HIV/AIDS Programme

JOINT WHO/UNAIDS ANNUAL CONSULTATION WITH PHARMACEUTICAL COMPANIES AND STAKEHOLDERS

GLOBAL FORECASTS OF ANTIRETROVIRAL DEMAND 2012–2013

31 OCTOBER–1 NOVEMBER 2011 GENEVA, SWITZERLAND

World Health Organization

UNAIDS

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I. INTRODUCTION

The World Health Organization (WHO) and the UNAIDS Secretariat jointly organized the annual consultation with pharmaceutical companies on the 31st of October and 1st of November 2011. The Secretariat of the Global Fund to Fight AIDS, Tuberculosis and Malaria was associated with this event and organized its annual meeting with pharmaceutical manufacturers back to back with the WHO & UNAIDS consultation on the 2nd November 2011.

The WHO/UNAIDS annual consultation meeting with pharmaceutical companies was opened by Dr P De Lay, Deputy Executive Director UNAIDS, and Dr H Nakatani, Assistant Director General of HIV, TB, Malaria and Neglected Tropical Diseases Cluster.

The main objectives were to present and discuss global forecasts of antiretroviral demand in the next two years, and brief the pharmaceutical organizations on key HIV developments in WHO, UNAIDS and other partner organizations.

This consultation brought together innovator and generic ARV producers, active pharmaceutical ingredient (API) producers, staff from partner organizations including the Global Fund to Fight AIDS, Tuberculosis and Malaria, US Office of the Global AIDS Coordinator (OGAC), UNITAID, Partnership for Supply Chain Management, the Bill & Melinda Gates Foundation, the Clinton Health Access Initiative, the Medicines Patent Pool, as well as representatives from other non-governmental organizations, including Médecins sans Frontières (MSF) and International Treatment Preparedness Coalition (ITPC).

The agenda and list of participants are found in annexes I & II. This report summarizes the main points discussed during the meeting. The presentations made during the meeting are listed in annex I and are available in the public domain at http://www.who.int/hiv/pub/meetingreports/consultation_pharmaceutical_companies/en/index.html.

II. MEETING SESSIONS

SESSION 1: ACHIEVING UNIVERSAL ACCESS: GLOBAL GUIDANCE FOR INNOVATION

This session covered the state of the response towards 15 millions by 2015 and the Treatment 2.0 framework as well as the short/midterm priorities for ARV drug optimization. In his presentation on progress towards 15 million by 2015, Yves Souteyrand (WHO) gave an overview of the achievements made on scaling up priority HIV/AIDS interventions in the health sector. In her intervention, Mariangela Simao (UNAIDS) expressed the need to increase the uptake of testing and counseling in order to have more people on ARV treatment and prevent that people come late for ART, as the delay in ART initiation increases the probability of dying. Testing and measuring CD4 counts in PLWHA would help to initiate treatment at the right time in line with WHO guidelines. The importance of a multi partner approach was also highlighted to increase access to treatment and to strengthen retention on ART for those who are already on treatment. Partner organizations, funding agencies, pharmaceutical companies and civil society organizations are all needed to achieve the commitment of 15 million people on ART by 2015. ART is effective not only for treatment but its effect on HIV prevention has also been proven.

Following her intervention, Craig McClure (WHO) presented the short /mid term priorities for ARV drug optimization. He presented the new global targets including elimination of new vertical HIV infections, having 15 millions people on ART by 2015, reducing by 50% TB deaths among PLHIV/AIDS. He also described the five pillars of the WHO/UNAIDS Treatment 2.0 Initiative to re-energize the HIV response, and explained the short and mid term priorities to achieve the above mentioned targets.

Following the above presentations, discussants from civil society organizations and innovator and generic manufacturers provided their views on how to achieve universal access. Mr A. Khanna (Emcure Pharmaceuticals Ltd) made a presentation which summarizes issues and challenges that were raised by many other drug manufacturers. For details, his presentation is accessible at the link provided above. The following issues and suggestions were made by the discussants.

1. ARV REGISTRATION AND PREQUALIFICATION

- Slow and costly drug registration process not sustainable for low volume or countries with small number of patients.
- Regulatory authorities have insufficient capacity in many developing countries.

Suggestions:

- To encourage fast track registration of ARVs: use WHO Prequalification and/or Stringent Regulatory Approval to fast track the regulatory process in partner countries.
- Prioritize ARV formulations which are recommended in WHO ARV guidelines in the WHO prequalification process (PQP) and in the national registration process.
- Remove formulations that are no longer recommended as part of WHO treatment guidelines from PQP.
- WHO should encourage regulatory authorities to ensure that WHO prequalified medicines get fast track registration by the use of the complete documentation submitted by manufacturers to PQ Programme.
- Manufacturers also suggested mutual regional registration agreement to facilitate ARV access to small market countries.
- Discourage inspections by NDRA when facilities have been inspected by Stringent Regulatory Authority or WHO.
- Fostering links between National AIDS Control Programmes and Drug Regulatory Authorities. The former should advise Drug Regulatory Authorities to give priority market authorization to all products in national or WHO treatment guidelines.
- Improve/intensify discussion between UN bodies and pharmaceutical companies in advancing efficiently towards a mutual aspiration of 15 by15.

2. UPTAKE OF SECOND LINE ARV TREATMENT

The discussants raised the following issues related to low proportion of patients on 2nd line ART:

- Medical practitioners feel uncomfortable handling many of the new treatment regimens.
- The capacity and coverage of public health laboratories in low income countries are limited.
- 2nd line treatment regimes are centralized at referral hospitals which is inconvenient and impractical for patients receiving these regimens.
- Governments and international organisations mainly concentrate their effort on putting more patients on ART to meet the target of 15 millions by 2015.

Suggestions:

- Training medical practitioners on the appropriate use of new generation of ARV formulations.
- Increased viral load testing for patients on ART to identify treatment failure.
- Promote diagnostics using point of care and other simplified laboratory technologies.
- Improve the quality of care and retention rate on ART, an area where the civil society organizations expressed interest to play a more active role if resources are made available to them.
- Mobilize communities, facilitate decentralization and protect human rights.

3. ROLE OF COMMUNITIES IN TREATMENT 2.0

ITPC elaborated on civil society organizations (CSO) needs and roles in Treatment 2.0:

- Need to have access to a fixed dose, a single pill per day in order to ensure increased sustainability and retention of treatment.
- Increased support and funding for community groups to allow them active involvement in implementation of Treatment 2.0: involvement of CSOs may increase retention rate.
- Improve treatment, follow-up and counseling at the community level to ensure retention to treatment regimens.

4. MARKET ACCESS FOR NEW/LOCAL MANUFACTURERS

- Small producers in Africa voiced concerns about their access to competitive international procurement and Global Fund VPP, even when their products are WHO prequalified. They inquired about national preference in international procurement which is not part of Global Fund and other international funding agencies. In response to this comment, the participant from Global Fund said that locally manufactured medicines, as long as they are HIV, TB and malaria medicines prequalified by WHO or approved by a stringent regulatory authority, and represent value for money can be purchased with Global Fund monies. But, as the Global Fund Secretariat clarified, its Board (in 2002) did not allow it to introduce in the procurement policy a price preference for locally produced medicines.
- UNICEF and other partners suggested that different models to sustain a healthy market exist – these models sometimes require paying a high price upfront which will then decrease costs in the long run as volumes increase.
- Manufacturers claimed that they do not have access to information on tenders done with Global Fund monies. UNICEF identified UNGM database and its own webpage as sources of information on coming tenders, and suggested that Global Fund list its tenders there.

SESSION 2: WHO & UNAIDS FORECASTS OF ARV GLOBAL DEMAND 2012–2013

The second session was opened with three presentations: Boniface Dongmo-Nguimfack (WHO) presented the trends in the market share of ARVs based on transaction data in the Global Price Reporting Mechanism (GPRM). Françoise Renaud-Théry (WHO) presented the results of a WHO survey on ARV use and their distribution among various ARV formulations in first and 2nd line ART. This was based on the responses from 66 countries, which are home to 5.8 million of patients on ART. Salient finding included that 2nd line ART is still low – there is less than 3% of patients on 2nd line ART in LMIC – except in Latin America. Based on the above, and trends over time, Adebiyi Adesina from the Futures Institute presented the global ARV demand forecasts. Linear regression with upper-bound limits, linear regression without upper-bound limits and country targets methodology showed that by the end of 2013 between 10.1 and 10.6 million patients will be on ART and the distribution of various ARV formulations were projected over the next 2 years. Details of these presentations are available on the link indicated at page 3 of this report.

The following issues and suggestions arose in the discussion:

1. COHERENCE BETWEEN DIFFERENT FORECASTS

Forecasts from WHO and those from Clinton Health Access Initiative (CHAI) are somewhat different.

WHO/UNAIDS/Futures Institute forecast that between 10.1 and 10.6 million people will be on ARVs in 2013. CHAI presented its forecast of 9.6 million by 2013. Further discussions revealed that the global forecasts are in fact coherent, the difference being due to the way both forecasts are presented. Indeed, the WHO/UNAIDS/Futures Institute presents numbers of people on ART at the end of each year while CHAI presents number of people on treatment at mid year. In addition, CHAI starting point in 2010 is 5.9 millions people on ART while more recent data used by WHO show that 6.6 M people are on ART. If this baseline number were taken into account in the CHAI model, it would project 10.3 millions people on ART by end of 2013, which makes both models substantively coherent in the outcome.

Other differences were d4T phase out rate and the distributions of various formulations (EFV versus NVP; FTC versus 3TC and LPV/r versus ATV/r). The origin of these differences and underlying assumptions will be clarified in follow-up discussions. However, the impressive coherence in our independent forecasts was emphasized by both CHAI and partners.

2. ECONOMIC VIABILITY OF THE ARV MARKET

Several generic manufacturers pointed out that for several ARVs the gross margin is now less than 10% – typically between 5 and 8%. As new opportunities arise (this year alone 67 medicines will come off patent in the USA) its is increasingly difficult to convince their shareholders to invest in production capacity for ARVs – and even to keep using production capacity now allocated to ARVs. While recognizing that there is still some scope to reduce prices for formulations for which there is little competition now (like TDF/3TC/ATVr), this makes then very reluctant to commit to further price decreases for "commoditized" formulations. Loosing production capacity when we need at least to double the production capacity within 3 years is dangerous. We prevent a situation like in TB, where several (generic) drugs have become single source products which increased the prices.

3. PREDICTABILITY OF DEMAND FOR INDIVIDUAL APIs

API manufacturers face unpredictable production demand, price reduction and short life cycle of ARVs which keep being replaced with revised guidelines and require improved access to procurement data and clear forecasts information.

Suggestions:

- Explore innovative generic partnerships: to reduce the risks, it is potentially beneficial to integrate API and finished pharmaceutical products.
- Exchange updated information between technical agencies and pharmaceutical companies in order that the development of products fits the ARV recommendations.
- Enhance collaboration between WHO and CHAI to increase coherence in their forecasts.

SESSION 3: ENSURING RESOURCES TO MEET DEMAND OF ARVs

Moderated by Mariângela Simao (UNAIDS) this session covered "Financing ART in low- and middle-income countries" presented by Carlos Avila, UNAIDS, "PEPFAR's contributions to the global scale-up of ARV treatment" presented by Lara Stabinski (Office of the Global AIDS Coordinator, State Department, USA) and "UNITAID Innovative Financing Mechanism", presented by Denis Broun, Executive Director, UNITAID.

All three presentations mentioned that funding has increased over time, reaching over US$ 15 billion in 2009, but there is a decline since 2010. However, this will likely not affect the scale up to ARV treatment in view of the efficiency and value for money strategies that have been developed in various ART programmes. In PEPFAR, for example, the cost per patient decreased over the years, as shown in an expenditure analysis across 17 countries.

These efficiencies open for opportunities to scale up towards universal access in the next 3–5 years despite the slight decreases in funding.

Innovative financing mechanisms are also being developed by UNITAID – specific mention was made of discussions on a tax on financial transactions. Domestic resources will be more and more needed to sustain ART programmes.
Details of the above presentations are available on the link indicated at page 3 of this report.

The following issues and suggestions were discussed:

1. OBTAINING A COST EFFICIENT APPROACH

- Programmatic areas where costs can be reduced and saving made need to be analysed.
- Other areas than drugs, could become more cost effective such as coordination of drug distribution, minimizing emergency drug deliveries, more efficient procurement and supply management.

Some encouraging initiatives with potential efficiency gains were mentioned: "Value for Money" in the Global Fund, "Efficiency, effectiveness and evaluation" (EEE), in UNITAID, Treatment 2.0 in UNAIDS and WHO, with focus on simplification of treatment regimens and delivery, and integration of HIV programmes within the health system.

SESSION 4: ACCESS TO CURRENT PRODUCTS AND INNOVATION FOR THE FUTURE

In session four, Tido von Schoen-Angerer from MSF/Access Campaign presented the access to current products and innovation for the future, a comprehensive topic which covered both medicines as well as diagnostics, currently marketed and those in pipeline; Marc Lallemant from DNDi presented treatment needs and strategies for young children where challenges related to elimination of vertical transmission and bottlenecks to access to pediatric formulations were discussed; Sandeep Junija from MPP an update on the medicines patent pool which showed significant progress; Stephen Becker from the Gates Foundation presented HIV Treatment Optimization and showed how this could be a great opportunity to increase access to ARV and diagnostics and cover unmet needs with efficiency by using the various Treatment 2.0 optimization principles. The Bill and Melinda Gates Foundation is supporting WHO in this area. WHO should monitor progress and assess at which extent Treatment 2.0 hypotheses about efficiency and simplification are validated; Kenly Sikwese from ITPC gave the community thoughts on access to current products and innovation. Details of these presentations are available on the link indicated at page 3 of this report.

The following issues and suggestions were discussed:

- Universal Access to ART needs the community involvement to successfully scale-up treatment and care. The community is ready to play a role in retention on ART and on informing about stock levels to prevent lengthy stock out situations.
- Manufacturers are committed to continue to play their role. They suggested a closer monitoring and more effective management of the supply chain at the country level.
- On the medicines patent pool (MPP), it was acknowledged that despite efforts accomplished by MPP, there is room for expanding the list of ARVs which can be allowed to be manufactured by generic manufacturers. Continuing negotiations are important as – with exceptions – countries have so far been very cautious in the use of TRIPS flexibilities to expand access to medicines.
- On paediatric formulations, a plea was made for simpler formulations and regimens that are more appealing to children and easier for parents to implement.

SUGGESTION 5: ADDRESSING CHALLENGES TO SCALE UP ACCESS TO ART

Moderated by Craig McClure (WHO), this session included presentations by Alan Staple (CHAI) on challenges facing generic manufacturers such as the market trends and competition, investment in new products, and investment in API production capacity. He presented also CHAI forecasts up to 2015. Lara Stabinski (OGAC) presented the challenges to scale up prevention of mother to child transmission – with focus on access to nevirapine liquid formulation. This was also elaborated upon by Marcel Hendriks (SCMS) who showed the challenges to respond to the increasing demand of NVP oral solution. Matthias Stahl (PQP in WHO) presented the progress on prequalification of medicines. Deus Mubangizi (PQP in WHO) discussed in detail the case of the falsified Zidolam-N. These presentations revealed the importance of quality assurance and a strong national regulatory authority to track falsified products and to ensure that only medicines of good quality are marketed in the country. Details of these presentations are available on the link indicated at page 3 of this report.

Discussions and suggestions:

- The falsified Zidolam-N® found on the Kenyan market reveals that there is a risk of more falsified products in the market for the future unless NDRA are strengthened. The PQ programme is training the national regulatory authorities to strengthen their capacity. In this effort, joint inspections are carried out with national regulatory authorities at manufacturing sites.
- For the specific case of Zidolam-N in Kenya, it was recommended that vigilance in picking up quality problems is needed and procurement should be from a quality assured supplier.
- As the inability of programmes to collect data on adverse events and quality failures was noted, strengthening pharmacovigilance and laboratory capacity for quality assurance were identified as actions to pursue.

III. CONCLUSION AND RECOMMENDATIONS

Limitations on financial resources such as recent situation in the Global Fund are real issues of concern. However, this will likely not affect the scale up of ART in the next 2 years. However, innovative financing mechanisms and increased domestic funding will likely be needed to sustain treatment scale up beyond 2013. More efficient programme management and resource allocation within HIV programmes will likely produce sufficient fiscal space for sustained expansion of the ART programmes towards the target of 15 by 15.

Recommendations:

1. Futures Institute will finalize the forecasts taking into account the comments made during the consultation and explain the assumptions and methodologies leading to differences with CHAI forecasts.
2. WHO/PQP should develop fast track registration processes and develop mutual regional registration agreements, building on its ongoing 6 pilot projects and collaborative inspections in PQP.
3. WHO should clarify its strategy to alleviate hurdles in the drug registration process and support QA of medicines after market authorization. This issue should be discussed at IPC.
4. WHO should remove formulations which are no longer recommended as part of WHO treatment guidelines from the list of WHO prequalified drugs. HIV/TAC will discuss with the PQ programme the feasibility of this suggestion.
5. National and international procurement institutions need to be aware that awarding all supplies to the cheapest supplier in a tender is not always the right policy to sustain the ARV market. They should consider a price mix policy in the award of their tenders.
6. In order to prevent that patients are exposed to stock outs, suppliers as well as recipient countries are recommended to use updated policies on procurement: the two related policies documents referring to shelf-life are Operational principles for good pharmaceutical procurement (http://apps.who.int/medicinedocs/pdf/whozip49e/whozip49e.pdf) and the Guidelines for Medicine Donations (http://whqlibdoc.who.int/publications/2011/9789241501989_eng.pdf) both developed by the Interagency Pharmaceutical Coordination Group and respectively published by WHO in 1999 and in 2011. The guidelines specify that, after arrival in the recipient country all medicines should have a remaining shelf-life of at least one year. Furthermore, exceptions may be made by the recipients if the medicines can be consumed prior to their expiry.
7. WHO and UNAIDS – through AMDS – should continue to produce forecasts and collate information on API capacity to inform the drug manufacturers and financing agencies.

8. WHO should, in the ARV use survey, analyse what drives decisions on fast or slow phase out of d4T, what drives the slower uptake of TDF compared to AZT, and what drives the slow uptake of second line treatment. Viral load measurement is vital in addressing the insufficient uptake of second line treatments. Suggestions by ITPC include not enough VL laboratory capacity, not enough awareness, not enough funding, not enough familiarity of professionals with the use of 2nd line ARVs.
9. The Annual WHO-UNAIDS-UNICEF Progress Report should include data that show not only the reported number of people receiving ARV therapy , but also the number receiving second-line therapy.
10. WHO should send follow up information to the manufacturers on the UNGM database and the UNICEF webpage as sources of information on coming ARV tenders.
11. Global Fund to consider publishing countries' tenders in the UNGM database.
12. WHO and UNAIDS should support work on financial transaction tax in the UNITAID Board and beyond.
13. WHO should support strengthening pharmacovigilance and QC laboratory capacity in its member states.

ANNEX I: AGENDA

JOINT WHO/UNAIDS ANNUAL CONSULTATION WITH
PHARMACEUTICAL COMPANIES AND STAKEHOLDERS ON
"GLOBAL FORECASTS OF ANTIRETROVIRAL DEMAND 2012–2013"
UNAIDS/WHO Building – Kofi A. Annan Conference Room – Geneva
Monday 31 October and Tuesday 1 November 2011

DAY 1 MONDAY, 31 OCTOBER 2011

Time	Agenda Item	Presenter
08:45–09:00	Registration	**Chair: Joseph Perriëns** WHO/HIV/TCO
09:00–09:30	Welcoming Remarks Objectives of the Consultation and Introduction of participants	**Paul De Lay** DXD/UNAIDS **Hiroki Nakatani** WHO/ADG/HTM **Joseph Perriëns** WHO/HIV/TCO
09:30–10:30	**I. Panel on Achieving Universal Access: Global Guidance for Innovation** Towards 15 Million by 2015 progress up-date *(20 minutes)* Treatment 2.0: A multi – partnership framework *(20 minutes)* Advancing Treatment 2.0 Short and Mid-Term Priorities for Antiretroviral Drug Optimization – and a glimpse of the future in PMTCT and in ART for prevention – *(20 minutes)*	 **Yves Souteyrand** WHO/HIV/SIP **Mariângela Simao** UNAIDS **Craig McClure** WHO/HIV/TAC
10:30–11:00	Coffee/Tea break	
11:00–12:00	**Discussants** Perry Mohammed, **Tibotec** Rahul Lande, **Cipla Ltd** Achieving universal access – Global Guidance for Innovation Lorena Maria Di Giano, **ITPC** Questions and Answers *(30 minutes)*	 **Arun Khanna,** Emcure Pharmaceuticals **All participants**
12:00–13:30	Lunch break	

13:30–14:30	**II. WHO & UNAIDS Forecasts of ARV Global Demand 2012–2013** Trends in ARVs volumes and API production capacity – Observations from the GPRM *(10 minutes)* WHO 2011 Survey on ARV Use and Trends in Implementing WHO 2010 Recommendations *(20 minutes)* Forecasting Global ARV Demand for Adult and Pediatric, 2012–2013 *(30 minutes)*	 **Boniface Dongmo-Nguimfack** WHO/HIV/TCO **Françoise Renaud-Théry** WHO/HIV/TCO **Adebiyi Adesina** Futures Institute
14:30–15:30	**Discussants** Isabelle Girault, **Merck** Anirudh Deshpande, **Matrix Laboratories Ltd** Jie Wang/Kenny Cheung, **Desano Pharma** *(30 minutes)* Questions and Answers *(30 minutes)*	 **All participants**
15:30–16:00	Coffee/Tea break	
16:00–17:30	**III. Ensuring resources to meet demand of ARVs** **Moderator:** Mariângela Simao, UNAIDS Financing ART in low & middle income countries PEPFAR's Contributions to the Global Scale up of Treatment UNITAID Innovative Financing Mechanism Questions and Answers *(30 minutes)*	 **Carlos Avila,** UNAIDS **Lara Stabinski,** OGAC **Denis Broun,** EXD/UNITAID **All participants**
17:30–18:00	Wrap-up and Next Steps	**WHO/UNAIDS**

DAY TWO TUESDAY, 1 NOVEMBER 2011

Time	Agenda Item	Presenter
9:00–10:30	**IV. Access to current products and innovation for the future** **Panel I: Access to current products and innovation for the future** **Moderator:** David Hoos, UNAIDS Access to current products and innovation for the future Treatment needs and strategies for young children Update on the Medicines Patent Pool HIV Treatment Optimization Access to current products and innovation for the future , Some Community Thoughts Questions and Answers *(30 minutes)*	**Chair: David Hoos,** UNAIDS **Tido von Schoen-Angerer,** MSF **Marc Lallemant** , DNDi **Sandeep Juneja**, MPP **Stephen Becker,** GATES **Kenly Sikwese**, ITPC **All participants**
10:30–10:45	Coffee/Tea break	

10:45–11:45	**Panel II : Addressing challenges to scale up access to ART** **Moderator:** Craig McClure, WHO Strategic issues facing generic manufacturers PMTCT NVP Challenges Challenges to Scale up NVP OS Prequalification of Medicines Programme Update on Falsified Zidolam-N Questions and Answers *(30 minutes)*	 **Alan Staple,** CHAI **Lara Stabinski,** OGAC **Marcel Hendriks,** SCMS **Matthias M Stahl,** WHO **Deus Mubangizi,** WHO **All participants**
11:45–12:15	Closing remarks	**WHO** **UNAIDS**
12:00–13:00	**V. Individual meetings with companies and staff from WHO, UNAIDS and all partner organizations** **Meeting Rooms – Department of HIV/AIDS** **4th floor:** D46031 D45018 D45022 D45043 D45044 D44020	
15:30–16:00	Lunch break	
14:00–16:00	Continuation of individual meetings	

ANNEX II: LIST OF PARTICIPANTS

JOINT WHO/UNAIDS ANNUAL CONSULTATION WITH
PHARMACEUTICAL COMPANIES AND STAKEHOLDERS ON
"GLOBAL FORECASTS OF ANTIRETROVIRAL DEMAND 2012–2013"

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