SUBSTANDARD AND COUNTERFEIT MEDICINES IN UGANDA

A Report on a One Day Workshop on Substandard and Counterfeit Medicines in Uganda Organized By Community Health and Communication Network (CHAIN) In Partnership with National Drug Authority (NDA)

Supported By: **Pfizer**

GRAND IMPERIAL HOTEL, KAMPALA
2ND February, 2011

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Introduction

The Community Health & Information Network (CHAIN) in partnership with National Drug Authority (NDA) organised a one day workshop on Counterfeit and Substandard Medicines in Uganda on 2nd February, 2011 at Grand Imperial Hotel. The major aim of the workshop was to bring together different stakeholders including representatives of patient organisations and relevant national authorities to discuss the problem of Substandard Counterfeit Medicines in Uganda, share experience and come up with strategies for responding to the situation.

The workshop attracted participants from World Health Organisation (WHO), Uganda Consumers' Protection Association (UCPA), National Drug Authority, Ministry of Health, Parliament of Uganda, Laborex Uganda (Pfizer), GSK, Health Professionals, Civil Society Organisations, line government departments, Development partners, consumers and relevant national authorities.

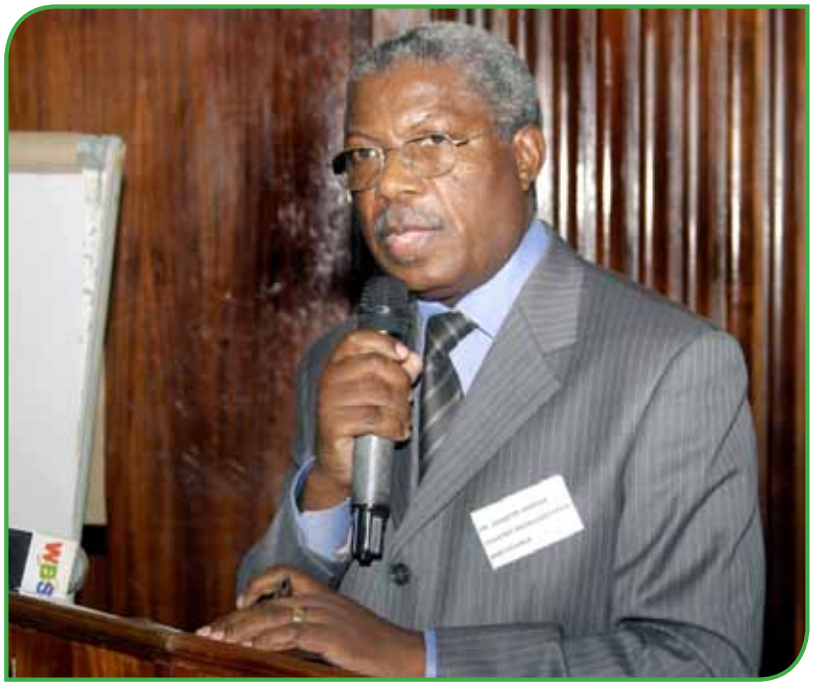
Welcome Remark

By Regina N.M.Kamoga
CHAIN Country Manager

The Country Manager of CHAIN Uganda, Mrs. Regina Kamoga, welcomed all participants to the workshop and highlighted the importance of coming together to discuss the problem of Counterfeit and Substandard medicines that is currently a big problem affecting the health and well-being of the nation. She informed the participants that the Counterfeit medicine problem was critical given the rising problem of poor quality medicines, particularly falsification and counterfeiting of medical products in Uganda; coupled with low levels of awareness particularly at the community level. Commenting on the magnitude and impact of the problem, Mrs. Kamoga observed that the use of counterfeit medical products is a global public health problem causing death, disability and injury to adults and children; and a threat to patient safety. If not properly attended to, leads consequently to loss of confidence in health systems, health professionals, pharmaceutical manufacturers and distributors. She therefore called for urgent attention with targeted joint strategies amongst key stakeholders to end the would be public health disaster.

She thanked all participants for having come to discuss the problem, especially National Drug Authority (NDA) for their technical support of the workshop and Pfizer for the financial support. Mrs. Kamoga finally called upon participants to come up with practical strategies that would end the problem of substandard and counterfeit medicines in Uganda.

Key Note Address



By Dr. Joaquim Saweka
WHO Country Representative

Thanking CHAIN Uganda and NDA for organizing the workshop, WHO Country Representative gave an elaborate definition of counterfeit medicine stating that; a counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and or/source. He further explained that counterfeiting can apply to both branded and generic products; may include products with correct ingredients or with wrong ingredients, without active ingredients, with insufficient ingredients or with fake packaging.

He informed the audience that all kinds of medicine all over the world have been counterfeited from the medicines for treatment of life threatening conditions to inexpensive generic versions of pain killers and antihistamines. The consequence of which he explained may lead to eroding public confidence in health delivery systems and treatment failure. WHO sees the problem of counterfeiting as a serious public health issue and commended the meetings like one organized by CHAIN Uganda and NDA as a right forum to kick start awareness among decision makers, health professionals and the general public.

Commenting on the extent of the problem, WHO estimates that as much as 10% of global world's drug trade and 25% or more in the developing world are counterfeit medicines worsened by internet sales from illegal sites that conceal their physical address. WHO has responded to the problem through provision of direct country and regional support for strengthening medicine regulation. In 2006, WHO helped to create the International Medical Products Anti Counterfeiting Taskforce with the aim of protecting people from buying and taking counterfeit medicines. In addition to organizing international health assemblies where countries pledge commitment and support to fighting counterfeit medicines, WHO supports legislative and regulatory infrastructure, enforcement, technology and communications in the fight against counterfeit medicines.

He finally pledged WHO continued support and called all stakeholders to join efforts to end the problem of substandard counterfeiting medicines through continued public awareness.

SESSION 1:

OFFICIAL OPENING

Session Chair: *William Babumba –International Red Cross, (IRC) Geneva*

Introduction and Presentation of Workshop Objectives

William Babumba –International Red Cross, (IRC) Geneva

The Workshop objectives included:

- Sharing information and best practices on the substandard and counterfeit medicine situation in Uganda.
- Raising awareness on substandard and counterfeit medicine in Uganda.
- Holding a discussion among key stakeholders about how to spur action to reduce the infiltration of counterfeit medical products in Uganda.
- Discussing challenges and action plans to address substandard and counterfeit medicine in Uganda.

Understanding of Substandard and Counterfeit Medicines: The Scope of the Problem of Counterfeit Medicines in Uganda.

By Kate Kitakule; Head Drug Inspectorate Services-NDA

She began by making an observation that counterfeit medicines still pose a great threat to the health of Ugandans. Several strategies have been laid down by NDA to address the problem. A number of operations have been held over the past 3 years to curb the perpetrators of counterfeit medicines, most notably Post-market Surveillance code named “Operation Mamba I, II & III”. Several counterfeit medicines have been unearthed in these operations and the number keeps increasing every year. Porous borders especially the Eastern border and the Lake Victoria shores are still the biggest source of imported counterfeits. The local manufacturers of counterfeits are also slowly on the increase. Out of the operations, a number of counterfeit medications were discovered to include: Sulphadoxine/ Pyrimethamine; Quinine Sulphate tablets; Chloroquine phosphate tablets; Amodiaquine HCl tablets; Magnesium Trisilicate/carbonate suspension; Chorpheniramine/Citric Acid/Menthol (Cough Linctus) and Cotrimoxazole tablets.

Ms. Kitakule noted that NDA has come out with strategies to address the problem of substandard and counterfeit medicines to include: establishment of Quality Assurance Systems among Distributors; the restrictions on bulk packaging of oral solid dosage forms that were recommended in 2009 have been agreed upon by stakeholders and a new guideline on Good Distribution Practice with special sections on fighting counterfeit medicines will soon be rolled out. Market Surveillance has been greatly enhanced and this has followed recruitment of a Law Enforcement Officer and intensive awareness amongst local leaders and the public.

She however noted that NDA still faces a number of challenges in the attempt to curb counterfeit medicines. Among those noted included:

- Lack of a clear and specific law against counterfeit medicines cripples prosecution of culprits.
- Limited funding for anti- counterfeiting programs.
- High costs of, and limited access to, essential medicines especially in the countryside.
- Illiteracy and Ignorance of the public about the issue of counterfeit medicines.
- Porous borders both land and lake.
- Poor packaging methods for oral solid dosage forms that enable counterfeiters to do business incognito.

Ms Kitakule therefore gave proposals for action towards fighting substandard and counterfeit medicines in Uganda to include:

- Advocacy to enact punitive laws against counterfeit medicines.
- Increase public awareness about the problem of counterfeit medicines and mobilization towards the fight.
- Inter-sectored cooperation and involvement of civil society and private sector in the fight.
- International and Regional cooperation in studying the source, trend & impact of the problem to society.
- Increased market surveillance and intelligence gathering activities.
- Improve laboratory capacity to test promptly and efficiently all suspected samples.
- Increase training in counterfeit detection for healthcare workers & key stakeholders.
- MOH should ensure accessibility and affordability of essential drugs to the population.

Counterfeit Bill in Uganda - The Anti Counterfeiting Goods Bill, 2010

By Hellen Wenene, Legal Counsel- Uganda National Bureau of Standards

Ms. Wenene shared the introductory part of the bill saying that it is divided into Seven (7) parts and twenty three (23) clauses. She informed participants that the bill was created because of defects in existing law and once the bill is passed, plays a policy part to prohibit the manufacture and trade in Counterfeit goods.

Ms. Hellen explained the bill's interpretation of Counterfeit goods, counterfeiting and counterfeit trademark good. Counterfeit goods mean counterfeit trade mark goods or pirated copyright goods. "Counterfeiting" means the process of producing counterfeit goods. Counterfeit trademark goods" means any goods including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark and which thereby infringes the rights of the trademark owner in Uganda.

She equally explained the concept of pirated copyright goods in relation to the bill. Pirated copyright goods means any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production & which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law in Uganda.

Part II: Administration

Act to be administered by Uganda National Bureau of Standards (Bureau). Bureau to cooperate with URA and any other organisation or agency whose operations relate to the implementation of this Act.

Part 111 Inspection

She discussed part III of the bill related to:

- Appointment of inspectors by the Council.
- Powers of inspectors.

- Duties of inspectors.
- Evidence and presumptions.
- Seized goods to be stored in a counterfeit goods depot.

Part IV – Offences

Key sections to include:
A person who knowingly for the purposes of trade-

- Has in possession or control counterfeit goods;
- Manufactures, produces or makes, counterfeit goods;
- Sells, hires out, barters, or offers or exposes for sale, hiring out, or donates, counterfeit goods;
- Distributes counterfeit goods;
- Imports into or exports from Uganda counterfeit goods;
- In any manner disposes of any counterfeit goods, commits an offence.

Penalties

Key penalties discussed in bill were:

- Minimum: A fine not less than five (5) times and not more than ten (10) times the market price of genuine goods or imprisonment not less than five years and not exceeding ten years or both.
- Maximum: a fine not less than twenty times and not more than thirty times the market price of genuine goods and in addition imprisonment not less than ten (10) and not exceeding ten (20) years

Part VII: Miscellaneous

- Matters of counterfeit medicines to be dealt with by the National Drug Authority.
- Immunity of officials for acts done bona-fide.
- Disposal of fines.

Plenary Discussions

- ***Definition of counterfeit in the proposed bill:*** Some of the issues discussed were related to definition of counterfeit goods as put in the proposed bill. Members argued that the definition as it stood in the proposed bill concentrated on “trademarks” rather than the content of the medicine. The bill was therefore seen in protecting patent rights rather than real content and harm it would cause to the potential user irrespective of trademark. Therefore called for broadening the definition in the bill.
- ***Branded Vs Generic goods:*** members raised an observation that if the definition of counterfeit medicines is not well thought out, people were likely to think that medicines which are not branded or generics are likely to be counterfeit medicines yet counterfeiting could apply to both.
- ***Roles of relevant bodies in the administration of the bill:*** Issues raised were that the bill mentions different bodies like Uganda National Bureau of Standards (NDA), Uganda Revenue Authority, Uganda National Drugs Authority (NDA) but fails to define the role of each authority in the administration of the bill. Participants suggested that their roles need to be clearly defined.
- ***Role of relevant Government line ministries:*** like ministry of health not well defined or mentioned in the bill. Since various departments mentioned to administer the bill have no national, mandate to on policy related issues accruing from the administration of the bill, the role of relevant government ministry should not be overlooked in the bill.
- Fines and penalties: some members suggested that the suggested fines and penalties in the draft bill were not deterrent enough to reduce counterfeiting and called for a revisit of penalties.
- ***Harmonization with existing legislations:*** participants argued that there was need to harmonize the bill with existing legislations in the East African Community countries.

SESSION 2:

Curent Interventions To Address Substandard And Counterfeit Medicines

Session Chair: *Ms. Rosette Mutambi-HEPS Uganda.*

Perspective of MOH on Counterfeit Medical Products in Uganda

By Seru Morris - Principal Pharmacist MOH

The Principal Pharmacist MOH began by giving an elaborate definition of counterfeit saying it refers to any good, including packaging, bearing without authorization a trademark which is identical to a trademark validly registered in respect of such goods or which cannot be distinguished in its essential aspects from such trademark and which therefore infringes the right of the owners of the trademark in question under the law of the country of importation (TRIPS).

He made an observation that there is confusion between drugs that are bad for health and those that are bad for business and equally stated that medicines that might do harm are those that do not contain enough or any good quality active ingredients. Mr. Seru noted that too many of these medicines are made by highly organized well-resourced sophisticated criminals but also by legal manufacturers that use poor raw material, manufacturing process, or storage facilities that allow material to degrade.

He however informed participants that the counterfeiting agenda has focused most attention towards chasing criminals (Counterfeiters) when substandard medicines produced by legitimate manufacture pose a much greater public health problem.

Commenting on the currently drafted counterfeit bill, he noted that the initial bill was created with only business and not health in mind. It had bypassed medicine regulators and gave responsibility of managing counterfeit medicines to another organization that oversees standards in other products like plastics, electronics etc. To MOH's delight, the current revised draft has narrowed the scope of the bill from covering all forms of intellectual property to only trademark and copyright infringement as provided under the TRIPS Agreement.

On the magnitude of the problem of substandard and counterfeit medicines in Uganda, the Principal Pharmacist MOH informed participants, Ministry of Health recognizes the importance of addressing the real problem of falsified and sub-standard medicines without hindering access to good quality and efficacious essential medicines particularly generics.

He finally commended work done by NDA and pointed out that it should be strengthened and provided with the required resources to help them to routinely track down and test the quality and safety of medicines before they reach the patient. MOH pledged continued support to NDA and other agencies in the fight against counterfeit medicines.

Monitoring and Reporting Adverse Events: Pharmacovigilance Unit

By Ms. Victoria Nambasa Bukenya - Drug Information Officer NDA

Role of the unit: Informed participants that the National Pharmacovigilance Centre in Uganda is based in the National Drug Authority and the major objective of the center is to promote patient safety through; early detection of unknown Adverse Drug Reactions (ADRs), increases in frequency of known ADRs and dissemination of information.

Definition of Pharmacovigilance: It is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. Explanation was given on the monitoring of drugs by the department so far:

- Information on safety/tolerability collected during drug development is incomplete.
- Animal tests are insufficient to predict human safety.
- Clinical trials evaluate limited numbers of carefully selected patients - may not represent general population.

- Information often incomplete or not available on rare but serious reactions: use in vulnerable groups (pregnancy, children); drug interactions and risks of long-term, repeated use.
- Humanitarian concerns.
- No drug is inherently safe unless it has no effect at all.
- Differing prescription practices.
- Genetic differences.
- Drug interactions.
- Co-morbidity.
- Economic concerns.

Need for Pharmacovigilance unit: 16% of hospital admissions are drug-related (medical ward). ADRs are the 4th to 6th leading cause of deaths in USA (*Nelson KM, Talbert RL, Pharmacotherapy 1996; 701-7*). Further explained the scope of pharmacovigilance saying that it looks at adverse reactions - the negative outcome of taking a drug and unanticipated abnormal reactions to a drug which may be pleasant or unpleasant.

Relationship between Pharmacovigilance and Counterfeit:

- Counterfeits may contain entities which can cause ADR.
- May contain over or under dose of drug component.
- May be adulterated.

***Role of Pharmacovigilance unit in the fighting of counterfeit*: obtain as much information regarding the drug's consumers, receive and report any unusual reaction when the public take your drugs. Further emphasized that it is the role of the consumer and the general public to fight counterfeit through:**

- Reporting to health providers when there is no adequate response to treatment- inefficacy.
- Reporting to NDA when one is not sure of the quality of the product.
- Avoid self medication.
- Getting one's medication from authorized premises.

She further cautioned members to report any response to drugs which is harmful; lack of efficacy (the drug failing to work on your condition); expired drugs, poor packaging/labeling and different color or smell from the usual one. Ms. Victoria gave mechanisms used by NDA to get feedback from the public. Some given included:

- NDA form.
- Telephone the unit.
- Internet.
- National centre at NDA.
- Your health provider.
- Regional Pharmacovigilance centers.
- NDA regional offices.

In her conclusive statement, she said there is a need for a regulatory tool to monitor quality, a tool where the public can participate in and improve patient safety. She finally called participants to contribute towards the safety of medicines by monitoring ADRs in their setting, Act upon them and report these ADRs to inform regulatory decision in Uganda.

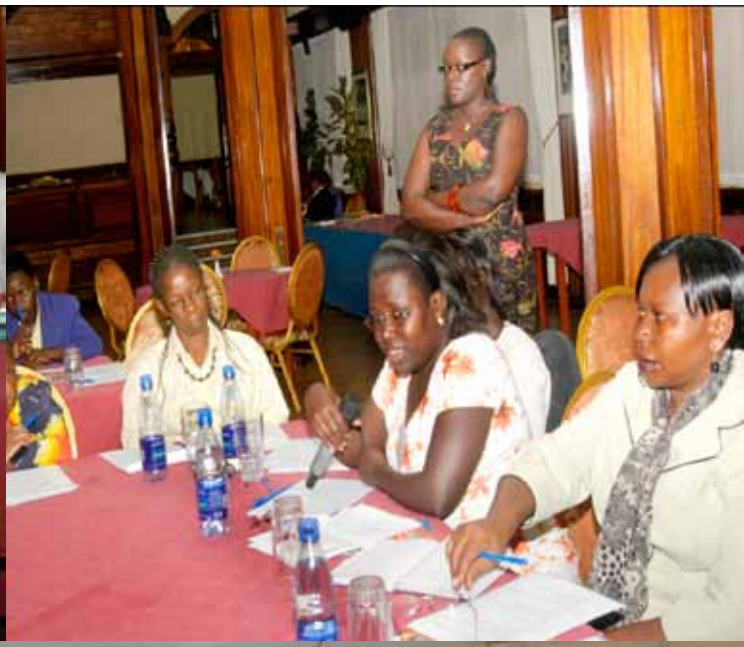
Plenary Discussions

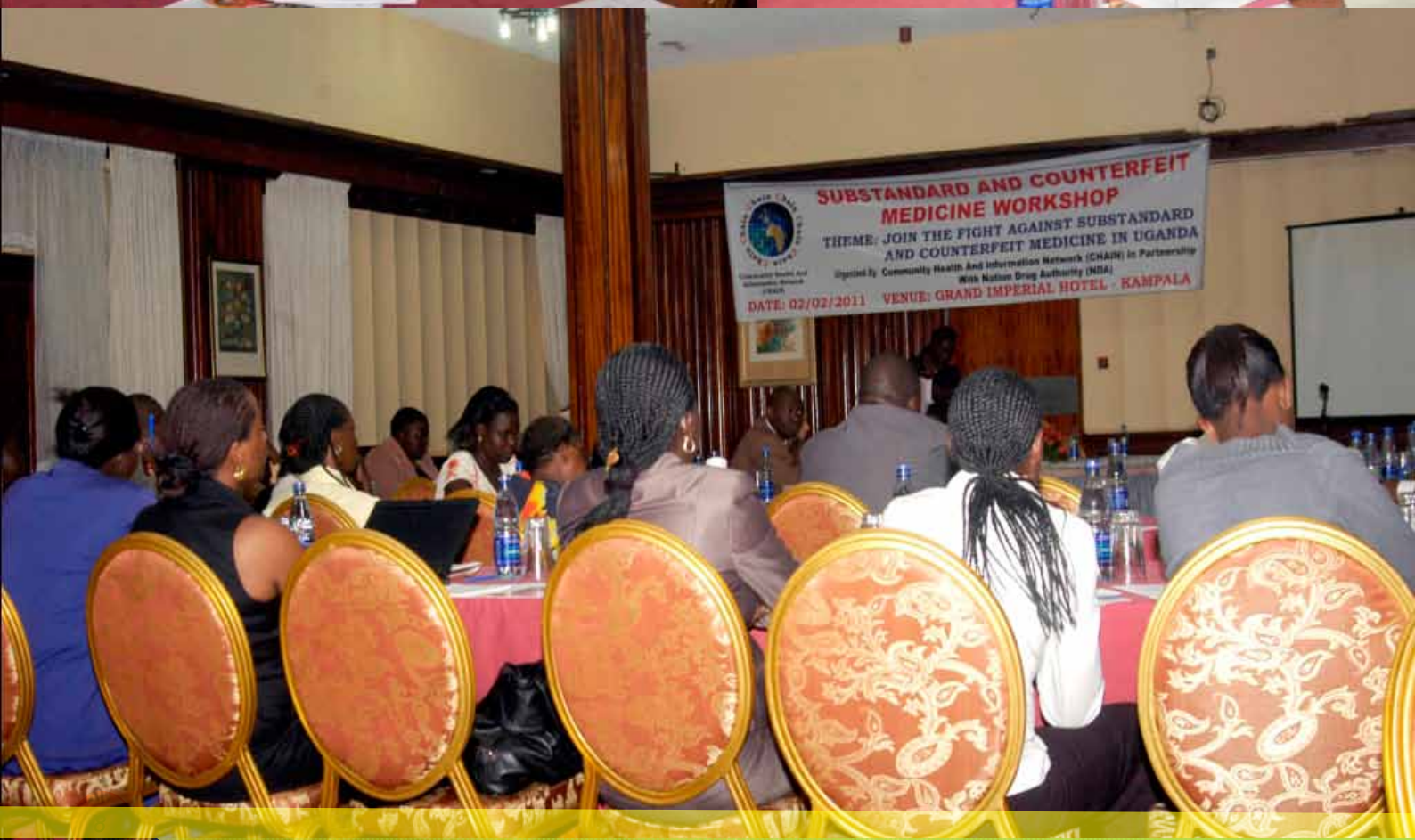
- ***NDA Feedback Mechanisms: A question was raised related to mechanisms used by NDA to get feedback from the public*** especially telephoning the unit, use of internet and the NDA form. Participants argued that some of these mechanisms were not effective citing reasons as; the public is not aware of the telephone number of contact neither have they ever came in contact with the NDA form. The general public in villages doesn't access internet services to give feed back to NDA. They therefore called upon NDA to improve the communication channels with the public.

- Role of NDA departments and Regional centres: effectiveness of NDA regional offices and regional Pharmacovigilance centers was raised. Participants argued that they have not heard any program run by these centres in sensitizing the general public on counterfeit medicines.

Neither is the public aware of their existence.

- Responding to the questions above, Victoria Nambasa Bukenya and Seru Morris -Principal Pharmacist MOH pointed to the fact that the fight against counterfeit medicines is a complex problem and cannot only be overcome by government single handedly. There is need for public-private partnership to fight the problem with CSOs taking a role in sensitizing the public.
- The government had managed to crack down counterfeit drug dealers as explained in Mamba I & II but has not done extensive campaigns as raised. Also agreed that there was need to widen communication channels reaching the public with the support of CSOs.





SESSION 3:

Key Players In The Fight Against Counterfeit Medicines: Their Roles And Efforts

Session Chair: *Robert Katsigazi-President of Uganda Association of Physiotherapy.*

Implications of the Anti Counterfeit Bill on Access to ARVS in Uganda - A Case of People Living with HIV in Uganda

By Flavia Kyomukama.

Background information regarding access to Anti Retroviral Treatment by PLWHA in Uganda: Informed participants that to date there is reduced stigma and discrimination with ART trials across health centers; cheaper generics and more PLHIV aging with HIV despite the complications. Since 2003, the average cost of treating an HIV patient has fallen from nearly $500 a year to $70. From 2001, Indian generics have provided antiretroviral treatment for 4 million HIV-positive people in the developing world. She however remarked that progress made may be under threat with the coming counterfeit bill as generics more especially ARVs from Indian may be curtailed.

Definition of counterfeit: she informed participants that in Uganda, a definition for counterfeit drugs has to be clarified to an extent and there is need to ensure Uganda and EA implement legislation that does not inadvertently restrict access to life-saving generic drugs e.g. ARVS.

Implications of the Anti Counterfeit bill on access to ARVS in Uganda

Ms. Flavia informed participants that the Uganda's Anti Counterfeit Bill may have implications on the availability of ARVs. Impact of this proposed legislation to access to ARVs may result in:

- Limited use of TRIPS flexibilities and encourage use of FTA which may lead to increase in cost of ARVS and less people enrolled on treatment.
- Legal uncertainty – protection for local ARVS industries not clear.
- Stifling of competition and domestic (generic) production and Innovation – the legislation will demoralize the production of generics and other essential medicines.
- Breach of GATT article V on goods in transition – ARVs maybe blocked as in the case of Holland blocking medicines which were destined for Brazil – implications: drug resistance and early deaths.
- Infringement of the authority of the national drug regularity institutions – already NMS and NDA are lacking, if other structures are set up will they make it easier for patients to access ARVS/reduce the rampant ARV stock outs?
- Creation of new norms e.g. extra territorial application of IPRs.

Gave some Recommendations to include:

- The need for other legal provisions as a country in support of NDA and UNBS to guard against counterfeit medicines to ensure PLHIV have access to regular and affordable ARVs.
- What is needed is the Justice Law and Order Sector, National Drug Authority, Uganda National Bureau of Standards and Ministry of Health departments responsible for regulation to be vigilant and get training on the IPR for effective negotiations, implementations and surveillance.
- The user/ consumer groups must be part and parcel of the framework – they are the best investigators if capacity is built.
- New bills carry new implementation structures and costs that may worsen the already difficult processes of procurement, monitoring and supply of ARVS and other medicines. An open secret is NDA and NMS ARV procurement, monitoring and supplies challenges and the recurrent /regular ARVs stock outs.
- Train consumers to detect and report counterfeit ARVS and their sources.

She concluded by commending the work done so far by NDA and MOH but called for a law that protects and promotes the lives of Ugandans. The law should not be a stepping stone to bypass the

TRIPS flexibilities for countries to access cheaper generics. Such a law she said should ensure more and safe ARVs to increase and promote prevention.

Role of Pharmaceautical Industry

By Ms. Sylvia Nabawagga- Medical Representative Pfizer Uganda

She informed participants that the issue of patient safety is critical to Pfizer and it is their ethical and regulatory responsibility to monitor the safety of the medicines developed from their first introduction in the research laboratory, throughout clinical testing, and for as long as they are prescribed to patients anywhere in the world.

Strategies used by Pfizer to protect Consumers from Counterfeiting

- ***Working closely with national authorities to fight the counterfeiting of medicines:*** Since 2004, collaborations with national authorities have prevented more than 65 million counterfeit dosages of Pfizer medicines from being dispensed to patients around the world. The partnerships formed with enforcement authorities that include training authorities from 94 countries and testing suspected Pfizer product at no cost, are the key to our success.
- ***Communicating Safety Information:*** Pfizer empowers patients, their caregivers and the public with up-to-date, meaningful information—trying to make certain that people can understand clearly the benefits, risks and proper use of our medicines. The Pfizer Medicine Safety Education Web site shows how a medicine's safety profile is determined, monitored and communicated. This highly interactive site has had more than 100,000 unique visitors since its launch in late 2008.
- ***Post-marketing surveillance:*** Sylvia informed participants that once medicine is brought to market, additional risks and benefits can become apparent especially when used by large numbers of patients. In many cases Pfizer conducts post-marketing surveys to analyze the "real-world" use of our medicines. Reporting on adverse events and side effects both listed on the packet insert and those that are not is encouraged from both the doctors and the patients
- ***Branding the medicines:*** special packaging with security seals and branding has been done to all Pfizer medicines that limit duplication of all medicines. Such brands are easily detectable from other medicines produced and this ensures safety of medicine produced by Pfizer.
- ***Employing high skilled professionals:*** Pfizer employs more than two thousand medicine safety specialists around the world; research scientists, physicians, nurses, pharmacists, epidemiologists, and others. These colleagues work with regulatory authorities to understand, as precisely as possible, the risks and benefits of our medicines both before and after they are approved for doctors to prescribe for patients. These professionals deploy highly advanced technologies to provide the earliest possible signals of any change in the benefit/risk profile of a medicine.
- ***Others safety measures include:*** collection of adverse event reports, observational studies and funding third party investigators on behalf of Pfizer to undertake independent medicine safety studies.

The Role of CSOs in Fighting Counterfeit Medicines

By Kibira Denis (MPS) Medicines Advisor/ Program Manager Health Policy Advocacy-HEPS-UGANDA

He started by giving an explanation of essential medicines stating that they are those that satisfy the priority health care needs of the population. Further explained that essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.

Mr. Kibira gave an explanation of access to medicines. Summed accessibility into 4As: Available; Accessible; Acceptable; Affordable.

He presented the situation of access to medicines in Uganda saying that prices of medicines in the private sector are 3-5 times the international reference prices. He further warned that prices of branded medicines will go beyond 10 times the international reference prices if serious checks are done.

The presenter explained the role of CSOs in the fight against counterfeit. Key roles includes:

Legal and policy framework

- CSOs provide neutrality in policy discussions on counterfeit issues.
- Have been at the forefront of ensuring that countries draft laws with no negative public health implication in the region. Cited a case in hand - the Anti-counterfeit Bills in Kenya and Uganda E.A Policy on Counterfeiting. He however warned that while it is important to fight counterfeiters, countries have to be very careful with IP laws that have counter effects on access to medicines.

Regulation

Noted that CSOs ought to work with Drug Regulatory agencies in fighting counterfeits especially:

- In information dissemination and information sharing.
- Reporting of suspicious cases.
- Working with academia and NDA through MeTA to develop mechanisms to build on regulatory work at sentinel sites.

Sensitization on IPR

He informed participants of recent pushes to combat counterfeits with strengthening of IPR. However, benefit would be in:

- Strengthening regulation and enforcement.
- Sensitizing the public and policy makers.
- Building local medicine production capacity.
- Building confidence of public in system.

Use of technology

- Tech. advances have enabled electronic reporting on health matters and counterfeit medicines e.g. in Ghana, Sri Lanka.
- CSOs can emulate/make use of NDA's SMS reporting or WHO's Rapid Alert system to report counterfeits.

Education and awareness

- Public sensitization on reporting of suspicious medicines.
- Training of policy makers, media and other stakeholders on concept of essential medicines, the impact of counterfeits and implications of legislations.
- Campaigns to improve access to medicines.

He concluded by noting that as we fight counterfeits, we have to be very clear about what is beneficial to our countries' development and public health as well as get a clear understanding of the counterfeits and substandard medicines debate.

SESSION 4:

Group Work Presentations

Facilitators:

Ms. Janet Obuni - Uganda Nurses and Midwives Association
Ms. Rita Sembuya - Joyce fertility Support Centre
Ms. Ruth Nankanja - Sickle cell Association of Uganda

Key Discussion Questions

- What are the key challenges in the fight against counterfeit medicine?
- What are the national strategies to address the counterfeit medical products problem or threat, and establish long-term aims for continuous cooperation?
- What kinds of structure and resources are needed to facilitate and coordinate action?
- What can specific groups commit to?
- How can key stakeholders e.g. Patient organisations, health professionals collaborate with regulatory authorities to contribute to counterfeit medicine activities?

Group Presentations

Group One, Question 1: What are the key challenges in the fight against counterfeit medicine?

- Limited public awareness.
- Weak legal and regulatory framework.
- Economic status of the country in relation to poverty.
- Limited access to medicines.
- Corruption.
- Inadequate capacity of NDA.
- Lack of commitment from public (users), law enforcers and lack of political will.

Group One, Question 2: National Strategies to Address the Counterfeit Medical Products Problem or *threat, and establish long-term aims for continuous cooperation*

- Awareness through different media, simple, clear and local languages.
- Organize communities from the grass root level.
- Get support groups in churches, hospitals, schools, health centres.
- M&E personnel at sub county level and the person is knowledgeable about counterfeit medicines.
- Government to punish perpetrators, heavy penalty and deportation of foreign counterfeiters.
- Price controls for the medicines.
- Advocacy-anti counterfeit bill to address the loop holes.
- Advocate for subsidized drugs.
- Political will-petition.
- Reveal unethical behavior among staff of NDA.
- Promote research.
- Develop feedback systems at local level.
- Set up a laboratory at national level to test drugs.
- Bring CSOs and CBOs on board to sensitize the public.
- Partnership between NDA and UNBS since most of them have expertise.

Group One, Question 3: What kinds of structure and resources are needed to facilitate and coordinate action?

- To have a common purpose and principal – one voice.
- Reach understanding – commitments.
- Plan to meet often to discuss counterfeit medicines.
- Human resources (expertise) training to identify (create a task force).
- Involving importers.

Group One, Question 4: What can specific groups commit to?

- Routine sport messages.

- Public awareness.
- Partnership/networking.
- Sharing information.

Group Two, Question 1: What are the key challenges in the fight against counterfeit medicine?

- Definition of counterfeit medicine not clear.
- Lack of a law against counterfeit medicine.
- Limited information about counterfeit medicines.
- Poverty.
- Mistrust between government and civil society.
- Corruption.
- Resources for surveillance.

Group Two, Question 2: Discuss National Strategies to Address the Counterfeit Medical Products Problem or threat, and establish long-term aims for continuous cooperation?

- To enact and enforce positive laws.
- Improve information flow and redress centers right to the grass root levels.
- Capacity building at all levels actors and framework e.g. CSOs.
- Strengthen relationship between government and private partnerships.
- Formation of CSO pressure groups.
- Ensure that MOH provides essential medicines (no stock outs).
- Create civil servants sensitization programs.

Group Two, Question 3: What kinds of structure and resources are needed to facilitate and coordinate action?

- Strengthen health and community systems to ensure quality medicines.
- Health education on rights and responsibilities in schools and communities.
- Ensure sensitization of communities to report back on substandard medications.
- Use line ministries, LCs or even volunteers, interns to work with NDA and monitor use of effects of medicines.
- Interpret reporting forms to local languages for reporting achievements.

Group Two, Question 4: What can specific groups commit to?

- CSOs can do research.
- Support monitoring.
- Reporting.
- Sensitization and creating awareness in the community and the media.
- Monitor NDA to ensure their duties.

Group Two, Question 5: How can key stakeholders e.g. Patient organisations, health professionals collaborate with regulatory authorities to contribute to counterfeit medicine activities?

- Dialogue meetings/workshops at the local level.
- Press releases.
- Claim/ensure CSOs are represented on national legal forums/committees.
- Create ambassadors to advocate for quality medicines.
- Partner with consumer organizations to sensitize and monitor issues on quality medicines.

Workshop outcomes

The outcome of the workshop included among others;

- Engagement of key stakeholders including WHO, Ministry of Health, regulators, pharmaceutical industry partners, healthcare professionals, Civil Society Organizations /patient organizations to discuss the magnitude of the problem; review the current strategies and come up with practical strategies to solve the problem of substandard and counterfeit medicines in Uganda.
- In the same meeting, key stake holders pledged commitment and support to fight the problem of counterfeit medicines through networking and interdepartmental collaboration

Final recommendations

- Wide scale sensitization and public awareness on the problem of counterfeit medicines and mobilization towards the fight.
- Increase public/private partnerships where Civil society and grass root organizations work with government to fight counterfeit and substandard medicines in Uganda.
- Build the capacity of civil society organizations and patient organizations to fight substandard and counterfeit medicines e.g. identifying substandard and counterfeit medical products.
- Workshop members called for research into the issue of counterfeit medicines to determine the magnitude of the problem, and enable the designing of appropriate interventions
- Revisiting the current bill, make it enabling and punitive enough to fight counterfeit medicines in Uganda as well as aligning it with other East African Legislations.
- Improve on the reporting mechanisms and generate feedback systems at the community levels on adverse effects of drugs.
- Increase on drug monitoring, market surveillance by NDA and involve more agencies to crack down illegal drug entry.
- International and Regional cooperation in studying the source, trend & impact of the problem to society.
- Share best practices at national and regional level
- Improve laboratory capacity to test promptly and efficiently all suspected samples.
- Increase training in counterfeit detection for healthcare workers & key stakeholders.
- MOH should ensure accessibility and affordability of essential drugs to the population.
- Reduce corruption tendencies of key personnel in the fight of substandard medicines.
- Widening feedback and communication channels from the public to national regulatory systems and authorities.



Workshop Agenda

08.00 - 08.30am	**Arrival and Registration of participants**
08.30-10.30am	**Session 1: Opening** **Session chair: William Babumba – International Red Cross,(IRC) Geneva** **Introduction and presentation of workshop objectives-10 mins** **Welcome remarks: Regina N.M.Kamoga-CHAIN Country Manager;10 mins** **Keynote speaker: Representative from WHO (tbc), 15 mins** **Invited speaker: Ministry of Health, 10 mins** **Understanding Substandard and counterfeit medicine:** **Substandard and Counterfeit medical products situation in Uganda-NDA ,15 mins** **Counterfeit bill in Uganda- Uganda National Bureau of Standards (tbc)-15 mins** **Q and A (20 mins)**
10.30 - 10.45am	**Break tea**
10.45 -1.00pm	**Session 2: Current interventions/initiatives to address substandard and counterfeit medicines:** **Session chair: Ms. Rosette Mutambi- Coalition for Health Promotion and Social Development (HEPS Uganda)** **Presentations by representative from ;** **Ministry of Health (MoH, Pharmacy Department)-15 mins** **National Drug Authority(NDA), Pharmacovigilance Unit-15 mins** **Q and A (30 minutes)** **Media to be invited**
1.00pm - 2.00pm	**Lunch**
2.00 – 3.25pm	**Session 3: Key players in the fight against counterfeit medicines; their roles and efforts** **Session Chair: Dr.Robert Katsigazi-President of Uganda Association of Physiotherapy** • Role of healthcare professionals-30 mins • Uganda Nurses and Midwives Association • Pharmaceutical Society of Uganda, PSU • Role of regulatory authority /bodies-10 mins • National Drug Authority • Role of Pharmaceutical industry–10 min • Role of Civil society organisations /Patient organisations- 20 mins • HEPS- Uganda **Q and A (25 minutes)**

	Session 4: Group work (35mins) **Introduction and explanation of group work** **Facilitators for group work :** **Ms. Janet Obuni- Uganda Nurses and Midwives Association** **Ms. Rita Sembuya-Joyce fertility Support Centre** **Ms. Ruth Nankanja-Sickle cell Association of Uganda**
3.25pm – 4.00pm	• What are the key challenges in the fight against counterfeit medicine? • Discuss national strategies to address the counterfeit medical products problem or threat, and establish long-term aims for continuous cooperation. • What kinds of structure and resources are needed to facilitate and coordinate action? • What can specific groups commit to? • How can key stakeholders e.g. Patient organisations, health professionals collaborate with regulatory authorities to contribute to counterfeit medicine activities?
4.00 – 4.40pm	**Group work Presentation and discussion (40minutes)**
4.40 – 5.00pm	**Summary remarks and closure-20 minutes**

List of participants

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