
AIDS Medicines and Diagnostics Services (AMDS)
Partners and Stakeholders Meeting
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WHO HIV Department
System Strengthening for HIV
AIDS Medicines and Diagnostic Services
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Acronyms

AMDS	AIDS Medicines and Diagnostic Service
API	Active pharmaceutical ingredient
ARV	Antiretroviral
CDC	Centers for Disease Control and Prevention
CHMP	Centrale Humanitaire Médico Pharmaceutique
CPS	Contracting and Procurement Service
DLT	Diagnostics and Laboratory Technology
EHT	Essential Health Technologies
GDF	Global Drug Facility
GMP	Global Malaria Programme
GPRM	Global Price Reporting Mechanism
HIV	Human Immunodeficiency Virus
HSS	Health Systems Strengthening
IDA	International Dispensary Association
MSH	Management Sciences for Health
OI	Opportunistic infection
PEPFAR	US President Emergency Plan For AIDS Relief
PSM	Procurement and Supply Management
REMEDI	Réseau Médicaments & Développement
SCMS	Partnerships for Supply Chain Management System
SOP	Standard Operating Procedure
SSH	Systems Strengthening and HIV
STB	Stop TB
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNICEF	United Nations Children Fund
USAID	United States Agency for International Development
WHO	World Health Organization

1. Introduction

Strengthening procurement and supply management (PSM) systems in developing countries requires effective partnership at global, regional and country levels. The AIDS medicines and diagnostics (AMD) network has been established for this purpose.

AMD partners and stakeholders meet annually to share PSM experiences and to identify PSM priorities on which effective collaboration can be engaged. Since WHO/AMDS and partner organizations had the last AMDS Partners Meetings in December 2007, significant progress has been made in various projects including Global Price Reporting Mechanism, forecasting of global ARV consumption, Procurement and Supply Management toolbox, monitoring and evaluation of procurement and supply management systems, capacity building, coordinated procurement planning, guidance on effective procurement of laboratory items, etc.

The purpose of the AMDS partners and stakeholders meeting organized on 2-3 April 2009 was to exchange with each other on progress made and identify areas for further collaboration.

2. Objectives of the meeting

- To take stock of the progress and achievements made on current projects
- To identify and agree on future projects for collaboration within the AMD network
- To define timeline and interested partners for the implementation of the identified joint priority PSM projects
- To discuss on individual basis, the implementation process of specific joint projects

3. Proceedings of the meeting

The meeting was chaired by Dr Jos Perriëns, Coordinator HIV/SSH. Following a short note of welcome and opening remarks, the Chair person invited the participants to present themselves. This meeting was attended by 35 participants representing the following 16 institutions: UNDP, Missionpharma, i+solutions, Crown Agents, SCMS, IDA Foundation, REMED, USAID/DELIVER PROJECT JSI, MSH/Center for Pharmaceutical Management, CHMP, CDC, UNITAID, UNAIDS, Global Fund, GDF/Stop TB Partnership, and WHO (EHT, EMP, HIV).

The draft agenda was reviewed by participants. Annex 1 presents the final version of the programme and the final list of participants is found in Annex 2.. All the presentations can be found in full on AMDS website at <http://www.who.int/hiv/amds/partners09/en/index.html>. The following topics were discussed in the order presented below.

3.1 Clearinghouse Database: Current Status and Next Steps

Boniface Dongmo Nguimfack (WHO/AMDS) presented the current status/progress and proposed list of enhancements to the GPRM, the regulatory database, the active pharmaceutical ingredient (API) database and the controlled medicines database. For the GPRM, he further clarified the definition of the duplication rate and the problems of duplicated data received by AMDS Secretariat. Following his presentation, there was a plenary discussion and the key points discussed include:

- The challenge of limited resources (funding) to improve the clearinghouse database
- Ways of increasing volume of data being received from different partners
- Ways of reducing error and duplication from data received
- Cleaning data submitted to AMDS Clearinghouse.

Participants suggested to include information on prices of ARVs and other essential drugs against TB, malaria and opportunistic infections (OIs). Some partners suggested that GPRM explore ways to include other price data sources such as MSH, WHO/AFRO to ensure that users have one single source of price information. On this, Dongmo Nguimfack responded that AMDS is working with UNITAID and GDF on including TB medicines. AMDS Secretariat will discuss with MSH, AFRO on how the suggestion of AMDS partners to include OI medicines can be implemented. The AMDS secretariat was encouraged to open a discussion with MSH and AFRO on sharing the AMDS data on ARV procurement through their Essential Medicine Price Indicator publications.

3.2 Forecasting Global ARV Demand

This topic was presented by Francoise Renaud-Thery (WHOAMDS). She highlighted the achievements to date, the activities being currently implemented and future plans. An electronic platform on ARV forecasts was established to make publicly available global ARV forecasts produced by WHO and UNAIDS, ARV pediatric forecasts produced by SCMS, country data, latest WHO treatment recommendations and trend analysis (e.g. national guidelines, ARV market) for the production of forecasts. On-going activities include the systematic review of literature to determine migration and retention rate for improving the forecasting of patients on 1st and 2nd line regimen, the 3rd round of the annual survey on ARV use in 40 countries to monitor country ARV use trends. By the end of 2009, the planned activities include: up-date of WHO/UNAIDS forecasts 2010-2012 with new data, the annual forecasting meeting with ARV producers, Q4 2009 and the follow-up of the SG meeting with ARV producers, (NY 9 Oct 2008).

The group discussed an impact maximization strategy on three points:

- improving technical products: it was suggested to look at funding channels with UNAIDS in the next production of global forecasts. The Global Fund provides forecasting information on grant disbursements for R7 and R8 approved proposals for ARV procurement.
- improving communication: continuation of efforts in joint publications, dissemination of contributions on electronic platform, AMD website, publication of reports and articles, conferences (Toronto, Mexico), high level meetings

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- partner contributions: continuation of forecasting working groups: technical working group and a consultation working group (UNAIDS, Futures Institute, SCMS, FATM, CHAI, UNITAID, UNICEF, USAID), coordinated by AMD Secretariat

The issue of a decrease in global production of ZDV was discussed.

3.3 Strengthening Laboratory Services

This topic was introduced by Sherry Orloff from CDC, Carmit Keddem from USAID | DELIVER PROJECT, JSI and David Jamieson from SCMS.

Sherry Orloff presented the national laboratory strategic planning guide, which is being developed in response to the Maputo Declaration on Strengthening Laboratory Systems. Integrated approach in strengthening laboratory services and cross-cutting laboratory elements to fight major public health problems were discussed. The cross-cutting issues include training, infrastructure development, supply chain & maintenance of equipment, specimen referral system and governance & regulatory policy. She emphasized that development of a national laboratory strategic plan should be based on the public health integrated approach. Steps to be followed when developing national laboratory strategic plan were also discussed.

Carmit Keddem discussed strategies for strengthening supply chain of diagnostics & other laboratory items. This discussion revealed the importance of 3 particular strategies for strengthening laboratory logistic systems: the need to assess first the laboratory systems; the process and the benefits of standardization of laboratory tests, equipment, and techniques; and the design and implementation of logistics systems for laboratory commodities. Carmit mentioned that experience has shown that for laboratory commodities it is necessary to evaluate lab management practices, capacity, and services, in addition to the supply chains; assessments will identify and prioritize further interventions. For example, assessments will help to identify whether standardization is necessary, which is a prerequisite for optimizing laboratory supply chains and should precede quantification and logistics system design. Designing and implementing logistics systems, is a key intervention to ensuring commodities are delivered when and where needed, and should follow the standardization exercise.

David Jamieson's presentation focused on the effects of standardization on procurement and quantification of laboratory commodities. He noted that standardization leads to fewer types of laboratory equipment, fewer laboratory items to be procured, better control of stock levels with improved availability of laboratory items, fewer stock outs, fewer expired laboratory supplies and better delivery times. Standardization makes quantification easier as there are fewer laboratory items for which quantification is to be done. Based on country experiences, David mentioned that the burden and frequency of procuring multiple laboratory items is reduced, the supply chain of fewer laboratory items is optimal provided that, prior to any procurement, specifications are well defined for each item to avoid duplication of items when purchasing. More benefits of standardized laboratory system include easier training of laboratory technicians, ensure maintenance of laboratory equipments and allow exchange of laboratory equipments and supplies between health facilities.

Plenary discussions were held on the above topics.

In line with the Maputo Declaration, all countries receiving support from PEPFAR and Global Fund to strengthen their national laboratory services are required to have a national laboratory strategic plan and standardized equipments and reagents.

3.4 PSM Challenges Faced within Countries of Destination

This topic was introduced by Bo Birk and Tia Laustsen (Missionpharma). They presented Missionpharma supply chain services and the different countries they are supporting. Challenges in local supply chain were highlighted and include: documentation and registration status, custom clearance, volume and warehousing of big volumes, local infrastructure and logistics, tracking the orders and the consumptions, procurement planning, etc. A case study from Ethiopia, on how various challenges were approached was presented. The following project management tools were mentioned as essential for successful project implementation: risk analysis with mitigation plans, clarity in roles and responsibilities, conduction of workshops, stakeholder analysis and having competent local partners.

Missionpharma also discussed the recently seized and released ARVs at the Amsterdam airport (Netherlands), a consignment for which Missionpharma was the appointed Procurement Agent by the UNITAID funded program of 2nd Line ARV managed by CHAI. Partners discussed how to prevent the occurrence of such incident. The Chairman informed the participants that the WHO Essential Medicines and Policy Department is handling this issue in close collaboration with WHO senior management.

3.5 UNITAID, an Innovative financing Mechanism for Scaling up Access to Medicines and Diagnostics for HIV, TB and Malaria

This topic was presented by Paulo Meireles from UNITAID. UNITAID is an innovative financing mechanism to scale up access to medicines and diagnostics for HIV, TB and malaria. This mechanism aims to influence market dynamics by reducing prices and builds partnerships to increase access to medicines and diagnostics for HIV, TB and malaria. Meireles shared information on the HIV niches funded (Pediatric, 2nd line and PMTCT) which have a total budget of USD 392 M. UNITAID is also working in partnership with technical institutions and funding agencies like CHAI. Over 34 countries are being supported by UNITAID and the following achievements were highlighted: drug price reduction up to 50% for some drugs, more adapted medicines to patients (e.g FDCs), better quality of medicines and rapid delivery of medical supplies to countries because suppliers are paid on time. One of the major challenges facing UNITAID is the need for a rapid registration of new products. This constitutes a big challenge because the choice of suppliers is sometimes determined by the registration status; therefore there is a need to expedite the registration process of effective, safe and more affordable medicines to increase competition and to further achieve price reduction. Collaboration between UNITAID and WHO on this issue could be helpful as there is the Regulatory Status project.

3.6 PSM Toolbox and its use in Capacity Building to Strengthen PSM Systems

AMDS and i+solutions prepared and presented on the PSM Toolbox which is an AMDS project involving several partners. The project started in 2006. The day-to-day activities are being carried out by i+solutions in collaboration with the AMDS Secretariat. Rino Meyers from i+solutions highlighted the key products of the PSM toolbox and the progress to date.

The toolbox has the merit of being a repository of PSM tools from all AMDS partners and many other institutions working on supply chain management. The PSM Toolbox currently covers HIV & TB related PSM tools. Efforts are ongoing to expand the toolbox to vaccine supplies and PSM tools for malaria. The PSM Toolbox contains over 150 tools and can be accessed online from: <http://www.psmtoolbox.org>. or on CDs for people who do not have reliable internet connection. Over 1500 CDs have been distributed so far.

Partners acknowledged that the PSM toolbox is useful and suggested more dissemination of the PSM toolbox. They supported the expansion to include other diseases as this is in line with the integrated PSM approach.

3.7 Capacity Building to Strengthen PSM Systems: GDF/STB Experience

The subject was introduced by Andrea de Lucia (GDF). In her presentation, she highlighted that the aim of the GDF is to ensure uninterrupted supply of quality assured affordable TB medicines. The target is to supply treatment to 15 M patients by 2010 and to 25 M by 2015. To achieve these targets GDF organizes regional and country TA and capacity building activities. Major areas for capacity building include quantification, LMIS and monitoring and evaluation. 60 missions per year are conducted using funds from the PSM grants. Partners are willing to provide funding for capacity building despite the financial crisis and great collaboration exists among TB stakeholders to avoid duplicative efforts. Integration efforts with other disease programmes in particular HIV are under way: for instance the next PSM workshop in Kampala is being organized in close collaboration with AMDS.

Ms Andrea de Lucia concluded her presentation by highlighting the following challenges:

- Limited funds committed for anti-TB drugs
- Short supply of quality assured raw materials for anti-TB drugs and too few suppliers of pre-qualified 2nd line drugs
- Short shelf life for 1st line pediatric and 2nd line TB drugs
- In-country challenges: capacity development for quantification, forecasting, financing, distribution and timely ordering of anti TB drugs; weak regulatory and policy framework for registration and tendering, quality assurance and rational use; coordination of partners in conducting country missions and measuring the impact of our TA.
- GDF challenges: how to monitor country stock levels to alert on imminent stock outs, how to have better national forecasting which could improve global forecasting in order to better inform the suppliers.

Discussions were around how the TA activities were organized in GDF: Ms Andrea de Lucia explained that the programmes' TA needs are identified with the NTP managers. Plans are established in order to identify partners who will provide the TA in collaboration with the NTP manager and RO Focal Points.

3.8 Harmonized Indicators for M & E of National PSM Systems

The harmonized indicators to monitor & evaluate PSM systems is an AMDS project involving several AMDS partners since its inception in 2005. The AMDS secretariat is carrying out this project in collaboration with i+solutions. The presentation was prepared jointly by AMDS and i+solutions. Rino Meyers from i+solutions made the presentation and highlighted the progress of the project and the various consultative processes which led to reducing the indicators from 52 to 12 core indicators which are still to be finalized based on the results of the field tests. The next steps are as follows:

- (1) To finalize the methodology for field testing the core indicators

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- (2) To conduct the field test in a few Anglophone and Francophone countries that will be supported by AMDS partners.
 - (3) After the field test, the core indicators will be finalized.

The importance of PSM M&E indicators was highlighted. Good inventory control and logistic management information data will be strengthened to measure M&E indicators which could prevent the frequently observed stock outs as well as expired drugs. A dashboard to monitor the stock level will be also developed. These indicators are therefore crucial elements for strengthening the national PSM systems. UNDP mentioned that the core indicators to monitor the PSM system are used in DRC and progressing well but would present a comprehensive report on the outcome during the next annual AMDS meeting. Other partners interested who expressed their interest to field test the core indicators include MSH, SCMS, Missionpharma and i+solutions.

3.9 The Medicine Patent Pool Initiative

The topic was presented by Ellen 't Hoen from UNITAID. She introduced the subject by giving the history of UNITAID which was created in 2006 with the support from the following five countries: Brazil, Chile, France, Norway and UK. In 2009, UNITAID is supported by 29 countries and the Gates Foundation.¹ T Hoen informed the participants that UNITAID was given a go ahead to create a medicine patent pool initiative on 3 July 2008; this initiative was established to increase access to new first line and 2nd line ARVs through decrease of their prices by increasing the number of generic producers, encouraging the development of FDCs containing new ARVs for both 1st and 2nd lines treatment, and encouraging 1st line and 2nd line pediatric ART. UNITAID is developing an operational plan for the implementation of patent pool Initiative. This is done by making the intellectual property, in particular patents - that would otherwise form a barrier to generic production or the development of FDCs - available to third parties through the patent pool against the payment of a royalty. Ellen 't Hoen concluded her presentation mentioning that there are clear signs that time is right for such an initiative quoting President Obama and Vice-President Joe Biden's support to humanitarian licensing of government funded inventions so people in developing countries can have access to AIDS medicines off patent.

Discussions were held on the incentives for manufacturers to use the patent pool initiative. Ellen 't Hoen explained the following incentives: economic (royalty payments); several manufacturers want to be aligned; opportunities for collaboration in developing FDCs, pressure in term of public relations and easy access to IP information to all manufacturers R&D as well as generic manufacturers. She mentioned also that the patent pool may help to facilitate pooled procurement in situation where patent status of products vary.

3.10 Voluntary Pooled Procurement (VPP)¹

This topic was introduced by Mariatou Tala Jallow from the Global Fund. The VPP Initiative was endorsed by the Board in April 2007 with the following 3 major objectives: (1)improving market outcomes, (2)improving grant management and performance and (3)addressing key

¹ VPP Initiative has recently changed its name to Procurement Support Service (PSS) to better reflect that this is a service for not only pooled procurement but also for capacity building & TA to strengthen national supply chain management systems.

procurement bottlenecks. Tala discussed the 5 key components of the VPP: (1) negotiation of prices and supplier selection; (2) procurement services (manage the operational processes); (3) Direct payment mechanisms, (4) VPP products (core products are ARVs, LLINs, ACTs; additional OIs and lab supplies); (5) monitoring the performance of procurement support services and manufacturers.

There are two components : (1) the Pooled Procurement Unit to deal with procurement & (2) the Capacity Building Unit to support PRs in efficient procurement and effective supply chain management. Tala also discussed the objectives of capacity building, the priority TA areas (quantification, LMIS & procurement planning) and types of TA (training, TA, developing PSM systems & tools). There are 8 confirmed countries and 12 potential countries willing to participate in the Voluntary Pooled Procurement. The list of countries is not definitive as some countries have decided to move from being potential to confirmed participants and vice versa, and new ones are joining. Further information and developments on the VPP can be found on the “Voluntary Pooled Procurement and Capacity Building Services section” on the Global Fund website.

In plenary discussions, Tala confirmed that capacity building will focus on national PSM system rather than on disease specific programme. She mentioned also that several partners already involved in PSM will be asked to provide TA.

3.11 Other PSM Capacity Building Opportunities with Global Fund

Joseph Serutoke from Global Fund Procurement Team mentioned that 15 approved grants need PSM plans to be developed along with an operational plan for TA and capacity building. The intention is to develop capacity building interventions to strengthen the national PSM system rather than strengthening the supply chain management for a specific HIV, TB or malaria programme. This integrated approach will lead to a more sustainable system by increasing the performance of the whole national supply chain system as well as for supply of the commodities related to specific programmes. The Global Fund Procurement Team is developing an ad hoc document which will be circulated to AMDS partners for comments and involvement in the implementation process.

3.12 Assessment Study on PSM Coordination

Helen Tata and Magali Babaley introduced the assessment study which was conducted in 2007 and 2008 by countries with the support of WHO/EMP Department. The study covered 10 countries: Cameroon, Senegal, Rwanda, Burundi, Mali, Congo- Brazzaville, Ghana, Nigeria, Tanzania and Zambia. The study had 2 parts: a mapping of all partners involved in country supply chain management system and the in-depth study to assess the strengths and weaknesses of the national PSM systems. The major findings highlighted by the presenters include:

- Complex structure of the medicines procurement and supply systems in country with a great deal of weak coordination among partners and with the Ministry of Health.
- Selection problem involving procurement of non registered medicines and medicines outside the national EML/STG
- Quantification issue involving lack of planning, lack of coordination and inadequate logistic information system

- Difficulties in managing various procurement and financial procedures from many partners
- Complexity of stock management with each partner stock having a different stock management tool and inadequate storage facilities
- Most partners deposit medicines at central medical stores without provision of funds for distribution
- No coordination between different partners in the distribution of medical supplies.
- Uncoordinated financial funding towards some diseases programs (especially HIV/AIDS, TB, Malaria and EPI) leading to over funded of some programmes on one hand and under supported programmes on other side.
- Complex monitoring and evaluation due to different reports from different programs using different reporting tools
- Insufficient human resources

During the discussions, areas for coordination were discussed such as M&E of PSM system, training, procurement planning, (e.g CPP). Harmonization and alignment principles needed to be defined country by country. An example of such partner alignment in Tanzania was discussed.

3.13 Coordinated Procurement Planning (CPP) Initiative

This topic was introduced by David Jamieson from SCMS. He explained that the CPP initiative was established in January 2006. It is in line with the Paris Declaration and the Accra Agenda for Action (AAA). The main aim of the CPP initiative is to provide a framework to improve and strengthen country-level coordination for the planning and procurement of HIV/AIDS related commodities. The initiative started with 6 countries (Ethiopia, Guyana, Haiti, Mozambique, Rwanda and Vietnam) with initial focus only on ARVs but now, additional countries (including Cote d'Ivoire, Malawi, and Zambia) and new commodities such as rapid test kits are being considered. The six supporting organizations of the CPP initiative are: GFATM, UNITAID, PEPFAR, WB, WHO and SCMS.

Discussions on basket funds for a better coordinated procurement were raised by the participants. SCMS replied that by law, US money cannot go into a basket fund system. More important was the discussion on how partners can work together in a coordinated and integrated manner. It was agreed that partners will work step by step to build and achieve sustainable national PSM systems. Country leadership is considered as crucial to achieve this goal. Evaluation of the CPP initiative is planned to document successes and challenges of the CPP and the report will serve as advocacy document for coordinated procurement planning processes.

3.14 The Revised Global Fund Quality Assurance and Price Reporting (PQR)

This topic was introduced by Joelle Daviaud from the Global Fund. She informed the participants that a revised QA policy has been developed. It was approved by the Board in November 2008 and shall become effective on 1 July 2009. The revised QA policy takes into account (1) the alignment with other partner's QA policies,(2) concerns about safety, stability and efficacy of products,(3) market dynamics and (4) lessons learned from implementation of the existing Global Fund QA policy. The 6 key changes to the Quality Assurance policy are: Clinical criteria

Quality criteria (authorized for use in recipient country, and prequalified by WHO (A) or registered by stringent regulatory authority (B) or recommended for use by the expert review panel (ERP) if not yet approved by WHO or a stringent regulatory authority (SRA)

Selection process of finished pharmaceutical products (FPPs): selection in priority among A or B products and if there is less than two A or B products available, selection of ERP recommended product can be accepted.

Amendment of the definition of SRAs : only International Conference on Harmonization (ICH) members and associated countries are recognized as SRA

Independent expert review panel is set up and

Monitoring product quality.

She further mentioned that the deadline for submission of ARVs, anti TB and Anti Malarial finished pharmaceutical products for ERP review to the Global Fund was the 3rd of April 2009. The Global Fund list of ARVs, Anti-Malaria, and Anti-TB according to the Quality Assurance policy would be published on the 15th of June 2009 and can be found through the link: <http://www.theglobalfund.org/en/about/procurement/quality/> while the revised Quality Assurance policy can be found at: <http://www.theglobalfund.org/en/procurement/quality/>

She also talked about Price & Quality Reporting (PQR) formerly known as PRM (Price Reporting Mechanism) which was launched in the first week of February 2009. There are currently 150 users from 71 countries using the PQR. More information on PQR can be found at the following website : <http://www.theglobalfund.org/en/procurement/pqr/?lang=en> For any enquiries, people can use the following email contact pqr@theglobalfund.org.

3.15 Prequalification of Medicines

This topic was presented by Matthias Stahl from EMP/QSM. The main aim of the Prequalification Programme is to increase choice and access to quality products without compromising with requirements for quality, safety and efficacy. These requirements have to remain unchanged. The programme is an action plan to expand access to priority essential medicines in HIV/AIDS, TB, Malaria, Reproductive Health and Selected products for other diseases like oseltamivir and Zinc sulfate. Matthias discussed the prequalification process in details. The process aims at:

- increasing transparency of the prequalification activities;
- publishing more details on prequalified products,
- defining responsibilities,
- confidentiality agreement with applicants and
- harmonizing technology and clarifying application procedures.

Presently, there are 206 prequalified pharmaceutical products [171 for treatment of HIV/AIDS and related diseases, 20 for treatment of TB and 15 for treatment of malaria] . In addition, on 10 March 2009, there were 114 pharmaceutical products under assessment in WHO Prequalification Programme: 60 for treatment of HIV/AIDS and related diseases, 35 for treatment of TB, 19 for treatment of malaria and 14 for reproductive health products.

Over 62 inspections of manufacturing sites were carried out in 2008 compared to 46 inspections carried out in 2007.

EMP/QSM also organized 11 QUA training courses and co-organized 4 training courses in different countries including Brazil, China, and Ghana with more than 500 participants in 2008.

He further pointed out some of the challenges which include:

- Poor availability of national experts in forthcoming years
- Increased demand for capacity building and ad hoc services regarding quality
- Increased demand for prequalified products of high public health value
- Trust building and information exchange to avoid duplication with constant need to improve communication
- Meeting the increased needs with the limited staff available

Further information can be found on the website: <http://healthtech.who.int/pq/>

3.16 Prequalification of Diagnostics

This subject was presented by Anita Sands from WHO/EHT/DLT. She gave a brief overview of the WHO Prequalification (PQ) of Diagnostics programme. The aim of the programme is to promote and facilitate access to safe and appropriate diagnostic technologies of good quality in equitable manner. Additionally, the programme aims to increase in-country capacity to effectively regulate diagnostics and the ability of Member States to monitor the quality of diagnostics in their national market. The PQ of Diagnostics process was reviewed in detail. Fifty-six Prequalification applications have been received since 16 June 2008; of the 56 applications: 11 were for HIV diagnostics and 4 for malaria diagnostics. The major issues during the review of the 56 application forms were inadequate design control, poor instructions-for-use and lack of test kit controls available to use with rapid assays. To show the complexity of the prequalification activity, Ms Sands explained the elements of a product dossier, inspection purpose and components, and the laboratory evaluation. The need for post market surveillance of prequalified diagnostics was also stressed. Furthermore, the role of the national reference laboratory and the national regulatory authorities was highlighted. More information on PQ of diagnostics can be found at this website: www.who.int/diagnostics_laboratory/en/ and e-mail can be sent to diagnostics@who.int.

Discussions were around the need to increase the number of prequalified diagnostics. Ms Sands explained that the DLT Team is doing its best to increase the number of prequalified items, but one needs to take into account the limited available human resources and the required long & careful prequalification process.

4. Conclusion and Recommendations

Based on various topics, the following recommendations were made:

GPRM

1. AMDS secretariat (dongmonguimfackb@who.int) should open a discussion with MSH, AFRO and other relevant agencies on the possible inclusion of AMDS ARV procurement data in the International Essential Medicines Price Indicator, and use of International Essential Medicines Price Indicator to inform procurement of OI medicines, and with AFRO on the possible inclusion of AMDS ARV procurement data in the AFRO Essential Drugs Price Indicator.

Forecasting

2. AMDS secretariat (theyf@who.int) will continue the collaboration with partners on ARV market surveillance and global forecasting.
3. AMD Secretariat (theyf@who.int) and SCMS will share information from the manufacturers to better ascertain possible problems with the global ZDV production.
4. AMD Secretariat (theyf@who.int), Missionpharma and EMP/QSM will work together on generic ARV transit problems in the EU.

Strengthening laboratory services

5. CDC (Orloff, Sherry : sll1@cdc.gov) shared the guidance for developing national laboratory strategic plan for comments.
6. The AMDS secretariat (habiyamberev@who.int) will continue the coordination of the ongoing working group on specification of laboratory items for defining generic specifications of selected laboratory items. This would include defining the supplies required to perform certain tests and their specifications, as they are essential information for the effective procurement of diagnostics and other laboratory items.
7. Partners will continue to produce and share country case studies on financial and operational benefits of standardizing procurement of laboratory items. The AMDS secretariat (habiyamberev@who.int) will ensure that these country case studies are disseminated through AMDS website and CDs.

PSM challenges in countries of destination

8. AMDS secretariat ((habiyamberev@who.int)) will raise the question within the CPP initiative whether CPP activities should be expanded to cover in-country distribution.
9. Partners interested to contribute towards the CPP initiative in any one of the target countries should contact the initiative's technical secretariat (Stephanie Xueref , sxueref@pfscm.org) for information and planning purposes.
10. CPP to consider results of the 2007 WHO/EMP Department study when implementing CPP initiative activities in countries covered by it, so as to ensure that coordination is strengthened and all stakeholders are represented in the CPP process under governmental leadership.

Capacity building

11. Partners to signal as soon as possible to AMDS secretariat (habiyamberev@who.int) and i+solutions (cmorris@isolutions.org) or via the PSM Toolbox website when new or updated products are available from their organization, to ensure that tools found in PSM Toolbox are updated.
12. GDF (deluciaa@who.int) and AMDS secretariat (habiyamberev@who.int) will continue efforts to collaborate to ensure that TA for strengthening the procurement and supply management of HIV and TB commodities are aligned and integrated.

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13. The GFATM VPP Team (mariatou.jallow@theglobalfund.org) will approach various partners on a bilateral basis to explore ways and means to collaborate on capacity building and TA activities for strengthening national PSM systems.
 14. The Global Fund (joseph.serutoke@theglobalfund.org) will share for review and comments by AMDS partners, the ad hoc Global Fund document on strengthening the supply chain management.

M&E indicators for PSM systems

15. AMDS (habiyamberev@who.int) will distribute the methodology for field testing the 12 core indicators to monitor the performance of the national PSM systems. The following partners expressed their interest to participate in the country field test: MSH, Missionpharma, UNDP, SCMS, i+solutions. The expectation is that they will proceed as quickly as possible with field testing of the proposed M&E indicators and report back to the AMDS secretariat on their findings soon.
16. The AMDS Secretariat (habiyamberev@who.int) will explore if other partners are interested in field testing and establishing harmonized PSM M&E indicators in countries they are supporting PSM activities.

Future AMDS Partners & Stakeholders meeting

17. The partners agreed to meet on a regular basis but not annually as preference will be given to technical working group meetings which discuss specific technical subjects identified by AMDS partners & stakeholders. The outcome of the technical group work on technical subjects will be reported and discussed in the AMDS Partners & Stakeholders Meetings which will be organized after Partners & Stakeholders have submitted to the AMDS Secretariat products to be discussed.

ANNEX 1 - FINAL AGENDA

Chairperson: Dr Jos Perriëns

Rapporteur: Dr Vincent Habiyambere

DAY 1: Thursday, 2 April 2009

10:00 – 10:30 Opening remarks

- Opening remarks: Dr Jos Perriëns, Coordinator, HIV Department
- Tour de table: self presentation of participants

10:30-10:45 Coffee Break

Exchange among partners on major projects: progress, achievement, challenges, next steps

10:45 - 11:00 Clearinghouse: Current status and next steps: **Boniface Dongmo Nguimfack**

11:00 - 11:15 Plenary discussion on the above topic

11:15 - 11:30 Forecasting Global ARV Demand: **Françoise Renaud-Thery**

11:30 - 11:45 Plenary discussion on the above topic

11:45 - 12:40 Strengthening laboratory services: Progress on ongoing work

- National strategic planning and progress of the working group on generic specification of laboratory items: **Sherry Orloff, CDC (15')**
- Strategies for strengthening laboratory supply chains (Assessment tools of laboratory system, standardization as a prerequisite for quantification, design/implement a lab logistic system): **Carmit Keddem, JSI (25')**
- Country case studies on procurement of standardized laboratory items Benefits & challenges of standardization of laboratory equipment and supplies : **David Jamieson, SCMS (15')**

12:40 - 13:00 Plenary discussion on the above topics

13:00 - 14:00 Lunch

14:00 - 14:25 PSM challenges faced within the countries of destination: **Bo Birk & Tia Laustsen, Missionpharma & Paulo Meireles, UNITAID**

14:25 - 14:45 UNITAID, an innovative mechanism for scaling up access to medicines and diagnostics for HIV/AIDS, TB & Malaria: Key achievements and Challenges: **Paulo Meireles, UNITAID**

14:45 - 15:00 **Plenary discussion on the above topics**

15:00 - 15:15 PSM Toolbox and its use in capacity building to strengthen PSM systems: Progress and PSM Toolbox expansion to other diseases: **Rino Myers, i+solutions**

15:15 - 15:30 Capacity building for strengthening PSM systems: GDF/STB experience: **Andrea de Lucia, GDF/STB Partnership**

15:30 - 15:45 **Plenary discussion on the above topic**

15:45-16:00 **Coffee Break**

16:00 - 16:20 The Medicines Patent Pool: **Ellen t'Hoen, UNITAID**

16:20 - 16:40 Voluntary Pooled Procurement (VPP), **Mariatou Tala Jallow, Global Fund**

16:40 - 17:00 **Plenary discussion on the above both topics**

17:00 **End of Day 1**

19:00 **Diner in Town**

DAY 2: Friday, 3 April 2009

09:00 – 09:20 Assessment Study on PSM coordination: **H. Tata & Magali Babaley, EMP/MAR**

09:20 – 09:45 Coordinated Procurement Planning (CPP) Initiative : **David Jamieson, SCMS**

09:45 - 10:00 **Plenary discussion on the above topic**

10:00 – 10:15 PSM M&E indicators: Field test Methodology and next steps: **Rino Myers, i+solutions**

10:15 - 10:30 **Plenary discussion on the above topics**

10:30-10:45 **Coffee Break**

10:45 - 11:00 Revised Global Fund quality assurance Policy and Price & Quality Reporting (PQR): **Joelle Daviaud, Global Fund**

11:00 - 11:15 Prequalification of medicines : **Stahl Matthias, EMP/QSM**

11:15 - 11:30 Prequalification of diagnostics: **Anita Sands, EHT/DLT**


11:30 - 11:45 **Plenary discussion on the above topics**

11:45 - 13:00 Identification from the discussions of new collaborative projects: time line and involved partners

13:00 **END OF THE MEETING**

13:00 - 14:00 **Lunch**

14:00 - 17:00 Individual or Group meetings on specific projects (Optional)



ANNEX 2 - FINAL LIST OF PARTICIPANTS

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