Poverty Impact Assessment of

The East African Community
Regional Pharmaceutical Manufacturing Plan of Action (2012-2016)

Final report

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February 2014

Acknowledgement:
The consultants express their thanks to the GIZ sector project "Trade Policy, Trade and Investment Promotion", the EAC-GIZ Regional Programme on Industrialisation, TRIPS and Pharmaceutical Sector Promotion and the EAC Secretariat for having supported and facilitated this poverty impact assessment. The team is very grateful to all the interlocutors who participated in the assessment and communicated valuable information as well as their views on the poverty impacts of the East African Community Regional Pharmaceutical Manufacturing Plan of Action. The final responsibility for the conclusions and the recommendations made in this report lies with the authors.

Content

List of tables

Acronyms

AIDS	Acquired Immunodeficiency Syndrome
API	Active Pharmaceutical Ingredient
BMZ	German Federal Ministry of Economic Cooperation and Development
CSO	Civil Society Organization
EAC	East African Community
FEAPM	Federation of East African Manufacturers
GDC	German Development Cooperation
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit
HDI	Human Development Index
HIV	Human Immunodeficiency Virus
GDP	Gross Domestic Product
GMP	Good Manufacturing Practices
MDG	Millennium Development Goal
OECD	Organisation for Economic Cooperation and Development
PIA	Poverty Impact Assessment
PTB	Physikalisch-Technische Bundesanstalt (German Metrology Institute)
RPMPOA	Regional Pharmaceutical Manufacturing Plan of Action
SME	Small and Medium Enterprises
TB	Tuberculosis
TRIPS	Trade Related Aspects of Intellectual Property Rights
UNIDO	United Nations Industrial Development Organization
WHO	World Health Organization
WTO	World Trade Organization

Executive Summary

The GIZ sector project “Trade Policy, Trade and Investment Promotion”, in cooperation with the EAC-GIZ Regional Programme on “Industrialisation, TRIPS and Pharmaceutical Sector Promotion” and the East African Community (EAC) Secretariat, commissioned this Poverty Impact Assessment (PIA) of the EAC Regional Pharmaceutical Manufacturing Plan of Action (RPMPOA). The overall goal of the RPMPOA is to ensure the availability of and access to affordable, high quality and efficacious essential medicines for the treatment of communicable and non-communicable diseases in the EAC. Its main objective is to improve the capacity of the EAC to sustainably and competitively produce quality essential medicines for local use and export. Implementation began in 2012 and is due to last until 2016.

The PIA was conducted between October and December 2013 in the five EAC Member States by a consultant team, composed of one international and six national experts. The team consulted stakeholders from Government agencies, the private manufacturing sector, civil society organizations, and bilateral and multilateral development agencies. The findings of the country-specific assessments were shared and discussed with the members of the EAC-RPMPOA Project Implementation Steering Committee Meeting in November 2013.

The PIA analytical framework consists of five modules that assess the overall poverty situation, the relevant stakeholders, the transmission channels of a development intervention, the outcome of the intervention regarding the capabilities of the stakeholders and its contribution to the Millennium Development Goals. The PIA team operationalized this framework to adapt it to the context in which the RPMPOA is being implemented.

Promoting the local and regional production of essential medicines has two main poverty-related dimensions: enhancing the access of the poor population to essential medicines and contributing to inclusive economic growth.

The PIA has confirmed that once fully rolled out and implemented, the RPMPOA will have positive impacts on the availability and quality of essential medicines for medicines’ consumers and poor population groups. Strengthening the production capacity of pharmaceutical manufacturers and the regulatory capacity of Governments is essential, but in itself not sufficient to guarantee the access of poor population groups to affordable products. Effective pro-poor health financing strategies are needed to ensure the affordability of essential medicines for poor population groups. Availability of medicines, particularly in remote rural areas, is also highly dependent on cost-effective distribution mechanisms in the public and private health system. In the short-term implementing the RPMPOA will not lead to significant employment effects. In the mid- and long-term, employment opportunities for skilled and unskilled workers will occur, if economies of scales are achieved.

The PIA team has made a number of recommendations to maximize the poverty impacts of the RPMPOA and address risks for its successful implementation. These recommendations relate to

- establishing steering mechanisms for the implementation of the RPMPOA at national level;
- mobilizing internal and external resources for the implementation of the RPMPOA;
- using the potential of civil society organizations and involving them in the implementation of the RPMPOA;
- striking the balance between production costs and technology requirements and
- improving monitoring and closing information gaps.

1 Introduction and background

This report summarizes the findings of an ex-ante Poverty Impact Assessment (PIA) of the East African Community (EAC) Regional Pharmaceutical Manufacturing Plan of Action (RPMPOA).

The RPMPOA was adopted by the EAC Council of Ministers in 2011. Implementation began in 2012 and is due to last until 2016. The overall goal of the RPMPOA is to ensure the availability and access to affordable, high quality and efficacious essential medicines for the treatment of communicable and non-communicable diseases in the EAC. Its main objective is to improve the capacity of the EAC to sustainably and competitively produce quality essential medicines for local use and export. The RPMPOA includes the following six main strategies to reach this objective:

1. Promotion of competitive and efficient regional pharmaceutical production;
2. Facilitation of increased investment in pharmaceutical production regionally;
3. Strengthening of pharmaceutical regulatory capacity in the region;
4. Development of appropriate skills and knowledge on pharmaceutical production in the region
5. Utilization of trade related aspects of intellectual property rights (TRIPS) towards improved local production of pharmaceuticals;
6. Mainstreaming innovation, research and development within regional pharmaceutical industry.

Under these six strategies The RPMPOA includes a range of policy measures and capacity development interventions at regional and national level[1].

The EAC Secretariat is responsible for the overall coordination of the implementation of the RPMPOA. An implementation steering committee, composed by representatives of the EAC Secretariat, Government institutions and pharmaceutical manufacturers associations was established in 2013 to guide and follow-up implementation. Depending on the specific measures, implementation responsibility in the five EAC Member States (Burundi, Kenya, Rwanda, the United Republic of Tanzania and Uganda) lies with Government institutions and/or pharmaceutical companies.

Promoting local and regional pharmaceutical production is part of the approach of the German Federal Ministry of Economic Cooperation and Development (BMZ) to improve both equitable access to essential medicines and sustainable economic development. The EAC-GIZ Regional Programme on Industrialisation, TRIPS and Pharmaceutical Sector Promotion has facilitated the development of the RPMPOA and supports some of the implementation measures. Technical assistance is currently also provided by the German National Metrology Institute (Physikalisch-Technische Bundesanstalt / PTB), the United Nations Industrial Development Organization (UNIDO), the World Bank and the Bill and Melinda Gates Foundation.

Poverty Impact Assessment (PIA) is an approach that was developed in the aftermath of the Paris Declaration on Aid Effectiveness by the Network on Poverty Reduction (POVNET) of the OECD Development Assistance Committee (DAC). PIA aims to help donors and partner countries inform themselves on the expected intended and unintended consequences of their interventions (policies, programs and projects) on the well-being of different social groups, by focusing on poor and vulnerable population groups (OECD, 2007). It therefore serves the purpose of defining more clearly which measures, and with whom, will make a greater contribution to poverty reduction.

[1] For more information on the RPMPOA see EAC (2011).

PIA takes a multi-dimensional approach to poverty, including economic, human, political, socio-cultural and protective aspects. Pro-poor growth is defined as a pattern of growth that enhances the ability of poor women and men to participate in, contribute to and benefit from growth. The multiple poverty dimensions are related to the capabilities of relevant stakeholders to implement a pro-poor agenda, in order to alleviate and overcome poverty. In the context of the RPMPOA a pro-poor agenda has two main dimensions: enhancing the access of the poor population to essential medicines and contributing to inclusive economic growth.

PIA is structured around five analytical modules that assess the overall poverty situation (module 1), the stakeholders (module 2), the transmission channels of the intervention and their results (module 3), the outcome of the intervention on the capabilities of stakeholders (module 4) and the contribution of the intervention to the MDGs and other strategic goals (module 5).

The GIZ sector project “Trade Policy, Trade and Investment Promotion” supports ex-ante poverty impact assessments in trade-related GIZ projects. In cooperation with the EAC-GIZ regional programme and the EAC Secretariat it commissioned this PIA, with the overall aim of assessing the potential poverty and social effects of the implementation of the RPMPOA. The PIA served three purposes: a) To clarify for the EAC and GIZ the key parameters for maximizing the poverty impact of the RPMPOA; b) to provide inputs for a strategic discussion about BMZ and GIZ’s approach towards pharmaceutical sector promotion c) to test the PIA instrument in the context of trade-technical assistance and draw lessons for the organisation and design of potential further assessments of trade-related programmes.

The PIA was conducted by a team of six national consultants and one lead international consultant between October and December 2013. A workshop was held in October 2013 to train national consultants in the PIA methodology, adapt the PIA methodology to the context and design the country-specific assessments. Following the workshop, stakeholders at the regional level were consulted and interviewed by the PIA team.

The country-specific assessments were conducted by the six national consultants in the respective EAC Partner States (Burundi, Kenya, Tanzania, Rwanda and Uganda) in October/November 2013. Stakeholders from Government agencies, the private manufacturing sector and civil society organizations were interviewed. The lead consultant held interviews with program managers of bilateral health programs supported by German Development Cooperation and multilateral agencies (the Global Fund and UNITAID).

The findings of the country-specific assessments were presented at the EAC-RPMPOA Project Implementation Steering Committee Meeting in November 2013. Joint challenges and risks identified in the PIA were discussed in working groups with stakeholders attending the Steering Committee meeting. Recommendations to improve the poverty impact of the RPMPOA were discussed and incorporated into the final report of the Steering Committee Meeting (EAC Secretariat, 2013). In December 2013 the findings were presented to and discussed with the BMZ and the GIZ sector project.

This synthesis report is based on the results of the country-specific assessments (see Annex 1) and on the subsequent discussions with representatives of the RPMPOA Steering Committee, the BMZ and GIZ. The main report focuses on the poverty impacts of the RPMPOA. The findings are presented in chapter 2 to 6 according to the five PIA modules that form the backbone of the PIA methodology. Chapter 6 draws recommendations with regard to maximizing poverty impacts, addressing risks and closing information gaps. Annex 2 describes the applied methodology and process and discusses lessons learned for the design of trade-related programmes and/or EAC regional strategic plans.

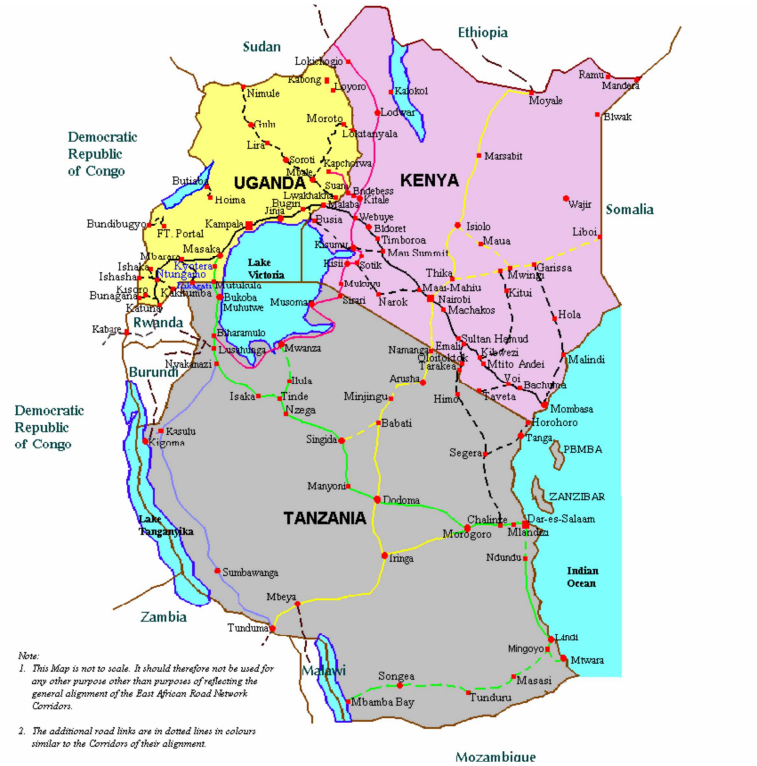
2 Poverty situation and relevance to regional and national strategies

This chapter provides an overview on the context within which the RPMPOA will be implemented in the EAC Member States. It describes the poverty situation, with particular focus on access to essential medicines for the poor. It also gives a brief assessment of how the RPMPOA aligns with relevant regional and national laws, policies and strategies.

2.1 General poverty situation

Overview of the East African Community

The East African Community is composed of five Member States: Burundi, Kenya, Rwanda, the United Republic of Tanzania and Uganda. The region has a total surface area of 1,817.7 thousand square kilometers with Burundi, Tanzania, Uganda, Kenya and Rwanda accounting for 1.5, 51.7, 13.3, 32.1 and 1.5 percent respectively (EAC Secretariat, 2012).



Source: EAC Secretariat (2011)

The region's population was estimated to be 135.4 million in 2011, an increase of 19.7 million people from its 2005 levels. The average population growth rate is 2.6 %, with the lowest rate in Kenya (1.6%) and the highest rate in Uganda (3.2%). The average total fertility rate declined from 5.9 children per woman in 2005 to 5.4 in 2011. Population density varies greatly between countries, with 50.3 persons/square kilometers in Tanzania, 67.6 in Kenya, 164.7 in Uganda, 312.2 in Burundi and 406.3 in Rwanda (EAC Secretariat, 2012).

Poverty situation

Alleviating poverty remains a major development challenge in the EAC. All EAC countries except Kenya are classified as least developed countries. Poverty indicators vary greatly between countries. Despite considerable economic growth in the last decade, across the region a substantial part of the population experiences both income poverty and multiple deprivations with regard to health, education and their standard of living (see table 1).

Table 1: General poverty situation in EAC Member States

Indicators	Burundi	Kenya	Rwanda	Tanzania	Uganda
HDI rank	178/186	145/186	167/186	152/186	161/186
GDP ($ billions)	4.6	62.7	12.0	59.8	41.0
GDP per capita	533	1,507	1,097	1,334	1,188
% Population below $ 1.25 / day	81.3	43.4	63.2	67.9	51.5
% Population below national poverty line	66.9	45.9	44.9	33.4	31.1
% Population in multidimensional poverty	84.5	47.8	69.0	65.6	69.9
% Population in severe poverty	61.9	19.8	34.7	33.4	31.2

Source: UNDP (2013)

In all countries poverty incidence is still much higher in rural than in urban areas. Other major determinants for poverty and vulnerability include gender inequality, age (children and elderly people are most vulnerable), and ill-health. In Burundi and Uganda political conflicts have at times led to the loss of essential assets such as land and livestock and to the deterioration of social services in conflict regions, and have negatively affected the living conditions and health situation of poor population groups.

2.2 Poverty, health and access to medicines

Life expectancy in the East African Region is still low. Significant differences remain between countries with regard to the health status of the population (see table 2).

Table 2: Health Status Indicators in EAC Member States

Indicators	Burundi	Kenya	Rwanda	Tanzania	Uganda
Life expectancy at birth (years)	50.9	57.7	55.7	58.9	54.5
Under five mortality (per 1000 live births)	142	85	91	76	99
Underweight children (% under age five)	28.8	16.1	11.4	15.8	15.9
Maternal mortality ratio (per 100.000 live births)	800	360	340	460	310
HIV prevalence (% of population ages 15 – 49)	1.3	6.1	2.9	5.1	7.2

Source: UNDP (2013); http://data.worldbank.org/indicator, accessed on 05.12.2013

Overall, MDG-related health indicators have substantially improved in the last decade, with faster progress in some countries than in others (see table 3). While Tanzania, Uganda and Rwanda have reduced their under-five mortality rates by over 60%, Burundi and Kenya are still far to reach MDG 4 until 2015. All countries are still off-track with regard to MDG 5, with very high maternal mortality rates in Burundi and high rates in all other countries. The HIV incidence rate has been considerably reduced and remains low in Burundi and Rwanda. Slow progress was achieved in Kenya and Tanzania, and no progress in Uganda, where HIV incidence has increased. In those three countries HIV incidence remains high.

Table 3: Progress of EAC Member States in reaching MDG targets

	MDG Target 4.A Reduce mortality of under-five-year-old by two thirds	**MDG Target 5.A Reduce maternal mortality by three quarters**	**MDG Target 6.A Halt and begin to reverse the spread of HIV/AIDS**
	Under-five mortality rate reduced by	Maternal mortality ratio reduced by	HIV incidence rate reduced by
Burundi	36% between 1990 and 2012 High mortality	27% between 1990 and 2010 Very high mortality	56% between 2001 and 2011 Low incidence
Kenya	26% between 1990 and 2012 Moderate mortality	10% between 1990 and 2012 High mortality	32% between 2001 and 2011 High incidence
Rwanda	64% between 1990 and 2012 Moderate mortality	63% between 1990 and 2010 High mortality	52% between 2001 and 2011 Intermediate incidence
Tanzania	68% between 1990 and 2012 Moderate mortality	47% between 1990 and 2010 High mortality	5% between 2001 and 2011 High incidence
Uganda	61% between 1990 and 2012 Moderate mortality	48% between 1990 and 2010 High mortality	Increased by 22% between 2001 and 2011 High incidence

Source: MDG global data base (country progress snapshots); http://mdgs.un.org/unsd/mdg; accessed on 11.12.2013

In all countries disparities between population groups remain regarding access to health care, with the poorest households less likely than the wealthiest to use health services. Overall, out-of-pocket expenses for health care account for a major part of health expenditure. Nonetheless, access to essential health care has improved through pro-poor health policies providing free health care for vulnerable groups such as pregnant women and children and/or health insurance coverage. Rwanda is the only country with a very high insurance coverage of poor population groups.

Accurate data on the proportion of the population with access to affordable essential drugs in the EAC is not available. Country-specific data indicate that access to essential medicines and health products has substantially improved over the last decade, particularly with regard to antiretroviral drugs and insecticide-treated bed nets. This progress was achieved with ample support from donor-funded programs to address HIV, TB and Malaria, which are major drivers of the high disease burden in East Africa.

As the following table shows, access to antiretroviral therapy has improved in all EAC countries, although with noticeable differences between countries.

Table 4: Population with access to ARV in the EAC Member States

Proportion (%) of population with advanced HIV infection with access to antiretroviral drugs		
Country	**2009**	**2011**
Burundi	35,3	53,5
Kenya	50,8	72,3
Rwanda	76,9	81,7
Tanzania	32,1	39,7
Uganda	41,0	53,9

Source: MDG global data base (country level data); http://mdgs.un.org/unsd/mdg; accessed on 11.01.2014

However, other communicable and non-communicable diseases, such as hypertension, diabetes and cancer, are a rising public health concern in East African countries as well. Treatment for many of these diseases is, if at all available, not affordable for low-income population groups. Unmet need for family planning is still substantial in all countries.

The structure of the pharmaceutical market differs greatly between EAC countries. Kenya has the biggest and most developed pharmaceutical sector with 42 companies listed as pharmaceutical manufacturers. Local production meets 30% of the national demand and 35 – 45% of local products are exported to neighbouring countries. Tanzania has five manufacturing industries, all producing generic pharmaceutical products using imported Active Pharmaceutical Ingredients (API). Local production meets 31% of national demand. Burundi, Rwanda and Uganda are still highly dependent on imports of finished products, which account for more than 90% of the national demand. Uganda has 11 licensed manufacturers; Burundi and Rwanda each have one manufacturing plant. In Rwanda the only pharmaceutical manufacturer is owned by the State (PIA country reports; EAC, 2011).

In all countries, drug distribution is channelled partly by the public sector, partly by the faith-based non-profit and the for-profit private sector. In the public health care system drugs are distributed by semi-autonomous procurement and supply agencies. The public health facilities cover the basic health care needs of poor and vulnerable groups. However, medicines are often not available due to weak supply and distribution chains and frequent stock-outs. Faith-based facilities offer an alternative for the poor and middle-income population but they are also not immune to stock-outs. Poor patients often have no other choice but to purchase medicines in private pharmacies at a higher price. The distribution system in the private sector is highly fragmented. In Kenya for example, a large number of unregistered outlets (estimated at 3.000 to 4.000) exist, which procure drugs from various wholesalers and retailers. The high number of intermediaries involved in the distribution chain has negative impacts on both the prices and the quality of drugs available in the private sector.

The quality of drugs both in the public and private sector is often negatively affected by poor storage facilities and weak capacities of health and pharmaceutical staff to manage and prescribe medicines. Faced with catastrophic expenditures for health care and medicine, the poor often forego treatment or procure substandard products with sub-optimal dosages.

2.3 Alignment of the RPMPOA to the regional legal and policy framework

The RPMPOA is aligned to and part of EAC regional policies and strategies. The RPMPOA fits into the vision of the **EAC treaty**, which emphasizes that EAC policies are people-centered and private sector-led (EAC 2007).

Strengthening the local production of medicines and other pharmaceuticals is one of the planned strategic interventions in the fourth **EAC development strategy** (2012 – 2016).

Promotion of pharmaceutical production is also one of the six strategic pillars of the **EAC Industrialization Strategy**. Pharmaceutical Manufacturing is considered to be one of the five industries with a regional comparative advantage. The main criteria for promoting these industries were the potential for growth and economies of scale, for pooling of resources and collaborative production in the region and the contribution to employment generation in the region (EAC 2012).

The EAC has recently developed a **Regional Intellectual Property Policy** on the Utilization of Public Health-Related WTO-TRIPS Flexibilities. The objective of this policy is to guide the EAC Partner States on how their national intellectual property legislation shall be adjusted in order to enable them to fully utilize the Public Health-related WTO-TRIPS Flexibilities (EAC 2013).

The diverse EAC policies and strategies with regard to pharmaceutical production and access to medicines are coherent. Recently, some tension occurred in the context of the debate on the planned EAC anti-counterfeit bill that undermines key provisions of TRIPS flexibilities.

2.4 Alignment of the RPMPOA to national laws, policies and strategies

Overall, the RPMPOA is also well aligned to the national legal and policy framework of the EAC Member States.

All EAC Member States have ratified the International Covenant on Economic, Social and Cultural Rights, which includes *"the right to the highest attainable standard of physical and mental health (Art. 12)".*The constitutions of all EAC Member States include provisions on the right to health either as a fundamental right of the citizens or as a State obligation. The Kenyan constitution has the most comprehensive provision, by stipulating that every person has the right to health care services, including reproductive health care (Art. 43).

All five EAC Member States have overarching poverty reduction strategies, to which their health and industrial strategies are aligned. These poverty reduction strategies recognize the health sector as crucial for social and economic development. All Member States have a national health sector strategic or development plan that outlines the major objectives and interventions to improve health care and the health status of the population. Most of these plans foresee enhanced accessibility and quality of essential medicines by improving the supply and distribution management in the public health care system, strengthening the regulatory framework, and establishing insurance or exemption mechanisms for poor and vulnerable groups. Not all plans explicitly address promotion of local pharmaceutical production. However, the latter is often taken up either in sub-strategies on the pharmaceutical sector or/and in industrial strategies. The pharmaceutical sector is identified as one of the priority sectors to drive industrialisation in the national industry strategies of Kenya, Rwanda and Uganda.

In all countries the legal and regulatory framework entails rules and guidelines under which the pharmaceutical sector is expected to operate. These provide for the existence of National Medicines Regulatory Authorities as well as registration and quality control procedures.

Coherence of objectives between industrial, trade and health policies is given, as they concur to promote a sector expected to be beneficial both to economic growth and to social development through enhanced access to medicines.

However, tensions remain regarding TRIPS flexibilities, which have not yet all been fully domesticated into national laws on intellectual property (EAC, 2013). The recurrent debate on anti-counterfeit bills that classify genuine generics as "fake" is symptomatic in this regard. In Kenya, the conflicting provisions of the anti-counterfeit act (2008) were declared unconstitutional by the High Court in 2012.

Likewise although investment policies are in place in most countries, there is still a lack of clear incentives to promote local pharmaceutical production.

2.5 PIA matrix 1: Poverty situation and relevance to regional and national strategies

Table 5: Poverty situation and relevance to regional and national strategies

Issue	Observations	Info Sources/ Quality of Info (high, medium, low)
General poverty situation in EAC Member States	All EAC countries except Kenya are classified as least developed countries. The EAC has experienced considerable economic growth in the last decade, but a substantial part of the population still experiences multiple deprivations. In all countries poverty incidence is still much higher in rural than in urban areas. Other major determinants for poverty and vulnerability include gender inequality, age and ill-health.	Information Sources: PIA Country Reports; Poverty Statistics; National Surveys; MDG Reports; Online Data Sources; Regional and National Policy and Strategy Documents; Interviews with Stakeholders. Quality of information: Overall high, insufficient quantitative data on access of population to essential medicines.
Specific observations on poverty, health and access to medicines	Overall, MDG-related health indicators have substantially improved in the last decade, with faster progress in some Member States (e.g. Rwanda) than in others (e.g. Kenya). Access to essential health care has improved through pro-poor health policies but the poorest households are still less likely than the wealthiest to access and use health services. Access to essential medicines and health products has improved over the last decade, particularly with regard to antiretroviral drugs and insecticide-treated bed nets. Treatment for many non-communicable diseases is, if at all available, still not affordable for low-income population groups.	
Existing regional and national strategies relevant to the intervention	• EAC Treaty, EAC Development Strategy, EAC Industrialization Strategy, EAC Regional Intellectual Property Policy on the Utilization of Public Health-Related WTO-TRIPS Flexibilities • National Poverty Reduction Strategies • National Health Policies, Health Sector Strategic Plans and pharmaceutical policies • National Industry and Trade Strategies	
Short description of the intervention and how it aligns to regional and national strategies	The overall goal of the EAC RPMPOA (2012-2016) is to ensure the availability and access to affordable, high quality and efficacious essential medicines for the treatment of communicable and non-communicable diseases in the EAC. Its main objective is to improve the capacity of the EAC to sustainably and competitively produce quality essential medicines for local use and export. To reach this objective, the RPMPOA includes six strategies and a range of policy measures and capacity development interventions at regional and national level. The RPMPOA is well aligned to EAC regional policies and strategies and to the poverty reduction, health and industrial strategies of the Member States.	

3 Stakeholder analysis

This chapter provides an assessment of the key stakeholders who are involved in and/or are expected to benefit from the RPMPOA. Five types of stakeholders were identified and consulted during the PIA:

- EAC Secretariat;
- Government agencies;
- Pharmaceutical manufacturers;
- Medicines' consumers, including poor and vulnerable groups, and civil society organizations representing their interests;
- Development partners.

The assessment defines the role of these stakeholders and identifies the constraints that may hinder them to have a pro-poor agenda or to benefit from and participate in the RPMPOA.

In the context of the RPMPOA a pro-poor agenda has two main dimensions: enhancing the access of the poor population to essential medicines and contributing to inclusive economic growth.

3.1 EAC Secretariat

Overall, the EAC Secretariat sees the RPMPOA as an important tool in promoting regional integration. *"The common citizen will benefit from a harmonized approach to pharmaceutical production." (interview with stakeholder)*

The EAC Secretariat's role is to foster awareness for the RPMPOA, mobilize external resources, coordinate and follow-up the plan's implementation. Two EAC departments were up to now involved in the RPMPOA, the Health Department and the Department for Industrial Development and SME Sector. While the Health Department was substantially involved in the development of the RPMPOA, the Department for Industrial Development and SME Sector has assumed the lead function since the beginning of the implementation phase.

For the EAC Secretariat the major constraints for rolling-out of the RPMPOA were financing and human resource gaps of the respective governments in the EAC Member States. Lack of a common understanding on TRIPS flexibilities in the EAC Secretariat itself, particularly in EAC departments that were not substantially involved in the RPMPOA was perceived by other stakeholders as a constraint for the successful implementation of TRIPS-related measures.

3.2 Government institutions

Health Ministries have a major role to play in ensuring access to quality drugs for poor population groups by overseeing and implementing national health policy and strategies. Their main interest is to provide essential medicines to the population at affordable cost.

In Kenya, Tanzania and Uganda **drug regulatory authorities** are semi-autonomous institutions. In Burundi and Rwanda the regulatory function is currently directly exercised by the Health Ministries. Regulatory authorities have an important role to play in controlling the quality of drugs, be they locally manufactured or imported and distributed in the country. Therefore their major interest is to ensure the protection of medicines' consumers and patients.

The role of **medical procurement and supply agencies** is to ensure an efficient procurement and supply of essential drugs in the public health care system. Therefore their

main interest is to make sure that costs related to the procurement of essential medicines are reduced, in order to increase the volume of available drugs.

The role of **Ministries of Industries and Trade** is to enable a favorable business and investment environment for pharmaceutical production, and to contribute to industrial growth and employment creation. Their interest is to develop a viable national pharmaceutical industry that can supply the national and potentially foreign markets.

The role of **Ministries of Finance and/or of Planning** is to mobilize and ensure sufficient domestic and external resources for the implementation of national strategies and plans. Hence they have to make sure that the RPMOA is aligned to overarching poverty reduction strategies and considered in national budget procedures. They also have an interest in increasing the revenue of Government (e.g. through taxes).

The main role of the **Ministries in charge of East African Affairs** is to coordinate between Governments of the Member States and the EAC Secretariat. Thus, they have an interest in bringing forward EAC policies and strategies, but no direct role with regard to the implementation of the RPMPOA.

In all countries, government institutions were faced with the following **constraints**:

Across the various involved institutions a shortage of human resources coupled with a still weak capacity of staff was seen as an obstacle for government institutions to comply with their mandate. For example, shortage of staff, particularly in countries with numerous outlets for drugs and long territorial borders has hampered the ability of regulatory authorities to control the quality of drugs available on the market. Weak influence on supply and distribution chains also has hindered government agencies to ensure access of poor population groups to essential medicines, particularly in remote rural areas.

In all five Member States a lack of coordination between involved Ministries and government agencies with regard to the implementation of the RPMPOA or of specific measures was observed. Many representatives of relevant Government institutions, other than those who had participated in the development of the plan or in Steering Committee meetings, were still unaware of the RPMPOA. A tendency to work in isolation from each other, without substantial mutual consultation, was noted.

Stakeholders also mentioned conflicting agendas between the interest of the Government to increase its tax revenue, e.g. through value-added taxes (Kenya), and its interest to promote the manufacturing industry.

Last but not least, lack of transparency was seen by many interviewed stakeholders as an obstacle to implement a pro-poor agenda. Stakeholders mentioned that government representatives were at times too sensitive to political pressure and/or prone to corruption.

3.3 Pharmaceutical manufacturers

The PIA focused on those companies that are members of the **Federation of East African Pharmaceutical Manufacturers** (FEAPM).

The **Federation of East African Pharmaceutical Manufacturers** was established in 2011. The founding members of FEAPM were: the Federation of Kenya Pharmaceutical Manufacturers, the Tanzania Pharmaceutical Manufacturers' Association and the Uganda Pharmaceutical Manufacturers' Association. In total, FEAPM now has 30 pharmaceutical manufacturers as its members, 18 from Kenya, 6 from Uganda, 4 from Tanzania and one each from Burundi and Rwanda. FEAPM´s mission is to strengthen local production capacity to meet at least 50% of the EAC's demand for affordable, quality medicines by the year 2020 through:

- world-class production facilities;
- utilization of WTO-TRIPS flexibilities;

- technical personnel training and skills enhancement;
- championing for an enabling operating environment;
- incentivizing of domestic pharmaceutical production;
- promotion of local research and development;
- facilitation of information exchange and transparency.

Sources: FEAPM 2012; www.feapm.com

FEAPM's main role is to serve as a platform for East African companies and represent the interests of pharmaceutical manufacturers at regional level. The main interest of the FEAPM and its member associations is to expand and improve the production capacity of pharmaceutical manufacturers and have an increased share in the East African market.

The FEAPM thus advocates towards Governments and other stakeholders to bring forward and implement incentives for pharmaceutical manufacturers. Based on the so-called Ghana model, the FEAPM has proposed several measures to support the East African Pharmaceutical Sector, including a price preferential margin for locally produced medicines in national tenders, tax incentives and import classification (FEAPM, 2012). In Kenya the FEAPM is involved in a dialogue with the Government to discuss the effect of the value-added tax on local pharmaceutical manufacturers and the prices of drugs.

The role and influence of national **pharmaceutical manufacturers** differs according to the structure of the pharmaceutical industry in the EAC member states and the importance of domestic production and the number of private companies. In general, pharmaceutical companies have an interest to produce essential drugs for the domestic market and in some countries (e.g. Kenya) for export as well. Thus they are interested in having enhanced access to capital and finance, upgrading their infrastructure and improving their capacity to meet good manufacturing practices (GMP) and WHO pre-qualification requirements, in order to gain access to the donor-financed market. Private manufacturers expressed the expectation to receive more support from government agencies through the RPMPOA than they currently have.

Against this background the following constraints were mentioned across countries by pharmaceutical manufacturers:

- Low economies of scale and low returns on investment;
- Limited access to finance and credit as well as high interest rates;
- Frequent power cuts and high electricity tariffs;
- In some countries, small domestic market coupled with difficulties to produce for regional market;
- Shortage of adequately trained pharmaceutical personnel;
- Lack of effective incentives and incoherence of tax measures;
- Regulatory over-enforcement of measures by Government officials, lack of transparency and risk of corruption.

Furthermore, the structures of the FEAPM are still weak and the sustained engagement of all members in terms of regular subscriptions is not yet fully secured. External funding is only provided by the GIZ, thus mobilization of resources is a challenge in the mid-term.

3.4 Medicines' consumers, poor and vulnerable groups and CSOs

Generally, medicines' consumers, whether poor or non-poor, are interested in having access to safe and affordable drugs. Affordability of drugs is a vital concern of poor population groups. Quality of drugs and protection from sub-standard or fake products is a concern for both non-poor and poor medicines' consumers.

Poor population groups in the context of the RPMPOA can be defined as those groups that cannot afford the medicines they require and therefore require pro-poor government interventions, either to provide medicine free of charge or to expand social protection schemes. Beyond this, vulnerable groups in the Member States include: Women and children; elderly people; disabled persons; chronically ill persons; persons living in remote areas; displaced persons and refugees.

The main **constraints** that hinder poor population groups to benefit from the RPMPOA are poverty-related factors, such as low income and purchasing power, remote location, insufficient social protection mechanisms (see section 2.2). Furthermore, many medicines' consumers have a very negative perception of locally manufactured medicines. Irrational prescription and use of drugs is also a constraint.

Civil society organizations (CSO) are commonly considered as representing the interests of poor and vulnerable population groups. This holds true to a great extent, as many CSOs in the region advocate for the health-related rights of vulnerable persons, including access to medicines. They do this either in the context of specific diseases (e.g. access to ARV for people living with HIV) or, much less common, as organizations representing the joint interests of patients and drug consumers (e.g. in Tanzania the Consumer Forum on Access to Medicines).

CSOs thus can play a major role in holding the Government accountable to ensure equitable access to essential medicines. They can push the government to adopt pro-poor health strategies. In some countries, such as Kenya, CSOs have also been actively involved in public health interest litigation. Finally, CSOs can use their communication channels to inform consumers and patients on their rights and responsibilities.

CSOs were faced with the following **constraints**: Up to now CSOs in all Member States are hardly aware of the RPMPOA. The involvement of CSOs in the development and implementation of the RPMPOA has been limited to a few experts, but no broad consultation process has taken place. Government representatives feared that by involving CSOs more substantially this would raise expectations they could not meet. CSOs are also quite diversified, with at times particular agendas. Although some networks exist, it is still a challenge for CSOs to come under a common umbrella and voice joint interests of drugs consumers and vulnerable population groups.

CSOs feared that the RPMPOA may not benefit the poor population groups as it was primarily designed to target manufacturers without including the consumers. Poor communication channels between pharmaceutical companies and CSOs exacerbate this perception at national level. At regional level communication has improved with the establishment of the East African Health Platform in 2012, which is an advocacy forum for private sector organizations, CSOs, faith-based organizations and other interest groups working on health in East Africa (www.eahp.or.tz; interview with stakeholder).

3.5 Role of development partners

German Development Cooperation (GDC) supports **bilateral health programs** in three East African countries, Burundi, Kenya and Tanzania. None of these programs includes the improvement of local drug production and drugs supply management as a major and explicit component. With regard to technical cooperation support to drug management is most likely to be incorporated in the context of quality improvement measures, mainly in the intervention

districts or regions of the above-mentioned programs. Financial Cooperation has mainly financed the procurement of contraceptives through medical supply agencies. Direct synergies and opportunities to support the RPMPOA capacity development measures in the context of these bilateral health programs are thus limited.

However, GDC, both in Kenya and in Tanzania (to a limited extent in Burundi) supports the development of social protection and health insurance mechanisms. This is an important complementary intervention to the RPMPOA as it contributes to improve the affordability of health care to poor population groups.

Development partners at global level have a major role in funding the procurement of essential medicines in developing countries. The **Global Fund to Fight AIDS, Tuberculosis and Malaria** is the main multilateral funder in global health. It channels 82 percent of the international financing for Tuberculosis (TB), 50 percent for malaria, and 21 percent of the international financing against AIDS. Besides vertical disease-based programmes, it also increasingly funds interventions to strengthen health systems.

With regard to access to essential medicines, the Global Fund supports the provision and procurement of essential drugs and health products to address major diseases, such as antiretroviral therapy for people living with HIV, TB treatment and insecticide-treated nets to prevent the transmission of malaria.

The Global Fund is currently undergoing major changes in procurement policy and procedures. In the past, procurement was outsourced, fragmented and often consisted in multiple small orders with slow procedures. Procurement has now been in-sourced, direct relationships and negotiations with manufacturers and the private sector have been established. According to the Global Fund management this will give more flexibility to structure tenders and negotiate agreements in such a way that local manufacturers benefit. One example is the recent contract with the Tanzanian company “A to Z Textile Mills” for the supply of long-lasting insecticide treated bed nets.

Local preference margins in tenders are not compatible with the Global Fund procurement policy (Global Fund, 2012). The Global Fund management´s view is that it would be untenable to reduce the volume of procured drugs through such protective measures and ultimately save less people’s lives for the sake of meeting industrial development objectives. Nevertheless, the Global Fund management recognizes that pharmaceutical manufacturers in East Africa are faced with serious challenges and constraints and need support to enhance their economic viability. The Global Fund procurement department is currently decentralizing and sending more staff to the regional level. The decentralization of Global fund procurement is a mixture of local capacity building and decentralized responsibility, within a global framework. At a global level, the Global Fund alleges to negotiate further upstream with API manufacturers, in order to reduce the price of APIs for local manufacturers.

UNITAID was originally established in 2006 as an “international drug purchasing facility” by the Governments of Brazil, Chile, France, Norway and the United Kingdom. It has evolved to a global health initiative with the aim of using innovative financing to shape drugs markets.

UNITAID’s mission is to contribute to increasing access to treatment for HIV/ AIDS, malaria and TB for people in developing countries by leveraging price reductions of quality drugs and diagnostics, which currently are unaffordable for most developing countries, and to accelerating the pace at which they are made available (UNITAID, 2013).

The main role of UNITAID is to get markets going at the global level. UNITAID has neither the mandate nor, in the view of the UNITAID management, the capacity to support processes at country or regional level. With regard to procurement, UNITAID aims to ensure both high quality and low prices. There is no preference margin for locally produced drugs. UNITAID thus works with big companies that have economies of scale and are able to offer lower prices. Indian companies account for a major part of ARV procurement.

3.6 PIA Matrix 2: Stakeholder analysis

The following tables summarize the main roles and constraints of stakeholders that are involved in the RPMPOA and/or expected to benefit from the intervention. It provides an overview of possible mitigating measures with a focus on those measures that are not yet or not sufficiently foreseen by the RPMPOA.

Table 6: Stakeholder analysis - Government institutions and pharmaceutical manufacturers

Stakeholders	Main roles and tasks	Interests and pro-poor agenda	Aspects that might hinder them to have a pro-poor agenda	Mitigating and/or reinforcing measures	Information source and quality of information
EAC Secretariat	Foster awareness for the RPMPOA, coordination and follow-up of implementation	Promote regional integration to improve living conditions of population in the EAC	• Shortage of human resources and weak capacity of staff to comply with their mandate • Weak influence on distribution chains • Lack of awareness on RPMPOA and lack of coordination between stakeholders • RPMPOA not sufficiently taken into consideration in national budget procedures • Conflicting agendas between interest to promote manufacturing industry and interest to increase government revenue; Lack of transparency,	• Major capacity building measures are already included in the RPMPOA. • Review of tax legislation towards a conducive investment environment is included in the RMPOA. • More awareness-raising on the RPMPOA among Government stakeholders in view of mobilizing domestic resources is needed. • More consultation and communication between involved Government institutions at national level is	<u>Information source:</u> Interviews with EAC Secretariat and with Government institutions in the five EAC Member States <u>Information quality:</u> Overall good but difficulty to reach interview partners in some countries
Ministries of Health	Oversee and implement national health policy and strategies	Ensure access of poor population groups to affordable drugs			
Drug regulatory authorities	Quality control	Protection of drug consumers and patients			
Medical procurement and supply agencies	Efficient procurement and supply of drugs	Procurement of essential medicines at low cost			
Ministries of Trade and Industry	Enable favourable business and investment environment for pharmaceutical production	Develop viable pharmaceutical industry Industrial growth and employment creation			
Ministries of Finance and/or Planning	Mobilize domestic and external resources for implementation of national plans and strategies	Ensure sector plans are aligned to overall poverty reduction strategies Increase revenue of Government			
Ministries in charge of East African Affairs	Coordinate between Member States and EAC	Bring forward EAC policies and strategies			

	Secretariat		sensitivity to political pressure and risk of corruption.	needed. • Develop transparent communication and reporting procedures for implementation of RPMPOA.	
FEAPM	Represent interest of pharmaceutical manufacturers and advocate for conducive investment environment	Expand and improve production capacity of pharmaceutical manufacturers and share in the East African Market	• Weak structures and at times engagement of national companies in FEAPM • Difficulty to mobilize resources	• Increase sensitization towards pharmaceutical companies in the region • Diversify external funding resources	<u>Information source:</u> Interviews and round table discussions with FEAPM members in five EAC Member States; website and report <u>Information quality:</u> overall good, though mainly qualitative.
Pharmaceutical companies	Produce essential drugs for local and regional market	Expand production capacity and gain access to market	• Low economies of scales • Lack of adequately trained staff • Limited access to credits • Frequent power cuts and high electricity tariffs • Incoherence of tax measures • Risk of over-enforcement of measures by Government officials and corruption, therefore mistrust of pharmaceutical companies	• Major capacity building measures are already included in the RPMPOA • Foster communication and dialogue with Government stakeholders through FEAPM and national pharmaceutical associations	

Table 7: Stakeholder analysis – Medicines' consumers, poor and vulnerable population groups and CSOs

Stakeholders	Main roles and tasks	Interests and pro-poor agenda	Aspects that might hinder them to benefit from the intervention	Mitigating and/or reinforcing measures	Information source and quality of information
Medicines' consumers	Use of essential drugs	Access to safe and affordable drugs	Negative perception of locally produced medicines Irrational use of drugs	• Marketing campaigns to promote domestic products are already foreseen by RPMPOA • Potential of CSOs in raising awareness of consumers could be explored and used	Information source: Interviews and round table discussions with CSOs in the five Member States Information quality: overall good, though no direct interviews of focus group discussions with poor and vulnerable groups
Poor population and vulnerable groups	Use of essential drugs	• Access to safe drugs • Affordability of drugs is a vital concern	• Poverty-related factors such as low income and purchasing power • Lack of social protection and health insurance mechanism • Remote location	Beyond the scope of the RPMOA but promotion of social protection mechanisms is part of bilateral health programmes	
Civil Society Organizations	Advocacy for health-related rights of vulnerable groups	Hold Government accountable to ensure equitable access to essential medicines	• Very low awareness of RPMPOA • Insufficient involvement in RPMPOA implementation mechanisms • Weak communication and dialogue with Government stakeholders and pharmaceutical manufacturers • Diverse agendas and difficulty to represent joint interests of consumers and vulnerable population groups	• Involve CSOs in RPMPOA implementation • Foster communication and dialogue mechanism between all stakeholders	

4 Analysis of transmission channels and results

This chapter provides an overview of the links between the RPMPOA and the results for the stakeholders by means of transmission channels. Transmission channels are defined as pathways through which a development intervention – the RPMPOA - generates changes and results. Six transmission channels have been identified in the PIA methodology (Prices, Employment, Transfers, Access, Authority, Assets) and linked in the assessment to the RPMPOA and its strategic objectives[2].

4.1 Prices

The PIA showed a mixed picture with regard to the effects of the RPMPOA on prices. Currently East African Countries import a majority of pharmaceutical products from mainly Asian countries. Local manufacturers face high costs of production which make it difficult for them to compete. On the one hand a major reduction of production costs was expected to occur through RPMPOA measures promoting regional pooled procurement of raw materials and other pharmaceutical production inputs. However, not all pharmaceutical manufacturers have been convinced that pooled procurement is to their advantage. On the other hand strengthening the capacity of pharmaceutical manufacturers to meet WHO-GMP and prequalification standards might, in the short term, increase production costs. Most interviewed pharmaceutical manufacturers appreciated this RPMPOA measure, as it would enable them to gain access to the donor-funded market. However, the process of attaining prequalification requires investments in quality management and equipment. Pharmaceutical manufacturers perceive this process as costly in the short-term. The costs involved would have to be passed on to the consumers which would inevitably raise the prices of medicines. Furthermore, concern was expressed that even if pre-qualification standards were met, products might still not be able to compete on the market with Asian products. In the long term, assuming successful economies of scale, prequalification was perceived as beneficial.

High or increasing energy costs and prices for APIs were seen as a factor that might affect production prices negatively. Economies of scale were thus considered to be the key element in reducing production costs and ultimately prices of locally manufactured products. In an increasingly competitive sector, local manufacturers are poised to lower the costs of their products. In the long run the implementation of the RPMPOA would therefore reduce the price of pharmaceutical products thanks to increased local pharmaceutical production capacity and more companies entering the sector.

Increasing productivity and competitiveness in the pharmaceutical sector will also have a positive impact on production cost. The extent to which these reductions will be passed on to the consumer is still unclear. Currently the prices of drugs available on the private market are still largely determined by the retail and distribution system, long transport distances and the high number of intermediaries. Increasing productivity and capacity might therefore not automatically lead to price reductions for consumers, if the supply and distribution chain is not also improved.

The RPMPOA will neither have a direct effect on the wages of employees in the pharmaceutical sector nor on their job security. Indirect positive effects may occur through enhanced skills thanks to training opportunities. Indirect negative effects may occur through rationalization of labor in the course of technology improvements.

[2] For more information on transmission channels and how they were operationalized in this PIA see annex 2 and 3.

4.2 Employment

Although most interviewed stakeholders assumed the RPMPOA would contribute to creating employment, information gaps remain as to the extent and the nature of these employment effects. A value chain analysis of the regional pharmaceutical sector is planned as part of the RPMPOA activities, but has not yet been conducted. Pharmaceutical manufacturing in the East African region currently offers limited employment opportunities, particularly in countries such as Burundi and Rwanda with only one production plant.

Limited positive employment effects were expected in the public sector, primarily through the creation (in Burundi and Rwanda) and/or expansion of regulatory institutions. In the private formal sector, a significant growth of the pharmaceutical manufacturing sector is likely to increase employment opportunities for skilled labor. The RPMPOA measure to develop appropriate skills and knowledge on pharmaceutical production in the region will have a positive effect on the availability of highly skilled local staff, which is currently a constraint for pharmaceutical companies. A positive effect of the implementation of the gender-based human resource development strategy foreseen by the RPMPOA would be to increase the number of skilled female staff employed by pharmaceutical manufacturing companies. However, investments in technology and automation might also lead to automation and rationalization of human resources. At the end, direct employment effects at this stage of the value chain might only happen, if the number of pharmaceutical manufacturers substantially increases.

Most stakeholders concurred in the view that job creation for poor and low-skilled population groups would not primarily occur in manufacturing but at other stages of the value chain. Opportunities were seen in the cultivation of locally sourced inputs such as medicinal herbs The RPMPOA takes up this issue on a pilot basis in the context of promoting innovation and research. However, significant employment effects are only likely to occur in the long term. Another major opportunity for employment of low-skilled workers was seen in the packaging and distribution of essential medicines, which in turn presumes a substantial increase in the volume of locally produced drugs.

4.3 Transfers

The RPMPOA foresees as one measure for the facilitation of investment in pharmaceutical production the review of current tax regimes. It does not include any explicit direct taxation or transfer measure. Nevertheless, improving the taxation regime in the East African region is considered by most stakeholders as a key measure in the context of promoting a conducive business environment for pharmaceutical manufacturers. Stakeholders concur in their view that the current taxation and trade regime is in general not favorable to pharmaceutical manufacturers, either because of high income tax rates (Burundi) or because it favors finished products to the detriment of raw materials (Kenya). In Kenya, for example, recent amendments of the VAT act, which have led to an increase of value-added taxes on all products, including raw materials, packaging materials and spare parts for machineries were mentioned as price drivers by local manufacturers.

Stakeholders however have diverging views with regard to the effect of tax incentives and protective measures such as price preferences in national tenders and import classification.

The FEAPM is strongly advocating for a preferential margin of 20% in national tenders, tax incentives and import classification, including banning and taxing of finished products that can be produced locally. Referring to the experience made in Ghana, the FEAPM argues that implementation of these measures will boost local pharmaceutical production, and reduce both the reliance on imports and the prevalence of counterfeit or sub-standard products in the country. Other stakeholders argue that evidence for the success of the Ghana model is weak. Protective and preferential measures might help companies to access the market, but

at the same time distort competition and prices. A direct causal relationship between such measures and a reduced prevalence of counterfeits on the market is also hard to establish.

Another argument against preference margins is that, at least in the short term, such measures would have a negative impact on the availability of drugs in the public health care system. If governments, with limited budget resources, would consistently apply a preferential margin in their tenders, this would imply that with the same amount of resources fewer drugs could be bought, thus negatively affecting the availability of drugs in the public health system and the access of poor population groups to essential medicines. Obviously, there is thus a trade-off between promoting local production of drugs and immediate public health priorities.

More generally, substantial growth of the pharmaceutical sector in the region would indirectly lead to increased tax revenue for the national authorities, mainly through income and pay-as-you-earn taxation. The positive effect of these taxes on public transfers to poor population groups was perceived as marginal.

4.4 Access

Ultimately, all strategic objectives of the RPMPOA are expected to contribute to the overall goal of ensuring access of the population to affordable and high quality essential medicines in the EAC. Access to medicines includes the dimensions of availability, affordability and quality of essential drugs, which are also key elements of the right to the highest attainable standard of health. The RPMPOA will have a positive effect on two dimensions: availability and quality.

Assuming that the RPMPOA is successfully implemented, the share of local manufacturers in the pharmaceutical sector of the EAC will increase, which will have a positive impact on the availability of essential medicines in the region and reduce the risk of over-reliance on imports. Access of local and regional manufacturers to the market will ultimately depend on their capacity to produce a larger volume of drugs at a lower cost (economies of scale) and improve productivity. Price preferences in national or regional tenders would certainly increase their access to the public health market. However, in the short-term this will most probably come at the expense of the availability of essential drugs for poor population groups (see 4.3).

Availability of essential medicines for the poor population groups will not only depend on the volume of local production, but also on a cost-effective supply and distribution chains in the public and private sector. Improving the affordability of drugs for poor population groups and thus their availability will also depend on the effectiveness of pro-poor health financing and social protection strategies of the EAC Member States. These are beyond the influence of the RPMPOA.

A major transmission channel of the RPMPOA is to improve the quality of both locally produced and imported drugs. Enhanced quality will be achieved on the one hand through measures that strengthen the capacity of manufacturers to meet GMP standards and develop skills and knowledge for pharmaceutical production. On the other hand positive effects will be triggered by interventions included under the third strategy of the RPMPOA (“Strengthening regulatory capacity in the region”), as national regulatory authorities will be better equipped to monitor and control the quality of drugs available on the local market.

The RPMPOA foresees to develop and implement a marketing campaign to promote domestic pharmaceutical products. This would have a positive impact on access to information by consumers, who often perceive locally produced drugs as sub-standard products. However, there is a risk that the information does not reach poor and vulnerable population groups, if it is not provided in adequate formats.

4.5 Authority

The RPMPOA includes a range of measures to facilitate the domestication of TRIPS flexibilities within national laws and to harmonize drug regulations. These measures will have a positive impact on the legal and regulatory framework in the EAC Member States. Conflicting trends in laws on intellectual property rights might create a risk for the successful implementation of TRIPS-flexibilities. Overregulation and overbearing stances by regulatory authorities might also discourage private manufacturers from voluntarily complying with the laws. Hence, there is a risk of manufacturers taking shortcuts and ultimately compromising the quality of products.

Partnerships and communication between stakeholders are channeled in the RPMPOA through a range of interventions that aim at enhancing regional collaboration. These include the establishment of the FEAPM, promotion of pooled procurement, harmonization of laws and regulation, as well as the creation of a regional pharmaceutical innovation fund. Promoting networks and regional collaboration is expected to have positive effects on production costs and volume, and speed up the development of a policy and legal framework conducive to local pharmaceutical production.

The following risks might impede effective participation and collaboration of stakeholders:

While a dynamic at regional level has been initiated by the establishment of the Steering Committee, at national level formal steering structures and communication and monitoring mechanisms have not yet been established. In Kenya, Government agencies and pharmaceutical companies have been involved in dialogues to discuss challenges that pharmaceutical manufacturers are facing. In some other countries national stakeholders have up to now only met at scheduled regional steering committee meetings.

Involvement of and communication with CSOs was not included in the design of the RPMPOA. Almost all interviewed CSOs across countries were not yet aware of the RPMPOA. Lack of awareness of the RPMPOA might lead to a reluctance of CSOs to support the RPMPOA.

Stakeholders also reported that successful coordination and implementation of the RPMPOA interventions at national level will ultimately depend on political commitment and buy-in from the highest level of Government. Despite alignment of the RPMPOA to national strategies and plans, the extent to which the RPMPOA would be incorporated into national budgeting processes was still unclear.

Finally, stakeholders expressed the view that particular interests both on the side of pharmaceutical manufacturers and of Government institutions might predominate, thus slowing down regional integration. *“We need to look at ourselves as East Africans and not as nationals of one specific country.” (Interview with stakeholder)*

4.6 Assets

The impacts of the RPMPOA on assets are mainly indirect effects, resulting from a combination of the other transmission channels.

Promoting investment in the pharmaceutical manufacturing sector through the RPMPOA will have positive effects on physical assets, as pharmaceutical manufacturers will invest in infrastructure either through the construction of new plants or through upgrading of existing facilities. It will also have a positive effect on the skills and knowledge (human asset) of both pharmaceutical manufacturers and employees of government institutions.

Identifying long term financing options for pharmaceutical manufacturers in the EAC is one of the planned RPMPOA activities to facilitate investment. In the mid-term, this might lead to better access of pharmaceutical manufacturers to credit (financial assets), which is currently a major constraint faced by manufacturers, and boost pharmaceutical production.

Precise information on the potential environmental impacts (natural asset) of the RPMPOA and the subsequent growth of the pharmaceutical manufacturing sector is not available. Stakeholders expressed mixed views with regard to the extent to which the growth of the pharmaceutical manufacturing sector would affect the environment. Some stakeholders mentioned that an increase in chemical waste would definitely have a negative impact, particularly in view of the lack of effective environmental regulations and waste disposal mechanisms. Likewise there might be a risk of inefficiency in the use of natural resources (e.g. water) for pharmaceutical manufacturing. Others were of the opinion that the chemical waste generated by pharmaceutical companies was minimal in comparison to other sectors and that control of potential negative effects was already covered by existing regulations. Finally, a few stakeholders also expected positive effects through the increased utilization of by-products of the gas and petroleum industry by pharmaceutical manufacturers, which was also expected to grow in coming years.

Indirect positive effects on the health status (human asset) of the population will occur if access of consumers and poor population groups to essential medicines, including their rational use, is substantially improved. In turn, better health is one factor that might lead to higher productivity and contribute to sustainable livelihoods.

4.7 PIA Matrix 3: Transmission channels used and overall results by channel

The following table summarizes the transmission channels used by the RPMPOA, the changes and results expected and the respective risks. The short term column (up to 2016) covers the implementation period of the RPMPOA. The medium term column covers the period up to the end of the TRIPS flexibilities (2021).

Table 8: Transmission channels used and overall results by channel

Transmission Channels		**Results by Transmission Channel**				**Quality of information and gaps**
		Details of the change and results generated by the intervention	**Short Term (+/-) up to 2016**	**Medium Term (+/-) up to 2021**	**risks that the results will not be achieved**	
(1)		(2)	(3)	(4)	(5)	(6)
Prices	Production	Decrease of production costs through pooled procurement, but short-term increase through compliance with GMP	-	+	Not all companies convinced of advantages of pooled procurement Increase in energy costs and API Economies of scale not achieved	Qualitative information based on interviews, no quantitative data available
	Consumption	Decrease of prices for	0	+	Prices still largely	

		domestic products through increased competition between manufacturers			determined by retail system	
	Wages	Indirect effects through skills development	+	+	Rationalization of human resources	
Employ-ment	Public formal	Limited effects through creation or expansion of regulatory institutions	+	+		Qualitative information based on interviews, no quantitative data available Value-chain analysis not yet conducted
	Private formal	Employment opportunities for skilled staff through expansion of manufacturing sector	+	++	Rationalization of human resources due to technology requirements	
	Informal	Very limited direct effects on job creation in manufacturing of products for poor and unskilled labour Indirect effects at other stages of the value chain	0	+	Economies of scale not achieved	
Transfers	Taxes	Review of taxation regime can lead to conducive business environment	++	++		Qualitative information based on interviews, no quantitative data available; More evidence on Ghana Model advocated by FEAPM is needed
		Tax incentives and preferential measures may boost domestic production but have negative effect on availability of drugs for poor population groups	+/- Trade-off	+/- Trade-off		
	Public		0	0		

	welfare/ subsidy					
	Private remittances		0	0		
Access	Availability	Increased availability of locally produced drugs in health care systems through increased production	+	++	Ineffective supply and distribution chain	Qualitative information based on interviews, no quantitative data available
	Affordability	No direct effect on affordability of drugs, which mainly depends on poverty-related factors (also see “Prices” above)	0	0	Might be further compromised by insufficient social protection mechanisms.	
	Quality	Quality of drugs improved through capacity development of regulatory authorities and manufacturing companies	++	++		
	Information	Marketing campaigns can improve access of consumers to information on locally produced drugs	+	+	Information might not reach poor population groups, if not provided in adequate formats	
Authority	Enactment and implementation of laws	Positive effects on legal framework through domestication of TRIPS flexibilities and harmonization of drug regulations	+	+	Conflicting trends in laws on IPR; Overregulation by authorities and lack of compliance by private companies	Qualitative information based on interviews
	Participation and dialogue between stakeholders	Dialogue between stakeholders improved through steering committee and dynamic at	+	+	Insufficient steering and dialogue mechanisms at national level. No involvement of	

		regional level			CSOs.	
Assets	Physical	Construction or expansion of production plants	+	+		Qualitative information based on interviews; More information on environmental impacts needed
	Natural	Very mixed effects	+/-	+/-	Inefficiency in use of natural resources Weak environmental regulations	
	Human	Indirect effects on health of population through enhanced access to essential medicines	0	+		
	Social		0	0		
	Financial	Better access to credits	0	+		

KEY	Strength/direction impact	**+ +**	**+**	**0**	**-**	**- -**
		very positive	*Positive*	*not relevant or significant*	*negative*	*very negative*

5 Assessment of stakeholder capabilities

This chapter provides an assessment of the outcomes of the RPMPOA on the capabilities of stakeholders to alleviate, escape or overcome poverty. There are five types of capabilities defined according to the OECD/DAC capability framework: Economic, Human, Political, Socio-cultural and Protective-security.

5.1 Capabilities of medicines' consumers, poor and vulnerable groups and CSOs

The RPMPOA does not target medicines' consumers directly. Hence, outcomes on the capabilities of medicines' consumers and poor and vulnerable groups, the ultimate beneficiaries of the RPMPOA, are not likely to happen in the short-term. In the medium and long-term, the RPMPOA is likely to have a positive impact on the health of medicines' consumers and poor and vulnerable groups by increasing both the availability and quality of essential medicines. Sensitization of medical practitioners, pharmacists and medicines' consumers on the rational use of medicines would however be crucial to maximize these benefits. Improved access to health care might in turn enhance the ability of poor population groups, particularly chronically ill persons, to cope with illnesses, withstand external shocks (protective-security capability) and pursue sustainable livelihoods in the long term.

Civil society organizations can play a major role in advocating for changes in laws and regulations or mobilizing public support for local industry (political capability). They can also be instrumental in informing medicines' consumers on the use of drugs as well as on their rights and duties. These potential capabilities however have not yet been taken into consideration by the RPMPOA.

5.2 Capabilities of Government institutions and agencies

Government stakeholders are a major target group of the capacity development interventions included in the RPMPOA. The RPMPOA will have a direct and strong impact on the political capability of Government institutions, by enhancing their capacity to strengthen and harmonize laws, regulations and surveillance mechanisms on essential medicines. It also directly affects the skills and knowledge of Government stakeholders (human capability) through training activities. If substantial pharmaceutical growth in the region is achieved, reliance on imports and aid dependency will be ultimately reduced. This would have a positive outcome on the protective-security capability of Governments, as they would be less exposed to vagaries in the global pharmaceutical market.

An essential requirement for these capabilities to be effectively used and expanded is political good will and the commitment of national Governments to allocate human and financial resources to implement the RPMPOA.

5.3 Capabilities of pharmaceutical manufacturers

Pharmaceutical manufacturers are also a major target group of the capacity development interventions included in the RPMPOA. Assuming successful implementation the RPMPOA will mainly have a positive outcome on their economic, human and political capabilities.

Economic capabilities will be enhanced through economies of scale, higher returns on investments and a greater share of the pharmaceutical market. Skills and knowledge of pharmaceutical manufacturers (human capability) will be improved through training activities.

The establishment of the FEAPM will increase the collective bargaining power of pharmaceutical manufacturers (political capability). It will have a positive impact on their capacity to advocate for law reform and push the Government to promote a conducive business and investment environment. Participation in FEAPM could also give pharmaceutical manufacturers more weight to protect themselves against unfair government decisions and interference.

Sustainable financing mechanisms for the FEAPM and its national member associations are required in order to make sure that these capabilities can be used and expanded in the mid-term and long-term.

5.4 PIA Matrix 4: Assessment of outcomes on stakeholders' capabilities

Table 9: Outcomes on stakeholders' capabilities

	Outcomes in terms of capabilities										Quality of information and gaps
	Economic (+/-)		Human (+/-)		Political (+/-)		Socio-cultural (+/-)		Protective Security (+/-)		
Stakeholder	short term	medium term	short term	medium term	short term	medium term	short term	medium term	short term	medium term	
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Government institutions and agencies	**0**	**0**	**++**	**++**	**++**	**++**	**0**	**0**	**0**	**+**	Qualitative information based on interviews; no direct interviews with poor population groups
Pharmaceutical manufacturers	**+**	**++**	**++**	**++**	**+**	**+**	**0**	**0**	**+**	**+**	
Medicines' consumers	**0**	**0**	**+**	**++**	**0**	**0**	**0**	**0**	**0**	**+**	
Poor and vulnerable groups	**0**	**0**	**+**	**++**	**0**	**0**	**0**	**0**	**0**	**+**	
CSOs	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	

KEY	Strength/direction impact	+ +	+	0	-	- -
		very positive	*Positive*	*not relevant or significant*	*negative*	*very negative*

6 Contribution to the achievement of the MDGs

This chapter provides an assessment of the contribution of the RPMPOA to the achievement of the Millennium Development Goals (MDGs) in the EAC.

6.1 Access to medicines in the MDGs

Enhanced access to medicines is part of MDG 8 (Develop a global partnership for development) and of the health-related MDGs 4 (Reduce child mortality), 5 (Improve maternal health) and 6 (Combat HIV/AIDS, malaria and other diseases). Access to essential medicines is explicitly mentioned under MDG 8. It is also directly or indirectly included in the health-related MDGs with a focus on access to vaccines, contraceptives, ARVs, and drugs for the treatment of malaria and TB (see table 8).

Table 10: Access to medicines in the MDGs

MDG Goals	Indicators related to access to essential medicines
MDG 4: Reduce child mortality	4.3 Proportion of one-year-old children immunized against measles
MDG 5: Improve maternal health	5.6 Unmet need for family planning
MDG 6: Combat HIV/AIDS, malaria and other diseases	6.5 Proportion of population with advanced HIV infection with access to antiretroviral drugs

	6.8 Proportion of children under 5 with fever who are treated with appropriate anti-malaria drugs 6.10 Proportion of tuberculosis cases detected and cured under directly observed treatment short course
MDG 8: Develop a global partnership for development	8.13 Proportion of population with access to affordable drugs on a sustainable basis

MDG 8 aims at developing a global partnership for development. It therefore contains a number of commitments of donor countries on increasing aid, market access for the poorest countries, technology transfers, taking particular account of the needs of small island states and landlocked countries and access to essential drugs.

Target 8.E. is to provide, in cooperation with pharmaceutical companies, access to affordable essential drugs in developing countries. It was originally intended to track the contribution of pharmaceutical, particularly multinational companies to increase access to affordable medicines in developing countries, and evolved to address several inter-linked commitments of the international development community such as:

- International initiatives to support the financing of essential medicines, e.g. the Global Fund;
- Promoting the utilization of TRIPS flexibilities by developing countries;
- Narrowing the so-called 10/90 gap through higher investments in research and development of drugs to treat neglected diseases.

The respective indicator 8.13 measures the proportion of the population in each country with access to affordable essential drugs on a sustainable basis. However, data is scarce and regional and country-specific reporting on this indicator is not available.

Despite the existence of major funding initiatives, the last UN report on MDG 8 concludes that little progress can be seen in access to essential medicines. Promoting local production of medicines and increased use of TRIPS flexibilities are thus seen as an important avenue to narrow the gap (UN MDG Gap Task Force, 2012).

Access to medicines is also an integral part of the right to the highest attainable standard of health. Hence, the UN Special Rapporteurs on the right to health have repeatedly taken a stance in the debate on TRIPS and highlighted the obligations of States and the responsibility of pharmaceutical companies to enhance the access of the population in developing countries to essential medicines (UN, 2008 and UN, 2011).

6.2 Contribution of the RPMPOA to MDG 8

The overall goal of the RPMPOA is nearly identical to MDG target 8.E, with a focus on the EAC. The link between the RPMPOA goal and MDG 8 thus mainly rests on the production capacity of East African pharmaceutical manufacturers, their ability to access markets and the proper use of TRIPS flexibilities by EAC Member States.

A significant contribution in quantitative terms (volume of essential drugs) is likely to occur, if economies of scale and substantial growth of the pharmaceutical sector in the East African region are achieved. In qualitative terms the RPMPOA is an important contribution to the MDG 8 as it incorporates many of the above-mentioned commitments. If successfully implemented, the RPMPOA will foster regional and international partnerships and technology transfer. It will ultimately strengthen the position of the EAC as a regional market for locally produced pharmaceutical products. In combination with pro-poor health and social protection strategies it will contribute to enhancing access to affordable essential medicines for poor population groups.

The following risks might jeopardize the achievement of this goal:

- Increase of TRIPS-plus provisions in bilateral and regional free-trade agreements, thus hampering the use of TRIPS flexibilities;
- Low commitment of companies to reduce prices of API, invest in research and development for neglected diseases or in joint ventures with East African companies.

In order to boost regional production and address the above-mentioned risks both strong ownership of EAC member states as well as support from bilateral and multinational donors is essential.

6.3 Contribution of the RPMPOA to health-related and other MDGs

Health-related MDGs

All impacts of the RPMPOA on the health-related MDGs 4, 5 and 6 eventually derive from the achievement of MDG target 8.E. The risks are therefore basically the same.

In the medium term the capacity of local manufacturers to contribute to the health-related MDGs will ultimately depend on their ability to meet WHO prequalification standards, which apply to most of the medicines for priority diseases and reproductive health targeted by MDGs 4, 5 and 6. In the short-term, contribution to the production of other essential medicines, which are also required for the treatment of childhood diseases or maternal health conditions, might be more substantial.

Other MDGs

The contribution of the RPMPOA to other MDGs is either marginal or of a very indirect nature.

A positive impact on MDG 1 (Eradicate extreme poverty and hunger) might occur in the long-term through employment effects, provided the growth of the pharmaceutical sector leads to job creation in the production of raw material and distribution of medicines. Better health might also lead to higher productivity and ultimately to improved livelihoods.

An indirect positive impact on MDG 2 (Achieve universal primary education) might occur, if increased access to health care and treatment reduces school drop-outs.

Positive impacts on MDG 3 (Promote gender equality and empower women) will indirectly derive form the achievement of MDG 5 and the increased access of women to sexual and reproductive health services, including contraceptives.

The RPMPOA does not contribute to MDG 7 (ensure environmental sustainability). Indirectly there might be negative impacts, if the environmental risks of pharmaceutical industrial growth (e.g. inefficient use of water resources) are not adequately taken into consideration.

6.4 PIA Matrix 5: Contribution to the achievement of the MDGs

Table 11: Contribution to the achievement of the MDGs

Millennium Development Goals	Contribution			Quality of information and gaps
	Short term Up to 2015 (+/-)	Medium term Post-MDG (+/-)	Details & risks	
(1)	(2)	(3)	(4)	(5)
MDG 1: **Eradicate extreme poverty and hunger**	**0**	+	Employment creation through growth of pharmaceutical sector Indirect effect: Improved productivity and livelihoods through better health	Information based on reports and Interviews Accurate information on indicator 8.13 is not available
MDG 2: **Achieve universal primary education**	**0**	+	Marginal effect: reduction of school drop-outs due to illness through enhanced access to medicines	
MDG 3: **Promote gender equality and empower women**	**0**	+	Enhanced access of women to contraceptives	
MDG 4: **Reduce child mortality**	**+**	++	Enhanced access to vaccines and medicines to treat childhood diseases	
MDG 5: **Improve maternal health**	**+**	++	Enhanced access to contraceptives and other medicines	
MDG 6: **Combat HIV/AIDS, malaria and other diseases**	**+**	++	Enhanced access to ARVs and drugs to treat malaria and TB	
MDG 7: **Ensure environmental sustainability**	**0**	-	Possible negative impacts if environmental risks of industrial growth are not taken into consideration	
MDG 8: **Develop a global partnership for development** Target 8.E: In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries	**+**	++	Increase of regional collaboration and technology transfer Stronger position of EAC as regional market for locally produced pharmaceutical products Economies of scale and growth of pharmaceutical	

			sector in EAC contributes to enhanced access to medicines Risks: Increase of TRIPS plus provisions Low commitment of companies to reduce prices of API, invest in research for neglected diseases or in joint ventures with East African companies	

KEY	Strength/direction impact	+ +	+	0	-	- -
		very positive	Positive	not significant	negative	very negative

7 Conclusions and recommendations

7.1 Major poverty impacts and limitations of the RPMPOA

Once fully rolled out and implemented the RPMPOA will have positive impacts on the availability and quality of essential medicines for medicines' consumers and poor population groups. The most important transmission channels directly used by the RPMPOA are **prices**, in particular with regard to production; **authority**, in particular with regard to the harmonization and enforcement of laws and regulations and **access**, with regard to improving both the availability and quality of locally produced drugs.

Strengthening the production capacity of pharmaceutical manufacturers and the regulatory capacity of Governments is essential, but in itself not sufficient to guarantee the access of poor population groups to affordable products. Effective pro-poor health financing strategies are needed to ensure the affordability of essential medicines for poor population groups. Availability of medicines, particularly in remote rural areas, is also highly dependent on effective distribution mechanisms in the public and private health system.

Major constraints of Government agencies and pharmaceutical manufacturers to implement a pro-poor agenda are already addressed by the RPMPOA. Constraints of medicines' consumers and poor population groups and CSOs are only partly addressed. Some constraints, e.g. the low purchasing power of poor population groups, are beyond the scope of the RPMPOA. Other constraints should be taken into consideration and the RPMPOA measures reinforced accordingly.

7.2 Recommendations to maximize the poverty impacts of the RPMPOA

In order to boost regional production and achieve significant growth of the pharmaceutical sector, strong ownership of EAC member states as well as support from bilateral and multinational donors is essential.

The EAC Secretariat and all involved stakeholders should therefore undertake more activities for awareness creation on the RPMPOA. The EAC Member States should establish national

steering mechanisms for the EAC RPMPOA. Existing platforms and networks should be used for stakeholder engagement with clear accountability, communication and reporting mechanisms.

As the RPMPOA is fully aligned with regional and national strategies, the EAC Member States should allocate more human and financial resources for its implementation and take affirmative action to mobilize external support. Bilateral health programs supported by the GDC offer very limited opportunities for direct support to the implementation of the RPMPOA. Hence, implementing actors should explore more avenues for external support from other development partners. In view of current changes in the Global Fund Procurement Policy, both Government institutions and the FEAPM should engage in a dialogue with the Global Fund procurement department and discuss opportunities for capacity development support.

Striking the balance between bringing down production costs and meeting technology and quality requirements is in the short and medium term a major challenge for pharmaceutical manufacturers. Hence, members of the Steering Committee recommended that the EAC Secretariat should promote the idea of developing a broad-based regional prequalification scheme that not only meets high quality standards but also reflects the region's technological achievements and procurement challenges.

The FEAPM should intensify sensitization activities towards pharmaceutical companies on the advantages of regional cooperation, including pooled procurement, and of membership in a pharmaceutical association. It should also strive to increase internal resources and diversify its external funding.

The potential of CSOs to support the implementation of the RPMPOA, advocate for changes in laws and policies and sensitize poor and vulnerable groups on locally produced products and rational use of drugs should be better used. Hence, CSOs or networks representing common interests of medicines' consumers and vulnerable groups should be included in national and regional steering structures, at least with an observer status.

Promoting pro-poor health financing and social protection strategies to ensure affordability of essential medicines is beyond the scope of the RPMPOA and more generally of approaches to promote the pharmaceutical sector. Health financing and social protection is however, very often an integral part of GDC bilateral health programs. The results chain developed on the GDC approach to promote local pharmaceutical production in developing countries should therefore illustrate this link.

In view of the already wide scope of the RPMPOA it seems unrealistic at the present stage to add a new strategy aimed at improving the distribution chain in the pharmaceutical sector. However, the EAC Secretariat, in cooperation with other stakeholders should undertake more awareness creation on the importance of strengthening the distribution chain to ensure equitable access to medicines, and consider this dimension when reviewing relevant sector strategies.

7.3 Recommendations to improve monitoring and close information gaps

The RPMPOA implementation framework includes key milestones for the implementation and output indicators for specific measures, but no specific outcome indicators at the objective level (EAC, 2011). This level is however important for the monitoring of poverty impacts. Poverty-oriented indicators could be integrated in the RPMPOA framework, and should be measured at national level. Such indicators could for example measure the share of locally produced drugs provided to public health care facilities or the consumer perception of locally produced drugs.

The EAC Secretariat has the lead responsibility for the coordination and follow-up of the RPMPOA. In collaboration with stakeholders at national level, the EAC Secretariat should

therefore consider integrating a few poverty-related indicators in the RPMPOA implementation framework and determine who should monitor these indicators.

The EAC Secretariat, in collaboration with other stakeholders, should monitor the risks of conflicting trends in IPR laws that might jeopardize the effective use of TRIPS flexibilities.

The extent to which the growth of the pharmaceutical manufacturing industry will lead to significant employment effects, particularly for low-income and low-skilled labor, should be assessed in the planned value chain analysis of the East African pharmaceutical sector.

The extent to which environmental regulations are effectively applied to mitigate possible negative impacts of the growth of the pharmaceutical manufacturing industry should be monitored.

The FEAPM should gather more evidence on the Ghana model of price preferences, tax incentives and import classification, in order to convince other stakeholders that these measures do not have negative effects on the availability of medicines for medicines' consumers and poor population groups.

Annex

Annex 1: References

PIA country reports:

Garuka, Christian (2013): Poverty Impact Assessment of the East African Community Regional Pharmaceutical Manufacturing Plan of Action (2012-2016), Rwanda.

Maleche, Allan and Nyachae Jacintha (2013): Poverty Impact Assessment of the East African Community Regional Pharmaceutical Manufacturing Plan of Action (2012-2016), Kenya.

Mhando Joseph (2013): Poverty Impact Assessment of the East African Community Regional Pharmaceutical Manufacturing Plan of Action (2012-2016), the United Republic of Tanzania.

Mulumba, Moses (2013): Poverty Impact Assessment of the East African Community Regional Pharmaceutical Manufacturing Plan of Action (2012-2016), Uganda.

Niyonizigiye, Pierre Claver (2013): Poverty Impact Assessment of the East African Community Regional Pharmaceutical Manufacturing Plan of Action (2012-2016), Burundi.

Other references:

EAC (2007): Treaty for the Establishment of the East African Community, amended on 20th August 2007.

EAC (2012): East African Community Industrialization Strategy (2012 – 2032).

EAC (2011): East African Community Regional Pharmaceutical Manufacturing Plan of Action: 2012 – 2016, Arusha 2011.

EAC (2013): Regional Intellectual Property Policy on the Utilisation of Public Health-Related WHO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legisation.

EAC Secretariat (2012): East African Community Facts and Figures – 2012, Arusha 2012.

EAC Secretariat (2013): The 2nd EACRPMPOA Project Implementation Steering Committee Meeting, 18th to 19th November 2013, Final Report, EAC/TF/20/2013.

Federation of East African Pharmaceutical Manufacturers (FEAPM) (2012): Yearbook 2012.

The Global Fund to Fight AIDS, Tuberculosis and Malaria (2012): Guide to Global Fund Policies on Procurement and Supply Management of Health Products, June 2012.

OECD (2007): Promoting Pro-Poor Growth. Practical Guide to Ex Ante Poverty Impact Assessment.

UN (2008): Report to the UN General Assembly of the Special Rapporteur on the right to the highest attainable standard of physical and mental health, 11. August 2008, UN document A/63/2008.

UN (2011): Report of the Special Rapporteur on the right to the highest attainable standard of physical and mental health, Expert consultation on access to medicines as a fundamental component of the right to health, 16 March 2011, UN document A/HRC/17/43.

UN MDG Gap Task Force (2012): Millennium Development Task Force (2012): Millennium Development Goal 8 – The Global Partnership for Development: Making Rhetoric a Reality, MDG Gap Task Force Report 2012, New York 2012.

UNDP (2013): Human Development Report 2013 – The Rise of the South: Human Progress in a Diverse World, New York 2013.

UNITAID (2013): UNITAID Strategy 2013 – 2016, April 2013

Annex 2: Methodology

Key elements of the PIA approach

Poverty Impact Assessment (PIA) is an approach that was developed in the aftermath of the Paris Declaration on Aid Effectiveness by the Network on Poverty Reduction (POVNET) of the OECD Development Assistance Committee (DAC). PIA aims to help donors and partner countries inform themselves on the expected intended and unintended consequences of their interventions (policies, programs and projects) on the well-being of different social groups, by focusing on poor and vulnerable population groups (OECD, 2007). It therefore serves the purpose of defining more clearly which measures, and with whom, will make a greater contribution to poverty reduction.

PIA takes a multi-dimensional approach to poverty, including economic, human, political, socio-cultural and protective aspects. Pro-poor growth is defined as a pattern of growth that enhances the ability of poor women and men to participate in, contribute to and benefit from growth. The multiple poverty dimensions are related to the capabilities of relevant stakeholders to alleviate and overcome poverty.

PIA is structured around five analytical modules that assess the overall poverty situation (module 1), the stakeholders (module 2), the transmission channels of the intervention and their results (module 3), the outcome of the intervention on the capabilities of stakeholders (module 4) and the contribution of the intervention to the MDGs and other strategic goals (module 5). In each module a matrix is used to summarize and visualise the results.

The PIA terminology, the analytical framework and the main steps of the assessment process are explained in a user guide. The guide stipulates that users may apply all modules or choose those modules most relevant to the context in which the PIA is conducted. The modules may also be modified to fit with the user's other appraisal approaches. PIA has been developed mainly for ex-ante impact assessment and should ideally be integrated in the design of an intervention. The PIA guide emphasizes the importance of a consultative and participatory process, including giving voice to stakeholders who are often not well consulted (OECD, 2007).

The PIA guide anticipates that donors will commission most PIAs but that partner countries may gain appreciation of the PIA benefits and use it to increase accountability towards their own constituencies (OECD, 2007). Up to the present date, PIA has been used in a number of projects and programmes, primarily those supported by German Development Cooperation.

The PIA process

The PIA of the EAC RPMPOA was conducted by a team of six national consultants and one lead international consultant between September and December 2013. In September 2013, the lead consultant drafted a concept note that was presented to GIZ and to the EAC Secretariat.

A workshop was held in October 2013 to train the national consultants in the PIA approach, adapt the PIA methodology to the context and design the country-specific assessments. An interview guideline was developed (see annex 3) as well as a list of useful information sources and indicators. Following the workshop, stakeholders at the regional level were consulted and interviewed by the PIA team.

The country-specific assessments were conducted by the six national consultants in the respective EAC Partner States (Burundi, Kenya, Tanzania, Rwanda and Uganda) in October/November 2013. Each country assessment took one week. The national consultants contacted and interviewed stakeholders from Government agencies, the private manufacturing sector and civil society organizations. The lead consultant interviewed programme managers of bilateral health programs supported by German Development Cooperation and multilateral agencies (The Global Fund and UNITAID).

40 interviews and 3 focus group discussions were held at country level, 5 interviews at regional level, and 4 interviews with programme managers from bilateral and multilateral development cooperation. Each interview was briefly recorded in a standard template, including information on the awareness of the interviewee(s) on the RPMPOA and the quality of the interview. The country-specific assessments were drafted according to an annotated outline.

The findings of the country-specific assessments were presented at the EAC-RPMPOA Project Implementation Steering Committee Meeting in November 2013. Joint challenges and risks identified in the PIA were discussed in working groups with stakeholders attending the meeting. Recommendations to improve the poverty impact of the RPMPOA were discussed and incorporated into the final report of the Steering Committee Meeting. In December 2013 the findings were presented to and discussed with the BMZ and the GIZ sector project "Trade Policy, Trade and Investment".

Adaptation of the PIA framework

The following table shows how the original PIA framework has been adapted and operationalized to fit to the context in which the RPMPOA is being implemented.

Table 12: Adaptation of PIA framework

Analytical Framework as in PIA Guide	Adaptation of PIA framework
Module 1: Poverty Situation and relevance to national strategies and plans	
Module 1 provides information on the context within which the assessed intervention takes place. It therefore describes the poverty situation in a country or project region, with particular focus on the sector on which the intervention is focused. It also gives an outline of the intervention and how it aligns with relevant national plans and strategies, particularly poverty reduction strategies.	The object of the PIA was a regional plan of action. Hence, module and matrix 1 were slightly modified to include an assessment of how the RPMPOA aligns to EAC regional policies and strategies.
Module 2: Stakeholder and institutional analysis	
Module 2 consists of a stakeholder analysis with a focus on the pro-poor agenda and interests of different groups. The PIA terminology uses the word "stakeholder" as a generic term for agencies, organisations, groups or individuals who have an interest in the intervention, including the target groups, as beneficiaries of the intervention. It defines the role of these groups and identifies the constraints/aspects that may hinder them to have a pro-poor agenda. Furthermore it gives a rating of the pro-poor agenda of various stakeholders. Module 2 also foresees an analysis of the formal and informal institutions that influence the implementation of an intervention.	In the context of the RPMPOA creating a win-win situation through dialogue and cooperation between various types of stakeholders from the private and public sector is essential for success. Thus, the explicit rating of the pro-poor agenda of various stakeholders might raise misunderstandings and sensitivities. Therefore, the PIA matrix the rating column in the PIA matrix deleted. Care was however taken to use the column on mitigating and reinforcing measures. Stakeholder and institutional analysis were merged to simplify the assessment. Analysis of the legal and policy framework was dealt with in module 1.
Module 3: Identification of transmission channels and overall results by channel	
Module 3 consists of an analysis of transmission channels and their results. Transmission channels depict the pathway via which an intervention triggers results at different levels and time horizons and how these affect various stakeholders. Thus, module 3 is a specific way of illustrating result chains and structuring outcomes and impacts of an intervention. Six transmission channels have been identified in the PIA Guide	The transmission channels were operationalized and translated into questions in the interview guideline. The access channel was broken down into the following categories: • Availability of essential medicines • Affordability of essential medicines • Quality of essential medicines • Access of consumers to information on

(Prices, Employment, Transfers, Access, Authority, Assets).	locally produced medicines The authority channel was broken down into the following categories: • Enactment and implementation of laws and regulations • Participation of and dialogue between stakeholders The PIA matrix was modified to include the above-mentioned sub-categories. Risks for the achievement of results were described in one column instead of two. The time period was specified in the respective columns according to the RPMPOA context.
Module 4: Assessment of stakeholders' and target groups' capabilities	
Module 4 builds upon module 3 and considers the outcomes of an intervention on the capabilities of the identified stakeholders The outcomes are assessed against the five capabilities required to alleviate, avoid or escape from poverty.	The risk column was deleted in the matrix, in order to avoid redundancy with module 3.
Module 5: Assessment of results on MDGs and other strategic goals	
Module 5 assesses the likely contribution of the intervention to MDGs and other strategic goals, thus considers impacts at a highly aggregated level.	The PIA focused on the assessment of the contribution to the MDGs as common strategic development goals for all five EAC Member States. The short term period was defined as up to 2015 and the medium term period as Post-MDG.

Lessons learned on the use of PIA

The following table summarizes the major strengths, weaknesses and constraints of the present PIA. Despite limitations regarding the quality of the information, the present assessment has confirmed that PIA is a useful instrument to assess the poverty impacts of an intervention during design or – as in the case of the RPMPOA – at an early stage of implementation.

Table 13: Strengths and weaknesses of the PIA of the RPMPOA

Strengths	Weaknesses and constraints
• The PIA provided in short time information on the poverty impacts of the RPMPOA. • The PIA was integrated in the steering mechanisms of the RPMPOA. • The PIA triggered a reflection and discussion among key stakeholders on how to maximize poverty impacts and address risks. • The PIA was based on a broad consultation process and consulted stakeholders from civil society, who had not been systematically involved in the design of the RPMPOA. • The expertise of national consultants was intensively used in the PIA	• Quantitative data was in many cases not available, thus triangulation of information was not possible. The PIA is thus mainly based on the analysis of interviews with stakeholders. • In some countries, it proved quite difficult to engage stakeholders for interviews. Many interviewed stakeholders were not or not fully aware of the RPMPOA. Some interviewees feared that their responses would be misused. In some cases, these factors negatively affected the quality of the information. • The complexity of a regional plan with regard to coordination and cooperation between all stakeholders was hard to grasp in a limited time period. Priorities in the choice of interview partners thus had to be set.

Responses to an internal appraisal of the PIA method by the PIA team revealed the following:

- All six national consultants responded that the PIA method was useful to assess the poverty impacts of the RPMPOA and could be applied to assess potential poverty impacts of other EAC regional strategies and plans.
- All consultants responded that both the PIA handbook and the specific instruments developed in the training workshop were useful for the assessment.
- Except for one consultant, all were of the opinion that the PIA approach could not be applied without prior training workshop. Two consultants responded that if the method was to be implemented without prior training, more specific guidance, explanations and examples should be given.

Based on these lessons-learned, for the future use of PIA as an instrument in the design of trade-related programmes and/or EAC regional strategic plans the following points should be taken into consideration:

The analytical framework of PIA can be used in a flexible way. Nevertheless, it needs to be updated to reflect the evolving context of development cooperation, e.g. the post-MDG agenda, or programme-based and sector-wide approaches.

The PIA handbook as such is a useful guidance for decision-makers and PIA implementers. However, it does not contain much information on how to operationalize the major concepts, adapt them to the context, find relevant information sources and conduct PIA interviews. It can therefore hardly be used as stand-alone instrument.

Further use of PIA by regional trade programmes and their partners, e.g. the EAC Secretariat, thus would require support and/or capacity building by experts already familiar with the PIA methodology. Another, probably less costly option is to simplify the PIA approach and translate it into specific guidelines adapted to the context of trade-related programmes. These guidelines could perhaps more easily be integrated into the appraisal and design process of new interventions.

Annex 3: Interview Guideline

General notes for the interviewer:

- Even if your interviewee has received the concept note and/or interview questions, briefly state the reason for the PIA: To obtain more information on the impacts of the RPMPOA on poverty from the perspective of various stakeholders.
- Explain that the individual responses of the interviewee(s) will be dealt with anonymously and confidentially, and that the overall findings of the PIA will be shared and discussed with the Steering Committee of the RPMPOA.
- Conduct the interview in a friendly way as a conversation. If necessary, explain that it is not an assessment of the performance of your interviewee(s) or of their institution/organization/company.
- Mention that the interview will be structured around three main issues: (1) The relevance of the RPMPOA for the institution/organization/company represented by the interviewee(s) (2) The contribution of the RPMPOA to poverty reduction (3) The specific impacts of the RPMPOA on various stakeholders and population groups.
- The questions listed below may help you to establish a logical sequence of questions in the process of the interview. But, the list of questions is not intended to be used as a questionnaire. Depending on the background of the interviewee(s), his/her/their function(s) and his/her/their comparative advantages for the provision of information relevant to the purpose of the interview, you may choose to focus on specific questions.
- Encourage the interviewee(s) to go into depth with regard to the impacts of the RPMPOA. It is important to ask him/her/them to differentiate between stakeholders and to describe possible impacts on poor population groups. The most common approaches are before/after comparisons ("What do you think will change for poor people after the RPMPOA or a specific RPMPOA objective has been implemented") and with/without comparisons ("What about the stakeholders who do not directly participate in the implementation of the RPMPOA?").
- Do not forget to ask if there are any risks that a positive impact might not be achieved. If the interviewee(s) mention(s) a negative impact, ask if and how one could mitigate this negative impact.
- Never openly question the truthfulness or correctness of the interviewee's responses. If you have doubts on the correctness of some information, rather say you have not yet quite understood the response and ask the interviewee(s) to give some more details.
- As a final question, ask whether the interviewee(s) has/have any other issues that he/she/they would like to share with you.

General information

No.	Information
1	Institution/Organization/Company:
2	Name(s) of the interviewee(s):
3	Function in the institution/organization/company
4	Contact details:
6	Venue, date and time:

1 Relevance of the RPMPOA for the institution/organization/company

No.	Questions
1.1	Are you aware of the RPMPOA?
1.2	What has the role of your institution/organization/company been in the development and implementation of the RPMPOA?
1.3	What is the importance of the RPMPOA for your institution/organization/company?
1.4	How does the plan match with the strategy of your institution/organization/company?

2 Overall contribution of the RPMPOA to poverty reduction

No.	Questions
2.1	How do you think the RPMPOA will contribute to reduce poverty and improve access to essential medicine?
2.2	Which population groups do you perceive as poor or vulnerable?
2.3	What can you say about the specific problems of these poor or vulnerable groups?
2.4	How will the RPMPOA benefit poor and vulnerable groups?
2.5	Will any groups be worse off due to the RPMPOA? If so, which groups?

3 Specific impacts of the RPMPOA

No.	Questions
3.1	Do you think the RPMPOA will influence the production costs of essential medicine? If so, how?
3.2	Do you think the RPMPOA will influence the prices of essential medicine for the consumer and for poor population groups? If so, how?
3.3	How will WHO prequalification affect the prices of essential medicine? What will be the effect be on pharmaceutical manufacturers and on consumers?
3.4	Do you think the RPMPOA will influence income, wages or salaries? If so, how, and for which stakeholders and population groups?
3.5	Do you think the RPMPOA will influence employment? If so, how, and for which stakeholders and population groups?
3.6	Do you think the RPMPOA will influence the job status, job security and workloads of men and women employed by pharmaceutical manufacturers? If so, how?
3.7	Do you think the RPMPOA will influence tax revenue and tax payments? If so, how, and for which stakeholders and population groups?
3.8	What do you think would the effect of tax incentives be (e.g. no duties on imports of raw and packing material, pharmaceutical manufacturing related equipment as well as spare parts for this equipment) or import restrictions (e.g. for drugs that can be produced locally)?
3.9	Do you think the RPMPOA will influence the transfer of public resources? If so, how, and for which stakeholders and population groups?
3.10	Do you think the RPMPOA will influence the distribution and sale of essential medicines? If so, how, and for which stakeholders and population groups?
3.11	Do you think the RPMPOA will influence access to information on essential medicines? If so, how, and for which stakeholders and population groups?
3.12	Do you think the RPMPOA will influence the quality and safety of essential medicines? If so, how?
3.13	Do you think the RPMPOA will influence the access of local manufacturers to the

No.	Questions
	pharmaceutical market? If so, how?
3.14	Do you think the RPMPOA will influence the communication between Government agencies, private manufacturers and civil society organizations? If so, how?
3.15	Do you think the RPMPOA will influence the enactment and implementation of laws and regulations on essential medicines? If so, how?
3.16	Do you think the RPMPOA will influence wealth (e.g. buildings, savings)? If so, how, and for which stakeholders?
3.17	Do you think the RPMPOA will influence skills and knowledge? If so, how, and for which stakeholders?
3.18	Do you think the RPMPOA will influence health status? If so, how, and for which stakeholders and population groups?
3.19	Do you think the RPMPOA will influence the natural environment (water, air, waste, etc.)? If so, how, and for which population groups?
3.20	Do you think the RPMPOA will influence people's ability to cope with external crises or other shocks? If so, how, and for which stakeholders and population groups?
3.21	What are the most important influences that the RPMPOA has had or will have on the poorest individuals and groups?
3.22	Do you think the RPMPOA will have any other influence that we have not yet mentioned? If so, what sort of influence?

Notes for the interviews with Government institutions

As discussed in the workshop, depending on the Ministry or agency you are interviewing, some questions will be more relevant than others and should therefore be dealt with more in depth. For example, for the Ministry of Health and affiliated institutions questions related to access to medicine or quality of essential drugs are very relevant.

Also use the interview to get more information on specific laws or sector strategies that were not available in the documents you reviewed for Module 1.

Notes for the interviews with pharmaceutical manufacturers

Most questions are relevant for the pharmaceutical manufacturers, but should be asked from their perspective. Ask for example: What is your main objective as a pharmaceutical company? What does the EAC-RPMPOA mean for you as a manufacturer? What is your target market (Government, Private Sector, NGOs)? Who does your company consider as poor in your target market?

Specific questions could also be: What effects will WHO prequalification have on your company? If production is increased, does it mean that you will employ more staff? If production is increased, what will the effects on the environment (e.g. chemical waste) be?

Notes for the interviews with Civil Society Organizations

As civil society organizations were not directly involved in the development of the RPMPOA, most interviewees will not be aware of it. Therefore the questions will be less specific. Major topics should be the poverty situation, access to medicines, and their perception of the role of key stakeholders in this context.

Guiding questions for the interview or round table discussion:

- Who do you consider as poor?
- Who do you consider as poor in terms of access to medicine?
- What can the Government do to improve access to medicine?
- How do you think local manufacturers can improve access to medicine?
- How can the Government support local manufacturers towards improving access to medicine?
- How do consumers perceive locally produced medicine?
- How do you perceive the communication between Government agencies, Pharmaceutical manufacturers and civil society organizations?
- How do you see your role as civil society organization to ensure that Government and pharmaceutical manufacturers are working towards increased access to medicine for the poor?

Notes for the interviews with EAC officers

At the EAC level, the interviews will be of a more generic nature. Major topics are: the effect of the RPMPOA on regional integration and harmonization and how this will affect poverty reduction and access to medicines in the EAC; the alignment of the RPMPOA with EAC policies and strategies; the role of the EAC Secretariat in coordinating the implementation of the RPMPOA.

Guiding questions for the interviews with EAC officials:

- What is the overall importance of the RPMPOA for the EAC?
- How will the RPMPOA contribute to reduce poverty and improve access to essential medicine?
- How does the plan fit into EAC policies and strategies (Development, Industrialization and Trade, IPR, Health)?
- How will the RPMPOA influence partnerships and the communication between Government agencies, private manufacturers and civil society organizations?
- How will the RPMPOA influence the harmonization of laws and regulations on essential medicines in the EAC?
- What is the role of the EAC Secretariat in coordinating the implementation of the RPMPOA?
- Who are you working with/advising at national level in the five EAC Partner States to bring forward the implementation of the RPMPOA?