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TENTH PARLIAMENT- FOURTH SESSION

THE DEPARTMENTAL COMMITTEE ON HEALTH

REPORT ON REGULATION OF THE PHARMACEUTICAL SECTOR IN KENYA

March, 2012

Clerk's Chambers
Parliament Buildings
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March 2012

During the investigations, the Committee took evidence from the Board and Management of the Pharmacy and Poisons Board, various local manufacturers, importers and distributors of pharmaceutical products. The Committee has also had meetings with the Director of CID and the head of the Anti-Narcotics Unit. I must say that, as a Committee, the findings were both shocking and appalling. The cartels and rot that is reported to be in the pharmaceutical sector in Kenya is real. The risks exposed to our citizenry are unimaginable.

It is therefore my pleasure to present and commend this report to the House.

HON. (DR.) ROBERT MONDA, MP

CHAIRMAN, DEPARTMENTAL COMMITTEE ON HEALTH,

March .....8th...2012

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ADOPTION OF REPORT

We, the undersigned Members of the Departmental Committee on Health were *present* during the meeting that *adopted* this Report and requested the Chairperson to present the Report to the House-

(i) The Hon. (Dr.) Robert Monda, M.P.- Chairman: .....

(ii) The Hon. Nuh Nassir, MP: .....

(iii) The Hon. Sheikh Dor, MP : .....

(iv) The Hon. Cyprian Omolo, M.P : .....

(v) The Hon. Thomas M. Mwadeghu, MP: .....

(vi) The Hon. Munyaka Kioko, M.P: : .....

(vii) The Hon. (Dr.) Eseli Simiyu, MP: .....

(viii) The Hon. Joseph Oyugi Magwanga, M.P: .....

(ix) The Hon. Fredrick Outa, M.P: .....

(x) The Hon. Joseph Lekuton, M.P: .....

March 09, 2012

REPORT ON REGULATION OF THE PHARMACEUTICAL SECTOR IN KENYA.

BACKGROUND

The pharmaceutical sector in Kenya- State of play

1. There are over 13,850 registered medicinal products registered in Kenya for treatment of various diseases and ailments in the country and for export. From the Pharmacy and Poisons Board (PPB) website, there are forty two (42) licensed local manufacturers who produce for local and regional market and also for export. There are also 1,250 manufacturers with market authorization in Kenya. The PPB also licenses the various importer most of whom bring in generic drugs. The availability of generics has greatly contributed to availability and access to fairly priced drugs in the Kenyan Market. Most of the suppliers of the generics drugs have their bases in India and China and a few in Europe.

2. The Pharmacy and Poisons Board was established as a regulatory Authority under the Pharmacy and Poisons Act, Cap 244 and commenced operations on 1st May 1957. Its mandate is to regulate the practice of Pharmacy and the manufacture and trade in drugs and poisons. It is also mandated to make better provision for the control of the profession of Pharmacy and the trade in drugs and poisons in Kenya. The core functions of the PPB include- product evaluation and registration; evaluation of applications for advertisements of medicines and medical devices; ensuring Good Manufacturing Practice (GMP); registration of Pharmacists and enrolment of pharmaceutical technologists; issuance of practice licenses; issuance of permits for pharmaceutical representatives; approval of institutions offering pharmacy training; approval

of pharmaceutical imports and exports; registration of pharmaceutical premises/outlets; Pharmacovigillance and post-market surveillance; provision of documentation and information services on medicine and pharmacy practice and public relations services for the pharmaceutical sector. PPB continues to functions as a department of the Ministry of Medical Services with the Chief Pharmacist doubling up as the Register and Chief Executive officer of the regulator. Officers of the board are seconded by the Ministries of health.

3. The Board is reported to have challenges in carrying out its mandate. The challenges are compounded by the lacunas existing in the 1957 Pharmacy and Poisons Act (CAP 244) which provides for regulation of the industry. There are also issues related to overlaps and conflict of roles by the various players in the regulation of the industry. These include the Kenya Revenue Authority, Kenya Bureau of Standards, private laboratories and the National Quality Control Laboratory (NQCL).

4. The NQCL, also established under CAP 244, is one of the laboratories among others that the PPB recommends in line with World Health Organisation (WHO) guidelines to carry out analytical aspects of drug registration. Quality assurance is continuous process carried through pre-registration analysis and post market surveillance. The NQCL Laboratory was commissioned in 1994 and since then has served as the technical arm of the Pharmacy and Poisons Board. The laboratory also serves as other clients such as government hospitals, KEMSA, special programs, non-government agencies, pharmaceutical manufacturing industries, private hospitals and drug distributors. One of the mandates of NQCL is the analysis of drugs for purposes of registration and

quality certification to various clients including PPB, Kenya Medical Supplies Agency (KEMSA) and Mission for Essential Drugs and Supplies (MEDS).

5. The menace of counterfeit drugs in Kenya is not new. However, over the period, cases of proliferation of counterfeit pharmaceuticals have increased, with the World Health Organization raising concerns on several occasions. *Al Jazeera*, an international media station had a documentary on November 24, 2010, titled "Fighting Fake drugs in Kenya". The station reported that fake drugs are big business in Kenya. They interviewed patients that were harmed by them. They stated that there are 44 registered drug companies in Kenya and more than 11,000 illegal products are sold every day. in October, 2011, the Kenya Association of Pharmaceutical Industry Chairperson was reported saying that 30 per cent of drugs in the Kenyan market were fake, with a black market value of over Ksh.13 billion. On October 24, 2011- Interpol is reported to have said that more than one-third of medicines available in Africa are fake. At the same time, WHO reported that, a random survey by the National Quality Control Laboratories (NQCL) and the Pharmacy and Poisons Board found that almost 30% of the drugs in Kenya were counterfeit. Some of the drugs are no more than just chalk or water marketed as legitimate pharmaceutical products. According to figures from the Kenyan Association of Pharmaceutical Industry (KAPI), counterfeit pharmaceutical products account for approximately $150 million annually in sales in the Kenya.

Committee interventions and the EMU Report

6. In course of carrying out its mandate, the Committee received several complaints regarding the regulation of the pharmaceutical sector. Most of the complaints, which were made formally related to proliferation of counterfeit

drugs, irregularities in parallel importations and inefficiency of the PPB. On several occasions in 2009 an 2010, the Committee held several meetings with most stakeholders in the industry with a view to understanding the nature of the allegations and proposing a way forward. The stakeholders included the two Ministries of Health at the level of Ministers and permanent secretaries, the director of medical services, the chief pharmacist, the pharmacy and poisons board, pharmaceutical society of Kenya, (PSK), the Kenya Pharmaceutical Distributors Association (KPDA), the Kenya Association of Pharmaceutical Industry (KAPI), the Kenya Medical Association (KMA), the National Quality control Laboratory and Medical Practitioners and Dentists Board, amongst other players.

7. One of the key issues as emphasized by most of the players was the proliferation of counterfeit pharmaceuticals in Kenya and the harm they are likely to pose on consumers. Having listened to the stakeholders, the Committee, at the time, concluded that the problem of counterfeits was due to poor regulation of the parallel importation. It was therefore agreed that the PPB gazettes regulations to be adhered to by all parallel importers. This was done towards mid 2010. Later in about six months time, the problem of importation of counterfeits was said to have been brought under considerable control- but this was not to last for long. Towards July 2011, fresh complaints were received by the Committee. This time, the nature of the allegations was beyond parallel importations. Most of the allegations related to general lethargy and conflict on the part of the regulator to the extent of a near collapse of the regulator function of the government. At the same time the attention of the Committee was drawn to the findings of the government's Efficiency Monitoring Unit (EMU) on management systems audit of the PPB of

2011. The EMU report identified various weaknesses and irregularities in the PPB. These ranged from irregular importations of drugs, proliferation of unregistered premises, proliferation of counterfeit drugs and poor inspection of the industry. In this regard, the Committee resolved to take more evidence on these findings with a view to identifying the causes of the irregularities, identifying the root problem in the regulation of the pharmaceutical industry in Kenya and proposing a lasting solution to the House.

8. From August to December, 2011, the Committee embarked on an inquiry and sought to find out the following matters-

(i) Irregularities in registration of drugs

(ii) Irregularities in importation of pharmaceuticals

(iii) Irregularities in licensing and inspection of premises

(iv) importation and mysterious losses on psychotropic substances-Ephedrine and Pseudo-Ephedrine

(v) how the regulation of the industry can be improved

Witnesses

9. On each item, the Committee involved most of the players in the industry. Where allegations touched on individual companies, evidence was taken from their representatives. The witnesses included-

(i) the Minister for Medical Services

(ii) the Chairperson and Board Members of the Pharmacy and Poisons Board;

(iii) the Registrar, PPB (who is also the Chief Pharmacist);

(iv) the Director of Criminal Investigations Department

(v) the head of Anti-Narcotics Unit;

(vi) the Efficiency Monitoring Unit;

(vii) the National Quality Control Laboratory

(viii) Kenya Medical Association

(ix) Kenya Medical Practitioners, Pharmacists and Dentists and Union.

(x) Dr. W.O. Wanyanga of PhamaQ Ltd and UNIDO pharmaceuticals expert.

Evidence was also taken from Chief Executives and/or representatives of the following companies-

(a) Cosmos Ltd

(b) Regal Pharmaceuticals Ltd

(c) Pharmaceutical Manufacturing Company Ltd

(d) GlaxoSmithKline Ltd

(e) Sphinx Pharmaceutical Ltd

(f) Laboratory and Allied Ltd

(g) Universal Corporation Ltd

(h) Elys Chemicals Industries Ltd

(i) Biodeal Laboratories Ltd

(j) Dawa Ltd

(k) Novelty Pharmaceuticals Ltd

(l) Surgilinks Limited;

(m) Sphinx Pharmaceuticals; and,

(n) Medisel Co. (K) Ltd.

Despite being mentioned adversely by various witnesses and presence of implicating documentary evidence, representatives of the following firms failed to appear before the Committee. Efforts by the Committee to obtain their records were also not successful, even at the Registry of Names and Companies at the State law office-

(a) Atken Pharmaceuticals Limited;

(b) Citizen Pharmaceuticals Ltd;

(c) Thorntree Chemists;

(d) Fortmed Enterprises Ltd;

(e) Metro Pharmaceuticals Ltd;

The Committee expressed concern that the PPB had authorised and or licensed these companies to transact business of pharmaceuticals, in one way or the other, but could not confirm their existence or registration as legal entities.

FINDINGS OF THE COMMITTEE

Claim for application of the doctrine of *sub judice*

10. At the beginning of the inquiry, the Registrar PPB claimed that the matters before the Committee were subject to a court case. He therefore moved the Chairperson to declare the inquiry as infringing on an ongoing case and the right of the accused to have a fair trial. The Registrar tabled documents related to HCCC No. 131 of 2011. In making his ruling, the Chairperson, having studied the documents and listened to the Registrar's claim, noted that the provision of Standing Order No. 80 on the application of the doctrine of ***sub judice*** require the claimant to provide evidence to show that the case is active and that the discussion of the matters is likely to prejudice its fair determination. In this regard, the Chairperson made a summary ruling as follows-

(a) That, the claim made by the Registrar referred to an application for judicial review before the High Court (Nairobi) vide Civil Case No. 131 of 2011 in which a decision by the Ministry of Medical Services to interdict a member of Staff of the Ministry from the functions of his office was being challenged. This was different from the matters before the Committee which related to irregularities within the Pharmacy and Poisons Board (PPB), supply and sale of counterfeit drugs in Kenya and alleged poor regulation of the industry by the PPB;

(b) That, the copies of the Application, dated 2nd June, 2011 tabled by the Registrar failed to show that the case was active- But even if the case was related and active, the registrar failed to justify that the continued debate

on the wide matters before the Committee was likely to prejudice the fair determination of the interdiction case; and,

(c) That, under the circumstances, the prayers sought by the Registrar are not granted and debate on and inquiry into the matters before the Committee touching on irregularities within the PPB, supply and sale of counterfeit drugs in Kenya and alleged poor regulation of the industry by the Pharmacy and Poisons Board continues.

Regulation of the pharmaceuticals sector

11. The Committee was informed that since its establishment in 1957, PPB has undergone major changes through administrative measures and amendment of the Act in response to need to strengthen the board capacity to effectively regulate the industry. Some of the changes effected through administrative and amendment of the Act include amongst others: changing the name of the Board from Drugs and Poisons to Pharmacy and Poisons and given a body corporate status; professionalizing the Board staff by replacing police drug inspectors with pharmacists/Technologists; discontinuing training at certificate level; allowing technologists to practice; amendment of the Act (in 1993) making the Chief Pharmacist the Registrar; establishing the National Quality Control Laboratory (NQCL) in 1992 with the responsibility for drug registration through examining medicines quality; and adoption and implementation of the National Drug Policy of 1994 as a guide for reforms in the sector.

12. The Board is currently placed under the Ministry of Medical Services under the Directorate of Medical Services. The Registrar and the Board Chairman doubles

up as the Chief Pharmacist and the Director of Medical Services respectively at the Ministry of Medical Services. The Board has no control over the Registrar or the technical staff in terms of the hiring, discipline or transfer. The Committee noted that the Chief pharmacist has absolute powers over the staffing and deployment of human resource. The Ministry regards the Board as any other station (department) of the Ministry. The Committee also established that because of this structure, pharmaceutical issues were still perceived primarily as a support function of medical services as was when the Board was formed in the 1960s whose role was dealing with supply and dispensing of medicines. However, due to the changes and complexity in scope, the sector cannot be addressed through its current policy and further that the current legal and institutional arrangements at PPB renders the Board's regulatory functions excessively weak.

Conflict of interest on the part of the regulator

13. There were also reports of conflict of interest on the part of the staff of the Board. This included inspectors who are supposed to carry out notified and impromptu audits of premises, including retail pharmacies to enforce regulation. The Committee established that more than one hundred and twenty (120) public officers were operating pharmacies. This was attributed to the poor linkage between the Ministry of Medical services integrated payroll and personal database and the manual system for registration of premises. The Committee was informed that the Board has since introduced a new licensing system which captures the data of all pharmacists and pharmaceutical technologists and tracks their employment and/or practice history thereby avoiding such errors. Considering that the Director of Medical Services is also represented in the Boards/managements of government facilities, the

Committee was also of the view that the PPB may not be impartial in ensuring that public facilities including hospital pharmacies adhere to regulations. The focus may be on private facilities and business leaving the public facilities unregulated.

Irregularities in registration of drugs

14. During the period of the inquiry, the following drugs were reported to be in the market despite failing laboratory analysis-

    (a) Malmed-fed (Junior/infant) manufactured by Madras Pharmaceutical limited (INDIA);

    (b) Lavina Repetabs manufactured by Sigma Pharmaceutical Industries (EGPYT);

    (c) Fluxate Dry Powder manufactured by Sphinx Pharmaceutical limited (Kenya)

    (d) Pcillin 250 mg manufactured by Zest Pharma (INDIA)

    (e) Kamox clav 1000mg manufactured by flamingo Pharmaceuticals (INDIA)

15. On inquiry, the Registrar informed the Committee that, the process of drug registration started in 1982 after legal notice 147 of 1981. The products are received for registration by the secretariat of the Board. These products are then evaluated for quality, safety and efficacy by an external committee of experts. He also informed the Committee that, until 1992 the Board entirely relied on dossier for evaluation. In 1992 the National Quality was established. It is worldwide practice to classify products into classes depending on the use. The PPB therefore based on this international standard practices classified products into low and high risk medicines. The high risk products belonged to the following therapeutic classes: antibiotics, antimalarials, ARV and Anti-TB

and all injectables, while technical dossiers were used for low risk medicines. The Committee also heard that because of emerging issues and in-consultation with the stakeholders, the PPB replaced the old procedure by adopting and gazetting a Common Technical Document (CTD) in March 2010. In the CTD format all products are to undergo laboratory analysis in any of the three laboratories (NQCL, DARU, and MEDs). In addition, the Board is supposed to carry out post-market surveillance on all products.

16. The Committee narrowed down the inquiry on this part to the five products, as follows-

Malmed-fed (Junior/infant)

(i) The Registrar appeared before the Committee on three occasions. Each time, he gave varying evidence on the question of irregularities in drug registration. In the case of Malmed- Fed Junior, the registrar first said that **Malmed-fed (Junior/infant)** was submitted for registration on 1st September 2008. Dossier evaluation was done on 31st October 2008 and manufacturer was requested to provide 100 tablets for analytical evaluation on 1st December 2008. The product was recommended for registration based on the adult preparation which had same batch and strength and had passed the laboratory test on 30th March 2009. However, Malmed-fed (Junior/infant) failed laboratory tests done on 8th May 2009 by NQCL and received by PPB on the 14th May 2009. The product was withdrawn from the market in February 2011 after it was realized that the product had the same batch numbers. Malmed- Fed Junior was never imported, marketed or sold in the Kenyan market. This is despite his evidence on August 16, 2011, that the PPB did not request for the tests on the products.

(ii) On further probe, the Registrar explained that the applicant appealed against the decision to reject the product on 13th April, 2010 by paying the appeal fees and answering the queries raised. The said product was thereafter granted registration due to an error at the laboratory occasioned by a mix-up with another product which has a similar name- Malmed-Infant. The Registrar further explained that the mix-up was due to the manual system which was in existence before electronic software was installed. It was during the installation of the software that the data was cleaned and the mistake realised. The Committee observed that the Registrar had not explained whether the product was retested after the error was detected and if this was the case, by which Laboratory. Later, the Board explained that the mix-up was attributable to the fact that the two products (Malmed – FD(Jr/infant) and Malmed- FD (Adult) Tablets) had the same Batch numbers- 706/70E and having the same presentation details.

(iii) The Committee noted that the laboratory analysis results/certificates for the two products were issued on different dates, in March and May 2009 for Malmed – FD (Adult)and Malmed- FD (Jr/ infant) respectively. The PPB Board was also in agreement that they had requested for tests for the two drugs to be carried out.

Lavina Repetabs Tablets

(i) Initially, the Registrar denied that the PPB ever applied for testing of samples of Lavina Repetabs, which is used to manage coughs, allergies and a running nose. However, appearing before the Committee on 16th August, 2011 he alluded that the PPB neither requested for the drug to be tested or

registered nor were the results shared with the PPB However, documents before the Committee including the Certificate issued and the Laboratory Analysis Requests Forms for showed that PPB was the client. The Laboratory conveyed the results to the PPB on 4th June, 2009 vide a forwarding letter addressed to the PPB. On further questioning, the Registrar later informed the Committee that the product was submitted for registration on 21st July 2008. Dossier evaluation was done on 4th September 2008. The product was considered a low risk drug and did not require lab analysis at that time. The product was recommended for registration by the committee of experts on 2nd February 2010 and a certificate of registration issued on 1st April 2010 based on the dossier examination and certificate of the Pharmaceutical product (COPP) issued by competent authority of the exporting Country (Egypt). However, the samples of the product were analyzed together with other submitted products from the same company and Lavina failed the analysis on 11th June 2009. He added that product was never imported, marketed or sold in the Kenyan market.

(ii) It was also observed that PPB used the certificate issued by the competent authority of the exporting country (Egypt) and recommended Lavina Repetabs for registration on 2nd February, 2010 since, according to the Registrar; the drug is classified as a low-risk drug. Furthermore, the Registrar appearing before the Committee on 16th August, 2011 alluded that the PPB neither requested for the drug to be tested or registered nor were the results shared with the PPB. The Committee also noted with concern that the Registrar had alluded that the certificate for Lavina Repetabs had been recalled on 10th February 2011. The Members wondered why the Registrar would recall a certificate of product which was never registered.

(iii) The Committee expressed grave concern on the contradictory evidence adduced by the Registrar on this product and other products, considering the exposure and health risks associated with consumption of such harmful drugs.

Fluxate Dry Powder

(i) The Registrar informed the Committee that, Fluxate Dry Powder was submitted for registration on 13th October 2008. Dossier evaluation was done on 19th February 2009 and manufacturer requested to provide 20 bottles for analytical evaluation. The results were brought on 29th June 2009 and the product failed the analysis. The manufacturer appealed against the results, as procedure and was asked to submit three 3 batches of the product. The three batches were sent for further analysis at NCQL. M/s. Sphinx Pharmaceutical Limited was initially inspected on 5th and 6th February 2008 and failed the Good Manufacturing Practice (GMP) test. Recommendations for areas of improvement were made and Sphinx later passed inspection of April 2011. Subsequently the Registration of drug certificate was issued on 31st March 2011.

(ii) From the papers laid, the Committee observed that the recall for the Sphinx Pharmaceutical Limited GMP certificate was done in February, 2011 a few weeks before the EMU report was officially released. Further, the registration of the drug was done even before the GMP certification.

Pcillin 250 mg

The Registrar informed the Committee that, the product Pcillin 250 mg was submitted for registration on 30th March 2009. Dossier evaluation was done on 18th June 2009 and manufacturer requested to provide three batches of 100 capsules for analytical evaluation. The product complied with all the specifications for the test performed as per certificate of analysis dated 18th November 2009 and issued by NQCL. Subsequently the Registration of drug certificate was issued in April 2010. The Committee established that, from the evidence adduced and papers laid, due registration process was followed in the case of this product, which was later duly registered.

Kamox clav 1000mg

(i) The Registrar informed the Committee that, the product **Kamox clav 1000mg** was submitted for registration on 21st May 2007. He also explained that, the dossier for the product which contains Amoxicillin 875 mg and Clauvulanic acid 125 mg and manufactured by Flamingo Pharmaceuticals Limited of India was evaluated on 25th October 2007 and manufacturer requested to provide 3 batches of 100 tablets for analytical evaluation. The result was brought back on 27th February 2008 and the product **failed** the analysis. Subsequently the Registration of drug certificate was issued on 1ST April 2010. However, **due to mix up of the product** documentation on the part of PPB, the certificate was issued but later recalled on February 2, 2011. The error has since been corrected and the product was not in the Kenyan market. Later in their evidence, the PPB confirmed that the unsafe drug-Kamoxclav 1000 mg was in sale in Kenya for more than three years and without registration.

(ii) The Committee established that Kenyans have been exposed to an unsafe drug (an antibiotic) on the basis of a mix-up for a period exceeding three (3) years. The Chairman of the Board also confirmed that Kenyans have been exposed to the unsafe drug- Kamoxclav 1000 mg-for a period exceeding three (3) years.

(iii) While noting that most of the recalls for the above-mentioned drugs were done after the commissioning of the EMU audit, the Committee also was concerned that the Registrar attempted to mislead the committee on several occasions regarding the irregularities on registration of **Kamox clav 1000mg , Malmed-fed (Junior), and Lavina Repetabs Tablets.** The Committee also expressed grave concern on the contradictory evidence adduced by the Registrar on these products, considering the exposure and health risks associated with consumption of harmful pharmaceuticals.

(iv) While the law allows the Registrar to register some drugs, such as donations and specialized pharmaceuticals without recourse to the Board, it was found out that, in most instances, the Registrar exercised this discretion without reasonable justification. In this regard, the Committee observed that, by exclusively registering most drugs for supply in Kenya without involving the Board or its Practice Committee, which is mandated with amongst others functions, to give authorization before any drug is given registration certificate, the Registrar acted *ultra vires.*

17. The Committee was also concerned on other allegations that there are many drugs in the market which are not registered hence endangering the lives of the consumers.

Other unregistered Drugs in the market

18. The Committee established that there were other unsafe products that are in circulation in the Kenyan market. These are the Beechams Night and Day Nurse and Panadol Advance Tablets. Samples of these two products which were procured from a pharmacy along Lang'ata Road were presented and displayed by the Committee during the sitting. The two products can be sold over the counter without a doctor's prescription. The Board and an officers from Glaxo Smithkline (K) Ltd (GSK) informed the Committee that though the two were GSK products, Beechams Night and Day Nurse was not registered for use in Kenya, while Panadol Advanced tablets has since been registered for sale in Kenya. The Committee noted that Panadol Advanced tablets were sold even long before the registration. The Committee also heard that GSK had formally written to the PPB seeking investigations on the two cases.

19. From the papers laid, the Committee established that a company named Metro Pharmaceutical Limited registered in Nairobi was issued a permit to import part I and part II of the products, permit no. 53390, bearing the Board's stamps and signature by one of the officers of the Board. The permit indicates that the samples are for sampling, promotion, trade and registration. However, the permit was not dated though it was ostensibly signed by an officer of the Board. The Registrar of Companies later indicated that the company was not registered in the national registry of companies.

20. The Committee also heard that counterfeit products of Postinor 2, an emergency female contraceptive have been on sale for a long period of time.

Despite efforts by the PPB, cases of fake Postinor 2 are reported on regular basis.

Irregularities in licensing and inspection of premises

21. Allegations were made to the Committee regarding poor or lack of inspection of premises, ranging from local pharmaceutical manufactures to pharmaceutical outlets. The Board informed the Committee that in 2012/2011, a total of 2,319 premises were inspected out of which 440 were charged in court, 17 recommended for EDC, 93 premises were found locked and 131 had their drugs seized during financial year 2010/11. For those charged with various offences, the exhibits were forfeited to the state. The Registrar added that during regular inspections of premises, some of the un-registered ones usually close for up to even a week to avoid being found by inspectors, hence the difficult in eliminating the proliferation of unregistered premises

22. The PPB, with effect from 2007 made it mandatory for any manufacturer or trader wishing to have its drug registered, traded or imported into Kenyan market to meet requirements of current Good Manufacturing Practice (cGMP) and Good Distribution Practices (GDP's). Further for any premise to be registered and licensed to trade in pharmaceutical products and services it must adhere to GDP. PPB has in place guidelines and Standard Operating Procedures (SOP's) on GMP and GDP's. GMP is one of the strategies the Board uses in addition to post market surveillance to ensure suspected substandard, spurious, false or counterfeit are not in the distribution channel. The inspection follows the human and material flow and focuses on the following area: change room, raw material store, sampling area, production area, in process quality control,

packaging area, quality control laboratory, stability testing, finished goods and retaining sample stores, utilities and documentation.

23. The Committee was informed that all pharmaceutical manufacturers both local and foreign must have their sites inspected for GMP compliance before their products allowed registration in Kenya. GMP license is given for 5 years to foreign firms and 3 years to local firms. PPB has very few qualified and trained GMP inspectors to lead inspection of over 1000 foreign firms and 42 local registered firms. Given the few GMP inspectors, PPB is unable to cope with the heavy workload resulting into a backlog of uninspected firms which have submitted their dossiers and paid the requisite fees. Since 2008 over 120 pharmaceutical manufacturing companies have been done In India, Egypt, Tanzania, Uganda, China, Bangladesh, Indonesia and Malaysia. Some companies especially from India have been denied GMP certification as they failed to measure up to WHO and PPB standards. Action plans for findings considered non critical have been also been demanded from certain companies and confirmation of action before certification.

24. In spite of this, the Pharmacy and Poisons Board was accused of licensing a number of local manufacturers, even without undertaking due diligence or proper inspections. The Board also was said to have failed to carryout post licensing inspections on some of the local manufactures. A case in point was that of Novelty Pharmaceuticals Ltd, a local manufacturing company, which has been in trade for years, making and selling drugs without renewal of registration or passing the requisite GMP. The Company, which is based in Thika was closed down in September, 2011 only after the Committee raised concerns with the PPB on licensing and inspections. When the managing

director of the company appeared before the Committee, he confirmed that he manufactured and sold the following products in Kenyan market for a period ranging from two to five years without registration-

(i) *Asprin tablets*

(ii) *Paraceta tablets*

(iii) *Numol suspension*

(iv) *Clopher Elixir*

(v) *Mezol tablets*

(vi) *Mezol suspension*

(vii) *Lesel Syrup*

(viii) *Novatrin Suspension*

25. The management alluded to having being in business for a long time and even presented samples of each of the above-mentioned drugs, which have been, or may still be in market from the company without registration. The management also informed the Committee that they had sought registration of the following new products, but which were already in the market-

(i) *Tummy Aid suspension*

(ii) *Tummy aid tablets*

(iii) *Vital syrup*

(iv) *Nufen suspension*

(v) *Nufen tablets*

(vi) *Nocet syrup*

26. The management also informed the Committee that the premises had been closed down for GPM non- compliance. The Managing Director explained that they learnt of the closure of the Company through the media (Television news). He also said that it was later explained by PPB that the Company had

failed the GMP compliance inspection that had been undertaken a year earlier on 25th October, 2010. However, the Company was yet to receive the Compliance Report from PPB though it had written to the Board to bring its attention to the corrective measures undertaken by the Company. The Company had not received any response from the Board as October, 2011.

27. The manager alluded that GMP inspections are undertaken yearly but no certificate is issued. The GMP inspection Report indicates the shortcomings of the company inspected and this is discussed with the individual company and the areas to be rectified are pointed out before a decision to suspend the company is made. However, manufacturers renew their manufacturing licences every year (January to December).

28. The Committee noted that, while it is a sound to attract and maintain investors in the pharmaceutical sector, they should not be allowed to do business at the expense of the health of the citizenry. The Committee also noted that the PPB failed to carry out regular post-market surveillance on registered pharmaceutical products to confirm that they maintain the standard of the licensed dossier.

29. The Committee also established that several pharmacies operated without a licensed pharmacist (or pharmaceutical technologist) over a long period of time. Most of such cases were in rural areas. In some cases, the qualification of persons dispending drugs was questionable. Some firms even used the name of one pharmacist to register several pharmacies. The Committee was concerned that, given the fact that some of the drugs sold over the counter in rural areas are a result of "self-prognosis" by patients, the consumer even puts their lives

at a higher risk when the person dispensing such drugs is untrained. The PPB is required, by law, to ensure that all pharmacies maintain a pharmacist at their dispensing premises at all times.

Irregularities in importation of pharmaceuticals

30. The PPB is also charged with the responsibility of controls, regulating and licensing importation of pharmaceuticals, including issuing import permits to importers and registration certificates to products. Allegations were made to the Committee that some companies, including M/s. Anglowmed East Africa had imported eight different products, ranging from syrups to injectables, into Kenyan market but sourced from non-compliant suppliers. The Anglowmed products mentioned by the EMU report were registered after meeting the entire drug registration requirement including NQCL analysis.

31. The Committee was informed that the Kilindini port, JKIA and the Eldoret International Airports occasionally recorded irregular imports of pharmaceuticals, some of which were impounded and destroyed. The Committee noted that there lacks cooperation between the PPB and the Kenya Revenue Authority (KRA) as regards timely sharing of information on importation of pharmaceuticals. Eldoret Airport was said to be recording the highest numbers of counterfeits. Due to weak detection mechanisms, importers of counterfeit drugs use the said facility for most of their products. At same airport, the committee was informed that that pharmaceutical imports were not declared at all making the Airport a conduit of unregistered pharmaceutical products smuggled into the country. It was note worthy that the PPB inspectors at the airport in collaboration with the police have, in some cases,

confiscated consignments of pharmaceutical products worth millions of shillings and intended for the local market.

32. The Committee heard of cases of drug registration certificates missing in some importations cases while other side one registration document to undertake multiple importations of similar products. In other cases, there were no import permits while others were either unsigned or even expired. Several cases of undated import permits were also cited, therefore rendering the import period undated. Most of the products imported in this manner originated from China, India, UK and South Africa. The Committee also heard that PPB drugs inspectors at the ports of entry rely on the goodwill of Customs Officers of Kenya Revenue Authority (KRA) who alerts them whenever they come across shipments of pharmaceutical entries captured by KRA at Kilindini port.

Importation and mysterious losses on precursors of psychotropic substances-Ephedrine and Pseudo-Ephedrine

33. Ephedrine and Pseudoephedrine are precursors of some psychotropic substances, but are also used in manufacture of syrups for managing treat asthma, fevers, and body and joint pain amongst other medical uses. Pseudo-ephedrine is a precursor for methamphetamine and is readily converted to methamphetamine which is a drug of abuse. World over, the two products are controlled drug under the UN Convention since the two psychotropic substances can be easily converted into narcotics when mixed with other products. In Kenya, any importation of the Ephedrine and Pseudo-ephedrine must be notified to the Board, and as a requirement, the Board also files

returns to the UN Office on Drugs and Crime, failure to which, the country cannot be allowed to import its quota of the substances.

34. The Registrar informed the Committee, due to mysterious losses associated with the two substances, local companies are restricted in terms of the amounts that they can import at any given time to between 50 kgs and 100 Kgs per an importation. The authorisation also depends on the local production capacity of each company. These national measures were not in place until 2008 when the Ministry of Health was alarmed by cases of losses, including armed robberies and carjacking.

35. However, copies of the import licenses seen by the Committee revealed that, even after adopting the upper limit policy, the PPB had, in many instances, licence single importations of up to 200 kgs of Pseudoephedrine. One company (Laboratory and Allied), was even granted licences to import over 400 kgs in span of two months. Prior to the policy in 2005, 2006, 2007, the same company was allowed to import more than 1000 kgs in a span of six months. This was despite the evidence by the Registrar that they do not licence a single import of more than 100 kgs of each of the substances. It was also evident that some losses were not recorded by the PPB. A case in point was that of 25kgs of each of the two products allegedly lost by Novelty Pharmaceuticals Limited. Further, the PPB did not maintain an updated record of the licence import amounts, their usage and any losses. This is contrary to the mandate of the PPB, the United Nations Convention on Psychotropic Substances and the United Nations Convention Against Illicit Traffic in Narcotic Drugs, of which Kenya is a signatory.

36. Since September 2009, various pharmaceutical manufacturing companies have been broken into and the raw material stolen. Cases of hijacking of the raw material when being transported from JKIA customs warehouse have also been reported. One case of a consignment that had gotten lost at the Amsterdam Airport was also reported and later found in containers with no labels. All the national cases were reported to the police and the Board and the same forwarded to the Anti-narcotics Police.

37. The Committee found out that a special import permits are issued after the consignment has arrived at the port of entry for the controlled product, e.g. ephedrine and pseudo-ephedrine, to allow KRA to clear the product from the port to the importer. Importers can apply for import permits at any given time. The permit specifies the amount that the importers are authorised to import and the drugs they are importing. The permit is given to the supplier who in turn issues export notification certificate to the International Narcotics Control Board (INCB) and to the importing country through a liaison officer (PPB) to verify whether the importing document is genuine.

38. During the investigations, the Committee was alarmed on the finding that in 2007, a private firm had been permitted to import 500kgs of Pseudoephedrine by the PPB and an import licence granted. During the hearings, the Committee was informed that the irregularity was not noted until the United Nations International Narcotics Control Board raised concern and questioned why such a huge amount had been permitted to be imported. Later, the transaction was cancelled. Efforts to establish the persons behind the importing company were fruitless. The PPB officers informed the Committee that the permit was a forgery. Whilst the Committee was concerned that even the management of

the PPB failed to inform their Board of the matter, the allegations of forgery were not reported to the police. The Committee has since requested the Director of CID to investigate the case and forward a report, soonest.

39. Since September 2009, various pharmaceutical manufacturing companies have been broken into and the raw material stolen. Cases of hijacking of the raw material when being transported from JKIA customs warehouse have also been reported. One case of a consignment that had gotten lost at the Amsterdam Airport was also reported and later found in containers with no labels. All the national cases were reported to the police and the Board and the same forwarded to the Anti-narcotics Police.

40. The Committee found out that, since 2008, the following local pharmaceutical manufacturing companies had reported losses of ephedrine and/or pseudoephedrine-

(a) Cosmos Pharmaceuticals Limited

(b) Regal Pharmaceuticals Limited

(c) Pharmaceutical Manufacturing Company (K) Limited

(d) GlaxoSmithKline Limited

(e) Sphinx Pharmaceuticals Limited

(f) Laboratory and Allied Limited

(g) Universal Corporation Limited

(h) Elys Chemical Industries Limited

(i) Biodeal Laboratories

(j) Dawa Limited

(k) Novelty Pharmaceuticals Limited

41. The Committee took evidence from the managements of the companies and noted that most of the losses of Ephedrine and Pseudoephedrine were reported in 2008 to 2010. The Registrar, PPB attributed the rise in losses to the 2010 FIFA world cup tournament in South Africa. It was suspected that the substances may have been stolen to manufacture narcotics targeting the high turnout at the tournament. In total, it was estimated that between January 2009 and March, 2011 from the reported cases, losses of Ephedrine accumulated to 450 kgs while those of Pseudoephedrine have accumulated to about 1,550 kgs. It was also established that, while a kilogramme of any of the products would cost about Ksh. 5,000, the same amount would fetch more than Ksh. 50,000 in the black market for manufacture of narcotics.

42. One consignment belonging to Regal Pharmaceuticals was carjacked in transit while in the possession of the company's clearing agent en-route from the airport to the company's premises. A 25kg container of Pseudoephedrine disappeared at the Cargo Service (Swissport) JKIA in October 2010, and a further 100kg also got lost at the same place later on January 2011. In all cases, no recoveries were made, and there were no arrests, save for the case of theft at Universal Corporation Ltd where culprits were arraigned in court and charged. Also, six suspects were also charged in relation to attempted theft at Lab and Allied Chemicals premises.

43. Appearing before the Committee on two occasions, the director of CID informed the Committee that, there seems to have been an attempt on the part of the PPB and the companies concerned to cover up the losses. Where they reported, there was no follow-up and they seemed only to have reported the cases to the police for the purpose of obtaining the statements required to

follow-up compensation from insurance companies. Further, while some companies dismissed some members suspected to be involved in the losses, most the Companies did not report the losses as associated with psychotropic substances, but reported them as ordinary thefts. Requisite police statements were also not recorded by the companies or witnesses to support investigations.

44. The Committee also noted that most of the losses that happened at the Jomo Kenyatta International Airport took place at the premises of one clearing company, Swissport international. The Director of the Anti-narcotics unit noted that there seemed to have been collaboration between the staff of the company and the users of the substances. Other companies reported that the products were intercepted while on transit from the JKIA to the companies' premises. A case in point is that of losses of precursor substances destined for Novelty Ltd which were intercepted on the way on 6th December, 2010

45. The Committee learnt that regulations require each importing company to file returns with PPB on the importation and utilisation of ephedrine and pseudo-ephedrine. However, this has not been followed closely and companies can fail to inform the regulator without any sanction. The Committee also heard that some companies, such as Sphinx Pharmaceuticals had even resorted to hiring private firms to keep the substances for them. However, the Committee noted that such premises had not been inspected by the PPB for storage of such substances as required by law nor were they under regulatory authority of the PPB.

46. The Committee also noted that previously, it was the responsibility of the supplier to ensure that the raw materials are safely transported from the warehouse to the airport and the importing company takes over from the airport to the company. This has since changed leaving the responsibility to the importing company.

Others irregularities

47. The Committee also heard that M/s Lab and Allied had attempted to sell unregistered product, Laefin Tablets in the Kenyan market, but they were impounded by the PPB and sanctions imposed on the company. At the same time, papers laid also indicated that Galaxy pharmaceuticals had sold unregistered medicines, Cach-Art Tablets over a long period in the local market.

OBSERVATIONS

The Committee made the following observations-

(i) That, even though the Pharmacy and Poisons Act (CAP)244 is lacking, the PPB seemed to be taking advantage of the perception that the law is weak and attribute clear irregularities on the gaps in the law. Most of the irregularities identified by the Committee and the EMU team were avoidable had the PPB applied the powers vested on it by the law in the current form;

(ii) That, some members of staff of the PPB may have been involved in or abetted the irregularities in importation of counterfeit pharmaceuticals and irregularities in licensing of importation of psychotropic substances;

(iii) That, there was direct conflict of interest on part of the staff of the Board who were running pharmacies or acted as superintended pharmacist in private pharmacies when in public service;

(iv) That, there may be issues of corruption on the part of the Registrar and officers of the Board, particularly on the alleged mix-up of and samples where drugs were first rejected for registration and later inexplicably said to have passed the tests and registered for sale;

(v) The director of CID and the police department has also not been helpful either. Even after a few of the cases of losses of the ephedrine and pseudo-ephedrine were reported to the CID, there was very little progress on investigations;

(vi) That, the capacity of the PPB to effectively regulate the pharmaceutical sector is highly compounded by the lean human resource at the Board and the fact that the Board continues to function as a department of the Ministry;

(vii) That, there also seemed to be collusion between the police officers, private security officers and the perpetrators of the thefts of the ephedrine and pseudo ephedrine.

RECOMMENDATIONS

Legislative recommendations

48. The Committee has identified various weaknesses in CAP 244 which render the Board less efficient. In this regard, the Committee is on the threshold of proposing amendments to the Act, aimed at strengthening the regulatory authority. Some of the proposed amendments will focus on-

(i) Establishing the Pharmacy, Poisons and Medicines Authority to replace the current PPB. The new Authority would be autonomous, with a lean board, and members of staff comprising the relevant professionals pharmacists but also other professionals;

(ii) Enhancing the powers of the new authority so as to regulate and bring order in the industry;

(iii) Creating a pharmacy practice board that would regulate the profession;

(iv) Introduce provisions for incorporating herbal products into healthcare system;

(v) Strengthen the National Quality Control Laboratory;

(vi) Provide for regular review of the medicines schedules;

(vii) Increasing the penalties and sanctions for the different categories of offenders to make them more deterrent;

(viii) Empowering the Board to investigate and follow-up licensed clinical trials.

Specific recommendations-

Restructuring the PPB

49. The Committee recommends-

(i) That, before coming into force of the new Authority as proposed in this Report, the Ministry of Public Service ensures that all officers of the board are subjected to a vetting exercise to be conducted by the Public Service Commission. The exercise should aim at professionalizing the Board and ensuring integrity of the officers of the board; and,

(ii) That, the Ministry of Medical Services recruits more pharmacists to be trained and deployed as inspectors. The inspectors should be provided with facilities and equipments necessary to carry out inspections.

Precursor substances

(iii) That the PPB, in consultation with local and international manufactures agrees on a suitable active pharmaceutical ingredients, such as *Phenylephrine*, that can be used as replacement of the Pseudo ephedrine and Ephedrine in formulation of the cold remedies;

(iv) That, the PPB strengthen and updates national mechanisms relating to the control of precursors used in the illicit manufacture of drugs strengthen monitoring and control systems at the points of entry of all precursor chemicals and to promotes the secure transport of such substances;

(v) That, the PPB increase international and regional cooperation in order to counter the illicit manufacture of and trafficking in precursor chemicals frequently used in the illicit manufacture of drugs and preventing attempts to divert these substances from licit international trade to illicit use.

Ports of entry

(vi) That, the PPB ensures that all ports of entry are *gazetted* and fully these includes Nadapal, Lokichogio, Lwakhakha, Liboi, Mandera and Moyale entry points and also ensure operationalization by deploying suitable inspectors to these ports of entry;

(vii) The Kenya Aiports Authority allows the PPB officers to have full access to inspect hand luggage at the arrival baggage hall concurrently with other stakeholders like customs officials, police and KEBS.

(viii) The Board enhances surveillance of more medicine across the market, including herbal and alternative medicine.

Local manufacturers

(ix) The Board ensures maintenance and adherence to high standards of quality and safety in products manufactured locally and supports the Local pharmaceuticals manufactures to raise production standards including assisting them to attain WHO and other international standards;

Further investigations

(x) The Director, CID investigates all the cases forwarded by the Committee and other mal practices in the Board relating to importation of precursor substances and follows the cases to their logical conclusions with a view to prosecuting any person(s) found culpable;

Contempt of the Committee- Board's Legal Officer (August 16, 2011)

On August 16, 2011, the Registrar, Pharmacy and Poisons Board (PPB) appeared before the Departmental Committee on Health in connection with an ongoing inquiry by the Committee on alleged registration, licensing and supply of unsafe medical drugs for use into the country. The Committee has had other meetings with the PPB in the past on alleged importation of counterfeit pharmaceuticals. The Registrar was accompanied by eight other officers of the Board, including the Board's Legal Officer, Mr. Joseph Yano.

In course of the meeting, where Members put supplementary questions to the Registrar, Members proposed that it may be appropriate for the Registrar to be asked to appear before them again as he appeared to be unable to provide evidence to support additional information before the Committee. He also admitted that he was not well prepared for the sitting. At this time and before the Chair gave the directions as to whether the Registrar would appear again, the Legal Officer made gestures (*by way of throwing hands in the air and shouting unintelligible words).* The Committee regarded the conduct as inappropriate. He also said that the Board was being harassed. For a while, the Chair allowed the Registrar to continue to give evidence, despite questions of "*Points of Order*" from the Members.

On a point of Order, a Member brought to the attention of the Chair that the earlier conduct and gesture by the Legal officer was not in keeping with parliamentary decorum and conduct expected of a public officer. After consulting the Members, the Chair thereupon directed the Legal Officer to withdraw from the room. He complied. However, as he rose to withdraw, the officer shouted

that "...you have something against me...I will come to parliament again, and you will not be MPs at that time.... (*other words were inaudible*)" The Members did not respond.

The meeting continued thereafter and the Registrar responded to part of the queries raised by the Members, but failed to provide sufficient documentary evidence on most issues. Thereafter, the Committee requested the Registrar to prepare adequately and appear before them again after a week.

At the end, the Committee expressed that the conduct of the Legal officer was improper, not in keeping the conduct expected of a public officer and that it amounted to contempt of the Committee. The Chair referred the Board to sections of the National Assembly (Powers & Privileges) Act (CAP6) related to offences and penalties. He asked the Registrar to encourage his officers to refrain from making any attempts that may be construed to be contemptuous. The Committee also directed the Secretariat to seek the Speaker's guidance on the matter and also require the Public Service Commission and the Minister for Public Service to take disciplinary action against the Legal officer. Since the meeting was open to the public, the incidence was reported in the electronic and print media for that day and following day, respectively. Following the incidence, all other meetings of the Committee relating to the inquiry on counterfeit medicines and irregularities at the PPB were electronically recorded by the Hansard Department. The matter was also forwarded to the Committee on Privilege.

Later, when the Minister for public service appeared before the Committee in the month of November, 2011, he was accompanied by the officer. The Committee asked the officer to step out. It was apparent that the officer was

attempting to block the Committee from proceeding with the inquiry and/or finding out the facts of the matters before it. The Committee also noted that they had not summoned him but he had been asked by his seniors to accompany them to the meeting. The Committee finds the conduct of the officer amounting to contempt of the Committee and disrespectful to the institution of parliament. The Committee was unable to find any precedence on handling such cases in independent Kenya. However, in the Commonwealth, where a public officer is found to have acted in a manner to show contempt of parliament or its committees or to show disrespect in any manner, the House may request the authorities in public office to discipline, suspend, or even terminate the services of the officer from public service.

In this regard, the Committee recommends that the officer Mr. Joseph Yano be barred from holding any public or any state office conferred by the Republic of Kenya for a period of two years commencing on the date of adoption of this Report by the House.