PARLIAMENTARY INQUIRY REPORT ON THE ACUTE KIDNEY INJURY AMONG CHILDREN

SELECT COMMITTEE ON HEALTH, DISASTER, REFUGEES AND HUMANITARIAN RELIEF

DECEMBER 20, 2022

NATIONAL ASSEMBLY, NEW ASSEMBLY BUILDING, REVEREND PYE LANE, BANJUL.

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(1) ACKNOWLEDGEMENT

The Honourable Members of the Select Committee on Health, Disaster, Humanitarian Relief and Refugees wish to express profound appreciation to all the stakeholders for their cooperation and understanding during the inquiry, especially the Hon. Minister for Health and team, Medicine Control Agency and Pharmacy Council Gambia.

The Select Committee wishes to thank the august Assembly for the mandate to conduct an inquiry of such nature and magnitude.

The timely support and prompt facilitation of the Office of the Clerk and staff of the National Assembly Service is deeply acknowledged and commended.

(2) MEMBERS OF THE SELECT COMMITTEE

1.	Hon. Amadou Camara	-	Chairperson
2.	Hon. Modou Lamin B. Bah	-	Vice-Chairperson
3.	Hon. Amie Colley	-	Member
4.	Hon. Dawda Jeng	-	Member
5.	Hon. Gibbi Mballow	-	Member
6.	Hon. Musa Badjie	-	Member
7.	Hon. Abdoulie Ceesay	-	Member
8.	Hon. Pa Dembo Sanneh	-	Member
9.	Hon. Bakary Kora	-	Member
10.	Hon. Omar Darboe	-	Member

(3) SUBJECT MATTER SPECIALIST

1.	Dr. Yahya Muhammed Bah	-	SMS
2.	Mr. Alpha Jallow	-	SMS
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(4) SUPPORT STAFF

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3.	Fatou K. Sisawo	-	Researcher

(5) INTRODUCTION

Background

1. The National Assembly has general constitutional power to perform oversight over government operations and activities. Section 109 of the Constitution of the republic of The Gambia, 1997 empowers the National Assembly to establish Select Committees with the general mandate to inquire into the activities or administration of ministries or departments of the government. Select Committees may also investigate or inquire into any matter of public importance.

2. The Select Committee on Health, Refugees, Disaster, and Humanitarian Relief, hereafter referred to as “The Select Committee”, was established by a resolution of the National Assembly in the Sixth Legislature. The Select Committee has the general mandate to examine such matters within its remit as it may determine appropriate or referred to it by the Assembly.

3. Both the Constitution and the Standing Orders accords each Select Committee, in the performance of its functions, all the powers, rights and privileges as are vested in the high court at a trial in respect of (a) enforcing the attendance of witnesses and examining them on oath, affirmation or otherwise; (b) compelling the production of documents; and (c) the issue of a commission or request to examine witnesses abroad. equally, standing order 100(6)(b) give Select Committees the power to hear and receive evidence relevant to the business of the Select Committee.

4. A resolution of the National Assembly dated 26th of October 2022 mandated the Select Committee to conduct a full-scale parliamentary inquiry into the

matter of the AKI and related deaths with a view of unearthing the truth and circumstance surrounding this unfortunate incident, and to advise the Assembly accordingly.

(6) OBJECTIVES

5. The Select Committee cognisant of its Constitutional and parliamentary mandate by a resolution of the Assembly initiated a parliamentary inquiry into the matter of the AKI with a view of unearthing the truth and circumstance surrounding the unfortunate incident, and to advise the Assembly accordingly.

6. The inquiry of the Select Committee seeks to establish the cause(s) and the impact of the AKI that killed at least 70 children in The Gambia. The inquiry establishes:
   (a) The root causes of the reported death of at least 70 children,
   (b) The effects of the contaminated medical syrups linked to the deaths,
   (c) The impact to access primary health care services on emergency cases especially for children,
   (d) The culpability of the suspected importer and pharmacy linked to contaminated drugs,
   (e) The impact that availability and access to medical drugs, especially for children has on emergency health service,
   (f) The effects of the prevailing legislation, the pharmacy council, medicine control agency on the pharmacy, licensing, and medical regime of the country,
   (g) To consider proposal for a review of the legal and regulatory regime governing the pharmacy, medical drugs importation and store and licensing administration,
   (h) How the pharmacy license scheme is administered,

(i) The effectiveness of current measures being undertaken by ministry of health to address the AKI cases and contaminated medical drugs,

(j) To draw on other international best practice and protocol, possible strategies, initiatives, and actions that ministry of health should consider addressing the administration and impact of medical importation, and

(k) Any other related matters.

(7) METHODOLOGY

7. The Select Committee conduct the inquiry through the following methodology:

(a) Internal Select Committee meetings

(b) Public sessions with key Ministries, Departments, Agencies, Councils and Associations and Non-State Stakeholders

(c) Site visits

(8) ACTIVITIES

Internal Select Committee Meetings

8. The Select Committee met and developed a work plan that guide the conduct of its work. It developed Term of Reference that it used as a guide during its meetings with stakeholders. During its first meeting, the Select Committee identified the following stakeholders.

a. Ministry of Health
b. Medicine Control Agency
c. Pharmacy Council Gambia
d. National Public Health Laboratory Services
e. Medical and Dental Council Gambia

f. Nursing and Midwives Council Gambia
g. Public and Environmental Health Council Gambia
h. Epidemiology and Disease Control Unit
i. National Public Health Laboratory Services
j. National Pharmaceutical Services
k. AKI Victims Association and Justice for 66+ children
l. Gambia Press Union
m. Parliamentary Reporters Association
n. Medical consultants in Paediatrics
o. Pharmaceutical Importers Association and Pharmacy Society Gambia
p. West Africa Postgraduate College of Pharmacist

9. The Select Committee during this period, had meetings and or public sessions with officials from the Ministry of Health, Departments and Agencies (MDAs), and Non-State Stakeholders.

Public sessions with Ministries, Departments, Agencies, Councils and Associations and Non-State Stakeholders

(9) FINDINGS

Ministry of Health, Medicine Control Agency, and Pharmacy Council Gambia

10. The MCA informed the Select Committee that Atlantic Pharmaceuticals is the importer of the Four Medical products that have been found through quality control laboratory testing in Switzerland to contain unacceptable levels of diethylene glycol and ethylene glycol. These contaminates are toxic and have been linked to the Acute Kidney Injure that killed the 66+ Children. MCA also informed the Select Committee that the Atlantic Pharmacy is licensed by the Medicine Control Agency as an importer of medicines and related products. Atlantic Pharmacy is licensed based on the Medicines and Related products Act 2014, the Medicine and Related Regulations 2020, Guidelines for licensing as importer of medicine and related products, and standard operating procedures for licensing of importers, storage facilities and repackaging of medicines and related products.

11. The Select Committee was also informed by the MCA that they approved the import clearance permit for Atlantic Pharmacy which contained the suspected four syrups on the 17 June 2022, namely ***Promethazine Oral Solution, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup and Magrip N Cold Syrup*** manufactured by Maiden Pharmaceuticals in India. According to them the import clearance permit was approved based on the regulations and standard operating procedures for import and export of medicine and related products.

12. Also, the imported products were inspected upon arrival, and everything was satisfactory because all the products came with the required certificate of

analysis from the Manufacturer and all the certificates indicating that the products are of good quality and fit for use. The Select Committee was also informed that this was not the first Maiden Pharmaceuticals products imported by Atlantic Pharmacy. The four suspected products were sent to Ghana and Switzerland for testing, and they turn out to be positive for Diethylene glycol and Ethylene glycol. After receiving the results, the MCA called for the suspension of the affected Maiden products and all other Maiden products.

13. The MCA informed the Select Committee that The Gambia has no Quality Control Laboratory facility for testing of medicines and related Products.

National Public Health Laboratories Services

14. According to them they received 89 clinical samples at the NPHLS from 6th August to 18th October, 2022. Among the samples received, 36% (32/89) and 64% (52/57) were classified as AKI (Acute Kidney Injury) and AWD (Acute Watery Diarrhoea) respectively. Majority (about 75%) of the sample received were stool.

15. In collaboration with EFSTH all the samples received at the laboratory were analysed to determine the presence of any organism, they have analysed both the stool and urine samples using conventional microbiological method and the result revealed the presence of E. COLI among the Analysed samples, and this founding came out the same with the test result from Senegal. Also, the Samples were tested for Rota Virus at the NPHLS, and they all came out Negative.

16. Due to the lack of Human Resource and Materials in NPHLS some samples were sent to Senegal, Pasteur Institute to conduct further analysis on

Molecular Detection of viruses. And all the samples tested for rotavirus were negative which is consistence with the Findings of NPHLS. The Select Committee was also informed that among the samples tested 28 samples were positive for the GII noroviruses, and the presence of Adenoviruses F in 14 samples and 7 viruses were detected with Sap viruses.

Epidemiology and Disease Control Unit Ministry of Health

17. The Select Committee was informed that from 4th June to 6th November 2022, a total of eight (8) suspected cases, two (2) probable cases, eight-two (82) confirmed cases and seventy (70) deaths (case fatality rate of 85%) of Acute Kidney Injury (AKI) were recorded in the country. And majority of this confirmed cases were male (50/82) and the children below 3 years of age is (68/82). The Select Committee found out that western 1 Health Region recorded the highest number of confirmed cases, followed by western 2. The outbreak went on for 5 months from June to October 2022.

18. The findings remain the same with the previous reports which indicates that Promethazine Oral Solution, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup and Magrip N Cold Syrup were contaminated with diethylene glycol and ethylene glycol.

19. In addition to the syrup samples, 57 Stool samples were collected from the public facilities within Western Health Region 1 from patients who Presented with acute watery diarrhoea and any other symptom and this samples were sent to Institute Pasteur de Dakar in Senegal for Microbiological analysis. The outcome of the test showed that 19 samples were negative and 38 had Escherichia coli growth. The Escherichia coli showed that (E. coli 0157; Enteroaggregative E. coli; 6, Enteroinvasive E. coli; 6, Enteropathogenic E. coli; 7 and Enterotoxigenic E. coli; 17). Escherichia fergusonii was also

isolated from the 4 stool samples of AKI cases from the Test conducted at MRC.

20. The Serum, Urine, and blood samples from the five (5) AKI cases were also collected and sent to Dakar for toxicology analysis and all the results indicates the presence of paracetamol. And the 7 samples that were collected from households of AKI cases, all were tested positive for faecal coliforms.

Meeting with the Association of AKI Victims and Justice for 66+ children

21. Mr. Ebrima Sanyang, the president of the Victims Association informed the Select Committee that their Children died due to the negligence in the enforcement of the laws, regulations, and guidelines by both the Medicine Control Agency and the Pharmacy Council of The Gambia.

22. They also informed the Select Committee that they believed their Children's death were linked to the Maiden Medicine that they had taken.

23. In their expressions, they felt that the Government has neglected them because they have not received any delegation or officials from the Government to console with them during their trying times.

24. They also expressed concern about the allocation of one (1) million dalasi as a condolence package to be used by the Ministry of Gender, Children and Social Welfare to visit families of the victims and until at the time of reporting to the Committee, they have not received them.

25. They also informed the Select Committee that several victims were receiving calls from officials asking them to report to the Governor's Office in Brikama without giving them the reasons for the invitation, therefore they decided not

to respond to their calls and not to receive the money given to them by the Government.

Professor Muoneke Vivian Uzoamaka
Professor of Pediatrics and Post Graduate Medical Trainer

26. The Select Committee was informed that the first case of AKI, was a 46-month-old boy who was seen at the Emergency Paediatric Unit (EPU) of the Edward Francis Small Teaching Hospital, in Banjul, on the 7th of July 2022. The patient presented with history of fever, vomiting for 4 days, and had accessed healthcare from a nearby private hospital where he was commenced on several oral medications including Ampicillin, Metronidazole and Paracetamol. Two days post-ingestion, the mother noticed that child was no longer making urine as she noticed that his diaper was dry most times. For this she went back to her private hospital from where the patient was referred to for specialist management.

27. From the time of the first presentation to the end of July about 21 patients had reported at the EPU of the hospital with similar history including inability to pass urine. This interval between the inability to pass urine and when some of these syrups were ingested varied amongst the patients ranging between 1 and 6 days. However, majority of the patients presented with the symptom of inability to urinate between 2 and 3 days after consuming those drugs.

28. This pattern was equally observed with the rest of the other patients who were also admitted, investigated, and given appropriate treatment albeit unsuccessfully. Out of the sixty-six (66) patients who were admitted for AKI, sixty-three (63) died, two (2) survived while 1 was discharged against medical advice (DAMA). The two (2) who survived had taken only 1 dose of

one of those contaminated drugs, developed anuria and were quickly brought to the hospital following which appropriate treatment was instituted.

29. The Select Committee was informed that, out of these children who died, 7 were referred, on request by their parents, to Senegal for continuing management bearing in mind that The Gambia doesn't have enough working tools or the manpower as the number of affected children kept increasing.

30. The Select Committee was also informed that efforts were made to reach out to senior colleagues and other colleagues outside The Gambia for help and to know the possible cause of this illness.

31. According to the Doctor they had suspected and associated it with the intake of certain oral medicines particularly Paracetamol and Promethazine. Also, several stakeholders' meetings including community surveillance to unravel the cause of these deaths were conducted. According to them in one of the meetings, they were made to understand that samples collected from children who had diarrhoea, fever and vomiting yielded species of Escherichia Coli (E. Coli) which can cause very severe disease in children including AKI. However, these samples were not taken from the patients since none of them had diarrhoea at the point of presentation to the clinicians.

32. The Select Committee was also informed that the Blood samples and aliquots of the submitted drugs were taken to a toxicology laboratory in Senegal where they noted that most of the blood samples had high levels of Paracetamol (PCM) in them but could not proceed further with the screening.

33. In addition, more samples were taken to 3 different countries: Ghana, Switzerland and France for more investigation.

34. And while they were waiting for the results of the toxicology screening from these 3 labs, they advise the Ministry to withdraw all oral PCM from the shops to see whether there would be any change in the number of children coming to them with this problem.

35. On the 10th of September, the 1st notice of ban on the use of Paracetamol syrup was issued which was highly contested since there was no “scientific fact backing” the claim according to those opposing the ban. Despite this opposition, the Ministry insisted on banning paracetamol syrup which resulted in crashing down the number of AKI patients presenting at the hospitals.

36. After 1 week following the ban, the preliminary toxicology report from Ghana was released as follows:

37. Out of 9 drugs samples tested, 8 samples (89%) had propylene glycol detected, 2 samples (22%) contained Ethylene glycol and 1 sample (11%) contained Diethylene glycol.

38. Further analysis from the Switzerland laboratory showed the proper quantities of these compounds (which turned out to be unacceptably high).

39. After these toxicology results were released, both promethazine and some cough syrups were now implicated; and another ban was issued on the 16th of September 2022 to include promethazine syrup. This further reduced the number of children with AKI.

40. The Medicine Control Agency (MCA) of the Gambia were contacted and on the 29th of September, they set up a strong surveillance unit that carried out physical closure and recall of the banned drugs from most pharmacies and other drug stores.

Gambia Press Union and Parliamentary Reporters Association

41. During the meeting with the Gambia Press Union and Parliamentary Reporters Association, they highlighted some gaps with regards to communication with the public from the Ministry of Health, which does not help people's understanding about the situation of AKI and how they can protect their children.

42. They informed the Select Committee that in August 2022, the Edward Francis Small Teaching Hospital issued a statement indicating that there was a rare condition currently under observation in patients presented with diarrhoea, vomiting and reduced urination output. However, without giving figures, the Hospital indicated that the condition "is severe and already causing mortality in children" and that doctors were working to establish the cause(s) – published on 9th August, 2022.

43. On 5th October 2022, the World Health Organisation warned that a deadly batch of cough mixtures are connected to the deaths of dozens of children in Gambia, identifying four syrups manufactured by Maiden Pharmaceuticals and that there were sixty-six (66) deaths.

44. The Union also informed the Select Committee that they observed there had been lack of information to both journalists and members of the public about Acute Kidney Injuries in children.

45. This indicated that members of the public, including parents, citizens and residents of The Gambia had limited information and, in some cases, no information for them to be able to make informed decisions, and to take life-saving decisions.

46. This information dissemination gap in terms of communication from various health stakeholders like the Ministry of Health and satellite institutions like the Edward Francis Small Teaching Hospital, the Epidemiology and Disease Control (EDC) Unit, the Medicines Control Agency, the Pharmacy Council among others, created a lot of misunderstanding about what this condition in children is, and the exact causes of the AKI in children.

47. Journalists also faced lack of access to information in instances where they requested for interviews from the Ministry of Health, the Medicines Control Agency and other health authorities.

48. Some international journalists, especially from India, who are covering the story about child deaths have also reported not receiving responses on their request for information or interviews with officials of the Ministry of Health, especially the Minister, the Director of Health Service, the Executive Director of the MCA, and the Registrar Pharmacy Council.

Dr. Abubacarr Jagne
Consultant Nephrologist

49. The Select Committee was informed that the blood, stool, and drug samples collected from the four patients were sent to Dakar with the help of WHO for toxicology and microbiology. They received the results of the Microbiology test on the 23rd of August 2022, which grow E. coli in stool samples, two of which were Nephrogenic strains. After several attempt, they never got the results of the Toxicology results from Senegal. Other samples were taken

from random patients without Acute Kidney Injury in hospital which grow several kinds of E. coli serotypes.

50. He also informed the Select Committee that after several meetings and analyses of the data, results, and review of previous publications by the multi-disciplinary team, then they decided to stop the use of paracetamol syrup and promethazine syrups. These drugs were the most frequently used medications for the children presenting with AKI as it was made in a press release. The drugs samples were collected again from patients and sent to Ghana and the results were positive for Diethylene Glycol. After the results from Ghana, the Ministry made the decision to stop all Maiden Pharmaceutical products. Further, additional samples were taken to Switzerland and France. These samples were taken from pharmacy shelves randomly. A decision was made to add cough syrups to the list of the quarantine drugs. Then with the help of the partners there was a house-to-house search for contaminated medicines. After the house-to-house search and publicity to stop the use of the medicine. Since the 5th of October 2022, they have not seen any new case of AKI in children.

51. The following clinical findings shows that poisoning led to the cause of Acute Kidney injury;

    i. The cases presented in a similar way, not making urine, there is no sign of dehydration although some had some diarrhoea and vomiting. They all had home or prior medications of some sort. Even though children do have acute kidney injury but having this number within such a short span of time was very unusual.

    ii. There were symptoms of some sort of illness that led to the children being given medication but none of those could consistently case this number

Acute Kidney Injury. Example E. coli causes AKI and even some viral AKI especially in the rainy season, but the number of cases and case fatality rate could never be explained by what we saw within this crisis.

iii. The lab results of the organ functions of these children showed very high levels of creatinine, liver enzymes and uric acid that is very inconsistent for children mostly under 2 years. The autopsy results of two of them showed multi-organ failure and fatty Necrosis explains that there was a toxin that was causing multi-organ failure.

iv. Despite dialysis (peritoneal and Hemodialysis) the children didn't show any clinical improvement. This is very atypical of acute kidney injury that has a recovery rate 85% and survival rate 98%. In these case series there was 84% mortality rate.

v. No sooner than the drugs were taken out of the community and pharmacy shelves the cases stopped coming.

Department of Pathology and Laboratory Medicine
Edward Francis Small Teaching Hospital

External Examination of the Post-mortem

52. The Select Committee found out from the post-mortem report, that the livers of this Children were grossly enlarged, yellowish with mottled appearance, the capsules were smooth and shining. Cut section show mottling appearance and both kidneys' capsules stripes with ease to reveal pale subcapsular surface. Cut section of both kidneys show marked corticomedullary differentiation, severe cortical pallor, moderate congestion

of the medulla, bulging of the columns of Bertine, the spleen is acutely congested, and both lungs and the heart are unremarkable.

Medical and Dental Council

53. The Chairperson of Medical and Dental Council informed the Select Committee that his Council has no information to share with the Select Committee on the issue of the management of AKI. The Medical and Dental Council as mandated by the Medical and Dental Practitioners Act 1988 has no responsibility or function related to the saga of the AKI.

54. He informed the Select Committee as per their Act, they are charged with the responsibility to regulate the profession and practice of medical and dentistry in The Gambia and matters therewith connected to it.

Nurses and Midwives and Council

55. The registrar of the Nurses and Midwives Council also share a similar position with the Select Committee. The council as per their Act is responsible for the regulation of the practice of Nurses and Midwives in The Gambia. He concluded that the council have no position in this and advised the Select Committee to call upon individual Nurses and Midwives who might have been involved in the management of some of these cases.

Public and Environmental Health Council

56. This is the newest council established by an act of parliament in 2016 and was not inaugurated at the time of meeting with the Select Committee. The registrar asked that the council be exempted from giving a position paper because neither the registrar nor the chairperson or the administration have been involved in any activity related to the AKI.

Gambia Bar Association

57. In their position paper The Gambia Bar Association expressed concerned with the tragic death of over sixty-six plus (66+) Gambian children from

Acute Kidney Injury allegedly caused or linked to the consumption of liquid cough and pain medication imported from India.

58. As a professional body representing legal practitioners in The Gambia, they informed the Select Committee their position on the matter which they request the matter to be investigated exhaustively to establish the facts. It is important to ensure that no stone is left unturned in the quest to get to the truth. They also informed the Select Committee that the victims of this tragedy have a right to know the truth and have redress if their rights are infringed. The outcome of the inquiry will help find answers and provide recommendations to prevent a reoccurrence of such a tragedy.

Gambia Pharmaceutical Importers Association

59. The Gambia Pharmaceutical Importers Association also appear before the Select Committee in ongoing efforts to address the current health concerns; as well as the continued collaboration with all stakeholders in ensuring improved healthcare delivery in The Gambia. They reported that, from the onset of this situation, they fully complied with the directives of the MoH and MCA. The directive to immediately discontinue the sale and distribution of all brands of paracetamol syrups, the directive to immediately discontinue the sale and distribution of all brands of Promethazine syrups, the directive to immediately discontinue the sale and distribution of all brands of Cough Syrups (both adult and infant), the immediate withdrawal of all the above-mentioned products by the MCA for quarantine. They reported that this was an issue of national interest, hence their sincere willingness to join hands with all stakeholders to ensure the safety of all Gambians and residence in The Gambia. Besides, they reported to the Select Committee about the growing concerns of their partners, patients, product users, and concerned persons regarding the imminent adverse implications that may arise if certain factors are neglected before the implementation of the stringent

decisions. These stringent measures include the regulations to put all medical products imported under quarantine until they are tested from an accredited WHO quality control laboratory. This they said is not a best practice and not practice anywhere within the sub-region.

60. There is a challenge of obtaining Certificate of Analysis (CoA) for every product because of the quantities required in The Gambia, they purchase some medicines from distributors and retailers in European and American markets. Such suppliers are unable to provide COA from manufacturers. Thus, insisting on CoA for these medicines implies they should not be imported into the country. There will soon be stockouts of these specialist medicines. There is an increased risk of fake and substandard drugs being imported/smuggled with this directive.

61. Batch testing of each product has several negative implications including delays in releasing consignments arriving in the country. Decisions taken depend on how fast contracting laboratories outside The Gambia can test samples. Stress on stocks of some essential medicines is already evident because imports have been quarantined. MCA is charging importers a fee of between USD1000 and USD1,400 for each batch to be tested. This has negative implications on drugs shortage and the potential to put many out of business with attendant problem of loss of jobs for many.

West African Postgraduate College of Pharmacist (WAPCP)

62. The Select Committee had consultation with a two-man delegation (Profs Mahama Duwiejua and Noel Wannang) from WAPCP. The team visited The Gambia on the saga of the AKI and were tasked to meet with various stakeholders including the Select Committee and advise appropriately on how the College can assist to avert future occurrences.

63. The Select Committee requested the WAPCP team to provide a position paper with advice / recommendations. The WAPCP Team, using questions posed by the Select Committee, responds as follows:

Question 1: What caused the problem?

64. *Answer***:** It is a quality assurance failure on the part of the manufacturer. All raw materials for production on arrival in a factory are quarantined and released only when quality control certifies the material as having met the required standard. Sampling is carried out at every stage of the production process for quality control till the final product. The final product is certified again with a label indicating contents and quantities. **It is obvious this was not done for the contaminated products. The manufacturer did not follow Good Manufacturing Practice (GMP).**

65. The company that imported the products from Maiden Pharmaceuticals, India, is duly registered. Documentation (import permit clearance and Certificate of Analysis) on the products in question were all submitted in accordance with the regulations. The MCA also followed their established protocols for granting the permits and release of the products.

66. Damage could have been minimized if a robust Pharmacovigilance unit existed at the MCA. The unit exists but it is severely limited by capacity. Efforts should be made to enhance safety monitoring as part of post-marketing surveillance activities. If the unit was functional and reporting protocols by clinicians implemented, the first cases reported would have been judged by the expert Committee as signals worth further investigations. The suspected product would have been detected and withdrawn earlier.

67. They noted the commendable efforts of MCA and WHO in setting up a Medicine Incidence Response Committee (MIRC). The collaboration with the Epidemiology Disease Control and Directorate of Public Health together with the AKI committee of the MoH can be built on to establish a standing committee of the MCA to address medicines safety.

Question 2: What can be done to prevent future occurrences

68. ***Answer*:** Appearance of contaminated products in the market can only be prevented if manufacturers follow GMP procedures. Related to this is the menace of fake and substandard products in the region. Constant post marketing surveillance is the answer. Monitoring of products in use should be enhanced. Unfortunately, this will be difficult for The Gambia with the current capacity of highly deficient human resource coupled with absence of a quality control laboratory and fledging safety monitoring unit. They noted the MCA is aware of these limitations and has drawn attention of authorities**.**

Question 3: Licensing of pharmacies

69. ***Answer***: The Pharmacy Council Act 2014 and Pharmacy Regulations 2018 show how licensing is done. The issue of conflict of interest of staff in regulation and having business relations in the private sector has been addressed. They recognize the special circumstances of the Country. The regulators are aware and have procedures in place on how to address issues of conflict of interest involving staff.

Question 4. How to ensure the population does not lose confidence in the health system

70. ***Answer*:** It is about managing communication. Fear and panic are created if such things are not communicated with circumspection. Rather than the

population losing confidence, they should rather recognize that it is because of the vigilance of healthcare providers that this was detected.

71. This is a product defect and not malpractice they concluded.

(10) OVERSIGHT/SPOT CHECK VISITS TO PHARMACEUTICAL IMPORTERS

72. The Select Committee visited and inspected 14 Pharmaceutical Importers and Drug Stores within the Greater Banjul as part of its investigation/inquiries into the Acute Kidney Injury (AKI). The following importers and/or drugs stores were visited by the Select Committee.
    1. Medical Control Agency
    2. Kairaba Pharmaceuticals
    3. Malak Chemist
    4. Stop Step Pharmacy
    5. City Pharmacy
    6. Al-Nuru Pharmacy
    7. Kombo Pharmacy
    8. Biogen Pharmaceuticals
    9. Sun Pharmacy
    10. Lucky Development Cor. Ltd Pharmacy
    11. Pharma Star Pharmacy
    12. Innovarx Global Consulting
    13. Sino Pharmacy
    14. National Pharmaceutical Services (Central Medical store, Kotu)
    15. Amin Pharmaceuticals
    16. Victory Pharmaceuticals

Objectives

73. The tour was meant to:

(a) Give the Select Committee the opportunity to find out the way and manner in which Medications are ordered, received, and stored

(b) Enable the Select Committee to identify any gaps that might happened in future

(c) Help the Select Committee to better advise the plenary on the issue of Acute Injury (AKI)

1. Medicines Control Agency

74. The Select Committee started the tour at the Medicines Control Agency and observed the following:

Findings

75. The Select Committee found out that since the incident of AKI all pharmaceutical products imported as of 1st October 2022 are put on quarantine.

76. Due to the quarantine, all the drug stores are full which compromise the Standard of storing drugs. Therefore, most of them are advised to rent stores to be able to keep their drugs as per the standards.

77. The Select Committee also found out that Testing of drugs is a big challenge faced by the MCA since there is no Toxicology lab in The Gambia.

78. The Select Committee was also informed by the MCA that most of the Medications coming into the Country comes with a Certificate of Analysis except those from Europe and America.

2. Kairaba Pharmaceuticals

Findings

79. Kairaba Pharmaceuticals was established in 1991, the second Pharmacy to operates after Banjul Pharmacy.

80. They have never been faced with any problem since they started operations in the Gambia

81. They have not sale any product from the Maiden pharmacy or any medications link to the AKI
82. Apart from Human Medications they also import veterinary products for Animals
83. They have sufficient Air Conditions in their main store
84. They have registered 85 products, 521 listed, 17 rejected and 21 pending.
85. The Select Committee also found out that not all Medications comes with Certificate of Analysis. Product from European Countries are not always accompanied by certificate of analysis but a certificate from Medicines and Healthcare Products Regulatory Agency (MHRA).

3. Malak Chemist

Findings

86. Operating in the Country for 28 years now.
87. Their products are mostly from the UK and Germany, and all comes with Medicines and Healthcare Products Regulatory Agency (MHRA) Certificate
88. They import directly from the Wholesalers and not from manufacturers
89. They have registered 119 products, 11 pending, and listed 766.
90. The Select Committee found out that Malak Chemist were not associated with the sales of the Maiden Drugs from India

4. Stop Step Pharmacy

Findings

91. The Select Committee found out that the Stop Step Pharmacy order their products mainly from UK, Germany, and India
92. They have 2 Main stores, currently applied for a third store with MCA but not yet approved.
93. They operate in various outlets as follows, Wholesale and Retail

94. They have pharmacists overseeing their operations
95. They also informed the Select Committee before they order any medication, they first seek approval from MCA.
96. They have not sold any Maiden medications linked to the AKI
97. Some of their Medications are being quarantine by MCA.

5. City Pharmacy

Findings

98. City pharmacy was established in 2013
99. Due to the quarantine, all their stores are overloaded which means the standard is compromised
100. 75% of their Medications are under quarantine by MCA and other Containers of drugs are with the Gambia Port also on quarantine.
101. They have storage problem

6. Al-Nuru Pharmacy

Findings

102. Most of their medications are on quarantine which led them to have storage challenges
103. The Select Committee also found out that some of the medical products they procured for the government has also been quarantine
104. They are not involved in the sale of the Maiden drugs that are linked to the AKI cases

7. Kombo Pharmacy

Findings

105. Started operations in March 2022, and they are currently working with 3 Manufacturers namely,
    1. Laborate Pharmaceutical

2. JMBs Health Care pvt Ltd
3. Nem Laborate pvt Ltd

106. They registered 49 products, 6 pending and 2 rejected.
107. The Select Committee was also informed that the 2 products were rejected based on the brand name of the products.
108. They also informed the Select Committee that 36 products of various batches are being quarantine
109. They have 2 Containers of Medications under quarantine.
110. They are not involved in the sale of the Maiden drugs that are linked to the AKI cases

8. Sun Pharmacy

Findings

111. Sun pharmacy was established in March 2022
112. They have registered 10 products, 15 pending and listed 9
113. They also have products that are currently on quarantine due to the new regulations
114. They are not involved in the sale of the Maiden drugs that are linked to the AKI cases

9. Lucky Development Corp Limited Pharmacy

Findings

115. It was established in 2019
116. They have one wholesale and one retail outlets
117. They also have products under quarantine due to the new regulations
118. They are not involved in the sale of the Maiden drugs that are linked to the AKI cases

10. Bio Gen Pharmacy

Findings

119. Bio Gen Pharmacy it's a new Pharmacy that was registered in April 2021 and started operation in April 2022.
120. They have applied for registration of 7 Products; 6 products were register successfully, 1 pending and 52 products listed.
121. They are not involved in the selling of the Maiden drugs from India linked to the AKI Cases

11. Pharma Star Pharmacy

Findings

122. They buy their products from the local stores, and most of their products were from the Atlantic pharmacy.
123. The have 2 products registered, 2 rejected, 1 pending and 21 listed.
124. They were involved in selling of the Maiden drugs that were linked to the AKI. But according to them, immediately they received the noticed that the dead of the 66+ Children was linked to the Maiden drugs from the Atlantic pharmacy they took it upon themselves to recall all the Maiden medications supplied to their various consumers.

12. Sino Pharmacy

Findings

125. The Select Committee found out that Sino Pharmacy was established in 2019 and that they have a sister Company in Mali.
126. Sino Pharmacy started operations in 2018, they deal with Human Products and Lab Materials only.
127. They are dealing with 5 Manufacturers, and they import directly from those manufacturers in China.

128. All their medications are from China and all their products are branded in their name
129. They have 18 products under quarantine
130. They have 113 products in total, 49 registered, 10 listed and 54 pending

13. Innovarx Global Consulting

Findings

131. Established in 2019
132. The Select Committee found out that Innovarx have not been registering or listing its products with MCA since its inception

14. National Pharmaceutical Services (Central Medical Stores kotu)

Findings

133. The role of the Central Medical Stores, is to ensure a continuous supply of good quality, cost effective supplies and pharmaceuticals products to all public health care institutions.
134. They are also responsible for Policy implementation
135. The Select Committee was informed that the CMS could not procure medications for the year 2022 because there was not enough budget allocation for that purpose
136. All drugs procured by the Government through the Central Medical Stores are not registered or listed with MCA.

15. Amin Pharmaceuticals

Findings

137. Amin Pharmaceuticals was established in 2020 and they deal with Ronak products only.
138. They also have products under quarantine due to the new regulations

139. They are not involved in the sale of the Maiden drugs that are linked to the AKI cases

16. Victory Pharmaceuticals

Findings

140. It was established in 2010
141. They mainly import from manufacturers in Ghana
142. Inadequate storage capacity due to quarantine of medications
143. Registered 37 products, 5 pending, 4 rejected and 160 listed

(11) MEETING WITH ATLANTIC PHARMACEUTICALS

144. Atlantic Pharmaceutical was established in 2019, they import mainly from two Manufacturers in India (Maiden Pharmaceutical and Lexine Technology PVT. LTD).
145. According to the proprietor, they have signed an agreement with the Maiden Pharmaceuticals a company incorporated and existing under the Indian Companies Act, 1956.
146. All the 4 contaminated products linked to the AKI where duly listed with MCA.
147. They have 76 products from Maiden, 10 are registered and 66 listed
148. As importers they followed all the rules and regulation given by MCA.
149. There products came with certificate of analysis which they submitted to the Select Committee plus import clearance permit issued
150. Before going into business, they visited the Maiden Company in India and established the link

151. The first importation from Maiden was in April 2022 and the second was 29 products which arrived in the Country in June 2022 which contain the 4 contaminated drugs.
152. Efforts have been made in contacting the Maiden Pharmaceuticals LTD. Company in India, but they have not been answering to their emails and calls.
153. All the 10 syrups that were collected by the Ministry, 6 came out to be perfect and only 4 where contaminated which are Makoff Baby, Kofexmalin, MaGrip Cold, Paracetamol Syrup and Promethazine Syrups.

(12) CONCLUSIONS

154. Having received several evidence from different stakeholders both in the public and private sectors, including the parents of the victims of Acute Kidney Injury, the Select Committee concludes that all the cases of AKI are linked to the consumption of the contaminated medical products imported by **Atlantic Pharmaceuticals and Manufactured by Maiden Pharmaceutical Ltd India**. The actual cause of death of these children is still under scientific investigations as causality test are currently being undertaken by the Ministry of Health and partners.

155. The Select Committee's engagement with two dozen of stakeholders has generated fundamental inadequacies in our entire health care delivery system. The findings are addressed in the recommendations of the Select Committee's report.

156. The government of The Gambia through the Ministry of Health should review these recommendations and take all necessary measures to address the gaps and challenges within the Health system.

157. Findings revealed that all Importers of pharmaceutical products (wholesale and retail) into The Gambia are following MCA regulations. Notwithstanding, they encounter difficulties within MCA operational shortcomings. The MCA is confronted with inadequate human and institutional resources.
158. The Pharmaceutical Council of The Gambia (PCG) which is responsible for quality control, inspection of pharmacy premises, and overseeing related regulations is faced with huge logistics and staffing constraints. These need to be addressed to ensure that all residents in The Gambia have access to quality medicines.
159. The Select Committee is convinced that Maiden Pharmaceuticals Ltd. is culpable and should be held accountable for exporting the contaminated medicines that was linked to the death of at least 70 children in The Gambia 2022.
160. Lack of quality laboratory in the country resulted in the delay of obtaining test result linking the substandard syrups to the AKI.

(13) RECOMMENDATIONS

161. Based on the findings of the Select Committee investigations on the issues of the Acute Kidney Injury among children, the following recommendations are submitted for due consideration by this August Assembly.

(1) There is urgent need for a functional National Medicines Quality Control Laboratory (NMQC Lab). The Select Committee is reliably informed by the ministry of health that the World Bank is funding the construction of one modern QC Lab. The Select Committee therefore recommends the government through the Ministry of Health to intensify

efforts to complete this task as quickly as possible bearing that it is a requirement under section 50 of the Medicines and Related Product Act 2014. The Committee further recommends at this stage to establish the laboratory under the control of MCA as it is the international best practice. A parallel/autonomous authority created now will generate conflicts of command with different priorities. Samples from MCA will be handled at the convenience of the lab authority which may result in delays. An independent national laboratory can be built in the future to support MCA with more advanced or confirmatory tests.

(2) The Select Committee stressed the need for an urgent establishment of a functional Pharmacovigilance (PV) unit at the MCA and hereby recommend for its immediate establishment in January 2023. Under-reporting of Adverse Drugs Reactions is not unusual but constant reminders and encouragement from the MoH and the MCA to both private and public sectors including public may improve the situation.

(3) The Select Committee also recommends for the harmonization of pharmacy regulations with the West Africa region. MCA should involve our sister countries such as Nigeria and Ghana and others and are encouraged to meet routinely for on-the-spot assessment.

(4) The Committee also recommend that the government through the Ministry of Higher Education, Research, Science and Technology to establish a School of Pharmacy at the University of The Gambia to train more pharmacists and strengthen regulatory and health care delivery institutions.

(5) The Select Committee recommends for MCA to blacklist Maiden Pharmaceuticals products and ban all their products in the Gambian market.

(6) The government should pursue legal action against Maiden Pharmaceuticals for exporting contaminated drugs to The Gambia with the Atlantic brand name. Investigation has revealed that Atlantic pharmacy in The Gambia had followed all regulations for importation of medicines including the batch that had the contaminated syrups.

(7) Government to strengthen MCA's capacity with the needed financial aid, infrastructure and Human Resources for more effective and efficient implementation of its regulatory functions.

(8) MCA to ensure compliance by both the public and private sector to the regulatory requirements of the Medicines and Related Products Act, 2014.

(9) MCA to operate as an autonomous Agency for effective and efficient regulation.

(10) Government to strengthen the hospitals with the required medical products/supplies for the effective and efficient management of patients.

(11) Ministry of Health to revive the primary health care system for early detection of medical cases for more effective and efficient health care delivery.

(12) MCA must increase background checks on companies from which pharmacies or importers buy medicines. In doing this, onsite visit to

manufacturing drugs companies should be done by MCA before granting permit to any importer.

(13) Pharmacies should be encouraged to buy jointly so that they have a higher buying power. This will ensure that they can purchase from the high-quality companies, and they could also get certificate of analysis for the products.

(14) As a temporary measure, the Select Committee believes the idea of every pharmacy having a supervisor should be reconsidered, and more emphasis should be placed on quality control at the point of purchase of the products, the processes, and the proper following of the regulatory frameworks. We therefore recommend MCA to strengthen supervisions at the ports of entries.

(15) Because the cost of medicines in the Gambia is high partly due to testing and importation payments levied on importers, MCA should consider a reduction in the cost of medicines for the public by collecting payments for registration and listing in Dalasi and by also accepting payments for testing in the local currency. MCA as an institution can convert these funds to foreign currency through the existing banks as a short-term measure. In the long-term MCA to minimize outsourcing testing abroad and establishing a laboratory.

(16) To ensure that all medicines brought into this country are registered and listed, MCA and PCG staff should be attached to GRA offices in key entry points (Airport, borders, and weekly markets) to monitor pharmaceutical products imported into the country.

(17) For the PCG to carry out its regulatory mandates effectively, it requires the establishment of a functional secretariat with an annual subvention to enhance its pre- qualifying, registration, supervision, enforcement, and monitoring functions.

(18) The MoH should continue with its extensive and rigorous sensitization of the population in local languages in all the healthcare outlets about the risks of self-medication and the consumption of medicines in the unregulated market.

(19) The relevant Government ministries and departments are recommended to revisit their initial emergency responses to the AKI tragedy in collaboration with relevant CSOs and CBOs to address the issues of the victims and their families.

(20) Ensure that all medicines are registered before importation in the Gambia. This will require MCA to conduct site visit to inspect the manufacturing sites. Where site visit is not feasible, the MCA can liaise with Gambian embassy/High Commission at the exporting country to assign an agent for the site visit and submit a report accordingly. In the absence of a Gambian embassy/ High Commission in the exporting country that of another Commonwealth country shall be authorized to assign an agent.

(21) For medicines from less stringent regulatory countries, the MCA shall assign WHO accredited laboratory to conduct the pre-shipment inspection and QC testing of each consignment and be further verified by MCA agents at ports of entry.

(22) All products should be subjected to screening before release into the market for distribution and use. This will ensure that what is ordered is what is delivered to avoid what happened in the case of Atlantic pharmacy.

(23) Revisit MCA's SOPs for importation to ensure that those suspected to be substandard, falsified, and counterfeit items are quarantined for further investigations including QC testing at the cost of the importer.

(24) Random sampling of each imported medicines should be conducted, and the result kept at the MCA. This practice will keep importers on their toes. Ensure at least 5% of all randomly sampled medicines are annually tested. (e. g. 2.5% each 6 months) at the cost of the importer.

(25) All premises (wholesale pharmacies, retail pharmacies and drugstores) shall maintain a real-time electronic database, tracing all medicines from importer to user. This will help tracing and recall of medicines as well as for easy retrieval of information.

(26) Provide compensation to the families of deceased and surviving children. This should include free medical care for the surviving children with Acute Kidney Injury until they obtain full cure and recovery.

(27) The Medicines and Related Products Act should be amended to give clear and direct powers to the MCA to regulate and impose sanctions on the sector without having to seek the approval of the Minister of Health. This is to prevent interference and ineffectiveness of the Agency and its decisions.

(28) Similarly, the Pharmacy Council Act should be amended to give clear and direct powers to the Pharmacy Council of The Gambia to regulate and impose sanctions without having to seek the approval of the Minister of Health.

(29) The Ministry of Health should become more vigilant and play an effective oversight over the MCA and PCG to ensure that they are effectively executing their functions, without interfering in their operations. Therefore, the Select Committee recommend for the government through the MoH to speed up reviewing of the laws and regulations governing the pharmacy and drug regime in The Gambia and table it before the National Assembly.

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Hon. Amadou Camara

Chairperson Heath Committee