer (sorafenib). The request for the CL filed by a generic company was based on Section 84 of the Indian Patents Act that allows interested persons to apply for the grant of a compulsory license *inter alia* on the grounds that reasonable requirements of the public with respect to the patented invention have not been satisfied and that it is not available at a reasonably affordable price. Another recent development in India is the decision of the Indian IP Appellate Board to revoke a patent initially granted for the hepatitis C drug peginterferon alfa-2a (Pegasys) following a post-grant opposition filed by a patient organization. Peter Beyer also described the developments that took place in the past years in the area of voluntary non-exclusive license agreements. Nearly all originator companies that own HIV/AIDS treatments now are engaged in license agreements or issue non-assert declarations. Such license agreements and non-assert declarations have the potential to lead to lower prices and increase access if they allow competition.

Sandeep Juneja (Medicines Patent Pool (MPP)), provided an update on the work of MPP. He discussed the MPP's role in ensuring access in the changing ARV patent landscape. He indicated that MPP received support from UNITAID, UNAIDS, the Global Fund, DFID and many other institutions. He showed that MPP follows a priority ARV list based on clinical and market criteria. The higher the priority, the higher on the list is the ARV formulation. More details are found in the PowerPoint presentation from Sandeep Juneja.

III. NEXT STEPS

At the end of the meeting, the following next steps were agreed upon:

1. Futures Institute will finalize the global ARV demand forecasts taking into account comments received during the consultation and explain the assumptions and methodologies as developed and agreed by the technical working group. The final product will be published and widely disseminated to meeting participants and other stakeholders by February 2013.

2. WHO will make all current PowerPoint presentations accessible on the WHO/AMDS web site.

IV. ANNEXES

ANNEX I: FINAL AGENDA

JOINT WHO/UNAIDS ANNUAL CONSULTATION WITH
PHARMACEUTICAL COMPANIES AND STAKEHOLDERS
GLOBAL FORECASTS OF ANTIRETROVIRAL DEMAND 2012–2015
UNAIDS/WHO D-Building, Kofi A. Annan Conference Room, Geneva, Switzerland
Monday 5 to Tuesday 6 November 2012

DAY 1 MONDAY 5 NOVEMBER 2012

Time	Agenda item	Presenter/participants
08:45–09:00	Registration	All participants
09:00–09:30	Welcome remarks	**Chair: Gottfried Hirnschall** WHO/HIV/AIDS **Hiroki Nakatani** WHO/ADG/HTM **Paul De Lay** DED, UNAIDS
	Objectives of the consultation and introduction of participants	**Joseph Perriëns** WHO/HIV/TCO
09:30–10:30	**I. Panel on achieving universal access: global guidance for innovation** *(15 minutes, each)*	
	1. Towards 15 million by 2015: progress update	**Yves Souteyrand** WHO/HIV/SIP
	2. Advancing treatment 2.0: progress on the consolidated 2013 WHO consolidated guidelines: What is new	**Meg Doherty** WHO/HIV/TAC
	3. Stavudine (d4T) phase out	**Nathan Ford** WHO/HIV/TAC
10:30–11:00	Coffee/tea break	
11:00–12:00	**Civil society update on access to ART and challenges** *(10 minutes each)* • Africa • Latin America • Europe	**Maurine Murenga**, Kenya **Lorena Di Giano**, Argentina **Nikos Dedes**, Greece
	Plenary discussion	All participants
12:00–13:30	Lunch break	

13:30–14:30	**II. WHO & UNAIDS forecasts of ARV global demand 2012–2015**	**Chair: Joel Kuritsky** USAID
	1. WHO 2012 survey on ARV use *(15 minutes)*	**Vincent Habiyambere** WHO/HIV/TCO
	2. Overview of ARV procurement in low- and middle- income countries: transaction data from GPRM *(15 minutes)*	**Joseph Perriëns** WHO/HIV/TCO
	3. Forecasting global ARV demand for adults and children 2012–2015 *(40 minutes)*	**Adebiyi Adesina** On behalf of the Forecasting TWG
	Questions and answers	All participants
14:30–16:00	**Feedback from the R&D and generic manufacturers** *(15 minutes each)*	**Robert Dintruff** Abbott **Michael Maynard** Quality Chemical Industries Ltd **Generic FP & API manufacturers** **Generic API Companie**s
	Questions and answers	All participants
16:00–16:30	Coffee/tea break	
16:30–18:00	**III. Ensuring resources to meet demand of ARVs** *(15 minutes each)*	**Chair: Joseph Perriëns** WHO/HIV/TCO
	1. Update on innovative financial resources for HIV	**Gulmira McHale** UNITAID
	2. National and international HIV expenditures	**Karl-Lorenz Dehne** UNAIDS
	3. Financial resources for HIV	**Lara Stabinski** OGAC
	4. Financial resources available for HIV	**Ade Fakoya** Global Fund
	Questions and answers *(30 minutes)*	All participants
18:00	Wrap-up of the day	**Carlos A. Passarelli** WHO/UNAIDS

DAY 2 TUESDAY 6 NOVEMBER 2012

Time	Agenda item	Presenter/participants
9:00–10:30	**IV. Panel discussion on regulatory, procurement and supply chain challenges to improve access to ARVs** *(15 minutes each)*	**Chair: Karl-Lorenz Dehne** UNAIDS
	1. ARV registration status	**Boniface Dongmo** WHO/HIV/TCO
	2. New procedure for more structured collaboration with NMRAs to fast track the national registration of WHO prequalified products	**Lembit Rägo** WHO/EMP
	3. PfSCM procurement policy	**Robert Staley** SCMS
	4. Global Fund procurement policy	**Sophie Logez** Global Fund
	Questions and answers *(30 minutes)*	All participants
10:30–10:45	Coffee/tea break	
10:45–12:15	**IV. Panel discussion on regulatory, procurement and supply chain challenges to improve access to ARVs** *(continued)*	**Chair: Carlos A. Passarelli** UNAIDS
	5. Update on public health and intellectual property related issues	**Peter Beyer** WHO/PHI
	6. Progress update on Medicines Patent Pool	**Sandeep Juneja** MPP
12:15–12:30	**Closing remarks: Wrap-up and next steps**	**WHO & UNAIDS**
12:30–14:00	Lunch break	
14:00–17:00	**V. Individual meetings with companies and staff from WHO, UNAIDS and all partner organizations**	

ANNEX II. FINAL LIST OF PARTICIPANTS

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ISBN 978 92 4 150507 9