Implementation Agreement

Between

University of Rwanda East Africa Community Regional Centre of Excellence for Vaccines Immunization na Health Supply Chain Management (UR/EAC RCE-VIHSCM)

and

Tanzania Medicines and Medical Devices Authority (TMDA)

For realization of the "*Minilabs Project*" "

PREAMBLE

WHEREAS the objectives of the East African Community is to improve the health of the population of the EAC, considering populations at risk in particular,

WHEREAS the EAC RCE-VIHSCM has received a grant of Euro Four Hundred Thousand (EUR 400,000) from the Federal Government of Germany through KfW Development Bank for financing the "*EAC Regional Network of Data Reporting and Sharing on the Quality of Tracer Antimicrobial and Antimalarial Medicines using Minilabs*":

WHEREAS the overall objective of the project to be met through the investment is to strengthen capacities in seven EAC Partner States to identify Substandard and Falsified Medicines (SFMs) and to move quickly to plug the gaps identified in the supply chain of the region.

CONSIDERING THAT, the implementation of the project will contribute to the strengthening of regional and national capacities of National Medicines Regulatory Autorities (NMRAs) for the collaborative regional solutions to the problem of porous supply chains that allow in SFMs;

RECALLING the Financing Agreement (dated 25/11/2019) and Separate Agreement (dated 25/11/2019) signed between the EAC RCE-VIHSCM and KfW Development Bank ("The Project Agreements");

WHEREAS, under Clause 5 of the Separate Agreement (Phase I), the EAC RCE-VIHSCM committed to subdelegating implementation of some aspects of the project to the Partner States; and under Clause 2.1.2 of the Separate Agreement (phase II) requires amendment to implementation Agreement signed under phase I, covering all additional activities and investments of the Project;

The parties have agreed to the provisions of the present Implementation Agreement as follows:

Article 1
Responsibilities of the EAC RCE-VIHSCM RCE-VIHSCM

1. **Procurement of equipment and training**

(a) The EAC RCE-VIHSCM shall, in line with KfW and University of Rwanda procurement guidelines and project agreements, utilise the funding to carry out the procurement of:

(i) Sixteen (16) Minilab packages; two for each EAC partner state for data generation and reporting on the quality of five antimicrobial and two antimalarial medicines, and two for the EAC RCE-VIHSCM for training purposes.
(ii) Replacement of broken glass ware and consumed reagents for a period of four years from 2023 to 2026.

(b) All EAC Statutory Due Processes and Consultations were complied with during the preparation of this Implementation Agreement.

2. Training of the staff members for the implementation of the project

(a) The UR/EAC RCE-VIHSCM, with the support of Tübingen University, Germany, shall organise and coordinate the Training of Trainers (Three staff members from each receiving EAC-Institution) on how to use the Minilab package and to report the analytical results.

(b) The UR/EAC RCE-VIHSCM will provide the technical/coordination and financial support for the planned in-country training on the use of the Minilab package.

3. Coordination

The UR/EAC RCE-VIHSCM shall be responsible for:

(a) Coordination of regional policy dialogue and exchange of knowledge, experiences and good practice;

(b) Recruitment of the training institution; and

(c) Facilitation for staffs during project related activities such as Mix-countries training and in-country training.

4. Transfer of assets

(a) The UR/EAC RCE-VIHSCM shall transfer the assets of the project to the receiving EAC-Institution as soon as the Minilab packages have been purchased, delivered, assembled and tested at a place agreed upon by both parties and the Training of Trainers (ToT) has occured.

(b) The transfer of assets will be documented in minutes duly signed by both parties with a description of technical specification.

Article 2
Responsibilities of the Implementing NMRA in the Partner State

1. Facilitation of customs clearance of donated equipment, supplies, reagents and consumables

The Implementing NMRA in the Partner State shall be responsible for the customs clearance of all donated equipment, supplies, reagents and consumables including securing all the necessary tax exemptions from the relevant national authorities.

2. Mobilisation of test reagents and consumables

(a) The Receiving EAC-Institution through its respective National Public Health Reference Laboratory (NPHL), shall mobilise resources to cater for any additional test reagents and consumables that may be needed during project implementation.

(b) In case of an emergency during the project implementation period, the Receiving EAC-Institution shall procure test reagents using its own budget and claim a reimbursement from the UR/EAC RCE-VIHSCM not exceeding 110% of the price reference provided for the core reagents and consumables for each Partner State.

3. Operation of the Minilab package

Throughout the implementation of the project. the Receiving EAC-Institution shall be responsible for:

(a) Proper operation and maintenance of the Minilab package;
(b) Storage of equipment and protection against theft and misuse;
(c) All operating costs related to sampling. analysis of samples and preparation of required reports;
(d) Carrying out in-country external quality assurance (EQA) in line with WHO and project guidelines;
(e) Reporting on the confirmed list of medicines and share data with EAC RCE-VIHSCM.
(f) Creation of a country project coordination team at the Receiving EAC-Institution.
(g) Organize the training of more staff members using the three staff members who benefited from the ToT, upon the specific national needs.
(h) Support for staff during country specific deployment missions

4. Communication and Reporting

(a) The Receiving EAC-Institution shall be responsible for the communication of project activities through creation of awareness. advocacy and stakeholder engagement.
(b) The Receiving EAC-Institution shall produce quarterly reports about the the quality of the selected medicines. used reagent and broken glass ware and submit to the UR/EAC RCE-VIHSCM.

(c) The reports referred to in clause (b) shall provide the following information:

(i) Number of samples and sampling sites for each medicine;
(ii) Description of the analytical procedure for each medicine;
(iii) Results found for each medicine batch of all the sampled brands;
(iv) Amount of used reagents and solvents and the amount og remaining amount for each reagent and solvent;
(v) Number of broken glass ware;
(vi) Number of new staff members trained;
(vii) Request of reagents, solvents and glass ware for replacement;
(viii) Plan of sampling for the next reporting period;
(ix) Any other important information.

5. Responsibilities of the Implementing NMRA in the Partner State after completion of the project (after 2026)

After the project phase-out, the Receiving EAC-Institution shall be responsible for continuing operations and maintenance of the Minilab package using harmonized Standard *Operating Procedures (SOPs)* and reporting systems. The Receiving EAC-Institution and UR/EAC RCE-

VIHSCM will develop a sustainability plan to ensure continuity of the project after the end of the project duration.

Every Receiving EAC-Institution shall report data focusing on the following seven medicines including five antimicrobials from the WHO's list of Critically important antimicrobials for human medicine. 6th revision (amoxicillin + clavulanic acid, gentamicin, rifampicin, ceftriaxone and ampicillin) and two antimalarials (artemether + lumefanthrine and quinine), as they were mentioned to be the most substandard and/or falsified medicines in Africa and Asia in 2017. The reporting shall be paper-based (the reporting template will be shared by the EAC RCE-VIHSCM) while waiting for the implementation of digitalization of the EAC Pooled Procurement Framework (EAC PPF) digital infrastructure. Data collection will start with ports of medicines entry, then progressively expand to points that are at high risk for substandard/falsified medicines. To ensure data completeness and accuracy, each Receiving EAC-Institution shall ensure the correctness and completeness of the submitted data. Seventy percent (70%) shall be the cutoff point for both the completeness and the quality of reported data.

Once data are received by the UR/EAC RCE-VIHSCM, information will be channeled through concerned Medicines Regulatory Authorities (MRAs) of the EAC Partner States for further actions.

Failure to report for two consecutive quarters shall be followed by:

(a) Disqualification of the institution as a partner of the EAC RCE-VIHSCM for future opportunities, and
(b) Reporting the incompetency of the failing institution to the EAC Secretariat for for decision.

Article 3 Entry into force

This Agreement shall enter into force upon signature by both parties.

Done at DODOMA on 11th September, 2023

EAC Regional Centre of Excellence for Vaccines, Immunization and Health Supply Chain Management (EAC RCE-VIHSCM)	**For Tanzania Medicines and Medical Devices Authority (TMDA)**
Stephen Karengera, MD **Director,** EAC RCE-VIHSCM, University of Rwanda -Kigali. E: stephen.karengera@gmail.com Phone: +250 788 501 320 Web: https://hscm.ur.ac.rw	**Mr. Adam M. Fimbo** **Director General** Tanzania Medicines & Medical Devices Authority P.O. Box 1253, Dodoma or P.O. Box 77150, Dar es Salaam, Tanzania. Telephone: +255 22 2450512 / 2450751 / 2452108 Email: adam.fimbo@tmda.go.tz, info@tmda.go.tz Web: https://www.tmda.go.tz/

Implementation Agreement

Between

University of Rwanda/ East Africa Community Regional Centre of Excellence for Vaccines Immunization na Health Supply Chain Management (UR/EAC RCE-VIHSCM)

and

The Receiving EAC-Institution

For realization of the "*Minilab Project*"

PREAMBLE

WHEREAS the objectives of the East African Community is to improve the health of the population of the EAC, considering populations at risk in particular,

WHEREAS the EAC RCE-VIHSCM has received a grant of Euro Four Hundred Thousand (EUR 400,000) from the Federal Government of Germany through KfW Development Bank for financing the "*Minilab project*" as part of phase II funding;

WHEREAS the overall objective of the project to be met through the investment is to strengthen capacities in seven EAC Partner States to identify Substandard and Falsified Medicines (SFMs) and to move quickly to plug the gaps identified in the supply chains of the EAC region.

CONSIDERING THAT, the implementation of the project will contribute to the strengthening of regional and national capacities of National Medicines Regulatory Autorities (NMRAs) for the collaborative regional solutions to address the issues of porous supply chains that allow in SFMs;

RECALLING the Financing Agreement (dated 29/06/2021) and Separate Agreement (dated 29/06/2021) signed between the German Financial Cooperation and the UR/EAC RCE-VIHSCM ("The Project Agreements");

WHEREAS, under Clause 1.1, project activity C, first bullet of the Separate Agreement (phase II) , the UR/EAC RCE-VIHSCM will buy Minilabs to be used for the detection and analysis of SFMs in the context of teaching, training and research on quality assurance. This includes procurement of 2 Minilabs for the UR EAC RCE-VIHSCM for teaching purposes and 2 Minilabs per each EAC Partner State to be donated to institutions such as NMRAs or Central Medical Stores (CMSs).

The parties have agreed to the provisions of the present Implementation Agreement as follows:

Article 1
Responsibilities of the UR/EAC RCE-VIHSCM

1. **Procurement of equipment and training**

   (a) The UR/EAC RCE-VIHSCM shall, in line with KfW and University of Rwanda procurement guidelines and project agreements, utilise the funding to carry out the procurement of :

      (i) Sixteen (16) Minilab packages: two Minilabs for each EAC Partner State for data reporting on the quality of selected five antimicrobial and two antimalarial medicines, and two Minilabs for the UR EAC RCE-VIHSCM for training purposes.
      (ii) Replacement of broken glass ware and consumed reagents for a period of four years from 2023 untill 2026.

(b) All EAC Statutory Due Processes and Consultations were complied within preparation of this implementation agreement.

2. Training of the staff members for the implementation of the project

(1) The UR/EAC RCE-VIHSCM, with the support of Tübingen University, Germany, shall organise and coordinate the Training of Trainers (Three staff members from each receiving EAC-institution) on how to use the Minilab pakage and to report alanytical results.
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(ii) Recruitment of the training institution: and
(iii) Facilitation for staffs during project related activities such as Mix-countries training and in-country training.

4. Transfer of assets

(i) The UR/EAC RCE-VIHSCM shall transfer assets of the project to receiving EAC-institutions as soon as the Minilab packages have been purchased, delivered, assembled and tested at a place agreed upon by both parties and the Training of Trainers (ToT) has occured.

(ii) The transfer of assets will be documented in minutes duly signed by both parties with a description of technical specifications.

Article 2
Responsibilities of the receiving EAC-institution

1. Facilitation of customs clearance of donated equipment, supplies, reagents and consumables

The Implementing NMRA in the Partner State shall be responsible for the customs clearance of all donated equipment, supplies, reagents and consumables including securing all the necessary tax exemptions from the relevant national authorities.

2. Mobilisation of test reagents and consumables

(a) The receiving EAC-institution, through its respective National Public Health Reference Laboratory (NPHRL), shall mobilise resources to cater for any additional test reagents and consumables other than those listed in the Minilab package that may be needed during the project implementation period.

(b) In case of emergency during the project implementation period, the Receiving EAC-Institution shall procure test reagents using its own budget and claim a reimbursement

from the UR/EAC RCE-VIHSCM not exceeding [illegible] reference provided for the core reagents and consumables for each EAC Partner State.

3. Operation of the Minilab package

Throughout the implementation of the project, the Receiving EAC-Institution shall be responsible for:

(i) Proper operation and maintenance of the Minilab package;
(ii) Storage of equipment and protection against theft and misuse;
(iii) All operating costs related to sampling, analysis of samples and preparation of required reports;
(iv) Carrying out in-country external quality assurance (EQA) in line with WHO and project guidelines;
(v) Reporting on the selected medicines and share data with UR/EAC RCE-VIHSCM.
(vi) Creation of a country project coordination team at the receiving EAC-institution.
(vii) Organize the training of more staff members using the three staff members who benefited from the ToT, upon the specific national needs;
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(c) The reports referred to in clause (b) shall provide the following information:

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(iv) Amount of used reagents and solvents and the amount og remaining amount for each reagent and solvent;
(v) Number of broken glass ware;
(vi) Number of new staff members trained;
(vii) Request of reagents, solvents and glass ware for replacement;
(viii) Plan of sampling for the next reporting period;
(ix) Any other important information.

5. Responsibilities of the Receiving EAC-Institution after the project phase-out (after 2026) and sustainability plan

After the project phase-out, the Receiving EAC-Institution shall be responsible for continuing operations and maintenance of the Minilab package using harmonized Standard *Operating Procedures (SOPs)* and reporting systems. The Receiving EAC-Institution and UR/EAC RCE-VIHSCM will develop a sustainability plan to ensure continuity of the project after the end of the project duration.

Every Receiving EAC-Institution shall report data focusing on the following seven medicines including five antimicrobials from the WHO's list of Critically important antimicrobials for

human medicine, 6th revision (amoxicillin + clavulanic acid, gentamicin, rifampicin, ceftriaxone and ampicillin) and two antimalarials (artemether + lumefanthrine and quinine), as they were mentioned to be the most substandard and/or falsified medicines in Africa and Asia in 2017. The reporting shall be paper-based (the reporting template will be shared by the UR/EAC RCE-VIHSCM) while waiting for the implementation of digitalization of the UR/EAC Pooled Procurement Framework (EAC PPF) digital infrastructure.

Data collection will start with ports of medicines entry, then progressively expand to points that are at high risk for SFMs. To ensure data completeness and accuracy, each Receiving EAC-Institution shall ensure the correctness and completeness of the submitted data. Seventy percent (70%) shall be the cutoff point for both the completeness and the quality of reported data. Once data are received by the UR/EAC RCE-VIHSCM, information will be channeled through concerned Medicines Regulatory Authorities (MRAs) of the EAC Partner State for further actions. Failure to report for two consecutive quarters shall be followed by:

1) Disqualification of the Receiving EAC-Institution as a partner of the UR/EAC RCE-VIHSCM for future opportunities, and
2) Reporting the incompetency of the failing Receiving EAC-Institution to the EAC Secretariat for decision.

Article 3 Entry into force

This Agreement shall enter into force upon signature by both parties.

Done at ..... on .....

DG TMDA

For the UR/EAC RCE-VIHSCM For the Receiving EAC-Institution

EAST AFRICAN COMMUNITY MEDICINES REGULATORY HARMONIZATION (EAC-MRH) PROGRAMME

19TH FORUM OF HEADS OF NATIONAL REGULATORY AUTHORITIES (NRAs), CONSULTATIVE MEETING WITH PHARMACEUTICAL INDUSTRY STAKEHOLDERS AND STEERING COMMITTEE

28TH NOVEMBER - 2ND DECEMBER 2022
FOUR POINTS BY SHERATON
DAR ES SALAAM, UNITED REPUBLIC OF TANZANIA

REPORT OF THE MEETING

EAC Secretariat,
EAC Close
P.O. BOX 1096,
Arusha, Tanzania.

1.0 INTRODUCTION

Access to medicines is a key element of a well-functioning health system. Strong governance of the pharmaceutical sector, effective, independent, and transparent regulatory systems provide the necessary foundation for greater access to medicines.

The East African Community Secretariat in collaboration with Partner States National Medicines Regulatory Authorities (NRAs) have been implementing a regional programme on Medicines Regulatory Harmonization (EAC-MRH) since March 2012.

The EAC forum of Heads of NRAs and steering committee provides technical and administrative oversight of EAC regional program on medicines regulatory harmonization. It is with this regard that the 19th EAC Forum of Heads of NRAs, consultative meeting with pharmaceutical industry stakeholders and steering committee was convened from 28th November to 2nd December 2022 with the following objectives:

(i) Receive Feedback from Pharmaceutical Industry Stakeholders on EAC Joint Regulatory Activities
(ii) Review EAC Service Charter, Implementation Plan and Mechanisms for Management of Coordination Fee by EAC Secretariat for EAC-MRH Sustainability Plan
(iii) Review Progress on Implementation of EAC Joint Assessment Procedure
(iv) Review Progress on Implementation of EAC Joint GMP Inspections
(v) Review Progress on Implementation of Joint Operation of Heads of NRAs to Curb Sub-Standard and Falsified Medical Products (SF) and Joint Quality Surveys of Cephalosporins
(vi) Review Report on Procurement and Regulatory Linkages

1.1 CONSTITUTION OF THE BUREAU

The bureau was constituted in the presence of the Heads of NRAs from the Republics of Burundi, South Sudan, Kenya, Rwanda, Uganda and the United Republic of Tanzania.

In accordance with the EAC Rules of Procedure, **Dr. Dedith Mbonyingingo,** Director General Autorité Burundaise de Régulation des Médicaments et des

Aliments (ABREMA-Burundi) chaired the meeting while **Dr. Mawien Atem Mawien,** the Secretary General, Drug and Food Control Authority (DFCA-South Sudan) served as the Rapporteur.

1.2 PARTICIPANTS

The meeting was attended by the Heads of NRAs/Representatives from the seven (7) EAC Partner States National Regulatory Authorities (NRAs) namely Autorité Burundaise de Régulation des Médicaments et des Aliments (ABREMA-Burundi), Drug and Food Control Authority (DFCA- South Sudan), Pharmacy and Poisons Board (PPB-Kenya), Rwanda Food and Drugs Authority (Rwanda FDA),National Drug Authority (NDA-Uganda), Tanzania Medicines and Medical Devices Authority (TMDA), Zanzibar Food and Drug Agency (ZFDA), Technical Staff from EAC Secretariat and EAC Centre of Excellence for Vaccines, Immunization and Health Supply Chain Management. The list of participants is hereto attached as ***Annex I.***

1.3 ADOPTION OF THE AGENDA

The agenda and programme of the meeting was adopted with additional agenda item on consideration of the project on Minilab Test Kits by the EAC Centre of Excellence for Vaccines, Immunization and Health Supply Chain Management (EAC RCE-VISCM). The revised agenda is hereto attached as ***Annex II.***

1.4 OPENING REMARKS

1.4.1 REMARKS BY THE CHAIRPERSON

Dr. Dedith Mbonyingingo, Director General Autorité Burundaise de Régulation des Médicaments et des Aliments (ABREMA-Burundi), expressed his pleasure and honour to attend and chair the meeting. He thanked the EAC Secretariat for organising the meeting and the United Republic of Tanzania for hosting it. He reminded members that this was the first face to face meeting since the Covid 19 outbreak.

He informed members that, despite the challenge of Covid 19, The Government of the Republic of Burundi was able to establish Burundi Food and Medicines Regulatory Authority "ABREMA" which is committed to the East African Community Medicines Regulatory Harmonization Program and the implementation of decisions made during the joint activities and meetings.

Dr. Mbonyingingo informed delegates that, the East African community is honoured to host the African Medicines Agency "AMA" whose headquarters will be located in the Republic of Rwanda and this will help harmonize the regulatory systems and will be a model in matters of regulation to ensure quality, efficacious and safe medicines and technologies.

He further informed members that the EAC is becoming bigger, greater with a wider mark by Democratic Republic of Congo (DRC) joining EAC. He welcomed DRC Medicines and Regulatory Authority in absencia.

He urged members to commit to the meeting, pay attention to the different presentations developed by the experts from the NRAs so that all agenda items are discussed and the objectives of the meeting are archived and wished them fruitful deliberations.

1.4.2 REMARKS BY THE REPUBLIC OF SOUTH SUDAN

Dr. Mawien Atem Mawien, the Secretary General, of the Food and Drug Control Authority (DFCA) of South Sudan thanked the chairperson of the meeting and appreciated the work of the expert working groups which provides a platform for discussion of agenda items during the forum.

He informed members that the Medicines Regulatory Harmonization Program is a pillar through which the experts work to ensure access to safe medicines.

1.4.3 REMARKS BY THE REPUBLIC OF KENYA

Dr. Ronald Mwende Inyangala, Deputy Director, Product Evaluation and Registration Pharmacy and Poisons Board (PPB), representing the Chief Executive Officer of PPB, expressed his happiness to see familiar faces after a long time of disruption of meetings by the Covid-19 pandemic outbreak.

He affirmed Kenya's support for all the processes and specifically takes pride in discussing the sustainability plan.

He urged members to support domestic manufacturers while maintaining standards and to address the concerns of the pharmacy industry stakeholders without compromising standards.

1.4.4 REMARKS BY THE REPUBLIC OF RWANDA

Ms Nadine Niyomahoro, an Assessor for Finished Pharmaceutical Products (FPP) and Active Pharmaceutical Ingredients (API), Rwanda Food and Drugs Authority (Rwanda FDA), expressed apologies from the Head of Rwanda FDA who could not attend the meeting because of other commitments and preparations for WHO benchmarking exercise. She appreciated the joint regulatory activities supported by the EAC-MRH program and wished members fruitful deliberations.

1.4.5 REMARKS BY THE UNITED REPUBLIC OF TANZANIA

Mr. Adam M. Fimbo, Director General of Tanzania Medicines and Medical Devices Authority (TMDA), thanked the Chairperson, the rapporteur and the EAC Secretariat for organizing the meeting.

He informed members that this was the first physical meeting since the Covid-19 outbreak in 2019. He welcomed members to the United Republic of Tanzania and specifically to the city of Dar es Salam and informed the members that TMDA has shifted its headquarters to Dodoma.

Mr. Fimbo informed members that TMDA will be re-benchmarked by WHO in February, 2023. He further informed members that, TMDA has granted marketing authorization to 105 medicines that have jointly been reviewed through EAC regulatory pathway. He expressed the need to conduct overall performance evaluation of the MRH program similar to one that was done by Boston Consulting Group (BCG) to assess progress and define the direction of the programme.

Mr. Fimbo congratulated Rwanda for having been selected to host the African Medicines Agency **(AMA).** He further informed members of the plan to merge the Zanzibar Food and Drugs Agency (ZFDA) with Zanzibar Bureau of Standards and Zanzibar Metrological Agency to have one agency that will

handle medicines regulation, standards and metrological matters. Delegates were informed that, draft Bill is ready and awaits to be tabled in Parliament.

1.4.6 REMARKS BY THE REPUBLIC OF UGANDA

Dr. Juliet Awori Okecho, Director, Product Assessment and Registration representing the Secretary to the Authority of the National Drug Authority (NDA) thanked the EAC Secretariat for organizing the meeting and the host country for the hospitality. She stated that the National Drug Authority remains committed to ensuring the success of the EAC-MRH programme and supports its progress towards its self-sustainability. She mentioned that this program continues to strengthen synergies between EAC NRAs; ensuring an efficient utilization of the technical and financial resources; and achieving cost-effective and timely marketing authorization of the products, without trading-off with the assurance of safety, efficacy, and quality.

Dr. Okecho re-iterated that, as the lead NRA for Good Manufacturing Practices (GMP) inspection, NDA is committed to achieving the efficiency demanded by the Service Charter in the coordination of joint GMP activities. This would ensure that the program delivers value to its clients on time. She committed to NDA's continued contribution of both the personnel and financial resources required by the experts' participation in the joint GMP audits and joint assessment sessions, in the cost-sharing arrangement. She noted that, at the national level, once NDA receives communication of a positive outcome from the joint assessments, it expeditiously carry the products through the final administrative steps and register them in the shortest time possible. She congratulated the Republic of Rwanda for being selected as the host country for the African Medicines Agency (AMA) and welcomed Democratic Republic of Congo (DRC) to the community. She concluded her remarks by wishing the delegates fruitful deliberations.

1.4.7 REMARKS BY THE EAC SECRETARIAT

Dr. Julius Simon Otim, Senior Health Officer, Medicines and Food Safety on behalf of the EAC Secretariat welcomed all the delegates to the 19th forum of Head of NRAs and appreciated the United Republic of Tanzania for hosting the meeting.

He affirmed the importance of medicines as a key pillar of the health care system and appreciated the support of the EAC NRAs to the MRH program through technical support and oversight.

He highlighted that the meeting was specifically important, because it is going to address the issue of sustainability of the MRH program given the fact that Development Partners support will come to an end in June 2024.

He informed members that, the sustainability plan had three dimensions for discussion and these included coordination fees, implementation plan and financial guidelines.

He further informed members that 22nd Sectoral Council meeting could not endorse the sustainability plan because of concerns regarding the modalities implementation and operationalization hence the directives to the EAC Secretariat and EAC NRAs to develop Service Charter, Implementation Plan, Financial Policy and Manual.

Dr. Otim informed members that based on the council directives, a meeting of Experts Working Group on Policy, Legal and Regulatory Reforms was held in Nairobi from 30th October to 4th November 2022 to address directive of the ministers.

He further informed members that the meeting will also receive feedback from the pharmaceutical industry stakeholders and also discuss progress of joint assessment, GMP inspections, joint quality surveys of cephalosporins and operation of Heads of EAC NRAs to curb substandard and falsified medical products.

2.0 PRESENTATION OF CLIENT CHARTER

Mr. Felchism Apolnary, Ag. Manager, Medicines Registration, TMDA, made a presentation of the Client's Service Charter highlighting service delivery timelines; commitments to the stakeholders and the rights and responsibilities of stakeholders as well as what the EAC Secretariat and Partner States NRAs anticipate from their clients.

The charter was developed based on experience gained during the joint assessment and joint inspection activities. It was also based on the client's charter of the individual EAC NRAs as well as stakeholders views.

During the discussion on the Charter, the Heads of EAC NRAs proposed further reduction in timelines for scientific evaluation and timelines for handling query responses by both regulator and applicant. The Clients Service Charter as agreed is hereby attached as ***Annex III.***

3.0 PRESENTATION OF THE EAC IMPLEMENTATION MATRIX OF SUSTAINABILITY PLAN FOR EAC- MRH PROGRAM

The draft plan was presented by **Dr. Robert Ssekajjugo, Regulatory Officer, NDA.** The plan was revised by experts to remove top up fees/coordination fees for renewals and retention. Additional fees include, fees for IVDs, Joint Desk Assessment of GMP, additional production lines and Joint Desk Assessment of Active Pharmaceutical Ingredient Master File Procedure (APIMF). The Heads of EAC NRAs proposed increase of fees for some joint regulatory activities and decrease in costs of some activities and maintain critical activities to ensure the program is self-sustained by 2024.

The forum of Heads of EAC NRAs endorsed the implementation plan/matrix for consideration by the 23rd Ordinary Meeting of the EAC Sectoral Council of Ministers of Health. The implementation plan/matrix as agreed by the heads of NRAs is hereto attached as ***Annex IV.***

4.0 PRESENTATION OF THE FINANCIAL POLICY AND MANUAL

The EAC Financial Policy and Manual was presented by **Ms. Caroline Jerop Too, Financial Expert, PPB.**

The Financial Policy and Manual provides the policies and procedures for the financial management of the EAC-MRH programme coordination fees. It guides the programme on how to manage finances with integrity and transparency. The financial policy and procedures manual for EAC-MRH is anchored to the EAC Financial Rules and Regulations 2012. The Manual will be reviewed annually to keep the financial policies current and relevant. The Financial Policy and Procedures manual as approved is hereby attached as ***Annex V.***

5.0 PRESENTATION OF FEEDBACK FROM PHARMACEUTICAL INDUSTRY STAKEHOLDERS ON EAC JOINT REGULATORY ACTIVITIES AND ACTION PLAN TO ADRESS CONCERNS

Ms. Jane Humphrey Mashingia, Technical Expert, EAC Secretariat provided highlights of the background paper and made a presentation which covered feedback from the pharmaceutical industry stakeholders and the action plan to address their concerns. **Ms. Mashingia** informed the meeting that, three stakeholders' consultative meetings were held since February 2022 to discuss the sustainability plan of EAC-MRH program. All the meetings were held virtually and the fourth consultative meeting was held on 29th November 2022 within the margins of the Forum of Heads of EAC NRAs. She informed delegates that, the last three consultative meetings involved EAC and Kenya Association of Pharmaceutical Industry (KAPI) which raised concerns regarding, the EAC requirements for registration of IVDs which are not fully domesticated by all Partner States and some NRA guidelines that recommend physical inspection of IVDs manufacturing facilities. With regard to domestication of compendium of guidelines for pharmacovigilance, KAPI noted that, the guideline requires qualified person responsible for pharmacovigilance (QPPV) be resident in the EAC Partner States. This requirement is implemented by only one NRA while the rest require Marketing Authorization Holders (MAH) to have a QPPV in each country where a marketing authorization (MA) has been granted.

Ms. Mashingia further informed the Heads of EAC NRAs that, KAPI commends progress made for EAC joint assessment procedure, except for the timelines for granting marketing authorization (MA) by EAC NRAs. It was

noted that, some EAC NRAs take more than 12 months to grant MA and some NRA repeat scientific evaluation process. KAPI and International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) is supporting the EAC joint assessment procedure, however they recommend accountability and efficiency of the joint regulatory process. KAPI noted that, it is not efficient for NRAs to take more than a year to grant MA and this was the main reason KAPI had put a rider to the endorsement of sustainability plan by the EAC Sectoral Council of Ministers of Health.

The Heads of EAC NRAs took note of the action plan to address concerns of KAPI and made inputs related to reliance mechanisms to expedite scientific review process. The Action Plan as agreed is hereto attached as ***Annex VI.***

RECOMMENDATIONS

The Heads of EAC National Medicines Regulatory Authorities (NRAs) Made the Following Recommendations:

(a) **Took note of the Action Plan which has addressed most of the concerns raised by Pharmaceutical Industry Stakeholders;**

(a) **Directed the EAC Secretariat to mobilize resources and engage a consulting firm to conduct overall evaluation of performance of the EAC-MRH Program to inform on progress, gaps and future plans;**

(b) **Considered and Endorsed the Clients' Service Charter for EAC-MRH Program for Implementation by 1st March 2023 and Recommended the Same to be Considered by the 23rd Ordinary Meeting of the EAC Sectoral Council of Ministers of Health;**

(c) **Considered and Endorsed Implementation Matrix for EAC-MRH Program for Implementation by 1st March 2023 and Recommended the Same to be Considered by the 23rd Ordinary Meeting of the EAC Sectoral Council of Ministers of Health;**

(d) **Considered and Endorsed Financial Policy and Manual for Coordination Fee for Implementation by 1st March 2023 and Recommended the same to be considered by the 23rd Ordinary Meeting of the EAC Sectoral Council of Ministers of Health.**

CONSULTATIVE MEETING BETWEEN EAC HEADS OF EAC NRAs AND PHARMACEUTICAL INDUSTRY STAKEHOLDERS -29TH NOVEMBER 2022

1.0 CONSTITUTION OF THE BUREAU

The Bureau was constituted in the presence of the Heads of NRAs from the Republic of Burundi, South Sudan, Kenya, Rwanda, Uganda and the United Republic of Tanzania. In accordance with the EAC Rules of Procedure, **Dr. Dedith Mbonyingingo**, Director General, Autorité Burundaise de Régulation des Médicaments et des Aliments (ABREMA-Burundi), chaired the meeting and **Dr. Mawien Atem Mawien**, The Secretary General, Drug and Food Control Authority (DFCA- South Sudan) served as the Rapporteur.

2.0 PARTICIPANTS

The meeting was attended by the Heads of NRAs/Representatives from the seven (7) EAC Partner States National Regulatory Authorities (NRAs) namely Autorité Burundaise de Régulation des Médicaments et des Aliments (ABREMA-Burundi), Drug and Food Control Authority (DFCA- South Sudan), Pharmacy and Poisons Board (PPB-Kenya), Rwanda Food and Drugs Authority (Rwanda FDA),National Drug Authority (NDA-Uganda), Tanzania Medicines and Medical Devices Authority (TMDA), Zanzibar Food and Drug Agency (ZFDA), Pharmaceutical Industry Stakeholders, Technical Staff from the EAC Secretariat and EAC Regional Centre of Excellence for Vaccines, Immunization and Supply Chain Management. The list of participants is hereto attached as ***Annex VII.***

3.0 ADOPTION OF THE AGENDA

The agenda and programme of the meeting was adopted by consensus by all the Partner States and Stakeholders and is hereto attached as ***Annex VIII.***

4.0 OPENING REMARKS

4.1 Remarks by the Chairperson

Dr. Dedith Mbonyingingo, Director General Autorité Burundaise de Régulation des Médicaments et des Aliments (ABREMA-Burundi), thanked the EAC Secretariat for organising the meeting and the United Republic of Tanzania for hosting it. He informed the meeting that, implementation of the EAC-MRH program over the last 10 years would not have been possible without the cooperation and collaboration with stakeholders among them pharmaceutical industry, importers, wholesalers and retailers.

He affirmed that pharmaceutical industries play an important role in strengthening the pharmaceutical regulatory systems across the EAC region and provision of quality, efficacious and safe medicines and health technologies hence supporting sustainability of the MRH program.

He informed stakeholders that the key agenda of the meeting was to understand the pharmaceutical industry perspectives on the EAC joint regulatory procedures such as joint assessment of medicinal product dossiers and joint GMP inspections. He assured them that, their concerns have been addressed and an action plan has been developed to outline status of implementing interventions to address the issues raised.

Dr. Dedith Mbonyingingo further informed stakeholders that, the Republic of Burundi is committed to implement decisions made for the sustainability, strengthening of the EAC MRH program and pharmaceutical regulatory systems across the EAC region and Africa.

He concluded his remarks by urging members to commit to the discussions in the meeting and actively participate in order to achieve the expected deliverables. He wished members fruitful discussions and deliberations.

4.2 REMARKS BY THE PHARMACEUTICAL INDUSTRY STAKE HOLDERS

4.2.1 REMARKS BY THE REPRESENTATIVE OF KENYA PHARMACEUTICAL INDUSTRY (KAPI)

Dr. Lilian Ngaruiya, KAPI Administrative Manager, informed members that KAPI was formed in 1968 and currently has 34 members. The aim of KAPI is to promote ethical practice in the Pharmaceutical Manufacturing Industry.

She expressed commitment of KAPI to create awareness for the MRH program since it is a window for access to quality safe and efficacious medicines.

Dr. Ngaruiya reiterated that regulatory harmonization simplifies trade processes for the pharmaceutical industry and enhances competitiveness in the market

She highlighted key areas of engagement as reliance practices and the need to share best practices in the region and on boarding the new EAC Partner State, the Democratic Republic of Congo and expressed their support for the sustainability program once their recommendations are addressed.

She called for increased effectiveness of the MRH processes and the transition to African Medicines Agency (AMA).

4.2.2 REMARKS BY THE REPRESENTATIVE OF TANZANIA ASSOCIATION OF PHARMACEUTICAL INDUSTRY (TAPI)

Mr. Mashaka Alison Shonza, Regulatory Affairs Manager, Department of Registration and Quality Assurance Synermed Pharmaceutical (T) Ltd, expressed happiness to have stakeholders from Tanzania participate in the discussions on the sustainability plan for EAC-MRH Program.

He highlighted the importance of stakeholder involvement in discussing the regulatory processes so that their concerns can be discussed and addressed.

He concluded his remarks by wishing delegates fruitful deliberations.

5.0 REMARKS BY THE HEADS OF NRAs

5.1 Remarks by the Republic of Kenya

Dr. Ronald Mwende Inyangala, Deputy Director, Product Evaluation and Registration Pharmacy and Poisons Board (PPB), on behalf of the Chief Executive Officer of PPB, appreciated the growth of the EAC to seven countries and the development of systems in the pharmaceutical industry where most of the NRAs are now ISO certified with many countries working to achieve maturity level 3 in terms of WHO maturity level. He informed delegates that, TMDA has achieved WHO maturity level 3 since 2019 and it was the first regulatory agency in Africa to achieve that status.

He informed delegates that, harmonized guidelines have been developed to ensure that things are done the same way and informed stakeholders that, EAC NRAs have developed reliance guidelines which has helped NRAs to rely on the work of WHO and other Stringent Regulatory Authorities (SRAs) without the need to repeat assessments.

Dr. Inyangala informed stakeholders that for the last 10 years the EAC-MRH program has been relying on donor funding, and this was dwindling and therefore the need to have a sustainability plan.

He urged the stakeholders to look at the sustainability plan positively though the timelines for evaluation and authorization processes have to be improved. He informed stakeholders that this is a dialogue and the EAC-MRH program listens and discusses recommendations. He thanked all delegates and wished them good deliberations.

5.2 Remarks by the Republic of Rwanda

Ms. Nadine Niyomahoro, an Assesor, Finished Pharmaceutical Products and Active Pharmaceutical Ingredient (API), Rwanda Food and Drugs Authority, thanked stakeholders for attending the meeting and encouraged the pharmaceutical industry stakeholders to apply for market authorization through the EAC joint assessment procedure. She informed members that only three products have been registered in Rwanda through the joint assessment procedure.

She affirmed Rwanda's commitment to collaborate with the pharmaceutical industry and concluded her remarks by wishing delegates fruitful deliberations.

5.3 Remarks by the Republic of South Sudan

Dr. Mawien Atem Mawien, the Secretary General, of the Food and Drug Control Authority of South Sudan, thanked the EAC MRH program for bringing the pharma industry stakeholders to discuss the sustainability program.

Dr. Mawien informed members that since the Republic of South Sudan joined the EAC in 2019 they have been committed to the joint assessment and all activities under the EAC-MRH program.

He expressed the limited awareness of the program as a challenge and the need to have a joint regional platform for information sharing between the pharma industry and regulators. He thanked delegates for coming for the meeting.

5.4 Remarks by the United Republic of Tanzania

Mr. Adam M. Fimbo, Director General of Tanzania Medicines and Medical Devices Authority (TMDA), welcomed the pharmaceutical stakeholders to the meeting and expressed the importance of engagement of regulators with the pharmaceutical stakeholders.

He highlighted the benefits of using the EAC joint assessment procedure as speeding up the process of scientific assessment and market authorization and optimizes use of resources.

He reminded stakeholders that the EAC-MRH program depends on donor funds and therefore the need to device mechanisms for sustainability.

Mr. Fimbo informed members that the TMDA has developed an action plan to promote domestic manufacturing which will be shared during national meetings. He concluded his remarks by wishing members fruitful deliberations.

5.5 Remarks of the Republic of Uganda

Dr. Juliet Awori Okecho, Director, Product Assessment and Registration who represented the Secretary to the Authority of the National Drug Authority expressed appreciation on participation of pharmaceutical industry stakeholders to the meeting.

She expressed the importance of discussing the sustainability of the EAC-MRH program that facilitates faster registration of products which is better for everyone.

Dr. Okecho informed members that, Uganda encourages local manufacturing because it is cheaper to have medicines from the domestic market than through importation.

She expressed the commitment of the NDA to ensure that the EAC process works well and as a lead agency on GMP inspections, commits to ensure efficiency and that the times lines in the client's charter are followed up to avoid unnecessary delays.

She promised to deliver the message from the meeting to the Ugandan manufacturers who were not in attendance and wished members good deliberations.

5.6 Remarks by WHO representative

Mr. Sunday Kisoma from the unit for regulation and safety thanked the chairperson and EAC for inviting WHO as a Strategic Partner.

He commended the evolution and progress of the EAC-MRH program which is a result of collaboration between the EAC Secretariat, NRAs and Pharmaceutical Industry.

Mr. Kisoma expressed his happiness to attend the meeting to discuss the sustainability plan which is a good initiative to ensure access to quality products across the EAC region.

He informed members that WHO will provide strategic leadership and is better placed to promote regulatory convergence and adoption of common standards.

He informed stakeholders that WHO promotes and facilitates product introduction pathways to avoid repetition of what has been done by trusted authorities so that resources are saved and allocated to other activities.
He expressed WHO commitment to support EAC joint assessment procedures through providing technical and procedural guidance to ensure quick access of medicinal products to patients. He informed members that WHO through another unit is supporting local manufacturing which is required for product access because dependence on foreign manufacturers delays access as demonstrated in the challenges on access to Covid-19 Vaccines.
He closed his remarks by wishing delegates good deliberations.

5.7 Remarks by the EAC secretariat

Ms. Jane Humphrey Mashingia, Technical Expert, on behalf of the East African Community Secretariat, thanked the Chairman, the heads of NRAs, and the stakeholders for the commitment in the last 10 years. She informed members that the joint regulatory activities are in line with EAC Treaty Chapter 21, Article 118 in which Partner States commit to collaborate and harmonize drug registration procedures so as to achieve good control of pharmaceutical standards regulation as a key policy priority.
She expressed commitment to working together with the pharmaceutical industry, regulators and to have regular dialogue to get feedback on areas that need improvement to ensure that patients have access to safe, efficacious and quality medicines. She concluded her remarks by wishing delegates fruitful deliberations

6.0 PRESENTATION OF PHARMACEUTICAL INDUSTRY PERSPECTIVES ON EAC JOINT ASSESSMENT OF MEDICINAL PRODUCT DOSSIERS AND JOINT GMP INSPECTIONS

Dr. Lilian Ngaruiya presented the perspectives of the pharma industry on the EAC joint regulatory process and highlighted the following issues:
On the New Registration Process, she highlighted successes which included responsive and supportive EAC Coordination team, prompt feedback on

queries from the EAC Secretariat, Stakeholder feedback and successful roll out of EAC Vaccines and Biologicals registration guideline.

She highlighted the following challenges; Lack of a seamless recognition process after positive outcome of joint assessment and limitation of product categories to be considered for joint scientific review.

On risk based GMP inspections she highlighted the following as successes; implementation of joint GMP inspections and utilization of risk-based approach and highlighted the following as challenges; differences in GMP fees per country Vs EAC fees and lack of recognition of the joint GMP inspection report by the NRAs.

On EAC guidelines on variations, she highlighted the following successes; stakeholder engagement in guideline development and review, mutual collaboration between industry and EAC Secretariat and Partner States and regular interactions and annual meeting schedules.

7.0 PRESENTATION OF THE CLIENT SERVICE CHARTER

Mr. Felchism Apolnary made a presentation of the Client's Service Charter highlighting service delivery timelines; commitments to the stakeholders and the rights and responsibilities of our stakeholders as well as what the EAC Secretariat and Partner States NRAs anticipate from their clients. Pharmaceutical industry stakeholders agreed to the content of the Clients Service Charter. The Clients Service Charter is attached as ***Annex III.***

8.0 PRESENTATION OF THE ACTION PLAN AND REVISED FEE'S STRUCTURE

Ms. Jane Humphrey Mashingia, Technical Expert, EAC Secretariat, presented the action plan and revised fee structure. She highlighted that, most of the issues raised by stakeholders were addressed in various ways including development of EAC guideline for renewals, removal of coordination fees for screening, retention and renewals, development of client's service charter and implementation plan. She further informed stakeholders that, fees for IVDs, joint GMP desk assessment, joint desk assessment of Active Pharmaceutical Ingredient Master File (APIMF) and fee for joint GMP

inspection for additional production lines were included in the new fees structure. Pharmaceutical Industry Stakeholders endorsed the revised fee structure which is attached hereto as ***Annex IX.***

RECOMMENDATIONS

Pharmaceutical Industry Stakeholders took note of the Action Plan in which most of the issues raised were addressed by the EAC NRAs and EAC Secretariat and Made the Following Recommendations:

(a) **Considered and recommended the EAC Clients Service Charter, Implementation Matrix and Revised Coordination Fee Structure for Consideration and Approval by the 23rd Ordinary Meeting of the EAC Sectoral Council of Ministers of Health; and**

(b) **Establishment of a Platform by Pharmaceutical Industry Stakeholders to Advocate for EAC Joint Regulatory Procedure and Promotion of Domestic Manufacturing.**

FORUM OF HEADS OF EAC NRAs AND STEERING COMMITTEE, 20 NOVEMBER TO 2ND DECEMBER 2022

1.0 EAC JOINT ASSESSMENT OF SAFETY, EFFICACY AND QUALITY OF MEDICINAL PRODUCTS

The forum of Heads of EAC NRAs took note of the progress of 24th and 25th EAC Joint Dossier Assessment Session which were hosted by Zanzibar Food and Drugs Agency (ZFDA), United Republic of Tanzania and Pharmacy and Poisons Board, Republic of Kenya respectively. The following were the main observations:

1. The lead NRA for GMP inspections (National drug Authority) should follow and confirm the GMP clearance after assessment and provide complete reports to guide informed decision making.
2. Expert working group for medicines evaluation and registration to prepare a public information report for medicinal products recommended for marketing authorization through EAC joint regulatory pathway.
3. Three products that were recommended for marketing authorization during 24th joint assessment session as highlighted in Table 1 below, be granted marketing authorization by EAC NRAs;

Table 1: List of Medicinal Products Recommended for Marketing Authorization by EAC NRAs

S/No	Reference number	Brand name	Generic name	Dosage form	Applicant	Outcome of assessment
New Applications						
1	EAC22/A10/009	Pansiptin 25	Sitagliptin	Tablets	Mega Lifesciences Public Company Limited	Recommended for registration
Query Responses						
2	EAC21/A10/025	Pansiptin 100	Sitagliptin 100 mg	Tablets	Mega Lifesciences Public Company Limited	Recommended for registration
3	EAC21/A10/026	Pansiptin 50	Sitagliptin 50 mg	Tablets	Mega Lifesciences Public	Recommended for registration

					Company Limited	

4. The marketing authorization of twelve medicinal products recommended for Marketing Authorization from the 25th EAC joint assessment with pending GMP status but with positive scientific assessment outcome will be determined by individual NRAs, however the experts working groups for medicines evaluation and registration and inspection were directed to develop clear guidelines and flow chart for both processes to support smooth implementation. The list of recommended products is as listed in Table 2 below:

Table 2: List of Medicinal Products Recommended for Marketing Authorization by EAC NRAs

S/N	EAC Ref Number	Brand name	Common name	Dosage form	Applicant	Outcome of the Assessment
			NEW APPLICATIONS			
1	EAC22/C03/017	Firialta 10	Finerenone 10 mg	Film Coated Tablet	Bayer East Africa Ltd, Kenya	Recommended for registration
2	EAC22/C03/018	Firialta 20	Finerenone 20 mg	Film Coated Tablet	Bayer East Africa Ltd, Kenya	Recommended for registration
3	EAC22/L01/015	Tecentriq	Atezolizumab	Solution for injection/concentrate for solution for infusion	F.Hoffmann-La Roche Limited (6386)	Recommended for registration
			QUERIES			
4	EAC21/SO1/017	Latoprost T	Latanoprost 50 mcg/ml & Timolol 5 mg /ml	Eye drops (Ophthalmic) Solution	Mega Lifesciences Public Company Limited	Recommended for registration
5	EAC20/N02/016	Panadol Extra Soluble	Paracetamol 500 mg and Caffeine 65 mg	Effervescent Tablets	GlaxoSmithKline Limited, Kenya	Recommended for registration
6	EAC21/V03/031	Sevmeg 800	Sevelamar Carbonate 800 mg	Film coated Tablets	Mega Lifesciences Public Company Limited	Recommended for registration
7	EAC21/SO1/018	Latoprost	Latanoprost0.05% w/v	Eye drops (Ophthalmic) Solution	Mega Lifesciences Public Company Limited	Recommended for registration
8	EAC21/C09/005	Dasartan 16	Candesartan Cilexetil 16 mg	Tablets	Dafra Pharma GmbH	Recommended for registration
9	EAC21/B02/032	Xyntha 1000 IU	Moroctogog Alfa 1000 IU	Powder and solvent for solution for injection	Pfizer Vienna Court, Kenya	Recommended for registration
10	EAC21/B02/033	Xyntha 250 IU	Moroctogog Alfa 250 IU	Powder and solvent for solution for injection	Pfizer Vienna Court, Kenya	Recommended for registration
11	EAC21/B02/034	Xyntha 500 IU	Moroctogog Alfa 500 IU	Powder and solvent for solution for injection	Pfizer Vienna Court, Kenya	Recommended for registration
12	EAC21/A02/019	Dafrazol (Omeprazole Injection	Omeprazole 40 mg, vial	Powder and solvent for solution for injection	Dafra Pharma	Recommended for registration

5. Apply reliance mechanism where possible especially when the medicinal product has already been granted marketing authorization (MA)by Stringent Regulatory Authorities (SRA) or through WHO collaborative registration procedure.
6. The lead NRA for registration to provide detailed information on 21 products which were removed from the register of medical products to guide the Heads of EAC NRAs to make informed decision.
7. Life cycle management of jointly assessed products and jointly inspected facilities and in-country model. There is disparity in terms of validity period for certificate of GMP compliance and validity period for medicinal product registration. The respective experts working group to address that gap.
8. The Lead NRA for medicines evaluation and registration to expand details of applicants to include details of manufacturer in the table , this will guide the Heads of NRAs to make risk-based approach in regulatory decisions.

RECOMMENDATIONS

The Forum of Heads of NRAs and Steering Committee:

a) **Considered and recommended to EAC NRAs to Issue Marketing Authorization to Fifteen (15) Medicinal Products which met EAC Safety, Efficacy and Quality Requirements as listed in Table 1 and Table 2;**
b) **Considered and Approved for Implementation the EAC Guidelines on Submission of Documentation for Renewal of Marketing Authorization of Human Medicinal Products with effect from 1st January 2023;**
c) **Urged the Lead NRA for Registration and Expert Working Group for Medicines Evaluation and Registration to Provide Detailed Information on 21 Products Which Were Removed from Register and Report to the Heads of EAC NRAs by 14th January 2023;**
d) **Directed the EAC Expert Working Group for GMP to ensure that by the time the Registration assessment is completed, the GMP status should have been established**

e) **Directed the EAC Expert Working Group for Medicines Evaluation and Registration (MER) to Develop EAC Guideline on Reliance and Convergence.**

2.0 EAC JOINT GOOD MANUFACTURING PRACTICES (GMP) INSPECTIONS

The forum of Heads of NRAs took note of the progress report from the EAC expert working group on GMP which conducted physical joint GMP inspections to 13 pharmaceutical facilities located in Kenya, Uganda and India between May to June 2022. The meeting further noted that, expert working group met virtually to review reports of physical joint GMP inspections and the list of facilities inspected and status of reports is summarized in table 3 below:

Table 3: Status of Physical Joint GMP Inspections

Sno	Name of Facility	Location	Dates Inspected	Inspectors	Type of Inspection	Status of EAC Joint GMP Inspection Report	Comments
1	Cipla Quality Chemicals Limited	Kampala, Uganda	6-10 May 2022	TMDA, Rwanda FDA, ZFDA & DFCA	Routine Re-Inspection	CAPA was submitted by the Facility & is undergoing Review.	
2	Abacus Parenteral Drugs Limited	. Kampala. Uganda	7th to 11- 13 May 2022	TMDA, Rwanda FDA, ZFDA &DFCA	Routine Re-Inspection	CAPA was submitted by the Facility & is undergoing Review.	
3	Ajanta Pharmaceuticals	Maharashtra,India	16-18 May 2022	TMDA, ABREMA & PPB	Routine Re-Inspection	Pending CAPA submission from facility	
4	Modi-Mundipharma Pvt Ltd Modi-Mundipharma Pvt Ltd	Uttar Pradesh, India	20-24 May 2022	TMDA, ABREMA & PPB	Follow up inspection	Pending CAPA submission from facility	

5	MSN Laboratories	Telangana, India	18-20 May 2022	NDA, DFCA & PPB	Follow up inspection	Pending CAPA Submission	
6	Serum Institute of India	Manjari, Pune, India	India.23-25 May 2022	PPB, NDA & DFCA	Follow up inspection	Pending CAPA Submission	
7	Beta Healthcare Int Ltd	Nairobi, Kenya	30 May to 1st June 2022	NDA, Rwanda FDA, DFCA	Follow up inspection	CAPA was submitted by the Facility & is undergoing Review.	
8	Biodeal Laboratories Ltd	Nairobi, Kenya	3-7 June 2022	NDA, Rwanda FDA, DFCA	Routine Re-Inspection	Pending CAPA Submission.	
9	Serum Institute of India	Hadaspar, Pune, India	6-8 June 2022	Rwanda FDA, PPB & ZFDA	Follow up inspection	Inspection report not ready	
10	Regal Pharmaceuticals	Nairobi, Kenya	8-10 June 2022	NDA, ABREMA & TMDA	Routine Re-Inspection	CAPA was submitted by the Facility & is undergoing Review.	
11	Globela Pharma PVT Ltd	Gujarat, India	10-14 June 2022	Rwanda FDA, PPB & ZFDA	Follow up inspection	Report not ready	
12	Laboratory & Allied Ltd	Nairobi, Kenya	13-15 June 2022	NDA, ABREMA & TMDA	Routine Re-Inspection	CAPA was submitted by the Facility & is undergoing Review.	
13	Njimia (K) Ltd	Kajiado, Kenya	17-21 June 2022	NDA, ABREMA & TMDA	Follow up inspection	The facility failed to comply with GMP standards	Requires re-inspection

The forum further noted that, the expert working group conducted joint GMP desk assessment of 8 applications, 3 applications were triggered by application for joint review of medicinal product dossier. Table 4 summarizes the facilities and status of desk review of GMP documentation:

Table 4: Summary of Facilities and Status of Desk Review of GMP Documentation

SN	Name of Facility	Address	Country	Inspectors to conduct desk review	Status	Comments
1	Alcon Singapore Manufacturing Pte.Ltd	Alcon Singapore Manufacturing Pte.Ltd	Singapore	NDA	GMP Compliant	
2	Lohmann Animal Health International	Lohmann Animal Health International	United States Of America	TMDA		
3	MSD International Gmbh, T/A MSD Ireland (Ballydine)	MSD International Gmbh, T/A MSD Ireland (Ballydine)	REPUBLIC OF IRELAND	Rwanda FDA		
4	Hovione Farmaciencia S.A., Sete Casas. 2674-506 Loures. Portugal	Hovione Farmaciencia S.A.	PORTUGAL	Rwanda FDA		
5	Excella Gmbh & Co. KG	Excella Gmbh & Co. KG	GERMANY	NDA	GMP Compliant	
6	F.I.S. – Fabbrica Italiana Sintetici S.P.A.	F.I.S. – Fabbrica Italiana Sintetici S.P.A.	ITALY	PPB		
7	Odyssea Pharma SPRL	Rue Du Travail 16. 4460 Grace-Hollogne	BELGIUM	PPB		

Observations made by the Forum of Heads of NRAs include:

(i) The EAC Expert Working Group for GMP to share inspection reports of Serum Institute by 14th December 2022 to guide the Heads of NRAs to assess the observations and make informed decision on the GMP compliance taking into account the same facilities were inspected by WHO during the same period of May/June 2022 and are WHO prequalified;

(ii) Delays in submission of GMP reports for more than the timelines stated in the EAC compendium of guidelines for GMP which is 14 working days

(iii) Regulatory reliance is not used especially for WHO prequalified manufacturing facilities i.e Serum Institute, which was inspected the same time EAC conducted joint GMP inspection;

(iv) The lead NRA for GMP to ensure proper planning of joint GMP inspections and use same inspectors to inspect facilities which are proximal to each other. The Serum Institute Facilities in Pune and Hadspar were inspected by different inspectors while they are located near each other;

(v) Lack of consistency of using terminologies, routine re- inspection is used interchangeably with re-inspection while they have different meaning;

(vi) The lead NRA for GMP to strengthen follow up and monitoring of timelines for joint GMP inspection by ensuring timely submission of inspections reports, follow up with EAC NRAs on the status of GMP certificate and share with both EAC NRAs and EAC Secretariat, inspections reports. There is need to strengthen communication between NDA with EAC NRAs and EAC secretariat; and

(vii) The lead NRA for GMP to follow up with lead Auditors to submit all pending inspection reports and plan for a virtual meeting to jointly review the reports.

RECOMMENDATIONS

The Forum of Heads of NRA took note of the progress made in conducting joint physical GMP inspections and joint desk assessment of GMP documentation and made the following recommendations:

a) **Urged the Lead Auditors from Pharmacy and Poisons Board (PPB) and NDA to expedite finalization of all pending GMP reports for joint physical GMP inspections and submit progress report by 14th December 2022;**

b) **Urged the Lead NRA for GMP to share all GMP documentation for desk assessment to other EAC NRAs by 6th December 2022;**

c) **Urged the Lead Auditors from EAC NRAs to expedite finalization of all pending GMP reports for joint desk assessment of GMP documentation and submit progress report by 14th December 2022; and**

d) **Urged the Lead NRA for GMP to share all joint inspection reports to other EAC NRAs and EAC Secretariat by 14th December 2022.**

3.0 JOINT QUALITY SURVEY OF CEPHALOSPORINS AND JOINT OPERATION OF HEADS OF EAC NRAS TO CURB SUB-STANDARD AND FALSIFIED MEDICAL PRODUCTS (SF) AND JOINT QUALITY SURVEYS OF CEPHALOSPORINS

3.1 EAC Joint Quality Survey of Cephalosporins

The forum of Heads of NRAs noted that, the expert meeting for post-marketing surveillance (PMS) was convened from 29th August to 2nd September 2022 to harmonize the protocol, strategy, tools and procedures for conducting quality survey of cephalosporins and joint operation by the Heads of National Regulatory Authorities (NRAs) to curb substandard and falsified medical products in EAC Partner States. The meeting was attended by experts from all EAC NRAs, WHO-AFRO and EAC Secretariat.

Cephalosporins that were selected for the survey based on how common they are used in the Partner States and frequency of reports on failure to safety and quality standards were as follows:

i) Ceftriaxone
ii) Cefuroxime
iii) Cefixime

The forum further took one that, WHO expert guided the EAC region to officially request for the EPIONE tool from WHO to be used for sampling. In addition, the WHO committed to provide sample collection bags with a specific barcode. The sample collection form was reviewed and updated. The meeting agreed to have hard copies of data collecting tool as backup.

The forum recommended that, the compendial testing be carried out by National Quality Control Laboratory (NQCL), Republic of Kenya. For samples from South Sudan and Burundi, both compendial and non-compendial testing will be done by National Quality Control Laboratory (Kenya).

The forum commended the quality deliverables by the expert working on post marketing surveillance which include:

- Final protocol for the quality survey of cephalosporins (***Annex X***)
- Final protocol for EAC joint operation by Heads of EAC NRAs to curb substandard and falsified medical products (***Annex XI***)
- The annexes to both protocols include EAC harmonized sample collection form, the PMS screening form, analysis request form, excel aggregation tool, PMS report format, sampling plan and budget

The forum of Heads of EAC NRAs noted that, the total budget for quality survey of cephalosporins and joint operations of the Heads of NRA to curb sub-standard and falsified medical products for 7 NRAs is USD 256,735 and USD 446,516.1 respectively.

Observations Made by the Forum of Heads of EAC NRAs:

(i) The protocol for quality survey and joint operations will be used for subsequent joint quality surveys and operations;
(ii) The budget is too high and recommended each EAC NRAs experts to review their budget and come up with realist budget since they have experience of conducting quality surveys and budget is known;
(iii) PPB to follow up with NQCL and negotiate for low rates/price for compendial test analysis;
(iv) NDA has two products (ceftriaxone and cefuroxime) in the PMS list for this financial year and the budget is available. The representative of the Secretary to the Authority confirmed resources to be available to support quality survey of cephalosporins;
(v) Rwanda, Burundi and South Sudan informed the meeting that they did not have a budget for sample collection and delivery to the Lab in Kenya;
(vi) TMDA committed to quality survey of cephalosporins and joint operations to curb SF;
(vii) The Heads of EAC NRAs proposed the joint quality survey of cephalosporins and joint operations to be carried out during the third week of January 2023; and
(viii) The Heads of EAC NRAs recommended the EAC Secretariat to utilize resources allocated for joint quality survey and operation to pay for compendial test analysis at NQCL.

RECOMMENDATIONS

The Forum of Heads of EAC NRAs took note of the progress made in planning and development of protocol, tools and budget for conducting EAC quality survey of cephalosporins and joint operations of the Heads of NRA to curb sub-standard and falsified medical products and;

a) **Urged all experts on Post Marketing Surveillance (PMS) from EAC NRAs to review the budget for quality surveys and joint operations and share revised budget to EAC Secretariat by 16th December 2022;**
b) **Recommended the EAC NRAs to Conduct Joint Quality Survey of Cephalosporins and Joint Operations to Curb SF between 16th to 20th January 2023; and**
c) **Directed the EAC Secretariat to Utilize Financial Resources Allocated for Quality Survey of Antibiotics and Joint Operation of Heads of EAC NRAs for costs related to Compendial Test Analysis by National Quality Control Laboratory (NQCL) of the Republic of Kenya**
d) **Directed the EAC MRH programme to support the Republic of Burundi, Rwanda and South Sudan on sample collection and delivery to the NQCL;**
e) **Directed the EAC Secretariat to write to the Ministry of Health, Kenya through the coordinating Ministry to do the analysis by NQCL with the clear Terms of Reference;**
f) **Directed the EAC MRH programme to ensure publication of the survey results.**

4.0 MINILAB TEST KITS PROJECT BY EAC REGIONAL CENTRE OF EXCELLENCE FOR VACCINES, IMMUNIZATION AND HEALTH SUPPLY CHAIN MANAGEMENT (EAC RCE-VIHSCM)

Dr. Thomas Bizimana, Deputy Research Coordinator from the EAC RCE-VISCM made the Minilabs Project presentation with a specific request for delegates to consider technical specifications for minilab, training of users, the implementation agreement or handover guidelines. The meeting was also informed that, the EAC RCE-VISCM intends to purchase 16 minilab test kits and collect data from EAC-receiving institutions to inform on quality of products in the market.

The delegates deliberated and made the following observations:

(i) All EAC NRAs noted that, the support is being provided without prior consultation with the agencies to identify their needs for optimal use of resources;

(ii) Some EAC NRAs indicated that, they have Minilab test kits and would be of value to receive support for reagents;

(iii) The type of products selected, some like Rifampicin should not be included, hence, recommended to be replaced on the list of products;

(iv) EAC RCE-VIHSCM should mobilise resources to procure TruScan which uses Raman Spectrometry in the next round of funding from its donors because minilabs have limited application;

(v) The Chief Executives of the EAC NRAs will be responsible for signing the implementation agreement; and

(vi) PPB representative informed the meeting that, their PMS experts will share EAC RCE-VIHSCM to strengthen collaboration and partnership with EAC-MRH program by sharing work plan in order to identify areas of synergy.

The annexes related to procurement of minilab test kits are hereto attached as ***Annex XII.***

RECOMMENDATIONS

(a) The Forum of Heads of EAC NRAs Recommended Procurement, Delivery and Supply of 16 Minilab Test Kits as per the Implementation Agreement; and

(b) Directed the EAC RCE-VIHSCM to conduct regular trainings on the use of Minilab test kits

(c) Directed the EAC RCE-VIHSCM to mobilize resources to procure Truscan or Raman test machines for EAC Partner State NRAs through the next negotiations with BMZ/KfW because minilabs have limited application.

STEERING COMMITTEE MEETING, 1st - 2nd DECEMBER 2022

The meeting was attended by Heads of EAC NRAs, WHO representative and EAC Secretariat Staff.

Remarks By WHO

Mr. Sunday Kisoma from the unit for regulation and safety representing WHO Team Lead, Regulation and Convergence, thanked the chairperson and EAC for inviting WHO to the Steering Committee. He informed the meeting that, the Assistant Director General for Medicines and Medical Devices retired.

He further informed delegates that, 10th annual General Meeting on Collaborative Registration Process (CRP) which started in 2012 will be held in Turkey-the meeting will be hybrid with priority on newly participating countries and champion countries with all product streams through CRP including medicines, vaccines, in Vitro diagnostics etc. A link will be shared in the WHO website for online participants to register

Mr. Kisoma informed the meeting that, the Global model framework for In Vitro Devices (IVD's) which provides guidance on how to start regulation at all levels i.e. basic, intermediate and advanced through the life cycle has been revised and improved by expert committee on commodities and biological standards to fit into modern technical advances and challenges like Covid-19 and will be tabled in the next World Health Assembly for final approval before sharing in the website.

Mr. Kisoma informed delegates that, international conference of Drug Regulatory Authorities (ICDRA) will be held next year in India and the announcement will be made in the first quarter of next year depending on the Covid-19 situation. He concluded his remarks by informing members of the online training opportunities for reliance and advised NRA to exploit the Global Benchmarking tool for institutional development. More support can be provided by WHO on request by individual member states to implement their institutional development plans.

The agenda and programme of the Steering Committee was adopted and the rapporteur presented report of the forum of Heads of EAC NRAs. The report was adopted without any changes.

There being no other business, the meeting was closed by the chairperson at 5:00pm.

Dr. Dedith Mbonyingingo	**Dr. Mawien Atem**	**Dr. Ronald Inyagala**	**Ms. Nadine Niyomahoro**	**Mr.Adam M. Fimbo**	**Dr. Juliet Aworl Okecho**
BURUNDI FOOD AND MEDICINES REGULATORY AUTHORITY	DRUG AND FOOD CONTROL AUTHORITY	PHARMACY AND POISONS BOARD	RWANDA FOOD AND DRUGS AUTHORITY	TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY	NATIONAL DRUG AUTHORITY
REPUBLIC OF BURUNDI	**REPUBLIC OF SOUTH SUDAN**	**REPUBLIC OF KENYA**	**REPUBLIC OF RWANDA**	**UNITED REPUBLIC OF TANZANIA**	**REPUBLIC OF UGANDA**