

AIDS MEDICINES AND DIAGNOSTICS SERVICE

MEETING REPORT

**JOINT WHO/UNAIDS ANNUAL
CONSULTATION WITH PHARMACEUTICAL
COMPANIES AND STAKEHOLDERS
ON FORECASTING GLOBAL DEMAND
OF ANTIRETROVIRAL DRUGS
FOR 2013–2016**

25-26 NOVEMBER 2013, GENEVA, SWITZERLAND

MARCH 2014



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WHO Library Cataloguing-in-Publication Data:

Joint WHO/UNAIDS annual consultation with pharmaceutical companies and stakeholders on forecasting global demand of antiretroviral drugs for 2013-2016: 25-26 November 2013 Geneva, Switzerland, March 2014.

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 150698 4

(NLM classification: WC 503.2)

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Printed in Switzerland

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ABBREVIATIONS AND ACRONYMS

| | |
|-------------|--|
| ABC | abacavir |
| API | active pharmaceutical ingredient |
| ART | antiretroviral therapy |
| ARV | antiretroviral |
| ATV | atazanavir |
| AZT | zidovudine |
| CD4 | cluster of differentiation 4 |
| CHAI | Clinton Health Access Initiative |
| ddl | didanosine |
| d4T | stavudine |
| DRV | darunavir |
| DTG | dolutegravir |
| Global Fund | Global Fund to Fight AIDS, Tuberculosis and Malaria |
| GPRM | Global Price Reporting Mechanism |
| EFV | efavirenz |
| ETV | etravirine |
| FDC | fixed-dose combination |
| 3TC | lamivudine |
| USFDA | United States Food and Drug Administration |
| FDC | fixed-dose combination |
| FTC | emtricitabine |
| IATT | Inter-Agency Task Team for the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Children |
| IDV | indinavir |
| LPV/r | lopinavir/ritonavir |
| NNRTI | non-nucleoside reverse-transcriptase inhibitors |
| NRTI | nucleoside reverse-transcriptase inhibitors |
| NVP | nevirapine |
| OGAC | Office of the U.S. Global AIDS Coordinator |
| OTIF | on time and in full |
| PEPFAR | U.S. President's Emergency Plan for AIDS Relief |
| PI | protease inhibitor |
| PMTCT | prevention of mother-to-child transmission |
| RAL | raltegravir |
| RTV | ritonavir |
| SCMS | Supply Chain Management System |
| SQV | saquinavir |
| TAF | tenofovir alafenamide |
| TDF | tenofovir disoproxil fumarate |
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| UNICEF | United Nations Children's Fund |
| USAID | United States Agency for International Development |
| VL | viral load |
| WHO | World Health Organization |
| XTC | lamivudine or emtricitabine |
| ZDV | zidovudine (AZT) |

1. INTRODUCTION

The World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) Secretariat jointly organized an annual two-day consultation with pharmaceutical companies and stakeholders to present them with the draft forecasts for the demand of antiretroviral (ARV) drugs in 2013–2016. These forecasts were prepared in collaboration with the Clinton Health Access Initiative (CHAI), Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), Office of the U.S. Global AIDS Coordinator (OGAC), Supply Chain Management System (SCMS), UNAIDS, United Nations Children's Fund (UNICEF), United States Agency for International Development (USAID) and WHO, supported by the Futures Institute. The consultation was held on 25–26 November 2013 in Geneva, Switzerland, and gathered 70 participants from the innovator and generic drug industry, active pharmaceutical ingredient (API) producers, professionals from partner organizations, a representative from the National Department of Health, South Africa, and civil society and other nongovernmental organizations.

The opening remarks were delivered by Hiroki Nakatani (Assistant Director-General, HIV/AIDS, TB, Malaria and Neglected Tropical Diseases, WHO) and by Mariângela Simão (Director of Rights, Gender, Prevention and Community Mobilization Department, UNAIDS). In his opening remarks, Hiroki Nakatani noted the importance of the meeting on global ARV demand forecasts to prevent stock outs while the international community is scaling-up access to ARV treatment towards the objective of 15 million people on antiretroviral therapy (ART) by 2015. He

thanked the ARV Demand Forecasting Technical Working Group for coordinating efforts to produce 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.

Mariângela Simão welcomed the participants and spoke about the inequalities in access to care and treatment, especially in key populations and children. The pillars of Treatment 2.0, on which UNAIDS is focused, were elaborated in her speech and she noted that with treatment optimization, better paediatric formulations and increased domestic funding, the target of 15 million people on ART by 2015 will be achieved.

Joseph Perriëns (Coordinator, HIV Technologies and Commodities, WHO) introduced the following objectives of the consultation meeting:

- present an update on ART coverage and on the impact of the 2013 WHO Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection;
- present and discuss ARV market trends and global demand forecasts for 2013–2016;
- present and discuss the situation on domestic and international financial resources for ARVs.

This report summarizes the main points discussed during the meeting. The agenda and list of participants are found in Annexes I and II.

2. MEETING SESSIONS

This report is focused on the discussions that followed the presentations. The presentations can be accessed on the following Dropbox link: <https://www.dropbox.com/sh/tyg0i07ub0d1tfb/9mje5fuhag?n=37718888>

Session I. Achieving universal access: global guidance for innovation

Chaired by Joseph Perriens (Coordinator, HIV Technologies and Commodities, WHO), this session covered an overview of the 2013 WHO *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection*, and an update on the UNAIDS Treatment 2015 Initiative.

Meg Doherty (Coordinator, HIV Treatment and Care, WHO) highlighted the 2013 WHO consolidated guidelines for HIV treatment and prevention. She noted that 9.7 million people were on ART at the end of 2012, or 61% coverage overall before the new WHO guidelines. The new eligibility criteria increased the number of people eligible for ART to 28.6 million. This increase of denominator reduces the ART coverage but it is a great opportunity to accelerate the number of people on ART. She expressed the need to prioritize treatment for paediatrics because ARV coverage rates are disproportionately lower for children (34%) compared with adults. The impact of the 2013 WHO consolidated guidelines has resulted in two major outputs: increased uptake of tenofovir disoproxil fumarate (TDF) + lamivudine (3TC) (or emtricitabine [FTC] + efavirenz (EFV), which is the preferred first-line regimen, and accelerated phase out of stavudine (d4T)-based regimens.

Badara Samb (Chief, Global Outreach and Special Initiatives, UNAIDS) voiced the need to expand ART coverage faster than it is today by incorporating three new concepts: speed, focus and innovation. These concepts are necessary, as an additional 5 million people have to be on treatment in 2 years from now in order to achieve the target of having 15 million people on treatment by 2015. A major challenge encountered is that many people do not have access to ART as a result of the distance to a health facility. In order to scale-up ARV treatment faster, we need to be innovative and to:

- focus on where greater impact is expected to occur: key populations, high prevalence populations or countries, high-risk groups in low-prevalence countries;
- increase the proximity of service delivery to improve access: task shifting, the involvement of the community.
- UNAIDS is committed to:

- motivating policy-makers to extend treatment to those who are missed out;
- generating increased demand for treatment, equity and helping mobilize resources for treatment;
- promoting country-level commitment;
- monitoring and reporting on progress.

Discussion

Participants asked about the increase in number of people eligible for ART if we moved to the test and treat approach. They also asked how to prioritize transition from current practice to new guidelines and how to be innovative as, in their view, the health systems are already overstretched with the current number of people in need of ART. Meg Doherty responded that the number of people eligible for ARV treatment would increase from 28.6 million to 32 million if we moved to "test and treat". However, there is as yet insufficient evidence that would lead to such a recommendation by WHO. Regarding innovation to deal with health system constraints, community involvement in ART and task-shifting are supported by WHO and should be considered.

Suggestions from the discussion

- Use more community involvement, task shifting and public-private partnership.
- Prioritize and focus on where quick wins can be made, in particular in high-prevalence countries and in the most at-risk key populations.
- Treatment should be seen as an investment rather than as a cost to countries and international community, as it contributes to prevention.
- Countries to expand access to CD4 and viral load monitoring services to ensure good-quality ART services and timely switch to second-line ART.
- Use treatment optimization: one fixed-dose combination (FDC) pill a day; less regimens in national ART programmes; efficiency in procurement and delivery of ART services; well-planned transitioning to new regimens. A policy brief has been developed on the transition to new ARV treatment regimens: http://apps.who.int/iris/bitstream/10665/104449/1/WHO_HIV_2014.4_eng.pdf and this will be updated in 2014.
- Patients on d4T-based regimens should be switched to TDF-based regimens.

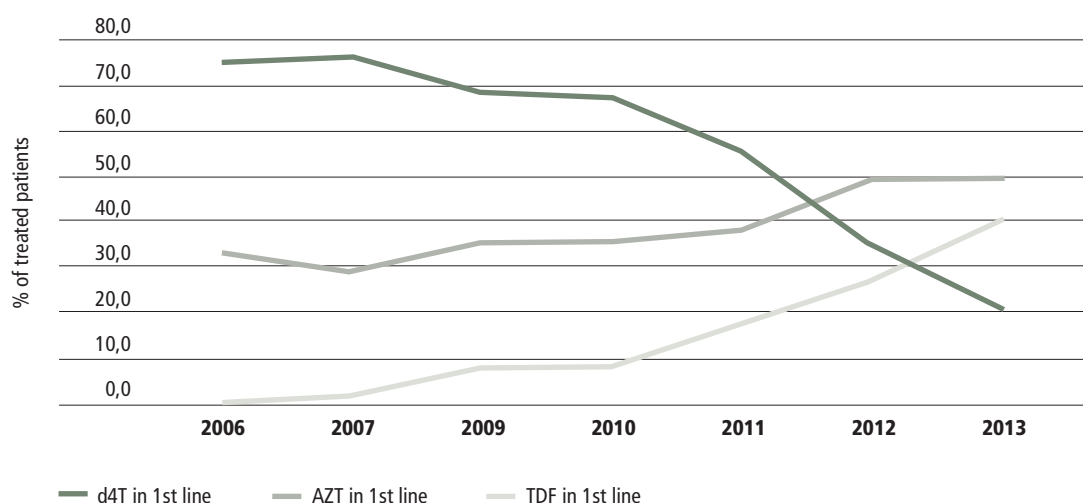
Session II. Forecasts of global ARV demand 2013–2016

Chaired by Joseph Perriens (Coordinator, HIV Technologies and Commodities, WHO), the second session was opened with three presentations:

1. Vincent Habiyambere (HIV Technologies and Commodities, WHO) presented the results of the 2013 WHO survey on ARV use for adults, including trends of regimens and APIs since 2006. The results presented from a sample of 96 low- and middle-income countries

(6.2 million people on ART at the end of 2012) revealed that the use of d4T was decreasing significantly and TDF-based regimens were increasing (Fig. 1). The trend analysis revealed that TDF increased from less than 1% at the end of 2006 to 36% at the end of 2012; d4T-based regimens decreased in the same period from almost 70% to 19%; and zidovudine (AZT)-based regimens increased from 29% in 2006 to 44% in 2012. This trend will continue. The number of first-line ART regimens in use is still high in several countries and the proportion of patients on second-line ART regimens is still low. Details of this survey will be published in 2014.

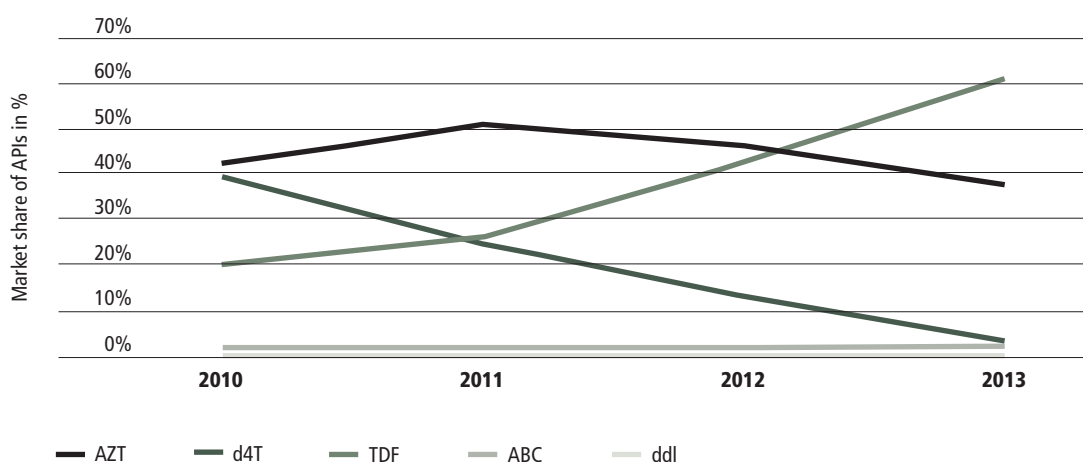
Figure 1. Evolution in the use of APIs in adults, 2006–2013



2. Boniface Dongmo-Nguimfack (HIV Technologies and Commodities, WHO) presented on the uptake of different ARV adult formulations from the Global Price

Reporting Mechanism (GPRM) database. In 2013, the market share of TDF increased to slightly over 60% and d4T sales dropped to less than 3% (Fig. 2).

Figure 2. Market share per API for nucleoside reverse transcriptase inhibitors



3. Global ARV demand forecasts were presented by John Stover (Vice President, Futures Institute) on behalf of the ARV Demand Forecasting Technical Working Group. The forecasts are based on data obtained from: the annual WHO survey on ARV use; transaction data from the GPRM database; CHAI projections; UNAIDS estimates of need for ART; and SCMS and Global Fund quantification data for 2014 and 2015. Three different

approaches were used to produce the forecasts: linear extrapolation; country targets; and CHAI projections in 21 high-burden countries. Based on these methods, it is projected that the "15 by 15" target will be achieved, and 16.8 million people will be on ART by 2016. The volume of ARV demand was forecasted and discussed with pharmaceutical industry and partners. The updated data are presented in Fig. 3 and Fig. 4.

Figure 3. Projected numbers of patients on ART: adults and children. Country targets, linear and CHAI projections

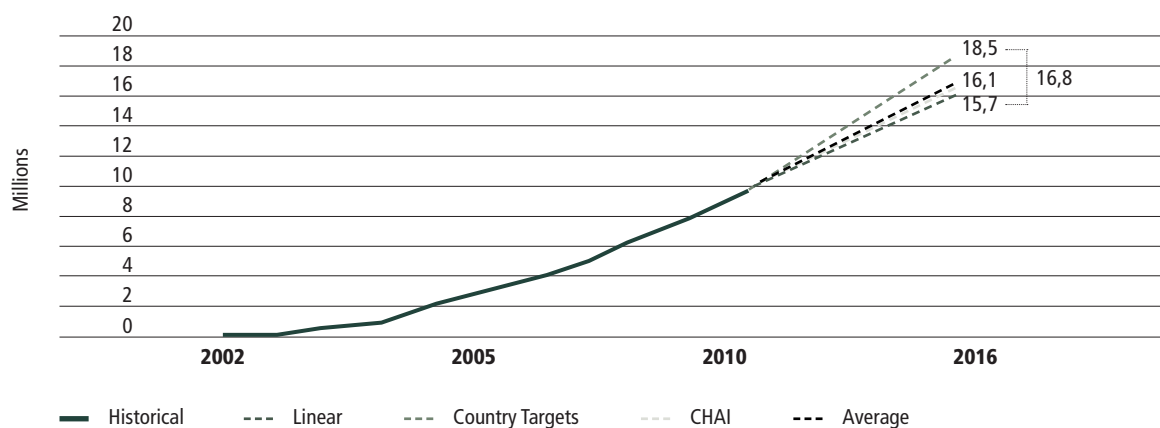


Figure 4. Volume of demand for ARVs (person-years).

Country target projections for ATV, atazanavir; EFV, efavirenz; FTC, emtricitabine; 3TC, lamivudine; LPV, lopinavir; NVP, nevirapine; d4T, stavudine; RTV, ritonavir; TDF, tenofovir; ZDV, zidovudine

| Drug | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 |
|-------|-----------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|
| d4t | 2,184,916 | 2,346,782 | 2,483,444 | 2,275,078 | 1,325,147 | 888,475 | 597,666 | 556,514 | 457,666 |
| ZTD | 1,459,080 | 1,667,437 | 2,340,551 | 2,960,099 | 4,121,762 | 4,379,451 | 5,215,481 | 6,163,919 | 7,064,711 |
| TDF | 327,869 | 366,573 | 796,197 | 1,660,226 | 2,464,062 | 4,872,593 | 7,352,937 | 9,451,619 | 11,390,251 |
| 3TC | 3,732,573 | 4,140,420 | 5,330,124 | 6,524,809 | 7,339,583 | 8,932,521 | 10,115,009 | 11,106,918 | 12,218,110 |
| NVP | 2,162,104 | 2,461,372 | 3,201,530 | 3,979,716 | 4,694,176 | 5,133,884 | 5,500,077 | 5,964,335 | 6,243,319 |
| EFV | 1,584,866 | 1,695,161 | 2,145,304 | 2,665,055 | 3,009,470 | 4,448,701 | 6,158,023 | 7,831,870 | 9,639,298 |
| FTC | 194,072 | 227,949 | 303,433 | 464,336 | 846,388 | 1,446,574 | 2,444,667 | 3,551,132 | 4,543,409 |
| LPV | 191,830 | 216,375 | 279,909 | 360,332 | 462,512 | 770,373 | 983,919 | 1,237,221 | 1,500,623 |
| ATV | 34,123 | 35,463 | 30,557 | 10,123 | 30,383 | 89,299 | 174,171 | 269,791 | 392,916 |
| RTV | 179,137 | 214,442 | 197,263 | 329,933 | 481,426 | 881,064 | 1,272,501 | 1,692,611 | 2,155,836 |
| Other | 164,218 | 171,617 | 199,549 | 232,562 | 261,216 | 466,447 | 658,235 | 841,390 | 1,068,775 |

Comments by ARV Demand Forecasting Technical Working Group members

CHAI noted that their projections did not take into account the new WHO guidelines, which may affect CHAI projections in the future.

SCMS noted that third-line regimens need to be

considered in the future and some formulations used in third-line regimens should be featured in the projections, even if their proportion is small. Their projection would be used in advocacy for maintaining their production.

These forecasts are critical to the work of the Medicines Patent Pool, as they are used for negotiating licences.

Suggestions from the discussion

- The continued production of forecasts of global ARV demand was welcomed and called for.
- The international community should continue its support to countries to reach their ART targets.
- A pooled procurement approach and early submission of orders should be adopted for low-volume products such as paediatric ART and second-line/third-line regimens.
- Modelling for new ARVs and products in the pipeline was also recommended for future forecasts. Factors to take into account include: U.S. Food and Drug Administration (FDA) approval; better efficacy and safety profiles; price evolution; changes in WHO and national guidelines; and national registration. Without these elements in place, the market for new products would remain low.
- Increasing access to viral load for early detection of treatment failure was recommended to increase the proportion of people on second-line ART. South Africa confirmed that access to a good laboratory network is an important factor explaining the high proportion of people on second-line ART observed in South Africa.
- Future forecasts of API demand should take into account the scenarios on the uptake of the new guidelines, and the availability of new diagnostics and new formulations.
- The capacity to produce TDF- and EFV-based formulations has increased and is sufficient to serve the demand but procurement practices need to be improved; for instance, placing orders ahead of time and using pooled procurement.

- Forecasting not only API uptake but also ARV formulations should be considered.

Session III. Forecasts of global paediatric ARV demand 2013–2016

Chaired by Joseph Perriens (Coordinator, HIV Technologies and Commodities, WHO), the third session was opened with four presentations:

1. David Jamieson (Deputy Director, SCMS) presented the optimal paediatric ARV formulary proposed by the Inter-Agency Task Team for the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Children (IATT). He noted that the present procurement is highly fragmented and explained that the reason for developing the optimal paediatric ARV formulary was to rationalize national procurement and reduce fragmentation of regimens. The formulary has three groups of ARV formulations:
 - optimal paediatric ARV formulary: the minimum number of ARV formulations needed to provide all currently recommended, preferred and alternative first- and second-line WHO-recommended regimens for all paediatric weight bands;
 - limited-use paediatric ARV formulary: formulations that may be needed during transition and for special circumstances;
 - nonessential paediatric ARV formulary: everything else (not needed ARV formulary).

The optimal and limited-use paediatric ARV formularies are shown in Fig. 5 and Fig. 6.

Figure 5. IATT optimal paediatric ARV formulary, 2013.

| Drug class (or FDC) | Product | Formulation | Dosage | Rationale for list |
|---------------------|-------------|----------------------------------|--------------|--------------------|
| NTRI | AZT | Oral liquid | 50 mg/5 ml | For use in PMTCT |
| NNRTI | EFV | Tablet (scored) | 200 mg | |
| NNRTI | NVP | Tablet (dispersible, scored) | 50 mg | |
| NNRTI | NVP | Oral liquid | 50 mg/5 ml | For use in PMTCT |
| PI | LVP/r | Tablet (heat stable) | 100 mg/25 ml | |
| PI | LPV/r | Oral liquid | 80/20 mg/ml | |
| FDC | AZT/3TC | Tablet (dispersible, scored) | 60/30 mg | |
| FDC | AZT/3TC/NVP | Tablet (dispersible, scored) | 60/30/50 mg | |
| FDC | ABC/3TC | Tablet (dispersible, scored) | 60/30 mg | |
| FDC | ABC/3TC/AZT | Tablet (non-dispersible, scored) | 60/30/60 mg | |

Figure 6. IATT limited-use paediatric ARV formulary, 2013

| Drug class (or FDC) | Product | Formulation | Dosage | Rationale for list |
|-----------------------------|-------------|------------------------------|-------------|--|
| NRTI | 3TC | Tablet (dispersible) | 30 mg | To be used with TDF single formulation |
| NRTI | TDF | Oral powder* | 40 mg/scoop | For use in special circumstances when ABC or AZT cannot be used or for patients with Hepatitis B, until an appropriate FDC becomes available *Product is administered as an oral powder, not reconstituted with liquids |
| NRTI | TDF | Tablet | 150 mg | See above |
| NRTI | TDF | Tablet | 200 mg | See above |
| NNRTI | ETV | Tablet | 25mg | Special circumstance in 3 rd line where appropriate |
| NNRTI | ETV | Tablet | 100 mg | See above |
| PI | RTV | Oral liquid | 400 mg/5 ml | For boosting of non-co-formulated PIs and super-boosting PI during TB co-infection |
| PI | ATV | Solid oral dosage form | 100 mg | Use in alternative 2 nd line for children over 6 years old when boosting with separate RTV is available |
| PI | ATV | Solid oral dosage form | 150 mg | See above |
| PI | DRV | tablet | 75 mg | Special circumstances in 3 rd where appropriate and when boosting with separate RTV is available |
| Integrase Inhibitors | RAL | Chewable tablet (scored) | 100 mg | For use in 3 rd line where appropriate |
| FDC | D4T/3TC/NVP | Tablet (dispersible, scored) | 6/30/50 mg | Special circumstance where patients cannot be transitioned to a preferred or alternative NRTI |
| FDC | D4T/3TC | Tablet (dispersible, scored) | 6/30 mg | See above |

2. Vincent Habiya (HIV Technologies and Commodities, WHO) presented the results of the 2013 WHO survey on ARV use for children, and trends of paediatric regimens and APIs since 2006. The preliminary results indicated that 95.5% of children in low- and

middle-income countries were on first-line ART regimens by the end of 2012, and that 4.4% of children were using second-line ART regimens and 0.1% on salvage. The first- and second-line paediatric ARV regimens used in 2012 are presented in Fig. 7 and Fig. 8.

Figure 7. First-line regimens used in 2012 for children in lower middle-income countries: 95.5% of children on ART by end of 2012 (n = 332 034)

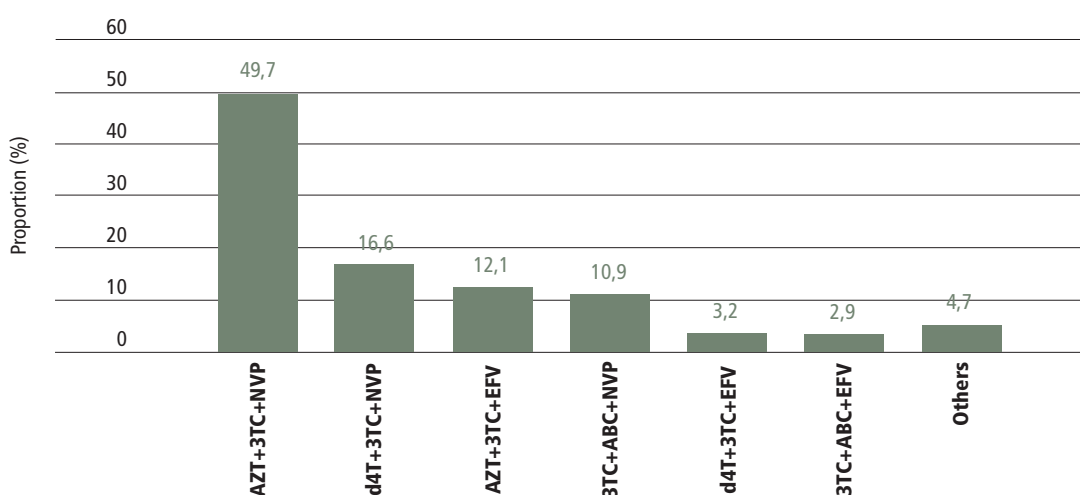
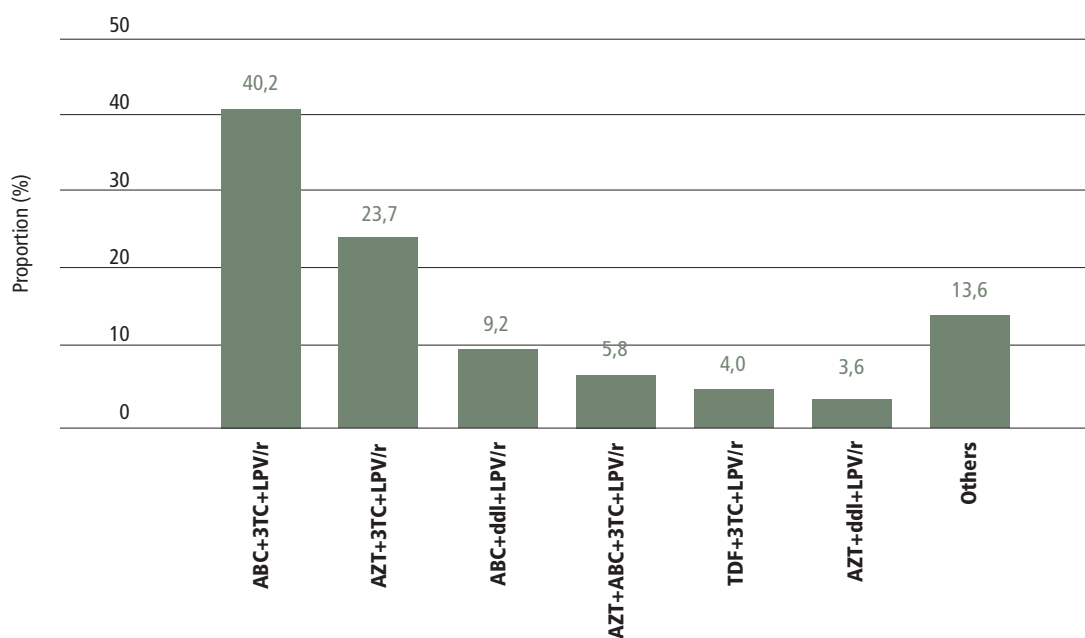


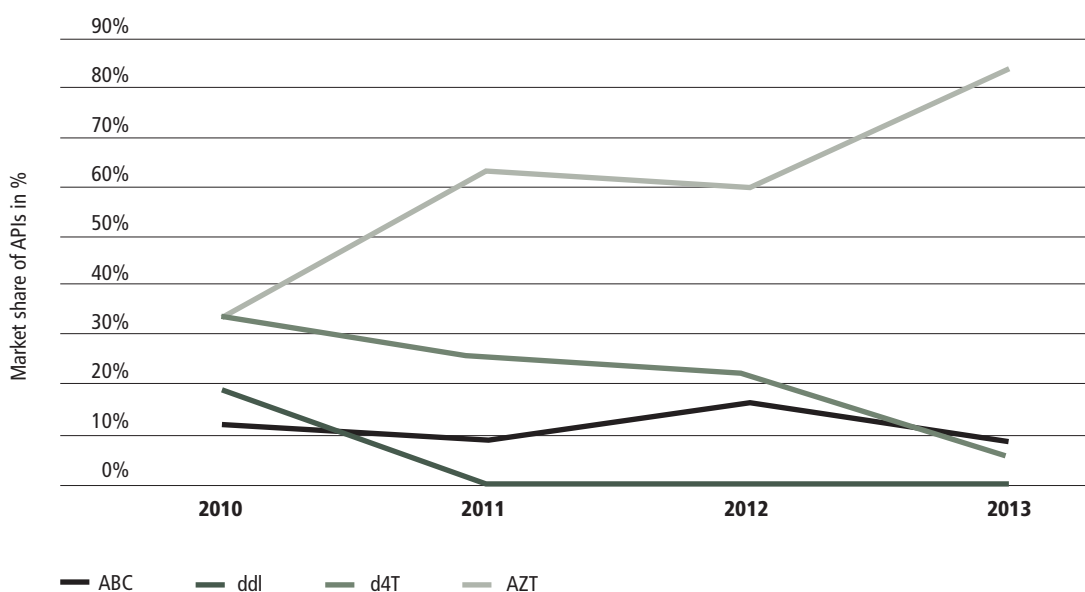
Figure 8. Second-line regimens used in 2012 for children in lower middle-income countries: 4.4% of children on ART (n = 15 324)



3. Boniface Dongmo-Nguimfack (HIV Technologies and Commodities, WHO) presented the trends of paediatric formulations uptake from the GPRM database. The

market share of AZT in 2013 was over 80% in recent transactions (Fig. 9).

Figure 9. Market share per API for nucleoside reverse transcriptase inhibitors



4. The detailed projections and related volume of ARV demand by 2016 were presented by John Stover (Vice President, Futures Institute) on behalf of the ARV Demand Forecasting Technical Working Group. The forecasts are based on data obtained from: the annual WHO survey on ARV use; transaction data from the GPRM database; CHAI projections; UNAIDS estimates of paediatric ART needs; and the Global Fund quantification data for 2014 and 2015. UNAIDS has estimated the ART needs for children aged 0–14 years by 2020 based on three scenarios:
- the “constant” scenario where prevention of mother-to-child transmission (PMTCT) remains at 64% coverage and the ART coverage remains at 35%;
 - the “likely” scenario where PMTCT coverage is 88% and the ART coverage is 77%;
 - the “maximum” scenario with a PMTCT coverage of 95% and an ART coverage of 100%.

UNAIDS estimates show that new HIV infections in children will continue to decline but ART needs will continue to increase due to the cumulative effect of children in need of ART, as well as the infections that will continue to occur (almost 5%) no matter how much effort of prevention the national HIV programmes can do. Based on UNAIDS estimates, 2.2 million children will need ART by 2016 and, based on the three different approaches used to produce the forecasts, only 1.08 million children are projected to be on ART in 2016.

Figure 10. Number of children on ART. Country target, linear and CHAI projections

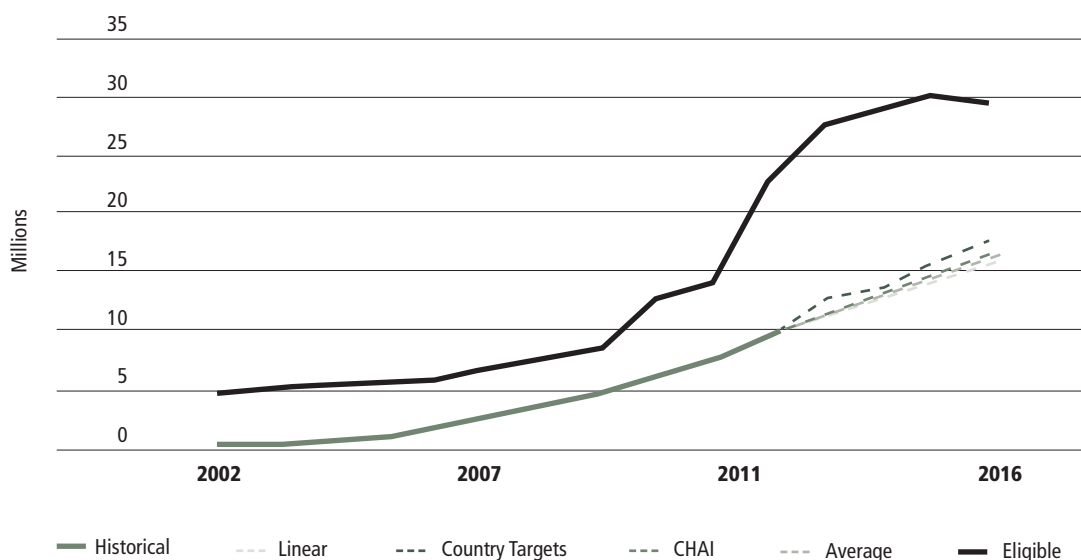


Figure 10 shows that the need for paediatric ART is well above the current and projected future demand for ART and there is therefore ample space to develop formulations for paediatric ART.

Suggestions from the discussion

- In view of the small number of children on ART, pooled procurement could speed up the production of key products, as well as minimize the risk of stock outs.
- Projection by age group 0–3 years, 3–10 years and 10–14 years was suggested. The lack of data on the age of children using ART makes this impossible, but these data may become available in the future if national paediatric ARV reporting systems adopt these three age groups of children.
- To prevent stock outs of paediatric ARVs, it was suggested to manufacturers to maintain stock piles

in their warehouses. It was mentioned that having stock piles for eventual orders is possible but the current 80% shelf life requirement is a real barrier to solving country problems. The policy brief on shelf life, accompanied by operational intervention at country level to change country procurement practices and counterproductive procurement policies requiring longer shelf life, has been discussed in early November 2013 at UNICEF in Copenhagen by the Interagency Pharmaceutical Coordination group, which consists of United Nations agencies and the Global Fund, the GAVI Alliance, the European Commission and the International Pharmaceutical Federation. Its finalization needs to be accelerated. During this forecasting meeting, the view was expressed that requiring 80% of the total shelf life for medicines that will be consumed in less than 12 months is counterproductive. Participants suggested that the Global Fund, SCMS, UNICEF and WHO work together to increase countries'

capacity and flexibility in the interpretation of their procurement guidance.

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

- The 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.
- The demand for paediatric ARV formulations will increase in the foreseeable future, even if new HIV infections decline, due to PMTCT scale-up.
- The ARV Demand Forecasting Technical Working Group is developing a longer-term perspective of drugs that will be needed in the future. There is a need to be more speculative to help manufacturers in their investment to innovate and produce new formulations.
- The IATT paediatric formulation list is welcomed as an approach to rationalize procurement of paediatric ARVs in particular, as this market is too fragmented. The pooled procurement approach proposed by the Paediatric ARV Procurement Working Group was welcomed.
- The lack of data from big ARV consumers, such as South Africa and India, needs to be addressed in future forecasts.

Session IV. Panel discussion on addressing challenges of procurement and supply chain management to improve access to ARVs: regulations, financial resources and procurement mechanisms

Chaired by David Jamieson (Deputy Director, SCMS), this session started on Day 2 and covered the following topics: regulatory and quality assurance aspects; financing and resources available to meet the global ARV demand; and procurement policies.

- Lembit Rägo (Coordinator, Quality Assurance and Safety: Medicines, Department of Essential Medicines and Health Products, WHO) presented the activities that WHO is undertaking to facilitate WHO prequalified medicines following an accelerated registration procedure at country level. The aim is to reduce the current lengthy registration procedures, thus allowing accelerated access to good-quality and sometimes lower-price medicines. Lembit Rägo gave updates on the prequalification of medicines, vaccines, and diagnostics and devices. WHO ensures that medicines procured with international funds
- are assessed and inspected for quality, efficacy and safety, which involves a prequalification programme for medicines (finished pharmaceutical products), prequalification of APIs, and prequalification of quality control laboratories. A prequalification programme is a powerful and effective mechanism to promote access to quality medical products. The prequalification programme is an action plan for expanding access to priority essential medicines in the following four areas: HIV/AIDS, tuberculosis, malaria and reproductive health. Diagnostics are now under the same WHO prequalification programme.
- Michael Johnson (Global Fund Attaché to the OGAC) and Christine Malati (Pharmaceutical Advisor, USAID) discussed the contribution of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) to the scale-up of ART. PEPFAR continues to secure 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 shift resources to treatment to meet coverage gaps, and to maintain the scale-up in coordination with other donor partners. PEPFAR was actively engaged with WHO in creating the 2013 guidelines. Christine Malati highlighted that continued attention to efficiency as illustrated by the continued decline of costs per patient treated, will enable even greater health impacts in the future. Recently, the United States Congress passed the Bill of PEPFAR Stewardship and Oversight Act of 2013, reaffirming its strong commitment to attaining an AIDS-free generation. The Bill also extended to contribute to the Global Fund.
- Martin Auton (Senior Specialist, Lead – HIV Portfolio, Global Fund) presented the financial review of current Global Fund investments in the HIV portfolio. In 2014, pledges are expected to increase as grants are coming up for renewal and signing: US\$ 15 billion is the target for HIV, tuberculosis and malaria. The Global Fund covers over 5 million of the 9.7 million people on ART. The Global Fund has large investments in ART, but at the same time the institution has encouraged domestic government contributions to ensure sustainability and to achieve the target of 15 by 15. Value for money, result-focused, transparency and efficiency continue to be the principles in Global Fund supported programmes.
- Robert Matiru (HIV Portfolio Manager, UNITAID) discussed the six strategic objectives of the UNITAID strategy 2013–2016. The various projects supported by UNITAID and partners working closely with UNITAID to fight HIV were elaborated. Various innovative mechanisms are used by UNITAID to raise funds required to support public health programmes,

including notably the air ticket levy that accounts for 65% voluntary contributions. UNITAID's grant is mostly to low-income countries (94 countries worldwide).

- Peter Ghys (Chief, Data for Action, UNAIDS) presented the international and domestic financial outlook for ART programmes. Treatment-related expenditures accounted for 54% of HIV expenditures in 2012 and US\$ 18.9 billion was available for HIV, of which domestic funding accounted for half. In the Southern African subregion (dominated by South Africa) and in the Latin American region, domestic funding for HIV/AIDS is considerably higher than international funding, while in other subregions of sub-Saharan Africa and in the Caribbean, dependency on international support for treatment is still very high. According to the new 2013 WHO guidelines, 28.6 million people in low- and middle-income countries are eligible for ART, which implies the need for additional resources. With treatment optimization, it is expected that HIV programmes will be more efficient, evidence based, and deliver better value for money services. WHO/UNAIDS will continue making the case to invest in ART by setting global targets, advocating for efficiencies, and providing guidance and technical support to countries for achieving their ART targets.
- Christopher Game (Chief Procurement Officer, Global Fund) made a presentation on the Global Fund's procurement initiatives to improve the current situation, which shows an on time and in full (OTIF) rate of only 36.8%. Using the private sector experience of better performance on OTIF, he presented what could be learned and applied to improve the situation. He highlighted the required changes in the ways the Global Fund used to do business in order to improve the situation for better performance in supply chain management. He highlighted the major principles of the approach:
 - earlier involvement and closer collaboration with manufacturers;
 - improving our purchasing capability and changing our contracting models;
 - optimizing the international supply chain to reduce cost;
 - better planning and scheduling to support continuity of supply;
 - delivering more products at the right time and place to more people.
- Martin Auton (Senior Specialist, Lead – HIV Portfolio, Global Fund and Chair for the Paediatric ARV Procurement Working Group) presented paediatric ARVs: promoting optimal ARV formulations and coordinated procurement. He showed the role of the Paediatric ARV Procurement Working Group procurement consortium, which coordinates orders across various funding and procurement mechanism,

including the Global Fund, PEPFAR/SCMS, UNICEF and UNITAID/CHAI. In 2013, 64 countries, including 51 with Global Fund grants, procured through this mechanism with shorter lead-times and more reliable supply being achieved. The 51 countries with Global Fund grants represent 29% by value of the Global Fund volumes with four other countries (Ethiopia, India, Kenya and South Africa) being responsible for the majority of the rest. The Paediatric ARV Procurement Working Group is engaging with these countries and also other funders and procurers to either participate in or align their timing with the consortium's coordination efforts.

Suggestions from the discussion

- Innovators would like to get products faster into the markets through collaboration with regulatory authorities and suggested to meet with the WHO prequalification programme to discuss how they could increase their cooperation.
- The civil society suggested to continue collaborations with manufactures to obtain reduced prices on ARVs and diagnostics for low-income and lower middle-income countries.
- Participants noted the need to continue advocacy for increased domestic financing to ensure sustainable national HIV programmes, as well as the need for the international community to support countries in using effectively HIV-allocated funds to reach the objective of 15 million people on ART by 2015.

Session V. Looking forward

In the last session, chaired by Joseph Perriens (Coordinator, HIV Technologies and Commodities, WHO), Meg Doherty (Coordinator, HIV Treatment and Care, WHO) presented WHO's normative ARV agenda for 2014–2015. She mentioned that the target product profile should have the following characteristics: tolerability (low incidence of side effects and toxicities, relationship to adherence); resistance (high barrier to resistance); convenience (once-daily dosing, low pill burden, no cumbersome testing requirements); special populations (pregnant women, HIV/TB, hepatitis B virus/hepatitis C virus, coinfection and children) and affordable costs.

For first-line ART, she noted that during the Second Conference on Antiretroviral Drug Optimization, chaired by CHAI and Pangaea with WHO participation, tenofovir alafenamide/ emtricitabine or lamivudine/dolutegravir (TAF/XTC/DTG) with a target cost per person per year of US\$ 50, and tenofovir alafenamide/emtricitabine or lamivudine/efavirenz (TAF/XTC/EFV) (400 mg), with a target cost per person per year of US\$ 70, could be potential future alternatives to tenofovir disoproxil fumarate/emtricitabine or lamivudine/efavirenz (TDF/XTC/EFV). However, since

these drug combinations have not yet been studied nor are they available in the market, these price points and FDCs are goals for future drug optimization studies. For second-line adult ART, Meg Doherty noted that the Second Conference on Antiretroviral Drug Optimization proposed the following future optimized ARV drugs: DRV/r to replace ATV/r or LPV/r, and an FDC one pill a day second-line ART such as DRV/r/DTG at a targeted cost of US\$ 250 per person per year.

Meg Doherty also discussed the Paediatric Antiretroviral Drug Optimization meeting in Dakar, which covered mainly the estimates of new HIV infection among children 0–14 years, projections of paediatric ART needs by 2020, and a review of the IATT paediatric ARV formulary list as a basis to guide countries and partners in the procurement of paediatric ARV formulations. The need for new paediatric ARV formulations was also discussed. However, in order to increase access to new ARV formulations for adults and children, there is a need to take into consideration patent and registration issues, in addition to the target product profile characteristics discussed above.

Suggestions from the discussion

- Robust and wider-target product profile new ARV drugs for first- and second-line ART are needed for adults and children.
- ARV manufacturers appreciated that the ARV development pipeline was discussed, as it guides them for investment in development of new ARV formulations.
- The need for support to manufacturers to do more clinical trials in paediatric ART was noted.
- The need for exchange of information on recommendations made by the Second Conference on Antiretroviral Drug Optimization and the Paediatric Antiretroviral Drug Optimization meetings was noted.
- Funding organizations were advised to increase their contributions for the production of new ARV formulations that meet the target product profile.

ANNEX I. FINAL AGENDA

DAY 1: Monday, 25 November 2013

| Time | Agenda item | Presenter |
|-------------|---|---|
| 08:45–09:00 | <i>Registration</i> | <i>All participants</i> |
| 09:00–09:30 | Welcoming remarks Objectives of the consultation Introduction of participants Designation of Chair | Hiroki Nakatani Assistant Director-General, HIV/AIDS, TB, Malaria and Neglected Tropical Diseases, WHO Mariângela Simão Director, Rights, Gender and Community Mobilization Department, UNAIDS Joseph Perriëns Coordinator, HIV Technologies and Commodities, WHO |
| 09:30–10:30 | I. Panel on achieving universal access: global guidance for innovation | Chair: Joseph Perriëns Coordinator, HIV Technologies and Commodities, WHO |
| | Progress on ART coverage: update on 15 million by 2015 and beyond, taking into account the 2013 WHO consolidated guidelines on the use of ARV drugs for treating and preventing HIV infection: what is new (20 minutes) | Meg Doherty Coordinator, HIV Treatment and Care, WHO |
| | Update on the UNAIDS Treatment 2015 Initiative (20 minutes) | Badara Samb Chief, Global Outreach and Special Initiatives, UNAIDS |
| | <i>Discussions: questions and answers</i> | <i>All participants</i> |
| 10:30–11:00 | <i>Coffee/tea</i> | |
| 11:00–13:00 | II. WHO and UNAIDS forecasts of ARV global demand 2013–2016: adults | Chair: Joseph Perriëns Coordinator, HIV Technologies and Commodities, WHO |
| | Results of the 2013 WHO survey on ARV use for adults and trends of adult ARV regimens and APIs from previous surveys (15 minutes) | Vincent Habiyambere HIV Technologies and Commodities, WHO |
| | Trends of adult formulations uptake from the GPRM database (15 minutes) | Boniface Dongmo-Nguimfack HIV Technologies and Commodities, WHO |
| | Consolidated forecast of global ARV demand for adults: scenarios, data and forecasts 2013–2016 (30 minutes) Comments from member organizations of the ARV Demand Forecasting Technical Working Group | John Stover Vice President, Futures Institute, on behalf of the ARV Demand Forecasting Technical Working Group: CHAI, SCMS, Global Fund, UNICEF, UNAIDS |
| | <i>Discussions: questions and answers</i> | <i>All participants</i> |
| 13:00–14:00 | Lunch break | |
| 14:00–16:00 | III. WHO and UNAIDS forecasts of ARV global demand 2013–2016: paediatric and global APIs demand forecast | Chair: Joseph Perriëns Coordinator, HIV Technologies and Commodities, WHO |

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|-------------|--|---|
| | Paediatric ARVs: promoting optimal paediatric ARV formulations and coordinated procurement | David Jamieson Deputy Director, SCMS, on behalf of the IATT Paediatric Working Group |
| | Results of the 2013 WHO survey on ARV use for paediatric ART and trends of paediatric ARV regimens and APIs (15 minutes) | Vincent Habiyambere HIV Technologies and Commodities, WHO |
| | Trends of paediatric ARV formulation uptake from the GPRM database (15 minutes) | Boniface Dongmo-Nguimfack HIV Technologies and Commodities, WHO |
| | Consolidated forecasts of global ARV demand for children: scenarios, data and forecasts, 2013–2016 Comments from the member organizations of the ARV Demand Forecasting Technical Working Group | John Stover Vice President, Futures Institute, on behalf of the ARV Demand Forecasting Technical Working Group: CHAI, SCMS, Global Fund, UNICEF, UNAIDS |
| | <i>Questions and answers (30 minutes)</i> | <i>All participants</i> |
| | Wrap-up of the day | Joseph Perriens Coordinator, HIV Technologies and Commodities, WHO |
| 16:00–16:30 | Coffee/tea | |

DAY 1: Tuesday, 26 November 2013

| Time | Agenda item | Presenter |
|------------|---|---|
| 9:00–10:30 | IV. Panel discussion on addressing challenges of procurement and supply chain to improve access to ARVs | Chair: David Jamieson Deputy Director, SCMS, on behalf of the IATT Paediatric Working Group |
| | 1. Regulatory and quality assurance aspects | |
| | Update on WHO prequalification programme and drug regulatory strengthening: progress, challenges and way forward (20 minutes) | Lembit Rago Head of Unit, Regulation of Medicines and other Health Technologies, Department of Essential Medicines and Health Products, WHO |
| | 2. Financial contributions | |
| | PEPFAR's Contribution to the scale-up of ART (15 minutes) | Michael Johnson Global Fund Attaché to the OGAC Christine Malati Pharmaceutical Advisor, USAID |
| | Global Fund grants to scale up access to ART (15 minutes) | Martin Auton Senior Specialist, Lead – HIV Portfolio, Global Fund |
| | UNITAID's 2013–2016 strategy and its market-shaping role in bridging the current gap towards universal access to ARV treatment (15 minutes) | Robert Matiru HIV Portfolio Manager, UNITAID International Drug Purchase Facility |

| | | |
|-------------|---|--|
| | International and domestic financial outlook for ART Programmes (15 minutes) | Peter Ghys Chief, Data for Action UNAIDS |
| | <i>Plenary discussions</i> | <i>All</i> |
| 10:30–11:00 | Coffee/tea | |
| 11:00–11:30 | 3. Procurement Initiatives | |
| | Evolution of Global Fund procurement strategies (20 minutes) | Christopher Game Chief Procurement Officer, Global Fund |
| | Paediatric ARV Procurement Working Group and coordinated ordering (20 minutes) | Martin Auton Senior Specialist, Lead – HIV Portfolio, Global Fund and Chair of Paediatric ARV Procurement Working Group |
| | Questions and answers | All participants |
| 11:30–12:30 | V. Looking forward | Chair: Joseph Perriëns Coordinator, HIV Technologies and Commodities, WHO |
| | WHO's normative agenda for 2015 (20 minutes) | Meg Doherty Coordinator, HIV Treatment and Care, WHO |
| | <i>Questions and answers (30 minutes)</i> | <i>All participants</i> |
| | Closing remarks | Joseph Perriëns Coordinator, HIV Technologies and Commodities, WHO Carlos Passarelli Senior Expert Treatment, Science for Action/Evidence, Innovation, Policy, UNAIDS |
| 12:30–13:30 | Lunch break | |
| | | |
| 14:00–17:00 | Individual meetings with companies and staff from WHO, UNAIDS and other partner organizations Meeting rooms located on 4th floor (D44020, D45022, D45043, D45044) | |

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ISBN 978 92 4 150698 4



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