



Lot 4_Sectoral and Project Evaluations

Reproductive Health Commodity Security Study

KEY FINDINGS AND RECOMMENDATIONS
FOR THE EUROPEAN COMMISSION

Final Report
(Fully Revised)

AUG2007

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RESPONSIBILITY AND AUTHORSHIP

This report was prepared with the financial support of the European Commission.

The opinions expressed are those of the authors and not necessarily those of the European Commission.

EXECUTIVE SUMMARY

Good reproductive health is a recognized human right. Many official declarations and policy documents have emphasized this right including the International Conference on Population and Development (ICPD) and the Millennium Development Goals (MDG). To attain good levels of reproductive health it is crucial that countries have well functioning and equitable reproductive health commodities security systems.

The European Union is committed to upholding the principles agreed upon at the ICPD and collectively sharing the financial burden defined in the Programme of Action.¹ The EU specifically notes the vital role of Reproductive Health Commodities Security (RHCS) in achieving better reproductive health for citizens in many of its statements.²

The present study has several objectives:

- To determine mechanisms of how countries can move from a situation of filling national RH commodity shortfalls using international support on *ad hoc* basis to a situation where sustainable and sufficient supplies of key reproductive health commodities are available at the country level;
- Propose mechanisms whereby future action on reproductive health commodity security can move away from simple tracking/monitoring of commodity availability and providing funding on request and mechanisms whereby all partners can work together to address RHCS issues;
- Propose methods to ensure that sufficient financial resources are allocated and that reproductive health commodity security is included in national development planning and policy documents.

Two countries were selected for closer analysis: India and Mozambique. The selection of these two countries was based on the recommendations made in the terms of reference for the present study. The study consisted of a mix of interviews with key individuals working on RHCS in each country and short field visits to view different parts of the supply chain. Time limitations imposed restrictions on the amount of data that could be gathered in the field. A review of the literature on the subject of RHCS was also carried out to place the information that was gathered within a broader perspective.

INDIA

India functions as a federal republic with 35 decentralised state health structures. General health policies are defined at the central level. Some centrally sponsored specific health schemes exist but most decision-making, budgeting and management is carried out directly by the states. The National Commission on Population (NCP) is charged with promoting inter-sectoral coordination across RH agencies at central and state levels to achieve population policy goals.³ The use of modern contraceptive methods in India is estimated 42.8% of all women of reproductive age and in union.⁴ The unmet demand for contraception by married women between the ages of 15

¹ Council of the European Union, Cairo/ICPD+10, Council Conclusions, 24 November 2004..

² See Section 3 for details.

³ National Commission on Macroeconomics and Health, 2006b.

⁴ United Nations Statistics Division, 2006b. "Contraceptive prevalence refers to the percentage of women of reproductive age, married or in union, currently using contraception, unless otherwise specified. The contraceptive prevalence for modern methods refers to the use of the following methods: female and male sterilization, the contraceptive pill, the intrauterine device (IUD), injectables, implants, female and male condom, cervical cap, diaphragm, spermicidal foams, jelly, cream, sponges and emergency contraception."

and 49 is 16%.⁵ It should be noted that only 20% of the pregnant women in India receive the entire package of ante-natal services recommended by the government.⁶

A new Reproductive and Child Health II programme (RCH II) was launched in April 2005. RCH II includes strategies to ensure improved outcomes through the integration of vertical programmes and a decentralised “Programme Implementation Plans”. RCH II emphasizes institutional strengthening at all levels, a pro-poor focus, results oriented indicators, monitoring, and promotion of public-private partnerships.

Government Expenditures on Health in India are only 1.2 of GDP, government expenditures on health are 25% of total expenditure on health⁷ and this represents 3.9% of total public spending.⁸ It should be noted, however, that the government has now committed to increasing public expenditure on health to 2.3% of GDP over the next five years.⁹

The European Commission is the largest donor in the health sector.¹⁰ The EC, DFID, World Bank, WHO, UNICEF, UNFPA and USAID are the principal donors supporting the national reproductive and child health programme.¹¹ Most externally aided projects in the sector have merged into the sector-wide based SWAp donor pool of the Reproductive and Child Health II programme.¹²

The Medical Supply Organisation (MSO) is in charge of supplying reproductive health commodities to implement the national RHC II programme. The government defines the estimated needs for RHC at the central level but states are free to adjust and adapt this list to their own needs. The government publishes advertised tender inquiries and provides limited direct tender inquiries to firms for concluding rate contracts.¹³ Tenders are judged primarily on price and manufacturing capacity. The Government distributes RHC through a multi-tiered public health system of sub-centres, primary health care centres, and community health centres as well as government hospitals. UNFPA considers that the Drug Management Information System is generally poor at the state level with a few exceptions.¹⁴

There are many drug distributors in the country that deal directly with private health facilities and private pharmacies that sell RHC including male condoms and contraceptive pills. Social Marketing Organisations participate in the supply chain for specific RH products such as pills and condoms. The current trend in SMO intervention is extended to Social Franchising which includes the provision of essential health services.

The Central Drugs Standard Control Organisation CDSO carries the prime responsibility for the approval of new drugs to be imported and manufactured, lays down standards and regulatory measures and acts as the Central License Approving Authority. Under the Licensing Procedures, a drug can be manufactured only under a manufacturing license issued in prescribed forms by the Licensing Authorities.¹⁵

⁵ World Bank, 2006b.

⁶ National Commission on Macroeconomics and Health, 2006b.

⁷ World Bank, 2006b.

⁸ WHO, 2006b.

⁹ National Commission on Macroeconomics and Health, 2006b.

¹⁰ European Union External Relations Department, 2006.

¹¹ European Union External Relations Department, 2006.

¹² National Commission on Macroeconomics and Health, 2006b. UN Country Team, 2006. See definition of SWAp in the Acronyms and Definitions Section.

¹³ National Commission on Macroeconomics and Health, 2006b.

¹⁴ Interview with UNFPA staff during field mission.

¹⁵ Partners in Population and Development and Ministry of Health and Family Welfare, Government of Republic of India, 2005, p. 7.

MOZAMBIQUE

The Health Sector Strategic Plan (PESS – Plano Estratégico do Sector da Saúde) is aimed at developing reforms and activities to achieve efficiency, transparency, accountability, equity, flexibility, diversification, partnership, community participation, integration and coordination. The PESS is integrated in the poverty reduction program PARPA (Plano de Accao para a Redução da Pobreza Absoluta).

There is no specific national reproductive health policy. Important aspects of reproductive health are, however, integrated in the Maternal Mortality Reduction strategy.

Government Expenditures on health are 3% of GDP.¹⁶ General government expenditure on health as percentage of total government expenditure is 11%.¹⁷ Public expenditure on health as percentage of total expenditure on health is 62%.¹⁸ The government does not have a specific budget for reproductive health.

Health financing is carried out through three principal mechanisms: through the state budget, the SWAp common funds and vertical funds. External resources account for 41 % of all expenditures on health.¹⁹ In 2006 external assistance on population related projects was over 58.5 million US \$. The Mozambican government and donors are moving towards generalised budget support instead of SWAp programmes. EC support to health and HIV/AIDS is now combined under one single Health Sector Support Programme.

The country has eleven provinces, one of which is the capital city of Maputo. Decentralisation is largely limited to the urban areas with little real autonomy outside of these areas.²⁰ All health institutions operate under the centralised Ministry of Health although some aspects of management has been decentralised to the provincial level. Municipalities and local administration have not yet participated in the decentralisation process.²¹ The lack of human resources is considered a major issue affecting all reproductive health care. Mozambique has only 3 medical doctors per 10,000 people.²²

The unmet demand for contraception by married women between the ages of 15 and 49 is estimated at 18%.²³ This figure probably underestimates the real need because there are many unmarried women whose needs are not included in this estimate.

The demand for RH services is growing, especially in the safe motherhood component. This growth is driven by increased access to health services and the expansion of the network of health centres having a maternity ward and providing antenatal care.

An analysis by WHO (2003) indicated that the pharmaceutical sector is performing relatively well despite problems originating from the economic situation. The supply chain is well balanced within the country and the system is *mostly* able to deliver the pharmaceutical products to the outreach health facilities. Tenders stress price over quality which can have detrimental effects. WHO (2003) does consider that forecasting of drug needs in

¹⁶ World Bank, 2006b.

¹⁷ WHO, 2006b.

¹⁸ WHO, 2006b.

¹⁹ World Bank, 2006b.

²⁰ Hodges, T & Tibana, R., 2004.

²¹ WHO, 2003.

²² WHO, 2006b.

²³ World Bank, 2006b.

Mozambique should be improved. Stock outs are not uncommon. RHC are integrated into the common distribution and procurement system and are handled the same as other drugs or medical commodities.

The National Drug Quality Control Laboratory works under several most important constraints including lack of equipment, reference substances, training and maintenance support. The Quality Assurance of imports still needs strengthening. There are two principal mechanisms for the distribution of RHC. Through a “classical” system of bulk supplies of RHC and through distribution of health kits.

The Health Information System (HIS) in Mozambique has been held as a model and is praised by some as one of the best in Africa.²⁴ A proliferation of new projects using parallel information systems has, however, contributed to the fragmentation of information.

OVERVIEW OF RECOMMENDATIONS

The consultants support the recommendations made in the Gates Foundation sponsored Mercer Report and the DFID sponsored synthesis report on Reproductive Health Commodity Security.²⁵ The case studies on India and Mozambique reinforce the findings of these previous reports and additionally lead to a focus on the following recommendations:

POLICIES, LEGAL FRAMEWORK AND COORDINATION WITH PARTNERS

1. Where National Reproductive Health policies do not yet exist they should be established including specific references to RHCS.
2. All other major policy documents on health, poverty, and gender should make specific references to ensuring RHCS including mechanisms on how RHCS should be realised.
3. The RHCS legal framework should be comprehensive and address all issues related to tendering, procurement and distribution.
4. Decentralisation processes down to the local level should be promoted and emphasise the importance of ensuring that RHC are accessible to the districts and communities.
5. The active role of civil society at all levels from national to local should be promoted because it has an important role to play in the form of advocacy on issues related to RHCS including equity of access.
6. Donors should be encouraged to perform regular assessments/monitoring of the RHCS situation so they can provide good technical support and input in coordination and other meetings.

FINANCING AND BUDGET RECOMMENDATIONS

7. Promote increased targeting of funding for health and funding for RHC specifically (as necessary) at each level, i.e. national, state/provincial/ district/community.
8. Budgets should directly reflect the priorities assigned to health, RH, and RHC in major national and state policy documents.

²⁴ WHO, 2003.

²⁵ Mercer Management Consulting, 2005; Druce, N. 2006.

9. Multi-annual revolving funds for commodity procurement and other mechanisms that help ensure sustained financing need to be supported, studied and introduced nationally and/or regionally.

MANAGEMENT OF REPRODUCTIVE HEALTH COMMODITIES SYSTEMS

10. A special department that focuses on the coordination, implementation of laws and regulations, and functioning of the supply chain on drugs needs to be created with a special unit focussing on RHCS.
11. *Assessments* of the number and type of human resources needed to adequately implement RHCS need to be carried out at all levels
12. The management capacities of all staff working in the supply chain should be regularly assessed using staff evaluation procedures. This will contribute to improved identification of capacity strengthening gaps and motivate staff.

HEALTH INFORMATION SYSTEMS AND RHCS

13. Health Information Systems need to be strengthened carefully and based on actual field information as much as possible
14. The *functioning* of Logistics systems for Drug and other RHC should be regularly monitored and evaluated.

PARTNERSHIPS AND INTEGRATION

15. The opportunities to develop a Total Market Approach to RHC should be studied in each country.
16. The development of public-private partnerships needs to be studied, regulated, and encouraged. An innovation/challenge fund for private sector partnership initiatives should be developed.

TENDERING

17. Tendering needs to also focus strongly on quality as opposed to judging primarily based on price and manufacturing capacity.
18. Tendering through on-line procedures should be encouraged since it improves transparency.

QUALITY CONTROL

19. More emphasis needs to be placed on good quality control at all levels of the supply chain. Specific areas of concern to improve drug quality need to be addressed such as improvement in the number and adequacy of testing facilities, increasing the number of drug inspectors, increasing the number of trained staff in general and for specific regulatory areas and creating a drugs data bank.
20. *Administrative mechanisms* need to be put in place that will ensure that quality control is transparent, well organised, and that laws and regulations are *applied*.
21. International support to address counterfeiting through studies and advocacy should be provided.
22. Studies need to be carried out determine the level of diversion of RHC illegally from public to private sector and how to address any problems identified.

DISTRIBUTION

23. Warehouses need to be properly maintained and have good efficient systems.
24. At the delivery level measures need to be developed to ensure that equity in access is assured.

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Reproductive Health Commodity Security Study

Key Findings and Recommendations for the European Commission

Final Report

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ACRONYMS AND DEFINITIONS OF IMPORTANT TERMS

ART	Anti Retroviral Therapy
ARV	Antiretroviral
CBO	Community Based Organization
CDSCO	Central Drugs Standard Control Organisation
CMAM	Central de Medicamentos e Artigos Médicos
CPR	Contraceptive Prevalence Rate
CS	Commodity Security
DFID	Department for International Development
DHS	Demographic Health Survey
DPS	Provincial Health Directorate (Direcção Provincial de Saúde)
DREAM	Drug Resources Enhancement against AIDS and Malnutrition
EC	European Commission
EDL	Essential Drug List
FCP	Provincial Common Fund (Fundo Comum Provincial, Mozambique)
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
HIV/AIDS	Human Immune Deficiency Virus/Acquired Immune Deficiency Virus
ICPD	International Conference on Population and Development
IEC/BCC	Information Education and Communication/ Behaviour Change Communication
IPPF	International Planned Parenthood Federation
I-PRSP	Interim Poverty Reduction Strategy Paper
ISO	International Organisation for Standardization
IT	Information technology
IUD	Intra Uterine Device
JICA	Japanese International Cooperation Agency
MEDIMOC	Central de Medicamentos e Artigos Médicos
MIS	Management Information system
MOH	Ministry of Health
NACO	National AIDS Control Programme
NGO	Non Governmental Organization
NHIS	National Health Information Systems
NHP	National Health Policy
NCP	National Commission on Population
OTC	Over The Counter drugs
PARPA	Poverty Reduction Strategy in Mozambique
PATH	Project for Appropriate Technology for Health
PESS	Strategic Health Plan (Plano Estratégico do Sector da Saúde)
PHC	Primary Health Centre
PLWHA	People Living with HIV/AIDS
PROSAUDE	Common Fund for Health (Fundo Comum de Apoio ao Sector de Saúde. Mozambique)
PRSP	Poverty Reduction Strategy Paper

PSI	Population Services International
QA	Quality Assurance
QC	Quality Control
RCHII	Reproductive and Child Health II Programme
RH	Reproductive Health
RHC	Reproductive Health Commodities
RHCS	Reproductive Health Commodity Security
RTI	Reproductive Tract Infection
SMO	Social Marketing Organizations
SPARCHS	Strategic Pathway to Reproductive Health Commodity Security
STI	Sexual Transmitted Diseases
SWAp	Sector Wide Approach for development
SWOT	Strengths, Weakness, Opportunities and Threats Analysis
TNMSC	Tamil Nadu Medical Services Corporation Limited
UNDAF	United Nations Development Framework
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
WAHO	West African Health Organisation
WHO	World Health Organisation

DEFINITIONS OF IMPORTANT TERMS USED IN THE REPORT

DEFINITION OF COMMODITY SECURITY

Commodity security may be described as a situation in which:²⁶

- **Commodities are available:** The products are available at the service delivery points where they are required; are provided by appropriately trained personnel; and without interruptions of supply.
- **Commodities are affordable:** The products are available at a price the user can afford. Where they are provided free-of-charge or at a subsidized price, the necessary quantities can be afforded by the purchaser, usually the public sector.
- **Commodities are of appropriate quality:** The products meet appropriate international quality standards.
- **There is sufficient choice:** This applies primarily to contraception, both in terms of the type of hormonal contraceptives available and between different contraceptive methods. It allows individuals to choose those preparations they feel most comfortable with in terms of side-effects and ease of use, as well as the ability to select methods appropriate for different times in their reproductive life.
- **Free Choice:** of different contraceptives guaranteed.
- **Commodities should be accessible:** physical structures where RHC are located should be accessible within reasonable distance (as defined by users) and should be socially and equitably accessible.

In line with parallel country case studies carried out by the Department for International Development (DFID) the study focuses primarily on the following list of reproductive health commodities:²⁷

CONTRACEPTIVES

- combined oral contraceptives
- emergency contraceptive pills
- injectable contraceptives
- sterilization kits
- IUDs
- condoms (male)
- condoms (female)

Note: A range of contraceptive products is listed in order to assess issues of choice. It does not include products that are only available at generally unaffordable price, such as vaginal rings, hormonal patches, implants and the levonorgestrel-releasing IUD.

²⁶ Obtained from DFID, 2005 with minor adjustment.

²⁷ DFID, 2005.

CONTRACEPTIVE PREVALENCE RATE

- Proportion of women of reproductive age who are using (or whose partner is using) a contraceptive method at a given point in time.

HIV AND OTHER STIs

- Diagnostic tests for HIV and STIs.

Note: Condoms are included under contraception.

MATERNITY CARE, DELIVERY AND ABORTION

- lignocaine (local anaesthetic)
- ferrous sulphate (to treat anaemia)
- folic acid (ditto)
- magnesium sulphate (to treat eclampsia)
- oxytocin (to facilitate labour)
- misoprostol (to treat post-partum haemorrhage and manage early abortion)
- MVA equipment (for early abortion and post abortion care)

SECTOR WIDE APPROACH FOR DEVELOPMENT (SWAp)

Definition of Sector Wide Approach for Development (SWAp):²⁸ The definition most commonly used is development cooperation in which:

- All significant public funding for the sector supports a single sector policy and expenditure programme;
- Under Government leadership;
- With common approaches adopted across the sector by all funding parties; and
- A progression towards relying on Government procedures to disburse and account for all public expenditure, however funded.

²⁸ UNESCO, 2006

1 INTRODUCTION

Good reproductive health is a recognized human right. Many official declarations and policy documents have emphasized this right including the International Conference on Population and Development (ICPD) and the Millennium Development Goals (MDGs). The European Union (EU) has frequently affirmed its support of the ICPD and MDGs. To attain good levels of reproductive health it is crucial that countries have well functioning and equitable reproductive health commodities security systems. The EU specifically notes the vital role of Reproductive Health Commodities Security (RHCS) in achieving better reproductive health for citizens in many of its statements.²⁹

The European Commission financed the present study on reproductive health commodities security in response to an invitation from the EU General Affairs and External Relations Council through its Conclusions on Cairo/ICPD+10, adopted on the 24 November 2004.

The EU Council recognized that there is a substantial need for additional funds for RHC which should be provided by the donor community through geographic and thematic instruments, multi-sector and/or budget support.³⁰ The EU Council invited the Commission and the Member States to provide additional resources to fill the gap as a response to the urgent need for RHC in the partner countries. At the same time the EU Council requested that feasible solutions be identified for guaranteeing the required level of RHC supplies, with the support of the donor community and public private partnerships. The study in this report is a partial response to this request.

The study has several objectives:

- Determine mechanisms of how countries can move from a situation of filling national RH commodity shortfalls using international support on *ad hoc* basis to a situation where sustainable and sufficient supplies of key reproductive health commodities are available at the country level.
- Propose mechanisms whereby future action on reproductive health commodity security can move away from simple tracking/monitoring of commodity availability and providing funding on request from governments, UNFPA and others.
- Propose mechanisms whereby all partners can work together to address RHCS issues.
- Propose mechanisms on how donors should address further support.
- Propose methods to ensure that reproductive health commodity security is included in national development planning and policy documents.
- Propose methods to ensure that sufficient financial resources are allocated for reproductive health commodities into the national financial planning process.

The report includes substantial discussion of the role of government, donors, NGOs, and other stakeholders in ensuring RHCS. The purpose of this detailed analysis is to learn how partners can work together to address RHCS issues. It is important to note that the current report provides an example of such coordination because it serves to complement similar studies carried out by the Department for International Development (DFID) and the Mercer Study sponsored by the Gates Foundation.

²⁹ See Section 3 for details.

³⁰ Council of the European Union, Cairo/ICPD+10, Council Conclusions, 24 November 2004.

2 METHODOLOGY

A team of 3 experts was contracted to carry out the study. The team was composed of a public health specialist, a specialist in drug management and a specialist in health financing and financial management. The team prepared a methodological framework to complement the terms of reference and to provide guidance during field visits.

The RHCS study benefited from the results of the earlier Mercer Study sponsored by the Gates Foundation on contraceptive availability and from the coordination and exchange of ideas with a team from the ongoing Department for International Development (DFID) study on Reproductive Health commodities. The methodological approach was designed to correspond to the DFID model and the countries chosen complement the range of countries studied by DFID.

The study consisted of a mix of interviews with key individuals working on RHCS in each country and short field visits to view different parts of the supply chain. Time limitations imposed restrictions on the amount of data that could be gathered in the field. A review of the literature on the subject of RHCS was also carried out to place the information that was gathered within a broader perspective. In the final phase two additional experts provided technical support to complete the literature research and analytical analysis of the data.

Two countries were selected for closer analysis: India and Mozambique. The selection of these two countries was based on the recommendations made in the terms of reference for the present study: willingness to address reproductive health commodities security in country, existing shortfalls in reproductive health commodities, existence of a Poverty Reduction Strategy Paper and a strong UNFPA local office. Mozambique and India were also selected because they have very different development and health system reform processes, have a high burden of reproductive health illnesses, and are implementing a Sector Wide Approach for health Development (SWAp).

The consultant team visited the state of Tamil Nadu³¹ in India, which is often cited as a model to be followed by other states in India, to learn lessons on RHCS that can be applied to the other states. India, given its diversity, does not have a single state that can be said to be representative of India as a whole. The experience of Tamil Nadu does, nevertheless, provide indications of general directions that can be followed by other states in India.

In Mozambique the consultancy team visited the Provincial Health Directorate (DPS) in Maputo province where the provincial medical director was interviewed. The team visited the provincial drug warehouse, a district hospital and a warehouse at Namahacha.

³¹ Tamil Nadu is a state at the southern tip of India and the sixth most populous state in the Indian Union with 62 million inhabitants.

3 OVERVIEW OF THE REPRODUCTIVE HEALTH COMMODITY SECURITY CONTEXT

The International Conference on Population and Development (held in Cairo in 1994) adopted a Programme of Action development agenda with three main themes: human rights, women's empowerment and sexual and reproductive health and rights.

The assessments carried out at ICPD + 10 years determined that significant progress in adopting and implementing a reproductive health approach and in strengthening efforts to improve gender equality and other areas had been made.³² The outcomes also show, however, that major challenges to the full implementation of the Cairo agenda remain, including addressing HIV/AIDS more effectively and strengthening data collection and analysis systems. The strengthening of data collection and analysis systems is of key importance to RHCS, particularly for accurate forecasting.

The Regional Ministerial Review Conference for ICPD+10 in the Africa region reaffirmed the agreements made under the ICPD and noted several specific key points of relevance to RHC:³³

- More countries should become more involved in the self-financing of family planning (FP) commodities.
- Population issues should be integrated into poverty reduction strategies and programmes.
- Attention should be given to sexual and reproductive health services for men as well as male involvement in Family Planning and infertility.
- Negotiations on regional production of ARVs at lower cost should continue.

Other international conferences of major importance for international policies on reproductive health include the:³⁴

- United Nations Fourth Conference on Women in Beijing in 1995 and Beijing +5 which re-emphasized women's right to free choice.
- Millennium Summit in 2000 which included the establishment of the Millennium Development Goals of which several are related to reproductive health (Target 3 on gender equality, target 5 on maternal health, and target 6 on fighting HIV/AIDS malaria and other diseases).
- United Nations General Assembly special session on HIV/AIDS (UNGASS) on 25, 27 June 2001.
- World Summit (2005) during which pledges were made to increase investments in health systems in developing countries and a global commitment to the Cairo goal of "universal access to reproductive health by 2015" was reaffirmed by the General Assembly final document
- The Conference on Financing for Development, Monterrey and Barcelona Council (2002) resolutions in which the EU Council renewed commitment to increasing member states' official development assistance with special emphasis on health.
- Paris Declaration on Aid Effectiveness, 2nd March 2005.

³² Fuersich, C.M. / United Nations Population Fund (UNFPA) , 2005

³³ Economic Commission for Africa, 2004.

³⁴ General Secretariat of the Council dated 15 December 2004.

3.1 European Union Support for Reproductive Health

The European Union has been involved in Reproductive Health Commodity interventions in developing countries for over a decade and has provided consistent support to the ICPD agenda since 1994. The European Union is committed to upholding the principles agreed at the ICPD and collectively sharing the financial burden defined in the Programme of Action.³⁵

The EU commitment was affirmed in 2000 in the context of the EU Millennium Declaration. On the 23rd of November 2004, the EU Council reconfirmed its broad support to the ICPD agendas, both at country and global levels.³⁶ This is reaffirmed in the European Development Consensus, the European Union Development framework, adopted by the European Commission, the Council and the European Parliament in 2006.³⁷ As advocated in the Development consensus, financial support to developing countries for SRHR is mainly pursued through bilateral aid (sector budget support or budget support) on the local ownership.

The European Union has also released an official "Statement on HIV Prevention for an AIDS Free Generation"³⁸ on the 24th November 2005 which reiterated the same basic points. The statement noted that the EU supports universal access to sexual and reproductive health information and services for women, men and young people, including people living with HIV and AIDS, to ensure that they have access to a full range of reproductive choices in accordance with the Cairo/ICPD Agenda. Reliable *access to essential sexual and reproductive health commodities* including male and female condoms is also specifically mentioned.

European Union support to reproductive health and development are provided for in Regulation No. 1567/2003 issued on the 15th July 2003 approved by the European Parliament.³⁹ The regulation reinforces the Cairo programme of Action adopted at the International Conference on Population and Development (ICPD) while at the same time aims to increase and accelerate efforts in light of achieving the Millennium Development Goals (MDGs). The regulation provides guidance to the implementation of all actions carried out by the EU in the area of reproductive health. Specifically, it states that "The Community shall provide financial assistance and appropriate expertise with a view to promoting a holistic approach to, and the recognition of, reproductive and sexual health and rights as defined in the ICPD Programme of Action, *including safe motherhood and universal access to a comprehensive range of safe and reliable reproductive and sexual health care and services.*" Various types of reproductive health commodities are mentioned specifically and indicates the importance attached to the issue of RHC by the European Parliament.

The European Commission (EC) is an active member of the International Coalition for Reproductive Health Commodities Security. The European Union also officially recognizes and supports the activities of UNFPA and its leadership function regarding ICPD⁴⁰ as well as WHO and UNIFEM.

³⁵Council of the European Union, Cairo/ICPD+10, Council Conclusions, 24 November 2004

³⁶ Council of the European Union, Cairo/ICPD+10, Council Conclusions, 24 November 2004.

³⁷ Joint statement by the Council and the representatives of the governments of the Member States meeting within the Council, the European Parliament and the Commission on European Union Development Policy: 'The European Consensus', 24 February 2006.

³⁸ EU Statement on HIV Prevention for AIDS Free Generation, General Secretariat, 24 November 2005.

³⁹ European Parliament, 2003. See reference list for details.

⁴⁰ European Union Presidency Statement, 14/10/2004

3.2 Reproductive Health and Commodities Shortfalls

Reproductive health programmes in most developing countries depend heavily on external donor assistance. UNFPA carried out an analysis of 49 countries and estimated a shortfall of contraceptives valued at 75 million US\$ in 2004 alone.⁴¹ Such shortfalls are worrisome because more clinics and community health programmes are continually created so the need for the delivery of RHC also increases correspondingly. UNFPA (2005) does note that international donors have invested heavily in helping sub-Saharan Africa by funding contraceptives and condoms for an amount of almost equal to the regional requirement. The amount provided (US\$ 105 million) figure does not, however, cover other reproductive health requirements.

The Conclusions of the European Council (2004) state that the Millennium Development Goals will not be attained without renewed efforts by donors to fulfil their financing commitments to the ICPD.

The EU has been pledging funds through the Commission, the European Parliament and Member States to secure the RHC in countries receiving international development or emergency assistance. The EU has expressed its support for UNFPA financially. In 2004, for example, the EU collectively (the 25 member states and the Commission) filled the entire reproductive health commodities gap with 75 million US dollars from Member States and 15 millions US dollars from the European Commission in 2004 through a special contribution to UNFPA's Reproductive Health Commodity Fund.⁴²

For the budget years 2003-2006, the EC budget line on aid for policies and actions on reproductive and sexual health and rights in developing countries totaling 74 million euros has enabled us to finance a number of important NGO-driven projects in the poorest countries.

For the financial perspectives 2007-2013 under the Development Cooperation Instrument - DCI - all human development issues are addressed on a thematic basis including health and SRHR. The budgets and numbers are not yet set but allocations for SRHR are expected to remain at same level as the previous thematic budget line.

The total cost of reproductive health commodities is difficult to calculate. UNFPA has, however, made some basic estimates to help donors and governments determine the overall scale of the issues they must address to ensure RHCS. Donor funding currently only represents about 22% of all funding for RHC needed annually.⁴³ The cost of reproductive health commodities was estimated at US\$ 2.34 billion for the whole period 2005-2010 and is expected to increase to US\$ 3.43 billion by 2015.⁴⁴

UNFPA (2005) has estimated, for example, that the total cost of contraceptives for the period 2006 to 2010 would be about US\$ 4.4 billion.⁴⁵ UNFPA also estimates that 4-5 billion condoms are needed annually for family planning and an additional 26 billion for protection in all episodes of unsafe sex. Ensuring that condoms are used in all episodes of unsafe sex is considered unrealistic, however, so UNFPA estimates that in fact about 15.3 billion condoms will be needed in these situations annually by 2015. The cost of covering condoms used in unsafe sex is estimated at US\$ 1.64 billion for the period 2006-2010. Although these figures may appear high, it is useful to recall

⁴¹ General Secretariat of the Council dated 15 December 2004.

⁴² European Union Presidency Statement, 14/10/2004

⁴³ Reproductive Health Supplies Coalition: Systems Strengthening Working Group, 2006.

⁴⁴ UNFPA, 2005.

⁴⁵ UNFPA, 2005.

that in 2004 the donor community supplied the developing world with less than 2 condoms per man of reproductive age.⁴⁶

The cost of other reproductive health commodities used in antenatal care, normal and complicated deliveries and postnatal care, treatment of sexually transmitted infections, etc. is estimated at US\$ 7.2 billion for the period 2006-2010. UNFPA has warned that many developing countries, NGOs and the private sector alone will not be able to cover these costs.

3.3 Organisations Addressing Reproductive Health

Some of the organisations working on RHCS are UNFPA, WHO, World Bank, European Commission, International Planned Parenthood Federation, and International Coalition for Reproductive Health Commodities Security Population Services International, Marie Stopes International, World Population Foundation, European Committee for Population and Development John Snow, Inc., DKT International and Population Action International. Several large foundations such as the Gates and Packard Foundations are supporting RHCS programmes. Many individual countries are also providing bi-lateral support or work indirectly through international and national NGOs.

UNFPA is spearheading the Global Programme to Enhance Reproductive Health Commodity Security which was launched in 2005.⁴⁷ The main objective of the Global Programme on RHCS is to act as a catalyst to facilitate nationally driven efforts to mainstream RHCS. The Global Programme aims to help address shortfalls in RHC and build national capacity for sustainable procedures and mechanisms, promotes condom programming, and endeavours to meet immediate shortfalls in reproductive health commodities.⁴⁸

3.4 Essential Components of a Well-functioning National RHCS system

The essential components of a well-functioning national RHCS system are quite evident in general terms but the challenge is on how to implement them.

Some of the essential elements for ensuring RHCS include:⁴⁹

- Adequate, reliable, predictable, and efficient public financing including specific budget lines for SRHR.
- RHCS coordination groups that allow coordination of all stakeholders including donors, government, Non State Actors and coordination of financing procedures.
- Supportive policies (attention to RHC specifically in policy documents)
- Supportive laws and regulations (on issues such as generics, import, quality control, registration, forecasting, tendering, distribution mechanisms, etc.)
- Good short, medium, and long term planning.

⁴⁶ http://www.unfpa.org/upload/lib_pub_file/590_filename_dsr-2004.pdf

⁴⁷ UNFPA, 2005.

⁴⁸ UNFPA, 2005. p. 6.

⁴⁹ See Figure 1 at the end of the Conclusions and Recommendations Section for a visual representation of the key issues.

- Transparency of all parts of the RHC supply chain (forecasting, procurement, distribution, delivery). Each decision point in the chain needs to function optimally in terms of transparency so that the system as a whole offers good-quality, cost-effective and safe medicines.⁵⁰
- Coordinated and well-balanced mix of public, private, and social marketing RHC systems.
- Good general management of all parts of the RHC supply chain: financial, logistics, production if applicable, stock keeping, distribution, human resources, marketing of RHC at each of the supply chain levels.
- Capacity to handle the necessary volumes at each level.
- Well functioning Health Information, Logistical and Drug Information Systems.
- Good physical structures/transport for manufacturing (if applicable) testing, processing, stocking, and distribution.
- Monitoring of the adequate functioning of the RHCS system.
- Equitable access at point of delivery (affordable, feasible distance to delivery site, socio-cultural aspects).

Some of the problems in RHCS that are very complicated to address are:

- Unpredictable donor funding.⁵¹
- Fractured procurement in some countries. Funding may move from donors and multilateral agencies through procurement agents to the country governments or pass through SWAp or common budget support programmes.⁵²
- The introduction of SWAp as a common pool funding mechanism in health sectors is intended to reduce aid fragmentation and facilitate policy dialogue but SWAp also means that donors lose the ability to track expenditures devoted to a specific activity.⁵³
- Timing of funding flow is driven by donor internal process cycles, not country needs.
- The inability to engage in longer-term and bulk purchase commitments with manufacturers. This compromises ability to achieve optimal commodity prices and complicates delivery schedules which in turn contributes to stock-outs. Approximately 50% of global public sector purchasing does not get the best price.⁵⁴

Some of these issues are currently under discussion so that equitable and affordable RHCS can be made available. The Reproductive Health Supplies Coalition published a study with proposals to address funding and global procurement problems.⁵⁵

⁵⁰ Transparency International, 2005. p. 79.

⁵¹ Reproductive Health Supplies Coalition, 2006.

⁵² See Definitions Section for details on SWAp.

⁵³ Ayala-Öström, B., Druce, N., Hall, P. Brown, A., (for DFID), 2005.

⁵⁴ Reproductive Health Supplies Coalition, 2006.

⁵⁵ Reproductive Health Supplies Coalition, 2006.

4 SUMMARY OF CASE STUDY ON REPRODUCTIVE HEALTH COMMODITY SECURITY IN INDIA



Kalakar Trust Clinic, Kamal Tamuli

4.1 Country Overview

The estimated population of India in 2006 was 1,119,538.5 with a population growth rate of 1.6% annually.⁵⁶ Per Capita Gross National Income is \$ 3,460.⁵⁷

The percentage of the population living below the poverty line is 36% and 80% live on less than \$2 per day.⁵⁸ India's Human Development Index⁵⁹ is 0.611 which gives India a rank of 126th out of 177 countries.⁶⁰

Life expectancy for men is 62 years and for women 65 years.⁶¹ The total life time fertility per woman is currently estimated at 3.1 children while the adolescent fertility rate is 80 per 1000 births.⁶²

⁵⁶ United Nations Statistics Division, 2006d.

⁵⁷ At purchasing power parity. World Bank, 2005.

⁵⁸ At purchasing power parity. World Bank, 2005.

⁵⁹ Human Development index is a composite index measuring average achievement in three basic dimensions of human development—a long and healthy life, knowledge and a decent standard of living.

⁶⁰ UNDP 2006.

⁶¹ United Nations Statistics Division, 2006c.

⁶² United Nations Statistics Division, 2006a.

4.1.1 Health Situation/Burden of Disease

The maternal mortality rate in India is currently estimated at 301 per 100,000 live births.⁶³ There are wide variations in maternal mortality within the country. Indian states such as Kerala, Tamil Nadu, and Punjab have rates below 100 per 100 000 live births while Rajasthan, Assam and Uttar Pradesh have from 445 to 517 deaths.⁶⁴ Over 100 000 women in India die of pregnancy related causes every year.⁶⁵ Haemorrhages cause over one quarter of all maternal deaths so RHC that can control haemorrhaging are essential.⁶⁶

Nine percent of all maternal mortality is attributed to unsafe abortions.⁶⁷

Infant mortality is an important figure that is considered to be at least somewhat related to the reproductive health of the mother. The infant mortality rate in India is 68 per 1000 live births.⁶⁸

The HIV/AIDS prevalence rate in India is estimated at 0.9% comprising a total of 5,700,000 people.⁶⁹ As with other health indicators there are wide regional variations within the country with infection rates reaching or exceed 5% in some districts such as Namakkal and Churachandpur.⁷⁰ The progress of the epidemic in different states varies with stable or diminishing rates in some areas while growing at a modest rate in others.⁷¹

4.2 National Reproductive Health Policy and Strategy Structures

In 2000 the government adopted a ten year National Population Policy.⁷² The policy framework includes goals to address:

- unmet needs for basic reproductive health services, *supplies*, and infrastructure;
- achievement of services for fertility regulation and contraception with a wide basket of choices.⁷³

The National Population Policy represents an implementation shift away from centrally fixed targets to target-free dispensation through a decentralised, participatory approach. The new policy is based on the main recommendations framed in the International Conference on Population and Development (ICPD) recommendations. The target-free approach is linked to a community needs assessment approach.

⁶³ UNICEF, 2006. Note: the United Nations Statistics Division (2006a) quotes a higher annual average of 510 mortalities for 100,000 live births for the period between 2000 and 2005.

⁶⁴ UNICEF, 2006

⁶⁵ UNICEF, 2006.

⁶⁶ National Commission on Macroeconomics and Health, 2006b.

⁶⁷ National Commission on Macroeconomics and Health, 2006a

⁶⁸ United Nations Statistics Division, 2006c.

⁶⁹ UNAIDS, 2006.

⁷⁰ UNAIDS, 2005b.

⁷¹ UNAIDS, 2006. National Commission on Macroeconomics and Health, 2006a. The states especially vulnerable to HIV/AIDS are Uttar Pradesh, Bihar, Madhya Pradesh, Chhattisgarh, Jharkhand, Rajasthan, Himachal Pradesh, and Jammu and Kashmir.

⁷² National Commission on Macroeconomics and Health, 2006b.

⁷³ National Commission on Macroeconomics and Health, 2006b. p. 2.

Box 1

Principal Objectives of the Indian National Health Policy⁷⁴

Extract from the National Population Policy of the Government of India

- The **immediate objective** of the National Population Policy 2000 is to address the unmet needs for contraception, health care infrastructure, and health personnel and to provide integrated service delivery for basic reproductive and child health care.
- The **medium-term objective** is to bring the total fertility rate to replacement levels by 2010 through vigorous implementation of inter-sectoral operational strategies.
- The **long-term objective** is to achieve a stable population by 2045, at a level consistent with the requirements of sustainable economic growth, social development, and environmental protection.

A new Reproductive and Child Health II programme (RCH II) was launched in April 2005. RCH II includes strategies to ensure improved outcomes through the integration of vertical programmes and decentralised "Programme Implementation Plans". RCH II emphasizes institutional strengthening at all levels, a pro-poor focus, results oriented indicators, monitoring, and promotion of public-private partnerships.

4.2.1 Government Expenditures on Health

Government Expenditures on Health are only 1.2% of GDP and this represents 3.9% of total public spending.⁷⁵ Government expenditures on health as percentage of total public spending and total health expenditure declined for the last five years (1998-2002) for which data is available.⁷⁶ It should be noted, however, that the government has now committed to increasing public expenditure on health to 2.3% of GDP over the next five years.⁷⁷

4.2.2 Principal Donors and Agencies Promoting Reproductive Health Commodity Security

External resources account for 1.6% of all expenditures on health.⁷⁸ Compared to many other developing countries (see case study of Mozambique in Section 5, for example) India is not dependent on overseas development assistance to cover its needs in RHC.⁷⁹ India also produces most essential RHC domestically.

The European Commission is the largest donor in the health sector through bilateral aid.⁸⁰ The EC, DFID, World Bank, WHO, UNICEF, UNFPA and USAID are the principal donors supporting the national reproductive and child health programme.⁸¹

⁷⁴ National Commission on Macroeconomics and Health, 2006b.

⁷⁵ World Bank, 2006b.

⁷⁶ WHO, 2005.

⁷⁷ National Commission on Macroeconomics and Health, 2006b.

⁷⁸ World Bank, 2006b.

⁷⁹ Partners in Population and Development and Ministry of Health and Family Welfare, Government of Republic of India, 2005.

⁸⁰ European Union External Relations Department, 2006.

⁸¹ European Union External Relations Department, 2006.

India has adopted a policy to retain government-to-government (bi-lateral) aid with only six donors: the UK, the US, the Russian Federation, Germany, Japan, and the EC.⁸² Other donors have been advised to route resources through NGOs or multilateral agencies.

The Government of India's policy is to accept bilateral aid only from the G8 and European Union countries which offer at least \$25 million per annum. Other countries are allowed to aid autonomous institutions, universities, NGOs and other organisations, but not to the Government of India. In addition, the Government rejects all tied aid.⁸³ These policies are intended to allow more effective use of aid and reduce administration costs.

Most externally aided projects in the sector have merged into the sector-wide based SWAp donor pool of the Reproductive and Child Health II programme.⁸⁴ All central and state projects supported by the development partners are included in the SWAp donor pool so that a coordinated approach can be promoted. The European Commission (EC) already started moving towards the SWAp in 1995. UNFPA provided direct support for RHC acquisition, distribution and manufacturing capacity of the country until the end of the 1980s but has now integrated its support into the SWAp donor pool.

The UNDP is financing a project to align Official Development Assistance more closely with national development priorities, as set out by the Government of India, and to improve efficiency and effectiveness of its utilization.⁸⁵ Assistance from the European Union is integrated into the project's Development Assistant Database (DAD).⁸⁶

It is important to emphasize that RHCS is now mainstreamed into the national health system and few specific donor projects on RHCS are supported. This means that specific donor support for RHCS cannot be quantified. The SWAp approach is in line with the current move in international development to integrate most vertical development projects into sectoral or even multi-sectoral programmes.

USAID finances the Innovation in Family Planning Services, Phase II (2003-2008) project in the states of Uttar Pradesh, Uttaranchal and Jharkand.⁸⁷ The project promotes RHC public-private partnerships as one of its key activities. During the project years 2000-2005 (Phase I and early Phase II) the availability of oral contraceptive pills in rural villages in Uttar Pradesh increased from 19% to 56%.

The principal donors supporting the National AIDS Control Programme (NACP), Phase III are the World Bank, DFID, USAID and various UN agencies.⁸⁸

4.2.3 The Role of the European Union in Promoting Reproductive Health Commodity Security

Projects that included reproductive health commodities were carried out by the EC prior to the introduction of the SWAp. The EC provided support to the Indian Government to improve the logistics and distribution of drugs through India's Health and Family Welfare Sector Programme (programme 1998-2004).⁸⁹ The EC financed social

⁸² UNFPA, 2004.

⁸³ UNDP, 2005.

⁸⁴ National Commission on Macroeconomics and Health, 2006b. UN Country Team, 2006. See definition of SWAp in the Acronyms and Definitions Section.

⁸⁵ UNDP India, 2006.

⁸⁶ UNDP India, 2006.

⁸⁷ USAID, 2006.

⁸⁸ UN Country Team, 2006.

⁸⁹ European Union External Relations Department, 2006.

marketing projects based on successful pilot schemes starting in Andhra Pradesh in 2000 and ending in December 2005.

The EC played an important role in promoting the SWAp approach during India's first Reproductive and Child Health (RCH) programme.⁹⁰ EC support also focussed on helping States to make a "paradigm shift" away from a target-oriented family planning approach to a more holistic health care system for families, focusing in particular on women and children.⁹¹

The EC has now started implementing the new Country Strategy Paper 2007-2013.⁹²

The EU has made several important policy statements on reproductive health in India in addition to providing financial support to the national reproductive health programmes. These include the Declaration of the European Parliamentary Delegation of the Inter-European Parliamentary Forum On Population and Development to India in January 2001.

4.2.4 Donor Coordination

The EU General Secretariat rightly states in a note to the European Council (2004) that changes in new aid financing mechanisms - such as SWAp and common budget support - requires even more effective coordination of aid efforts between donor agencies and recipient governments.⁹³

The SWAp framework in India provides the context for the coordination of the main donors with the central and state governments. The country coordination mechanism includes donor representation, the Indian government and civil society. Monthly Development Partners meetings with Ministry of Health and Family Welfare help to increase the convergence of interventions of the different partners. Agreements are institutionalised through Memoranda of Understanding with each state involved in the process.

Input from all partners was obtained to prepare the Reproductive and Child Health II Programme and the National AIDS Control Programme II. Some of the international partners that were involved were the EC, WHO, World Bank, DFID and UNFPA.

4.2.5 Description of the Health System and Reproductive Health Services

STRUCTURE OF THE MINISTRY OF HEALTH AND FAMILY WELFARE

India functions as a federal republic with 35 decentralised state health structures. General health policies are defined at the central level. Some centrally sponsored specific health schemes exist but most decision-making, budgeting and management is carried out directly by the states.

⁹⁰ European Commission, 2002, p. 17.

⁹¹ European Commission, 2002, p. 17.

⁹² European Union External Relations Department, 2006.

⁹³ European Council, 2004

The federal system partially explains the wide diversity of health indicators across the different states. Each state develops its own budget, makes most of its own decisions and manages the state health system and not all have the same level of resources and competence. Some states have their own internal SWAp budget for their health system but most donors work through the central level. Each state does have to function within the context of a national legal framework on drugs and other health commodities.

The Reproductive and Child Health programme II (RCH II) and the National AIDS Control Programme II are centrally developed programmes with an impact on RHC.

In the budget year 2005-2006 the new centrally located National Rural Health Mission (NRHM) started becoming operationalised with the purpose of improving quality and providing more equitable access to primary health care.⁹⁴ The NRHM will have offices in all states with special attention in terms of coordination and support to 18 states with poor health indicators. The two previously existing directorates of the Ministry of Health and Family Welfare have been integrated into one under the new NRHM.

The Reproductive RCH II Programme, including RHCS actions, are also integrated into the National Rural Health Mission (NRHM). The NRHM serves to coordinate and improve the integration and coordination of vertical programmes within the SWAp. The executive arm of the NRHM at state level is the Integrated Health Society. The District Health Mission, Village Health & Sanitation Committee, locally elected bodies (the Payanchayati Raj), and various Non-State Actors all have institutionalised roles in the new NRHM system.

The Ministry of Health and Family Welfare has 17 Regional Directors who coordinate with and provide technical support to each of the 35 State Ministries of Health and Family Welfare.

The public health infrastructure includes 145,000 health "Sub-Centres" each covering a population of 5,000 and which form the first level of contact with patients. At the second level there are 23,109 "Primary Health Centres" covering 30,000 people and 3222 "Community Health Centres" each covering a population of 120,000.⁹⁵

India's health system reflects the development diversity of States such as Andhra Pradesh where 65% of birth deliveries are attended by a skilled attendant as compared to Bihar where only 23% were attended⁹⁶

The National Commission on Population (NCP) is charged with promoting inter-sectoral coordination across RH agencies at central and state levels to achieve population policy goals.⁹⁷ The National AIDS Control Organisation (NACO) is the central agency responsible for HIV/AIDS responses with State AIDS Control Societies at state level.

The Central Drug Research Institute is responsible for developing contraceptive agents and devices. Other government agencies important to the RHCS are discussed in the relevant sections.

The coordination mechanism between the NRHM and other government health offices is still being developed. For that reason it is not yet possible to identify the exact roles and interactions that all offices within the health system

⁹⁴ National Commission on Macroeconomics and Health, 2006b.

⁹⁵ National Commission on Macroeconomics and Health, 2006b, p. 1. Please note that, contrary to the implication of its name the "Community Health Centre" is actually the referral centre for 4 Primary Health Centres and provides emergency obstetric care and specialist consultations.

⁹⁶ National Commission on Macroeconomics and Health, 2006a.

⁹⁷ National Commission on Macroeconomics and Health, 2006b.

will eventually attain. Since the system is in a state of flux it is also difficult to determine the influence of the changing situation on the role of existing offices working on RHCS.

The public sector only provides about 20% of health services while the remainder is almost all covered by private services and also by some other non-state agencies.⁹⁸ It is useful to note that, while many Indians are of the opinion that private services are better than public services, there are many unscrupulous health professionals or unqualified "doctors" who provide services. As an example, some private health practitioners provide ample quantities of steroids as a "quick" fix for a wide variety of ailments.⁹⁹ The public is led to believe that these private practitioners offer better services.

4.2.6 Organisational and Management Issues Affecting the Indian Health System

Many problems persist in the Indian health system including poor maintenance of the public health infrastructure, lack of accountability, the unregulated private sector and continued multiplicity of vertical programmes.¹⁰⁰ Despite the intention of the government to integrate vertical health programmes into a holistic system a large number have not yet been integrated.

A recent internal evaluation indicated that the number of sub-centres and capacity of staff within Sub-Centres are inadequate to cover needs. It is also important to note that *serious shortages of equipment and medicines* were identified.¹⁰¹ During the background field study to prepare the present report a recurrent point raised by MOHFW officers was that the lack of human resources had very important negative consequences for RH in general and RHCS in particular. Positions are budgeted but are frequently vacant, sometimes for long periods. Lack of staffing influences health planning and management at central and state level as well as the management of implementation procedures throughout the supply chain.

Only 7% of People Living With HIV AIDS are currently receiving ant-retroviral treatment while the demand is far greater.¹⁰² Demand in 2004 was estimated to be at least 500 000 to 1 000 000 or approximately 25% of PLWHA.¹⁰³

4.3 Reproductive Health Commodities Security System: Demand, Gaps and Equity

4.3.1 Gaps Between Types of Reproductive Health Commodities Demanded and Used

Information on the demand and use of contraceptive RHC are relatively well documented. Information on the demand and use of other RHC proved to be more difficult to obtain.

The use of modern contraceptive methods in India is estimated 42.8% of all women of reproductive age and in union.¹⁰⁴ The unmet demand for contraception by married women between the ages of 15 and 49 is 16%.¹⁰⁵ The

⁹⁸ National Commission on Macroeconomics and Health, 2006b.

⁹⁹ Information obtained from key informants with NGO the Kalakar Trust and other NGOs based in New Delhi.

¹⁰⁰ According to an analysis carried out by the government: National Commission on Macroeconomics and Health, 2006b.

¹⁰¹ National Commission on Macroeconomics and Health, 2006b. Uttar Pradesh, Bihar, Orissa, and Jharkand States.

¹⁰² UNAIDS, 2006.

¹⁰³ AmfAR, 2004.

government Annual Report for 2005-2006 states that the total number of contraceptive acceptors in 2004-2005 decreased by 3.3% over the previous year.

Surprisingly condom demand decreased by 2% although the number of condoms supplied to the states increased by over one third to 515 million pieces for the budget year 2005-2006. About half of all women aged 15-24 (51%) and 59% of men used a condom the last time they had sex with a casual partner.¹⁰⁶ The government does not appear to have considered *actual demand* for condoms when determining the amount to supply. Supply may, however, have been correctly *estimated* in terms of the *actual* need for condoms as a preventive measure for STI and HIV/AIDS transmission.¹⁰⁷ There is no direct link between National AIDS Commission and the family planning agencies for coordination on condoms.

Social Marketing Organisations distributed over 615 million condoms and 406 million (cycles of) contraceptive pills in the year 2004-2005.¹⁰⁸ Social Marketing Organisations distributed an additional 156 million weekly oral contraceptives developed and produced within India.

Demand for oral pills decreased during 2005-2006 by 13% while vasectomies increased by 14%.¹⁰⁹

Copper-T-380-A are being procured and supplied to the States through the National Family Welfare Programme.¹¹⁰

Women who receive ante-natal and post-natal care, and are attended by a trained birth attendant are most likely to use RHC of all kinds. It should be noted that only 20% of the pregnant women in India receive the entire package of ante-natal services recommended by the government.¹¹¹ The package includes three antenatal visits, two doses of tetanus toxoid and iron-folic acid tablets/syrup for three months. The percentage of women receiving antenatal care varies widely throughout the country. Even in the State of Tamil Nadu, which has relatively good indicators, only 50% of pregnant women receive the entire package.¹¹²

4.3.2 National Production of Reproductive Health Commodities

Three brands of condoms are produced by selected companies through the government and 13 brands that are produced by Social Marketing Organisations (SMOs) are sold in the market. Only one brand of contraceptive pill is produced through the government and eight brands by SMOs.¹¹³

There are at least 13 manufacturers of generic ARVs in India, many of which also produce the active ingredients.¹¹⁴ India produces sufficient RHC for all domestic needs and also produces RHC for export to other countries.

¹⁰⁴ United Nations Statistics Division, 2006b. "Contraceptive prevalence refers to the percentage of women of reproductive age, married or in union, currently using contraception, unless otherwise specified. The contraceptive prevalence for modern methods refers to the use of the following methods: female and male sterilization, the contraceptive pill, the intrauterine device (IUD), injectables, implants, female and male condom, cervical cap, diaphragm, spermicidal foams, jelly, cream, sponges and emergency contraception."

¹⁰⁵ World Bank, 2006b.

¹⁰⁶ UNAIDS, 2006.

¹⁰⁷ National Commission on Macroeconomics and Health, 2006b.

¹⁰⁸ National Commission on Macroeconomics and Health, 2006b.

¹⁰⁹ National Commission on Macroeconomics and Health, 2006b.

¹¹⁰ National Commission on Macroeconomics and Health, 2006b. Statistics on quantities were not provided in the report.

¹¹¹ National Commission on Macroeconomics and Health, 2006b.

¹¹² National Commission on Macroeconomics and Health, 2006b.

¹¹³ National Commission on Macroeconomics and Health, 2006b.

¹¹⁴ American Foundation for AIDS Research (AmfAR) (2004).

4.3.3 Availability of Sufficient Choice

The government “National Family Welfare Programme” provides only four methods of contraceptive services: sterilisation, intra-uterine devices, daily oral contraceptive pills, and condoms.¹¹⁵ Other kinds of contraceptive methods are available in the private sector.

4.3.4 Equity and Access to Reproductive Health Commodities

Almost 400 million people (36% of the population) in India live below the poverty line.¹¹⁶ They are spread throughout the country and found in even the comparatively richer states. This population has special health and reproductive health needs, particularly with regards to maternal health, because maternal mortality rates are substantially higher in the poorer areas and states.

AFFORDABILITY

The cost of drugs and medical treatment is a major issue in India where out-of-pocket expenditures represent 97% of the total expenditure on health.¹¹⁷ RHC are supplied free-of-charge through the public health system, however, and at heavily subsidised rates through Social Marketing Organisations. In theory RHC are affordable. Discussion about wastage that appears to occur as a result of the free supply of contraceptives has continued for several years.¹¹⁸

Details about actual costs and expenditures on RHC are not easily available. One study in the state of Karnataka does provide some interesting information. Please note that Karnataka is in the middle range of Indian states on maternal health indicators.¹¹⁹ Nearly two-thirds of all household expenditure on reproductive health in Karnataka was used to pay for medical treatment, drugs and contraceptive commodities.¹²⁰ The study found that the average household spent Rs. 1,200 (USD 28), which is approximately 4% of the average household income and consumption indices.

Drug price regulation is carried out by the Ministry of Petrochemicals and Pesticides but only covers a very limited number of drugs considered to be life saving.

Affordability is also influenced by corruption in the health system. A household survey by Transparency International indicated that a quarter of 5000 respondents admitted that they had had paid bribes for health care services.¹²¹ Transparency International (2002) also reported, for example, that in one study in Bangalore 61% of women in maternity wards had to pay for medicines that were supposed to be free. Medicines and equipment can also be diverted from public to private clinics by physicians serving in the public sector who are allowed to work in private practice. This also means that studies of the distribution and consumption of medicines in the public and private sector need to take such possible diversions into account.

¹¹⁵ National Commission on Macroeconomics and Health (2006b).p. 1. Please note that, contrary to the implication of its name the “Community Health Centre” is actually the referral the referral centre for 4 Primary Health Centres and provides emergency obstetric care and specialist consultations.

¹¹⁶ World Bank, 2005.

¹¹⁷ World Bank, 2006b.

¹¹⁸ National Commission on Macroeconomics and Health, 2006b.

¹¹⁹ UNICEF, 2006.

¹²⁰ UNFPA/UNAIDS/NIDI, (2006).

¹²¹ Kumar, 2003

PHYSICAL FACTORS AFFECTING EQUITY AND ACCESS

In India 71% of the population lives in rural areas so ensuring that rural areas are well covered with warehouses for stocking commodities and RHC distribution locations is essential.¹²² The number of clinics at the community level (sub-sector centres) is still insufficient in some rural areas and many are understaffed.¹²³ Out of almost 30,000 rural health posts for doctors, over 4000 remain unfilled and about 40% absenteeism has been estimated among doctors and other health care workers.¹²⁴ India has only one doctor trained on HIV/AIDS and its treatment for every estimated 10,000 PLWHA.¹²⁵

SOCIAL FACTORS AFFECTING EQUITY AND ACCESS

One limiting factor, especially for the lowest income groups, is the stigmatisation associated with the use of RH commodities such as condoms. Demand creation for contraception remains a major challenge in general. Special conditions need to be created so that potential users can discretely access such products. Women's empowerment is a major issue affecting the use of RHC. Both husbands and mothers-in-law play a major role in managing a woman's fertility. Membership in low status groups such as the "scheduled tribes" and "scheduled castes" (Dalits) also play a role in the level of access and use of RHC and other health commodities and services.¹²⁶

4.4 Forecasting, Procurement and Distribution Arrangements

4.4.1 The Role of Government

The Medical Supply Organisation (MSO) is in charge of supplying reproductive health commodities to implement the national RHC II programme. The MSO is supported by the Procurement Supply Agencies and 7 specialised regional Government Medical Storage Depots located throughout the country.

FORECASTING

The government defines the estimated needs for RHC at the central level but states are free to adjust and adapt this list to their own needs. Demand is estimated in the states which submit their list of needs to the Ministry of Health and Family Welfare. Each state prepares a forecasting action plan using government specified procedures. State program officers for the different health programmes assess needs on a bi-annual basis using evidence from the National Health Information Systems (NHIS) and an analysis of health facilities' passbooks.

In Tamil Nadu, for example, the estimated needs list is prepared with a coordination committee of technical personalities from the Tamil Nadu MOHFW with assistance from health and pharmacy educational institutions. The

¹²² United Nations Statistics Division, 2006e. Rural urban migration is a net of 1% annually.

¹²³ National Commission on Macroeconomics and Health, 2006b.

¹²⁴ Willbond *et al.* 2001 in National Commission on Macroeconomics and Health, 2006a.

¹²⁵ American Foundation for AIDS Research (AmFAR) (2004).

¹²⁶ National Commission on Macroeconomics and Health, 2006a.

drugs to be used in the health system are clearly marked on the list, including the basic RHC approved by the central government

The forecasted needs are forwarded to the central Ministry of Health and Family Welfare where they are compiled by the Medical Supply Organisation.

PROCUREMENT METHODS OF REPRODUCTIVE HEALTH COMMODITIES

The government publishes advertised tender inquiries and provides limited direct tender inquiries to firms for concluding rate contracts.¹²⁷ The National AIDS Control Organisation (NACO) also publishes tenders on its website for diagnostic kits (which are included under the definition of RHC used for the current study and parallel DFID studies).¹²⁸

Supply orders are placed by the Procurement Supply Agencies upon comparison of competitive prices and manufacturing capacity. Tenders are valid for two years at a time.

The National AIDS Control Organisation (NACO) is responsible for assisting all the Sexually Transmitted Diseases Clinics at District level with laboratory equipment and STI drug kits including for diagnosis. NACO publishes the technical specifications for the approved diagnostic kits on their website.¹²⁹

The majority of procurement for RHC in both the public and private sectors is from domestic sources.

QUALITY CONTROL OF REPRODUCTIVE HEALTH COMMODITIES

A survey conducted in 2002 indicated that 9% of the drugs in the Indian market were substandard and 0.3% inactive.¹³⁰ See also Section 4.5 for details on regulations.

Quality is tested at the time of acceptance of batches of drugs and equipment and a second testing may also be carried out after delivery. Regional Directors of the Ministry of Health and Family Welfare are also responsible for tests during the shelf life of the commodities which are carried out in government approved laboratories.

The Central Indian Pharmacopoeia Laboratory is specifically charged with the testing of *condoms* among other tasks.¹³¹ The National Centre for testing of *IUDs* and *Tubal Rings* provides training to testing laboratories and also on good manufacturing procedures for industries manufacturing contraceptives.

The Good Manufacturing Practices certification has been strengthened to help decrease the manufacture of spurious drugs. The Schedule M amendment of the Drugs & Cosmetics Rules 1945 lays down revised requirements for Good Manufacturing Practices. The amendment includes emphasis on plant maintenance and the quality of equipment used to manufacture drugs.

¹²⁷ National Commission on Macroeconomics and Health, 2006b.

¹²⁸ See the Definitions Section. <http://www.nacoonline.org/tendernotices.htm>

¹²⁹ <http://www.nacoonline.org/guidelines/Test-Kits.htm>

¹³⁰ Pincock, 2003.

¹³¹ National Commission on Macroeconomics and Health, 2006b.

Medical devices are tested for quality by the Bureau of Indian Standard Specification (ISS) which has also produced booklets on standards. In Tamil Nadu, for example, samples of medical devices are tested by a panel of clinical experts before being selected. It should be noted, however, that the tenders do not include specific requirements for compliance with pre-defined standards or technical specifications. Including specifications and standards explicitly in the tenders would help in the quality control of the proposed devices.

It has to be stressed that the tenders are judged primarily on price and manufacturing capacity. This approach does not create an appropriate environment for continuous quality improvement of drugs by manufacturers.

The report of the Expert Committee on "A comprehensive examination of drug regulatory issues, including the problem of spurious drugs" commissioned by the Ministry of Health and Family Welfare (2003) identified several key problems. Areas of concern include inadequate testing facilities, shortage of drug inspectors, non-uniformity of enforcement, lack of specially trained cadres for specific regulatory areas, non-existence of data bank and non-availability of accurate information.

The report noted that in 31 states and territories only 17 drug-testing laboratories were found to be operating and of these only 7 were reasonably equipped and staffed.

DISTRIBUTION METHODS OF RH COMMODITIES (AND AS COMPARED TO OTHER ESSENTIAL MEDICINES)

(Central, State, local health facilities; stock management)

The Government distributes RHC through a multi-tiered public health system of sub-centres, primary health care centres, and community health centres as well as government hospitals. Various systems exist to distribute contraceptives, particularly oral pills and condoms, through other systems such as through Social Marketing Organisations and related mechanisms. Condom vending machines have, for example, been installed in over 11,000 locations in 68 high HIV/AIDS prevalence districts around the country.¹³²

Community based volunteers function as depot holders for contraceptives in all states through The Accredited Social Health Activist (ASHA) program. The volunteers are selected by community leaders who are members of the local Panchayat (a body of local elected leaders). The volunteers are supplied with a basic drugs kit, contraceptive supplies and RH IEC materials.

RHC are issued from the seven Government sector Medical Stores located throughout the country to the State Medical Stores. States may decide whether to supplement their allocations from the national level. The Government Medical Storage depots are supported and maintained by the Medical Supply Organisation. All RHC are supplied through this system with the exception of HIV diagnostic tests and Anti Retroviral Therapies (ART), which are managed by the National and State AIDS Control Societies

The private commercial sector is not subsidised by the government and has increased its share in selling condoms and pills slightly, reaching 14% of the pills sold/distributed in India and close to 15% in the condom share of the market.¹³³ The sale of RHC through the private commercial sector is limited in areas with low income per capita.

¹³² National Commission on Macroeconomics and Health, 2006b.

¹³³ UNFPA, 2001.

DRUG MANAGEMENT INFORMATION SYSTEM

UNFPA considers that the Drug Management Information System is generally poor at the state level with the exception of some locations such as in Tamil Nadu.¹³⁴ The Tamil Nadu model can be considered a good practice to scale up to other states. All health offices in Tamil Nadu have a Health Management Information System that tracks services provided and drugs used.

4.4.2 Overview of a Case Study of Tamil Nadu

The consultant team visited the State of Tamil Nadu, which is often cited as a model to be followed by other states, to learn lessons on RHCS that can be applied to the other states. India, given its diversity, does not have a single state that can be said to be representative of India as a whole. The experience of Tamil Nadu does, nevertheless, provide indications of general directions that can be followed by other states in India.

Tamil Nadu has two systems that manage drug and supplies for the State. One system is through the Government Medical Store (GMS) while the other is through the Tamil Nadu Medical Services Corporation Limited (TNMSC). The consultant team observed that the TNMSC to be well functioning and able to ensure better RHCS than the Government Medical Store system. Infant mortality in Tamil Nadu is 44 per 1000 and deliveries in health institutions and by trained staff account for 99.6% of all the deliveries.¹³⁵

Although the consultant team found that RHCS is relatively well assured in Tamil Nadu, some important difficulties were still identified. Problem areas include the fact that there are two parallel systems which do not have the same level of quality of service and poor storage of commodities.

THE GOVERNMENT MEDICAL STORE AT CHENNAI

The Government Medical Store located in Chennai provides drugs and equipment to the states of Tamil Nadu, Karnataka and Kerala representing a population of about 150 million.

The Government Medical Store specialises in vaccines and also distributes several RH drugs and medical devices, including copper T IUD, condoms and the Pill, but not oxytocine, antibiotics or HIV tests at the present time. It has 18 pharmacists.

The Government Medical Store has a small quality control laboratory that performs physical and chemical tests on samples sent by the Medical Supply Organisation. The Government Medical Store sends monthly stock statements to the Medical Supply Organisation and receives supplies from manufacturers.

Health facilities send their orders to the State Medical Organisation on a quarterly basis which forwards the order to the Government Medical Store. The Government Medical Store then subcontracts the transport to transport companies which deliver the orders to the facilities.

¹³⁴ Interview with UNFPA staff during field mission.

¹³⁵ Health and Family Welfare Department: Policy Note - 2005 – 2006

Some health facilities collect their medicines from district warehouses. Emergency deliveries can be delivered to the sub-centres from the primary health care centres within 24 hours.

THE TAMIL NADU MEDICAL SERVICES CORPORATION LIMITED (TNMSC)

The Tamil Nadu Medical Services Corporation Limited (TNMSC) is one of the 12 directorates and corporations of the Ministry of Health and Family Welfare that was created to centralize the procurement of drugs. The aim of the TNMSC is to improve the quality as well as the cost of state supplied drugs and to prevent corruption in the supply system. The tasks of the TNMSC include the confirmation of forecasts; checking of tenders, contracts and orders; forwarding drug samples for testing and taking coercive action if necessary; paying suppliers; storing and distributing drugs. The TNMSC has its headquarters in Chennai and has 24 warehouses throughout the state.

The TNMSC supplies 11,059 facilities including health facilities such as medical teaching institutions, district headquarter hospitals, primary health centres, national institutions such as all police medical facilities, juvenile homes, prison medical facilities, co-operative sugar factories, veterinary institutions, etc.

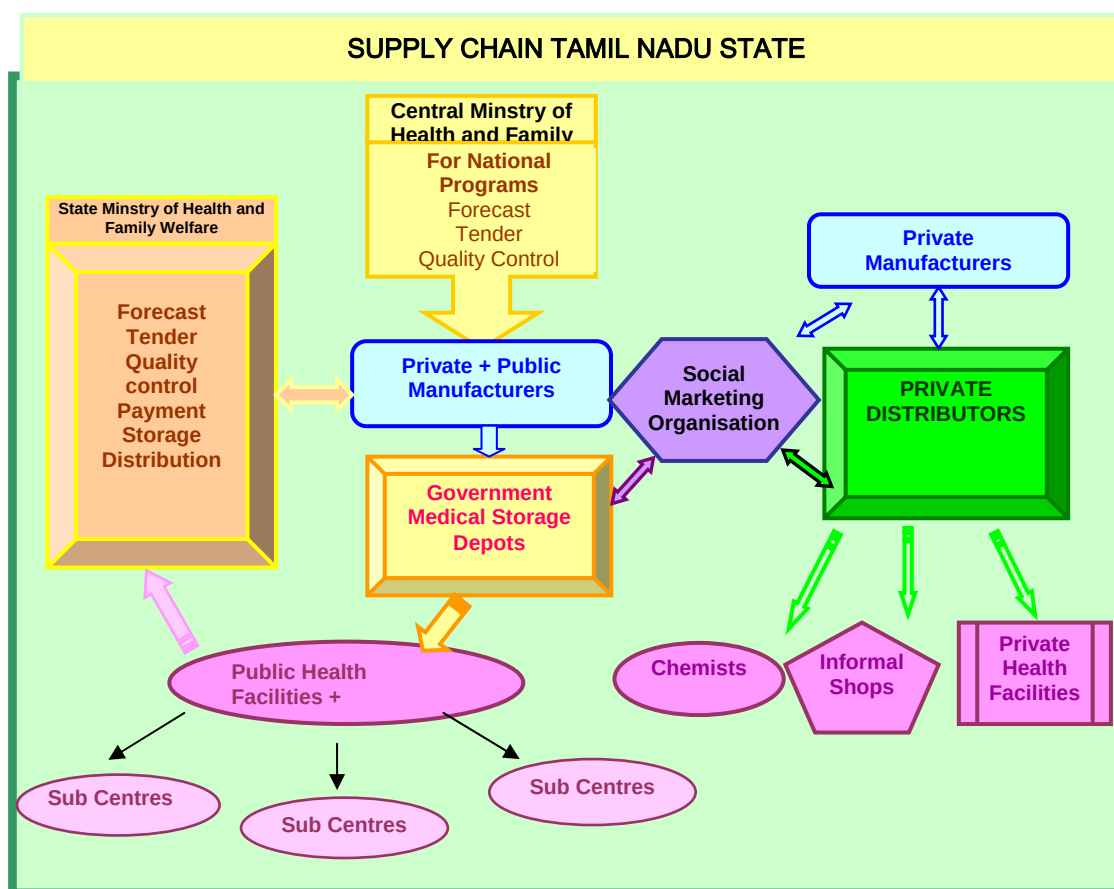
The TNMSC Drug Committee collects the forecasted needs for drugs, including RHC, from the health facilities and makes yearly forecasts based on past consumption levels.

The national open tender is decided by the TNMSC headquarters and is valid for one year at a time. The TNMSC inspects the manufacturing premises of new bidders and experts evaluate drugs and surgical/suture samples before deciding on bids.

Orders are sent from the headquarters and the goods are sent directly to the warehouses. The contract delivery time is 60 days. Quality control on selected samples is also carried out after delivery.

The TNMSC has an online tracking system that allows suppliers to follow the state of their deliveries directly thus removing any possibility of corruption.

Figure 1
Tamil Nadu Case Study Sample of Distribution Network



4.4.3 Role of Non-State Providers

ROLE OF THE PRIVATE COMMERCIAL SECTOR IN MANUFACTURING, PROCUREMENT, SUPPLY INFRASTRUCTURE AND SERVICE DELIVERY

The private for profit health commodities sector has grown very fast and is now believed to be a potential market of more than US\$ 1 billion a year.¹³⁶ The rapid growth is the result of extensive support and laws facilitating the development of this sector. In states such as Kerala, the private sector is estimated to be able to provide as much as 70% of all RH services but in others this value is less than 30%.¹³⁷

There are many drug distributors in the country that deal directly with private health facilities and private pharmacies that sell RHC including male condoms and contraceptive pills. Private health facilities and pharmacies sell primarily to the more affluent strata of society that have the power to pay market prices for RHC.

¹³⁶ Based on interviews with during field mission.

¹³⁷ Based on interviews with during field mission.

NON-GOVERNMENTAL AND SOCIAL MARKETING SECTOR IN INDIA

The government has developed other distribution mechanisms jointly with social marketing organisations and the private sector. A social marketing programme for the sale of subsidized condoms was initiated in 1968 and for oral contraceptive pills in 1987.¹³⁸ Subsidies to Social Marketing Organisations range from 70-85% depending on procurement prices in a given year.¹³⁹ The Government has a specific Social Marketing policy and strategy.

Social Marketing Organisations participate in the supply chain for specific RH products such as pills and condoms. The SMOs sell their products through late-night informal shops in urban areas and other small shops in rural areas. They do not use private pharmacies. SMOs buy their own brands from selected manufacturers at a rate contracted through the Medical Supply Organisation. Storage for SMOs is subcontracted. SMOs sell to selected distributors chosen because of their sales network and good financial health.

SMO distributors stock the products and work at around a 20% margin. The distributors sell the products to the chemists and small shops and provide many incentives (free gifts, posters, stickers, etc.). Retail prices for products marketed through SMOs are very similar to each other. The social marketing organisations are very dependent on donors such as Mary Stopes International, the Bill Gates Foundation and USAID.

Fifteen SMOs are formally listed by the government to provide social marketing services. One of the producers of RH commodities (Hindustan Latex) has a specific department which is an SMO. The three most prominent SMOs are Population Services International (India); Janini (DTK international) and Population Health Services (a Marie Stopes International organisation). Some of the SMOs have their own clinics and carry out STI/HIV control interventions.

The current trend in SMO intervention is extended to Social Franchising which includes the provision of essential health services. The most common services are in family planning at community level and in health clinics through private franchised providers.

4.5 National Legal and Regulatory Issues

The quality control of drugs marketed in India is regulated by the Drugs and Cosmetics Act (1940) and the Drugs and Cosmetics Rules (1945).¹⁴⁰ The Pharmacy Act 1948 and the Drugs & Magic Remedies (Objectionable Advertisements) Act 1954 are also important. Implementation of the laws and regulations, safety, efficacy, import, manufacture, distribution and sale are the responsibility of agencies at the central and state levels.

The Central Drugs Standard Control Organisation (CDSCO) and the Drug Control Organisations in the states carry out these important obligations. Four zonal offices and seven port offices are also managed by the CDSO. The port offices carry the responsibility of ensuring the quality of imports. The zonal offices inspect drug manufacturing units and drug testing laboratories. Most testing is carried out in private laboratories.

¹³⁸ National Commission on Macroeconomics and Health, 2006b.

¹³⁹ National Commission on Macroeconomics and Health, 2006b.

¹⁴⁰ National Commission on Macroeconomics and Health, 2006b. p.162.

The CDSO carries the prime responsibility for the approval of new drugs to be imported and manufactured, lays down standards and regulatory measures and acts as the Central License Approving Authority.

A special committee, the Mashelkar Committee, is charged with studying and making recommendations to improve the drug regulatory structure and the problem of spurious and sub-standard drugs.

State governments are responsible through the State Drugs Controller for:

- licensing manufacturing establishments and sales premises;
- carrying out inspections of licensed premises;
- drawing samples for tests and monitoring the quality of drugs and cosmetics;
- taking actions such as the suspension/cancellation of licenses;
- instituting legal action, wherever needed, as provided in the Drugs and Cosmetics Act and Drugs and Cosmetics Rules;
- monitoring objectionable advertisements pertaining to drugs.

The central government is preparing to create a more efficient drug controlling agency like the U.S. Food and Drug Administration. The Ministry of Health and Family Welfare is reinforcing its central capacity towards that end with the support of DFID. The new agency is expected to help the government change their approach from a strictly administrative/bureaucratic to a more technically-oriented approach to commodities logistics.

4.5.1 Regulatory and Market Authorization Requirements for Drugs, Diagnostics and Devices

Under the Licensing Procedures, a drug can be manufactured only under a manufacturing license issued in prescribed forms by the Licensing Authorities.¹⁴¹

All new drugs to be imported are submitted to an examination and clinical testing by the Central Drugs Standard Control Organisation in India before approval for marketing. The Central Drugs Laboratory has four units and is charged with testing new drugs for manufacture or importation.

4.5.2 National List of Essential Medicines and RH Drugs on the List

The only items not on the national list that do appear on the list RHC cited in the Acronym/Definition Section is misoprostol.¹⁴² The central government publishes extensive lists of services, equipment, drugs and personnel that are needed at each level of the health system.¹⁴³

4.6 Key Issues for Recommendations

The situation in India with respect to RHCS is quite different from many other developing countries. It is not highly dependent on outside resources to cover its RHC needs and has already met the first two objectives to be

¹⁴¹ Partners in Population and Development and Ministry of Health and Family Welfare, Government of Republic of India, 2005, p. 7.

¹⁴² Directorate General of Health Services, 2003.

¹⁴³ National Commission on Macroeconomics and Health, 2006a

addressed in the current study. It has already developed the mechanisms internally to move from a situation of filling national RH commodity shortfalls using international support on *ad hoc* basis to a situation where sustainable and sufficient supplies of key reproductive health commodities are available at the country level. India has also developed mechanisms whereby future action on reproductive health commodity security can move away from simple tracking/monitoring of commodity availability and providing funding on request and mechanisms whereby all partners can work together to address RHCS issues. It should be noted, however, that there are wide disparities within the country that need to be addressed to achieve reproductive health commodities security.

Because India has a federal system with very wide disparities in terms of RHCS it is necessary to consider these differences in any analysis of the RHC supply chain. It is impossible to make adequate recommendations that will address the situation of RHCS in the country as a whole without detailed studies of supply chains and the implementation of policies, laws and regulation in *each state*. Lessons learned in states that are more able to provide RHCS can be applied to states with difficulties in this area.

4.6.1 Policy Recommendations

- (1) Promote the development of RH policies with specific subcomponents on RHC in each Indian State.
- (2) Promote that national and state policies and regulations include explicit detail on accepted procurement and tendering procedures so that transparency can be improved.
- (3) During coordination meetings donors, participating agencies, and civil society can continue to ensure that adequate attention is paid to increasing funding in accordance with estimated requirements. Policies on public funding for commodities are currently adequate to cover current utilisation levels but future needs may far outstrip funding if present trends continue. Good reproductive health coverage—especially of the very poor who cannot afford or access private health services—will require the establishment of more clinics and consequently more utilisation of RHC. Increased levels of HIV will also require increased funding to treat both opportunistic illnesses and antiretrovirals to fight HIV/AIDS.

4.6.2 Gaps in Procurement Systems, Financing, and Distribution Systems

India needs to ensure that domestic quality is maintained and counterfeiting is addressed in the public as well as the private/social marketing sectors.

- (1) Studies of the distribution and consumption of medicines in the public and private sector need to take possible public to private sector drug diversions into account. Medicines and diagnostic materials that are diverted from public to private clinics may negatively influence forecasting, for example. Such diversions also influence equitable access and add to general problems of transparency.

FORECASTING

- (2) A study is recommended of the advantages and disadvantages of a centralised system of forecasting and tendering of essential RHC because it could permit:
- economies of scale at procurement;
 - a uniform quality of drugs for the whole country;
 - an optimized management of the drugs information system.

PROCUREMENT

- (3) A study to integrate parallel public procurement and supply chain processes for health commodities to attain economies of scale and avoid inefficiencies can be useful.

TENDERING

- (4) Tendering needs to also focus more strongly on quality as opposed to judging primarily based on price and manufacturing capacity. Tenders should include specifications and standards explicitly for all RHC. Current approaches that focus heavily on price and manufacturing capacity do not create an appropriate environment for continuous quality improvement of drugs by manufacturers.
- (5) Tendering through on-line procedures should be encouraged since it improves transparency.

CAPACITY STRENGTHENING

- (1) Weaknesses in management systems and poor health professional and administrative skills need to be identified and addressed at all levels.
- (2) Increases in the number of human resources at all levels of the supply chain need to be addressed in policies and planning.
- (3) The number of staff and number of clinics in some rural areas needs to be increased. Inadequate delivery of RHC at the individual level can have negative repercussions all the way up the supply chain and should be addressed. Inadequate staffing also interferes with good forecasting of RHC at the community level. The low number of doctors trained on HIV/AIDS likewise has a negative impact on adequate treatment of opportunistic infections and provision of antiretrovirals.
- (4) Health Information Systems need to be strengthened carefully and based on actual field information as much as possible. Demand and actual requirements need to be brought in line to avoid problems such as the excess stock of condoms or lack of oral contraceptives in some areas.
- (5) The Drug Management Information Systems at state level need to be assessed and improved wherever problems are identified during such assessments.

QUALITY CONTROL

- (1) Specific areas of concern to improve drug quality need to be addressed such as improvement in the adequacy of testing facilities, increasing the number of drug inspectors, improving uniformity of enforcement, increasing the number of trained cadres for specific regulatory areas and creating a drugs data bank.

DISTRIBUTION

- (1) The existence of several government sponsored general drug distribution systems in some states such as Tamil Nadu also needs to be reviewed. The existence of these two parallel systems may not necessarily optimise functioning. At a minimum the two systems should coordinate closely with each other or share common tasks.
- (2) Online tracking distribution tracking systems such as used in Tamil Nadu should be encouraged . Such tracking systems allow suppliers to follow the state of their deliveries directly thus contributing to removing possibility of corruption.
- (3) Ensuring adequate RHCS at the personal level means addressing issues such as the stigmatisation associated with the use of RH commodities such as condoms.
- (4) The approach of using community health practitioners as active agents that even provide some diagnostic tests and supply over the counter drugs should be promoted and extended to more areas to allow for greater access to RH services including commodities.
- (5) It is important to broaden the range of reproductive health commodities, particularly contraceptives, to increase the availability of choice because currently some types of RHC are not included in the National Family Welfare Programme, particularly with regard to family planning. As stated in Section 4.3.3. the choice offered through the public health system is limited to four types of contraceptive methods: sterilisation, intra-uterine devices, daily oral contraceptive pills, and condoms.
- (6) An innovation/challenge fund for private sector partnership initiatives should be developed.

4.6.3 Impact of the Wider Reform Environment on RHCS Systems Developments

- (1) It is important to emphasize that RHCS is now mainstreamed into the national health system and few specific donor projects on RHCS are supported. This means that specific donor support for RHCS cannot be quantified. Donors should be encouraged to perform regular assessments of the RHCS situation so they can provide good technical support and input in coordination and other meetings.
- (2) Decentralisation processes down to the local level should be promoted. Such decentralisation helps to ensure that reproductive health services, including RHC, are accessible to the district and communities. Decentralisation needs to be associated with capacity building and close supportive monitoring and supervision.

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- (3) Close links between state SWAp mechanisms and state reproductive health, and specifically RHC policies and strategies need to be established in all relevant states.
 - (4) Donors can provide support to develop improved systems for linking the new National Rural Health Mission (NRHM) and all other government agencies within the health system.

5 SUMMARY OF CASE STUDY ON REPRODUCTIVE HEALTH COMMODITY SECURITY IN MOZAMBIQUE



5.1 Country Overview

Mozambique has a population 20,158,000 with an annual population growth of 2%.¹⁴⁴ Life expectancy for men is 41 years and for women 43 years.¹⁴⁵ Per Capita Gross National Income is US \$1,270.¹⁴⁶ The percentage of the population living below the poverty line is 69% and 78% live on less than \$2 per day.¹⁴⁷ The Mozambique Human Development Index is very low at 0.390, which gives Mozambique a rank of 168th out of 177 countries.¹⁴⁸

The total life time fertility per woman is currently estimated at 5.5 children.¹⁴⁹

The adolescent fertility rate is 104 per 1000 births.¹⁵⁰

The country suffered a devastating civil war until the beginning of the 1990s which had a strong impact on the economy. Draught and flooding in certain areas of the country in 2000, associated with a dramatic shortage of food, contributed to increase poverty.

¹⁴⁴ United Nations Statistics Division, 2006d.

¹⁴⁵ United Nations Statistics Division, 2006c.

¹⁴⁶ At purchasing power parity. World Bank, 2005.

¹⁴⁷ At purchasing power parity. World Bank, 2005.

¹⁴⁸ UNDP 2006.

¹⁴⁹ United Nations Statistics Division, 2006a.

¹⁵⁰ United Nations Statistics Division, 2006a.

5.1.1 Health Situation/Burden of disease

The Mozambican burden of disease is typical of low-income countries and is overwhelmingly composed of infectious diseases such as acute respiratory diseases, acute intestinal illnesses, malaria, HIV/AIDS and tuberculosis. High maternal, infant and child mortality rates are also principal causes of mortality and morbidity. Mozambique has suffered from cholera epidemics in recent years.

Maternal mortality is estimated at over 1000 per 100,000 live births.¹⁵¹ The main causes of maternal mortality are haemorrhage, puerperal sepsis, uterine rupture and eclampsia. Infant mortality is an important figure that is considered to be at least partially related to the reproductive health of the mother. The infant mortality rate in Mozambique is 101 per 1000 live births.¹⁵²

HIV/AIDS prevalence is very high at 16% of adults aged 15-49 years.¹⁵³ A total of 1.8 million adults are living with the virus. An additional 140,000 children are also living with HIV/AIDS. The highest and most-steeply rising HIV prevalence levels are found in Mozambique's central and southern provinces.¹⁵⁴

5.2 The National Reproductive Health System: Policies, Partners and Structures

The Health Sector Strategic Plan (PESS – Plano Estratégico do Sector da Saúde) is aimed at developing reforms and activities to achieve efficiency, transparency, accountability, equity, flexibility, diversification, partnership, community participation, integration and coordination. The PESS is integrated in the poverty reduction program PARPA (Plano de Acção para a Redução da Pobreza Absoluta).

There is no national reproductive health policy in the broad sense. Important aspects of reproductive health are, however, integrated into the Maternal Mortality Reduction strategy. The Maternal Mortality strategy is a comprehensive integrated approach which includes sexual reproductive health, family planning, and safe motherhood interventions.

Mozambique has not had a formal National Drug Policy for many years. Reportedly the government has now developed a comprehensive drug policy draft, which is expected to be approved in the near future.

In September 2006 an African Union meeting of health ministers agreed upon a Plan of Action for the Operationalisation of the Continental Policy Framework for Sexual and Reproductive Health and Rights 2007-2010.¹⁵⁵ Mozambique is one of the countries that adopted the action plan and as such it is considered as integrated into the national policy framework. The plan includes special attention to strengthening RHCS with emphasis on family planning and emergency obstetric care and referral. Improving the security of antiretrovirals also receives special attention in the plan.

¹⁵¹ United Nations Statistics Division, 2006a.

¹⁵² United Nations Statistics Division, 2006c.

¹⁵³ UNAIDS, 2006.

¹⁵⁴ UNAIDS, 2005.

¹⁵⁵ African Union, 2006.

Box 2

Sexual and Reproductive Health Commodity Security Strategies

Sexual and Reproductive Health Commodity Security Strategies (As included in the Plan of Action for the Operationalisation of the Continental Policy Framework for Sexual and Reproductive Health and Rights 2007-2010)	
Advocacy	Develop national/regional strategies and action plans for forecasting, procurement and distribution of RH commodities.
	Establish a national and/or regional RHCS committee.
	Develop national and where appropriate regional RHCS strategy and action plans.
	Revise essential medicines lists to include reproductive health commodities.
	Establish a budget line for SRH commodities.
Capacity building	Develop and implement logistics management system (LMS) for RHCS.
	Train relevant staff in logistics management system for RHCS.
	Establish effective commodity management system for the full range of commodities.
	Develop capacity for bulk purchasing through pooling of purchase orders at national and regional levels.
	Provide training in commodity management.

Figure adapted from the African Union 2006 Plan of Action p. 17.

Mozambique was also signatory to the Delhi Declaration on Maternal, Newborn and Child Health.¹⁵⁶ The Declaration emphasizes several points of importance to RHCS and includes a specific mention of the necessity to address the issue of RHCS (see last point listed here):

- Build systems for the collection and use of high-quality data to inform policy and programmes.
- Invest in strengthening health systems to ensure sustained and long-term improvements in reproductive, maternal, newborn and child health.
- Incorporate specific strategies to address inequities in reproductive, maternal, newborn and child health.
- Build effective partnerships comprising governments, development partners, donors, civil society, the private sector, professional associations and academia.
- Develop urgently, integrated national plans with *national targets for coverage, outcomes and resource allocations*, with active participation of all stakeholders.
- Plans of action need to include methods to achieve such coverage, meet shortages of skilled health personnel and *commodities*, and devise mechanisms to involve all partners.

5.2.1 Government Expenditures on Health

Government Expenditures on health are 3% of GDP.¹⁵⁷ General government expenditure on health as percentage of total government expenditure is 11%.¹⁵⁸ Private expenditure on health as percentage of total expenditure on

¹⁵⁶ Meeting of Health Ministers and agreement dated April 9, 2005.

¹⁵⁷ World Bank, 2006b.

health is 38%.¹⁵⁹ This means that out of pocket spending by individuals is quite high in a country with high rates of poverty.

The value of pharmaceutical products managed through the Ministry of Health was estimated at 40 million US \$ in 2004.¹⁶⁰ Funds from donors for medicine and medical supplies managed by the public system was estimated at US \$30 million. Turnover of pharmaceutical products in the private sector was approximately US \$ 15-20 million.

The government does not have a specific budget for reproductive health. To gain understanding of RHC financing it is necessary to analyse the global financing of the health system. Health financing is carried out through three principal mechanisms: through the state budget, the common funds and vertical funds. The health sector is mostly financed through the Common Fund of Support for the Health Sector (PROSAUDE), the Provincial Common Fund (FCP) and the Common Fund for Drugs and Medical Supplies (FCMSM).

PROSAUDE (created in November 2003) is a multi-donor pooled funding mechanism in support of the Health Sector Strategic Plan. The FCP (created in May 2004) is a joint mechanism that combines funding from some bilateral agencies led by Switzerland to finance current costs in the health sector in the provinces. Provincial departments are responsible for planning, budgeting and allocating the FCP funds according to the criteria defined in the integrated financial planning framework approved by the Ministry of Health.

The FCMSM (created in 2004) is a multi-donor pool that supports the central procurement and supply of drugs and medical supplies. The resources must be allocated in accordance with the objectives of the country's strategic health plan (Plano Estratégico do Sector da Saúde, PESS). The management of the FCMSM is carried out through an approved plan and budget by the Drugs and Medical Supplies Centre (CMAM), a department within the Ministry of Health.

An evaluation of the government budget systems carried out for the Department for International Development (DFID) drew some critical conclusions with important consequences for issues such as RHCS.¹⁶¹ There are significant weaknesses in budget formulation and implementation. Planning and resource allocation within the executive are highly dispersed, mainly due to the diversity of funding sources. There is a plurality of partially overlapping budget systems. Few civil society organizations have the technical capacity to analyze budget issues and cannot contribute effectively to the planning process.

The SWAp in health is, however, contributing to some useful results despite lingering inadequacies.¹⁶² Some of the indications that the SWAp is yielding some positive outcomes include improvements in the quality of yearly health plans which is important for RHCS.

The management capacity of programmes financed through the common funding pools need strengthening. Actual spending is far below budgeted spending. It is also important to note that information on actual spending in the provinces is often inaccurate because of poor data systems. Obtaining reliable spending data is complicated by the diversity of local funding sources. In many cases provincial off-budget income is not reported to central government departments.

¹⁵⁸ WHO, 2006b.

¹⁵⁹ WHO, 2006b.

¹⁶⁰ Information provided to the consultant team that carried out the background study in Mozambique for the present report.

¹⁶¹ Hodges, T & Tibana, R., 2004.

¹⁶² DFID, 2006.

The approved budget for the health sector provides only a very rough guide to what is actually spent as indicated by the low execution of expenditures from the funds provided by different donors in 2004.¹⁶³

Table 1
Donations Received and Actual Expenditure

Fund	Donations Received	Expenditures	Balance	Estimated percentage of Execution
PROSAUDE	46,842,940 USD	22,971,463 USD	23,871,477 USD	49
FCP	13,791,902 USD	11,144,622 USD	2,647,280 USD	81
FCMSM	33,576,036 CHF	20,591,795 CHF	12,984,241 CHF	61

Information collected by consultants during field mission.

5.2.2 Principal Donors and Agencies Promoting Reproductive Health Commodity Security

External resources account for 41 % of all expenditures on health.¹⁶⁴ In 2006 external assistance on population related projects was over US\$ 58.5 million. Projected donor disbursements for 2007 will increase to almost 70 million US \$.¹⁶⁵ The EC is the largest donor after the World Bank and the U.S.¹⁶⁶

In large sectors, such as health, much donor assistance is off-budget and often outweighs the resources made available through the State Budget.¹⁶⁷ Programme aid (general and sector budget support) is substantial but is still less than half of total aid. The identification and management of resources is complicated even within line ministries.¹⁶⁸ Power over resources is dispersed because donor funding of projects is managed by different directorates and departments.

Most agencies have aligned themselves with government development strategy frameworks. The United Nations Development Framework (UNDAF) priorities have, for example, been fully aligned with Mozambique's poverty reduction strategies.¹⁶⁹ At the same time, UNDAF carried out dialogue with all the stakeholders to advocate for UN concerns and national targets towards the attainment of the millennium development goals.¹⁷⁰ Such processes indicate that, despite the high continued dependence on donor assistance, development efforts and decision-making are now seen as increasingly the responsibility of the Mozambican government and Mozambican stakeholders.

DFID funded a project to assist the Mozambican government to move to a well coordinated and well targeted SWAp system and also supports the move towards general budget support.¹⁷¹

¹⁶³ Information provided by interviewees during field mission to Mozambique.

¹⁶⁴ World Bank, 2006b.

¹⁶⁵ Overseas Development Assistance to Mozambique Data Base, 2006.

¹⁶⁶ DFID, 2006.

¹⁶⁷ Definition of the term "off budget": "A large proportion of resources and expenditure is not recorded in the approved or in the government accounts." Hodges, T & Tibana, R., 2004.

¹⁶⁸ Definition of the term "off budget": "A large proportion of resources and expenditure is not recorded in the approved or in the government accounts." Hodges, T & Tibana, R., 2004.

¹⁶⁹ Resident Coordinator Mozambique, 2005a and 2005b.

¹⁷⁰ Resident Coordinator Mozambique, 2005.

¹⁷¹ DFID, 2006.

The Mozambican government and donors are moving towards generalised budget support instead of SWAp programmes. The aim of general budget support is to assist governments to implement crosscutting reforms, improve the effectiveness of government processes and service delivery.¹⁷²

Mozambique has over 25 projects that focus on reproductive health related issues such as family planning, maternal health, and HIV/AIDS.¹⁷³ The principal donor countries and agencies working in this sector are Austria, Canada, France, Ireland, Italy, the Netherlands, Norway, Sweden, the United States and the United Kingdom. Multilateral agencies are the EC, UNDP, WHO, and the World Bank. There is no project that addresses RHCS as a vertical project but RHCS is a component in several of the projects. A DFID project on Essential Medicines focussed on ensuring the availability of vital drugs nationally.¹⁷⁴

The World Bank is funding a 30 million US dollar programme to improve health service delivery with the Ministry of Health.¹⁷⁵ The United States is funding several reproductive health projects through the President's Emergency Plan for AIDS Relief (2004) in collaboration with international NGOs.

UNFPA has been very involved in reproductive interventions during the last decade at central but also at provincial level. UNFPA has provided direct programs and technical assistance. UNFPA has also assisted with the procurement of certain commodities such as pills and RH equipment for emergency obstetric care. Over the course of the last 5 years UNFPA has decreased its directly managed projects and has moved to systems building and advocacy interventions as well as direct technical assistance support to provinces and the central level. UNFPA supports the Reproductive Health office in the Ministry of Health to prepare an RHC security plan.

EC support to health and HIV/AIDS is now combined under one single Health Sector Support Programme. The EC is supporting the Ministry of Health through SWAp with a funding of 25 million Euros that will continue to 2007. The programme consists of supporting the Ministry of Health to further develop the SWAp approach and improve the delivery and quality of basic health services, particularly those related the treatment and prevention of sexually transmitted diseases and HIV/AIDS *including access to RHC*.¹⁷⁶ The EC also supports a specific programme on maternal health in the province of Gaza. The EC has, further, committed 9 million Euro for the 2007 census in Mozambique.¹⁷⁷

EC programmes also include the rural system health rehabilitation programme. One component of this programme was support for equipment, essential drugs and supplies with a concentration on the province of Zambezia.¹⁷⁸ The programme is still ongoing but very close to completion.

The European Commission has contributed € 14.87 million in 2006 to help UNFPA provide equipment and supplies for obstetric and maternal health in 17 African, Caribbean and Pacific countries, including Mozambique. The contribution will last for two years and is intended to contribute to improved RHCS in Mozambique.¹⁷⁹

¹⁷² DFID, 2006, p. 51.

¹⁷³ Overseas Development Assistance to Mozambique Data Base, 2006.

¹⁷⁴ DFID, 2006.

¹⁷⁵ Overseas Development Assistance to Mozambique Data Base, 2006.

¹⁷⁶ European Commission (2006); European Commission Delegation to Mozambique (undated)

¹⁷⁷ Overseas Development Assistance to Mozambique Data Base (2006)

¹⁷⁸ European Commission (2006), "The project has contributed to strengthening the management of essential drugs at the provincial and district levels. Stock keeping has improved and the distribution of essential drugs to the Districts has been rationalised." European Commission in Mozambique (undated)

¹⁷⁹ UNFPA, 2006.

Little information is available on the funding of many of the vertical projects because some of the partners channel their funding through intermediate agencies and NGOs.

5.2.3 Donor Coordination

Inter-donor coordination is partially carried out through the Programme Aid Partner pool of donors who participate in the budget support programme.¹⁸⁰ A working group of key donors meets with the Ministry of Health to support the health SWAp effort (Grupo de Trabalho SWAP).¹⁸¹ Other donor coordination efforts are carried out through the Country Coordination Mechanism linked to Global Fund projects. Civil society representatives are represented in the Country Coordination Mechanism.

The Poverty Reduction Strategy (PARPA) consultative group meeting also provides a venue for significant coordination discussions, including on policies and priorities in reproductive health. UNFPA is one of the leading agencies assisting the government in organising a thematic group on Sexual and Reproductive Health.

5.2.4 Description of the Health System and Reproductive Health Services

The country has eleven provinces, one of which is the capital city of Maputo, and 128 districts. The districts are further sub-divided into 393 administrative posts. Decentralisation is, however, largely limited to the urban areas with little real autonomy outside of these areas.¹⁸² All health institutions continue to operate under the Ministry of Health although some aspects of management has been decentralised to the provincial level. Municipalities and local administration have not yet participated in the decentralisation process.¹⁸³

There is an impetus to provide the provinces with more power and capacity to strengthen the decentralization approach. Some activities, such as supervision and training, are being shifted to the direct responsibility of provincial directorates.

The National Health System has three basic levels of administration and management the central, provincial and district levels.¹⁸⁴ The central level is based in the Ministry of Health which has four national directorates and some autonomous services. The central level is responsible for formulating policies, strategies, norms, and standards and coordination with other government sectors and with partners.

Reproductive Health is placed under the National Directorate of Community Health in the Department of Community Health. Strategic planning and coordination of donors is carried out by the Directorate of Planning and Cooperation. The specific Reproductive Health programme at the Ministry of Health (MoH) does not have a specific line of financing.

The provincial level health system includes 11 provincial directorates that are placed under the Provincial Governor for administrative matters and under the Minister of Health for technical matters.¹⁸⁵ The provincial level is

¹⁸⁰ DFID, 2006.

¹⁸¹ European Commission Delegation to Mozambique (undated)

¹⁸² Hodges, T & Tibana, R., 2004.

¹⁸³ WHO, 2003.

¹⁸⁴ WHO, 2003.

¹⁸⁵ WHO, 2003.

responsible for implementing the sector's national directives as well as coordination and supervision of activities at the provincial level.

The district level comprises 144 district health directorates and is responsible for the implementation and delivery of health services to the population.¹⁸⁶

Health services are delivered at several levels through 4 central hospitals, 12 provincial hospitals, 25 rural hospitals, 276 (district) health centres and 736 health posts. Rural and district centres can provide some emergency obstetric interventions. It is estimated that about 40 percent of the population have access to basic public preventive and curative health services and live within 10 km of a facility.

Table 2
Hospital and Health Service Provision

Level	Category of Health Unit	Approximate Number of Functioning Units	Types of Health Care Offered
I	Health Posts (PS)	736	Primary (preventive and curative)
	Health Centres (CS)	276	
II	Rural Hospitals and General Hospitals (HG)	30	First reference and basic surgery
III	Provincial Hospitals (HP)	12	Surgery, obstetrics, gynaecology, paediatrics, internal medicine, orthopaedics
IV	Centrals Hospitals (HC)	4	Same as above except more differentiated, with multiple specialties and certain sub-specialties (especially in the HC Maputo)
	Psychiatric Hospitals	2	

At community level, the health system includes community health workers known as APS/APE (*Agente Polivalente de Saude* or the *Agente Polivalente Elementar*). The APS/APE provide limited curative services and are capable of distributing medicines from a simple drugs kit. The APS/APE are currently mostly trained by NGOs using a national Ministry of Health training guide.

Doctors are mainly concentrated in cities, provincial hospitals and a few districts. The system still needs significant improvement in terms of quality of diagnosis and treatment.

The Central de Medicamentos e Artigos Medicos (CMAM) is the Ministry of Health unit in charge of the planning, warehousing and distributing of drugs throughout the country. The Central de Medicamentos e Artigos Medicos (MEDIMOC) is a private company hired by the CMAM and is responsible for all procurement, storage, and distribution for the public sector. MEDIMOC also distributes commodities directly to private pharmacies and NGOs.

¹⁸⁶ WHO, 2003.

5.2.5 Organisational and Management Issues Affecting the Mozambican Reproductive Health System

The lack of human resources is considered a major issue affecting the whole health care delivery system. Mozambique has only 3 medical doctors per 10,000 people.¹⁸⁷

An assessment of emergency obstetric care in four rural and two general urban hospitals indicated that there were an insufficient number of trained personnel, *scarcity of drugs* and inadequate surgical conditions, both in terms of material and equipment.¹⁸⁸

5.3 Reproductive Health Commodities Security: Demand, Gaps and Equity

5.3.1 Gaps Between Types of Reproductive Health Commodities Demanded and Used

Contraceptive use of modern methods in Mozambique is estimated to be only 11.8% of all women of reproductive age and in union.¹⁸⁹ The unmet demand for contraception by married women between the ages of 15 and 49 is estimated at 18%.¹⁹⁰ This figure probably underestimates the real need because there are many unmarried women whose needs are not included in this estimate.

Only 29% of women aged and 33% of men aged 15-24 years used a condom the last time they had sex with a casual partner.¹⁹¹

The most recent statistics on the number of antenatal visits quoted by WHO in 2006 are quite dated. In 1997 71% of pregnant women had at least one antenatal visit and 41% had 4 visits.¹⁹² Close to half of all deliveries (48%) were attended by a skilled attendant according to more recent statistics (2003).¹⁹³

Only nine percent of PLWHA are receiving antiretroviral treatment.¹⁹⁴ The percentage of pregnant women receiving treatment to reduce mother-to-child transmission is only 3.4%.¹⁹⁵

The demand for RH services is growing, especially in the safe motherhood component. This growth is driven by increased access to health services and the expansion of the network of health centres having a maternity ward and providing antenatal care.

The Reproductive Health programme has developed case management methods and standardized technical procedures. Medical kits for sexually transmitted infections, family planning and essential obstetric care have also been developed. Kits to equip delivery rooms and surgical wards to provide C-sections, tubectomies or emergency obstetric surgery are being made available through the health system.

¹⁸⁷ WHO, 2006b.

¹⁸⁸ Jamisse, L. 2004. p.2.

¹⁸⁹ United Nations Statistics Division, 2006b.

¹⁹⁰ World Bank, 2006b.

¹⁹¹ UNAIDS, 2006.

¹⁹² WHO, 2006b.

¹⁹³ WHO, 2006b.

¹⁹⁴ UNAIDS, 2006.

¹⁹⁵ UNAIDS, 2006.

5.3.2 Equity and Access to Reproductive Health Commodities

Despite substantial investments in public health out-of-pocket expenditures on medicines and health still represent 31% of the total expenditure on health.¹⁹⁶

In Mozambique 66% of the population live in rural areas.¹⁹⁷ There are substantial differences in access to reproductive health services between urban and rural areas. In urban areas 81% of deliveries are attended by a skilled attendant while in rural areas the figure is only 34%.¹⁹⁸ Disparities between provinces in terms of level of modern contraceptive use are also very high and range from 0.7% to 28.5%.¹⁹⁹

AFFORDABILITY

Reproductive health commodities are free of charge or sold at a symbolic price in the public system. In the private sector the prices of drugs fluctuate widely and are currently prohibitive for the majority of the population.²⁰⁰

Mozambique has two forms of social security.²⁰¹ The National Institute for Social Security provides social security for private enterprise employees, and the Medical Assistance Fund exists for government workers. The social security package is compulsory for all workers in the private sector. The large population in Mozambique that is active in the informal economy is not covered by any social security scheme to date. Private health insurance is still incipient and community based health insurance is poorly documented as it is still at its inception.

Corruption is a major issue affecting RHCS at all levels of the supply chain. A government anti-corruption unit, set up in 2002, has proved ineffective so far and the will for serious action to address this problem remains uncertain.²⁰² Excessive centralisation of decision-making authority continues to hinder accountability.²⁰³

5.4 Forecasting, Procurement and Distribution Arrangements

The supply chain is well balanced within the country and the system is mostly able to deliver the pharmaceutical products to the outreach health facilities. An analysis by WHO (2003) indicated that the pharmaceutical sector is performing relatively well despite problems originating from the economic situation and the health and social sectors. WHO considers, however, that there are some well-defined opportunities for improvement. Stock outs are not uncommon.

RHC are integrated into the common distribution and acquisition system and are handled the same as other drugs or medical commodities.

¹⁹⁶ World Bank, 2006b.

¹⁹⁷ United Nations Statistics Division, 2006e. Rural urban migration is a net of 3.4% annually.

¹⁹⁸ UNFPA, 2003b..

¹⁹⁹ UNFPA, 2003b..

²⁰⁰ WHO, 2003.

²⁰¹ WHO, 2003

²⁰² DFID, 2006. p. 20.

²⁰³ DFID, 2006. p. 20.

Personnel working in drug management are regularly trained and supervised, mainly by central level Ministry of Health professionals, who go to the provinces. The training is mostly funded through the Provincial Common Fund.

RHC availability sometimes poses problems. In one example, the currently prescribed oral contraceptive pill, Microgynon, was out of stock throughout the supply chain in 2005. New organizational arrangements led to a delay in providing the CMAM with timely information on the needs. UNFPA procured Microgynon at the request of the Ministry of Health.

5.4.1 The Role of Government

The public supply chain follows the classical process from the central level to the district level through provincial warehouses. The public supply chain is totally subsidized by the MoH and the RHC are mostly funded by the donor common fund which poses a significant constraint for sustainability in the future for both general drugs and the RHC. If at any point in time the donor common fund is reduced the government may have difficulties supplying the required RHC.

FORECASTING

WHO (2003) considers that forecasting of drug needs in Mozambique should be improved. The forecasting of drugs is carried out on an annual basis by the National Health Directorate and CMAM. The forecasting for medical devices and equipment is made by the Ministry of Health Logistics Department.

Forecasting is carried out by pooling the consumption levels from the previous year. This data is then combined with other information supplied by the districts through the provincial level to the central level.

The consulting team preparing the present report noted that interviewees described the forecasting process as weak. A management manual exists which includes forecasting guidelines and personnel are trained on the implementation of the manual. In practice, it is not very well followed. UNFPA assist with the forecasting for RHC.

PROCUREMENT METHODS OF RH COMMODITIES

WHO (2003) considers that the present system of drug procurement is sound, and should essentially be maintained.

The majority of RHC are supplied by donors directly to CMAM or to the vertical programs. Condoms supplied by Population Services International (PSI) are included in health kits through the social marketing approach. From 2005 onwards the procurement of certain contraceptives has started to be made by CMAM.

QUALITY CONTROL OF RH COMMODITIES

The National Drug Quality Control Laboratory has one chemistry and physics department and one microbiology department. Its equipment was donated by the Italian cooperation in 1983 and most of it is broken. New equipment is being acquired. The Laboratory currently only works for the public system but is unable to even

analyze all the drugs from the Essential Drugs List. The chemistry-physics department performs 500 medicine analyses per year while the microbiology department performs 200-300 injectable analyses per year. The most important constraints are the lack of equipment, reference substances, training and maintenance support.

The laboratory was evaluated during 2006 by the WHO at the request of the MoH but the data was not yet available at the time of preparing the current report. The evaluation is part of a broader plan to improve the capacity of the laboratory with WHO support.

The Quality Assurance of imports still needs strengthening. At present, the regulations on goods imports do not differentiate drugs from other commodities and the medical devices are not taken into consideration at all.

Training on pharmaceutical management is planned through regular training and supervision. In 2005, the funds were, unfortunately, unavailable although the Ministry of Health does intend to continue such capacity strengthening at the provincial level. The Ministry of Health will provide funds for this purpose to the provincial health directorates.

PRE-SELECTION OF SUPPLIERS

The pre-selection of RHC is carried out every 2 years and the results are published in the UN business magazine as well as in local newspapers. The consultant team was told that less than 25 suppliers are pre-selected. Observations by the consultancy team in the provincial warehouse and information obtained through interviews show that drugs are mostly procured from Mission Pharma and IDA, two European distributors.

The pre-selection procedure is exclusively documentation based. No on-site audits of pre-selected companies are performed because of budget constraints and the need for specialized human resources. The consultant team was informed that audits are carried out if any problems arise.

TENDERING

A specific normative standard procedure for tendering has been agreed to by donors, the Ministry of Health, CMAM and MEDIMOC. The procedure is the only one that is applied by MEDIMOC. A copy of the bidding documents "Supply of Surgical Material – IFB No. 26/WB-MMC/05 – closing date 29 September 2005" was provided to the consultant team.

The schedule of requirements is composed of descriptions of the required articles, the delivery schedule and the shipment mode. The technical specification requirements to be supplied include a description of the items, the manufacturer's name, the country of origin and extent of compliance with the description. No standard for compliance is included in the technical specifications.

Tenders stress price over quality which can have detrimental effects.

DISTRIBUTION METHODS AND OF RH COMMODITIES (AND AS COMPARED TO OTHER ESSENTIAL MEDICINES)

The majority of drugs and specially RHC are distributed by the public sector and to some extent by private non-profit organisations. In the main cities there is an incipient for profit sector that is quite expensive so only high economic income can afford to access it.

There are two principal mechanisms for the distribution of RHC. Through a “classical” system of bulk supplies of RHC and through a health kit scheme.

Three basic types of health kits are distributed in the country:

- Kit A is for health facilities with a medical doctor.
- Kit B is for health facilities with a nurse only.
- Kit C is for health facilities with an “Agente Polivalente de Saúde” (Community Health Worker). This kit does not include any antibiotics but does include condoms.

The RHC products that follow the classical system—i.e., those that are not part of health kits—are supplied quarterly on the basis of requisitions by the Provincial Depots.

THE CENTRAL WAREHOUSES

Central Warehouses are located in Maputo for the southern and northern provinces and in Beira for the central provinces. The delivery is planned by CMAM/MEDIMOC. Suppliers send products directly to the 2 central warehouses in the case of bulk orders of drugs while some other drugs and drugs requiring a cold chain are sent to Maputo's central warehouse.

THE PROVINCIAL DEPOTS/WAREHOUSES

There are 11 provincial depots/warehouses, 1 in each province, except in Maputo province where there is only the central warehouse. The Provincial Depots store the medicines and distribute them to the district level. The provincial warehouses receive the RHC from the warehouse in Maputo and maintain contacts only with the CMAM. The delivery of kits uses a “push” system based on requests made by the districts to the provincial warehouses which pool the requests and sends them quarterly to the central level.

DRUG MANAGEMENT INFORMATION SYSTEM

The health information system (HIS) in Mozambique has been held as a model and is praised by some as one of the best in Africa.²⁰⁴ A proliferation of new projects using parallel information systems has, however, contributed to the fragmentation of information. Despite the recent computerisation of the system, reliable information for developing policies, planning, budgeting, monitoring and evaluation are scarce.

²⁰⁴ WHO, 2003.

The Health Information System allows for a coordinated management of the drugs from the MoH to the Provinces, through the CMAM and the MEDIMOC.

5.4.2 Case Study of Distribution in Maputo Province

The consultancy team visited the Provincial Health Directorate (DPS) in Maputo province where the provincial medical director was interviewed. The team visited the provincial drug warehouse, a district hospital and a warehouse at Namahacha. The district hospital distributes condoms and (other) contraceptives.

The example of the Matola provincial warehouse was chosen by the consultant team for illustrative purposes. The Matola Provincial Warehouse has 12 personnel. The personnel includes 1 pharmacist, 4 pharmacy technicians and 3 pharmacy assistants. The role of the pharmacist's technical assistant is to supervise the district warehouses and train health workers and district warehouse chiefs. All training is carried out using management manuals. The training is very often carried out by the provincial warehouse staff during supervision visits to the district warehouses. Only one supervision visit was carried out and no training in 2005 because of budget constraints. The norm was previously to carry out 3 to 5 training actions a year in this province.

STOCK MANAGEMENT

A special area is reserved for sensitive products where drugs are stored on shelves in their original packaging. This area has only one entrance for security reasons. Other drugs are stored on wooden pallets in the cartons in a warehouse that also has only one entrance. Stock management is very well carried out on paper sheets and data is entered into a computerised information system at the end of the day. Inventories are performed quarterly and when a requisition is made it is forwarded to the CMAM.

A 500-liter refrigerator, a computer and a 7-ton truck for district deliveries were available. No shelves were found except in the "sensitive products area" and a fork-lift was also missing, limiting the functioning of the warehouse.

Stock-outs of male condoms and contraceptive pills were registered during the year in this warehouse but the duration of the stock-outs was unavailable.

THE DISTRICT WAREHOUSE

The district warehouse is frequently located in a room in the district hospital. The consultant team visited the Namaacha district hospital. The district warehouse is managed by 2 pharmacist's agents. The 3 by 3 meter room is used as the district warehouse and as the public pharmacy at the same time. District drugs, including RHC, are stocked on shelves on one side while the other side is reserved for goods distributed through the public pharmacy.

The kits are stored in a separate room due to their large volume. None of those rooms are air-conditioned. In this district warehouse, contraceptives were out of stock for the previous 3 months. There is no specific process to follow-up RHC in the warehouse

5.4.3 Role of Non-State Providers

The current government health policy recognises the role of the profit and non-profit private sectors.²⁰⁵ The non-profit sector, which is essentially composed of international non-governmental organisations (NGOs), bilateral agencies and some religious institutions, is regulated by the Ministry of Health.

THE PRIVATE COMMERCIAL SECTOR

The for profit private health service sector is gradually growing, especially in cities.²⁰⁶ The presence of drugs manufacturers is insignificant in Mozambique.

There is only a limited network of private health practitioners. This hinders the development of a social franchising network on RH or public private partnerships to increase the access to quality RH services.

It is important to notice that the private sector is also selling generic drugs. The law currently does not, however, allow for pharmaceutical substitution, i.e. substituting patented drugs with generic drugs.

NON-GOVERNMENTAL AND SOCIAL MARKETING SECTOR

Many international NGOs are working in Mozambique to address various health issues including RHCS related issues. In most cases RHC are integrated into a larger project such as on maternal or adolescent health, HIV/AIDS, etc.

The social marketing of condoms is strongly promoted by Population Services International (PSI). PSI works in approximately half of the provinces and has a significant share of almost 90% of the distribution of condoms by the private sector and 50% of the total.

PSI does not foresee expanding its interventions in the near future to other technical areas, mainly because there is a limited number of clients with capacity to buy the commodities, even at very subsidized prices. PSI is more interested in expanding its areas of intervention *geographically*. Nevertheless, should the opportunity arise, PSI in Mozambique could be interested in developing actions with other commodities and possibly in providing services such as FP/RH services.

A number of other international NGOs are working on RH projects in the area of safe motherhood, prevention of mother-to-child transmission of HIV, and in voluntary counselling and testing. Most of these NGOs include condom promotion and distribution, treatment of STIs, treatment of opportunistic infection, IEC-BCC interventions and antiretroviral treatment on a limited scale.

World Vision, Populations Services International, Save the Children, Chemonics and several others are carrying out a USAID financed project "Improve Maternal Health and Nutrition, Reduce Unintended Pregnancy and Improve Healthy Reproductive Behaviour" that includes a component on improving the logistics of RHC.²⁰⁷ The same

²⁰⁵ WHO, 2003.

²⁰⁶ WHO, 2003.

²⁰⁷ USAID, 2005.

agencies provide support to the Ministry of Health to build better health systems including emphasis on better family planning and maternal and child health.²⁰⁸

Other NGOs that include the distribution of RHC in their work in Mozambique include Save the Children, CARE, and Project Hope. Many small NGOs based in European countries such as Italy and Austria also provide assistance in the area of reproductive health.

Pathfinder International has a program on adolescent reproductive health that includes the distribution of contraceptives through a peer counselling programme and the International Planned Parenthood Foundation.²⁰⁹ The Pathfinder programme also includes a component on prevention of mother-to-child transmission of HIV. Pathfinder International provides iron and folate to pregnant mothers through its programme in Mozambique.²¹⁰ Family Health international works with the Mozambican government and other NGOs such as Médecins Sans Frontiers, and the private sector to expedite the availability of nevirapine for prevention of mother-to-child transmission in Zambezia province.²¹¹

The Associação Moçambicana para Desenvolvimento da Família (AMODEFA) is largest Mozambican NGO working in the RH field with the objective of contributing to population policy and providing RH services including AIDS control. AMODEFA is affiliated with the International Planned Parenthood Federation (IPPF). It is partially funded by the IPPF and the National Aids Council.

AMEDFA has a health centre where family planning counselling, check ups and distribution of contraceptives are carried out among other activities. AMODEFA has 9 projects in Maputo, Maputo province and other 3 provinces and develops adolescent reproductive health actions in schools and in the community. Commodities are provided by the IPPF and the Ministry of Health.

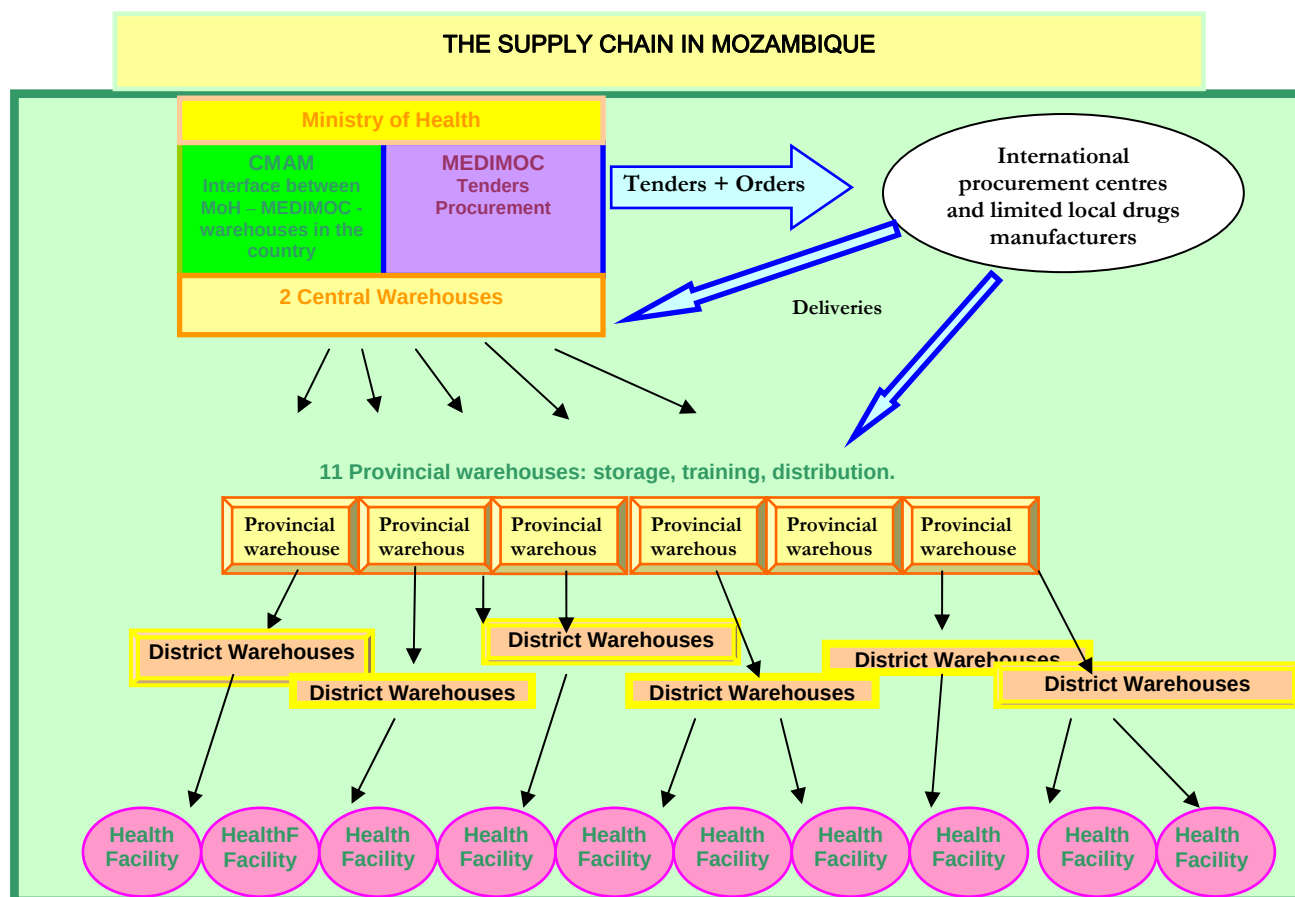
²⁰⁸ USAID, 2005.; USAID Mozambique, 2006.

²⁰⁹ Ministry of Foreign Affairs of Denmark, DANIDA, 2006; Pathfinder International, 2006.

²¹⁰ Pathfinder International, 2006.

²¹¹ Family Health international, 2006.

Figure 2
The Supply Chain in Mozambique



5.5 National Drugs Policy, Legal and Regulatory Issues

In Mozambique regulatory aspects related to the import, manufacture, sale and advertising related to drugs are covered by laws that are now in the process of being integrated into the National Drugs Policy (NDP). Drug legislation on using, prescribing and dispensing of drugs, and the importation and export of drugs was adopted in the years immediately after independence.²¹² A new drugs law is under consideration. The national pharmaceutical policy is in the process of approval and complements the expected drugs law.

The objective of the pharmaceutical policy includes the attainment of good quality assurance of drugs and the need to regulate prices in association with all the partners from the public and private sector. The new policy does not include details on how adequate quality control will be achieved.

The regulation for acceptable margins on prices is the same for generic and for brand-name drugs, 13% at importer level. The distributor margin is not regulated. The regulated margin is 60% at the pharmacy level. To date, however, prices have not yet been regulated in practice. The new pharmaceutical policy to be approved does take and include specific price regulation policies.

Import licenses are regulated by law.²¹³ There is also a law that regulates the opening of pharmacies.²¹⁴

5.5.1 Drugs Registration

The registration of drugs for import has been required since 1999. An extraordinary registration procedure valid for 3 years was implemented at that time for the registration of drugs already available in the country. It must be highlighted that the same regulations apply to RHC as to other health commodities.

Registration of drugs process:

- Submission of drug dossier: WHO Good Manufacturing Practices certification, certificate of pharmaceutical product, quality certificate, marketing authorization from the manufacturing country, bioavailability for specific generic drugs (ATB, pills, etc.).
- First review of the documentation by the head of the pharmaceutical department in the MoH; second review by the technical commission of pharmaceuticals, compounded by 6 medical doctors and 2 pharmacists. Following approval of the reviews the importer is authorized to import drugs.

For generic drugs the procedure is shorter because generic drugs are already well known. The complete procedure is launched for drugs "that are less known or in the pharmaceutical industry for a shorter time" such as antiretrovirals, cytostatics, etc. In this procedure EU recognition or USA/FDA approval is taken into consideration. The importation of ARV is made using the WHO's pre-qualified suppliers list.

²¹² Savelli and Haak, 1994.

²¹³ Licensing of the importer/warehouseman of Pharmaceutical Products – Law 4/98 – Law on Medication; Decree no. 22/99 – Regulation of the Registration System – June 05.

²¹⁴ Licensing of Pharmacies; norms to open up pharmacies – Ministerial Measure no. 39/2003 of 2 April 2003 – Approves the requisites for setting and opening up pharmacies.

Decree no. 21/99 of 4 May 1999 – Approves the Regulation for the Exercise of the Pharmaceutical Profession – April 05.

The authorization to import provides the importer with exclusivity and must be renewed every 5 years. The registration of each drug costs around 5 million meticals (roughly EUR 166) and is in line with registration fees found in other developing countries.

In Mozambique, there is currently no registration, law or quality control of medical devices. No medical device is included in the Mozambican EDL²¹⁵.

²¹⁵ This EDL is updated every 3 years; the last update was in 2005.

Analysis of Strengths, Weaknesses, Opportunities and Threats in Reproductive Health Commodities Security

	Strengths	Weaknesses	Opportunities	Threats
Policy & Legal Framework	- Political will to continue with health reform and to give RH priority; - Ongoing SWAp and Poverty. - Reduction Strategies programs. - MOH is preparing a RHCS plan at national level and is improving its drugs management system. - The drugs registration is ongoing. - National Drug Policy is expected. - Essential Drugs List exists and is updated.	- Heavy dependence on donor funding. - Some donors are not integrated in the common funds system. - Pharmaceutical substitution is not permitted by law. - There are no specific regulations on drug imports.	- Willingness to integrate RH issues as priority in MOH strategies in the Maputo Plan of Action. - Decentralization process needs to be supported and strengthened. - New Drugs and Pharmaceutical Law that will provide the drugs and pharmaceutical sector with legal framework. - Department of Pharmacy will become a National Pharmacy Directorate and will be in charge of legislation to provide norms and inspections - Role of partners, especially UNFPA, in maintaining an integrated and comprehensive approach to RH and RH commodities Security.	- Difficulties in integrating more partners in common fund/SWAp approaches. - Level of support from the international community diminishes too quickly. - Development objectives and economic growth are less than expected. - Health does not receive sufficient funding in the common budget.
Supply chain	- There is a public supply chain system. - Training and supervision actions are included in planning. - RHC are free of charge for patients.	- Limited number of differentiated and trained health systems staff. - Lack of availability of funds leads to stock-outs of essential RH drugs. - Lack of availability of funds led to absence of training and supervision actions during the year. - Quality assessment system for imports is weak.	- Harmonization of origin of equipment and thus improve maintenance process of medical equipment. - WHO asked to evaluate the National Drugs Quality Control Laboratory?	- Only some drugs from the EDL are analyzed. - Health kits' contents are not updated and can lead to huge excess of stocks. - Pharmaceutical products are not imported on best ratio quality/price due to poor procurement procedures.
Financial Resources	Funding of commodities for RH through the national health system appears adequate under current levels of utilization taking into account that other vertical funding is available.	- Lack of human resources for implementation, poor accounting and management skills, poor monitoring and control at provincial level. - Continued large proportion of vertical funding out of the state budget and out of account.	- Partners continue funding the RHC. - Transition of larger quantities of funding to the provincial level starting in 2006.	- Quality of services compromised by poor management. - New financial management system that with a lack of human resources trained to implement it.

5.6 Key Issues for Recommendations on Mozambique

5.6.1 Policy Recommendations and Coordination with Donors

- (1) The existence of vertical programs dedicated to specific diseases should be considered as an opportunity to integrate them into one national common strategy.
- (2) Increase the role of civil society in the Country Coordination Mechanism because it can help contribute to more equitable access to RHC.
- (3) Donors should be encouraged to perform regular assessments of the RHCS situation so they can provide good technical support and input in coordination and other meetings.
- (4) The strengthening of the recently developed RH thematic group in the SWAp coordination meetings is useful and can be more clearly oriented to focus on ensuring the regular and continuous pluri-annual flow of resources for RH commodities.
- (5) Promote the establishment of regulations for drug imports including on methods for quality assessment.

5.6.2 Increasing Financing

- (1) Promote increased targeting of funding for health from 11% to 15% as agreed to in the Maputo Declaration of July 2003 by the Heads of States of the African Union.
- (2) Promote AU SRHR policy implementation as set out in the Maputo Plan of Action 2006.
- (3) The common fund approach needs to be generalised to include all donors. Common funds allow for a more stable financial base for the acquisition of RHC. As experience with common fund budgeting increases within the country local governance and accountability, capacities are likely to increase.
- (4) Budget allocations should be brought more closely in line with the priorities identified in the annual Strategic Health Plan (PES).
- (5) Joint funding and better monitoring are needed. Address distortions in health system cost analysis caused by the multitude of funds that are off-budget, off-treasury and off-account. Improved cost analysis can contribute to more efficient systems thus reducing costs.
- (6) Donors can provide support for the allocation of funds within the SWAp to the National Laboratory for equipment, reference materials and training. The donors' support should support the purchase of equipment easily maintainable in the country.
- (7) Information on the functioning of the Provincial Common Fund (FCP) should be integrated in the National Health Information System it. Better monitoring and control systems will provide all the donors with the

confidence to continue support. Integrating the Provincial Common fund will contribute to ensuring that all funds are on budget, on treasury and on account. Good information will be very useful for the government and external partners.

5.6.3 Gaps in Procurement and Distribution Systems

- (1) An overview of the RHCS actions of the many small NGOs in Mozambique should be carried out. Subsequent mapping and tracking of their actions should be carried out on a continuous basis and integrated with data on other RHCS actions.
- (2) The possibilities for public-private partnerships should be explored in greater detail.
- (3) The future national pharmacy directorate should develop legislation on margins that differentiate generic drugs from brand name drugs and diagnostic kits. The Directorate should work together with the private sector to develop the regulations.

FORECASTING

- (1) Forecasting methods of drugs and other commodities that are needed should be strengthened.
- (2) Health and diagnostic kits need to be frequently updated so that they conform to actual needs. Currently they are sometimes developed independently of the epidemiological needs and some contents are wasted.

CAPACITY STRENGTHENING

- (1) Provide support to improve the management, control and monitoring system of RHC.
- (2) The new financial management system (SISTAFE) which started in 2006 can help improve financial management but the low capacity of implementing staff needs to be addressed.
- (3) The inclusion of "management by objectives" in expenditure implementation plans is important and should be promoted. Management by objectives will contribute to increased motivation and provide identification keys to all the stakeholders. To achieve that purpose the RHC and other health objectives should be specific, dated, monitored and regularly evaluated.
- (4) The integration of parallel health information systems used by the proliferation of new projects should be supported. The Mozambican health information has been held as a model and is praised by some as one of the best in Africa but the many parallel systems have weakened its effectiveness.²¹⁶ Despite the recent computerisation of the system, reliable information for developing policies, planning, budgeting, monitoring and evaluation are scarce.

²¹⁶ WHO, 2003.

- (5) The strategic approach to HIV/AIDS prevention and control in the country, which focuses more on treatment, will demand a reshaping of the pharmaceutical sub sector so that it can cope with the expected additional burden. This will entail an exponential increase in value terms of the volume of drugs passing through the system. Especially in the periphery, both managerial and technical capabilities and the physical infrastructure will need to be expanded as part of an effort to strengthen the entire health system.

QUALITY CONTROL

- (1) The Quality Assurance of pharmaceutical products still needs strengthening. At present, the regulations on imports do not differentiate drugs from other commodities and the medical devices are not taken into consideration at all.
- (2) Technical assistance should be provided to the future national department of pharmacy to build a well functioning quality assessment system. This will contribute to strengthening the quality of tender procedures and drug registration.
- (3) A specific training program on regulations and the implementation of quality assurance assessment should be carried out for all concerned agents in the supply chain. Health professionals will also need to be trained so that they can update their knowledge and be assured of the measures taken to ensure the quality of generic drugs.

DISTRIBUTION

- (1) Promote the concept of social franchising through which some social marketing and other organisations can develop actions to promote security of a broader range of RHC than is currently the case.

6 GENERAL CONCLUSIONS AND RECOMMENDATIONS

The attainment of the human right of reproductive health requires a concerted effort by all partners involved at all levels of societies. Dependable and equitable access to reproductive health commodities is crucial to ensuring reproductive health. Governments can ensure that policy, legal and financing frameworks are responsive to the realities they face to ensure reproductive health commodities security for all their citizens. The role of donors in coordination meetings and through the provision of financial and technical support to strengthen Reproductive Health Commodities Security is significant. Their partnership with national governments and all national stakeholders can provide benefits for all. The role of civil society and the private commercial sector—jointly known as Non State Actors—is also of vital importance to assure RHCS in every country.

The consultants support the recommendations made in the Gates Foundation sponsored Mercer Report and the DFID sponsored synthesis report on Reproductive Health Commodity Security.²¹⁷ Some of the key recommendations from these studies include:

- The importance of advocacy to focus attention on RHCS and the advocacy entrance point provided by the SWAp approach.
- The need for detailed national reproductive health plans including budgets and indicators supported by a RH coordination group.
- The mainstreaming of RHC into the wider health and development system.
- Continued need for donor financing and technical support.
- UNFPA should continue and widen its role as a leader in RHC.
- Reproductive health needs to be positioned as key to MDG 4 (Reduce Child Mortality) and MDG 5 (Reduce maternal Mortality).
- Establish linkages between RH services on HIV/AIDS and all other RH services.
- Improve the accountability of policy makers and providers.
- Ensure equitable access to RH services and commodities.
- Stronger public sector engagement with the overall market for RHCs and with other providers.
- Donors need to make more long term and predictable commitments to RH supplies.
- Continued pooling of finance at the global level is needed to support reproductive health commodity security.
- Global financing mechanism must be in line with international commitments to aid harmonisation.
- Accelerate the development of prequalification processes for manufacturers.

The findings of the country case studies on India and Mozambique indicate that most of these recommendations are also of importance to these two countries. India is not highly dependent on external aid but would benefit from many of these recommendations in other ways. India is a highly diverse country in which some poor states more closely resemble the situation in very poor sub-Saharan and other countries. Lack of transparency is a major problem and equitable access is not yet achieved. Inadequate human resources in health in terms of quantity and capacities are a problem in many Indian states. The management of the supply chain can also be improved in most states. As a major producer of RHC, India would also benefit from improved quality control through pre-selection and other such mechanisms since it will contribute to higher confidence in Indian products.

²¹⁷Mercer Management Consulting, 2005; Druce, N. 2006.

Mozambique is a country with wide ranging problems that is struggling to address them in a concrete way. Many problems exist in the area of RHCS including poor forecasting, a multiplicity of health providers with competing systems, poor management, poor quality control, and inadequate infrastructure for the storage and distribution of commodities. The SWAp and common budget approaches being implemented in the country provide the opportunities described in the recommendations of the DFID (2006) report. The country has a good Health Information System that can be used as a model for other countries although it needs to increase the integration of data from parallel HIS systems in the country.

6.1 Policy and Legal Framework Recommendations and Coordination with Donors

- (1) Where National Reproductive Health policies do not yet exist they should be established including specific references to RHCS.
- (2) All other major policy documents on health, poverty, and gender should make specific references to ensuring RHCS.
- (3) The legal framework should be comprehensive and address all issues related to tendering, procurement and distribution. The legal framework should also cover issues such as pre-selection, import regulations, and quality control mechanisms. The legal consequences for agents that do not adhere to the laws and regulations should be clearly indicated. National and state laws and regulations should include explicit detail on accepted procurement and tendering *procedures* so that transparency can be improved.
- (4) Vertical programmes that continue to exist should be integrated into a comprehensive system. This does not mean that vertical programmes should be abolished but that they are placed within a multisectoral and more holistic setting making monitoring of the sector possible.
- (5) Decentralisation processes down to the local level should be promoted. Such decentralisation helps to ensure that reproductive health services, including RHC, are accessible to the districts and communities. Decentralisation needs to be associated with capacity building and close supportive monitoring and supervision.
- (6) The active role of civil society at all levels from national to local should be promoted. Civil society has an important role to play in the form of advocacy on issues related to RHCS including equity of access. At local level administrative and civil society organisations should be promoted to allow RHC projects to have local support and sustainability.
- (7) During coordination meetings donors, participating agencies, and civil society can continue to advocate for adequate attention to increasing funding in accordance with estimated requirements.
- (8) Donors should be encouraged to perform regular assessments/monitoring of the RHCS situation so they can provide good technical support and input in coordination and other meetings

6.2 Financing and Budget Recommendations

- (1) Increased targeting of funding for health and funding for RHC specifically as necessary at each level, i.e. national, state/provincial/ district/community should be promoted.
- (2) Budgets should directly reflect the priorities assigned to health, RH, and RHC in major national and state policy documents.
- (3) Budget allocations for RH and RHC should be clearly *designated* in health budgets.
- (4) Where off-budget projects and activities exist they should be traced and included in national accounts systems.
- (5) Multi-annual revolving funds for commodity procurement and other mechanisms that help ensure sustained financing need to be supported, studied and introduced nationally and/or regionally.

6.3 Addressing Gaps in Management, the Procurement and Supply Chain

COORDINATION AND MANAGEMENT OF RHC SYSTEMS

- (1) A special department that focuses on the coordination, implementation of laws and regulations, and functioning of the supply chain on drugs needs to be created with a special unit focussing on RHCS.
- (2) Assessments need to be made of the RHCS at *state* and *provincial levels* (as appropriate) so that bottlenecks can be identified and addressed. Weaknesses in management systems and poor health professional and administrative skills need to be identified and addressed at all levels. Capacity strengthening needs to receive an important focus to increase the efficiency and effectiveness of the RHC systems.
- (3) *Assessments* of the number and type of human resources needed to adequately implement RHCS needs to be carried out at all levels. Strategies should then be developed to fill the gaps in staffing both in terms of number and quality of human resources.
- (4) The management capacities of all staff working in the supply chain should be regularly assessed using staff evaluation procedures. This will contribute to improved identification of capacity strengthening gaps and motivate staff.
- (5) The cost-benefit of integrating current parallel systems to *distribute* RHC and those related to HIV/AIDS needs to be studied.

HEALTH INFORMATION SYSTEMS AND RHCS

- (1) Health Information Systems need to be strengthened carefully and based on actual field information as much as possible. Health Information Systems should also be integrated to avoid having a multitude of parallel HIS systems that do not provide a good overview of the situation. The HIS should include a sub-component that integrates the monitoring of logistics on RHC throughout the supply chain.
- (2) The *functioning* of Logistics systems for Drug and other RHC should be regularly monitored and evaluated.

PARTNERSHIPS AND INTEGRATION

- (1) The opportunities to develop a Total Market Approach to RHC should be studied in each country.
- (2) The development of public-private partnerships needs to be studied, regulated, and encouraged. An innovation/challenge fund for private sector partnership initiatives should be developed.

TENDERING

- (1) Tendering needs to focus more strongly on quality as opposed to judging primarily based on price and manufacturing capacity. Tenders should include specifications and standards explicitly for all RHC.
- (2) Tendering through on-line procedures should be encouraged since it improves transparency.

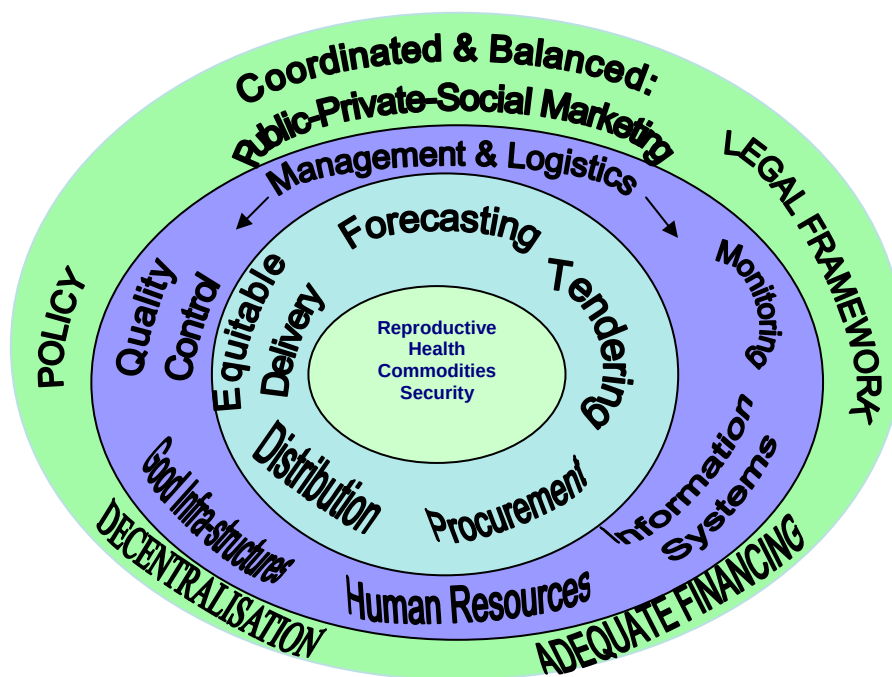
QUALITY CONTROL

- (1) More emphasis needs to be placed on good quality control at all levels of the supply chain. Specific areas of concern to improve drug quality need to be addressed such as improvement in the number and adequacy of testing facilities, increasing the number of drug inspectors, increasing the number of trained staff in general and for specific regulatory areas and creating a drugs data bank.
- (2) *Administrative mechanisms* need to be put in place that will ensure that quality control is transparent, well organised, and that laws and regulations are *applied*.
- (3) International support to address counterfeiting through studies and advocacy should be provided. It is important to ensure quality is maintained and counterfeiting is addressed in the public as well as the private/social marketing sectors.
- (4) Studies need to be carried out to determine the level of diversion of RHC illegally from public to private sector and how to address problems identified.

DISTRIBUTION

- (1) Warehouses need to be properly maintained and have good efficient lay-out inside buildings, equipment for moving commodities, good quality shelves and other storage furniture. Stock keeping in warehouses needs to be computerised and well managed.
- (2) At the delivery level measures need to be developed to ensure that equity in access is assured. This also means addressing such issues as stigma associated with using condoms, access of adolescents to contraceptives, use of ARVs, etc.
- (3) The approach of using community health practitioners as active agents that even provide some diagnostic tests and supply over the counter drugs should be promoted and extended to more areas to allow for greater access to RH services including commodities.

Figure 3
Summary of Key Points



ANNEXES

Annex1/ References

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Annex2/ List of Individuals Interviewed

IN INDIA (OCT–NOV2005)

Name	Position/ Structure	Information Provided	Contact
Dra Paula Quigley	EU H&FWS Program ECTA Team Leader	H&FW sector Investment Program	+91 11 2649 02 04 / 02 27 +91 11 5175 02 90/ 91/ 92 Fax: +91 11 2649 82 34 paula@echfwp.com www.echfwp.com
Dr. Karan B. SINGH	EU H&FWS Program Program Health Adviser	Help in setting the meeting with various partners and introduced the subject on RHCS	Same as Paula +91 9811 0243 30 karan@echfwp.com karansingh56@hotmail.com
J.P. Misra	EU H&FWS Program/ Program Adviser (Specialist on Procurement and supply chain)	Revision of the main steps on procurement procedures in RH and Health supplies in MoHFW and characterization of the system at various levels	Same as Paula and also +91-11-2649 9337 Mishra@echfwp.com
-	EU H&FWS Program/ Program Adviser	Helped in Trying to contact MR BP Sharma in the MoHFW (with no success)	
Dr Rajandra Mishra	Ministry of Development of North Eastern region Join Secretary (ex responsible for the procurement of health supplies including RHC in the MoHFW	Provided support in contacts in Tamil Nadu	Tel- +91 11 2379 48 66 Fax - +91 11 2302 23 07 Rajendra_mishra1@yahoo.com
25-10-05			
Dr. G.V. Ramana	Senior Public Health Specialist – The World Bank Delhi	Overview of Health sector and of health services organization and projects .supported by the W.B. General information on funding in health sector and essential medicines.	91-11-2461 9491 Ext. 117 91-11-5147 9117 (D) Fax +91- 11- 2461 9393 +91- 11- 2462 8074 gramana@worldbank.org
Mr. Mam Chand	Senior Procurement Specialist The World Bank Delhi	Provided more detailed information the procurement process and intervention of Gol, control bodies in the Drug and medical devices arena	+91-11- 4652 2904 Ext. 631 +91-11- 4614 9491/3 Fax: +91 – 11 – 4652 2293 mchand@worldbank.org
Dr. Dinesh Agarwal, M.D.	TSG Manager & Tech. Advisor (Reproductive Health) UNFPA India	Information on the involvement of UNFPA and the Activities on RCH.	+91 – 11- 2464 9247 Ext.301 Fax +91 – 11- 2464 1679 dinesh.agarwal@unfpa.org.in www.unfpa.org.in

Name	Position/ Structure	Information Provided	Contact
Venkatesh Srinivasan	Assistant Representative UNFPA India	Provided copy of the condom committee document	+91 -11- 2465 1801; +91-11- 2462 8877 Ext.372 Fax: +91-11-2462 8078 venkatesh.srinivasan@unfpa.org.in
Sharareh Amirkhalili	Deputy Representative UNFPA India	Provided general information on role of UNFPA in India	+91-11-2464 6782 +91-11-2462 8877 Fax: +91-11-2462 8078 s.amirkhalili@unfpa.org.in
Dr. K. Weerasuriya (Kris) MD	WHO – Regional Adviser Essential Drugs and Medicines Policy	General overview of the Drugs in the Health sector main players and on state level health projects. Arrange meeting with MSO	+91-11-2330 9314 Fax: +91- 11- 2337 0197 Mobile: +91 – 9810 4163 66 weerasuriyak@whosea.org
Dr. Razia Pendse	Reproductive Health Research – SEAR- WHO	Supported and complemented the information	pendser@whosea.org
William Starbuck	Head Contract & procurement Advice Section – DFID India	General information about the operational situation in terms of investment in health and great process limitations	+91-11-2652 9123 Ext. 3359 +91-11-5279 3359(D) Fax: +91- 11-2652 9296 Wi-starbuck@dfid.gov.uk
26-10-05 Chennai			
Mr. T. Rajasekar	Hindustan Latex Limited Head Consumer Business Division	Reception in Chennai by request of Mr. Rajendra	Tel/Fax +91 – 44 -2245 3478/6641/ 2244 1504/1727 Cell: 9444 4076 42 rajasekar@hindlatex.com www.indlatex.com
Mr T. Suresh Kumar	Hindustan Latex Limited Assistant Liaison Officer	Provided support and help to prepare the majority of the meetings	Tel/Fax +91 – 44 -2245 3478/6641/ 2244 1504/1727 Cell: 9444 4507 00 parisu@rediffmail.com
Mr. V. Rao	Deputy Assistant Director General of Government Medical Stores Depot – MoHFW – Directorate General of Health Services	Description of GMSD functioning and stock situation	Tel: 91-44-2561 2922 Fax: 91-44-2561 1459 msdchn@vsnl.in
Dr. Amala Devi J.	Project Officer (MTP – Medical Termination of Pregnancy) – Director of Family Welfare	Activities of FP, and RH and provide manuals of activities of Family Planning, use of contraceptives, norms and procedures of sterilization and list of drugs/supplies used in these procedures	
Dr. Paul Kandasamy	Additional Director of Public Health	Presentation of functioning of health system in TN and organize visits to Health facilities. Mapping of supply chain in the MoHFW	Cell- +91- 98 4043 3520 Office- + 91-44 -2432 15 69 + 91-44 -2433 50 75 Ext-273
Dr. Murugan	Director of Directorate of Public Health and Directorate of Family Welfare	Presentation of the organization of the Directorates of Public Health and Family Welfare	Phone + 91 44 2432 08 02(Direct) + 91 44 2433 50 75 Ext-203 Fax + 91 44 2432 39 42
27-10-05			
Mr. P. Srinivas	Territory Sales Manager - Population Health Services - India (MSI)	Insides of the process activity of SMOs	Cell- 09345103185 09841141431 phsindia@phsindia.org

Name	Position/ Structure	Information Provided	Contact
28-10-05			
Mr. Sanwat Ram	Managing Director; TamilNadu Medical Services Corporation LTD	Overview of the functioning of TNMSC, supply chain, procurement and quality assurance.	+91 – 44 – 2819 1891(D) Fax: +91- 44- 2819 0636 enquiry@tnmsc.com www.tnmsc.com
Mr S. Dinakaran	Broadline – Vice president Systems. Head of team that provides technical support to the DMIS in TNMSC	Complemented some of the information by Mr. Sanwat	+91-44 – 2833 30 83 – 85 Fax: +91-44 – 5204 30 86 Cell:+91 9884 2588 66 s.dinakaran@broadline.net
Dr. M. Arumugam	Managing Director – Broad Line	General information about the company and it's work in other states developing a system similar to the TNMCS	+91-44 – 2833 30 83/ 88 (D) Fax: +91-44 – 5204 30 86 Cell - +91- 98 4003 1000 m.arumugam@broadline.net
29-10-05			
Mr. Joson Meloot	Regional Coordinator PSI TN	Not contacted. Is reference for contact by Derek	+91-44-2499 58 08 jason@psi.org.in
Mr. A. Samson	Counselor – JSI – OPL project Chennai	Described the functioning of the center	+91 -44 – 2535 19 18 Chennai@psi.org.in
Mr. Jacob	Counselor – JSI – OPL project Chennai	Call center operator helped in the description of the center activities	+91 -44 – 2535 19 18 Chennai@psi.org.in
Dr. Padmanaban	Joint Director RCH project director- MoHFW Tamil Nadu	Overview of project - Reproductive and Child Health	+91- 44- 2432 13 10 Fax: +91- 44 – 2433 67 15 Cell: +91- 93 8101 4264 Padmanaban_paddu@yahoo.com
31-10-2005			
B.P Sharma I.A.S	Joint Secretary MoHFW	Presented a global vision of the process of procurement and of the supply chain in the MoHFW	Fax: +91 – 11 2306 1723 bhanushrama@nic.in ; jsbps@nb.nic.in
Gopi Gopalakrishnan	Programme Director Janani - DKT International in India	Provided detailed information about Janine. A SMO working in Bihar including community level , Gave CD	+91- 9431 0093 82 gopi@dknternational.org www.janani.org
Mrs. Mungu Sharma	MoHFW Deputy director supply and procurement		Cell: +91 9810 2816 03
Mr. Mutiakalaivanan I.A.S	Project Director RCH Project – MoHFW Tamil Nadu		+91 - 44 – 2433 6715 Fax: +91- 44 -2432 0563
Mr. Sridharan	Finance Office of the RCH – MoHFW Tamil Nadu		
Mr. G. Namadesikan I.A.S	Finance Secretary – Government of Tamil Nadu		

IN MOZAMBIQUE

Nov-Dec2005

Name	Position/ Structure	Information Provided	Contact
Petra Lantz	UNFPA Representative		lantz@unfpa.org
RATIDZAI NDLOVU	UNFPA Deputy Representative	Participate in first meeting and provided general information of UNFPA in Mozambique	ndlovu@unfpa.org
Dr Maria de Luz V. Vaz	Assistant Representative – RH team leader	Complementary information on RH strategy and programs and UNFPA strategy for next years	Phone : 00 258 214 906 86/ 944 69/ 971 64 Fax: 00 258 214 935 77 mluzvaz@unfpa.uem.moz vaz@unfpa.org
Douglas Hamilton	European Union – European Commission Delegation in Mozambique – Health Specialist	General overview of health system, reproductive health and supply chain	Phone : 00 258 214 810 00 Fax: 00 258 214 918 66 Douglas.hamilton@cec.eu.int
Dr Humberto Cossa	World Bank - Public Health Specialist	General overview of health systems, and health system financing	Mobile: 00 258 823 083 150 Phone: 00 258 214 823 46 hcossa@worldbank.org
Dr. Martinho Djedje	Head Department of Community Health – MOH	General overview of health system and Reproductive Health actions	
Dr. Noémia O. Muissa	Deputy Chief of Pharmaceutical Department	General overview on Drugs and Pharmaceutical Policy and norms	Mobile: 00 258 827 116 560 noemuissa@yahoo.com.br
Dr. Tânia Vuyeya	Technician of Pharmaceutical Department	General overview on Drugs and Pharmaceutical Policy and norms	Mobile: 00 258 824 422 690 Vuyeya78@yahoo.com
Dr. Paulo Nhaducue	Pharmacist and Director of Central Medical Stores (CAMAM)	Informed about the procurement, forecasting, storage and supply chain process related to Medical supplies	Phone : 00 258 213 087 35 Fax : 00 258 213 058 27
Dr. Gertrudes J. Machatine	National Director of Directorate of Planning and cooperation	Information of budgeting and prioritization process on health sector and related to health commodities	Phone : 00 258 213 260 07 Fax : 00 258 213 084 01 mgertrudes@tropical.co.mz
Mr. Brian Smith	PSI – Country Representative	Overview of the PSI interventions and programs	Phone : 00 258 214 850 25 Fax : 00 258 214 850 29 bsmith@psi.org.mz
Dr Boubakar Toure	WHO Representative in Mozambique	Overview of WHO intervention areas in RH and on health sector reform	Phone : 00 258 214 937 32 Fax : 00 258 214 989 98 Cell: 00 258 823 083 070 toureb@mz.afro.who.int
Dr. Alicia Carbonell	WHO – National Program officer - FHP	Information of WHO-Family Health program intervention	Phone : 00 258 214 937 32 Fax : 00 258 214 989 98 Cell: 00 258 823 085 250 carbonella@mz.afro.who.int