

EXTERNAL EVALUATION – SUMMARY REPORT

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Establishment of a Regional Quality Infrastructure for the Pharmaceutical Sector
of the East African Community (EAC)

Country | Region: East African Community (EAC):
Burundi, Kenya, Rwanda, Tanzania, Uganda

Project number: 2012.2533.3
Implementation period: March 2013 – February 2016

Executing agency: EAC Secretariat
Implementing partner: EAC Directorate of Productive and Social Services: Health Department;
Industry Department

PTB | Working group: Q.55 Sub-Saharan Africa
PTB | Project coordinator: Tobias Diergardt
Date: 30.11.2015

This evaluation is an independent assessment. The content represents the view of the reviewer and does not have to agree with the view of PTB.

List of Abbreviations

EAC	East African Community
CRS	Chemical Reference Standards
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
PT	Proficiency Testing
NSB	National Standards Body
NMRA	National Medicines Regulatory Authority
NQCL	National Quality Control Laboratory
PPB	Pharmacy and Poison Board
PPP	Public Private Partnership
PMQS	Post-Market Quality Surveillance
PV	Pharmacovigilance
QI	Quality Infrastructure
RPMPoA	Regional Pharmaceutical Manufacturing Plan of Action

1. Project Description

The East African Community (EAC) in collaboration with its Partner States is currently implementing the EAC Regional Pharmaceutical Manufacturing Plan of Action 2012-2016 (RPMPoA) to improve access to safe, efficacious and affordable essential medicine. The PTB, on behalf of the German Government in partnership with the EAC Secretariat is implementing the project “Establishment of a Regional Quality Infrastructure for the Pharmaceutical Sector” (herein after referred to as the EAC PTB QI project) to support the implementation of the RPMPoA. The objective of the project is: *Implementation of the RPMPoA has made considerable progress in the work areas "Strengthening of local producers` capacity for the introduction of WHO-GMP standards" and "Strengthening of regulatory authorities", owing to a quality infrastructure which has been adapted to the needs of the pharmaceutical sector.* The project is an integral part of the German development program “Support to the EAC Integration Process”.

The pharmaceutical industry in the EAC is currently undergoing significant changes towards evolving to a globally competitive sector that adopts international best practices. The EAC Secretariat and the Partner States recognize the strategic importance of the pharmaceutical sector in promoting access to affordable quality essential medicines. The size and complexity of the pharmaceutical sector across EAC varies from country to country. The Kenyan pharmaceutical sector is the most developed among the five countries (number of local manufactures: 22) followed by Uganda (6 local manufactures) and Tanzania (4 local manufactures), while those of Burundi and Rwanda are still in their infancy (one local manufacturer in each country). The regulatory regime in the region is characterized by a move towards the creation of semiautonomous government agencies to spearhead the national regulatory affairs. The pharmaceutical industry in East Africa is taking efforts in many different fields to increase competitiveness. To adapt its production to highest quality standards a specific pharmaceutical quality infrastructure is lacking.

Scope of the Evaluation

The purpose of this evaluation has been to assess the EAC PTB QI project’s design, scope, relevance, performance and achievements. It also looks for early signs of potential impact and sustainability. The evaluation covered the full range of activities and geographic scope of the project over the last two and half years, from its inception in March 2013 till September 2015. The field mission took place from 21st till the 28st of September 2015.

The evaluation has been based on three main data sources: Firstly, a wide variety of relevant documents covering project design, planning and implementation. Secondly, face-to-face consultations with a range of stakeholders from selected EAC partner states, using “semi-structured” interviews. Due to limited resources and priorities of the evaluation sampling of the total stakeholder has been done. Kenya, Tanzania and Uganda have been selected among the five EAC partner states to be visited due to the high number of manufacturers as well as NMRAs having their own quality control laboratory. In total 16 interviews with project staff respectively GIZ programme staff, stakeholders, regional and

international consultants as well as representatives from other donor projects have been conducted. Thirdly, there have been direct observations of project results and activities at selection on-site visits at the NQCL and the private company “Universal Cooperation” in Kenya. Overall the data analysed and collected provides sufficient evidence regarding the evaluation criteria.

The project is based on a regional approach covering all EAC partner states and it targets all citizens of the EAC. The project addresses the core impediment of the pharmaceutical industry in East Africa its insufficient quality infrastructure at manufacturers' and at the regulatory authorities'. The lack of a quality infrastructure strongly restricts the potential of the pharmaceutical industry for development. Improving and harmonizing regulatory environments supports the development of a regional market (economies of scale; creation of comparative advantages), creating a level playing field for fair competition leading to consumer benefits. Through promoting better synergies between regulators and local manufactures the project addresses key challenges and opportunities for ensuring the availability of safe and efficacious medicines of acceptable quality. The projects indicators are defined as following:

- Original Indicator 1: The amount of "critical non-conformities" in the control laboratories of the regulatory authorities has been halved.

This indicator has been revised for evaluation purpose: 4 improvements have been made to overcome identified "critical non-conformities" in the control laboratories of the regulatory authorities.

- Indicator 2: The internationally prescribed traceability of the measuring and analysing instruments at pharmaceutical manufacturers' is increasingly ensured by service providers located in the region.

To achieve these objectives the project has defined five key outputs: i) Support rendered to the regional metrology institutes to offer calibration services required by the pharmaceutical sector; ii) Employees from control authorities and industry are trained in the field of quality standards; iii) Specialist assistance in the carrying out of comparison measurements; iv) Support in the production and marketing of secondary reference materials; v) Strengthening of the market surveillance authorities by means of training and by means of test equipment for on-site controls.

The project design and selection of project interventions has a clear scope with its sector specific approach on the pharmaceutical sector. Lessons learnt from previous projects in the field of quality infrastructure have been incorporated into project design (e.g. capacity development measures for metrology departments/institutes). The different intervention areas to achieve the objective are appropriate but the project is pursuing a rather broad spectrum of interventions given the limited resources. The core interventions of the project are targeting quality assurance issues. They respond to contextual institutional, legal and regulatory settings of the pharmaceutical sector in the EAC.

2. Assessment of the project

From an overall perspective the project displays a coherent concept, combining various modes of delivery appropriately in its implementation strategy. Some minor qualitative weaknesses in the system of objectives and indicators at module level are made up by a very good overall performance with respect to the set of DAC-criteria.

The EAC PTB partnership project is well organized and structured. In general a regional approach has by character its limitations due to resources (time and budget) to support effectively the implementation on the national level. The project found good entry points and has a clear added value in creating the conditions for interregional co-operation. By concentrating on the institutional level (meso level) as main intervention area the project took a realistic approach toward implementation.

With its horizontal approach it has been able to create networks and exchanges of experience but it remains challenging to provide common solutions to rather diverse stakeholders - more advanced stakeholders from Kenya, Uganda and Tanzania compared to stakeholders from an emerging pharmaceutical sector in Burundi and Ruanda. Overall the steering structure has been well and realistically designed. Involving national and regional stakeholders more in monitoring and planning issues will be an ongoing challenge.

The good cooperation culture within the GDC programme for the EAC integration process is a great asset for the EAC PTB QI project. It has been able to set up an appropriate mix of stakeholders from national and regional level as well as from public and private sector. A clear asset of the project has been that it has successfully fostered a constructive dialogue between the different interest groups providing impetus to a better understanding and new perspectives of common challenges.

A multi-stakeholder approach encompassing regulators and industry has proven to be an important success factor. More involvement of the private sector in many intervention areas would be appreciated.

2.1 Assessment according to the DAC Evaluation Criteria

Effectiveness

Overall the project has made very good progress in achieving its objective to strengthen capacities of regulatory authorities and their control laboratories as well as increasing knowledge about GMP at industry level. All interview partners underlined the comparative advantage of the training concept of bringing people from public and private sector together. This facilitates an important forum for discussion and networking and is an added value. Skills gained of laboratory staff are applied in daily work. Confidence level of analysts has been raised. The Interview results and feedback forms of the training courses and PT clearly show that the training courses met the expectations regarding i) quality of course content, ii) of instructor's teaching, iii) organization and structure, iv) integration of theory and practice as well as the v) training materials and resources. In the intervention field CRS the supported

concept paper is a good foundation for further steps in this field – a political consultation process at EAC level will follow. Owing to these evaluation findings the criterion “effectiveness” is rated with good (2). Owing to in-depth analysis with NBS in the intervention field “Calibration of equipment” and time intensive consultation processes within the EAC structures the level of achievement has not fully matched the intended outcomes and results in the current project phase.

Impact

The interventions of the project contribute to strengthening integration and trade in the EAC region. It clearly links to the RPMPoA and its main objective to enhance the capacity of the EAC to sustainably and competitively produce quality essential medicines for local use and export. Enhancing the regulatory capacity of the public sector at national and regional level will contribute to develop a conducive policy framework for the pharma sector geared to the needs of the industry (contribution to participatory development and good governance). It will accelerate harmonization and integration aimed at facilitating trade and economic growth. Strengthening the pharmaceutical manufactures in quality assurance issues will in the long run with a high likeliness contribute to inclusive economic growth, local employment and income generation and better access to affordable essential medicines (contribution to poverty reduction). On the basis of the evaluation results the criterion “impact” is rated with good (2).

Sustainability

The new, trustful relationships forged in the EAC PTB QI project among individuals are apparently sustainable, and will with a high probability lead to better organisational ties. Stakeholders show a high commitment to continue and broaden their regional cooperation regarding QI issues in particular PMQS, CRS and PT. It is anticipated that the positive cooperation results will be durable on the individual level. At the organizational level and regarding framework condition stakeholder have a clear understanding of necessary changes in order to make achieved results sustainable, in particular regarding increasing awareness and willingness to pay for qualified services and trainings. Better results for sustainability could have been reached if more structural issues (e.g. necessary organisational changes within the NQCL; involvement of local training provider) would have also taken into account. So far it is not clear yet how trainings for the pharmaceutical sector could be shifted to local training providers but there is a very good team up with local and/or regional experts. Results of the interviews show that the involvement of qualified local/regional experts is highly appreciated by project partners. The criterion sustainability is rated with satisfactory (3) which is very good result given the complex setting of requirements to be met for sustainability in economic and political terms (fair balance of interest; change of attitudes for training; institutional changes; ownership of national stakeholders for regional issues).

Efficiency

The various modes of delivery have been carefully applied in a partner oriented and process oriented approach. Being part of the overall GDC programme for the EAC as well as the sharing of technical personnel (local long-term expert for pharma sector related activities of the GIZ is also the liaison person for the EAC PTB QI project) contributed to a good costs-results ratio. The cooperation quality within the overall GDC programme is appreciated by both sides and assessed as fruitful and efficient. Effective coordination and a good division of labor with other donor initiatives bring additional gains and avoid unnecessary duplications. In the current phase travel costs for project activities are mainly covered by the project. Regarding the efficiency of the project, the available human and financial resources have been used in an appropriate way. PTB's personal concept to coach development measures without locally stationed long-term experts adds to the projects good efficiency. Owing to these findings the criterion "efficiency" is rated with good (2).

Relevance

The project approach matches to a high degree the needs and priorities of the policy document RPMPoA as well as the related policies of EAC partner states (e.g. *Kenya Pharmaceutical Sector Development Strategy/GMP roadmap*). Activities are to a large extent stakeholder-driven and correspond closely to the needs of the involved partner institutions (NBS, NMRA, control laboratories, industry). It is a great achievement of the project that it has been able with its activities to emphasize the importance of quality assurance issues for achieving the objectives of the RPMPoA. With its regional approach it provides an important platform to tackle issues of regional concern of QI, e.g. PMQS based on the principle of subsidiarity. The project is in line with the relevant strategies of the BMZ as commissioning party. The criterion "relevance" is rated with very good (1).

The EAC PTB QI has been successfully implemented with an overall rating of 2 – good rating, fully in line with expectations.

2.2 Success factors for the observed results and change processes

Strategy

The evaluated project is a regional-type project. It pursues a comprehensive strategy to improve key elements of the QI with its regional approach. The cause of action taken encompasses two main entry points:

- I. Interventions targeting issues where regional-action is an added value. The project is tackling QI regulatory issues where there is a clear need and added-value for collective/regional action such as for a better provision of CRS or PMQS related issues.
- II. Interventions in the sense of horizontal cooperation (multi-country approach): In this regard training, knowledge sharing and peer-learning is supported within the project

with a strong focus on quality assurance issues of laboratory staff (public and private) and calibration issues of NBS staff.

From its subject matter the project has pursued a rather broad strategy in the current phase with a focus on quality management issues at the institutional level. For important issues such as PMQS and the availability of CRS in the EAC region good foundations have been laid to build up a consistent intervention strategy in the next phase. Interventions in these fields need however, more steering and process management. Thus, a clear scope regarding what the project is able to deliver in these fields as a regional project should be set.

The project is cooperating with the right partners in order to reach the desired objectives and results. It is working with relevant public stakeholders: policy makers (EAC Secretariat: Department of Health; Department of Industry; national line ministries), regulatory authorities and its executing agencies (e. g. control laboratories) and NSB. It has been able to find a balanced strategy regarding the divergent interests and needs of the health and industry department. The project has also a good partner structure regarding the industry side: selected pharmaceutical manufactures as well as the regional federation of the pharma sector (FEAPM) are key partners. Moreover, it also works closely with selected academic institutions such as the *Muhumbili School of Pharmacy in Daressalaam* or the *Kilimanjaro School of Pharmacy in Moshi* to achieve multiplier effects regarding skills development. The political counterpart the EAC Secretariat is regularly informed about the results the project wants to achieve in the pharma sector with regard to the RPMPoA. Among the various stakeholders there is clear understanding of what are objectives and changes to be made related to the specific intervention areas (output level) they are mainly involved and which are geared specifically to the need of the pharma sector (e.g. training for NQCL). In the field of calibration there is more effort needed to raise awareness among stakeholders to care more specifically to the need of the pharma sector. An overall understanding of the project's objectives among stakeholders has not emerged yet. As a general implementation principle interventions encompass an equal share of participants from all EAC countries (including Zanzibar). This approach does foster regional exchange, networking and trust building. But it is questionable whether trainings based on this principle are able to be most effective given the great heterogeneity of the knowledge and skills of the participant from all EAC partner states and the existing levels of QI development in the region. Being part of the overall GDC programme for the EAC the project has a clear scope and coordinates well with other donor activities. The directions given by the political counterpart the EAC Secretariat are the result of concerted effort and consultation to define and set objectives for the pharmaceutical sector. Capacity Development (CD) is an element of the project's strategy with a strong emphasis on the individual level (skills acquired and applied). Increasingly more attention on required structural changes (e.g. legal and regulatory issue for PMQS; developing a viable institutional and financial solution regarding PT schemes as important incentive structure for laboratories) is given by the project but more attention and effort in regard to planning, communicating and implementation of necessary activities is needed to increase effectiveness and the sustainability of the intended change process.

Cooperation

The CW factor cooperation is focusing on issues of who cooperates with whom, in which role and how coordination works among project stakeholders. Regular planning of the project activities and strategy is done together with the main political and implementation partners. The project uses to a great extent synergy effects that result from being part of the overall GDC programme for the EAC as well as cooperation with other relevant donor projects whenever possible (e.g. UNIDO, MRH, etc.). A well-functioning communication and coordination structure between the project coordinator, the local liaison person and its partners at the EAC Secretariat as well as on national level is established. Regular visits to the political partner the EAC Secretariat are made by the project coordinator in order to discuss the overall strategy, work plans as well as progress made. With its approach to facilitate dialogue between regulators and industry the project promotes the creation of networks among partners and their organizations. Bringing industry and regulators together is an outstanding strength of the project as it supports a better understanding of interests and needs of both sides. This fact has been underlined by interview partners from the public and private sector involved in the project.

Steering structure

The project coordinator located at PTB headquarter in Germany is responsible for the overall implementation of the project. For technical issues an interim international short-term expert has been assigned in 2014 and has a clear advisory function. Being part of the GDC Programme is a great asset for steering the project as it can rely on existing communication channels and working relations. The local liaison person of the project has a very important function for linking the project coordination with project partners, in particular the political partners and to support processes. Due to the regional approach the project has a complex steering structure. In the narrower sense there is no formal steering group for the project. For monitoring the implementation of the RPMPOA a steering committee representing key stakeholders from both public and private sectors in all the five EAC Partner States has been established on regional and national level. The project co-ordinator has participated in some of these annual meetings. More presence and active involvement of the project staff (project coordinator, interim short-term expert and/or the liaison person) would increase the visibility of the project. A key mechanism for steering has been the joint planning with partners, in order to make important decisions related to activities strategy and resources (work plans, activity planning). Regular (activity/impact) monitoring data concerning project activities and progress is collected by the project coordinator and provided to the partners in a transparent manner. The monitoring responds strongly to internal requirements and is missing information about outcome and results. Shortcomings arise also from the fact that it is not yet linked to partner institutions processes and their internal monitoring activities.

Processes

The partners' processes that shall be improved with support of the project are defined to different degrees depending on the intervention field. In the field of enhancing capacities for laboratory staff processes are more detailed described and taken into account compared to other intervention fields which are in an emerging stage. This is the case, especially with PMQS due to the fact that in this intervention field the strategy and approach is being formulated and prioritized by partners. The projects' core inputs as well as intervention areas have been defined and documented (operational planning/activity planning; responsibilities of partners). To interact and liaise with partners from the EAC Secretariat the local liaison person plays a crucial role that goes beyond its formally assigned task as it also includes providing the project with important context knowledge of the functioning of the EAC Secretariat, the local pharma sector, its mechanism and structures.

Learning and innovation

The project has been able in a suitable manner to adjust operational planning to new developments and changes regarding to framework conditions. There is active knowledge management regarding each training course and its feed-back mechanism at the end of the training. Aggregated lesson learned of all trainings have not yet been elaborated or done on a regular basis. Concerning capacity development of laboratory staff there is a good understanding of what laboratories shall learn through the project (skills and capabilities for staff in the identified areas; organizational level: PT schemes as benchmarking for the whole laboratory; networking among control laboratories in the EAC region; frame conditions: increasing awareness for the relevance of QI for competitive and safe products). The results of key studies and analysis done by the project are disseminated well with relevant stakeholders.

3. Recommendations

Recommendations for the current Implementation Phase

The following general recommendations are relevant for the current term of the EAC PTB QI project. They will also gain relevance in the follow-on measure. Though time is limited in the current phase it would be important to take necessary steps of adjustment till the end of the current term.

- It is recommended to find appropriate steps to gradually introduce a more cost sharing scheme for participating in project activities, especially trainings and PT to maintain sustainability.

- Regarding requirements for sustainability of training achievements it is recommended to further explore opportunities of strengthening the academia-industry interface and/or to set up public-private-partnership schemes with potential local training institutes (e.g. Edulink in Nairobi).
- It is recommendable to further explore how the results of the UNIDO GAP analyses for the Kenyan pharmaceutical sector could be used to develop necessary capacity development measures.

General Recommendations for the Next Implementation Phase of the Project

It is recommended to further develop and align the project design based on lessons learned and changes of the development context (e. g. GDC with Burundi suspended; upcoming review of the RPMPoA; withdrawal of support by the GDC programme for the School of Pharmacy in Moshi). The successful implementation in the current phase, created a sound basis for fruitful cooperation among stakeholders and further capacity development that is expected to create further significant improvements of the QI in the pharmaceutical sector in East Africa. Further support measures are necessary to bring about changes and to maintain positive results of laboratories, regulatory authorities and industries.

The project objective should be reformulated in a more simple way to concentrate on the key positive changes to convey the main message of what the project intends to achieve (for example: “The quality infrastructure of the EAC region has been adapted to the needs of the pharmaceutical sector”).

Module indicators should be defined according to priorities of the specific intervention areas in the next implementation phase. It is recommended to redefine Indicator 1 regarding positive results to be achieved for a) the laboratories and b) the industry. Indicator 2 is still valid but its target might be necessary to be adjusted accordingly.

The intervention strategy should continue to consolidate capacity development for laboratory staff and support identified key regulatory issues at regional level. More effort is needed to match important requirements for sustainability. Concerning the strategy in the field of calibration, CRS and PMQS outcomes should be clearly and realistically defined. It is strategically important to narrow down the scope (achievement levels at regional and national level) in the next project phase as these interventions and processes do need more intensive support to be rolled-out.

The successfully pursued strategy of the project whereby a forum is provided for representatives of regulators, bureau of standards and industry to train together, learn from one another and create networks should be continued.

It is recommended to explore through which channels and mechanism lessons learned of the project in the field of developing a QI for the pharma sector in EAC could be further discussed with stakeholders at the regional and national level. This is an important input for the upcoming review of the RPMPoA. Active involvement of the project would be an asset for the review process.

The good practice of “twinning or mentoring arrangements” made by the AMRH programme could be leveraged upon for training programs to facilitate maximum participation of the private sector (e.g. offering training for sub-groups of the EAC partner states: Kenya and Ruanda; Uganda and Zanzibar) and to adjust project activities more to the varied levels of interests and needs (knowledge and equipment level) of each country. Twinning modalities could apply for Kenya and Ruanda as well as for Uganda and Zanzibar. In this way the project could take advantage of the existing heterogeneity in QI development in the region. Through such a “twinning-approach” more advanced participating countries could contribute actively by hosting events and bringing in their expertise in favor of the less advanced countries.

Concerted efforts should be made together with the key stakeholders to further develop a more result-based monitoring. There is room for improvement regarding conducted baseline studies concerning sample size to become truly valid for the project regional outreach. It is recommended to invest also more into outcome monitoring of each training regarding whether the skills and knowledge obtained is applied in the working context of the participants and what are key lessons learned for trainings.

4. Learning processes and experiences

A multi-stakeholder approach encompassing regulators and industry has proven to be an important success factor. More involvement of the private sector in many intervention areas would be appreciated.

Using local and regional knowledge and experts has been very supportive for the intended change processes. Moreover, the peer-learning from other regional economic communities has been an important learning process for the various stakeholders.

Strengthening local representation of the EAC PTB QI might increase visibility of the project (e.g. role and function of the liaison person could be reconsidered).

The steering and coordination capacities of the EAC Secretariat to follow up on implementation as well as taking on initiative for the QI integration process of the pharma sector are limited. The EAC Secretariat faces challenges in providing required coordination support with its current staff as well as having the political mandate and power to steer the implementation of the RPMPoA effectively.

Supporting QI issues for the pharmaceutical sector means to deal with two different departments of the EAC Secretariat. The project has been able to find a good balance between the interest of the Department of Health and the interest of the Department of Industry. It deals with both in a constructive and transparent manner.

Annexes
Annex 1: List of partners involved in the evaluation (interview; participation in debriefing workshop)

		Interview	Debriefing-Workshop
EAC Secretariat	• George Ndira (Department of Industry)	X	
	• Jennifer Gache (Department of Industry)	X	X
German Development Programme “Support to the EAC Integration Process”	• Wesley Ronoh (GIZ)	X	X
	• Thomas Walter (GIZ)	X	
	• Bernd Multhaup (Programme Manager, GIZ)	X	
National Medicines Regulatory Authorities (NMRA)	• Angole Apollo Uganda, NDA		X
	• Ugullum Charys Tanzania, TFDA		X
	• Chesaro Sara Kenya, Pharmacy and Poison Board (PPD)		X
	• Toroitich Anthony Kenya, PPD		X
	• Alex Gisara (EAC National Medicines Regulatory Officer, Rwanda)		
	• Ali Sharifa Yussuf Zanzibar, ZFDB		X
	• Buheti Nassir Salum, Zanzibar ZFDB		X
National Bureau of Standards (NBS)	• Mboloi Stephen Kenya, KEBS		X
	• Lemeriga Yasin Uganda, UNBS		X
National Quality Control Laboratory’s (NQCL)	• Mbae Ernest Kenya, NQCL	X	X
	• Dr Annette Senkindo (National Drug Authority, Uganda)	X	
International and Regional Consultants	• Dr Dirk Feldmann (Coordinated PTs, Germany)	X	
	• Dr von Jan (Quality control, Germany)	X	
	• Joel Kioko (Metrology, Kenya)	X	X
	• Joseph Mhando (Post Market Surveillance, Tanzania)	X	X
Companies/Private Sector	• Michele Maungu (Secretariat FEAPM)		
	• Muriithi George Mugi (Universal Corporation Limited, Kenya: Quality Manager)		
	• Nazeem Mohamed (KPI Uganda; CEO and chairman FEAPM)	X	
	• Palu Dhanani (Universal Corporation Limited, Kenya: CEO)	X	

	• Dr Shahn, Biodeal Laboratories	X	
	• Wanjiku Freshia Kenya Biodeal		X
	• Michael Maynard (Quality Chemical Industries, Uganda)	X	X
Universities and Training Institutions	• Kaale Eliangiringa Tanzania Muhumbili University		X
Other Donors	• Dr Wilberforce Wanyanga (UNIDO)	X	

Annex 2: Interview Guidelines

Questions will be asked, during the stakeholder interviews along the following guiding question, adjusted appropriately for the particular context:

Relevance

The extent to which the objectives of a development intervention are consistent with beneficiaries' requirements, country needs, institutional priorities and partner and donor policies.

- What challenges do the EAC Partner States have to face in terms of establishment and harmonization of services, legislations, regulations and procedures with respect to quality assurance?
- What is the priority/benefit of the project for the responsible institutions/stakeholders at EAC level and in the Partner States?
- To which degree has the project contributed to implement the RPMPoA in the two selected work areas (local producers' capacity for WHO-GMP standards; strengthening of regulatory authorities)?
- Are there any implications expected of the upcoming review of the RPMPoA for the years beyond 2016?

Effectiveness

The extent to which the intended direct results (objectives) of the project are being achieved (comparison of actual situation with targets).

- What changes are perceived by stakeholders/implementation partners due to the cooperation with the project regarding the main intervention areas (calibration of equipment; quality standards; proficiency testing; certified reference standards; maintenance and repair of equipment; post-market surveillance)?
- How did the project activities correspond to the work priorities of the involved stakeholders (manufactures, laboratories, regulatory authorities)?
- To which extent have the 4 identified critical non-conformities in the control laboratories of the regulatory authorities been reduced?
- To which extent are calibration services offered by local providers/institutes (quantitative and qualitative)? What is the

progress made by the involved metrology institutes?

- In which way is the trained staff (manufacturing staff; regulatory authorities) using its new skills and knowledge?
- Have the conducted trainings matched the actual training needs?
- What progress has been made regarding strengthening post-market surveillance?
- What has been supportive or hindering project implementation?
- Are any adjustments regarding project design and approach needed for extending the project?

Impact

Contribution of the project to overarching results.

- What contributions can the project realistically make to overarching development results such as consumer protection, health protection and economic development – among others?
- What kind of (positive and negative) overarching changes can be observed in the pharmaceutical sector (supply and demand side) and regulatory environment (e.g. awareness of quality management issues)?

Efficiency

To which degree resources invested by the project are appropriate compared to the outputs and results achieved.

- What resources has the project been using for the intervention areas and various forms of *modes of delivery* (long-term experts, short-term-experts, operating and administrative costs, etc.)?
- To which extent has the project coordinated with or been complementary to other donor projects for task-sharing?
- Have the outputs been produced cost-efficiently (cost-benefit ratio)?

Sustainability

The likeliness that the positive results of the project will continue beyond the end of the project support.

- What approaches, instruments, methods or concepts are likely to be lastingly used, institutionalized or further developed by the involved implementation partners?
- To what extent are - organizational, personnel, financial, economic - resources and capacities available at EAC regional partner level as well as in the Partner states for maintaining the results achieved?



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