Background

On 11 December 2007, the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) held the second consultation with companies on ARV market forecasts. The meeting was opened by Kevin De Cock, Director, WHO Department of HIV/AIDS and Paul De Lay, Director, Evidence, Monitoring & Policy, UNAIDS Secretariat.

Objectives of the meeting:
1. To present to ARV producers the joint publication by WHO, UNAIDS, the Clinton Foundation Initiative on HIV/AIDS (CHAI) and the Mexico National Institute of Public Health (INSP) - "Demand forecast for antiretroviral drugs in low and middle income countries, 2007-2008" and discuss key considerations for next forecast generation;
2. To exchange information regarding WHO paediatric and 2nd line ARV recommendations, current use of ARVs, market trends and funding agencies activities that may influence future ARV demand in developing countries;
3. To discuss needs and possible contributions by industry and partners to the establishment of a common information platform for the production of ARV forecasts.

The publication, meeting agenda, list of participants and presentations made during the meeting are available on AMDS website at http://www.who.int/hiv/amds/en

Action and next steps

Establishment of a global electronic information platform for the production of forecasts:
- The AIDS Medicines and Diagnostics Service Secretariat of the WHO Department of HIV/AIDS and UNAIDS Secretariat will initiate the development of software and the production of rolling ARV forecasts (starting with 2008-2009 forecasts), taking into account the elements that were discussed during the consultation.
- The AMDS Secretariat and the UNAIDS Secretariat will work on the establishment of the electronic platform and will follow-up with partners on making their contributions available to the platform.

Interaction with companies
- The AMDS Secretariat will continue to organize consultations with companies and partners, as exchanges were found very informative by all parties.
Minutes

Morning session: Global market forecasts for antiretroviral medicines: adults, children and next steps in forecasting

Global market forecasts for antiretroviral medicines for adults:

The topic was introduced with three presentations:
1. "Financial resources required to achieve Universal Access to HIV prevention, treatment, care and support" presented by Carlos Avila-Figueroa, UNAIDS Secretariat
2. "Key observations on ART scale-up scenario 2007 and 2008" presented by Robert Greener, UNAIDS Secretariat
3. "Trends and analysis of adults ARV forecasts" presented by Megan O'Brien, Clinton Foundation Initiative on HIV/AIDS (CHAI), and Omar Galarraga, the Mexico National Institute of Public Health (INSIP)

Discussion points:
- The attrition rate used in the forecast was calculated using data from available studies. It was noted that new patients are often very sick patients with a high rate of mortality. In countries improving ART coverage, patients are getting treatment progressively earlier and consequently attrition rate tend to decrease. It does not seem to have a clear straight line influence on global forecast but this would need to looked at more carefully in the next forecast exercise (UNAIDS).
- The switching rate reported by countries is very variable. WHO will hold a meeting in February 2008 to define treatment failure and review studies on 2nd line migration rate (WHO). Factors influencing the switching rate likely include the availability of CD4 and viral load monitoring methods, the size of the facility, training of physicians and the availability of funding to pay for 2nd line medicines and lab monitoring tests (Aspen, Abbott).
- It was also noted that HIV testing policies strongly influence the growth of ART programmes (Merck). The next forecast exercise will look at diagnostic availability and information (UNAIDS, WHO).
- The lack of laboratory support is a major constraint in access to treatment especially for children. A policy meeting will take place in Mozambique in 2008 sponsored by WHO AFRO and PEPFAR, with Clinton Foundation, Gates Foundation and the Global Fund as secondary sponsors to propose recommendations to expand laboratory services across the health system, including CD4 count at first health care level and viral load measurements at district level (WHO).
- WHO is working with the Global Health Workforce Alliance to support task shifting, pre-service and in-service training. There will be a policy meeting in February 2008 bringing together Ministers of Health from Africa and Asia to discuss task shifting and agree on recommendations (WHO).

Global market forecasts for antiretroviral medicines for children:

The topic was introduced with two presentations:
1. "Development of a reliable and replicable methodology for forecasting the global demand for pediatric anti-retroviral medicines" presented by David Jamieson, Partnership for Supply Chain Management (PfSCM)
2. "Paediatric ARVs: WHO recommendations for ART" presented by Siobhan Crowley, WHO Department of HIV/AIDS

Discussion points:
- Review evidence on disease progression and on when to start treatment (6 or 9 months) by the expert group established by WHO.
- The lack of access to diagnostics for children is a major barrier to treatment. There is a need to expand diagnostic capacities where mothers are, as most mothers do not know their status, as well as to reach HIV positive babies. The implementation of the revised PMTCT strategy will help addressing these issues (WHO).
- Adoption of national treatment guidelines for children and implementation of paediatric treatment programmes in numerous countries would encourage companies to invest in user-friendly paediatric formulation production, particularly fixed dose combinations (FDCs) (Ranbaxy).

Next steps in forecasting ARVs:

The topic was introduced with three presentations:
1. "Prioritizing second-line ART within a public health approach" presented by Marco Vitoria, WHO Department of HIV/AIDS
2. "Up-take of ARVs in selected low and middle income countries: results of survey 2007" presented by Françoise Renaud-Théry, WHO Department of HIV/AIDS
3. "Use of normative forecasting approach, need to model shifts, and quantifications for UNITAID programs", presented by Anil Soni, Clinton Foundation Initiative on HIV/AIDS (CHAI)

Discussion points:
- It was noted that generic companies were very concerned by the issue of sustainability of the ARV market. There is no question about the availability of funding up to 2010 but much more uncertainties regarding 2015 and beyond. For 1st line antiretrovirals, companies are also concerned by the potential risk of a high rate of resistance emergence within a few years. These concerns make decisions on investments very difficult (Aspen).
- It was also noted that market shifts presented by CHAI are based on an order of magnitude of price reduction. Generic companies have the feeling that the market of 1st line ARV drugs is not sustainable as prices are currently below production cost (Strides).
- Regarding sustainability of funding, UNAIDS is developing a model of resource need estimates where funding levels are included, including in-country assessment and percentage of countries expenditure (January 2008).

Afternoon session: round table on the establishment of a global ARV electronic information platform for the production of forecasts

Introduction:
F. Renaud-Théry (WHO Department of HIV/AIDS) introduced the roundtable with a presentation on the “Establishment of an electronic platform for ARV forecasts”. The main idea for WHO and UNAIDS is to improve the availability of data necessary to the production of forecasts by the creation of a web-based information platform. As a matter of fact, one of the most important
challenges faced in the production of the 2007-2008 forecasts was the limitation of data available to formulate the assumptions. Some of the data were not in the public domain, others were available but not easy accessible from one central location. With the establishment of a platform, the aim would be to make data available in the public domain, up-date them regularly as new data become available either from researchers, partners, funding agencies, companies or countries. A forecasting software and baseline rolling forecasts would also be made available with the possibility for any interested parties to produce their own forecasts.

Roundtable on needs and possible contributions of partners to the electronic information platform

J. Perriëns, Coordinator, WHO Department of HIV/AIDS, moderated the round table. Participants included representatives from UNAIDS, CHAI, PISCMS, GFATM, UNITAID. The efforts to make ARV data and forecasts available in the public domain were recognized by participants interesting for all parties: companies, national planning responsible persons, technical partners and funding agencies. Participants agreed that a global electronic platform would help improving ARV market forecasts and ARV market clarity, contributing to secure ARV availability at global level. Partners successively discussed what their organization could contribute to the platform, starting by WHO in the introductory remarks. Representatives of innovator and generic companies who contributed to the discussion, supported the establishment of the global ARV platform and highlighted its added value in helping company decision making about production. However, contribution by companies would be difficult because of confidentiality of information and anti-trust law. The lists of contributions are reported below.

Contribution by WHO:

1. Epidemiological data and treatment guidelines:
   a) Treatment data with number of patients receiving ART (annually),
   b) WHO treatment guidelines,
   c) National treatment guidelines collected from countries,
   d) Data on switching rate, loss to follow up and survival rate compiled from study reviews,
   e) Data on distribution and up-take of ARVs in country collected from an annual survey.

2. Quality data:
   a) Prequalification list (PSM)

3. API production capacity, in collaboration with companies

4. Baseline rolling ARV forecast:
   a) WHO and UNAIDS will produce a baseline forecast using data in public domain. The resulting ARV forecast will be made available in public domain on the platform.
   b) The software developed for the baseline forecast will be made available on the platform with possibility for any party to use the software and use different assumptions to make its own targeted forecast.
   c) WHO and UNAIDS have an on-going collaboration with other agencies producing forecasts, CHAI and SCMS, and will encourage their forecasts to be made available on the platform.
Contribution by AMDS Network
1. ARV regulatory database compiled by AMDS, in collaboration with companies and SCMS.

2. Procurement data from Global Price Reporting Mechanism (AMDS partners):
   Data on volumes purchased, prices of transactions, manufacturers and procurement agencies; currently contains data on 40% of the total transactions in low and middle income countries with objective to cover up to 60% in 2008 (AMDS website).

Contribution by UNAIDS Secretariat:
1. Epidemiological information: data on prevalence country by country, in agreement with national authorities in each country (June 2008).
2. Estimates of resource needs country by country that will include treatment and care, 1st and 2nd line. These data could be uploaded with the agreement of countries, or aggregated at regional level.
3. Analysis of resources available: reports from countries with sources of funds (donors, domestic funds) that would set the basis for other analysis regarding the question of sustainability.
4. Projection of finances available up to 2010.
5. Analysis of OECD trends and fiscal spaces.

Contribution by CHAI:
1. National treatment protocols,
2. Data on ARV orders with agreement from countries,
3. CHAI baseline ARV forecasts and tool.

Contribution by the Future Institute:
1. SPECTRUM Model, providing people in need in ART and assumptions used such as disease progression, MTCT, age, sex distribution, migration rate.
2. Software to produce forecasts of ARV demand with estimates of number of people who will be receiving treatment.
3. Software on resource needs from which the estimated number of people receiving testing can be extracted.
4. Participation in regional workshops on epidemiology organized by UNAIDS with possibility of getting feedback from countries.

Contribution by SCMS:
1. Data on ARV delivery and future purchases in PEPFAR focus countries plus Zimbabwe,
2. ARV paediatric forecasts for PEPFAR focus countries plus Zimbabwe and the software,
3. ARV quantification and supply plans developed by countries with John Snow Inc. technical support and in partnership with SCMS, subject to agreement by the countries concerned.

Contribution by Global Fund
1. The Preliminary Lists of pharmaceuticals that countries plan to procure during the first two years of the grant from all approved Round 7 HIV proposals (A total of US$ 537 million for 26 HIV programs in 39 countries) can consist in preliminary information in forecasting (R7 approved HIV proposals are available on the Global Fund website),
2. Price, volume and source of purchased ARVs under Global Fund grants are reported in the Price Reporting Mechanism (PRM database available on Global Fund website at: http://web.theglobalfund.org/prm/index.jsp),

3. The Global Fund will explore the possibility to make procurement and supply plans publicly available once plans are approved by the Secretariat.

Contribution by UNITAID
1. ARV forecasts and financial commitments,
2. Diagnostic forecasts, financial commitments and expected resources,
3. Facilitate, through coordination with partners and countries, the supply of data on registration status and pharmacovigilance
4. Data on impact on ARV market and ART programme in-country: a format of data transmission will be developed in collaboration GF, CHAI, UNICEF.

Contribution by innovator companies:
1. The innovator companies work through a neutral party to compile sales data and calculate the number of patients treated. No data would be released or included that could reveal sales of ARVs from individual companies (BMS & Abbott)

Generic companies:
1. The generic companies could explore the possibility to work through a neutral party to share aggregated sale volumes (Mylan, Strides)