

MINISTRY OF ENVIRONMENT AND FORESTRY

BRIEF BY THE PRINCIPAL SECRETARY TO THE SELECT COMMITTEE ON IMPLEMENTATION ON THE IMPLEMENTATION STATUS OF HOUSE RESOLUTIONS —A REPORT OF A PETITION REGARDING THE LIFTING OF THE B AN ON LOGGING AND HARVESTING OF THE MANGROVES IN LAMU COUNTY

The Select Committee on Implementation requested the Principal Secretary to apprise it on the implementation status and challenges faced, if any, in the implementation of a report of a petition regarding the lifting of the ban on logging and harvesting of the mangroves in Lamu County as communicated vide a letter Ref No. NA/DLP/PP/2018/ (025) dated 19th October 2018.

Response

Background

Hon. Chair, arising from the Moratorium on logging in Public and Community forests issued by the Government on 24th February 2018, the residents of Lamu County petitioned the Government to lift the Moratorium on harvesting of mangroves. The residents justified their petition on the basis that the moratorium had negatively affected over 15,000 people especially the residents of Ndau, Kiwayu, Faza, Kizingitini, Pate, Siyu, Manda, Kizuke and Mkunumbi. They also stated over the years they have depended on the Mangroves for their culture and livelihoods.

- 1. In response, the National Assembly Department Committee on Environment and Natural Resources visited Lamu and submitted a report which was tabled and adopted by the full house. Parliament resolved and directed the Ministry of Environment and Forestry to provide information on key matters which has been raised by the community.
- 2. Subsequently, the Cabinet Secretary, Ministry of Environment and Forestry sent a fact finding team to assess the issues relating to the petition in consultations with the local community and leaders on the ground and come up with recommendations and conditions on special exemption on harvesting of Mangroves in Lamu County.
- 3. The Team recommended for the special exemption on Mangrove harvesting in Lamu County on the basis of safeguards to ensure sustainable harvesting and restoration.
- 4. To this end, the ministry developed a model on safeguards for special exemption on harvesting of mangroves from the moratorium in Lamu county and was approved by the cabinet The model provided guidelines and conditions on which the harvesting of mangroves was to be based on. The ministry recommended exemption of mangrove harvesting in Lamu County and instructed all eligible applicants to apply for licenses.
- 5. Three sensitization meetings involving KFS, KEFRI, Lamu County Government and community were held. In the meeting the community was sensitized on the model of safeguards and the license application process. After the meeting a total of forty one (41) interested community members collected application forms from the office of the Ecosystem Conservator. Out of theses only twenty nine (29) applicants compising of four (4) women, five (5) youth, one self—help group and nineteen (19) men managed to return fully filled forms to the office of the of Ecosystem Conservator.

- 6. The applications were opened and evaluated by an Ad hoc committee composed of officers from KFS, KWS, NEMA, County Government of Lamu, and Kenya Maritime Authority.
- 7. The evaluation criteria was on the basis of citizenship, KRA pin and ID, area of operation, quantity required previous performance in mangrove harvesting etc. During evaluation, women, youth, the venerable and people living with disabilities were given priority.
- 8. The Evaluation committee recommended the approval of issuance of forest general license for applications and the results forwarded to the Head of Conservancy Coast region.
- 9. Forest Conservation Committee Coast region held a special meeting and reviewed the recommendations of the County Committee and upheld the decision of the Ad hoc committee of Lamu County.
- 10.A Procurement Committee appointed by the Chief Conservator of Forest at KFS head quarter recommended to KFS Board to approve issuance of General Forest License to the applicants
- 11.On 21st march 2019, the Hon. Cabinet Secretary Ministry of Interior and Coordination of National Government Hon. Dr. Fred Matiangi presided over the handing over of the twenty two (22) successful applicants with timber license for mangrove harvesting by the Chief Conservator of Forest on behalf of KFS Board of Directors.
- 12.On 22rd March 2019 –A meeting was held by the successful licensees to take them through the special licenses as a way of familiarization on all the obligations, requirement and implementation procedures.
- 13.On 27th March 2019-Sensitization was done to Senior Agencies Commanders at Operation Fagia Msitu in Manda Naval Base.

- 14. The Licensees gave out names of members of public whom they have authorized to harvest mangrove on the areas they were allocated.
- 15.On 22nd to 29th March the old licensees removed the old stock of harvested mangroves.

Progress of mangrove harvesting since the moratorium on harvesting was lifted

Month	Boriti	Vigingi	Mazio	Pau	Fuel wood
April	857.5	221.5	356	6035	615
May	787.5	173	45	594	787.5
June	637.5	226	0	1245.5	-
Total	2282.5	620.5	401	1839.5	1300.5

Thank you, Chair.

Dr. Ibrahim Mohamed, CBS

PRINCIPAL SECRETARY



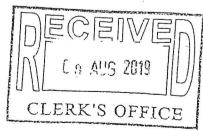
MINISTRY OF LANDS AND PHYSICAL PLANNING

SELECT COMMITTIEE ON IMPLEMENTATION SUBMISSIONS ON THE IMPLEMENTATION STATUS OF HOUSE RESOLUTIONS

Honourable Chair,

Pursuant to a letter NA/DCS/CO1/2019 (69) dated July 23, 2019 the National Assembly Select Committee on Implementation requested the Cabinet Secretary, Ministry of Lands and Physical Planning to provide written submissions on the following-

- Report on the alleged irregularities in the compensation for part of LR. No. 7879/4 to Ms. Afrison Import Export Ltd and Huelands Ltd by the National Land Commission
- ii. Report on the alleged irregular allocation of land set aside for settlement of Ontulili squatters
- iii. Report on a petition regarding the alleged irregular allocation of LR No. 11379/3 on behalf of Mowlem ward, Embakasi West
- iv. The report on a petition on non-issuance of title deeds to land owners of Embakasi west constituency.
- v. The report on a petition on the notice of demolition issued by nema and water resource authority to homeowners of seefar apartments
- vi. The report on a petition on rectification of records in the register for land parcel number Igembe/Ndoleli /Athina Ruujine/ 2554



Honourable Chair, I wish to submit as follows-

1. REPORT ON THE ALLEGED IRREGULARITIES IN THE COMPENSATION FOR PART OF LR. NO. 7879/4 TO MS. AFRISON IMPORT EXPORT LTD AND HUELANDS LTD BY THE NATIONAL LAND COMMISSION

1.1 Background and Context

The National Land Commission compulsorily acquired part of L.R. No. 7879/4 measuring 5.727 hectares (ha) or 13.77 acres for Drive In Primary School and Ruaraka High School from Afrison Export Import Limited and Huelands Limited. The Commission made an award of Kshs. 3,269,040,600/= in compensation to Afrison Export Import Limited and Huelands Limited. Subsequently, the Commission paid the sum of Kshs. 1,500,000,000/= to Afrison Export Import Limited and Huelands Limited as partial compensation leaving a balance of Kshs. 1,769,040,600/=. The acquisition drew a great deal of public controversy which resulted in various entities inquiring into the matter including the National Assembly's Departmental Committee on Lands and the Senate Committee on County Public Accounts.

The National Assembly Departmental Committee on Lands conducted investigations into the acquisition of the land and prepared a report dated June 5, 2018. The Committee concluded that the acquisition of the land was illegal and contrary to the Land Act; that it failed to secure the public interest by ensuring that the title to the land acquired was registered in the names of the two schools and that it was contrary to Article 201 of the Constitution on responsible financial management. The Committee made various recommendations.

Recommendations by Parliamentary Committee on Lands

In the report of Parliament dated June 5, 2018 by the Departmental Committee on Lands, the following recommendations were made-

- i. The Chairperson of the National Land Commission and other officers of the Commission should take personal responsibility for acting contrary to the Land Act, 2012 and the Constitution
- ii. The Directorate of Criminal Investigations should investigate possible collusion among Afrison Export Import Limited and Huelands Limited, the National Land Commission, National Treasury and the Ministry of Education to fleece and swindle public funds

- iii. The EACC should take responsibility for loss of public funds for delay and failure to safeguard against loss of funds, by failing to act on time to freeze the accounts holding the funds pending conclusion of its investigations
- iv. The National Treasury should take responsibility for loss of public funds amounting to Kshs.1,500,000/- and for authorizing payment of Kshs.1,500,000/- without an express request from the Ministry of Education
- v. The National Land Commission should immediately secure the interest of the Government on the land compulsorily acquired in portions of LR. No. 7879/4 by taking possession of the title documents of the said parcel of land.

1.2 Implementation Status

According to the report, no recommendations were made by the Committee for implementation by the Ministry of Lands and Physical Planning.

Pursuant to the recommendations of the Committee, The National Lands Commission filed *Nairobi ELC Reference No. 1 of 2018 National Land Commission v Afrison Export Import Limited & 10 others* in which the Ministry of Lands and Physical Planning was made an interested party.

In a Judgement delivered on June 28, 2019 in the said case, Justice E. O. Obaga held that the two schools sit on public land. He further held that the land on which the two schools sit could not be the subject of compulsory acquisition. The portion on which the two schools sit was surrendered for public purposes and had accordingly been reserved for that purpose.

2. REPORT ON THE ALLEGED IRREGULAR ALLOCATION OF LAND SET ASIDE FOR SETTLEMENT OF ONTULILI SQUATTERS

Honourable Chair, I wish to submit as follows-

2.1 Background and Context

In the Petition before Parliament, it was alleged that land excised from the Mt. Kenya Forest in Ontulili area in Meru for settlement of squatters was irregularly issued to an individual instead of being issued in favour of the squatters.

2.2 Recommendation by Parliamentary Committee on Lands

In response to the prayers of the petitioners, the Departmental Committee on Lands recommended that the National Land Commission should determine the historical injustices case HS 085/2017 lodged by the Petitioners within three months from the date of tabling this report with a view to settling the genuine squatters.

2.3 Implementation Status

According to the report no recommendations were made by the Committee for implementation by the Ministry of Lands and Physical Planning.

3. REPORT ON A PETITION REGARDING THE ALLEGED IRREGULAR ALLOCATION OF LR. NO. 11379/3 ON BEHALF OF MOWLEM WARD, EMBAKASI WEST

Honourable Chair, I wish to submit as follows-

3.1 Background and Context

The National Land Commission and the Ministry of Lands and Physical Planning held different views on the ownership of LR. NO. 11379/3. The Commission stated that the land belonged to Kiambu Dandora Farmers Company while the Ministry indicated that it belonged to Dandora Housing Scheme Ltd.

3.2 Recommendations by Parliamentary Committee on Lands

- i. The National Land Commission does compensate the common membership of two hundred and twenty-five (225) members of Dandora Housing Scheme Limited and Kiambu Dandora Farmers Company Limited in accordance with the law
- ii. The Directorate of Criminal Investigations and the Ethics and Anti Corruption Commission does investigate allegations of fraud and forgery of documents such as titles and court orders regarding the ownership of LR. No. 11379/3 with a view to recommending the prosecution of any person found culpable of having committed a criminal offence.

3.3 Implementation Status

According to the report no recommendations were made by the Committee for implementation by the Ministry of Lands and Physical Planning.

4 THE REPORT ON A PETITION ON NON-ISSUANCE OF TITLE DEEDS TO LAND OWNERS OF EMBAKASI WEST CONSTITUENCY.

Honourable Chair, I wish to submit as follows-

4.1 Background and Context

The Petitioners were allocated houses by the then City Council of Nairobi under the Umoja Estate Tenant Purchaser Scheme in 1976. The agreement for the purchase of the said houses stipulated that after full payment of the purchase fees each owner was to be issued with a title deed. However, the beneficiaries of the scheme were not issued with the titles deeds even after settling the purchase fees.

4.2 Recommendations by Parliamentary Committee on Lands

In the Report of Parliament dated April 30, 2019 the Departmental Committee on Lands made amongst others the following recommendations: ~

- i. The National Government in collaboration with the Nairobi City County Government caters for all the costs of processing fresh applications to be made by allottees for the purpose of processing lease documents in order to facilitate the completion of issuance of title documents within six months of receipt of applications from the allotees
- ii. The Ministry of Lands and Physical Planning conclude the survey of the remaining 10% of unsurveyed land in Embakasi West Constituency within ninety days of tabling of this report to facilitate the processing of lease documents and subsequent issuance of title deed.

4.3 Implementation Status

- i. The Ministry of Lands and Physical Planning waived payment of all statutory fees for processing and issuance of Title Deeds to the beneficiaries under the National Titling Programme.
- ii. The survey has been done by the Nairobi City County Government and is in the process of quality control.

- iii. Once Nairobi City Government forward the leases to the Ministry we will proceed to title
- 5 THE REPORT ON A PETITION ON THE NOTICE OF DEMOLITION ISSUED BY NEMA AND WATER RESOURCE AUTHORITY TO HOMEOWNERS OF SEEFAR APARTMENTS

Honourable Chair, I wish to submit as follows-

5.1 Background and Context

Seefar Apartments registered as LR No 209/12108 consists of a development that has 288 residential apartments located within Nyayo Highrise Estate along Mbagathi Road. It was developed by Erdemann Property Limited in 2011. The apartments have a total of 1000 people with about 40% of the homeowners having acquired mortgages with various financial institutions and servicing loans.

Despite National Environment Management Authority (NEMA) and Water Resources Authority (WARMA) approving development of the apartments vide letters reference numbers PR/8208 dated 29th June, 2011 and WRMA/NRB/RIPARIAN/1(56) dated 17th April, 2015 respectively; NEMA issued an improvement notice (NEMA/5/4/Vol II) while WARMA issued Order Serial Number 30366 earmarking the apartments for demolition on allegation that they had been constructed on the riparian reserve along the Nairobi Dam and Ngong River.

5.2 Recommendations by Parliamentary Committee on Lands

- i. NEMA and WARMA undertakes an audit of all licences issued across the Country to verify the levels of compliance with licence conditions, the extents and reasons for causes of noncompliance, if any with a view to taking appropriate action against any person whose actions are established to be inconsistent with the Law and table a report before the National Assembly within three months of the tabling of the Report
- ii. The Ministry of Environment and Forestry, the Ministry of Water and Sanitation and the County Government of Nairobi should set up a task force to undertake a comprehensive study on the safety of the Nairobi Dam, its potential and the socio economic implications of rehabilitation

- or decommissioning it and table a Report before the National Assembly within three months of the tabling of the Report
- iii. The Inter-Agency Technical Team commissioned to assess the safety and viability of the dam should expedite its report to facilitate for further discussion between the home owners and the Government to determine the way forward. In the meantime, the Team should address any immediate safety concerns
- iv. The Ministry of Water and Sanitation and the Ministry of Environment and Forestry, should spear head consultations with the Ministry of Lands and Ministry of Agriculture to harmonize the definition of the riparian land and subsequently submit an amendment to Parliament for consideration and enactment, and table a report before the National Assembly within three months of the tabling of the Report.
- v. The Government should adopt harmonized position relating to the principles and process of the demolition exercise so as to assure the investors that the exercise is being undertaken in a manner that is not discriminatory
- vi. The Ministry of Water and Sanitation should expedite the installation of sewer line facilities under the Nairobi Regeneration Programme to mitigate the pollution of the Nairobi Dam by effluent from the neighbouring residential areas.

5.3 Implementation Status

The recommendation referring to the Ministry of Water & Sanitation and the Ministry of Environment & Forestry spearheading consultation with our Ministry and Ministry of Agriculture is pending.

The Ministry is ready to give its input when the spearheading agencies initiate the consultations.

6 THE REPORT ON A PETITION ON RECTIFICATION OF RECORDS IN THE REGISTER FOR LAND PARCEL NUMBER IGEMBE/NDOLELI ATHINA RUUJINE 2554

Honourable Chair, I wish to submit as follows-

6.1 Background and context

The Petitioner claims that a Mr. John Bernard Nthuku of land registration no. 2554/Igembe/Ndoleli/Athiru Ruujine has been in occupation of the land. That

the ground measurements of the parcel of land are larger than the scaled area indicated in the Registry Index Map of the Meru North Land Registry.

6.2 Recommendation by Parliamentary Committee on Lands

The Ministry of Lands and Physical Planning conducts a new survey and rectifies the record in the land registry for parcel Igembe/Ndoleli/Athiru Ruujine 2554 within sixty (60) days from the date of tabling this report.

6.3. Implementation Status

The land parcel has been re-surveyed and the register rectified as directed. A copy of the green card is Annexed Marked Annexure 1.

Farida Karbney, OGW CABINET SECRETARY

August 7, 2019

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THE COMPETITION AUTHORITY OF KENYA'S UPDATE ON INVESTIGATIONS OF BUSINESS PRACTICES AMONG OIL MARKETERS COMPANIES (OMCs) INVOLVED IN THE SUPPLY AND DISTRIBUTION OF JET A1 FUEL.

A. Background

- 1. This Report is pursuant to a request by the Select Committee on Implementation status of House resolutions specifically that the Competition Authority of Kenya(`the Authority`) to review and investigate the business practices among the oil marketing companies with a view to ensure a level playing field among the operators.
- 2. Section 31 of the Competition Act empowers the Authority to investigate any conduct or practice which is alleged to constitute an infringement of prohibitions relating to restrictive trade practices or abuse of dominance. In addition sections 32 and 33 of the Act, provides the mode of procuring evidence while conducting investigations.
- 3. To conduct the Investigation, as recommended by the House Committee, the Authority developed the following RoadMap:
 - i. Identification of the key Agencies/players/Stakeholders and their Mandate/role/objectives;
 - ii. Appreciation of the Jet Fuel Industry including the key logistics in supply and distribution channels;
 - iii. Determine the relevant market and market shares of each market player;
 - iv. Establish existing contractual agreements, if any, and practices and their effect on competition (do they suppress forces of supply and demand in the relevant market?)
 - v. If Market shares point to a dominant firm in the relevant market; does the Dominant firm abuse its dominant position as encapsulated under section 24 of the Competition Act;
 - vi. The Authority makes a determination after analyzing the gathered evidence.



- B. Identification of the key players/stakeholders and their mandate/objective
- 4. The Authority has identified the following Agencies/Stakeholders/players as key to inform the investigations:
- a. Energy and Petroleum Regulatory Authority (ERPA): it licenses persons engaged in the importation, refining exportation, wholesale, retail, storage or transport of petroleum in Kenya. Accordingly persons engaged in the sale of Jet AI in Kenya ought to satisfy the licensing conditions;
- b. Kenya Airports Authority (KAA): it provides facilitative infrastructure for aviation services; Its main functions are: Administer, control and manage aerodromes;
- c. National Environmental Management Authority (NEMA): to get a license for storage of petroleum products include the Environmental impact Assessment License from NEMA and a Confirmation from KEBS that the facility complies with Kenya Standard (Inspection Report); Fire clearance certificate; OSHO certificate; and valid certificate of calibration of the petroleum tanks;
- d. Oil Marketing Companies (OMCs): these are the firms that are licensed to undertake the importation and distribution of petroleum products in the country. These are Kenol-Kobil; Gulf Energy, Aspam Energy, Oryx Energies, GAPCO, Vivo Energy, Galana, Total; Hass and Kencor. Pacific Aviation & Consulting Company and ASM Kenya.
- e. Petroleum Institute of East Africa (PIEA) it is the Industry's association which conducts research relating to the oil and gas industry in the East African region.
- 5. To date, the Authority has interacted and gathered evidence from the following stakeholders: Kenya Airports Authority, Energy and Petroleum Authority, Pacific Aviation Management and Consultancy Company and Total (K) ltd.
- The Interaction with the following institutions is ongoing: Kenol-Kobil Ltd, ASM Kenya, Petroleum Institute of East Africa and a follow-up meeting with EPRA.

B. Identification of Key Logistics in supply and distribution channels

- 7. The Authority has documented the importation and pricing mechanism in the industry including the landing costs. We have also established the existing storage and operational infrastructure and juxtaposed it with International practices, in other aerodromes.
- 8. The Investigations have also so far covered the business (arrangement) for sourcing for Jet Fuel. We have identified the existing different arrangements employed by the accused and



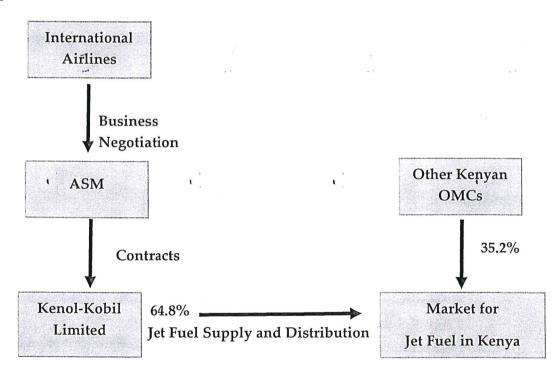
the other parties and which and why certain arrangements are preferred by International Airlines.

C. The determination of the relevant market and market shares for each player

- 9. The investigation has identified the relevant Jet A1 fuel also known as aviation turbine fuel or avtur imported as a Dual Purpose Kerosene (DPK) as the relevant Product Market. The identification is based on its use; its use and handling. Therefore, this is the focal-point of the investigation.
- 10. The process of collecting and collating data/turnover in order to determine market shares for each player in the Market is ongoing. This process involves summoning evidence from all market players and PIEA.

D. Existing Contractual Arrangements

11. Towards establishing the contractual arrangements; the Investigation has so far identified the supply chain arrangement for the relevant product. The vertical arrangement can be depicted as follows: -



12. We have summoned for the Contract between ASM and Kenol-Kobil to interrogate it and determine if it contains provisions which infringe any provision of the Competition Act.



E. Conclusion

- 13. The Competition Authority wishes the Committee to Note that the Authority has: -
 - Initiated investigations into the Industry as recommended;
 - b. Documented an investigation roadmap, as guided by the Competition Act and internal guidelines. The Roadmap encompasses:
 - i. Identification of the key Agencies/players/Stakeholders and their Mandate/role/objectives;
 - ii. Appreciation of the Jet Fuel Industry including the key logistics in supply and distribution channels;
 - iii. Determine the relevant market and market shares of each market player;
 - iv. Establish existing contractual agreements, if any, and practices and their effect on competition (do they suppress forces of supply and demand in the relevant market?)
 - v. If Market shares point to a dominant firm in the relevant market; does the Dominant firm abuse its dominant position as encapsulated under section 24 of the Competition Act;
 - vi. The Authority makes a determination after analyzing the gathered evidence.
 - c. So far fully the Authority has actualized the above Roadmap up to (iii) while (iv) and (v) are partially achieved. Fulfillment of (iv) and (v) will cause the Authority's determination (Conclusion of the investigation).

F. Request

- 14. The Authority therefore requests the Committee to indulge it in order to:
 - i. Summon evidence from the following players/key stakeholders ASM Kenya, Kenol-Kobil and Petroleum Institute of East Africa.
 - ii. Conclude collection and collation of data/sales to determine market shares of each and every player in the relevant market.
 - iii. Interrogate the contractual agreement/arrangement between ASM and Kenol-Kobil to determine if it contains clause/s which offend any provision of the Competition Act.



15. The grant of the above request will facilitate the Authority to conclude the investigation and make a determination.

Wang'ombe Kariuki, MBS

DIRECTOR-GENERAL

7th August 2019





THE COMPETITION AUTHORITY OF KENYA'S MEMORANDUM ON THE STATUS OF AMENDMENT OF THE INFORMATION AND COMMUNICATIONS ACT, 1998 AND THE COMPETITION ACT NO. 12 OF 2010 WITH THE SOLE MANDATE TO DETERMINE COMPETITION MATTERS ARISING FROM THE TELECOMMUNICATIONS SUB-SECTOR

A. Background

- 1. The Competition Authority of Kenya ("the Competition Authority") in response to the request by the Select Committee on Implementation submits on the 'the status of amendment of the Information and Communications Act, 1998 and the Competition Act No. 12 of 2010 to empower the Communications Authority with the sole mandate to determine competition matters arising from the telecommunications sub-sector.'
- 2. Although our view is that the suggested amendments of the legislative framework mainly is under the purview of the sector-specific regulator, (CA the Communications Authority), we wish to update the committee regarding our ongoing initiatives towards informing the actualization of the recommendation in order to achieve an optimal position.
- 3. The Authority has developed a Road Map. The Road Map entails; (a) review of the current arrangement, (b) review of international practices (c) review of emerging issues including the Digital economy, (d) engagement with key stakeholders, and then, (e) develop a policy paper. Up to date the Authority has actualized (a), (b) and (c) and we are in the process of actualizing (d) specifically interacting with The National Treasury and Planning, Ministry of Information Communications and Technology, the Communication Authority and the Central Bank of Kenya.
- 4. Thus, premised on the above, the Authority wishes to update regarding the following:-

i. Review of the current arrangement

a. As per the International Best Practice there is concurrency between the Competition Authority and CA mandate with regard to regulation of competition in the telecommunications sub-sector.



- b. When promulgating the Competition Act, Parliament was not only alive to the necessity of concurrent jurisdiction but also to the challenges it may cause. Therefore, under Section 5 of the Competition Act, it provides that in all matters concerning competition, the Authority has primary jurisdiction. However, it provides for development of a working framework with sector regulator/s which may have concurrent jurisdiction with the Competition Authority.
- c. Towards this the Competition Authority and CA signed MOU/framework in 2015 which has the objective of:
 - ii. Identifying and establishing procedures for management of areas of concurrent jurisdiction;
 - iii. Promoting cooperation;
 - iv. Providing for the exchange of information and protection of confidential information; and
 - Ensuring consistent application of the principles of the Competition Act.
- d. So far the MOU has achieved its objective since there has been no contradictory decisions emanating from the two agencies.
- 5. We also note that, Kenya is a signatory to regional treaties and therefore one of the Partner States of the East African Community (EAC) and a Member State of the Common Market for the Eastern and Southern Africa (COMESA). It therefore follows that Kenya is bound by these regional laws and their implementing regulations.
- 6. The EAC Competition Act and the COMESA Competition Regulations which originates from their respective treaties have mandate to all economic activities and sectors having cross-border effect. We note that the EAC competition Act is anchored under Article 75 of the Treaty establishing the East African Community.
- 7. It is important to recall therefore and as guided by the Constitution of Kenya 2010, that the National Competition legislations be aligned to the Regional statutes. The Kenyan Competition Act, upon review of the EAC competition experts, has been found to be approximated to the regional competition law.
- 8. Thus, any amendment to the Kenyan Competition Act will cause disharmony with the requirements of the regional statutes to which Kenya is a signatory.



ii. Review of international best practices

- 9. We have established that concurrence jurisdiction in regulation of matters relating to competition is very common in the network and utilities sectors. Experiences with regulation of competition in network and utilities sectors illustrates the need for better coordination between the competition authorities on the one hand, and the sector regulators on the other.
- 10. The management of concurrent jurisdictions in these sectors has been clearly demonstrated by experiences and guidance in the European Union, its member States like United Kingdom, Germany, among others, and in South Africa as well. The situation in these jurisdictions, like in Kenya currently, requires that the primary jurisdiction in the regulation of competition in these sectors, as is the case in all other sectors, is bestowed on the macro-competition regulator.
- 11. In the United Kingdom, Competition and Markets Authority (CMA) which is the macro-regulator of competition, has concurrent jurisdiction with all sector regulators including the Ofcom. Ofcom regulates electronic communications, broadcasting and postal services.
- 12. It is important to highlight that the sector-specific regulators are only accorded the powers to apply the macro-competition laws and <u>not to promulgate parallel competition provisions in their respective sector-specific laws</u>.
- 13. This principle has been replicated in South Africa.
- 14. The common feature in all these countries with concurrent jurisdictions (and also with mature competition agencies and their law enforcement) is that they have developed and are implementing frameworks or MOUs to ensure smooth management of the areas of concurrency.
- 15. Another emerging institutional arrangement can be identified in the Netherlands where both ex-ante and ex-post regulation of the telecommunications sector are merged under the macro-competition regulator. This mandate has been conferred on the Netherlands Authority for Consumer and Markets (ACM). ACM is the macro-competition regulator whose mandate is to ensure fair competition between businesses and protection of consumer interests.



- 16. Indeed, and generally so, within the European Union territory, the EU regulation framework advocates for sector-specific regulations to become more embedded in the general competition law.
- 17. We note that the changing approach to regulation of the telecommunications sector has been motivated by the emerging issues elaborated below.

iii. Review of Emerging issues

- 18. We note that there have been changes in the information technology sector leading to closer integration and therefore provision of services have been interlinked. The term Information and communications technology (ICT) is therefore a current term that is commonly used to an extensional information technology (IT) that unified communications and the integration of telecommunications (telephone lines information and wireless signals) and computers, as well as necessary enterprise software, middleware, storage, among others.
- 19. This level of integration and interrelation of these activities/services in the information and communications sector has blurred the boundary between the telecommunications and other subsectors.
- 20. This integration has taken cognizance of by the *Kenyan Digital Economy Blue Print*, 2019 which has highlighted that Kenyan businesses are improving their productivity buoyed by both adoption and adaption of new technologies through e-government and financial services, among others. Specifically, the *Blue Print* envisages a situation where the economy is moving away from internet economy to digital economy where "the entirety of sectors operate using digitally-enabled communications and networks leveraging internet, mobile and other technologies" irrespective of industry
- 21. This scenario of close integration of activities in the digital economy therefore renders it very difficult to hive out the provision of telecommunications services to be subjected to a separate and exclusive legal regime.

B. Way Forward

22. We wish to request the committee to note that the next phase is engaging the relevant stakeholders which include, The National Treasury and Planning, Ministry of Information



Communications and Technology, the Communication Authority and the Central Bank of Kenya and the Parliamentary Committee on Finance, Planning and Trade. In addition, the Authority shall interact with EAC Competition Authority and COMESA Competition Authority in order to develop a comprehensive position paper to inform the recommendations.

Wang ombe Kariuki, MBS

DIRECTOR-GENERAL

7th August 2019





KRA/M&CD/SEEM/19/08/E057

9th August 2019

Mr. Michael Sialai, EBS Clerk of the National Assembly Parliament Buildings P. O. Box 41842-00100 NAIROBI

Dear Sir,

RE: REQUEST BY THE SELECT COMMITTEE FOR THE IMPLEMENTATION STATUS OF HOUSE RESOLUTIONS

Your letter REF:NA/DCS/COI/2019/(66), dated 23rd July 2019 on the above matter refers.

In response to your request, we hereby summit status update on the following items;

1. The report of the Public Investments Committee on the inquiry into procurement and implementation of the Excisable Good Management System for printing, supply and deliver of Security Revenue Stamps complete with Track and Trace System and an Integrated Production Accounting System by the Kenya Revenue Authority as communicated vide a letter Re: No. NA/DLP/TBO/RES.11/2019 dated 7th June 2019.

2. The report on a petition on licensing of oil marketing Companies by the Energy Regulatory Commission as communicated vide a letter Ref: NA/DLP/PP/2018/38 dated 10th December 2018.

This is forwarded for your kind attention.

Yours

GRACE WANDERA

For: COMMISSIONER GENERAL

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REPORT FOR THE SELECT COMMITTEE ON IMPLEMENTATION FOR THE IMPLEMENTATION STATUS OF HOUSE RESOLUTIONS

August 9th, 2019

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1.0 INTRODUCTION

The Committee on Implementation is a select Committee of the House established pursuant to Standing Order 209 of the National Assembly Standing Orders. The Committee is mandated to scrutinize resolutions of the House (including adopted Committee reports), petitions and the undertakings given by the executive and to examine whether such decisions and undertakings have been implemented and whether such implementation has taken place within the minimum time necessary.

In this regard, the Committee vide their letter Ref: NA/DCS/COI/2019/(66), dated 23rd July 2019, herewith attached request to be appraised on the implementation status and challenges faced by the Authority, if any, in the implantation of observation and recommendations contained in:-

- 1. The report of the Public Investments Committee on the inquiry into procurement and implementation of the Excisable Good Management System for printing, supply and deliver of Security Revenue Stamps complete with Track and Trace System and an Integrated Production Accounting System by the Kenya Revenue Authority as communicated vide a letter Re: No. NA/DLP/TBO/RES.11/2019 dated 7th June 2019.
- The report on a petition on licensing of oil marketing Companies by the Energy Regulatory Commission as communicated vide a letter Ref: NA/DLP/PP/2018/38 dated 10th December 2018.

2.0 RESPONSES TO QUERIES RAISED BY THE COMMITTEE

2.1 The report of the Public Investments Committee on the inquiry into procurement and implementation of the Excisable Good Management System for printing, supply and deliver of Security Revenue Stamps complete with Track and Trace System and an Integrated Production Accounting System by the Kenya Revenue Authority as communicated vide a letter Re: No. NA/DLP/TBO/RES.11/2019 dated 7th June 2019.

	Recommendation	Response
1.	Whereas Kenya Association of Manufacturers and the Kenya Revenue Authority confirmed that there was public participation in the roll-out of the Excisable Goods Management System, the Kenya Revenue Authority, thee Kenya Bureau of Standards and the Anti-Counterfeit Agency should conduct extensive and all-inclusive public participation prior to implementing systems such as EGMS	
2.	The Kenya Revenue Authority should share their current Excisable Goods Management System with the Kenya Bureau of Standards and the Anti-Counterfeit Agency at no	1



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extra	cost to	the	manufacturers.

- 3 Upon expiry of the existing contract, the Kenya Revenue Authority, the Kenya Bureau of Standards and the Anti-Counterfeit Agency should develop a multifunctional stamp for use by the three government entities, or any other that will need the system, which will ensure efficient monitoring and reduce wastage of public funds utilized in developing different stamps.
- i. Excise Duty Act 2015, and related subsidiary legislation
- ii. The Standards Act Cap 496, Laws of Kenya.
- iii. The Anti-Counterfeit Act, 2008

In addition, the three institutions have to develop a joint administrative arrangement to facilitate compliance with regulatory requirements. Upon the development of this joint administrative arrangement, the system can be adopted by the other regulatory agencies and thus have a single stamp implemented.

KRA will engage other agencies through multiagency framework in order to progress this matter.

2.2 The report on a petition on licensing of oil marketing Companies by the Energy Regulatory Commission as communicated vide a letter Ref. NA/DLP/PP/2018/38 dated 10th December 2018.

2.2.1 Recommendation for Action by KRA

(i) The Kenya Revenue Authority to investigate Ms. Pacific Aviation, Ms. ASM Kenya and all other companies providing hospitality for Oil Marketing Companies in the sale of Jet A1 fuel in the country to ascertain their tax compliance and their status of registration in Kenya.

KRA has reviewed the tax compliance of the companies providing hospitality for Oil Marketing Companies and the report is provided herein below:

SN:	Company	Tax Status
1.	PACIFIC AVIATION MANAGEMENT AND CONSULTING CO	Filing
. 2.	ASM	Filing
3.	KENYA PIPELINE CO LTD	Filing
4.	VIVO ENERGY KENYA LTD	Filing
5.	LIBYA OIL KENYA LIMITED	Filing
6.	TOTAL (K) LTD	Filing
7.	GULF ENERGY LIMITED	Filing
8.	FLAMEX PETROLEUM LIMITED	Filing
9.	VIVO ENERGY KENYA LTD	Filing
10.	TOTAL (K) LTD	Filing
11.	GULF ENERGY LIMITED	Filing
12.	FLAMEX PETROLEUM LIMITED	Filing

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KENYA REVENUE AUTHORITY

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P.O. Sox 48240-00100, NAIROBI

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SN:	Company	Tax Status
13.	AEROGLOBAL AVIATION SERVICES LTD	No itax Pin
14.	FINEJET LIMITED	Filing
15.	TRISTAR TRANSPORT LIMITED	Filing
16.	KENOLKOBIL LIMITED	Filing
17.	HELLER PETROLEUM LIMITED	Filing
18.	DALBIT PETROLEUM LTD	Filing
19.	BAKRI ENERGY LIMITED	Filing
20.	HARED ENERGY LIMITED	Filing
21.	MOGAS KENYA LTD	Filing
· 22.	TEXAS ENERGY LIMITED	Filing
23.	ZACOSIA TRADING LIMITED	Filing
24.	LAKE OIL LIMITED	Filing
25.	WORLD FUELS SERVICES KENYA LIMITED	Filing
26.	SKYTANKING (K) LTD	Filling

(ii) Kenya Revenue Authority (KRA) put in place similar Tax regime on Jet A1 fuel at Wilson Airport similar to the one at Jomo Kenyatta International Airport since several airlines at Wilson Airport are/becoming regional in their operations. An example is Safarilink Aviation which flies to Kilimanjaro Airport but are subjected to different Jet A1 Tax regime from Jambo Jet flying to Entebe Airport from Jomo Kenyatta International Airport.

Legal Notices 47 of 2005 and No. 102 of 2015 allowed for warehouse of Jet A1 at JKIA, Moi International Airport and in Lokichoggio in duly licensed depots maintained by petroleum companies. Wilson Airport is yet to be gazetted as one of places for warehousing of Jet A1 to enable delivery of duty free fuel to aircraft.



PUBLIC NOTICES

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The University of Eldoret Credit Accumulation Transfer System Policy, an option for diploma and other equivalent professional graduates to enter degree programmes by transferring credits is now offered.

Hailly transmission formula

All academic and admission information is availed on the University website at Costson websites. For further enquires contact:

> Visa-Thomasiku (Arademic & Simionis' & Julio). University of Uldovat, IVO. Dan Tusa-Guicu. Uldosel.

Varail:

oill albiesn@sv

ragiotisvacadesales@neekl.na.bs

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University of Efebruaria interpositions Continue

Xarama University wishes to recruit qualifier vacant positions listed below: Specific special sky website transliture.ac.ito

ADVEST

	Widte		P
1	Senior Lecturer/Lecturer (NURSING)	13/12	
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5	Deputy University Librarian	16	1
3	Medical Officer	13	1
£	Senior Accountant	13	1
5	Senior Internal Auditor	13	1
6	Senior Assistant Student Counsellor	()	
7	itegistry Supervisor	7	1

For information related to job specifications, a requirements, kindly visit our website where should send the applications quoting the relev received on or before Yuesduy 2nd July, 2019.

Karatina University is an equal opportunity of eliner gender, persons with disability and are encouraged to apply.

KENYA REVSNUE AUTHORITY

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Management of Molocokes Derks seculos at of Trader Traseromes 200, 2008 and Devision field at Section 200 of This Mest Advised Continues the Security Assault

Through Gazette Motioe No. 12046 dated 19th November, 2018 and Gazette Motioe No. 1086 dated 1st February, 2019, the Commissioner General delegated the powers and functions relating to the handling of objections under the Tampropadures Act, 2016, and the reviews under the Sast African Community Customs Management Act, 2004 to the Commissioner responsible for tax dispute resolution.

This transformation has the affect of distinguishing tex assessment processes up to the issuance of an assessment with the post assessment dispute resolution process from the point of an objection of review. The Commissioners responsible of Comestic Taxes and Customs and Sorder Control will condition to handle the pre-objection and pre-review processes respectively whereas the Control of the processes until a decision is made. The transformation aims to consolidate, centralize and ensure independence of the management of the objections and review processes within Kenya Pevenue Authority to the convenience of Taxpayers.

The changes srebeing implemented in phases. Those impacting on the Large Texpayers Office (LTO) and the Medium Texpayers Office (MTO) are attractly in place. The roll out programme for other stations shall be communicated in due a course.

For any distribution in relation to this mader, pisses call our Contact Cerms on Tel: 020 4 999 999, 0711 099 990 or Email: calibentre@kra.go ke 'rou may also visit the meanest KPA Office, or Hudums Centre.

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Implementation of Integrated Customs Management System (ICMS) for Cargo Clearance

Kenya Revenue Authority notifies the Shipping Lines/Agents, Importers, Exporters, Clearing & Forwarding Agents, Consolidators and all other parties related to cargo clearance process of the commencement of implementation of the Integrated Customs Management System (ICMS) at the Port of Mombasa, Inland Container Depot Mairobi (ICDN) and the Border Stations.

The following Cargo Clearance documentations will be submitted through iCMS for all cargo whose expected date of arrival/ent is 7th July 2019:

- Import Declaration Forms (IDFs),
- Sea Manifests/ Baplie/ IAR,
- Security Bonds,
- Cargo Declarations,
- Exemptions

Kindly note that:

- Sea manifests (Imports/Expons) will only be submitted in ICMS through system to system data exchange 48 hrs before vessel arrival/ departure;
 All House Manifests must include the Courier/ Consolidator PIN to enable cargo deconsolidation process;
- Cargo Handlers are required to ensure their systems are ready to receive system to system Customs Release Messages (CUSRES) as manual releases will be discontinued.

iCMS training and user creation is currently on-going and any of the above parties who desires to be trained should send a request to tpstraining@kra.go.ke

For clarification, please call our Contact Centre on Teh (0)20 4 999 999; 0711 899 999 or Email: callcentre@kra.go.ke. You may also visit the nearest KRA Office or Huduma

Commissioner to: Customs and Border Control

Disclaimer: RRA notibes trace you that it will not account responsibility for payments not occaved, profited and validated in the relevant RAA accounts. Corruption Reporting: 1254 (0728) 301 834 (2012) 1900 (20

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The Commissioner General is required under the Excles Buty Act. 2015 to adjust for inflation the rates of excise duty on all products that have a specific rate of excise duty, annually.

Kenya Revenue Authority would like la inform mould livers and importers of excisable goods falling under the authority and members of the public that the Commissione. Tene of will adjust the rates of excise duty using the aversal lates of excise duty using the aversal lates of excise duty using the aversal lates of the financial year 2019/2020, as determined by the control of the adjusted rate of villates the adjusted rate of villates the adjusted rate of villates. The adjusted rate of villates the adjusted rate of villates the control of the adjusted rate of villates.

In compliance with an one provisions. Kenya Revenue Authority invites internal in their public and stakeholders to submit their views of the excise inflation adjustment, addressed to the Commissioner deneral Kenya Revenue Authority P.O. Box 48240-. 00100. Natrobl or emailed to stakeholder@kra.go ke to be received on or before monday. 2016 June 2018.

Commissioner General

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Public Notice

Public participation fora on 2019/2020 Financial Year Budget

Kenya Revenue Authority will carry out countrywide public participation fora on the 2019/2020 Financial Year Fiscal Budget. The fora target tax professionals, business leaders, the media and the general public, and will begin from 9.00am to 1.00pm on the dates and venues below:

DATE	TOWN	VENUE
19th June 2019	Nakuru	Hotel Waterbuck
	Nyeri	Green Hills Hotel
	Mombasa	Kenya School of Government
	Kisumu	The Vic, Hotel
20th June 2019	Eldoret . **	Starbucks Hófel
25 th June 2019	Năirobi	Hilton Hotel

For confirmation of attendance kindly Email: statisholder.engagement@tra.go.tte or please call our Contact Centre onTel: (0) 26 d 998 999; (711 099 999 or Email: callcentre@kra.go.fte

You may also visit the nearest KRA Office or Huduma Centre.



Inflation Adjustment on Excise Duty Rates

The Commissioner General is required under the Excise Duty Act, 2015 to adjust for inflation the rates of excise duty on all products that have a specific rate of excise duty, annually.

Kenya Revenue Authority would like to inform manufacturers and importers of excisable goods falling under the above category and members of the public that the Commissioner General will adjust the rates of excise duty using the average inflation rate for the financial year 2013/2019, as determined by the Kenya National Bureau of Statistics. The adjusted rates will be effective from 1st July 2019.

In compliance with statutory provisions, Kenya Revenue Authority invites interested members of the public and stakeholders to submit their views on the excise inflation adjustment, addressed to the Commissioner General, Kenya Revenue Authority, P.O Box 48240-00100, Nairobi or emailed to stakeholder@kra.go.ke to be received on or before Wonday, 24th June 2019.

Commissioner General

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Tender Notice

Kanya Revenue Authority invites sealed bids from eligible candidates for the following tenders:

อิบริเศารูฟิลก	Eligibility	Pre- Bid Date, Time	Closing Daie
		and Ventie	and Time
GNANOSROB-976/2018-2010: Supply, Delivery and Implementation of a Vieb-Based Anonymous Reporting System	OPEN	27 TH JUNE, 2019 . 10.00 AM	16 th JULY, 2019 f1.00 AM



Public Particiation on Integrated Customs Management System (ICMS)

Kenya Revenue Authority was established by an Act of Parliament – the Kenya Revenue Authority Act, Chapter 469 of the Laws of Kenya, KRA is manuated with the responsibility of assessing, collecting and accounting for revenue on behalf of the Government of Kenya.

To enhance efficiency in service delivery, KRA is implementing the Integrated Gustoms Management System (iCMS). The iCMS Air Cargo Services were rolled out on 10th May 2019 and the Land & Sea Cargo Services will be rolled out on 7th July 2019.

In this regard, KRA invites the Shipping Lines/Agents, Importers, Exporters, Clearing & Forwarding Agents. Cargo Consolidators, and the General Public to engagement forums as follows:

DATE	AEWOR
	Starbucks Hotel, Eldoret
3 ^{rr} July, 2019	OSBP KRA Conference Hall, Namanga
	OSBP KRA Canteen, Malaba
	Hilton Hotel, idairobi
4th July, 2019	OSBP Boardroom, Busia
	OSBP Boardroom, Tavata
5" July, 2019	OSBP Boardroom, Isebania
	Kenya School of Government, ฟอกกโวลลล
9th July, 2019	OSBP KRA Conterence Hall, Moyale
10" July, 2019	OSBP Boardroom, Lunga Lunga

All the above engagements will be held from 9.00am to 12.00pm.

For confirmation of attendance kindly Entail, stakeholder.engagement@kra.go.ke
or pleass call our Contact Centre onTel: (0) 20 4 999 999; 071; 099 999 or Email; callcentre@kra.go.ke
You may also visit the nearest KRA Office or Huduma Centre

Commissioner for Customs and Border Control

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Public Participation Fora on the Go Live for the Exclaable Goods Wanagement System (EGWS)

Kenya Revenue Authority notifies the Public of the Go Live of the Excisable Gooda Management System on Bottled Water, Juicas, Soda and other non-alcoholic beverages and cosmetics effective 1" September 2019 as stipulated by Section 28 of the Excise Duty Act, 2015 and the Legal Notice 53 of 30° March 2017 (Excisable Goods Management System Regulations).

In this regard, KRA will carry out sector based and General Public Participation for on EGMS. The fora target licensed manufacturers, importers, distributors and retailers, of Bottled Water, Juices, Soda and other non-alcoholic boverages and cosmetics, the media and the general public. The fora will be held from 9.00am to 12.00pm on the dates and venues below:

1 0	0	11	71	Targei Audlence	
Dato	Countles Covered	Venue	Time		
15" July, 2019	All	Sth Floor Convention Centre, Times Tower, Nairobi	9:00am-12pm	Manufacturers, Importers distributors and rotaliters of Bottled Water	
16° July, 2019	All	5th Floor Convention Centre, Times Tower, Natrobl	9:00am-12pm	Manufacturers, Importers distributors and retailers of of Juices	
July, 2019 ۳۳	All	5th Floor Convention Centre, Times Tower, Nairobi	9:00am-12pm	Manufacturers, Importers distributors and retailers of Mon-alcoholic beyerages	
	Mombasa & Kwale	Kenya School of Government, Mombasa			
22° July, 2019	Kışumu and Siaya	The Vic Hotel Klsumu	9:00am-12pm		
	Nyeri, Nyandarua, Laikipia & Muranga	Green Hills Hotel Nyer!			
	Malindi, Kilifi , Tana River ĉ: Lamu	Pine Court Hotel Matinal			
24° July, 2019	Busia, Bungoma, Kakamega & Vihlga	OSBP Boardroom Busis	9:00am-12pm	General Public	
	Embu, Tharaka Nithi & Kirinyaga	Mountain Breeze Holei Embu			
	Voi, Taita Taveta, Kilui & Makueni	Maghenyi Hotel Vol			
26" July, 2019	Kisii, Migori, Homabay & Nyamira	The Dans Holel KIsil	9:00am-12pm	9	
	Meru, Isiolo & Marsabit	The Alba Holel Meru			
	All	Hillon Holel Natrobl		Manufacturers, Importers distributors and retailers of Cosmetics	
29° July, 2019	Narok & Bornet	Seasons Hotel Narok	9:00am-12pm		
	Moyale, Turkana & Samburu	OSBP Boardroom Moyalo			
07 July, 2019	Nairobi, Kiambu, Kajiado & Machakos	The Hillon Hotel Natrobl	9:00am-12pm		
я	Nakuru, Kericho & Baringo	Waterbuck Hotel Nakuru		General Public `	
1= July, 2019	Garissa, Wajir & Mandera	Lantern Hotel Garlssa	9:00am-12pm		
× August, 2019	Uasin Gishu, Nandi, Elgeyo Marakwet, Turkana & Trans Nzoia	Starbucks Hotel Eldoret	9:00am-12pm		

For confirmation of attendance kindly Email: stakeholder.engagement@kra.go.ke or please call our Contact Centre on Tel: (0) 20 4 999 999; 0711 099 999 or Email: callcentre@kra.go.ke

Commissioner for Domestic Taxes

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Draft Excise Duty Regulations 2019

Kenya Revenue Authority informs members of the public, manufacturers and importers of excisable goods that Draft Excise Duty regulations, 2019 have been developed and currently hosted on the Kenya Revenue Authority website (www.kra.go.ke)

In order to ensure wide consultation and public participation as stipulated in the Constitution of Kenya, 2010, Kenya Revenue Authority invites institutions, organizations, individuals and the public to submit their views and comments on these draft regulations.

The views and comments should be addressed in writing to: The Commissioner General, Kenya Revenue Authority, P.O Box 48240-00100, Natrobi or emailed to stakeholder.engagement@kra.go.ke to be received on or before. Monday , 26th August , 2019 to facilitate the review and finalisation of the Regulations.

For clarification please call our Contact Centre on Tel: (0) 20 4 999 999; 0711 099 999 or Email: callcentre@kra.go.ke

Commissionar General

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Revised Electronic Tax F

Kenya Revenue Authority informs the fiscal devices about the issuance of a Tax Registers in line with the require

The enhancements follow review o require online transmission of transa Invoice Management System (TIMS) population to the taxpayers VAT retand ultimately reducing the cost of tax

The revised ETR technical specifical portal (https://itax.kra.go.ke)

For clarification, please call our Contr 999; 0711 099 999 or Email: callcentr the nearest KPA Tax Service Office o

Commissioner for t

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PUBLIC FORUM

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KEY ISSUES RAISED DURING THE PUBLIC PARTICIPATION FORUM ON THE ROLL OUT OF EGMS HELD ON 15^{TH} JULY 2019

No	Concern area	Key concern & recommended action
1.	System Roll- Out/Go-live	The Roll-Out date having been set on 1st Sept. 2019, there were concerns whether KRA is prepared to go live on that date since there have been
٠	Date	registered issues with the systems' encoding upon installation.
		There were also concerns about the Roll-Out date since representatives from KAM felt that they have had talks with KRA surrounding the system which are yet to be addressed and the same would affect all the players in the Industry.
		A section of the stakeholders also felt that owing to the large number of players in the Industry the Roll-Out date should be delayed to be sure that everything is well set and ready.
		KRA stated that it is well prepared for the Roll-Out and that whichever system teething challenge that was previously present is now resolved.
		The issues raised by KAM (13 issues) were not new and consultations have been on-going since 2016 where most (11 issues) have been resolved to the satisfaction of both parties, leaving two issues (cost and export) which were escalated and a compromise position arrived at. For cost, the compromise position was by reduction of the duty fee from 1.5 shillings per item to 50 cents per item. For export, stakeholders were advised to be content with the adjustments implemented to leverage even though they might not be exactly what they wanted.
		It was firmly asserted that the stakeholders should concentrate on Operation issues which can be addresses through the forum other than Policy issues which require redress through the Parliament. For policy issues the stakeholders were further advised to use the mechanisms in place that could address such issues that touch on the laws of the land.
		About the large number of stakeholders presenting a challenge to the Roll-Out, stakeholders were assured that KRA was ready for it.

2.	Impact on the cost of doing business	A section of stakeholders were concerned about the cost implication of going digital. This was a concern mainly by the SMEs. They feared that system would negatively interfere with their manual processes.
		There was also the question whether the installation of the system and maintenance was for the manufacturers and who will bare the burden in case of an accident/incident that affects the system.
,		These fears were laid to rest after the stakeholders were informed that there operations will not be affected. The only imperative is that they be connected to the system through the internet (even through their phones with requisite security elements), since they should declare their processes online and in real time.
		KRA will purchase and install the system. The manufacturers will give space and security to the same.
3.	Property Rights	Since EGMS is managed by a third thirty, traders wanted to know if there will be secrecy in handling their business data.
		Traders were assured that their business information will treated with confidentiality. Furthermore, the current laws already provide for secrecy in such matters and to add to that KRA has an agreement with the third party to ensure that there will be utmost secrecy in regards to dealing with business data.
4.	Operations	KRA affirmed that the system has been tested and approved to be capable of serving manufacturers in the bottled water Industry. The unique challenges for specific players can be looked into by discussions between KRA and the Manufacturers to find specific ways of dealing with the same. EGMS can handle a speed of 5000 units per minute. This is fast enough for any player in the Industry. The system is already working well in the alcoholic drinks Industry which is more exacting than the bottled water Industry.
	•	Other challenges that were mentioned were as a result of lack of adequate knowledge on how deal with excise duty and had ways on working around them even in the current system. Traders were advised to visit their Tax Service Stations for help and/or attend the regular training sessions offered by KRA from time to time.
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Associations P	resent	
KAM	Kenya Association of Manufacturers	
AKS	Association of Kenya Suppliers	
WBA	Water Bottlers Association	

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ISO 900 1: 20 15 CERTIFIED

KEY ISSUES RAISED DURING THE PUBLIC PARTICIPATION FORUM ON THE ROLL OUT OF EGMS HELD ON 16TH JULY 2019

No	Concern area	Key concern & recommended action
1.	System Roll-	1st Sept. 2019 is the official Roll-Out date. KRA is well prepared to go
	Out/Go-live	live and all stakeholders were assured that all systems are in place for
	Date	this and were urged to be ready to adopt and embrace the new system.
2.	Damaged goods	Concern was raised on what happens to goods that get damaged after production and more so, when the damaged goods pose a health risk.
	a a	Damaged goods should be promptly reported to KRA through the system and directly through the relationship manager. KRA has enforcement officers on duty 24/7 to address such problems in verifying the damage and facilitating for destruction. The juices that pose health risk can be poured but their containers kept for evidence and later destruction. The system has means of allowing for crediting the loss incurred through the spoilage and issuance of replacements.
3.	Stolen/spoilt stamps	The question arose whether KRA can monitor and detect stolen stamps and whether KRA can guarantee speedy resolution of spoilt stamps cases.
		Traders were asked to report stolen or spoilt stamps immediately on the system. By this, the system status of the stamps will change to reflect the situation. When enforcement officers come across such stamps in the market then enforcement procedures will take effect to deal with the
		problem.
4.	Contract manufacturers	Contract manufacturers who deal with multiple items which sometimes are from different clients wanted to know how configuration will be done to suite their business and who will do projections for future stamp production.
		KRA explained that configuration is done per product. The system can handle the multiplicity. On projections, KRA explained that the owner of the products is required to do the projections.



5. Ope	erations	Traders enquired on what will happen to those who bought stamps in bulk and are not utilized after the go-live date; also if the products are already out in the market. They also sought to know if there will be continued system maintenance. KRA will offer a window period (90 days) for utilization of stamps already procured by the go-live date; and for products already in the market. In case the stamps are too many then replacement with the new stamps can be organized. For products, KRA will allow for complete sale. But after the Roll-Out, all new production should be through EGMS.
	q	The Authority will also carry out regular system maintenance.
6. Pro	oduction	Stakeholders wanted to know if EGMS will affect production
		It was affirmed that EGMS will not affect production. If anything, it will enhance production. Experience from the alcohol and tobacco Industries has proved the system to be both effective and efficient. EGMS lines can run very fast and can allow synchronization with the existing speed of production.
		In case of break downs, increase or decrease of production or stoppage of production, the manufacturers should report promptly to KRA so that the status is noted.
7. Un:	ique cases	For unique cases the manufacturers have to liaise with KRA for a unique solution to be sought.
8. Wa	aste/Spillage	The allowable quantity of spillage/waste is 1%

EGMS is pegged on Sec. 28 Excise Duty Act 2015 under Legal Notice No. 53 of 2017

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KEY ISSUES RAISED DURING THE PUBLIC PARTICIPATION FORUM ON THE ROLL OUT OF EGMS HELD FROM 22 ND JULY 2019 TO 26 TH JULY 2019

No	Concern area	Key concern & recommended action
1.	System Roll-	1st Sept. 2019 is the official Roll-Out date. KRA is well prepared to go
	Out/Go-live	live and all stakeholders were assured that all systems are in place for
	Date	this and were urged to be ready to adopt and embrace the new system.
2.	Stamp delivery	Taxpayers raised concern on how they will easily and readily get stamps considering the distance from Nairobi. Basically, the cost of delivery and the time delivery will take.
		Stamp application is through the system. The processing and approval is through the Tax Service Office (TSO). So after application the taxpayer is supposed to liaise with the TSO for the approval. If getting to the KRA Head Quarters in Nairobi is a challenge, the taxpayer
		through the system has a provision for specifying the person (or courier) to pick the stamps. Decentralization of stamp issuance is under consideration but owing to the huge security implication surrounding the stamps, stamp issuance remains at Times Tower for now.
		In case stamps get lost on delivery then the taxpayer should report to the police and KRA. Anyone caught with the lost stamps will be held liable.
3.	Stamp	Taxpayers wanted to know how to verify stamps.
	verification	KRA will publish through a gazette notice the stamp security verification features. To add to the KRA has provided a mobile phone App (Soma Label) that is empowered to tell if a stamp is legit or fake.
4.	Spoilt stamps	Taxpayers asked how spoilt stamps will be dealt with.
		The party responsible for spoilage bears the cost of replacement. If in the unlikely event it's KRA then upon return of the stamps to KRA a credit will be declared on the system and replacement done. If it's the manufacturer, then the manufacturer should not destroy the spoilt stamps but should keep them aside for KRA to verify before a replacement is done. In this case, the manufacturer bears the cost.

5.	Stamp utilization	Traders asked how manual stamp affixing will be done; how equality is realised in having stamp price fixed regardless of quantity; and how the manual stamps are packed.
		The manual stamps will be affixed in an area where on opening the container they'll be destroyed. This is to prevent recycling.
		On the question of equality, KRA said that as an Authority it has looked into equity instead where the pricing of the stamps is different with a graduation based on type of good. For water it's 50 cents, for juices and soda it's 60 cents, for bear, spirits and wine it's 2 shillings and 50 cents and for ready to drink beverages with minimal alcoholic content it's 1 shilling and 50 cents.
,	(6)	The manual stamps are packed in a serialized reel.
6.	EGMS relation to excise duty	Taxpayers wished to know if there is a direct link between stamp price and excise duty.
		Stamp cost is not part of excise duty. It is an allowable expense which will be used to run EGMS. However, with time, the data from EGMS may be used to provide pre-populated data for use in excise duty filing.
7.	Operation cost	The question of who will bear what cost in EGMS use came up.
		KRA will bear the system cost, its installation and maintenance. The taxpayer is to bear the cost of space, security, power and internet.
8.	Excisable goods importation	For excisable goods importation, the goods have to be declared within five days. Then an order should be made through the system for the number of stamps. Issuance of the stamps will depend on the compliance status of the taxpayer.
9.	Illegal products or stamps	The question of who is blameworthy when goods are found without stamps or with fake stamps arose from taxpayers.
	· ·	Investigations will tell the blameworthiness of the parties involved but it is crucial for all parties to know their responsibility to verify the legitimacy of products and stamps using the available physical security features of stamps and the soma label App. The penalty for trading in illegal products or stamps is not less than 5M.
10.	Operations	Traders enquired on what will happen to those who bought stamps in bulk and are not utilized after the go-live date; also if the products are already out in the market.
		KRA will offer a window period (90 days) for utilization of stamps already procured by the go-live date; and for products already in the market. In case the stamps are too many then replacement with the new stamps can be organized. For products, KRA will allow for complete

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		sale. But after the Roll-Out, all new production should be through EGMS.
11.	Allowable number of stamps	Traders asked if there is a minimum or maximum number of stamps that they are allowed to purchase at any given time.
		There is no set limit of the number of stamps that a trader can purchase. However, traders are advised to purchase a reasonable number in relation to their business. Forecasting will help in this where KRA will make sure that there are always stamps for sale and it will also help advise where the Authority is planning to change the security features.
12.	Production	Traders were informed that to check overproduction of stamps, there will be no new issuance of stamps by KRA until at least 75% consumption of those already produced. Stakeholders wanted to know if EGMS will affect production
	rioduotion	
		It was affirmed that EGMS will not affect production. If anything, it will enhance production. Experience from the alcohol and tobacco
		Industries has proved the system to be both effective and efficient.
		EGMS lines can run very fast and can allow synchronization with the existing speed of production.
		In case of break downs, increase or decrease of production or stoppage of production, the manufacturers should report promptly to KRA so that the status is noted.
13.	Large scale	For large scale importers, KRA will liaise with the producing companies
	importers	to enable affixing of the stamps at the country of production. This will facilitate importation and distribution by allowing faster clearance.
14.	Payment mode	Stamp payment will be done through any National Bank. It is the
		collection that is restricted to Times Tower – Nairobi.
15.	Waste/Spillage	The allowable quantity of spillage/waste is 1%
16.	Sampling	Sampling is allowable on request to the commissioner.

NB: It was noted with great concern that most of the bottled water manufacturers did not indicate the production date and expiry date of their products.

EGMS is pegged on Sec. 28 Excise Duty Act 2015 under Legal Notice No. 53 of 2017

THE PHARMACY AND POISONS ACT

(Cap. 244)

THE PHARMACY AND POISONS (PARALLEL IMPORTED MEDICINAL SUBSTANCES) RULES 2019

ARRANGEMENT OF RULES

Rule

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- 2— Application.
- 3— Interpretation.

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- 4— Qualification to parallel import medicinal substances.
- 5— Application for a certificate of parallel importation.
- 6— Issuance of a certificate of parallel importation.
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- 9— Rejection of an application for a certificate of parallel importation.
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- 12— Additional requirements by the Board.
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- 23— Inventory of parallel imported medicinal substances.
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PART IV- PHARMACOVIGILANCE

- 25— Pharmacovigilance issues.
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- 27—Principles of pricing of parallel imported medicinal substances.
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29— Labelling and packaging guidelines.

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- 30-Places authorised officers may enter.
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LEGAL NOTICE NO.

THE PHARMACY AND POISONS ACT (Cap. 244)

IN EXERCISE of the powers conferred by section 44 of the Pharmacy and Poisons Act, the Cabinet Secretary for Health, after consultation with the Pharmacy and Poisons Board, makes the following Rules—

THE PHARMACY AND POISONS (PARALLEL IMPORTED MEDICINAL SUBSTANCES) RULES, 2019

PART I- PRELIMINARY

Citation.

1. These Rules may be cited as the Pharmacy and Poisons (Parallel Imported Medicinal substances) Rules, 2019.

Application.

- 2. These rules shall apply to medicinal substances which are parallel imported and distributed on the Kenyan market except—
 - (a) a medicinal substance prepared by a pharmacist in the pharmacy and dispensed without promotion, blood, blood plasma and blood preparations containing cellular elements of blood, or substances such as dental fillings and plates, or surgical preparations such as catgut and plaster of Paris bandages;
 - (b) non-registered patented medicinal substance for compassionate use;
 - (c) an orphan medicinal substance; or
 - (d) non-registered medicinal substance for named patient use and hospitals.

Interpretation.

3. In these Rules, unless the context otherwise requires—

Cap. 244.

"Act" means the Pharmacy and Poisons Act;

"Appeals Committee" means Parallel Importation Appeals Committee established under rule 48;

"authorized officer" means the registrar, pharmaceutical analyst, pharmaceutical inspector, a medical officer, an inspector of medicinal substances, an administrative officer or a police officer in the rank of Superintendent and above;

"branded generic medicinal substance" means a medicinal substance usually intended to be interchangeable with the originator brand product, manufactured without a licence from the originator manufacturer and marketed after the expiry of patent or other exclusivity rights;

"certificate" means the certificate of parallel importation issued under rule 6;

"country of origin" means a country from which the parallel imported medicinal substance is imported;

"licence" means a licence granted under rule 14 to allow the licensee to carry on parallel importation of a medicinal substance;

"licensee" means a person licensed to engage in parallel importation of a medicinal substance under these rules;

"marketing authorization" means the certificate of registration issued by the competent medicinal substance regulatory authority in the country of origin for the purpose of marketing or free distribution of a medicinal substance after evaluation for safety, efficacy and quality;

"marketing authorization holder" means a person who holds a marketing authorization;

"notification" means the process of entering actual movement and state of each unit of a medicinal substance into the tracing system established under rule 43;

"parallel importation" means the importation into Kenya, by a licensed importer of medicinal substance other than the marketing authorization holder or his or her technical representative of the following medicinal substances which require marketing authorization in Kenya—

No. 3 of 2001.

- (a) patented medicinal substances under section 58(2) of the Industrial Property Act, 2001;
- (b) non-patented medicinal substances; or
- (c) branded generic medicinal substances;

"parallel imported medicinal substance" means a medicinal substance imported into Kenya under these rules:

"pharmacovigilance" means the detection, assessment, understanding and prevention of adverse effects or any other medicinal substance-related problem; and

"risk management plan" means a detailed description of a plan that contains—

- (a) a description and analysis of the safety profile of the medicinal substance including a summary of the safety concerns; and
- (b) a set of medicinal substance vigilance and risk minimization activities designed to identify, characterize and manage risks relating to the medicinal substance including the assessment of the effectiveness of these activities and interventions.

PART II - CERTIFICATE OF PARALLEL IMPORTATION AND PARALLEL IMPORT LICENCE

Qualification to parallel Import medicinal substances.

- 4. A person shall not parallel import a medicinal substance into Kenya unless—
- No. 17 of 2015.
- (a) the person is incorporated as a limited liability company under the Companies Act, 2015;
- (b) the person has been granted a certificate of parallel importation;
- (c) the person is licensed to parallel import the medicinal substance;

L.N. 147/1981.

- (d) the medicinal substance has a valid registration in Kenya under the Pharmacy and Poisons (Registration of Drugs) Rules; and
- (e) the medicinal substance has a valid market authorization in the country of origin.

Application for a certificate of parallel importation.

- **5.**(1) A person who wishes to undertake parallel importation shall apply, to the Board, for a certificate of parallel importation in the Form 1 set out in the First Schedule.
 - (2) The application form shall be accompanied by—
 - (a) a certified copy of the applicant's certificate of incorporation;
 - (b) a certified copy of the applicant's memorandum and articles of association or its equivalent under the Companies Act, 2015;

No. 17 of 2015

(c) the applicant's company profile as may be appropriate for parallel importation of medicinal substances;

- (d) a copy of certificate of registration, issued under section 9 of the Act, to the registered pharmacist who shall be at the premises;
- (e) a copy of certificate of registration of premises issued under section 23 of the Act;
- (f) a copy of wholesale dealer's licence issued under section 27 of the Act;
- (g) a copy of manufacturer's licence issued under section 35A of the Act, where applicable;
- (h) a copy of certificate of membership of Pharmaceutical Society of Kenya;
- (i) such other information as the Board require from time to time; and
- (j) the application fee prescribed in the Second Schedule.

Issuance certificate parallel importation.

6. The Board shall consider an application made under rule 5 and where satisfied that all the necessary requirements have been met, issue a certificate of parallel importation to the applicant, within a reasonable time of the applicant lodging the application.

Certificate parallel importation transferable.

of 7. A certificate of parallel importation issued under rule 6 shall not be transferred, assigned or encumbered in any way.

Validity certificate parallel importation. of 8. The certificate of parallel importation granted under rule 6 shall expire on 31st December of every year.

Rejection of an application for a certificate of parallel importation.

- 9.(1) The Board may, within fourteen days of receipt of an application under rule 5, consider and reject an application which in the opinion of the Board—
 - (a) is substantially defective; or

- (b) has not met the requirements of rule 4.
- (2) The Board shall communicate the rejection of an application to the applicant within fourteen days of the Board's decision and shall state the reason for the rejection.

Application for renewal of certificate of parallel importation.

- 10.(1) The holder of certificate of parallel importation may apply to the Board for renewal of the certificate at least three months before the expiry of the certificate.
- (2) The application referred to under paragraph (1) shall—
 - (a) be in Form 1 set out in the First Schedule; and
 - (b) be accompanied by the renewal fees prescribed in the Second Schedule.
 - (3) The Board may renew a certificate where—
 - (a) it is satisfied that the licensee has been operating in compliance with these rules; and
 - (b) the certificate holder has fulfilled its tax obligations and submitted a current certified copy of a tax compliance certificate or its equivalent as issued by the Kenya Revenue Authority.
- (4) Where the holder of a certificate submits an application for renewal of a certificate under paragraph (1), the certificate shall be deemed to be valid until the application for renewal is determined.
- (5) A holder of a certificate of parallel importation who does not wish to renew a certificate shall inform the Board and specify the parallel imported medicinal substances within its possession and how it intends to dispose off the substances.

- (6) The certificate of parallel importation of a holder who fails to apply for renewal of the certificate within the period prescribed in paragraph (1) shall, at the expiry of its validity, be deemed to have lapsed and the holder shall not parallel import or sell such medicinal substances or purport to do anything in relation to the medicinal substances in Kenya.
- (7) A person who contravenes paragraph (6) commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding ten years, or to both.

Application for parallel import licence.

- 11.(1) The holder of a certificate of parallel importation shall apply to the Board for a license to parallel import a medicinal substance in Form 2 set out in the First Schedule.
- (2) An application made under paragraph (1) shall be accompanied by—
 - (a) copies of the package insert and patient information leaflet translated into English or Kiswahili, where available;
 - (b) an appropriately labelled sample of the medicinal substance to be imported;
 - (c) information on the exporter, stating whether it is a manufacturer, packer, or wholesaler;
 - (d) a statement of justification for importation of the medicinal substance including but not limited to the economic advantage of reduced price;
 - (e) evidence that the medicinal substance is covered by an existing market authorization in the country of origin;
 - (f) an undertaking that the applicant will ensure the continued safety, efficacy and quality of the

medicinal substance as determined by the Board in Form 3 set out in the First Schedule;

- (g) such other information as may be required by the Board from time to time; and
- (h) the application fee prescribed in the Second Schedule.

Additional requirements by the Board.

- 12.(1) The Board may, when considering an application made under rule 11, make inquiries and request for such additional evidence and documents as the Board may consider necessary.
- (2) The Board shall, within seven working days, specify to the applicant such additional evidence and documents as it may require under paragraph (1).
- (3) The Board shall reject an application where an applicant fails to provide additional evidence and documents under paragraph (2).

Board inquiries in country of origin.

- 13. The Board may, where it considers it necessary,—
 - (a) make inquiries to the authorities in the country of origin of a medicinal substance to ensure that the medicinal substance in question has a valid marketing authorization in the country of origin;
 - (b) verify manufacturer details, the marketing authorization holder, the complete composition, the shelf life and the storage conditions; or
 - (c) carry out audits on the exporters.

Issuance of parallel import licence.

14.(1) The Board may, if satisfied that an applicant has met all the requirements, issue a parallel import licence to the applicant, within a reasonable time of the applicant lodging the application.

(2) The licensee may, upon receipt of a licence, proceed with the importation of the medicinal substance after the medicinal substance has been licensed.

Licence not transferable.

15. A licence issued under rule 14(1) shall not be transferred, assigned or encumbered in any way.

Validity licence.

of 16. The licence issued under rule 14(1) shall expire on 31st December of every year.

Rejection of an application for a parallel import licence.

17.(1) The Board may, within fourteen days of the applicant lodging the application under rule 11, reject an application which in the opinion of the Board—

- (a) is substantially defective; or
- (b) has not complied with the requirements under rule 11.
- (2) The rejection referred to under paragraph (1) shall be communicated to the applicant within fourteen days of the Board's decision and shall state the reason for the rejection.

General conditions of parallel import licence.

18. A licensee shall—

- (a) take measures to ensure the safe use of the medicinal substance and include them in the licensee's risk management plan;
- (b) comply with obligations on the recording or reporting of suspected adverse reactions;
- (c) comply with any other conditions or restrictions with regard to the safe and effective use of the medicinal substance; and
- (d) establish an adequate pharmacovigilance system.

Application for renewal of a 19.(1) A licensee shall apply to the Board for renewal of

parallel import a licence to parallel import medicinal substances at least three months before the expiry of the licence.

- (2) An application under paragraph (1) shall—
 - (a) be in Form 2 set out in the First Schedule; and
 - (b) be accompanied with the renewal fees prescribed in the Second Schedule.
- (3) The Board may renew a licence where—
 - (a) it is satisfied that the licensee has been operating in compliance with these rules; and
- (b) the licensee has fulfilled its tax obligations and submitted a current certified copy of a tax compliance certificate or its equivalent as issued by the Kenya Revenue Authority.
- (4) Where the licensee submits an application for renewal of a licence under paragraph (1), the licence shall be deemed to continue in force until the application for renewal is determined.
- (5) A licensee who does not wish to renew a licence shall inform the Board and specify the parallel imported medicinal substances within its possession and how it intends to dispose off the substances.
- (6) The licence of a licensee who fails to submit an application for renewal of license within the period prescribed in paragraph (1) shall, at the expiry of its validity, be deemed to have lapsed and the licensee shall not parallel import or sell such medicinal substances or purport to do anything in relation to the medicinal substances.
- (7) A person who contravenes paragraph (6) commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a

term not exceeding ten years, or to both.

Revocation, variation and suspension of parallel import licence. 20.(1) The Board may revoke, vary or suspend a parallel import licence if the Board determines that—

- (a) the medicinal substance to which the parallel import licence relates is harmful;
- (b) the medicinal substance's qualitative or quantitative composition is not as described in the application for the parallel import licence or the material supplied with it;
- (c) the application or the material supplied with it was incorrect;
- (d) there has been a breach of any of the terms of the parallel import licence or a requirement on packaging and leaflets;
- (e) a general condition of the parallel import licence has not been fulfilled;
- (f) the licensee has not complied with rule 12;
- (g) the licensee has ceased to be established in Kenya; or
- (h) urgent action to protect public health is necessary, in which case it may suspend the parallel import licence.
- (2) A person aggrieved by the decision to vary, revoke or suspend a licence may lodge an appeal to the Appeals Committee within thirty days from the date of the decision.

Suspension of use, sale, supply or offer for sale or supply of medicinal 21.(1) The Board may suspend the use, sale, supply or offer for sale or supply within Kenya of a medicinal substance or batches of a medicinal substance to which a parallel import licence relates if the Board determines

- (a) the medicinal substance to which the parallel import licence relates is harmful;
- (b) the positive therapeutic effects of the medicinal substance do not outweigh the risks of the medicinal substance to the health of patients or of the public;
- (c) the medicinal substance lacks therapeutic efficacy, given that therapeutic results cannot be obtained from the medicinal substance;
- (d) the medicinal substance's qualitative or quantitative composition is not as described in the application for the parallel import licence or the material supplied with it; or
- (e) there has been a breach of any of the terms of the parallel import licence or a requirement on packaging and leaflets.
- (2) The Board shall notify a licensee, in writing, of a suspension under this rule for a specified period that is to take effect from a date specified in the notice and shall also state reasons for the suspension.
- (3) The Board may, in exceptional circumstances and for such a transitional period as the Board may determine, allow the supply of the medicinal substance to patients who are already being treated with a medicinal substance that is the subject of a suspension under this rule.
- (4) A person who contravenes this rule commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding ten years, or to both.
- (5) A person aggrieved by a decision made by the Board under this rule may appeal to the Appeals

direct healthcare professional communication letters.

(2) For the purposes of this rule—

"direct healthcare professional communication" means a single, additional risk minimisation measure sent by marketing authorization holder to healthcare providers to directly inform healthcare professionals about new and important information about a medicinal substance.

- (3) The licensee shall submit periodic safety update reports to the Board twice a year.
- (4) A periodic safety update report submitted under paragraph (3) shall contain—
 - (a) summaries of data relevant to the benefits and risks of the medicinal substance, including results of all studies, with a consideration of their potential impact on the licence for the medicinal substance;
 - (b) a scientific evaluation of the risk-benefit balance of the medicinal substance; and
 - (c) data relating to the volume of sales of the medicinal substance and any data the licensee has relating to the volume of prescriptions, including an estimate of the population exposed to the medicinal substance.
- (5) A person who contravenes this rule commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.
- (5) The court may, in addition to the penalty imposed under paragraph (4), order any medicinal substance in respect of which the offence has been committed or which has been used for the commission of such offence to be

forfeited.

Additional obligations.

26. In addition to the obligations under rules 23 to 25, a licensee shall—

- (a) declare information on its supplier, including the name, location and contacts of each of parallel imported medicinal substance;
- (b) take full responsibility of quality, efficacy, safety, potency, and security of parallel-imported medicinal substance;
- (c) ensure that the storage conditions, Good Distribution Practice and Good Manufacturing Practice are observed during transport and distribution of parallel imported medicinal substances:
- (d) have standard operating procedures;
- (e) comply with Pharmacy and Poisons Board guidelines on Good Distribution Practice;
- (f) recall and destroy parallel imported medicinal substances if the medicinal substances are determined not to comply with quality, safety or efficacy; and
- (g) declare the cost benefit of the medicinal substance to the public.

PART V-PRICING OF PARALLEL IMPORTED MEDICINAL SUBSTANCES

Principles of pricing of parallel imported medicinal substances.

- 27. The following principles shall guide all aspects of pricing of parallel imported medicinal substances—
 - (a) the economic circumstances prevailing in the country;

- (b) the price of the locally available medicinal substance;
- (c) the cost of importation or packaging, where applicable;
- (d) government policy or directives; and
- (e) such principles as may be considered necessary.

Pricing guidelines.

- 28.(1) The Board shall develop guidelines on the pricing of parallel imported medicinal substances to give effect to rule 27.
- (2) A person who contravenes any provision of the guidelines developed under paragraph (1) commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

PART VI— PACKAGING AND LABELLING OF PARALLEL IMPORTED MEDICINAL SUBSTANCES

Labelling and packaging guidelines.

- 29.(1) The Board shall make guidelines on the labelling and packaging of parallel imported medicinal substances.
 - (2) The guidelines shall provide for the following—
 - (a) the form and content of the package insert;
 - (b) the form and content of the patient information leaflet;
 - (c) the labelling of the parallel imported medicinal substance; and
 - (d) any other information on labelling and packaging that may be deemed necessary.

(2) A person who contravenes any provision of the guidelines commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

PART VII- INSPECTIONS

Places authorized officers may enter.

- **30.**(1) The authorized officers shall—
 - (a) carry out regular inspections of premises; or
 - (b) inspect consignments of medicinal substances at the port of entry.
- (2) The authorized officers may, at any reasonable time, carry out regular inspection of premises and consignments of medicinal substances at the port of entry.
- (3) Despite paragraph (2), authorized officers may enter any place in which the authorized officers believe, on reasonable grounds, that any person or persons is in any way contravening the provisions of these Rules.
- (4) The authorized officer entering any premises under this rule shall, if so required, produce for inspection by the person who is or appears to be in charge of the premises his or her job identification card.

Powers of authorized officers.

- 31.(1) In order to carry out an inspection in any place pursuant to rule 30, an authorized officer may—
 - (a) enter and inspect the premises or a port of entry;
 - (b) take samples of any medicinal substance;
 - (c) examine any medicinal substance;
 - (d) require any person in such place to produce for inspection, in the manner and form requested by

the officer, the medicinal substance;

- (e) open or require any person in the place to open any container or package in the premises;
- (f) conduct any test or analysis or take any measurements; or
- (g) require any person found in the place to produce for inspection or copying, any written or electronic information that is relevant to the administration or enforcement of these Rules.
- (2) The authorized officer shall submit a report to the Board after carrying out an inspection in accordance with paragraph (1).

Use of records.

- 32. When carrying out an inspection in any place, an authorized officer may—
 - (a) use or cause to be used any computer system in the place to examine data contained in or available to the computer system that is relevant to the administration or enforcement of these rules;
 - (b) reproduce the data in the form of a print-out or other intelligible output and take it for examination or copying;
 - (c) use or cause to be used any copying equipment in the place to make copies of any data, record or document; or
 - (d) scrutinize any other record system in use in that place.

Entry of dwelling place.

33. An authorized officer may not enter a dwelling place except with the consent of the occupant or under the authority of a warrant issued under rule 34.

Magistrate court to issue warrant.

- 34.(1) Upon an *ex parte* application by an authorized officer, a magistrate may, if the magistrate is satisfied by information on oath, issue a warrant authorizing an authorized officer or officers named in the warrant to enter and inspect a dwelling place, subject to any conditions specified in the warrant such as—
 - (a) the dwelling place is a place referred to in rule 33;
 - (b) entry to the dwelling place is necessary for the administration or enforcement of these rules; or
 - (c) the occupant does not consent to the entry, or that entry has been refused or there are reasonable grounds for believing that it will be refused or seeking such consent shall hamper investigations.
- (2) The time of such entry shall be between six o'clock in the forenoon and six o'clock in the afternoon of any day of the week.

Use of force.

35. An authorized officer executing a warrant issued under rule 34 shall not use force unless the authorized officer is accompanied by a police officer of the rank of an inspector and above and the use of force is specifically authorized in the warrant.

Certificate of analysis.

36. An authorized officer who has analyzed or examined a medicinal substance or a sample of it, under these Rules, shall issue a certificate and report setting out the results of the analysis or examination.

Assistance of an authorized officer.

- 37.(1) The owner of a place or the person in charge of a place and every person found in a place to be inspected by an authorized officer under these Rules shall—
 - (a) provide all reasonable assistance to enable the authorized officer to carry out his or her duties under these Rules; and

- (b) furnish the authorized officer with such information as the authorized officer reasonably require for the purpose for which entry into the place has been made.
- (2) The authorised officer shall issue an inspection certificate once satisfied with the inspection.
- (3) A person who fails to provide assistance or furnish an authorized officer with the required information commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

Obstruction.

- 38.(1) A person shall not obstruct or hinder, or knowingly make a false or misleading statement to an authorized officer who is carrying out duties under these Rules.
- (2) A person who obstructs or hinders, or knowingly makes a false or misleading statement to an authorized officer who is carrying out duties under these Rules commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

Seizure.

- 39.(1) An authorized officer may, during an inspection under these Rules, seize any medicinal substance which or in relation to which the authorized officer believes, on reasonable grounds, that these Rules have been contravened and the authorized officer shall make a full inventory of the substances seized.
- (2) The authorized officer may direct that any medicinal substance seized be kept or stored in the place where it was seized or that it be removed to another place.
 - (3) A person shall not remove, alter or interfere in any

manner with any medicinal substance seized unless authorized by an authorized officer.

Order for restoration.

- 40.(1) Any person from whom a medicinal substance has been seized under rule 39 may, within thirty days after the date of seizure, apply to the Board for an order of restoration.
- (2) The Board may order that the medicinal substance seized under these Rules be restored immediately to the applicant if, on hearing the application, the Board is satisfied that—
 - (a) the applicant is entitled to possession of the medicinal substance seized; and
 - (b) the medicinal substance seized is not and will not be required as evidence in any proceedings in respect of an offence under these Rules.

Rejection of an application for order of restoration.

- 41.(1) The Board may, within fourteen days of the applicant lodging the application, reject the application that fails to satisfy the requirements under rule 40(2).
- (2) The Board shall communicate the rejection under paragraph (1), in writing, to the applicant and shall state the reason for the rejection.

Appeal.

- 42.(1) A person aggrieved by the decision of the Board under rule 41 may appeal to the Appeals Committee within thirty days of the Board's decision.
- (2) The Appeals Committee may order that the medicinal substance be restored immediately to the applicant if, on hearing the application, the Appeals Committee is satisfied that—
 - (a) the applicant is entitled to possession of the medicinal substance seized; and
 - (b) the medicinal substance seized is not and will not

medicinal substance; or

(b) procures the sale, supplies or offers for sale or supply of the medicinal substance,

commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

(2) In addition to the penalty imposed under paragraph (1), the court may order any medicinal substance in respect of which the offence has been committed or which has been used for the commission of such offence to be forfeited.

General offence of breach of provisions in these rules.

55.(1) A person commits an offence if that person—

- (a) is the holder of certificate of parallel importation or licensee who fails to comply with any requirement or obligation in these Rules;
- (b) contravenes any prohibition in these Rules; or
- (c) fails to comply with any requirement imposed on a person by the Board pursuant to these Rules.

FIRST SCHEDULE

Form 1

(r.5(1), 10(2)(a))

APPLICATION FOR CERTIFICATE OF PARALLEL IMPORTATION OR RENEWAL OF CERTIFICATE OF PARALLEL IMPORTATION

(to be submitted in six copies)

CONFIDENTIAL

The application shall be addressed to the Registrar, Pharmacy and Poisons Board, P.O. Box 27663, Nairobi

Application (Tick as appropriate):

Grant of	Renewal of	Year
new	certificate	
certificate	of parallel	
of parallel	importation	
importation		

	parallel ortation		importation			
шр	Jitation		********************************	L		
Plea	se use Bl	ock (Capit	als) Letters			
1	l. Name	of applica	nt			
2	2. Physi	cal and pos	stal address of t	the compar	ıy:	
	(a) C	ity/Town				
	(d) B	uilding				
			umbers			
			ess			
3			ation			
4			corporation No			
5	5. CR12	search				
6			ate of issue			
		tation		1075ASL		===
7	_		imployees of th			
8			Director/Secret			
A.						
	I thous	doraionad	hanahri daalama			
	i, me un	dersigned,	hereby declare			
		T the parti nowledge a	culars set out hand belief;	erein are t	rue and corre	et to the best
	transact with the rules an	parallel in provisions	nted certificat nportation of a s of the Pharma s, guidelines or pard.	nedicinal a	substances in sons Act, Ca	accordance p. 244, these
	Name					
	Signatur	e				
	Date					

SECOND SCHEDULE

FEES

(r. 10(2(b), 19(2)(b))

1. The following are the prescribed fees for the various licences as outlined in the table.

Type	Fees (Kshs)
Application for certificate	
of parallel importation	
П	AST ST
Application for renewal of certificate of parallel	
importation	
Application fee for a new	
parallel import licence	***
Appeal of rejected	
application for parallel	
import licence	
Application for renewal of	
parallel import licence	

- 2. Any fee payable under paragraph (1) shall be paid by bankers cheque payable to the Board or by any other means prescribed by the Board.
- 3. The prescribed fees in paragraph (1) may be reviewed by the Board from time to time.

THIRD SCHEDULE

(r. 48)

CONDUCT OF PROCEEDINGS OF THE PARALLEL IMPORTATION APPEALS COMMITTEE

Quorum.

1.(1) The quorum of the Appeals Committee shall be five members, including the chairperson.

(2) Despite paragraph (1), members shall not be allowed to delegate their responsibility to their subordinate officers.

Majority decision.

- 2.(1) Decisions shall be taken by simple majority.
- (2) In case of a tie, the proposal supported by the Chairperson shall prevail, and shall be signed by the members agreeing thereto.

Disclosure of interest.

3. If any member of the Appeals Committee has any interest in any particular proceedings before the Appeals Committee, he or she shall inform the Chairperson who may after considering the interest, appoint another person in his or her place for the purpose of that particular appeal.

Venue.

4. The Appeals Committee shall sit at such a place as it may consider most convenient, having regard to all the circumstances of the particular proceedings.

Rules.

- 5. Subject to the provisions of this Schedule, the Appeals Committee shall have power to make the rules governing procedures.
- Proof o documents.

6. A document purporting to be a copy of an order of the Appeals Committee and certified by the Chairperson to be a true copy thereof shall in any legal proceeding be prima facie evidence of that order.

Pharmacy and Poisons Board	PHARMACEUTICAL PRICE AND MARK-UP MANAGEMENT REPORT	PPB/REG /TRA /RPT/04/18-19	9
		Rev No	



MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

REPORT

PHARMACEUTICAL PRICE AND MARK UP MANAGEMENT

COMMITTEE

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Abbreviations, Acronym and Definitions

Active substance: An ingredient that alone or in combination with one or more other ingredients is considered to be responsible for the therapeutic effect of a medicine (WHO Collaborating Centre for pricing and Reimbursement policies 2016).

Generic medicine: A Pharmaceutical product with the same qualitative and quantitative composition in an active substance and the same form as the reference medicine, and whose bioequivalence with the reference medicine has been demonstrated (WHO Collaborating Centre for pricing and Reimbursement policies 2016).

Generic reference pricing (GRP): A reimbursement policy in which products containing the same Active substance are clustered into a reference group. Third party payer funds at maximum to the reference price, while the patient must pay the difference between the purchasing price and the reference price, in addition to any co-payments. (WHO Collaborating Centre for pricing and Reimbursement policies 2016).

Generic substitution (GS): The practice of substituting a medicine with a less expensive medicine containing the same active ingredient (s). (WHO Collaborating Centre for pricing and Reimbursement policies 2016).

Originator medicine: The first version of a medicine. Developed and patented by an originator pharmaceutical company, which has exclusive rights to market the product for the duration of the patent or other exclusivity rights. Often also referred to as Brand medicines. (WHO Collaborating Centre for pricing and Reimbursement policies 2016).

Pharmaceutical group: Grouping of active substances according to the organ or system on which they act, and according to their chemical, pharmacological and therapeutic properties. (WHO Collaborating Centre for Drug Statistics Methodology 2018)

Reference price: A reimbursement ceiling, or the price up to which a third-party payer is willing to pay reimbursement for. (WHO Collaborating Centre for pricing and Reimbursement policies 2016).

A reference price system (RPS): A reimbursement policy in which identical medicines or similar medicines are clustered into reference price, while the patient must pay the difference between the purchasing price and the reference price, in addition to co-payments. (WHO Collaborating Centre for pricing and Reimbursement policies 2016).



Therapeutic Reference Pricing (TRP): A reimbursement policy in which chemically related, pharmacologically equivalent products or products with similar therapeutic effect are clustered into reference groups. The third-party payer funds at maximum to the reference price, while the patient must pay the difference between the purchasing price and the reference price, in addition to any co-payments. (WHO Collaborating Centre for pricing and reimbursement policies 2016).

Market Authorisation Holder (MAH): Holds the authorization to place and keep a medicine on the market. (WHO Collaborating Centre for Pricing and Reimbursement Policies 2016.)

1.0 Executive Summary

According to Adam smith, the invisible hand of the competitive market results in more benefits to a society than any markets with government-regulated prices could hope for (Smith 1776). The government of Kenya and health insurance providers in Kenya strive to contain costs while providing effective healthcare for their patients, thus need for a national pricing strategy or policy that willinclude various direct and indirect pricing controls.

Inpharmaceuticals, the issue of pricing and reimbursement isinextricably linked and interdependent.

Kenyan public areconcerned about the higher expenditures for their prescriptions which require strategic interventions and services that are justifiable in order to assure cost effective outcomes.

Realization of Universal Health Coverage (UHC) requires a balance between the limited financial resources against optimal health outcomes. Thus, cost-effective evaluations of pharmaceutical cost intervention based on sound pharmacoeconomic is key for the attainment of adequate reimbursement and payment for healthcare services rendered.

Kenyan Market remains a liberalized market where market forces dictate the price of medical products which ultimately lead to high cost of healthcare that is in-accessibility by majority of the population. The result is increasedmorbidity and mortality in addition to reduced quality adjusted life years (QALY) among Kenyans.

To address this problem, the Pharmacy and Poisons Board together with stakeholders set up a committee to look into the issue of pricing of health products and technologies within the supply chain. This committee, the Pharmaceutical price and mark up management committee held its meeting as from September 2018 though to November 2018.

The pharmaceutical industry stakeholder presented their position papers which was reviewed and summarized in into five key recommendations. The recommendations if implemented will play a pivotal role in realization of UHC in line with the government 'Big 4' Agenda. The recommendations include;

- 1. Implementation of a policy on prescribing by use of generic names
- 2. Implementation a pharmaceutical pricing portal available to the public
- 3. Strengthening the regulatory capacity of the Pharmacy and Poisons Board
- 4. Implementation of a national formulary that is harmonized with clinical treatment guidelines.
- 5. Establish a medical products price advisory committee at the Pharmacy and Poisons Board.

alternatives, Cost effectiveness(CEA), Cost utility (CUA) to express QALYs gained, Cost benefit analysis(CBA),

The information obtained from the analysis above can be used to support various decisions at several healthcare strata. This include: Clinical decisions, Formulary Management, Drug use policy, disease management, Resource allocation.

8.0 Pharmaceutical Price Regulation

8.1 Reference Pricing

In a reference price system, third party payers set a reimbursement threshold (median price) for a group of products regarded as interchangeable. In this case drugs are organized into limit groups (groups of chemically equivalent, therapeutically similar products, each sharing the same reimbursement limit). Drugs are placed into limit groups on the basis of their international non-proprietary name (INN) or, if the INN varies, drugs with similar effectiveness and the same indication). The purpose is to promote competition between pharmaceutical companies and to encourage consumers to make rational decisions. Typically, reference pricing is applied to off-patent markets. After an originator product's patent expires, generic products can enter the market and start to compete for a share. The diffusion of generic products and price reductions are interlocked; markets with a high share of generic products typically show larger decreases in prices than markets with a low share of generics (Dylst and Simoens 2011).

8.2 Supply and Demand Side Measures In Cost Containment

Rising pharmaceutical expenditures have lead governments to balance with containing public expenditure while still ensuring patient access to affordable medicines. Cost containment measures can be divided roughly into measures aimed at the supply side and measures aimed at the demand side. Supply side measures can target the manufacturer, wholesaler and the retailer at the pharmacy level. These measures can include: pricing at the manufacturer level, price control (Generic substitution, reference pricing, pharmacoeconomic evaluations of treatment regimens, addressing TBT's like tariffs). Demand side measures can include: Cost-sharing, co-payments, moving products to over the counter status, rational prescribing and use, National/County medicine formularies, Essential drug list items, Advertising restrictions, Educational interventions to public.

Pharmaceutical pricing is determined by five principle elements: Import prices, Internal mark-ups, Reimbursement prices, Mark ups in the public institutions, Competition to the private sector.

8.2.1Import Prices

Import prices charged by the MAH or its agent are established based on the manufacturing costs and the assigned operational costs. Whereas these costs should be the basis of a fair pricing to the consumer, they are unlikely to be fully divulged by the manufacturer to the MAH or its agent.

8.2.2 Supply Chain Mark-ups

Prices charged in the trade/channel are dependent on commercial and financial variables. Whereas the financial variables may be outside of the handler at any stage in the trade channel, commercial interests should not be permitted to override the common principle to deliver medicines to the consumer at the most acceptable prices.

8.2.3 Reimbursement prices.

Prices paid for by key payers such as employers, insurance companies and the NHIF drive and shape prices charged by the final dispensers.

8.2.4 Pricing in the public sector

Public sector institutions provide the largest bulk of healthcare and pharmaceutical procurements in Kenya by volume. Procurements in this sector/institution are supported by direct funding and do not depend on self-generation of operational revenues.

8.2.5 Competition to the private sector

Whereas the private sector provides impactful provision of health and supply of products, it is not subjected to significant counterbalancing competitive pressure to modify prices charged downwards or to stability.

8.3 Generic Substitution

In generic substitution, pharmacists have either the right or the obligation to substitute a prescribed product with a chemically equivalent but less expensive one. Generic clustering is narrowest form of clustering. In generic clustering pharmaceuticals are clustered according to the active substance. This is typically referred to as generic reference pricing. In therapeutic reference pricing, pharmaceuticals with chemically-related, pharmacologically equivalent active substances or a similar therapeutic effect are grouped together. (Dylst et al.2011)

9.0 RECOMMENDATIONS

Generally, after discussions and deliberations, the following are the key recommendations and the industry position on pricing;

9.1 COMPEL PRESCRIBING BY USE OF GENERIC NAMES IN PUBLIC SECTOR:

- Implement and enforce prescribing by use of generic names rather than trade names by all healthcare prescribers in public sector.
- There is need to have legislative reforms to make it compulsory for medical practitioners to prescribe medicines by generic names rather than by brand names.
- The pharmacist should be empowered to enforce generic substitution i.e. substituting the same chemical entity in the same dosage form for one prescribed by a different company.
- There need to educate healthcare professionals about the role of a pharmacist in generic substitution which is different from Therapeutic Substitution.

9.2 DEVELOP AND IMPLEMENT A PRICING PORTAL FOR THE PUBLIC

• The portal should contain prices of different brands to encourage competition and facilitate medical product reimbursement systems in addition to dissemination of price information to the public. It should be accessible by a short code message (sms). Pricing transparency in this form will inform manufacturer pricing activities as well as doctors in advising on patient treatment options, incorporating both the clinical benefit as well as cost considerations.

9.3 STRENGTHEN REGULATORY CAPACITY OF THE PHARMACY AND POISONS BOARD

- Establish it as an independent regulatory entity to enable it increase its technical human resource capacity.
- Continuous positive public relations by the Pharmacy and Poisons Board in order to assure the public on the quality of generic medicines in the market. The public needs to be reassured on the quality of generic products in the country through enhanced Pharmacovigilance and surveillance activities.
- Strengthen regulation and enforcement of pharmacy practice in Kenya.
- Streamline the process and regulation of parallel importation of medicines to allow patients to get the price benefit.
- Align registration and retention of health products and technologies to their cost implications to the patient (price declaration).

9.4 DEVELOP AND IMPLEMENT A NATIONAL FORMULARY THAT IS HARMONIZED WITH CLINICAL TREATMENT GUIDELINES.

- The national formulary should indicate the attendant costs.
- Promote adherence to the national standard treatment guidelines.

9.5 SET UP A PHARMACEUTICAL AND HEALTH PRODUCT PRICE ADVISORY COMMITTEE at The Pharmacy And Poisons Board whose ToR's shall include inter alia;

- Develop and continuously review mechanisms in place for *Internal and external price referencing(median price-limit groups)* to inform reimbursement mechanisms and copayments.
- Define information requirements and establish processes to institutionalize routine collection of data that will be appropriate for pricing of health services and commodities
- Institute a mechanism to monitor medicine price increases through notification to MoH/PPB with a view to regulating excessive increases;
- Routinely conduct market research and review prices based on market indices and inflation rates;
- Compensation based on outcomes. Work closely with other agencies to ensure healthcare providers get paid/rewarded and monitored for a best treatment outcome;
- Routinely come up with a pharmacoeconomic model of a treatment for an appropriate outcome measure to promote quality adjusted life years (QALYs) among Kenyans;
- Routinely using appropriate pharmacoeconomic techniques (Costminimization, cost-effectiveness, cost-utility, cost-benefit, cost of illness, cost consequence) recommend appropriate treatment options that inform the national formulary;
- 9.6 MINISTRY OF HEALTH (MOH) TO DEVELOP NATIONAL POLICY GUIDELINES THAT SHALL PROVIDE A ROADMAP TOWARDS PRICE REGULATION of medical products and health technologies.
- 9.7 TO ENSURE THE MOST EQUITABLE AND COMPARABLE PRICE GLOBALLY, MAH SHOULD BE REQUIRED TO SUBMIT PUBLIC/CONSUMER PRICE CHARGED IN RELATABLE COUNTRIES OR COUNTRIES OF SIMILAR ECONOMIC STATUS AND HEALTHCARE REGIME. EVIDENCE OF THIS PRICING COMPARISON MUST BE SUBMITTED BY THE MAH DURING PRODUCT REGISTRATIONAND RETENTION and the Board shall retain an absolute right to verify, accept or

reject the submitted reference prices. The final import (FOB) price shall then be established by the MAH in liaison with PPB with all records available for public scrutiny at will.

- 9.8 THE NATIONAL REIMBURSEMENT FRAMEWORK SHOULD CONSIDER THE MEDIAN PRICE CHARGED ON ANY MOLECULE/GENERIC AS BEING THE STANDARD REIMBURSEMENT POINT.
- 9.9 PUBLIC INSTITUTIONS SHALL BE COMPELLED TO CURB MARK UPS CHARGED ON ALL DRUGS PROCURED. Any mark ups charged should be limited to full purchase cost recovery and associated logistics.
- 9.10 PUBLIC INSTITUTIONS SHOULD BE EMPOWERED TO DISPENSE TO ANY VALID PRESCRIPTION INCLUDING THOSE FROM THE PRIVATE SECTOR. The public facilities should be empowered to dispense to any patient bearing a valid prescription regardless of origin. This provides competition to the private sector. KEMSA can consider partner retail outlets.

LIST OF TABLES:

Table 1: Various % across the supply chain Table:2 Example of Healthcare Cost Categories

FIGURES

Fig. 1: Number of Registered Health Facilities;

Fig.2: Typical proportion of add-ons of final patient price for locally produced generic drug in private sector;

Fig 3: Typical proportions of add-ons of final patient price for a generic imported product in the private sector;

ANNEXES:

Annex 1: PSK Position Paper

Annex 2: KAPI Position Paper

Annex 3: KPDA Position Paper

Annex 4: KPA Position Paper

Annex 5: MTRH Contribution

Annex 6: County Pharmacist Forum

Annex 7: FKPM Position

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Name: Dr. Aneez Rahemtulla
Signature:
Signature:
Date: 27 November 2018
Chairman of the Committee

Name: Dr. Allan K. Wambua/Dr. Anthony Toroitich

Signature: 271128

Joint Secretariat

Committee Members

S/No.	Name	Organization	Signature
1.	Dr AneezRahemtulla	PSK <	T WATER TO
2.	Dr Gerald Macharia	PPB/MOH	
3.	Mr Newton Siele	KPA	
4.	Dr KamamiaWamurichu	KPDA	
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7.	Dr Mary Wangai	MOH	
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11.	Mr Vinod Guptan	KAPI	
12.	Mr John Sabaya	KPA	
13.	Dr Nancy Njeru	MOH/UHC	
14.	Yoshinda Kumiko	MOH/UHC	
15.	Dr Allan Wambua/Dr Anthony Toroitich	PPB/MOH	Allantes



REPUBLIC OF KENYA

MINISTRY OF EAST AFRICAN COMMUNITY AND REGIONAL DEVELOPMENT

STATE DEPARTMENT FOR EAST AFRICAN COMMUNITY

.....<>.....

REPORT

ON

THE IMPLEMENTATION STATUS OF RECOMMENDATIONS AND OBSERVATIONS BY THE NATIONAL ASSEMBLY SELECT COMMITTEE ON REGIONAL INTEGRATION

REF NO. ADM.1/CONF/13/ VOL III (72)

AUGUST 2019

1.0 BACKGROUND

The National Assembly select Committee on Implementation vide letter REF/ NA/DCS/COI/2019 (85) of 23rd July, 2019 required the Ministry of East African Community to submit an appraisal on the status and challenges faced, if any, in the implementation of observations and recommendations in the following reports.

- Report by Committee on Regional Integration on the ratification of the East African Community Protocol on Cooperation of Meteorological Services as communicated vide a letter Ref. No. NA/DLP/RES.14/2018 / (044) dated 22nd August 2018.
- ii. Report on the Committee on Regional Integration on the East African Community Protocol on Information and Communication Technology Networks, which approves the ratification of the EAC Protocol on Information and Communication Technology Networks as communicated vide a letter Ref. No. KNA/L&P 2028/CERT./ (025) dated 19th December 2018.
- iii.Report on inspection visit to the Isebania One Stop Border Post in Migori County as communicated vide a letter Ref. No. NA/DLP/RES. 14/2018 (0420 dated 15th October 2018.

2.0 STATUS OF IMPLEMENTATION OF THE RECOMMENDATIONS OF THE REPORT BY THE COMMITTEE ON REGIONAL INTEGRATION ON THE RATIFICATION OF THE EAST AFRICAN COMMUNITY PROTOCOL ON COOPERATION OF METEOROLOGICAL SERVICES

S/N	Recommendation	Status of Implementation
1.	The following bills await reintroduction into the 4th Assembly of the East African Legislative Assembly (EALA) • EAC Cross Border Trade in Professional Services Bill, 2017 • EAC Prohibition of Female Genital Mutilation Bill, 2016 • EAC Retirement Benefits for specified heads of Organs Bill, 2016 • EAC Youth Council Bill, 2017	The first batch of the Bills lapsed with the 3 ^{1d} Assembly. Only the Youth Council Bill has since been reintroduced and Partner States' public hearing conducted.
2.	The Ministry of EAC should submit the versions forwarded for assent of the EAC Counter-Trafficking in persons Bill, 2016 and EAC Prohibition of FGM Bill, 2016 before the Committee gives its input in respect to the same.	The final versions of the two Bills passed by EALA have not yet been shared with the Partner States for assent.
3.	Having considered the Protocol, the Committee recommended that the National Assembly approves	instrument of ratification of

the ratification of the EAC Secret
Protocol on Cooperation in
Meteorological Services.
Protocol

Secretariat. The other Partner States are at various stages of ratifying the Protocol. The Protocol will come into force upon ratification by all the Partner States.

OF THE IMPLEMENTATION OF 3.0 STATUS RECOMMENDATIONS OF THE COMMITTEE ON REGIONAL INTEGRATION ON THE EAST AFRICAN COMMUNITY PROTOCOL ON INFORMATION AND COMMUNICATION THE WHICH APPROVES TECHNOLOGY NETWORKS, **PROTOCOL** EAC RATIFICATION OF THE INFORMATION AND COMMUNICATION TECHNOLOGY **NETWORKS**

S/N	Recommendation	Status of Implementation
1.	The Committee recommends ratification of the East African Community Protocol on Information and Communication Technology Networks as it would facilitate successful operation and cross border interconnection of broadband Information Communication technology networks in EAC	ratified the Protocol. Kenya, Burundi and Tanzania are yet to ratify the Protocol. The Protocol will come into

4.0 STATUS OF IMPLEMENTATION OF THE RECOMMENDATIONS AND OBSERVATIONS OF THE REPORT ON INSPECTION VISIT TO THE ISIBANIA ONE STOP BORDER POST IN MIGORI COUNTY

S/N	Recommendation	Background	Status of
			Implementation -
1.	Partner States to	The principles of	1.The Ministry
	sensitize and	the Common	integrated
	encourage citizens	Market as	sensitization in
	to embrace the	enshrined in Article	her 2018/19
	EAC spirit by	3(2) of the CMP	Workplan and
	enhancing regional	commits Partner	undertook
	integration and	States to: observe	sensitization in
	reciprocity	the principle of	various Counties.
	treatment as	non-discrimination	2.Kenya and
	demonstrated by	of nationals of EAC	Tanzania have
	H.E the President		mutual
V	directive on free	the ground of	understanding of
	movement within	nationality, accord	allowing border
	EAC without	nationals of other	residents free
	requirements of	Partner States not	movement up to
	passports. This is	less favourable	a distance of
	not reciprocated in	treatment than	15km on either
	Tanzania.	accorded to third	side of the border
		parties, and ensure	without need for
		transparency in	travel
		matters concerning	documents. This
		other Partner States	issue was
		and share	reiterated by
		information for the	Hon. Ministers
		implementation of	from MEAC

S/N	Recommendation	Background	Status of
	277	100%	Implementation
		the Protocol. The	Kenya and
		concept of free	Tanzania in 2012
		movement of	and 2013 in
		persons as provided	Namanga and
		in the CMP does	Isibania/Sirari
		not translate to	borders
		unregulated	respectively.
		movement of	3.The Ministry in
		persons in and out	
		of the territories of	
		the EAC Partner	
		States. The CMP	1-10-10-10-10-10-10-10-10-10-10-10-10-10
		facilitates easier	
		movement of East	
ŀ		African citizens to	
		move, reside and	
		exit the territories	The state of the s
		of Partner States by	
		providing a	
		predictable legal	
		environment. EAC	to a second to the
		citizens moving	
		from one Partner	- 0000000000000000000000000000000000000
		States to anothe	
		must undergo	1
		normal immigration	A.
1		processes at port	
		of entry and be in	
		possession of valid	d

S/N	Recommendation	Background	Status of
			Implementation
-		travel documents.	
2.	The Partner States should implement uniform application of procedures at all border post facilities along the Kenya/Tanzania border in terms of clearing goods and people at the entry/exit points	In all border posts designated as points of entry and exit, there are border regulatory agencies such as the immigration, customs, police, bureau of standards, plant health, human health, veterinary controls, food and drug safety at certain borders. Due to the need for clearance by such agencies, all the border posts experience prolonged delays thus long queues of vehicles and people. This therefore calls for harmonization of procedures and documentation. To address this need, the EAC Partner States adopted the concept of One-	asymmetry in clearance of goods and persons and reduce on time taken to undertake border clearance formalities.

S/N	Recommendation	Background	Status of
			Implementation
		Stop-Border-Posts (OSBP) along their borders.	
		Under OSBP operations procedures, government agencies operating on both sides of the border jointly undertake clearance of goods and persons in each direction of traffic. The	
		implementation of OSBP concept as an aspect of Coordinated Border Management is aimed at facilitating cross-border movements through reduction of the	
0		time taken in clearance procedures. Along the Kenya borders Malaba, Busia Isebania, Namanga Taveta an LungaLunga borde	3 5, 1, 1,

S/N	Recommendation	Background	Status of
			Implementation
		posts were selected for this concept. The six OSBPs have been completed and among them Taveta and Namanga, Busia and Malaba are operational. LungaLunga and Isebania, though the buildings are completed, are not operational due to ICT connectivity challenges. To facilitate the operations of the OSBP, an EAC OSBP Act 2016 has been formulated along with the Procedures Manual. The Act grants officers from adjourning Partner State right to implement their national laws while operating in a host Partner State.	
3.	Kenya and	Tanzania has a	Kenya is

Tanzania should policy on export of lift the periodical fish and fish ban on exports of fish and levies and fees imposed on exports. Tanzania enforces the ban on export of unprocessed fish. The same policy applies to export of agricultural products. The policy entrenches the need for value addition to raw materials prior to their export. Fish	
lift the periodical ban on exports of fish and levies and fees imposed on exports. Tanzania enforces the ban on export of unprocessed fish. The same policy applies to export of agricultural products. The policy entrenches the need for value addition to raw materials prior to	tion
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policy entrenches the need for value addition to raw materials prior to	
the need for value addition to raw materials prior to	
addition to raw materials prior to	
materials prior to	
·	
their export. Fish	
products that are	
exported to Kenya	
are in the form of	
animal feeds and	
fish maws used in	
pharmaceutical	
manufacturing.	
Tanzania exports	
fish products to the	
international	
market vide	
Isibania border and	

S/N	Recommendation	Background	Status of
			Implementation
		through Mombasa	
		Port. Such exports	
		normally transit	5
		through Kenya.	
	İ	In view of the	
		stated policy on	
		export of fish and	
		fish products	
		traders are expected	
		to meet stringent	
		requirements to be	
		issued with export	
		permits.	-
		Therefore, as per	
		the practice,	
	5	Tanzania does not	
		have a policy of	
		banning export of	
		fish and fish	
		products	
		periodically.	
		Traders who meet	
		the requirements as	
		stipulated in the	
		policy are allowed	
		to export. However,	
		those who fail to do	

S/N	Recommendation	Background	Status of
			Implementation
		so are denied permits.	
4.	The Department of	The United	Kenya held
	Immigration	Republic of	bilateral meeting
	Services through	Tanzania charges	with Tanzania in
	Ministry of Foreign	East African	April, 2019 and the
	Affairs, should	business visa fee.	issue of charging
	harmonize	This charge applies	Kenyan business
	requirements for		persons a fee of
	business visa and	and is therefore not	USD 100 as
	other related	discriminatory. The	business pass was
	requirements	charge is, however,	discussed. It was
		preferential	agreed that talks be
		compared to	initiated with a
		charges levied on	view to abolish it.
		SADC nationals.	The two Countries
		East African	are scheduled to
		nationals are	meet again in
		charged USD 100	September to
		and SADC	discuss the issue
		nationals USD 200.	
5.	Partner States	The Treaty for the	
	should heighten	establishment of	border related
	security at the	EAC gives	engagement
	border areas and	prominence to	between Kenyan
	encourage joint	cooperation in	and Tanzanian
	border coordinating	security matters. To	security agencies.
	committee	this end cross	0.0
	meetings to ensure	border security	takes place through
	meetings to chear	and seconds	

S/N	Recommendation	Background	Status of
			Implementation
	structured	cooperation is	cross border
	engagements.	being implemented	committees and
		in the region.	Joint Border
			Coordination
		Security issues	Committees that
		around	have been
		Isibania/Sirari area	constituted
		include but are not	particularly at One
		limited to:	Stop Border Posts.
		1. Human	MEAC&RD liaises
		smuggling	with these
		involving	agencies.
		Ethiopians and Somalis being	In Migori the
		trafficked to	County Security
		South Africa.	team normally
		2. Cross border	holds regular
		livestock theft.	meetings with its
		This is facilitated	counterparts from
		by the culture of	Mara Region of
		local communities.	Tanzania.
		3. Availability of	
		unlicensed	1
		firearms and use	
		of the same to	
		commit cross	
		border crimes. 4. Smuggling of	,
		4. Smuggling of restricted and	
		prohibited goods	1
		including	

S/N	Recommendation	Background	Status of
Onv	Recommend		Implementation
		ethanol. These security issues among others call for cross border collaboration and coordination.	
6.	The additional PoEs including Muhuru Bay, Nyamtiro and Kopanga be gazetted and a law enacted to create mobile border stations and manned by all border agencies.	the National Security Advisory Committee on advice from the Border Control and	Interior and Coordination of National Government in liaison with other MDAs has already inspected potential points of entry in Migori, Narok and Kajiado counties with a view for gazettement as new PoEs to address this challenge. The findings were
7.	The Committee		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
	recommended	barrier at the	
	removal of the	entrance of the	attention of Migori

S/N	Recommendation	Background	Status of
O/1 \			Implementation
	barrier at the	OSBP at	County by
	entrance of Isibania	Isibania/Sirari by	MEAC&RD in
	OSBP facility	Migori County for	2016 and similarly
	erected by Migori	purposes of	MEAC&RD wrote
	County	collection of local	to National
	•	levies is against the	
		spirit of EAC	
		integration and	National Treasury
		gives an impression	wrote to Migori
		that trucks are	County demanding
		double charged,	1
		Migori County may	
		consider removing	is still there.
		the barrier.	However, talks are
			ongoing between
		-X	KRA, MEAC&RD
			and Migori
			County. MEAC&RD has
8.	The OSBP		MBROCKE
	authorities should		1 1
	ensure multi-		
	stakeholder	at borders to	n
	collaboration and	Mark to Market to	John Land
	partnership	Coordinated	
		integrated approach to facilitating trade,	N N N N N N N N N N
	communities and		Pilling
	other relevant		
	agencies.	people, and improving security	
		improving sesarrey	CONTRACTOR NO.

S/N	Recommendation	Background	Status of
3/11	Recommendation	zeg.	Implementation
		The concept	from the local
		eliminates the need	community on both
		for travelers and	sides of the border.
		goods to stop twice	
	1.	to undertake border	The Lead Agencies
		crossing	in OSBPs with
		formalities; and	support from
		calls for the	The second of the second
		application of joint	
		001111	Committees
		minimize routine	
		activities and	
		duplications.	system to enhance
		OSBP is a shared	1
		facility bringing	
		together border	
		regulatory agencies	
		of the two	•
İ		adjoining Partner	
		States. Other	
		stakeholders	institutionalized a
		including service	The state of the s
		providers and the	1 2 2 2 2
		local community	1
		play a critical role	
		in OSBP	communities.
	2	operations.	
		Seamless	
		operations of OSBP	

S/N	Recommendation	Background	Status of
			Implementation
		are grounded on the	
		support from border	
		regulatory agencies,	
		traders, shippers,	
		clearing agents,	
		local community	
		and the local	
		administration. It is	
		in this regard that	
	1	multi-stakeholder	
		engagement is	
		essential in	
		ensuring optimal	
		operations and	
		continuity. The	
	0	EAC OSBP Act	ž
		and Kenya	
		Citizenship	
		Amendments Act	
		(2014) provides for	
		a structured	
		stakeholders	
		engagement	
		framework through	
		the Border	
		Management	
		Committees, Joint	
		Border	
		Coordination	

S/N		Dackground	Status of
			Implementation
	The Ministry of EAC should fast track efforts to harmonize policies in order to facilitate cross border trade within the region	Committees and the Lead Agency. The Treaty for the establishment of East African Community in Article 126 2(b) stipulates that "Partner States through their national institutions shall take necessary steps to harmonise all their national laws appertaining to the Community."	The Ministry in collaboration with the Office of the Attorney General and the Kenya Law Reform Commission and other stakeholders is developing a Policy on Harmonization of National Laws
			approximation of laws to be in line with Treaties and other international
			obligations. Kenya as a country has a gap when it comes to amending its laws to be in line with the Treaties it

S/N	Recommendation	Background	Status of
			Implementation
			has ratified.
10.	The Governments of Kenya and Tanzania should enhance the public private dialogues between the Governments and business community	The EAC Treaty places private sector development at the heart of its strategy for accelerating growth, creating wealth and reducing poverty. At the regional level, there is a Consultative Dialogue Framework for engagement of the private sector in the integration process which is fully anchored in the Treaty. The Dialogue Framework provides for an Annual Secretary General's forum which is a platform that provides for regular dialogue between the EAC Secretary General and the private sector, civil society	The Government holds the following meetings with the private sector - Quarterly Ministerial Stakeholders' forum that brings together the public and private sector to discuss the deepening of the integration of the markets. - Annual National Dialogue Forum that brings together the private sector, civil society and other interest groups to discuss the progress and challenges in the EAC integration. - Various targeted stakeholder engagement

S/N	Recommendation	Background	Status of Implementation
		and other interest groups on how to improve the EAC integration process. The forum is cascaded at the Partner States as the National Dialogue Forums.	Chambers, of Commerce, Students, and cross border traders among others.
11.	Partner States should heighten security along the borders and encourage joint border coordinating committee meetings to ensure structured engagement.	The EAC Common Market Protocol provides for the free movement of persons. This freedom has unanticipated outcomes that negatively impact peace and security and call for closer collaboration among the security agencies. The region is confronted by security threats such as: o intra-state conflicts, o terrorism, radicalization	Approach has been adopted along all borders across the country and has been instrumental in structuring dialogue and cross

S/N	Recommendation	Background	Status of
			Implementation
		and violent extremism, o porous borders and border conflicts, o piracy, human and drugs trafficking, o money laundering, o cybercrime, o motor vehicle theft, and o proliferation of Small Arms and Light Weapons. To facilitate structured response to the threats the following instruments have been developed: o EAC Peace and Security Protocol, o EAC Regional Strategy for Peace and Security, o EAC Protocol on Combatting Illicit Drugs Trafficking,	border and the team has structured engagement with security agencies of adjoining Partner States.

S/N	Recommendation	Background	Status of
	v		Implementation
		o EAC Regional Small Arms and Light Weapons Policy, East and Southern Africa Indian Ocean Regional Maritime Strategy, EAC Conflict Management and Resolution Framework, EAC Refugee Management Policy.	