The Department of Technical Cooperation for Essential Drugs and Traditional Medicine (TCM), WHO, organized a meeting on multi-country regional pooled procurement of medicines in Geneva, Switzerland, on 15th - 16th January 2007. The objective of this meeting was to provide a forum for sharing experiences from the ongoing regional and global pooled procurement programmes and also to explore priority areas for inter-regional collaboration. The meeting brought together experts from various regional and global initiatives, representatives of sub-regional economic groups and development partners interested in pooled procurement.
Multi-country Regional Pooled Procurement of Medicines

Identifying key principles for enabling regional pooled procurement and a framework for inter-regional collaboration in the African, Caribbean and Pacific Island Countries

Geneva, Switzerland
15-16 January 2007

Meeting Report
Multi-country Regional Pooled Procurement of Medicines.
Identifying key principles for enabling regional pooled procurement and a framework for inter-regional collaboration in the African, Caribbean and Pacific Island Countries.

WHO/TCM/MPM/2007.1

This document has been produced with the financial assistance of the European Community and the Department for International Development (DFID), UK. The views expressed herein are those of the authors and can therefore in no way be taken to reflect the official opinion of the European Community or the Department for International Development (DFID), UK.

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## Acronyms

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<td>ACAME</td>
<td>Association of Central Medical Stores for Generic Essential Medicines</td>
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<td>AIDS</td>
<td>Acquired Immunodeficiency Syndrome</td>
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<td>ARV</td>
<td>Antiretroviral</td>
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<td>CMS</td>
<td>Central Medical Stores</td>
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<td>EAC</td>
<td>East African Community</td>
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<td>ECOWAS</td>
<td>Economic Communities of West African States</td>
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<td>GCC</td>
<td>Gulf Cooperation Council</td>
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<td>GDF</td>
<td>Global Drug Facility</td>
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<td>GFATM</td>
<td>Global Fund Against AIDS, TB and Malaria</td>
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<td>GMP</td>
<td>Good Manufacturing Practices</td>
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<td>GPP</td>
<td>Group Purchasing Programme</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>IPR</td>
<td>Intellectual Property Rights</td>
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<td>MDGs</td>
<td>Millennium Development Goals</td>
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<td>MIS</td>
<td>Management Information System</td>
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<td>NMRA</td>
<td>National Medicines Regulatory Authorities on Medicines</td>
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<td>OECS</td>
<td>Organisation of Eastern Caribbean States</td>
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<tr>
<td>PAHO</td>
<td>Pan American Health Organization</td>
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<td>PPS</td>
<td>Pharmaceutical Procurement Services</td>
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<td>PSM</td>
<td>Procurement and Supply Management</td>
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<td>RPP</td>
<td>Regional Pooled Procurement</td>
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<td>SADC</td>
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<td>USAID</td>
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Executive Summary

The Department of Technical Cooperation for Essential Drugs and Traditional Medicine (TCM), WHO, organized a meeting on multi-country regional pooled procurement of medicines in Geneva, Switzerland, on 15th - 16th January 2007. The objective of this meeting was to provide a forum for sharing experiences from the ongoing regional and global pooled procurement programmes and also to explore priority areas for inter-regional collaboration. The meeting brought together experts from various regional and global initiatives, representatives of sub-regional economic groups and development partners interested in pooled procurement. The meeting was organized to include plenary presentations on lessons learnt, i.e. strategies, achievements and constraints, and group work and discussions on the key principles of effective pooled procurement.

Presentations made on sub-regional and global experiences included successful pooled procurement initiatives such as:

a) the Pharmaceutical Procurement Services of the Organisation of Eastern Caribbean States (OECS) which operates a centralized tendering and procurement system based on a drug revolving fund for its nine member countries;

b) the Group Purchasing Programme of the Gulf Cooperation Council whose core function is pooled procurement of pharmaceuticals and medical supplies for the ministries of health of its six member states;

c) the Pan American Health Organization (PAHO) Strategic Fund that links technical cooperation in procurement and supply management with acquisition of strategic public health supplies and

d) The WHO Global Drug Facility which apart from its pooled procurement programme for anti-TB medicines and supplies also provides services in response to specific constraints and requests. Emerging pooled procurement initiatives such as i) the experience of pooled procurement of TB medicines in the South African Development Community (SADC); and ii) the East African Community (EAC) experience of pooled procurement of HIV medicines were also shared. The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) also shared a study it is conducting to assess the feasibility and operational costs of voluntary pooled procurement as a possible facilitator of improved availability. The harmonization of medicines regulations for regional pooled procurement was also presented.

The main strategies adopted by the Caribbean and the Gulf States for their pooled procurement initiatives include ensuring the political commitment of their member states, establishing a permanent secretariat and adopting a centralized tendering system. The OECS highlighted achievements such as strong bargaining power, average cost savings of 37% for 25 selected items over a five-year period, enhanced quality control, sharing of information and experiences, and measurable increased access to medicines. The GCC reported that its pooled procurement services have demonstrably reduced costs, saved millions of dollars over the years and enhanced the efficiency of health services for its member states. The GDF identified quality, competitive procurement, long-term agreements with manufacturers, forecasting and planning as lessons learnt on good practice and sustainability.

The EAC and SADC highlighted the initial steps taken towards adopting pooled procurement initiatives, ongoing and planned harmonization activities and their current status. They reiterated their interest in forging ahead with pooled procurement.

The key principles of an enabling pooled procurement system, including shared political will, models of pooled procurement, organization, pricing, patents, financing, sharing of information and experience, capacity building and harmonization, were further discussed during group work.
The challenges and constraints, principles, and solutions for the various elements were discussed, with the following key issues highlighted:

- The level of political commitment is critical and the price and non-price, i.e. value-added, benefits of pooled procurement should be used as advocacy tools.
- Regional pooled procurement should be tailored to meet the needs of the countries and can be initiated with a limited list of products.
- High standards and transparency are critical in the procurement process and prices from pooled procurement must therefore be transparent.
- The procurement process of multi-year contracting is recommended to ensure stable sources of supply.
- The need for clear transparency on patent status and support for countries to use TRIPS flexibilities to promote public health was emphasized, with the recommendation to incorporate patent pooling in pooled procurement activities.
- Financing of regional pooled procurement must be sustainable, predictable and timely and resources must be mobilized for a capitalization fund to stabilize initial regional pooled procurement efforts.
- The sharing of information and experiences through cross-training, study tours or twinning to disseminate lessons learnt is considered beneficial to both experienced and emerging groups, and should be facilitated at political and technical levels.
- Developing databases on key issues such as prices, patent status, prequalification of suppliers and medicines registration can be useful and, in some cases, necessary for regional pooled procurement.
- Capacity building based on best practice should be undertaken at country and regional levels, and should also address the particular needs of member countries.
- Regional pooled procurement can be promoted to support local manufacturing using the principles of fair competition, with basic GMP established for all.
- Harmonization in regulatory policies, quality assurance, patent laws and pooling of local production for sub-regional consumption are expected to improve access to medicines, and also send strong message on quality assurances and prices.
- The harmonization of donor procurement or development of mechanisms for integration to ensure synergy with donors is also considered essential.

Six priority areas identified for inter-regional collaboration and technical assistance were:

a) workshops and meetings for advocacy and in assisting sub-regional bloc in the selection of appropriate procurement model;

b) operational research, surveys and studies to conduct feasibility studies, cost benefit analysis and review patent laws;

c) sharing of information and experiences through study visits, documents on pooled procurement related strategies, policies and processes;

d) capacity building through training or technical assistance on patents and flexibilities, national forecasting regulatory activities, negotiation skills and resource mobilization;

e) harmonization of activities between regional pooled procurement blocs and global financing mechanism, procedures, tools and guidelines on medicines registration and quality assurance; and

f) facilitate collaboration in key areas such as the WHO/UN prequalification scheme, inter-regional collaborative activities among the various sub-regional blocs and regional collaborative action to use TRIPS flexibilities.
1. **Background**

Lack of access to medicines contributes to millions of deaths annually, including those resulting from diseases such as HIV and AIDS, tuberculosis and malaria that can be treated with existing medicines. Inefficient procurement and supply systems, weak regulatory and quality assurance mechanisms and high medicine costs continue to be the main obstacles to regular access to quality essential medicines in countries, including those in the African, Caribbean and Pacific regions.

The procurement of medicines is an important component of an effective medicines supply system, and therefore a major determinant in the quality of health delivery services. It is a complex process involving activities which range from the selection of items; quantification of needs; identification of appropriate method of procurement; selection of suppliers; award of contracts; negotiation with suppliers for deliveries and payment; and monitoring the status of orders. Key elements in the medicines supply chain such as quantity, cost and quality are influenced by the procurement process.

Over the past three decades, governments and their development partners have made great efforts to improve availability and affordability of quality medicines, particularly for vulnerable populations. Despite these efforts, access to essential medicines remains a major public health problem, and WHO reports that an estimated 270 million people in Africa, which represents nearly half the population, still lack regular access to even the most essential medicines (*WHO Medicines Strategy, countries at the core, 2004-2007*).

Innovative approaches for ensuring a consistent and sustainable supply of essential medicines are therefore needed at country, regional and global levels. Pooled procurement is an example of one such widely recognized initiative. Also known as group purchasing, pooled procurement is defined as “Purchasing done by one procurement office on behalf of a group of facilities, health systems or countries. Group members agree to purchase certain drugs exclusively through the group.” (Management Sciences for Health (MSH), *Managing Drug Supply*). The concept of pooled procurement is currently based on four models, reflecting the level of collaboration and integration among the parties concerned, which can range from information sharing to collective purchasing through to decentralized or centralized mechanisms. These models are:

- **Informed buying** – defined as information sharing, in which purchasers or countries share information on prices and suppliers but procurement is done individually.
- **Coordinated informed buying** – is also defined as information sharing, whereby purchasers or countries conduct joint market research, share information on supplier performance and prices, but procurement is done individually.
- **Group contracting** – member countries negotiate prices collectively and select suppliers based on the agreement that procurement will be from the selected suppliers, while the actual purchase can be conducted individually.
- **Central contracting and procurement** – this generally involves a central buying unit established by the member countries to act as their procurement agent in the tendering and award of contracts.

Successful pooled procurement schemes have reported major reductions in unit prices of medicines, for example, prices more than 25% lower than individual country prices in the Organisation of Eastern Caribbean States (OECS) (Burnett 2001). In addition, efforts to establish pooled procurement mechanisms and inter-country harmonization, have led to improvements in procurement and quality assurance systems and capacity in individual countries.
2. Rationale and Objectives of the Meeting

Policy-makers in the least developed countries are faced with challenges on access to medicines, such as the lack of transparent information on quality, prices and supplier sources, including information on new and expensive medicines for priority diseases. The pooled procurement strategy has been adopted over the past two to three decades, with success stories of the Gulf Cooperation Council, Group Purchasing Programme; the Organisation of the Eastern Caribbean States, Pharmaceutical Procurement Services; the Pan American Health Organization (PAHO) Revolving and Strategic Funds; and the WHO Global Drug Facility. Reports have indicated significant achievements in lowering medicine prices and producing cost savings, as well as improvements in procurement processes, supply sustainability and quality assurance expertise and capacity.

A number of sub-regional economic blocs have decided to explore if pooled procurement of medicines would be a suitable approach for them and they have sought support from WHO in doing this. In addition, international agencies and funding bodies have also shown increasing interest in the pooled procurement approach for achieving cost-effective procurement and sustainable availability of medicines.

The mandate of WHO is to support Member States in their efforts to strengthen their capacity for improving availability and affordability of medicines, and the Organization's collaboration with sub-regional economic blocks is being expanded. These blocks provide an appropriate setting for promoting information exchange and harmonization of procedures and tools among countries. In addition, their mandate, structure and financial resources offer the potential for sustainability.

The meeting held in Geneva on 15-16 January 2007, was organized by WHO to provide a forum for sharing experiences on the ongoing regional and global pooled procurement programmes and for exploring priority areas for inter-regional collaboration. The lessons learnt, i.e. strategies, achievements and constraints, were presented and the key principles of effective pooled procurement were reviewed and discussed.

The specific objectives of the meeting were to:

- give updates on progress and share experience on ongoing pooled procurement programmes – strategies, achievements and constraints
- identify key principles for enabling effective and sustainable pooled procurement within the various models
- identify challenges and constraints for implementing pooled procurement and propose solutions to address them
- identify priority areas for collaboration and technical assistance, and to outline a framework and timeframe for implementation.
3. The Meeting Process

The WHO Meeting on Multi-country Regional Pooled Procurement of Medicines was organized by the Department of Technical Cooperation for Essential Drugs and Traditional Medicine. The meeting brought together experts from various regional and global initiatives, representatives of sub-regional economic groups and development partners interested in pooled procurement initiatives (see Annex 1 for the list of participants).

The two-day meeting was organized in two main sessions:

1) plenary presentations; and
2) group work and discussions (see Annex 2 for the agenda). Participants were provided with a draft document that summarized global, regional and sub-regional pooled procurement initiatives as well as specific reports describing the various initiatives.

The first day involved plenary presentations on ongoing regional and global pooled procurement initiatives, and also on the sub-regional economic blocs plans and strategies for establishing suitable pooled procurement mechanisms. In addition, a presentation was made on medicines regulations and harmonization within the context of pooled procurement. A presentation outline was provided to presenters to address core issues such as:

1) rationale and objectives of the pooled procurement initiative;
2) core functions, strategy and mechanisms for achieving sustainable pooled procurement;
3) achievements, success factors and added value of the initiative;
4) challenges and constraints;
5) priority areas for inter-regional collaboration. The meeting was facilitated by a chairperson assisted by rapporteurs assigned to take notes during the presentations, questions and discussions.

Day two of the meeting was spent on group discussions on the main elements of pooled procurement highlighted during the plenary presentations, based on structured questions relating to challenges and constraints, solutions and principles, and potential areas for collaboration. Three groups were organized around the following themes:

- Shared political will, pooled procurement models and organization;
- Pricing, patents and financing;
- Sharing of information and experiences, capacity building and harmonization.

The latter part of the second day consisted of group presentations and discussions to consolidate and finalize recommendations. A chairperson and rapporteur were nominated for each of the three groups to moderate and present the group work.

The Director of the WHO Department of Technical Cooperation for Essential Drugs and Traditional Medicine (TCM), Mrs M. P. Matsoso made the meeting’s opening and closing remarks. She welcomed participants and noted that it was the first time that WHO had brought together the various sub-regional groups for such a meeting. She emphasized the importance of inter-regional collaboration, especially between the existing and emerging sub-regional initiatives and structures. Welcoming participants, Dr Anthony So, Chair of the meeting, noted the high level of expertise present, with both successful and fledgling initiatives. He highlighted the basic rules of the meeting and the expected outline for the plenary presentations.
Dr Gilles Forte, Coordinator, TCM, gave an overview of the meeting’s rationale and objectives prior to the plenary presentations.

In her closing remarks, Mrs Matsoso thanked participants and reiterated the main objective of pooled procurement, which is sustainable and uninterrupted supply, irrespective of the procurement model. She emphasized the need for advocacy and inter-regional collaboration for the optimal use of shared knowledge and pooling of expertise to address the challenge of access. In conclusion, she requested that the action steps should be finalized, with the various stakeholders identified – WHO, development partners and sub-regional blocks – and a timeline defined for implementation of activities.
4. **Plenary Presentations**

**Group Purchasing in the Organisation of Eastern Caribbean States (OECS) – Mr Francis Burnett, Managing Director, Pharmaceutical Procurement Services, OECS**

The Organisation of Eastern Caribbean States (OECS) is a nine member group representing a total population of 570,000, with Antigua & Barbuda, Dominica, Grenada, Montserrat, St Kitts & Nevis, St Lucia and St Vincent & the Grenadines as member states and Anguilla and the British Virgin Islands as associate members. The OECS/PPS was established as a project with USAID funding in 1986 and it implemented its first procurement activity in 1987. The OECS/PPS has a permanent secretariat in St Lucia and is self-financing, with revenue generated from an administrative fee, initially of 15% but later reduced to 13%, charged to its member countries. It became financially self-sufficient in 1989.

The OECS/PPS pooled procurement system is based on the centralized tendering and procurement model, with a financial mechanism based on a revolving drug fund. Payment is centralized and carried out by the Eastern Caribbean Central Bank supported by a common currency, the East Caribbean dollar, which is stable. The product portfolio has approximately 700 items, 70% of them pharmaceuticals, representing an estimated 80% of the member countries' public sector needs. Between 1997 and 2006, the value of annual purchases increased by more than 100%. The average cost savings for 25 selected items over a five-year period (1998-2002) are reported to be 37%.

The 10 critical success factors for pooled procurement for the OECS/PPS are:

- A credible procurement agency with a permanent secretariat with professional staff and transparent procedures e.g. international competitive bidding
- Key common elements among member countries such as culture, political system, currency and banking, umbrella organization
- Gradual process for country membership and development of product portfolio
- Increased volume contributing to price reduction (although not enough to attract and sustain competitive prices)
- Administrative and political commitment based on formal signed agreements and active client participation
- Payment which is timely and in full
- Harmonization of drug policy, e.g. essential drugs, treatment regimens, dosage forms
- Quality assurance, i.e. testing, purchase agreements and prequalification of suppliers
- Monitoring and evaluation of suppliers and procurement agencies, and
- Tackling the four aspects of the drug management cycle – selection, procurement, distribution and use – in an efficient manner.

Some of the PPS benefits highlighted are: strong bargaining power; the mechanisms in place for sharing information and experience and for regional cooperation; enhanced quality control; the development of a common regional formulary and of drug utilization studies; the consistent provision of staff training; and measurable increased access to medicines.
The main challenges faced by OECS/PPS are: late payments by member countries; the opposition and influence of suppliers; purchase outside the cartel; the management of donations; poor forecasting and small purchase orders. Areas identified for inter-regional collaboration include:

a) harmonization of: donations policy; supplier/vendor registration and evaluation; bidding documents and evaluation of tenders;
b) information sharing on: suppliers and products; drug test results and quality control laboratories; medicine prices, negotiation and purchasing; criteria for formulary development and revision; patent status of medicines; and tender committees and procedures.

**The Gulf Cooperation Council (GCC) / Group Purchasing Programme (GPP) – Dr Ahmed Khateeb, Director, Group Purchasing Programme, GCC**

The six member states of the Gulf Cooperation Council are Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates, representing 35 million people. The Group Purchasing Programme of the Gulf States was established in 1978 by the Gulf Cooperation Council, with a permanent Secretariat in Saudi Arabia. The Secretariat is funded through member countries’ contributions, supplemented by revenue generated from tender activities and drug registration.

The Programme's core function is pooled procurement of pharmaceuticals and medical supplies for the ministries of health of the Council's six member states. In addition, it also purchases for 12 public health sector hospitals in Saudi Arabia. The delivery of supplies and payment to suppliers are conducted directly between the respective ministries of health and the suppliers.

The procurement activity of the GCC/GPP started with 32 items of medicines with an estimated value of one million US dollars in 1978, and has evolved over the years to over 9000 products valued at US$ 680 million, reported as completed tenders in 2006. By 2006, the product list had also expanded to 11 categories of supplies, ranging from hospital sundries, to vaccines, laboratory, orthopaedic and spine items and radiopharmaceuticals.

After 27 years of using a centralized tendering system, the GPP has successfully demonstrated that its pooled procurement services, based on a collective decision-making policy, have reduced costs, saved millions of dollars over the years and enhanced the efficiency of health services for its member states.

The continuous annual cost-saving has reinforced the procurement service as an excellent cost-benefit model of economic and functional cooperation among member countries. It has also ensured the purchase of high-quality products through prequalification of manufacturers, based on their compliance to good manufacturing practices (GMP).

Among other achievements and benefits outlined are: achieving Gulf drug security by supporting the Gulf pharmaceutical industry; training on GMP and other quality assurance activities; registering companies and encouraging procurement from registered generic manufacturers, conducting product evaluation; providing formularies; and facilitating exchange of information among the GCC states.

The GPP highlighted a number of software programs currently used in the management of its activities, such as programs for bank guarantee management, management of health research funds, company registration and administrative communications. The main / anticipated challenges for the GPP are the current health reforms in the region, namely, inclusion of payment systems / health insurance in the public health sector, the implications of membership of the World Trade Organization and patent issues.
The PAHO Strategic Fund – Linking technical cooperation in procurement and supply management with acquisition of strategic public health supplies – 
Mr James Fitzgerald, Coordinator, Strategic Fund, PAHO

The Pan American Health Organization (PAHO) Strategic Fund is a regional pooled procurement initiative under the umbrella of WHO. It is based on the concept of linking technical cooperation in procurement and supply management (PSM) with acquisition of strategic public health supplies. A Strategic Public Health Supply is based on specific criteria such as:

a) inclusion of items in the WHO Model List of Essential Medicines;  
b) inclusion in treatment protocols recommended by WHO and considered highly effective in the treatment and prevention of diseases;  
c) significant contribution to reducing disease mortality and morbidity and  
d) achievement of economies of scale with increased volume. A Strategic Public Health Supply addresses as priorities HIV and AIDS, malaria, TB and neglected diseases.

The PAHO Strategic Fund, which is a country-based initiative, was established in 2000 and was endorsed and supported through a number of Directing Council's resolutions on Access to Medicines (2004), HIV and AIDS (2004 and 2005) and Public Health, Health Research, Production and Access to Essential Medicines (2006).

Membership is from ministries of health, social security systems and Global Fund projects in participating countries. A Consultative Group and a Working Group have been established and they provide assistance to the participating countries with the support of WHO Collaborating Centres in the region of the Americas and other partners, for example, MSH, UNICEF and GDF.

A number of key activities to strengthen and expand the Strategic Fund network were carried out in 2005-2006, such as revision of the operational framework; organization of sub-regional workshops for rolling out the Strategic Fund in Central America and Andean and Caribbean sub-regions; and development of country work programmes involving priority areas. The latter included supply system assessments, procurement planning and capacity building; linking with global and regional prequalification and regional networks of quality control laboratories.

Current achievements include the participation of 17 countries (a 30% increase in two years), two social security agencies and five Principal Recipients (Global Fund). Positive country experiences include a single procurement plan for all GFATM beneficiaries in Haiti and the elimination of vertical PSM programmes in Venezuela; and antiretroviral (ARV) price referencing with regional negotiations, resulting in the procurement of 14 ARV medicines in 24 presentations, with a total value of US$ 9.8 million for four member countries – Brazil, Guatemala, Haiti and Nicaragua.

The Strategic Fund procurement activities increased from purchasing 28 products valued at US$ 3.4 million for three countries in 2004 to 41 products with a total value of over US$ 9.9 million for six countries by the end of September 2006.

The Strategic Fund's main perspectives and challenges include the continued and increasing interest of countries; consolidating existing relations with partners and establishing new ones; updating the product list, taking into consideration second- and third-line ARV and paediatric formulations, building capacity to meet country needs and resource mobilization for technical support activities. Forecast procurement for 2006 was US$ 12 million and for 2007 it is estimated at US$ 20 million.
The WHO Global Drug Facility: practices for procurement of TB medicines – Mr Robert Matiru, Manager, GDF, WHO

The Global Drug Facility (GDF), which is a global pooled procurement programme, is the initiative of the Global Partnership to Stop TB and is housed in WHO headquarters in Geneva. It was established with the aim of supplying quality-assured, affordable drugs where and when they are needed. Its key objectives include the supply of treatments for 15 million patients by 2010, rationalizing procurement mechanisms, improving the quality of TB drugs worldwide and creating a successful model of cooperation for confronting a global epidemic. The GDF client-base comprises government institutions, donors and nongovernmental organizations.

The GDF is described as a bundled facility, providing a number of services in response to specific constraints and requirements. Its services are categorized into three areas:

1) grant services for first-line TB drugs for those with inadequate financial resources;
2) direct procurement services for those with sufficient financial resources but inadequate procurement and /or quality assurance capacity; and
3) technical support services for those with inadequate in-country TB drug management and drug monitoring. The GDF product list includes TB drugs for first- and second-line treatment including paediatric dosages and diagnostic kits.

GDF’s main achievements include the provision of over nine million patient treatments within a six-year period, with deliveries to more than 60 countries, based on an annual procurement value of US$ 45 to 50 million. It also provided over 200 monitoring and technical support missions. The GDF guarantees same services, i.e. quality-assured products and low prices to all its clients irrespective of the size of country or demand.

Lessons learnt on good practices and sustainability include quality first; competitive procurement and long-term agreements with manufacturers; forecasting and planning; standardization; openness and transparency; and accuracy, efficiency and economy.

Future challenges for the GDF are the increased demand for TB medicines resulting in reduced availability of critical raw materials; strengthening regional procurement initiatives and introducing global and regional stockpiling; building local manufacturing capacity; and increasing partner support and funding to meet the growing demand for monitoring and technical support.

Priority areas identified for collaboration with regional and global initiatives are quality assurance; prequalification of suppliers; information sharing on pricing; and the regulatory status of TB products. Sharing best practices / the benefits of the GDF model for global pooled procurement, and strengthening grant-dependent TB drug beneficiaries to promote self-sufficiency are also GDF priorities.

The experience of pooled procurement of TB medicines in the South African Development Community (SADC) – Mr Joseph Mhetwa, Senior Programme Manager, SADC

The South African Development Community (SADC), which originated from the South African Development Coordination Conference of 1980, was launched in 2002. It represents 14 countries (Angola, Botswana, Democratic Republic of the Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, South Africa, Swaziland, United Republic of Tanzania, Zambia and Zimbabwe), with an estimated total population of 200 million people. The Secretariat is based in Botswana. SADC’s pooled procurement programme is still in the preparatory phase.
SADC established a pharmaceutical programme in line with its health protocol and policy, in order to enhance the capacities of member states to treat diseases of major public health concern in the region effectively. Its objectives for harmonization are to improve the quality of medicines, optimize the use of resources and standardize regulatory requirements and so address the core problems of inadequate availability of medicines and the poor or inconsistent quality of medicines in some member states.

In 1999, SADC commissioned a study involving 11 member countries, to identify opportunities for joint procurement of anti-TB drugs. The study focused on key issues, such as the existing regulatory framework, procurement procedures, funding mechanisms, the drug supply and management chain, and the challenges for bulk purchasing.

Key findings highlighted the various methods of quantification of TB medicines, the varying storage conditions and limited storage capacity, disparities in the existing infrastructure for stock management, and persistent shortages of anti-TB medicines. Variations in treatment regimen and disparities in implementation of procurement regulations, quality assurance procedures and registration of medicines were also among the significant findings.

Recommendations on practical steps to achieve effective bulk procurement of anti-TB medicines included the creation of the position of bid manager and a joint evaluation steering committee; standardizing the bid format, a list of approved suppliers, scope of supply and common currency for procurement; harmonize the registration requirements and quality assurance and agree on the schedule for the procurement cycle.

In November 1999 a decision was taken to harmonize two areas – registration and medicines control – which resulted in the establishment of two technical working groups.

The harmonization process focused on three initiatives, namely the development of technical guidelines and policies on registration and control of medicines; improvement in the quality, safety and efficacy of medicines circulating in the region; and the establishment and maintenance of a regional shared network for drug regulatory authorities.

The current status report in the SADC region highlights the printing of regulatory guidelines on registration, stability, GMP and registration forms; implementation of a strategic plan, development of a shared network and the establishment of a joint procurement protocol for HIV and AIDS, tuberculosis and malaria.

**The East African Community (EAC) experience for pooled procurement of HIV medicines – Dr Stanley Soroiya, Health Coordinator, EAC**

The East African Community (EAC) comprises five member countries, Burundi, Kenya, Rwanda, Tanzania and Uganda, with a secretariat in Tanzania. The EAC identified a number of priority areas including education, agriculture, customs and trades, and health, with the ultimate aim of moving towards an East African political federation by 2013. Approval of plans and recommendations for regional pooled procurement is based on a hierarchical approach, going through an expert taskforce / technical working group, health committees, ministers of health and ultimately to the Summit of EAC Heads of State.

The EAC institutional management structure for regional pooled procurement of essential medicines and supplies has resulted in approval for establishing an EAC pharmaceutical programme office, as well as treatment protocols for HIV, AIDS and TB. A number of harmonization activities on national medicines regulations, national medicines procurement systems and legislation, and national health service delivery systems are reported to be ongoing, with support from collaborating partners.
The challenges faced include the lack of organizational structures and/or capacity at the EAC regional level to respond to the HIV and AIDS epidemic within the sub-region; the lack of a common currency and heavy reliance on convertible foreign currencies; no adequate or reliable local manufacturing capacity; issues related to sovereignty and different national regulations and procedures for procurement of essential medicines; and the heavy dependence on donors for the provision of ARVs.

Looking to the future, a number of activities are proposed that are geared towards the establishment of a taskforce and a tripartite committee on regional pooled procurement; approval from the EAC Heads of State, and technical and financial support from collaborating partners.

The development phase for regional pooled procurement of HIV and AIDS medicines resulted in consultative meetings in November and December 2006. Plans are underway for a SWOT (strengths, weaknesses, opportunities and threats) analysis of medicines procurement in member countries, submission of recommendations for approval to the EAC Ministers of Health in May 2007, and for the approval of regional level procedures and regulations to the EAC Council of Heads of State scheduled for July 2007.

Strategies for strengthening regional level medicines procurement involve enhancing regional collaboration among the various stakeholders, developing strong links with development partners; enhancing manufacturing capacity and quality at regional level; capacity building; and harmonization of programmes and policies.

**Update on the Global Fund pooled procurement feasibility study – Ms Sophie Logez, Procurement Team, GFATM**

The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) identified procurement and supply management (PSM) of health products as an implementation challenge and a major bottleneck in achieving access to medicines for the public health diseases within its remit. The GFATM is conducting a study to assess the feasibility and operational costs of voluntary pooled procurement as a possible facilitator of improved availability.

The objectives and scope of the study were to:

a) identify and analyse the opportunities for pooled procurement of medicines with the greatest impact on availability, quality, affordability and sustainability; and

b) assess the potential pooled procurement models based on operational, policy and costs implications, also defining the roles and responsibilities of the GFATM and its partners.

Preliminary findings identified the criteria for potential procurement models linked to:

a) the extent to which they allow the GFATM to leverage its buying power, influence market sustainability, and promote visibility and transparency in its transactions,

b) the cost implications for the principal recipients (workload, speed and reliability) and the GFATM (if it is contracted to a purchasing agent) and

c) the type of change required to create and maintain the potential procurement model. It further identified the scope of activities (flow of data/funds, tendering, negotiations, order management, supplier performance), expected key elements of a model formulation for a voluntary procurement system for a range of health products, with the possibility of outsourcing operations.

The initial conclusions are that one model might not be adequate to meet the varied needs of the GFATM's principal recipients, and therefore a hybrid procurement model, i.e. a combination of several models, may be considered. All the options will be evaluated on benefits and costs.

The next steps are to finalize the recommendations, propose an implementation plan and develop a decision paper for presentation to the GFATM Board Meeting in April 2007.
Harmonizing Medicine Regulations for Regional Pooled Procurement – Mrs M. P. Matsoso, Director, TCM, WHO

The integrated approach adopted for most regional/sub-regional and global initiatives are geared towards pooling of resources to deal with capacity challenges, reducing duplication of effort and redirecting resources. Standardizing requirements; streamlining regulatory processes; identifying legal areas for joint negotiation; and promoting good governance are also important factors.

Progress reported on integration efforts in African countries is exemplified by removal of barriers to trade and interconnectivity, for example, transport links and telecommunications. The main constraints are conflicts, the high disease burden, the multiplicity of regional economic communities leading to duplication, overlap and waste of scarce resources; and the slow pace of implementation in some regions.

Among a number of challenges facing countries are the complexity of regulatory processes and requirements, limited regulatory capacity, increased funding for medicines and various other health commodities, the various initiatives to improve supply chains in countries and also the absorptive capacities in countries.

Regulatory challenges include delays and backlogs, a lack of tools, guidelines and access to appropriate technology, and substandard medicines, counterfeits and illegal trade.

A number of current sub-regional, regional and global initiatives are examples of harmonization, and can be considered for pooling of resources to deal with capacity challenges. The benefits of global harmonization, such as the WHO/UN Prequalification Programme, WHO's vaccine regulatory network and the International Conference on Harmonization, are to improve the approval and review processes to match the increasing complexity of applications for biotechnology products, new drugs and vaccine technologies etc. However, the main challenge is that global initiatives are not a complete solution for resource-constrained settings, as they depend on successful implementation of a model based on sharing the regulatory burden between participating countries.

Opportunities for harmonization are mainly within medicines regulatory activities, pooled procurement, legal and policy areas, and information management. Various approaches, such as the WHO modular approach to assess NDRA, joint efforts to fight counterfeit medicines and practical approaches to information sharing, can be considered.

Key activities for harmonization were highlighted:

a) obtaining information that is relevant, with added value;

b) sharing of information to maximize the use of available resources and achieve effectiveness;

c) packaging available tools for information exchange;

d) streamlining and improving procedures and processes;

e) pooling expert knowledge and directing resources to facilitate access.
5. **Group Discussions and Recommendations**

During the plenary presentations the main elements identified for enabling pooled procurement were: shared political will; pooled procurement models; organization; pricing; patents, financing, sharing of information and experience, capacity building and harmonization. In discussing these elements, the group focused on issues relating to challenges/constraints, principles, solutions and recommendations.

5.1. **Shared political will**

5.1.1 The benefits of regional pooled procurement were defined and categorized in two main groups:

*Price benefits*

- Achieving economies of scale
- Maximizing the use of already limited resources
- Sharing price information / price referencing.

*Non-price, i.e. value-added benefits*

- Universal benefits within public health perspectives
- Harmonization (standard treatment guidelines, prequalification of suppliers, etc.)
- Confidence-building with purchasers and suppliers
- Common standards of quality within quality assurance
- Rationalizing of procurement processes
- Facilitating demand forecasting
- Facilitating political and social objectives in the long term
- Entry point for political integration
- Political compatibility.

**Recommendation**

The price and non-price (value-added) benefits could be used as an advocacy tool.

5.1.2 The level of political commitment was considered critical and in making a case to policy-makers, certain tools, evidence and options should also be made available, for example:

- Political momentum and benefits that will promote political mileage
- A sound cost benefit analysis supported with practical feasibility studies
- Number of additional patients that can be treated with the savings made
- Other solid arguments with an evidence base from respective countries
• Performance indicators that are directly linked to the national health data and country health accounts.

5.1.3 Certain strategic opportunities that might give momentum to the creation, development and implementation of regional pooled procurement efforts were identified:

• The momentum at global, sub-regional and national level as a political driver
• The existing funding initiatives and new innovative financing mechanisms e.g. UNITAID
• Meeting the Millennium Development Goals (MDGs)
• The increased demand for accountability and transparency in procurement of medicines
• Combating the counterfeit market.

5.1.4 The main advantage of having large member countries in regional pooled procurement initiatives is the lower prices that can be achieved through economies of scale. The challenge however is in involving the large countries on a regular basis as they can achieve the lower cost on their own. Optimizing the participation of big countries in regional pooled procurement efforts should be argued on these factors:

• Promotion of integration
• Regional leadership, political exposure and visibility
• Economies of scale, especially in price negotiations
• Capital fund for procurement
• Addressing local manufacturers' concerns
• Assisting smaller countries.

5.2 Pooled procurement models and organization

5.2.1 Regional pooled procurement (RPP) should be tailored to a list of priority products that each country agrees upon, in line with the objectives of pooled procurement. Furthermore, a start can be made with a limited list of products.

5.2.2 In identifying a model for pooled procurement, certain factors that determine the choice of model should be considered: i) level of control at national level and ii) the expected price and non-price benefits; and iii) the degree of collaboration/integration of the procurement process.

5.2.3 The issue of how to ensure sustainability of RPP was discussed, with the following factors identified:

• Leadership – the importance of leadership for regional pooled procurement is paramount and can raise the level of the initiative
• Institutionalize the initiative, especially in data collection, costing, management information system (MIS) and appropriate technology
• Harmonize reporting tools, which should be simple and easy to use
• Human resources – personnel should be dedicated and motivated
• Incorporate activities to develop or invest in systems in proposals to development partners.

5.3 Pricing

5.3.1 The need for high standards and transparency in the procurement process, which is essential to protecting regional pooled procurement efforts, was emphasized. Prices secured in pooled procurement must therefore be transparent, and the non-transparency of manufacturers’ selling prices and the various benchmarks that might be applied were identified as challenges.

5.3.2 Calculating the estimated cost savings at individual country level was identified as a challenge, underscoring the need to standardize the assessment of pooled procurement prices using a median price for comparison. A systematic method of assessing prices or developing reference prices to evaluate cost savings should be considered as part of inter-regional collaboration.

5.3.3 In comparing prices to calculate cost savings from pooled procurement efforts, it was agreed that policy-makers might find it more persuasive when provided with a triangulation of several benchmarks such as:

• Previous local tender prices
• MSH indicator prices
• Australian pharmaceutical benefit scheme information
• Global Fund price indicators
• AFRO price indicators.

Recommendation

Consolidate and provide only a few relevant international or regional benchmark prices and not just a collection of reference prices.

5.3.4 The problem of insufficient collective action and lack of shared pricing information in regional price negotiations was discussed. Certain conditions were identified in which collective action for price negotiations among countries in a region is feasible:

• Where value-added benefits of regional procurement is demonstrable
• Where the presence of a large country might help neighbours
• When endemic disease requires special focus.

5.3.5 The issue of differential pricing and pooled procurement activities, and cases where manufacturers insist on identifying participating countries during price negotiations were discussed. Challenges/constraints identified on the issue of differential pricing were:

• Collusive pricing and anti-competitive behaviour contributing to higher prices
Differential pricing often leaves the basis for the lower price non-transparent
Limited supply base often exists for products subject to differential pricing
Combination of price negotiation for generics and innovator drugs can dilute the pooled procurement prices.

In principle, it was agreed that generic or therapeutic price competition is preferred as a more sustainable approach to ensuring affordable prices than differential pricing. Furthermore, differential pricing should be limited to single-source products.

Recommendations
- Use international competitive bidding for multi-source products
- Support registration of more generics
- Encourage registration of therapeutic substitutes
- Support prequalification of more generic manufacturers
- Conduct an audit or affordability analysis to support or refute differential prices sets.

5.3.6 The main challenges identified with price components were:

- Lack of transparency; high margins
- Non-compliance with margin level tariffs
- Cumulative margins, i.e. on top of high purchase prices, which add disproportionally to retail prices
- Differences between warehouse-to-warehouse prices and CIF (cost, insurance, freight) prices.

The general agreement was that:

- Price components should be rational, transparent and minimal
- Margins should correspond to value-added benefits, distinct from subsidizing other health services
- Savings achieved through pooled procurement should be passed on to the consumers / patients.

Recommendations
- Increase transparency of price components
- Advocate for appropriate price regulations and controls.

5.3.7 In reducing costs to the lowest possible level, the issue of supplier-sensitive conditions should also be taken into consideration, to avoid risks of under-pricing and losing the competitive field of suppliers.

Recommendation

The procurement process of multi-year contracting should be adopted to ensure stable sources of supply.
5.4 Patents

5.4.1 Discussion focused on whether pooled procurement can work for patent medicines, and the possibility of patent pooling. The impact of TRIPS and IPR on local manufacturers and anticipated higher future costs were also discussed, with the challenges related to patents identified:

- High prices on single-source, patented products
- Limited cross-licensing for combination products
- Decreased supply of generic products as more countries comply with TRIPS
- Adverse impact on local, generic drug manufacturers
- Varying levels of compliance with TRIPS within regional blocks
- Lack of capacity in dealing with IPR regimes.

It was agreed that there should be clear transparency on the patent status of medicines, and countries should be supported to use TRIPS flexibilities to promote public health.

Recommendations

- Disseminate clear guidance on latitude to procure generic products
- Support opportunities to challenge inappropriately patented medicines at country level
- Incorporate patent pooling as part of pooled procurement activities.

5.5 Financing

5.5.1 The main challenges related to financing and financial arrangements of regional pooled procurement are:

- Inadequate total financing for procuring essential medicines
- Foreign exchange impact on drug procurement
- Different procurement laws in different countries
- Lack of convertible or stable currency
- Delays in payment and inefficient payment procedures.

Financing must be sustainable, predictable and timely, and the administrative costs of a pooled procurement mechanism have to be offset by the savings on drug purchases.

Recommendations

- Find ways of harnessing initially government, and then donor funds, for pharmaceuticals, to promote pooled procurement efforts
- Mobilize resources for a capitalization fund to stabilize initial efforts for regional pooled procurement.
5.6 Sharing of information and experiences

5.6.1 The issue of how to promote inter-regional networks for those interested in establishing sub-regional initiatives was discussed. The sharing of information and experiences through cross-training, study tours or twinning were identified as potential grounds for inter-regional collaboration, with the main objective of disseminating lessons learnt on procurement efforts. It is considered beneficial to both experienced and newer groups, as it will provide the experienced groups with fresh perspectives on existing processes, while assisting emerging groups to build structures and organizations, and provide confidence during start-up.

Recommendations

- Build regional collaboration through meetings to decide on best practice (e.g. ECOWAS /UEMOA) and workshops as an approach to build momentum for a broader regional effort (e.g. PAHO)
- WHO and the regional blocks should work together to facilitate the exchange of experiences of the benefits gained which should be done at political and technical levels

5.6.2 Developing databases on, for example, prices, patent status, prequalification and drug registration was considered helpful, and in some cases necessary for regional pooled procurement

- For prices, the central medical stores (CMS), tender committee or procurement office should be assigned to create, provide and maintain the source of information. The information should be made available to donor agencies providing funds, health professionals, civil society and public procurement agencies. The main source of constraint is the master list of quotations, which can be perceived in some quarters as confidential due to either pressure from suppliers or self-imposed constraint to avoid potential litigation
- The main constraints identified with patents are that the patent status is not always known or there is no patent office or the data are inaccurate or there are difficulties in accessing the relevant information. Political pressure should be put on patent offices and the information should be made available to the relevant ministry (health or trade) or CMS or NDA or tender board
- The collation of information for a database on prequalification of manufacturers, suppliers, distributors and wholesalers should be the responsibility of the NDA or procurement entity or CMS. The tender documents to prequalify suppliers should be standardized and shared. Responsibility for maintaining the information, including the operational cost, would depend on the procurement model selected.

5.7 Capacity building

5.7.1 The discussion was on how to link pooled procurement with capacity building. It was agreed that regional pooled procurement could occur when national systems are efficient, as it cannot replace them. The expected value-added benefits are to complement national capacity, and regional pooled procurement should be seen as a
service, as more resources will be available to focus on building capacity based on best practices.

**Recommendation**

Capacity building should be at both country and regional levels, and should also address the particular needs of member countries.

5.7.2 The role of local manufacturing efforts in regional pooled procurement was discussed. Regional pooled procurement can be promoted to support each country’s social and economic developmental agenda at the regional level through local manufacturing, using the principles of fair competition, i.e. quality and cost. Basic GMP standards should be established for all involved.

5.8 **Harmonization**

5.8.1 The potential areas for the harmonization process:

- Regulatory policies on product registration
- Quality assurance – harmonization of tests / monographs; identifying one reference laboratory (minimizing costs, especially for smaller countries); sharing results of tests, products, incidence of counterfeit products
- Coordinated, informed visits of manufacturing sites, cross-inspection of local and offshore manufacturers
- List of products for procurement from treatment guidelines, drug formulations and demand forecasting
- Patent laws / patent pooling
- Tariffs and duties on essential medicines and essential health products
- Movement of public health goods within regions
- Pooling of local production for sub-regional / regional consumption.

It is envisaged that the harmonization of such activities would send a strong message on quality assurance and prices to manufacturers, and also improve access to medicines.

5.8.2 There was discussion on how to resolve the issue of overlap countries in regional blocs, which was perceived as a challenge, for example in Tanzania in EAC and SADC, and Burundi and Rwanda in EAC and ACAME. It was agreed that the overlapping countries can be used to facilitate collaboration between two regional blocs and their expertise harnessed for adapting processes and activities already finalized or implemented by one group.

5.8.3 The need to harmonize donor procurement or develop mechanisms for integration to ensure synergy with donors was discussed, with a number of options identified:

- Harmonization of country positions and policies
- Government-led coordination of donors / donor coordination meetings
- Implementation of sector-wide approaches
• Joint implementation (donor / sub-regional block) in a twinning arrangement, aligned to the common goals of regional pooled procurement, with a view to strengthening regional trading blocks

• Mutual results-based management for both parties (for transparency)

• Regional pooled procurement can provide data on markets and manufacturers, and provide some mechanisms to share related information

• Regional pooled procurement can also be used to advocate with donors to achieve donor harmonization, strengthening etc.
6. Priority Areas Identified for Collaboration and Technical Assistance

Six main activities were identified for collaboration and technical assistance:

i) meetings;
ii) operational research, surveys and studies;
iii) sharing information and experiences;
iv) capacity building, including technical assistance;
v) harmonization and
vi) collaboration.

Meetings

- Workshops and meetings to share information on the benefits of pooled procurement for advocacy at political, legislative and donor levels, and also to assist groups in selection of a procurement model.

Operational research, survey and studies

- Conduct cost benefit analysis and non-cost benefit analysis as well as feasibility studies
- Establish mechanisms to determine cost savings
- Develop a consistent methodological approach for price benchmarking (commission study method accounting for volume, supplier, method of procurement, terms of trade and region)
- Develop case studies (e.g. Latin American country negotiations over HIV and AIDS medicine prices) featuring elements for success
- Consider potential test opportunities to use a minimum volume buy approach and remove differential pricing from the hands of companies to countries within a regional pooled procurement system
- Review of patent laws and use of flexibilities.

Sharing information and experiences

- Study visits by potential / interested regional blocks to GCC, OECS and PAHO which will benefit regional pooled procurement
- Share information on pricing strategy and policies (flat dispensing fees)
- Share standard documents, e.g. tender process documents, from well-established regional pooled procurement agencies.

Capacity building (training and technical assistance)

- Support training and technical assistance for dealing with intellectual property rights issues in procurement
- Support and strengthen NDRAs
Multi-country Regional Pooled Procurement of Medicines

- Regional training on national forecasting/quantification and how to implement MIS at country level
- Develop skills for negotiating strategies (surveys, policy, cost-benefit analysis)
- Support in developing business and strategic plans; business models and resource mobilization.

**Harmonization**

- Deepen and expand the relationship between regional pooled procurement blocs and global financing mechanisms (e.g. GFATM, GDF, the Gates Foundation, UNITAID, UNICEF)
- Develop harmonization mechanisms (tools and guidelines) on medicines registration and quality assurance.

**Collaboration**

- Partner with the HAI/WHO Medicine Pricing Project to establish a repository for global price benchmarks
- Support the WHO/UN Prequalification Programme to cover a broader range of essential medicines and health products
- Facilitate collaborative activities – study tours, twinning and information sharing
- Encourage regional collective action to use TRIPS flexibilities
- Eliminate tariffs on essential medicines and essential health products.
# Annex 1

## List of Participants

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<th>Family Name</th>
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Annex 2

Meeting on multi-country regional pooled procurement of medicines

Identifying key principles for enabling effective regional pooled procurement and a framework for inter-regional collaboration in the African, Caribbean and Pacific Island countries

15 - 16 January 2007, Executive Board Room
WHO Geneva, Switzerland

Monday 15 January 2006

08h30-09h00 Registration of participants
09h00-09h45 Welcome and introduction; Mrs M.P. Matsoso, Director, TCM
  Self introduction of participants
  Meeting objectives; Dr Gilles Forte, Coordinator, TCM
09h45 -10h05 The experience of group purchasing in the Organization of East Caribbean States; Mr Francis Burnett, Managing Director OECS/PPS
10h05 - 10h25 The Gulf Cooperation Council/Group Purchasing Programme;
  Dr Ahmed A. Khateeb, Director of Group Purchasing Dept., GCC
10h25 -10h45 Discussions
10h45-11h00 Coffee break
11h00-11h20 The experience of pooled procurement of TB medicines in the South African Development Community (SADC); Mr Joseph Mhetwa, Senior Programme Manager for Health and Pharmaceuticals, SADC
11h20-11h40 The Strategic Fund in countries in the Americas;
  Mr James Fitzgerald, WHO/PAHO
11h40-12h15 Discussions
12h15-14h00 Lunch break
14h00-14h20 The East African Community (EAC) experience for pooled procurement of HIV medicines; Mr Stanley Sonoyia, EAC Health Coordinator
14h20 -14h40 The WHO Global Drug Facility: practices for procurement of TB medicines; Mr Robert Matiru, GDF Manager
14h40-15h15 Discussions
15h15 -16h00 Coffee break
16h00-16h20 Update on the Global Fund pooled procurement feasibility study;
  Ms Sophie Logez, Procurement Team, The Global Fund
16h20-16h40  Medicines regulations and harmonization process in the context of regional/sub regional pooled procurement of medicines;
Mrs M.P. Matsoso, Director WHO/TCM

16h40-17h15  Discussions

18h00 -19h00  Cocktail

**Tuesday 16 January 2006**

09h00-09h15  Introduction to group work to: Identify key principles for enabling effective regional pooled procurement of quality medicines; and identify potential areas and framework for inter-regional collaboration on pooled procurement; Dr Gilles Forte, WHO/TCM

09h15-10h30  Group work

10h15-10h30  Coffee break

11h00-12h30  Group work

12h30-13h30  Lunch break

13h30-15h30  Presentation of group work in plenary session and discussions

15h30-17h00  Consolidation of recommendations

17h00 - 17h30  The way forward and closure of the meeting