TECHNICAL REPORT

MEETING REPORT

AIDS MEDICINES AND DIAGNOSTICS SERVICE

JOINT WHO/UNAIDS ANNUAL MEETING WITH PHARMACEUTICAL COMPANIES AND STAKEHOLDERS ON GLOBAL FORECASTS OF ANTIRETROVIRAL DEMAND FOR 2014-2018 AND PROJECTION MODELLING OF NEW ANTIRETROVIRAL FORMULATIONS FOR 2015–2024 AND UPDATE ON HEPATITIS B AND C

OCTOBER 2015

World Health Organization

HIV/AIDS Programme

UNAIDS

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CONTENTS

LIST OF FIGURES

ABBREVIATIONS AND ACRONYMS

3TC	lamivudine
ABC	abacavir
ACT	Accelerating Children's HIV/AIDS Treatment
API	active pharmaceutical ingredient
ART	antiretroviral therapy
ARV	antiretroviral
ATV	atazanavir
AZT	zidovudine
CD4	cluster of differentiation 4
CHAI	Clinton Health Access Initiative
d4T	stavudine
ddI	didanosine
DNDI	Drugs for Neglected Diseases Initiative
DRV	darunavir
DTG	dolutegravir
EFV	efavirenz
ETV	etravirine
FDC	fixed-dose combination
FTC	emtricitabine
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GPRM	Global Price Reporting Mechanism
IAS	International AIDS Society
IATT	Interagency Task Team for the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Children
IDV	indinavir
LPV/r	lopinavir/ritonavir
MSF	Médecins sans Frontières
NNRTI	non-nucleoside reverse-transcriptase inhibitors
NRTI	nucleoside reverse-transcriptase inhibitors
NVP	nevirapine
OGAC	Office of the U.S. Global AIDS Coordinator
PAPWG	Paediatric ARV Procurement Working Group
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
USFDA	United States Food and Drug Administration
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 organize an annual meeting with pharmaceutical companies and stakeholders to discuss antiretroviral (ARV) drug demand forecasts for adults and children. These forecasts, developed by an ad-hoc multi-agency technical working group, are based on current consumption and likely future uptake indicated by observed upward or downward trends in response to new WHO policy guidelines and other market factors.

The March 2015 meeting went beyond the usual three-year forecast by including a model of new ARVs that will be needed up to 2024. This was deemed useful as it would accelerate access to new treatments by patients if producers were aware of the type and quantities of new ARVs needed, leading to a reduction in the time required for production and regulatory approval of new ARV formulations.

For the first time this year, the meeting also included a discussion on hepatitis B and C medicines. WHO's Global Hepatitis Programme is housed in WHO's HIV Department, and in view of the dynamic developments in treatment options for these infections, it was deemed important to inform pharmaceutical companies and stakeholders of WHO's perspectives and plans in the area of hepatitis treatment.

The meeting was held on 19–20 March 2015 in the UNAIDS Kofi A. Annan Conference Room at WHO Headquarters in Geneva.

The main objectives of the meeting were to:

- present an update on ARV policy guidelines and new procurement and treatment initiatives
- present ARV market trends and global ARV demand forecasts for 2014–2018 for adult and paediatric patients
- present ARV market trends and global projection modelling of new ARV formulations for 2015–2024 for adult and paediatric patients
- present the situation on domestic and international financial resources for ARVs, and
- present an update on hepatitis B and C treatment recommendations and provide an overview of the hepatitis-treatment landscape.

The meeting brought together innovators and generic producers, active pharmaceutical ingredient (API) producers, and partner organizations. The list of participants is in Annex II.

The opening remarks were delivered by Gottfried Hirnschall, Director, HIV, WHO, and Peter Ghys, Director, Strategic Information and Evaluation, UNAIDS.

In his opening remarks, Gottfried Hirnschall, Director, HIV, WHO, noted that the meeting comes at a critical time for meeting the targets for treatment by 2015, and at a time when new goals, such as 90-90-90 are being set whose targets will require massive treatment and scale up. Hepatitis is starting to receive more attention and WHO's work on hepatitis B and C has been strengthened. He thanked the ARV Demand Forecasting Technical Working Group for the coordinated efforts to produce the global ARV demand forecasts, and welcomed all participants.

Peter Ghys, Director, Strategic Information and Evaluation, UNAIDS, welcomed the participants and noted that the number of people on ART continues to increase, adding that they will be on target for the 2015 goal for treatment access, but that the number of people on treatment will need to more than double to reach the 90-90-90 targets.

To achieve these targets it will be important to ensure equity in treatment between adults and infants on one hand, and between different subpopulations on the other. Local production of ARVs, notably in the sub-Saharan African region, needs to be considered to support treatment scale-up efforts. Innovation, particularly in the delivery models of treatment, is required to reach the ambitious treatment goals.

Joseph Perriëns, Coordinator, HIV Technologies and Commodities, WHO, introduced the agenda. He emphasized that even though the 90-90-90 targets were ambitious, they will likely be met. He drew attention to the fact that while WHO and UNAIDS are convening this meeting, it would have been impossible to present the substance of the agenda without the input of the members of the ARV Demand Forecasting Technical Working Group. This Working Group includes, in addition to WHO and UNAIDS, Clinton Health Access Initiative (CHAI), the Global Fund, the Medicines Patent Pool, the Partnership for Supply Chain Management of PEPFAR, the United Nations Development Programme (UNDP), the United Nations Children's Fund (UNICEF), UNITAID and the United States Agency for International Development (USAID), and benefited from the input of Avenir Health.

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

2. MEETING SESSIONS

This report focuses on what was discussed during the meeting; details of each presentation can be accessed at http://www.who.int/hiv/amds/ARV-forecasting-meeting-2015/en/.

SESSION 1: Panel on Achieving Universal Access: Global guidance for innovation

Chaired by Gottfried Hirnschall, Director, HIV, WHO, this session included an overview of guidelines, presented by Meg Doherty, Coordinator, HIV Treatment and Care, WHO; and an update on hepatitis B and C treatment guidelines with an overview of the hepatitis-treatment landscape, presented by Philippa Easterbrook, Global Hepatitis Programme, WHO.

The 2013 ARV guidelines have been well received across all WHO regions, but viral load testing coverage is still low and not implemented in many countries. Once-a-day regimens and fixed-dose combinations (FDCs) are increasingly being used. WHO is promoting harmonization of paediatric treatments. The ENCORE trials are looking at various dosage possibilities, but more studies are needed, especially for paediatric treatments and their comparisons. Prices of FDC medicines remain high, especially in middle- and high-income countries. WHO's anticipated ART guideline updates can be found in the link mentioned above.

There is a lack of data on several new hepatitis drugs and defining where treatment of hepatitis should be delivered in health systems is a challenge. Although, unlike HIV, there is no global fund to support the efforts against hepatitis, the disease is moving fast on the global agenda. As for preventive measures for hepatitis, there has been a major scale up of childhood vaccination. Although there are notable successes in some countries, overall the coverage of birth dose vaccination is still too low.

Guidelines on hepatitis C were launched in April 2014, and will be updated by the end of 2015. The focus will likely remain on treating people with advanced disease and cirrhosis as a priority. Major challenges are low rates of diagnosis and awareness of the disease; and major barriers to access to treatment of hepatitis are lack of testing and screening. For the first time ever, global hepatitis targets are being developed by WHO, with a vision towards elimination of hepatitis B and hepatitis C as public health threats by 2030.

Discussion

Gottfried Hirnschall assured participants that WHO is looking at new issues that could be added to the guidelines and that they will be revised accordingly. He also pointed out that the issue of raising the eligibility threshold is under consideration, and what that might mean in terms of treatment.

A civil society participant proposed a measure of equity for key population groups, noting that some subpopulations in middle-income countries are left out because they do not fall in any priority population groups.

SESSION 2: WHO and UNAIDS forecasts of ARV global demand 2014–2018 and modelling projections of new ARV formulations 2015–2024 for adults

I) WHO and UNAIDS forecasts of ARV global demand 2014–2018 for adults

Chaired by Joseph Perriëns, Coordinator, HIV Technologies and Commodities, WHO, this session was opened by Vincent Habiyambere, HIV Technologies and Commodities, WHO, who presented the results of the 2014 WHO Survey on ARV use and the trends in regimens and APIs from previous surveys. This survey covered 77 countries (10 million people), home to about 90 % of patients on ART at the end of 2013. He shared with participants the proportions of adults on different regimens by the end of 2013, showing those regimens that are frequently and less frequently used.

In the period under review (2008–2013), the uptake of tenofovir disoproxil fumarate (TDF) has increased, and the use of stavudine (d4T) has decreased dramatically in the 18 countries that have been followed since 2008 and where complete reports are available for each year. These countries comprise: Botswana, Burkina Faso, Burundi, Cambodia, Cameroon, China, Ethiopia, Ghana, Iran, Kenya, Malawi, Namibia, Nigeria, Democratic Republic of Congo, Uganda, Ukraine, Zambia and Zimbabwe. For details on this presentation, please see the link mentioned above.

Boniface Dongmo-Nguimfack, HIV Technologies and Commodities, WHO, presented the trends in the uptake of adult formulations from the Global Price Reporting

Mechanism (GPRM) database. This database covers about 74% of ARVs procured by low- and middle-income countries in 2013. The figures are broadly consistent with the ARV survey data, but the uptake of d4T is lower and that of TDF higher in GPRM than in the ARV survey. However, data for 2014 are not complete, so the trends for 2014 require prudent interpretation.

Biyi Adesina, Avenir Health, presented the consolidated forecast of global ARV demand for adult ART for 2014–2018 on behalf of the ARV Demand Forecasting Technical Working Group. Data sources include:

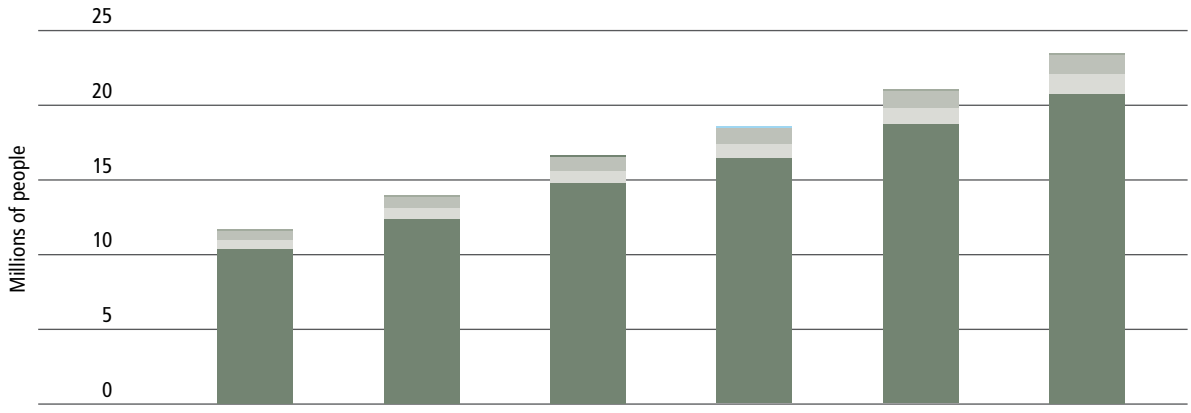
- WHO ARV Survey
- GPRM procurements
- CHAI forecasts
- UNAIDS estimates of need for ART
- Global Fund quantification of ARV use for 2014 and 2015, and
- Supply Chain Management System (SCMS) quantification for PEPFAR for 2015 and 2016.

The methods used to forecast the number of patients who need ART up to 2018 include four scenarios:

- Linear extrapolation: linear extrapolation over the last three years of UNAIDS/WHO reported data on the number receiving ART in 154 low- and middle-income countries (LMICs).
- Country targets: ARV demand up to 2020 extrapolated from 2013 baseline demand using national targets stated by 46 countries, from the 2013 WHO ARV survey, scaled up to all LMICs.
- Fast track: 90% of people living with HIV (PLHIV) identified and started on treatment, 90% retained on treatment by 2020.
- CHAI projections: linear extrapolation of trends from the last three years for the 21 highest burden countries, plateauing at universal access under existing WHO guidelines, then scaled up to all LMICs.

Fig. 1 shows the number of patients forecasted to be on ART up to 2018 and the demand for different ARVs different APIs in metric tonnes. For details, follow the link to all the presentations.

Fig. 1. Number of people to be on ART (average of the linear, country target and CHAI scenarios)



	2013	2014	2015	2016	2017	2018
Children SL	37 000	46 000	54 000	61 000	69 000	83 000
Children FL	700 000	840 000	950 000	1 040 000	1 130 000	1 320 000
Adult SL	550 000	680 000	840 000	970 000	1 100 000	1 300 000
Adult FL	10 400 000	12 400 000	14 800 000	16 500 000	18 800 000	20 800 000

Conclusions, for the adult API market, are:

- There will be continued growth in the number of people on ART, adding about 1.5 million per year;
- There will be a slow but steady increase in the proportion of adults on second-line regimens;
- The largest volume gains will be for TDF, efavirenz (EFV), emtricitabine (FTC), lamivudine (3TC) and zidovudine (ZDV); and
- Demand for atazanavir (ATV) is projected to grow, but lopinavir (LPV) is expected to retain the majority of the protease inhibitor (PI) market.

Biyi Adesina's presentation was complemented by that of Joseph Perriëns, WHO, which showed the forecast uptake of different ARV formulations in 2015 and 2016. Two data sources were used: one an extrapolation of the quantifications of ARV procurement by the Global Fund and SCMS for 2015 and 2016, to the total size of the low- and middle-income country market in corresponding years, and the other a similar forecast produced by CHAI for the same years.

While trends in the uptake of different formulations were in most cases the same in both sources, there were important differences in the volumes forecast for several key formulations. This can be attributed to the inclusion of different countries in the two data sets. The CHAI quantifications include South Africa and Thailand, both of which have significant volumes, whereas the Global Fund and SCMS quantifications do not include these countries, but there could be additional explanations. An assessment of country-by-country comparisons and consolidation of the two data sources will be presented at the IAS 2015 conference.

II) Modelling projections of new ARV formulations 2015–2024 for adults

Vineet Prabhu, CHAI, reported on modelling the uptake of new ARV formulations for adults for 2015–2024. Three levels of uptake of new products – aggressive, moderate and conservative – were considered. Three variables – anticipated price differential, relative clinical improvement and anticipated launch year – were considered in deciding which uptake trajectory should be assumed.

Tenofovir alafenamide (TAF) is expected to rapidly account for the vast majority of first-line tenofovir patients, although there are other considerations for the first-line TAF forecast, including:

- Timing of TAF launch in LMICs (i.e. generic SRA approval, inclusion in WHO guidelines) is highly dependent on the availability and acceptability of clinical data from cobicistat un-boosted studies.
- Dose -reduced TDF has the potential to provide a cost-saving bridge to eventual availability of TAF, but clinical data are not yet available.

On the replacement of EFV 600 mg and nevirapine (NVP), by EFV 400 mg and dolutegravir (DTG), DTG is likely to represent the majority of first-line patients who would have otherwise been on non-nucleoside reverse-transcriptase inhibitors (NNRTIs). Forecast results for first-line DTG and EFV 400 mg should be treated with caution because uptake will depend on the timing of the DTG launch in LMICs. It is also highly dependent on the availability and acceptability of clinical data from studies with tenofovir; one of the assumptions made is that licensing agreements will allow combination with all current and future first-line backbone agents, including TAF.

The replacement of all second-line TDF and AZT treatment by DTG (likely by 2025) will likely depend on whether DTG is included as an alternative option in the 2015 guidelines, leading to some use in LMICs prior to 2017. However, uptake of second-line DTG will be even faster if FDCs with PIs (one pill once-a-day) become available, further reducing the pill burden relative to today's second-line regimens (2 pill minimum).

On replacing adult atazanavir/ritonavir (ATV/r) and lopinavir/ritonavir (LPV/r) by darunavir/ ritonavir (DRV/r), DRV/r could represent the majority of second-line PI patients by 2025, but there are considerations to be taken into account; for instance, uptake of DRV/r is highly dependent on presumed price reductions to achieve compared to ATV/r; and timing of use in LMICs assumes promotion of DRV/r to preferred/alternate in the WHO guidelines.

Even faster uptake of DRV/r is possible if:

- Dose reduction efforts work out, further reducing the price, and
- FDCs with DTG and TDF/3TC and/or TDF/FTC become available, further reducing pill burden relative to incumbent second-line regimens (2 pill minimum).

Fast/first movers will the benefit from opportunity presented by these products as current drugs are replaced by cheaper and more efficacious products, and encourage manufacturers to position themselves favourably by securing timely SRA approvals and country registrations, and preparing production capacity as necessary. Even though several products are identified with clinical and price benefits, the rate of uptake will be highly dependent on the timely inclusion in the WHO guidelines.

Aastha Gupta, MPP, gave a presentation on modelling the uptake of new ARV formulations for adults for 2015–2024 on behalf of the Working Group. The lack of visibility causes a gap between demand and generic production for

new drugs and creating early visibility of demand through forecasts can speed the benefits of generic competition.

Three scenarios were used to estimate the future use of ART:

- The 'status quo' scenario, in which the WHO guidelines do not change. When new products are introduced, they only show a marginal uptake. Integrase inhibitors are limited to third-line treatment.
- In a second scenario, the WHO guidelines accept and recommend new products using the treatment optimization framework, so new products have a good uptake. Assuming that new FDCs such as those containing DTG, TAF and heat stable DRV/r are made available as generics, and the use of integrase inhibitors is recommended as preferred options in second- and third-line treatments in initial years, later moving to first-line use as more safety data become available.
- In the third scenario, WHO guidelines recommend aggressive use of new products, and use of integrase inhibitors as the preferred option is recommended for first-line use.

MPP presented the number of people living with HIV projected to be on new ARV formulations from 2018–2024. Discussions raised a number of issues:

- The 2018-2020 projections will be affected by the recommendations in WHO ARV guidelines.
- The decreasing level of international funding for HIV, including from the Global Fund may affect the projected demand for ARVs.
- Noting the very small volumes of didanosine (ddI) being used in both the CHAI and WHO/Global Fund/SCMS quantifications, and that the drug is no longer recommended in any WHO guideline on the use of ART, it was suggested to phase out ddI.
- Clarification was requested on whether prices were considered in the modelling (this is considered in the CHAI model as one of the decision parameters, but not in the MPP model). The factor of how long it takes for an old product to exit from consumption practices needs to be taken into account when forecasting. This is the reason why WHO conducts ARV use surveys to inform the trend in ARV use. However, if the new product is significantly cheaper, then the old one is quickly replaced.
- Given that TDF is still used in three formulations there was concern that replacing TDF with TAF overnight would have a major impact on manufacturers currently producing TDF. Studies on TAF are ongoing and WHO will wait for their completion before making any recommendation on the use of TAF in WHO guidelines. Their completion will likely take several years.

SESSION 3: WHO and UNAIDS forecasts of ARV global demand 2014–2018 and modelling projections of new ARV formulations 2015–2024 for Children

I) WHO and UNAIDS forecasts of ARV global demand 2014–2018 for children

This session was chaired by Meg Doherty, Coordinator, Treatment and Care, WHO and opened with a presentation by David Jamieson, SCMS, on behalf of the Interagency Task Team for the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Children (IATT).

He summarized challenges, rationale for paediatric ARV formulary optimization, 2015 revised optimal and limited-use paediatric ARV formulations and the next steps. He noted that there are too many paediatric ARVs for a rather small population. The market risks for paediatric ARVs are:

- Inability to procure low-volume formulations, since highly fragmented low-volume products may not be supplied, for example nonessential products on the IATT list;
- Suppliers have lower incentives to register products in low-volume markets; and
- Limited new product options create further challenges to suppliers realizing a return on investment for new products.

Those most at risk are LMICs procuring a large number of formulations including multiple/redundant formulations, and/or drugs considered suboptimal that most countries have transitioned away from, for example liquid formulations and ddI.

The IATT optimal list includes the minimum number of ARV formulations needed to provide all currently preferred and alternative first- and second-line WHO-recommended regimens for all paediatric weight bands. The limited-use list includes formulations that may be needed during transition and/or for special clinical circumstances, and the nonessential list includes all other formulations not recommended for use.

The aim of the optimal list is to:

- address adherence and market challenges for paediatric HIV treatment;

- decrease pill burden and ease administration for caregiver and patient;
- promote adherence to simplified regimens, fewer bottles, fewer liquids, more temperature tolerance;
- improve availability by reducing complications in procurement, storage and distribution;
- simplify and clarify the market for suppliers; and
- decrease costs over time.

There has been a decrease in the number of formulations on the optimal list from 15 in 2011, to 10 in 2013 and 9 in 2015. Oral liquid AZT (50 mg/5 ml), and abacavir (ABC)/AZT/lamivudine (3TC) (60 mg/60 mg/30 mg), which were on the optimal list in 2013 have been removed from the 2015 list, and ABC/3TC (120 mg/60 mg) has been added.

For the limited-use list, the number of products increased from 11 in 2011 to 13 in 2013, and decreased again to 11 in 2015. Between 2013 and 2015, five products were removed – 3TC/30 mg tablet, TDF/40 mg/scoop, oral powder, TDF/150 mg unscored tablet, d4T/3TC/NVP 6 mg/30 mg/50 mg, tablet(dispersible, scored) and d4T/3TC, 6 mg/30 mg tablet(dispersible, scored). New products added to the limited-use list in 2015 are: AZT 50 mg/5 ml–100 ml, oral liquid, ABC, 60 mg tablet (dispersible, scored), and AZT 60 mg, tablet (dispersible, scored).

Details on the optimal list and limited-use list are found in the presentation in the link mentioned above.

IATT continually looks for new formulations and currently they are monitoring developments related to TDF 200 mg; ATV 100 mg and 150 mg; etravirine (ETV) dosage formulations (25 mg, 100 mg); LPV/r pellets – acceptability and effectiveness, abacavir (ABC) 60 mg and AZT 60 mg.

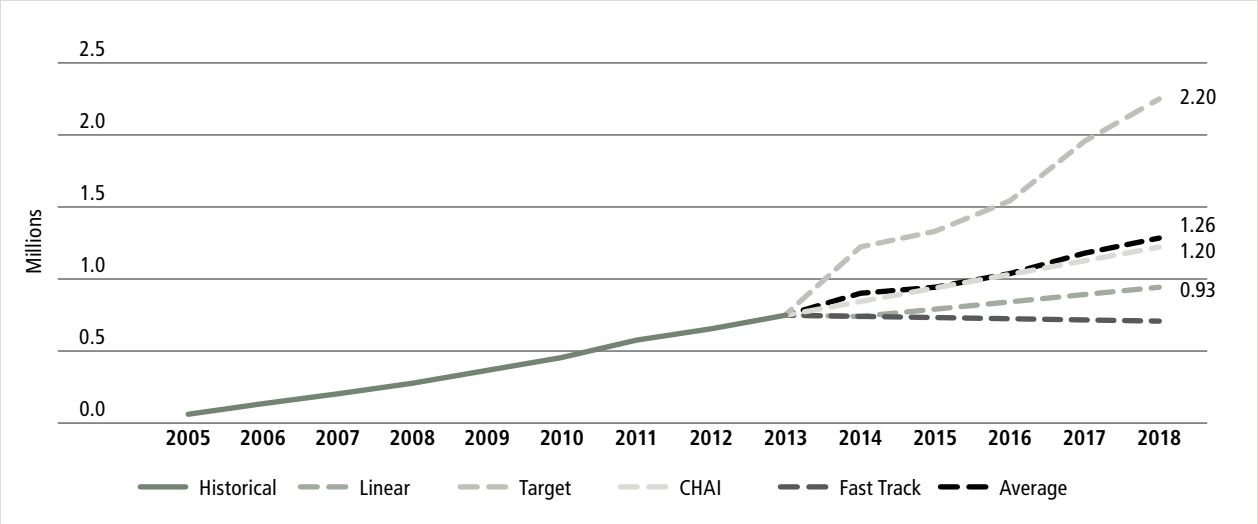
The next steps forward include publicizing the new lists, preparing additional communications for countries, working with manufacturers on supply challenges, coordinating with the PAPWG and other stakeholders to address outlier countries.

Vincent Habiyambere, WHO/HIV, presented the results of the 2014 WHO survey on ARV use and trends in paediatric regimens and APIs. There are big differences between adult and paediatric ARV use in the 77 countries which participated in the 2014 WHO survey on ARV use. The survey included 14 Pan American Health Organization (PAHO) countries and 63 from the rest of the world. PAHO, compared to the rest of the world had more infants on second-line treatments (55% on first-line, 43% on second-line treatments and 4% salvage, compared to rest of the world with 95.7% on first-line, 4.3% on second-line treatments and 0.01% salvage). More details on this presentation are found in the link mentioned above.

Boniface Dongmo-Nguimfack, WHO/HIV presented the trends in paediatric formulation uptake from the GPRM database, showing trends broadly similar to those reported in the ARV survey.

Biyi Adesina, on behalf of the ARV Demand Forecasting Technical Working Group, presented a consolidated forecast of global ARV demand for ART paediatric coverage 2014–2018. The number of children on treatment is expected to continue to expand in spite of reductions in new paediatric infections, and there will be gradual changes in market share for ARVs, except for d4T, the volume of which will decline sharply. Even with decreasing incidence of HIV in children, it is clear that between now and 2020, an important treatment gap remains; therefore, there will be ample space to increase the number of children on ART in the years to come (Fig. 2). These forecasts were developed before country scale-up plans were available from ACT. This factor will be taken into account in the 2016 updates of the global ARV forecasts.

Fig. 2. Number of children on ART; country target, linear and CHAI projections



II) Modelling projections of new ARV formulations 2015–2024 for children

Aastha Gupta, MPP, made a presentation on the uptake of new ARV drugs for children during 2015–2024 on behalf of the Working Group. As in the case of adult ARV use, three scenarios for paediatric ARV use were presented, which are well developed in the presentation found in the link where all presentations are located.

1. The status quo scenario

While considered less likely, in this scenario there is no recommendation by WHO to introduce new molecules. Consistent with current guidelines, the uptake of ABC increases, becoming the main first-line treatment; consequently, AZT becomes the preferred option in second-line treatment. Because generic manufacturers are already developing low-cost FDCs which may be compelling for potential use in developing countries, there is limited uptake of the newer drugs. There is minimal uptake of TAF for children <10 years.

2. Likely use scenario

In this scenario, INI is introduced in first and second-line treatment, and ABC becomes the main backbone in first-line ART. Due to the increased use of ABC in first line, AZT becomes the preferred option in second-line treatment, and therefore uptake of TDF and TAF is limited.

3. Aggressive adaptation scenario

In this scenario WHO obtains more data on INIs earlier and recommends its use earlier.

Discussion

On the issue of marginal products such as ddl, it was noted that, despite the optimal list of paediatric formulations, there will be countries that will continue to use obsolete products, which is also the case for adult ART. This is likely to be addressed as demand for and procurement of the obsolete drug will decrease over time and prescribers will switch patients to available drugs.

The incidence of HIV infection in children is declining, so the question was raised if there really is a need to double treatment figures. To this a member of the presenting group responded that the purpose of the model is to provide a range, bottom and top so that manufacturers can have the best and worst scenarios, but that the number of children needing treatment will in all likelihood increase within the time horizon (up to end 2018) considered in the forecasts. This is because PMTCT coverage is still too low, the uptake of early infant diagnosis is expected to increase, and the treatment gap in older children is still considerable.

During the discussion, manufacturers were asked whether the modelling and forecasting work provided them with useful information. The responses were generally positive, but more accurate/focused forecasts with age/weight breakdowns would improve their utility. Presenters from the Paediatric ARV Use Working Group responded that with the data presently available, this disaggregation is hard to achieve, but agreed that it is important for the future.

SESSION 4: Procurement initiatives and challenges

This session was chaired by David Jamieson, Deputy Director, and began with a presentation from Martin Auton of the Global Fund. He presented an update on the Fund's Procurement Strategy – Procurement for Impact (P4i) – that aims to improve access to products.

The new strategy brings opportunities for manufacturers as the Global Fund makes commitments by offering contracts of between two and five years. This enables manufacturers to make financial plans and optimize API sourcing and production, provides financial volume commitment to mitigate risks and searches for value-added services which encourages innovation and investment. Key quality requirements are WHO prequalification (PQ) and/or SRA approval, and national registration.

This new procurement approach is broad based and designed to address a range of objectives – it is not just about price – and is based on

- Sustainable supply:
  - continued supply of all products through all stages of the lifecycle;
  - continued API supply chain;
  - improved forecasting, payment and administrative processes.
- Competitive pricing and affordability:
  - more affordable first- and second-line regimens through leveraged volumes;
  - improved planning and longer-term contracts;
  - use supplier expertise; and
  - collaboration to protect reasonable margins.
- On-time delivery:
  - shorter lead times;
  - improved delivery performance.
- Quality and regulatory:
  - longer shelf-life;
  - broader country registration footprints.

The product strategy is based on lifecycle management to drive affordability and availability. Initial volume commitments will be made to the end of 2016, and new entrants will be encouraged by capping volume commitments in the early lifecycle stages. Suppliers will be encouraged to supply both high-volume and low-volume products by bundling contracts through the tender process.

A number of criteria are evaluated before tenders are awarded; overall weighting is 46% based on price criteria and 54% on other technical and value elements.

Key outcomes are:

- Long-term collaborative agreements will support continuous supply through improved lead times and better delivery performance;
- Supply risks will be mitigated with multiple awardees per product and diversification of API sources;
- Proposals received for improvements to the supply of paediatric products;
- Cost reductions for optimal first- and second-line regimens for adults and children: immediate with further reductions over time;
- The new approach will drive further improvements through the deployment of objectivized annual business plans;
- Vendor-managed inventory linked to commitments will be a viable solution to respond to stock outs across the Global Fund portfolio; and
- The new approach delivers the Global Fund's Market Shaping Strategy through underpinning long-term sustainability both at the product and market level.

Wesley Kreft, SCMS, made a presentation on behalf of the Paediatric ARV Procurement Consortium focusing on the consolidated paediatric ARV quantities planned for procurement in 2014–2015. The PAPWG membership consists of:

Working Group members	Procurement Consortium	Working Group observers
• CHAI • Pharmaceuticals Fund and Supply Agency (PFSA)	• Global Fund Pooled Procurement Mechanism	• DNDi
• Global Fund to Fight AIDS, TB and Malaria	• UNICEF	• IAS
• Organization of Eastern Caribbean States(OECS)	• SCMS	• Early Infant Diagnostics Working Group
• Partnership for Supply Chain Management	• CHAI	• MSF
• SCMS	• OECS (observer)	• WHO
• UNICEF	• MSF (observer)	
• UNITAID	• PAHO	
• PAHO	• Kenya Medical Supplies Authority (KEMSA)	
• KEMSA	• PFSA	

The objective of the Consortium is to reduce the risks of supply disruption of paediatric ARVs (improving supply security) by ensuring sustained supply through coordinated procurement mechanisms, strategically managing demand, reducing fragmentation through streamlined product selection, and advocating for transition countries to use the IATT formulary list of optimal and limited-use products.

The Consortium is working towards an improved engagement thorough:

- active engagement with countries and partners to adopt/transition to the prescribed IATT formulary to guide selection and procurement of paediatric ARVs;
- periodic review of forecasts to communicate to manufacturers/suppliers anticipated orders by Procurement Consortium members;
- ongoing monitoring of market challenges and development of solutions as a group (such as, registration/WHO PQ/FDA approvals, sub-batch orders, lead times);
- implementing reporting point indicators to track and validate progress made by the group;
- working with countries not part of the Procurement Consortium to join or at least adopt coordination practices; and
- continue to engage with suppliers individually and collectively as the PAPWG.

Christine Malati, OGAC/USAID, gave an update of the PEPFAR/ACT and its impact on paediatric ARV formulation uptake.

As part of the US-Africa Leaders' Summit, the ACT Initiative was announced in August 2014. ACT is a public-private partnership between PEPFAR and the Children's Investment Fund Foundation. The U.S. Government intends to double the number of children on treatment. Applications for selected countries have been approved, thus there will be a big increase in the demand for paediatric ARVs. The expected additional number of children gaining access to ARVs under the initiative is 300 000.

Countries are selected based on their paediatric HIV burden, disparity between adult and paediatric coverage and, and on being PEPFAR Long-Term Strategy countries. They include: Cameroon, Democratic Republic of Congo, Kenya, Lesotho, Malawi, Mozambique, Tanzania, Zambia and Zimbabwe.

Boniface Dongmo-Nguimfack, WHO, then made a presentation on current API production capacity, and on whether this is sufficient to meet the growing ARV demand and to ensure smooth procurement. In considering the feasibility of guideline recommendations, WHO needs to have a reasonable assessment of whether enough API is available to cover the needed formulations. WHO aims to answer this question through surveys of manufacturers. Many manufacturers provide data on their production capacity, but some do not. With the present amount of data, WHO is not in position to say whether

there is enough API production capacity, and therefore manufacturers are again requested to provide the data needed to support the WHO guideline development process.

Discussion

In the discussion on API production, companies agreed to supply WHO with updates to their API production capacity before August 2015.

Commenting on the presentation on the Paediatric ARV Procurement Consortium, more involvement of caregivers in the PAPWG was suggested by a civil society representative. Wesley Kreft agreed that it would be useful and will explore how this can be achieved. Concern was expressed about recurring stock outs for paediatric ARVs and the need for improved delivery at the community level.

David Jamieson answered that the SCMS and other partners can ensure timely deliveries to the country level but recognized that timely delivery and avoidance of stock outs at the community level is a challenge and requires strengthening distribution systems. Martin Auton of the Global Fund confirmed that this should be a point of focus, also in country grant development.

Commenting on ACT, the question was asked whether there will be enough products to almost double paediatric treatment in a very short time. Christine Malati responded that USAID has already started discussing stockpiling paediatric ARVs, but that no procurement commitments have so far been made. However, as most of the increased uptake is expected in 2016, there is still some time left to finalize the discussions. Further questions were about the size of the target population, and its distribution in age and weight bands, for the countries selected for the ACT Initiative.

Joseph Perriëns acknowledged that the Global Fund had done a lot to improve transparency in the ARV market, but wanted to know how the new mechanism would ensure transparency. Martin Auton responded that there is no change in transparency strategy – they will continue publishing all transactions as was the case under the old strategy. He also mentioned that tender documents are in the public domain on the Global Fund website.

SESSION 5: Financial contributions

This session was chaired by Carlos Passarelli, Senior Expert Treatment, UNAIDS. The first presentation was from Christine Malati, OGAC/USAID, on PEPFAR's contribution to the scale up of ART. Since 2003, PEPFAR's work has included voluntary male circumcision, training of new health care workers, and putting 7.7 million people on ART. This will continue and the new ACT Initiative is an example of the PEPFAR commitment to increasing access to ART.

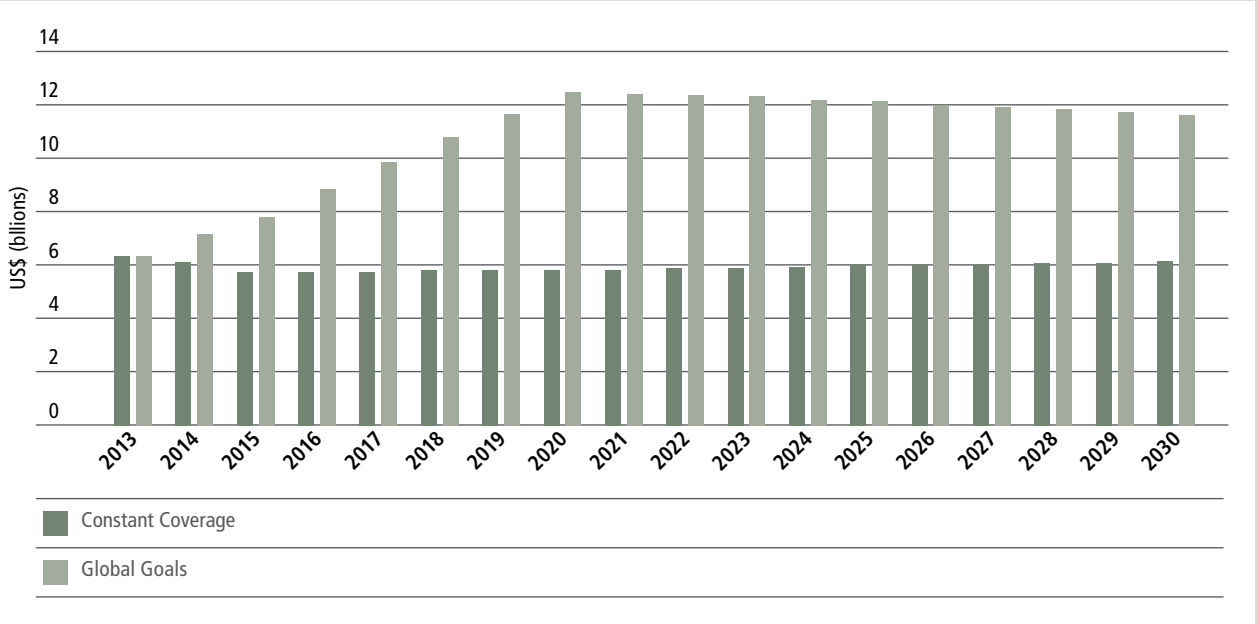
Martin Auton of the Global Fund then talked about the Global Fund grants to scale up access to ART. Global Fund support focuses mainly on the procurement of medicines; in most countries it is between 70 and 90% of the grant budget. Between 2014 and 2016, Global Fund expenditure to combat the three target diseases (malaria, tuberculosis and HIV) will be US$ 14.6 billion, including US$ 7.8 billion for HIV, across 105 countries. Based on historical trends, this translates into an expenditure of at least US$ 3.4 billion on medicines and health products.

Robert Matiru of UNITAID made a presentation on UNITAID's contribution to scaling up access to ART towards the 90-90-90 targets. UNITAID is changing its operating models, and will increasingly be working with private partners; even so the task ahead to achieve 90-90-90 is still big. A significant focus of UNITAID is on diagnostics – especially early diagnosis of infant HIV infection, and access to viral load testing. UNITAID is also working with other partners towards optimized first-line regimens for children.

José Antonio Izazola, UNAIDS, made a presentation on the international and domestic financial outlook for HIV programmes and discussed what it would take to eliminate the AIDS epidemic as a public health threat by 2030. By rapidly scaling up HIV services, the 90-90-90 treatment targets by 2020 could be achieved – but, access to ART is crucial to meet these targets. It will depend on expanding testing, ensuring linkage to care and strengthening health systems for a rapid scaling up on facility and community-based delivery. Attaining these targets depends, among other factors, on expanding community-based service delivery from the current 5% to 30% of total provision of care and treatment.

Figure 3 shows the projected expenditure on ART (including the cost of drugs, diagnostics and service delivery) to maintain current coverage rates versus attaining 90-90-90 targets.

Fig. 3. Resource needs for ART at constant coverage as of 2013 versus expanding coverage to meet ambitious targets



1. In order to finance the aggressive scale up of ART, there will be a need for:
2. Increased efficiencies and service delivery models will be needed to finance the aggressive scale up of ART.
    - Lower prices of commodities (ARV and tests) especially in upper- and middle-income countries:
    - Target to halve the price differential between lower-income and upper- and middle-income countries
3. New service delivery models.
    - Decentralized and community-based delivery of ARVs
    - Community and home-based testing
    - Move from conventional to point of care CD4 count, viral load count, EID
4. Integration into national health financing schemes depends on the burden of disease, service delivery models, dependency on international aid, and the strength of public health system financing.

Discussion

The presentations on financing elicited few questions; however, it was noted that with US$ 19 billion available for HIV programming in 2012, there should be no problem in covering the cost of medicines for HIV programmes. From the presentations, expenditures for ARV were estimated at around US$ 1.5 billion on an annual basis. With rationalization and efficiency gains in other domains in HIV programming, increasing domestic funding, economic growth in many high prevalence countries, governments will likely find the fiscal space to continue supporting treatment scale up, even if the donor community does not increase its support for HIV programmes.

SESSION 6: Regulatory and quality assurance aspects

This session was chaired by Robert Matiru, Manager, UNITAID, and opened by Boniface Dongmo-Nguimfack, WHO, with an update on the ARV regulatory database. Manufacturers are requested to provide data in order to:

1. Inform the WHO guideline committee on whether drugs that are/will be included in the guideline can be accessed; and
2. Inform state and non-state procurement officers, donation programmes and countries using Global Fund grants, which drugs are registered in which country, so as to facilitate their procurement.

WHO called on manufacturers to update the regulatory status of their products regularly. During the past year

(2013) only 50% of countries included in the regulatory database had regulatory approval for all adult formulations recommended by WHO for first-line treatment, and even fewer had regulatory approval for all paediatric formulations needed to administer first-line treatment.

Lembit Rago, Coordinator, Prequalification Programme, WHO, gave an update on the WHO Prequalification of Medicines Programme (PQP) and regional harmonization of drug registration. When it began in 2001 PQP focused mainly on HIV drugs, but quickly expanded to include products to treat tuberculosis, malaria, reproductive health, influenza and neglected tropical diseases. The programme is mainly, but not exclusively, funded by donors – UNITAID and the Gates Foundation. Fees were introduced in September 2013 for new dossiers and a fee structure for major variations will be introduced soon.

Dr Marie-Paule Kieny, Assistant Director-General, Health Systems and Innovation, WHO, made a presentation on the new PQ financing model. This new model aims to maintain the ability of the PQP to provide safe, efficacious and quality drugs, vaccines, diagnostics and devices while increasing supply and access. However, the programme needs sustainable funding to reduce reliance on grants from donors. The objective of the new strategy is to raise 50% of the needed operational funds.

Prequalification is not only for HIV drugs, other therapeutic areas, vaccines and diagnostics are also included. The PQP has created and continues to create benefits for manufacturers and because of this win-win situation for both Member States and manufacturers, its continuation needs to be secured. In view of the resource limitations under which the system operates, it was suggested in various consultations with donors and selected producers that manufacturers should be charged a fee to facilitate the WHO prequalification process. A fee of 1% of PQP-leveraged eligible sales (that is, from international procuring and funding agents which include, UNICEF Supply Division, the Vaccine Alliance (GAVI), the Global Fund, PAHO and UNITAID) was suggested. This fee will be voluntary and payable in a period that is not restricted; it is due to be introduced in April 2015 and implemented from January 2016.

Discussion

Commenting on the new funding model for the PQP, some concerns were voiced by manufacturers. Dr Kieny reassured them that WHO will hold discussions with individual manufacturers to come up with the best solution for both WHO and the manufacturers.

Company representatives commented that their companies would likely be prepared to pay adequately for PQP if and efficient and timely programme could be assured.

WHO agreed that the time taken to prequalify products and variations needs to be reduced, but also emphasized the importance of quality, to do a thorough job, and not merely to rubberstamp applications. WHO does not see the PQP as unlimited in time: the endgame in the regulatory area should be strengthened national regulatory authorities capable of ensuring the safety and efficacy of medicines circulating in the territories which they serve.

Different ways of applying the fee were suggested, among them to apply the fee to sales of APIs, not finished formulations, and charging the cost to the donors (especially the Global Fund).

Closing Remarks and next steps

The meeting was closed by Joseph Perriëns (WHO) and Carlos Passarelli (UNAIDS), and a final statement was made by the WHO Assistant Director-General, Marie-Paule Kieny.

In their closing remarks, several key messages were articulated:

1. The treatment target 15 by 15 will in all likelihood be met, and probably exceeded.
2. The funds to pay for the drugs will be there. In HIV budgets there will be efficiency gains. HIV budgets will likely grow with economic growth and increased domestic investment, while the donor community will remain engaged.
3. The forecast for paediatric ART presented at this meeting are likely underestimated, because the ACT programme of the U.S. Government has not been included in the estimates.

The 'to do' list for the ARV Demand Forecasting Technical Working Group was recalled:

- Clarify the formulation forecasts by solving the discrepancies between the CHAI and the combined Global Fund and SCMS quantifications for 2015 and 2016, and make a joint presentation on the ARV demand forecast at the IAS 2015 conference.
- In the long-term forecasts regarding the uptake of new ARV molecules, clarify, review and refine the assumptions used, including on switching and resistance.
- Integrate the ACT estimates in the paediatric forecasts when they are ready.

The manufactures were thanked in advance for their expressed commitment to communicate updates on the regulatory status of their ARVs to WHO and update the information on their API production capacity. It was also mentioned that in off-line discussions questions were asked on the future of NVP-XR and ATV/COBI and DRV/COBI.

While closing the plenary session of the meeting all speakers expressed the hope to continue the information exchange between WHO, UNAIDS and the manufacturers in the future for the benefit of the many people who need to access ART. The meeting continued with one-to-one discussions in the afternoon.

ANNEX 1: FINAL AGENDA

	AGENDA ITEM	PRESENTER
DAY ONE THURSDAY, 19 MARCH 2015		
08:00–09:00	Registration	
09:00–09:30	Welcoming remarks	Gottfried Hirnschall Director, HIV Department, WHO Peter Ghys Director, Strategic Information and Evaluation Department, UNAIDS
09:30–10:30	Objectives of the meeting Introduction of participants	Joseph Perriëns Coordinator, HIV/TCO
	I. Panel on Achieving Universal Access: Global guidance for innovation	
	Chair: Gottfried Hirnschall, Director, HTM/HIV	
	Update on CADO/PADO: What are the challenges in using the current guidelines and foreseen ARV revisions? (20 minutes)	Meg Doherty WHO/HIV/TAC
	Update on hepatitis B and C treatment guidelines and overview of hepatitis-treatment landscape. (20 minutes)	Philippa Easterbrook WHO/HIV/GHP
	Discussions: questions and answers	All participants
10:30–11:00	COFFEE/TEA	
11:00–13:00	**II. WHO and UNAIDS Forecasts of ARV Global Demand 2014–2018 and modelling projections of new ARV formulations 2015–2024: Adults**	
	Chair: Jos Perriëns, Coordinator, HIV/TCO	
	Results of 2014 WHO Survey on ARV use and trends of regimens and APIs from previous surveys (15 minutes)	Vincent Habiyambere WHO/HIV/TCO
	Trends of adult formulations uptake from the GPRM database (15 minutes)	Boniface Dongmo-Nguimfack WHO/HIV/TCO
	Consolidated forecast of global ARV demand for ART adult coverage 2014–2018: Scenarios, data and forecasts (30 minutes)	Biyi Adesina On behalf of the ARV Demand Forecasting Technical Working Group
	The uptake of individual ARV formulations 2015–2016	Jos Perriëns WHO/HIV/TCO
	CHAI Modelling the uptake of new ARV formulations for adults for 2015–2024: Scenarios, assumptions and projections (20 minutes)	Vineet Prabhu CHAI

	Modelling the uptake of new ARV formulations for adults for 2015–2024: Scenarios, assumptions and projections. (20 minutes)	Sandeep Juneja and Aastha Gupta, MPP, on behalf of the Working Group
	Comments from the member organizations of the ARV Demand Forecasting Technical Working Group	CHAI, SCMS, The Global Fund, UNICEF, UNAIDS
	Discussion: questions and answers	All participants
13:00–14:00	LUNCH BREAK	
14:00–17:00	**III. WHO and UNAIDS Forecasts of ARV global demand 2014–2018 and modelling projections of new ARV formulations 2015–2024: Children**	
	Chair: Meg Doherty, Coordinator, HIV/TAC	
	Update on the IATT Paediatric Formulary (20 minutes)	David Jamieson, SCMS, on behalf of the IATT on the Prevention and Treatment of HIV infection in Pregnant Women, Mothers and Children
	Results of 2014 WHO Survey on ARV use and trends of paediatric regimens and APIs (15 minutes)	Vincent Habiyambere WHO/HIV/TCO
	Trends of paediatric formulation uptake from the GPRM database (15 minutes)	Boniface Dongmo-Nguimfack WHO/HIV/TCO
	Consolidated forecast of global ARV demand for ART paediatric coverage 2014–2018: Scenarios, data and forecasts (30 minutes)	Biyi Adesina on behalf of the ARV Demand Forecasting Technical Working Group
	Modelling the uptake of new ARV formulations for children for 2015–2024: Scenarios, assumptions and projections (20 minutes)	Aastha Gupta, MPP, on behalf of the Working Group
	Comments from the member organizations of the ARV Demand Forecasting Technical Working Group	CHAI, SCMS, Global Fund, UNICEF, UNAIDS
	Questions and answers (30 minutes)	All participants
	Wrap-up of the day	Joseph Perriëns WHO/HIV/TCO
16:30–17:00	COFFEE/TEA	
DAY TWO FRIDAY, 20 MARCH 2015		
9:00–10:30	**IV. Procurement Initiatives and challenges**	
	Chair: David Jamieson, Deputy Director, PFSMC/SCMS	
	Update on the Global Fund's Procurement Strategy (20 minutes)	Martin Auton Global Fund
	Paediatric ARV Procurement Working Group: the consolidated paediatric ARV planned for procurement by the Consortium, 2014–2015 (20 minutes)	Wesley Kreft, SCMS on behalf of Paediatric ARV Procurement Consortium
	Update on PEPFAR/Accelerate Children Treatment (ACT) and impact on paediatric ARV formulation uptake (20 minutes)	Christine Malati OGAC/USAID

	Is the current API production capacity sufficient to meet the growing ARV demand for a smooth procurement? (15 minutes)	Boniface Dongmo-Nguimfack WHO/HIV/TCO
	Questions and answers	All participants
10:30–10:45	COFFEE/TEA	
10:45–11:45	**V. Financial contributions**	
	Chair: Carlos Passarelli, Senior Expert Treatment, UNAIDS	
	PEPFAR's Contribution to the scale up of ART (15 minutes)	Christine Malati OGAC/USAID
	Global Fund grants to scale up access to ART (15 minutes)	Martin Auton Global Fund
	UNITAID contribution to scale up access to ART towards the 90/90/90 targets (15 minutes)	Robert Matiru UNITAID
	International and domestic financial outlook for ART programmes (15 minutes)	José Antonio Izazola UNAIDS
	Questions and answers	All participants
11:45–13:00	**VI. Regulatory and quality assurance aspects**	Joseph Perriëns WHO/HIV/TCO
	Chair: Robert Matiru, Manager, UNITAID	
	Update on ARV registration status (15 minutes)	Boniface Dongmo-Nguimfack WHO/HIV/TCO
	Update on PQ programme and regional harmonization of drug registration (15 minutes)	Lembit Rago, WHO/EMP
	New PQ financing model (15 minutes)	Marie-Paule KIENY, ADG Health Systems and Innovation
	Questions and answers	All participants
	Closing remarks and next steps	Jos Perriëns, WHO Carlos Passarelli, UNAIDS
13:00–14:00	LUNCH BREAK	
14:00–17:00	Individual meetings	

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