

GENERIC DRUGS SAVE LIVES

INTELLECTUAL PROPERTY AND
ACCESS TO ESSENTIAL MEDICINES



The story of Masumbuko community

WORDS TO LOOK OUT FOR

My name is Mtetezi. Let me take you through some important definitions that you will come across throughout this booklet.

Essential Medicines:

Are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. 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 adequate information, and at a price the individual and the community can afford. (Source: http://www.who.int/topics/essential_medicines/en/ <Accessed on 1/8/2011 at 11.40hrs>)

Generic Medicines:

Contain the same active medicinal substance as an originator pharmaceutical product. Because it acts in the same way in the human body, it is interchangeable with the originator product. Generic medicines are launched when the originator product's patent has expired (or under voluntary or compulsory licensing). (Source: <http://www.egagenerics.com/FAQ-generics.htm> <Accessed on 1/8/2011 at 12.40hrs>)

Counterfeit Medicines:

Are those that are deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging (Source: <http://www.who.int/medicines/services/counterfeit/overview/en/> <Accessed on 1/8/2011 at 13.40hrs>)

Substandard Medicines:

medicines are products whose composition and ingredients do not meet the correct scientific specifications and which are consequently ineffective and often dangerous to the patient. Substandard products may occur as a result of negligence, human error, insufficient human and financial resources or counterfeiting. (<http://www.who.int/mediacentre/factsheets/2003/fs275/en/> <Accessed on 1/8/2011 at 15.40hrs>)



PREFACE

The HIV and AIDS scourge is a crisis in Kenya. About 1.5million are estimated to be infected. It is also estimated that there are about 100,000 new infections annually.

Previously, a person diagnosed of HIV and AIDS was condemned to death as a result of opportunistic infections. Currently, the use of anti-retroviral (ARV) drugs has enabled many people to live long lives.

However, the challenge remains making accessible these medicines for everyone in need. Currently, out of 800,000 people in need of ARVs only 420,000 have access.

Several barriers have made access to ARVs difficult. Intellectual property rights (IPRs) is one such barrier. IPRs make medicines expensive because of remittances in form of royalties. In addition, it can impede the development of better regimens and formulations for pediatric use.

Paul Ogendi

Intellectual Property and Access
to Essential Medicines Fellow

This comic booklet illustrates the impact of IPRs on the welfare of a society (Masumbuko community). It underscores the basic fact that Kenya, like many developing countries, rely on generic medicines. Therefore, when the IP regime fails to accommodate importation, exportation or manufacturing of generic medicines the society suffers.

Poor health results into a violation of the constitutional right to health and loss of lives result into a violation of the constitutional right to life.

The author hopes that the booklet will be able to inspire the different segments of the society – community members, civil society organizations, and policy makers - into defending access to generic medicines.

Stand up and take action!

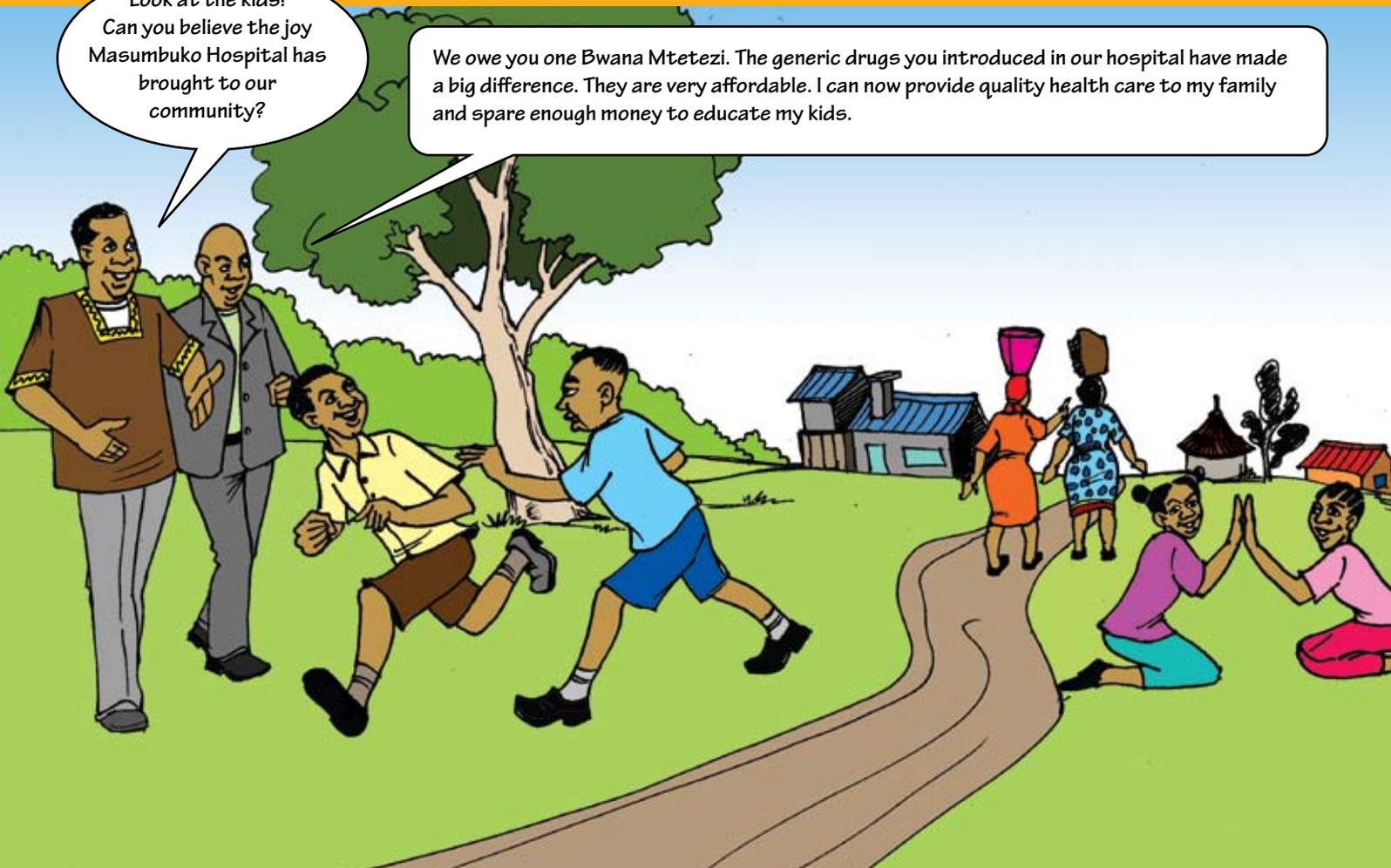
Jacinta Nyachae

Executive Director
AIDS Law Project

Masumbuko community has enjoyed peace, prosperity and affordable healthcare. A new proposed law on intellectual property that threatens access to affordable generic medicines is about to be implemented causing the people to rise up and protest against it....

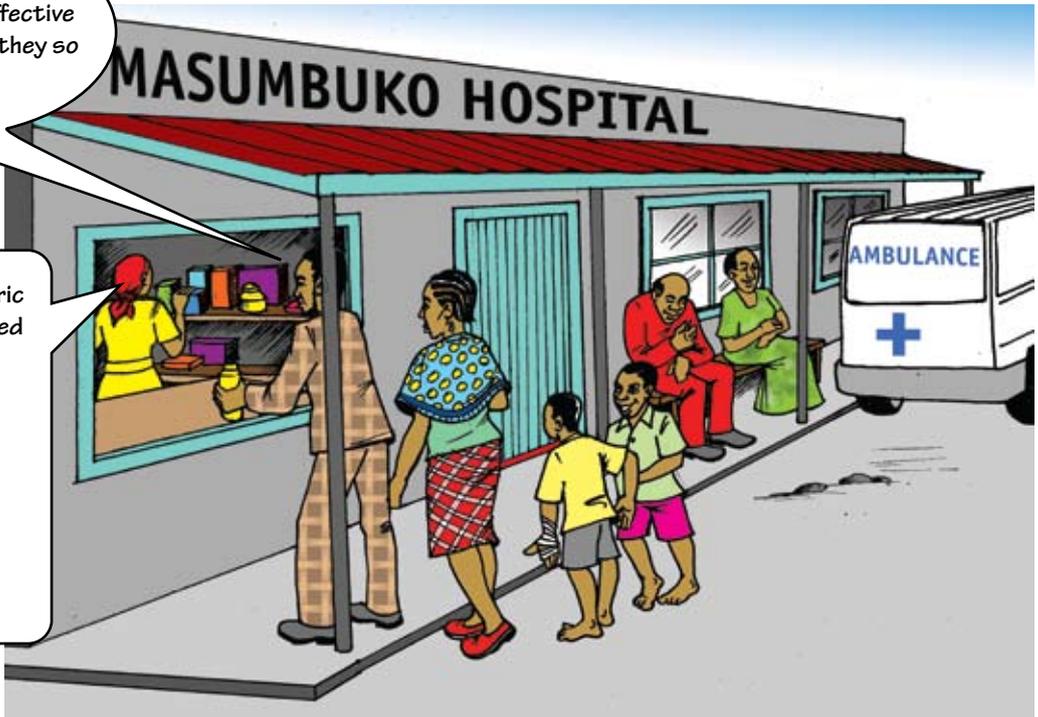
Look at the kids!
Can you believe the joy
Masumbuko Hospital has
brought to our
community?

We owe you one Bwana Mtetezi. The generic drugs you introduced in our hospital have made a big difference. They are very affordable. I can now provide quality health care to my family and spare enough money to educate my kids.



I hope the medicine
you are selling are effective
Mama Tiba. Why are they so
cheap?

Look Mr Shaka, these are generic
medicines that have been tested
and approved by the Pharmacy
and Poisons Board. They are as
good as the expensive branded
medicines but more affordable.
I get positive feedback from
members of Masumbuko
community who use them. Try
and see for yourself.





In the background, a foreign investor is surveying the drugs market in Masumbuko and cannot believe the immense opportunity that lies untapped here. As a scout for a multinational pharmaceutical company, he knows there is a killing to be made here, literally... but there is the small and annoying matter of the Generics standing between him and the dollars.



That evening the investor makes a call to his bosses abroad to report the findings of his mission.



Don't worry about that, you know we have ways of taking care of that. We will be jetting in next week to set the plan in motion.

I tell you boss, this is untapped market. I smell money, lots of money, in these shores. The only stumbling block is this cheap business of Generics, but I'm sure we can find a way of keeping them off local market... you know what I mean?

Good job. This time you nailed it! Now I think we can start talking about insurance for your balding head! (Chuckling). You've earned it.

After a few days, the investors fly into the country and are met at the airport by a government delegation that promises them 'co-operation' if they serve the interests of the State.

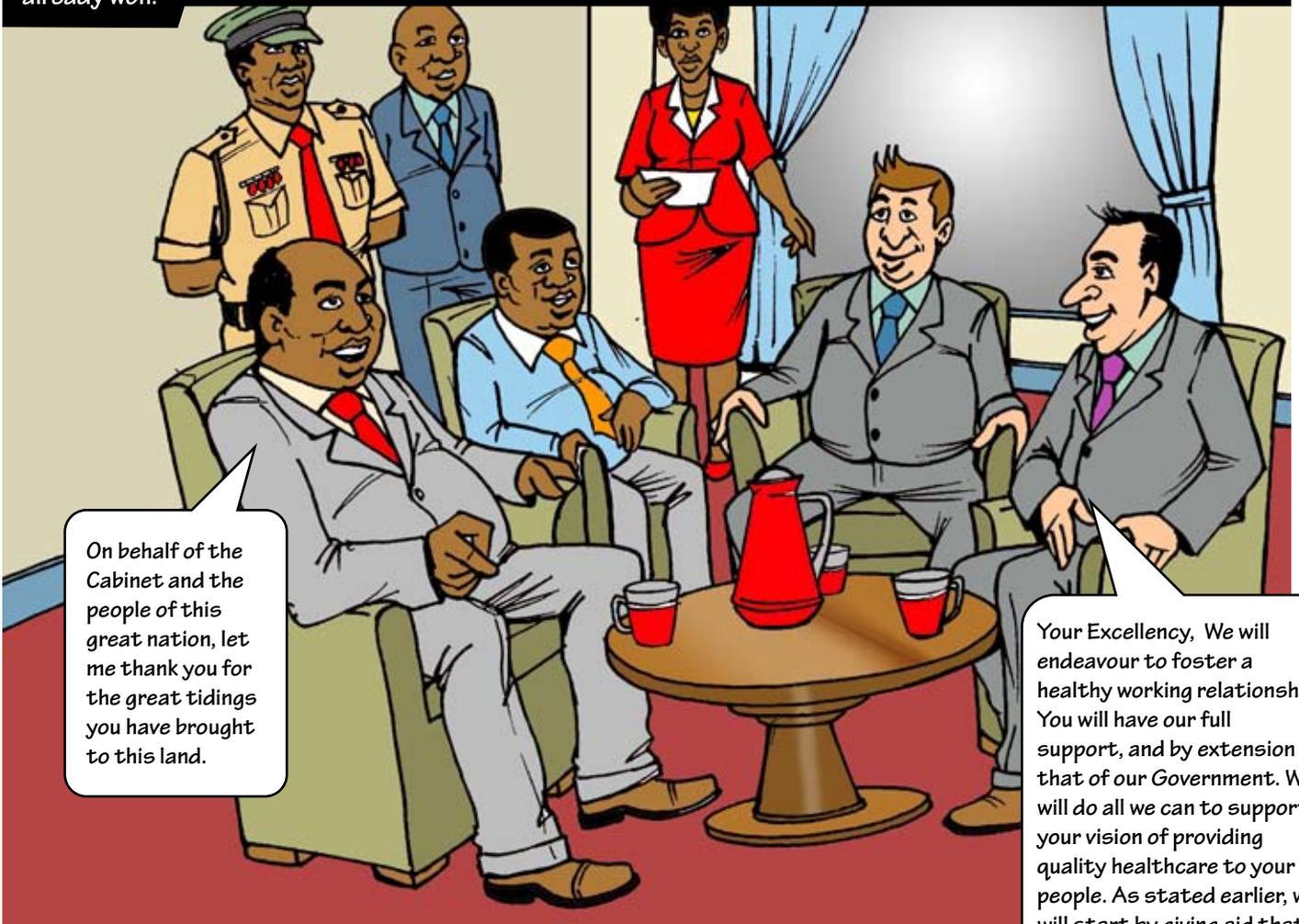


Welcome to this great land, Sir. We are glad to host you.

The pleasure is all mine, and I look forward to a fabulously rewarding stay here. I know I can trust you on that.

Totally. Everyting is organised. Again, you are most welcome. I have already arranged a meeting with a senior Government official.

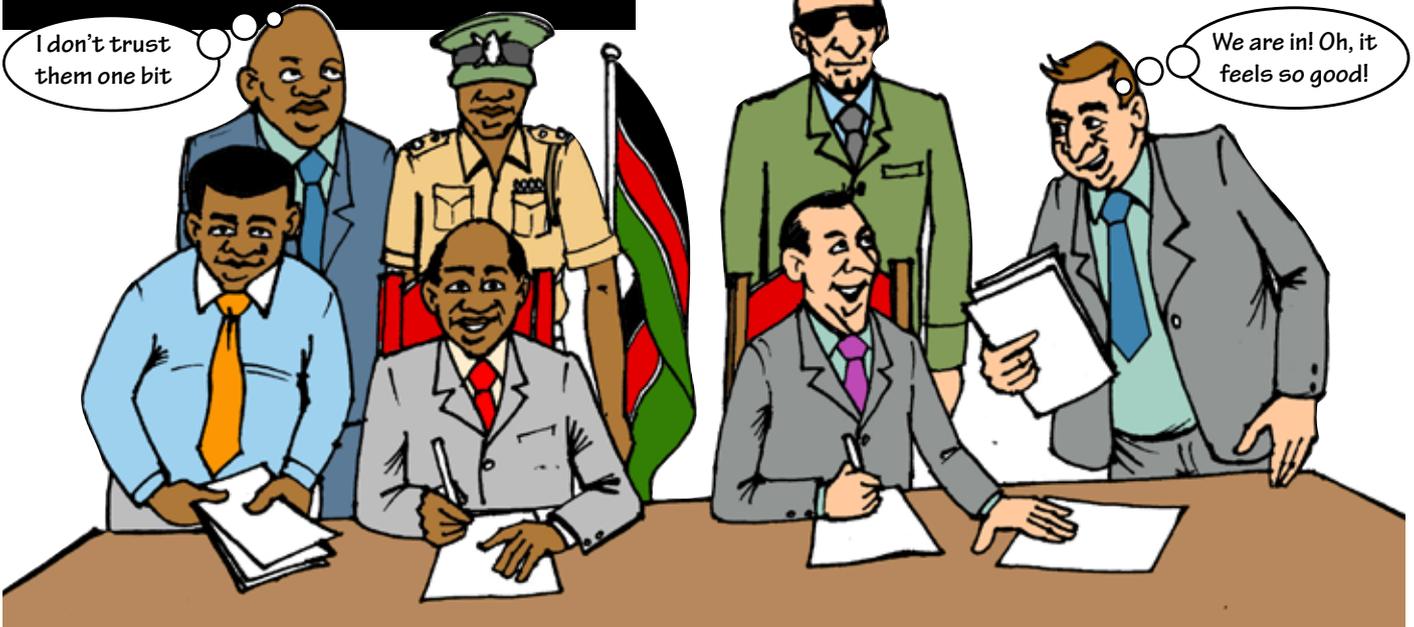
Later that evening at a meeting with the senior government official, the 'investors' have only one thing in mind; to hoodwink the Government into signing an agreement that favours their business in exchange for financial aid and subsidies. By giving money to a government already struggling with a huge budget deficit, they know the game is already won.



On behalf of the Cabinet and the people of this great nation, let me thank you for the great tidings you have brought to this land.

Your Excellency, We will endeavour to foster a healthy working relationship. You will have our full support, and by extension that of our Government. We will do all we can to support your vision of providing quality healthcare to your people. As stated earlier, we will start by giving aid that will go towards buying good medicines.

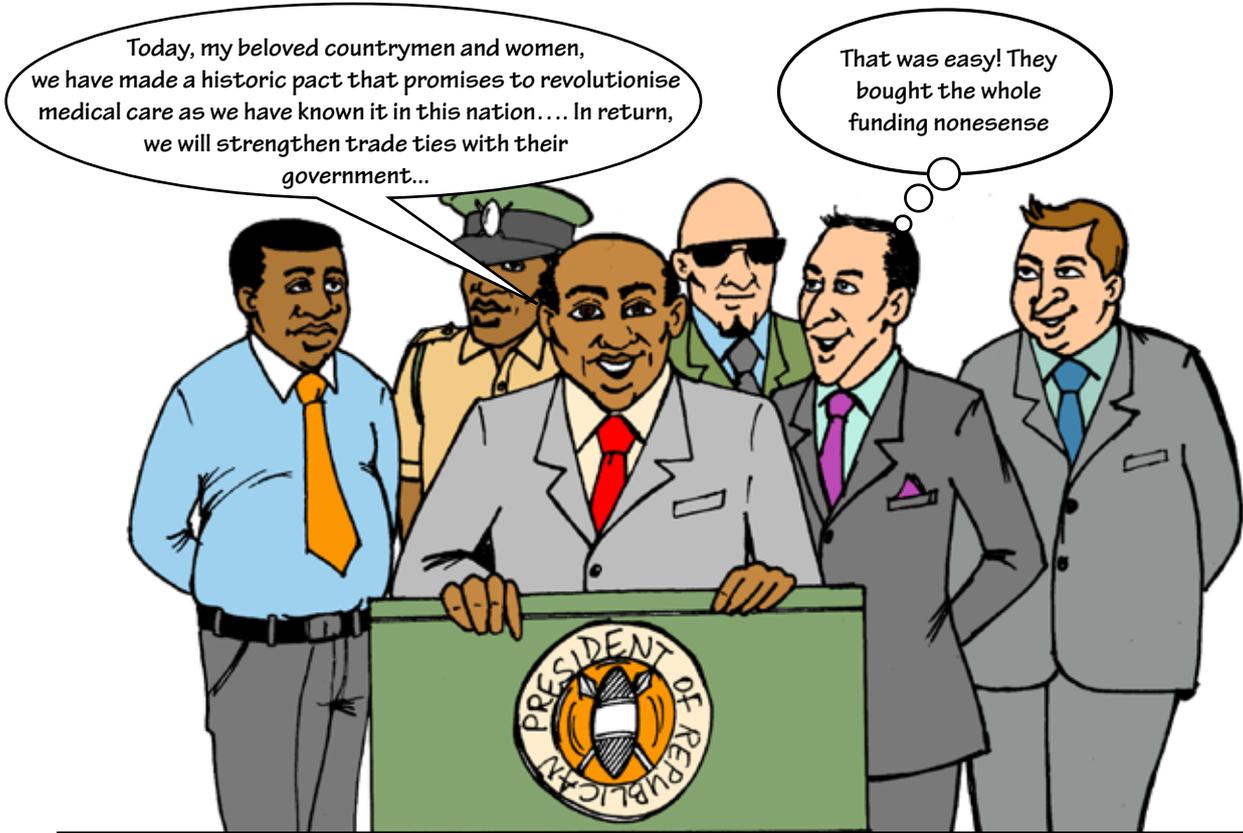
After the meeting, the two parties sign an agreement that gives the pharmaceutical company a free hand in doing business in the country in exchange of development aid.



I don't trust them one bit

Let the party begin!

We are in! Oh, it feels so good!

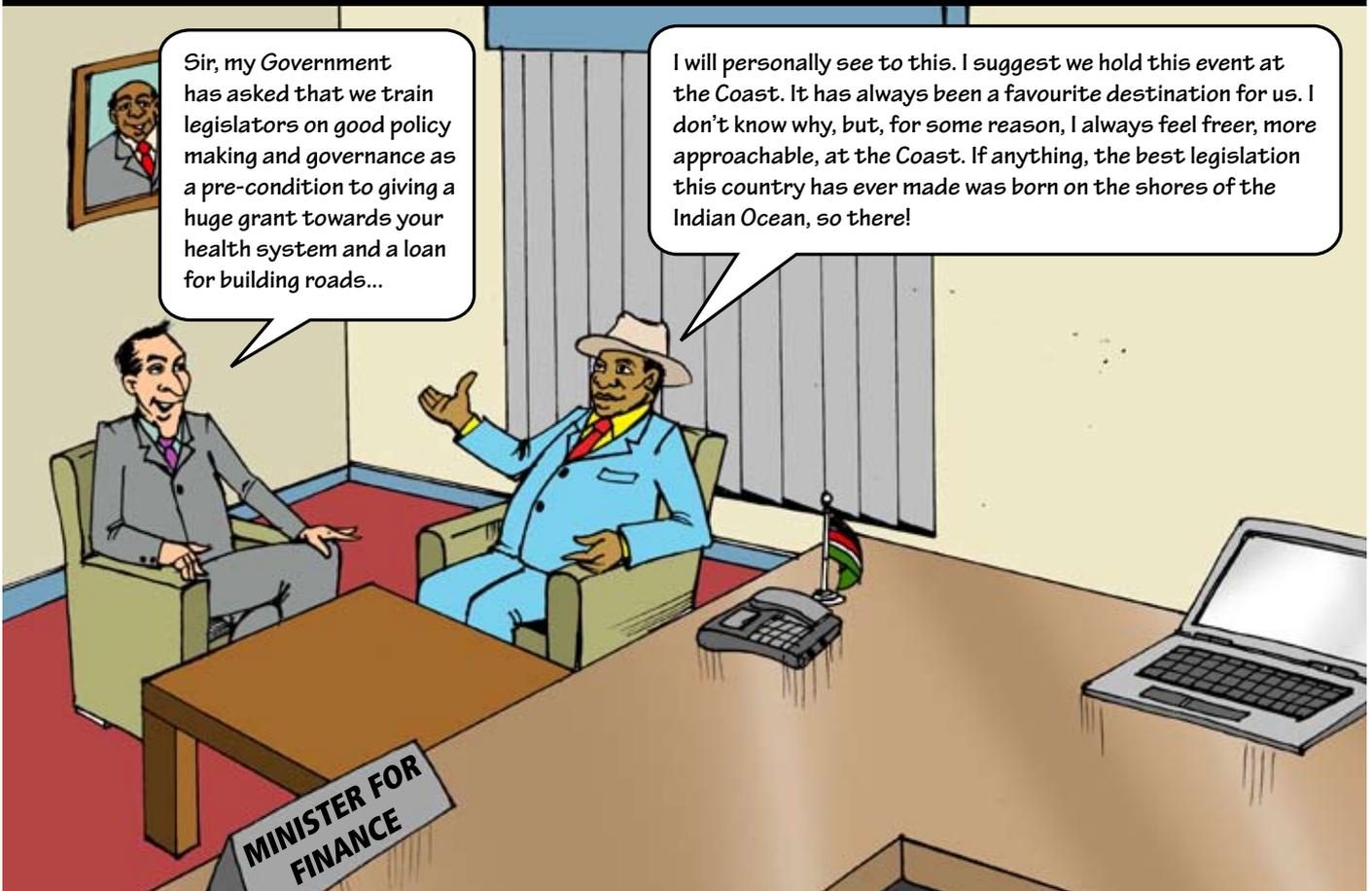


The President, flagged by the investors, announces the signing of the pact to the republic.

Having received public acknowledgement from the highest office, the investors waste no time in extending their influence to other sections of the government. At the Ministry of Trade, they give more 'aid' and in return are assured of personal assistance to help deal with the numerous bureaucratic obstacles that may stand in their way. They come under the guise of fighting counterfeit medicines which are not safe....taking advantage of the confusion in definitions, they convince the minister that generics are dangerous counterfeits which need to be banned.

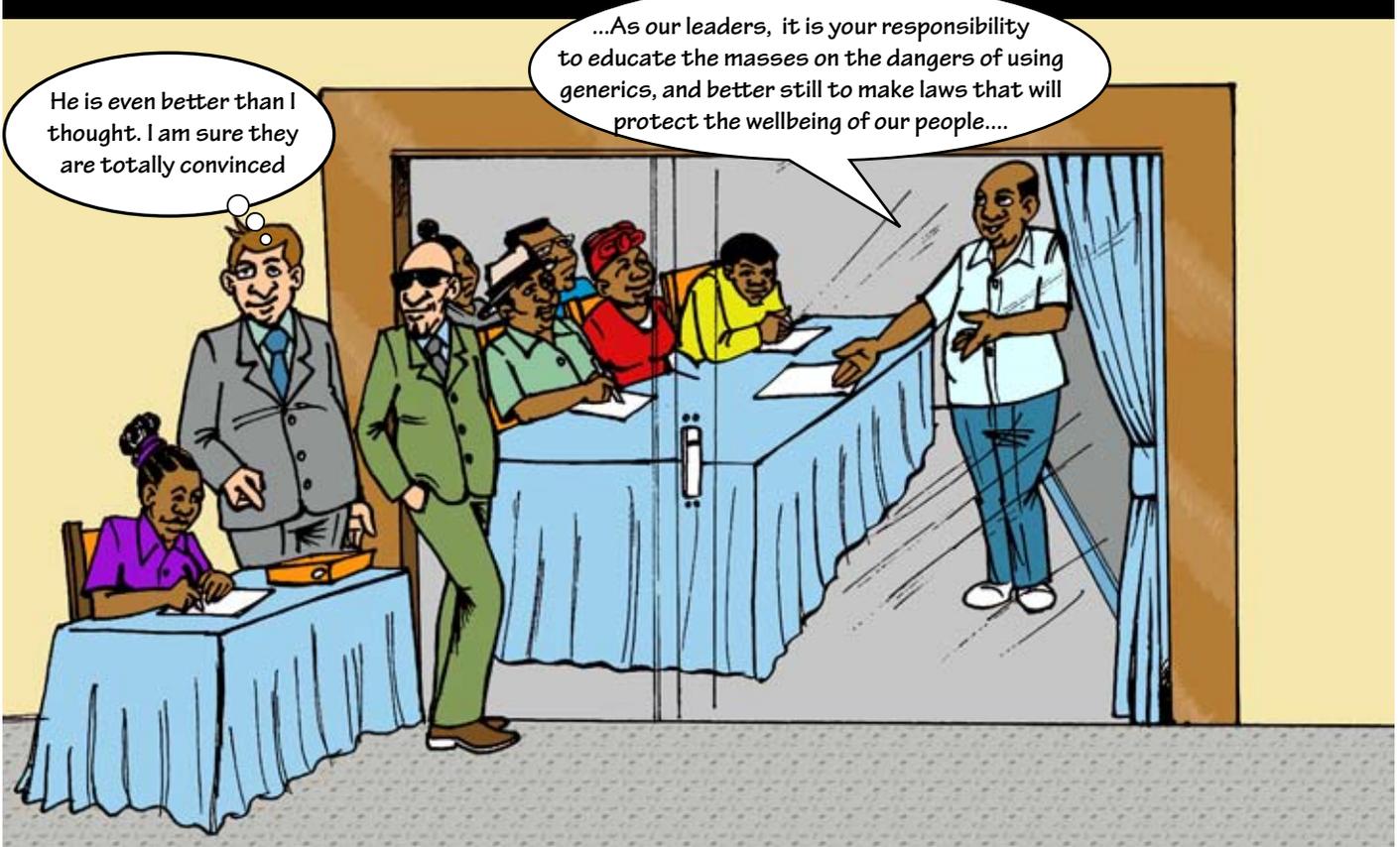


The investors, now assured of Government backing, move into the second phase of their mission; pushing all Generic medicines off the shelves of pharmacies and hospitals. To do that, they will require a lot of advocacy, and the best people to do the dirty job are Members of Parliament. They approach one of the MPs, who agrees to organise an 'educational fair' for his colleagues.



The businessmen meet to map out a strategy for the trip to the coast with MPs. Their approach will be guided by two things; advocacy against the use of generic medicine in the country, and a shameless arm-twisting of the 'ignorant' lawmakers through promises of financial aid to their Constituency Development Fund kitties.

At the coast, the investors employ the services of a compromised medical specialist to instill fear of generic medicines. Members of Parliament are asked to ensure that their constituencies are free of these cheaper versions of drugs which, according to the investors, do not respect the law of intellectual property rights and are thus a stumbling block to development.



He is even better than I thought. I am sure they are totally convinced

...As our leaders, it is your responsibility to educate the masses on the dangers of using generics, and better still to make laws that will protect the wellbeing of our people....



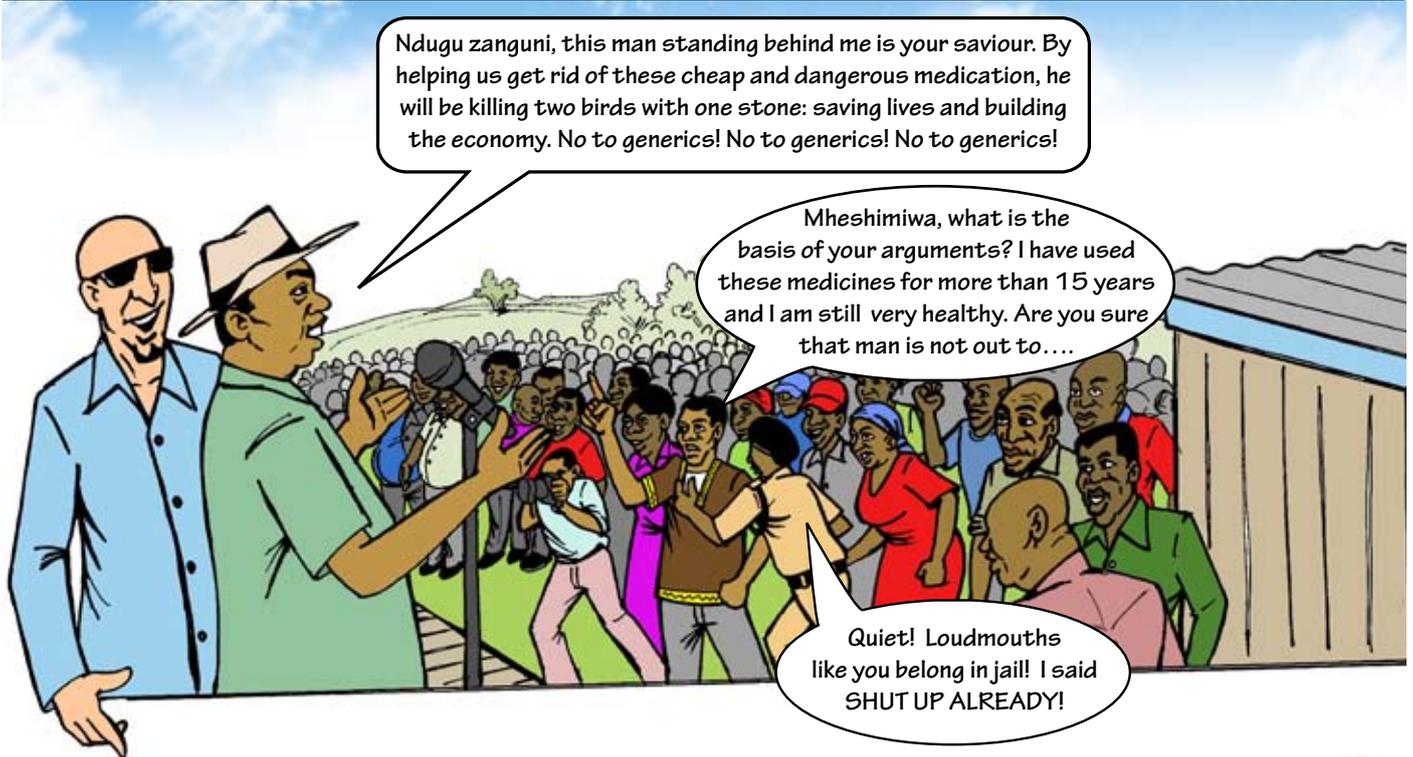
Waheshimiwa, how come we never thought of this generic debacle before?

Who cares? Eeer...Hic!... Gulp *#\$\$**... I have had a long day, and every time I look at thish finesht French wine, I thank the gods that sent me to Parliament. Life is a bliss, generics or no generics.

A trip to the coast, free French wine, dinner by the best chefs on this land and money for my CDF kitty. What more can a man possibly ask for?

With this kind of life, I will be this big before the next polls. And guess what... my bank account will be even better!

Back in their constituencies, the MPs go on overdrive mode campaigning against the generics. At Masumbuko, Bwana Mtetezi tries to counter the arguments tendered by the local MP but is whisked away by security personnel for being 'disorderly'.



Afterwards, Bwana Mtetezi tries to petition the MP with facts about generics but is shoed away.



In order to safeguard the interests of the masses, legislators need to familiarize themselves with the following flexibilities...

FLEXIBILITIES UNDER TRIPS AGREEMENT

From a right to health perspective, developing countries including Kenya should incorporate the following flexibilities under the TRIPS Agreement in their national laws:

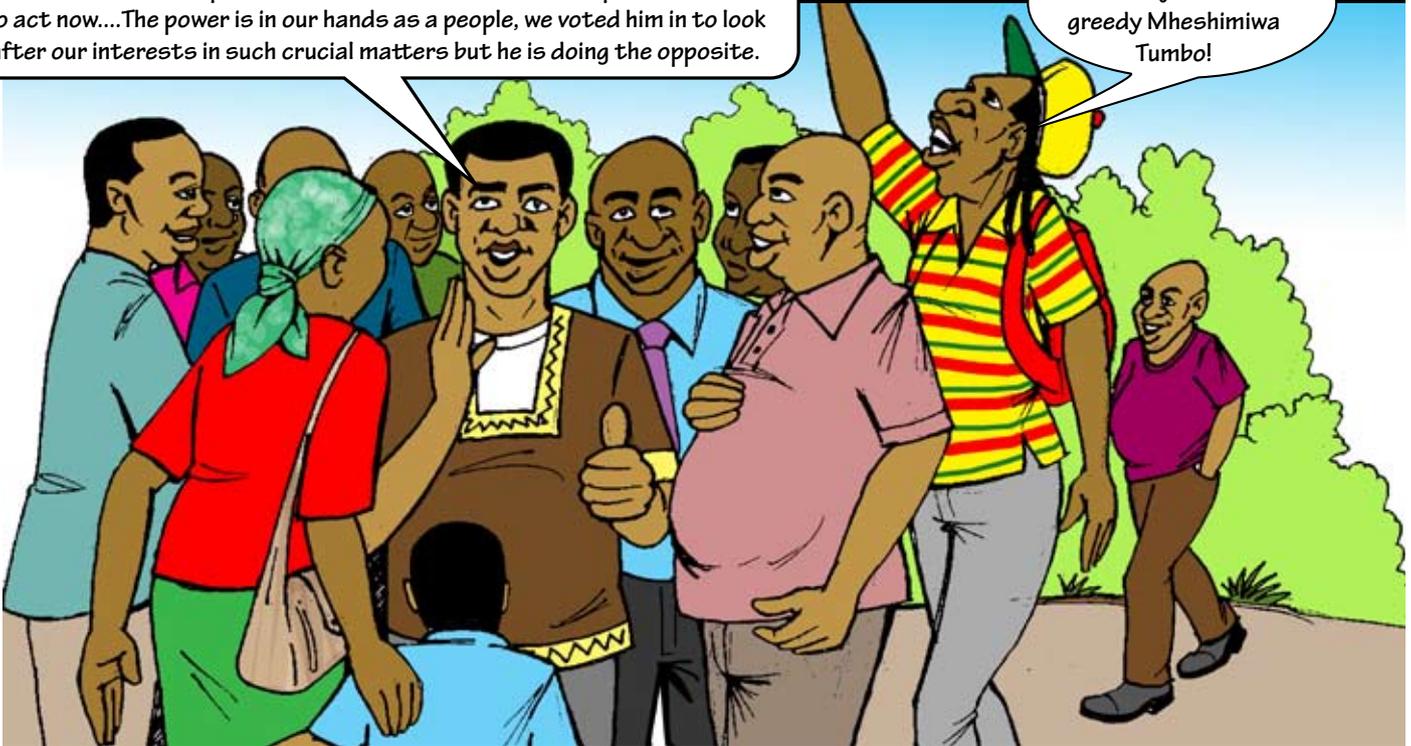
- Make full utilization of the transition periods;
- Define the criteria of patentability;
- Issue compulsory licenses and provide for government use;
- Adopt the international exhaustion principle, to facilitate parallel importation;
- Create limited exceptions to patent rights; and
- Allow for opposition and revocation procedures.

(Source: Report of the Special Rapporteur on the Right to Health, March 2009)

Mtetezi gets busy educating the masses on why generic medicines are beneficial to them. As the people get enlightened on their rights, they begin to apply pressure on their leaders to make policies that will guarantee access to affordable medicines.

Our Constitution guarantees us access to medical care. Our MP doesn't want to listen to our plea on this issue and that is unacceptable. We need to act now....The power is in our hands as a people, we voted him in to look after our interests in such crucial matters but he is doing the opposite.

Mtetezi for MP! Away with that greedy Mheshimiwa Tumbo!

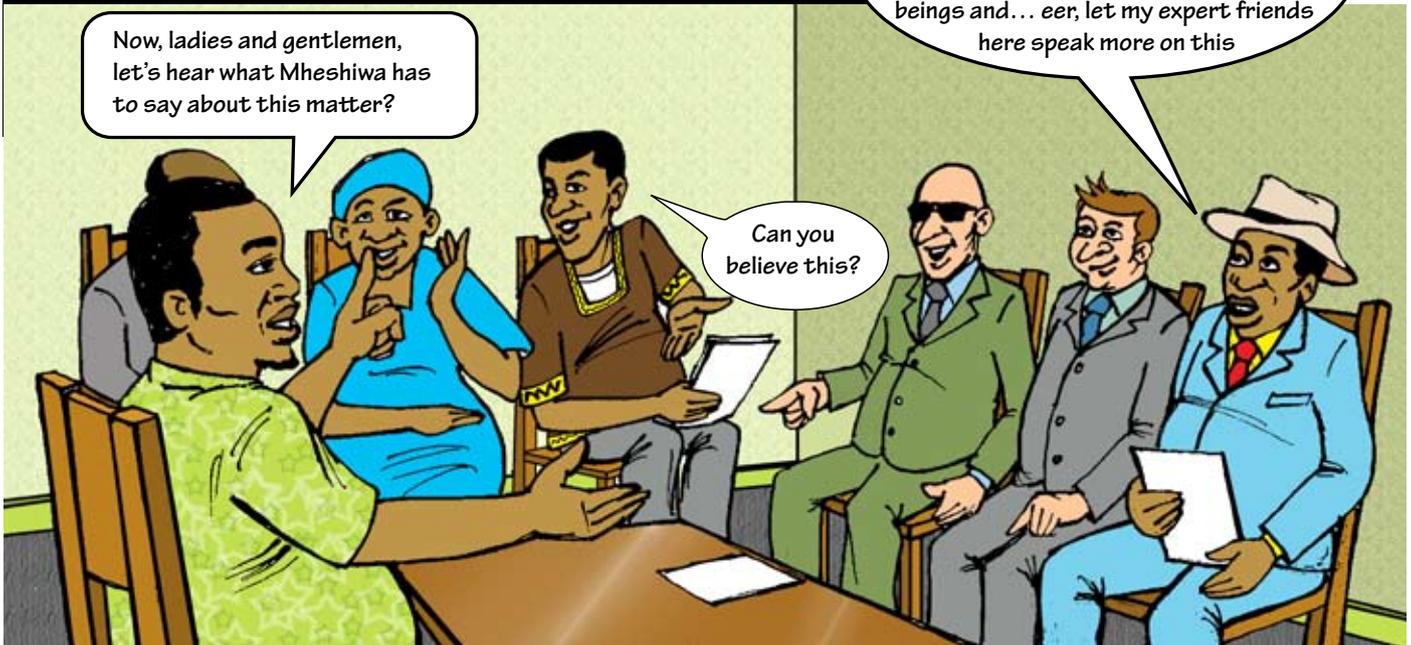


The generics debate attracts a lot of national debate and soon every journalist is on it. The media coverage generates mixed opinions, but the general feeling is that the generics should be allowed to stay.

These fake medicines are very dangerous and must be banned in this nation! I hear they cause... ummmh... bad breath and... eer...infertility in human beings and... eer, let my expert friends here speak more on this

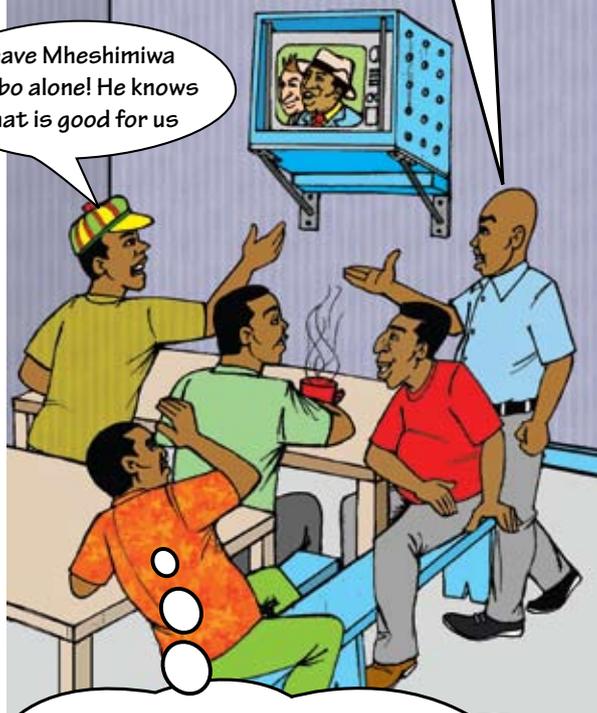
Now, ladies and gentlemen, let's hear what Mheshiwa has to say about this matter?

Can you believe this?



What is that man talking about? By that stroke of genius displayed on national television, your wizard just lost my vote.

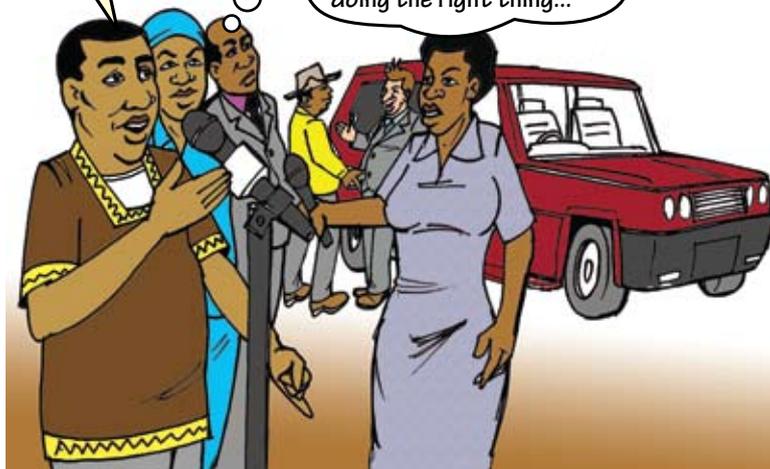
Leave Mheshimiwa Tumbo alone! He knows what is good for us



The nerve! I'm a trained doctor, and I know all the WHO guidelines on this matter. Generics are as good as branded medicines, only cheaper

The ignorance displayed today by my MP is monumental. I urge all residents of Masumbuko to seek expert opinion on this matter. From where I stand, generic medicine is as good as what these investors are selling to us at sky-high prices. That is why governments all over the world have accepted the use of these drugs in their countries. Let me explain what will happen if generics are banned....

I think Mheshimiwa honestly believes that he is doing the right thing...



Mtetezi takes his crusade to the media in a bid to win support of the people

Their voices ignored, residents of Masumbuko take to the streets on the day MPs debate the fate of generic drugs in Parliament. But their agitation is in vain, for Mheshimiwa Tumbo has greased enough palms in the House to get a landslide win in support of the Law on Intellectual Property Rights....



Mheshimiwa Tumbo ignores the people's voices and marshals his lieutenants to pass a law that renders generics illegal. Outside Parliament, he is spotted congratulating fellow MP's for a job well done...

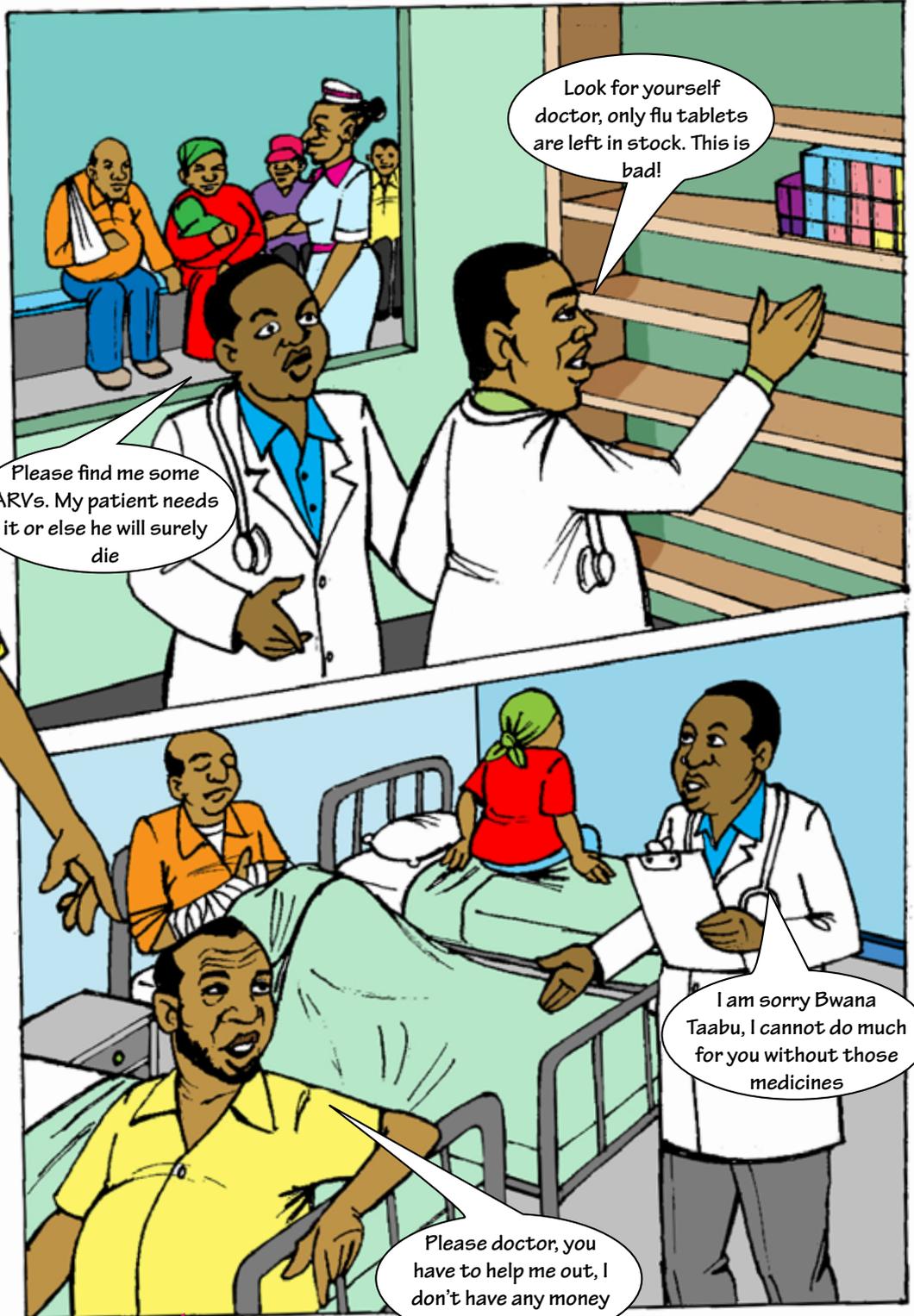


Ignored by his MP and knowing all too well what would happen should the government withdraw generic drugs from Masumbuko Hospital, Bwana Mtetezi files a case at the law courts. The courts temporarily suspend the dangerous provisions affecting access to medicines.



Bwana Mtetezi continues to enlighten the people and local leaders on what to expect should the new laws be enacted.

...First, our hospitals will experience acute shortage of essential medicines, then, doctors will have no option but to leave those patients who cannot afford expensive branded drugs without treatment...



Remember

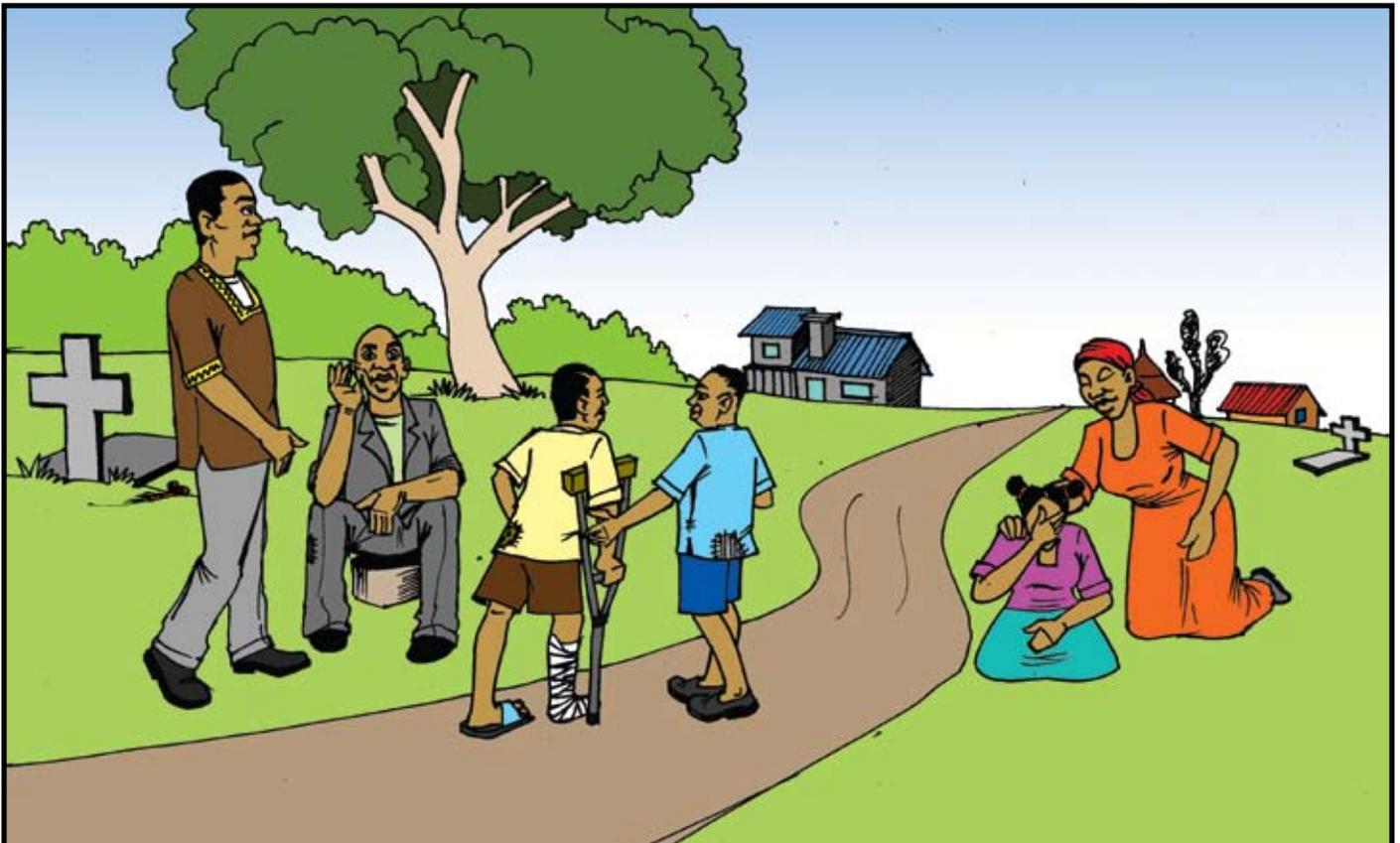
The bulk of medicines currently being used in public and private health care system to combat diseases such HIV and AIDS, TB and malaria are generic.

Generics make up for an estimated **90%** of all medicines consumed in Kenya

By pulling the cheaper generic drugs off the shelves, the government is going to make access to health care even more expensive for the majority of us. In this era of HIV/AIDS and Tuberculosis and Malaria, what will happen to this nation when eventually hospitals run out of drugs because they cannot afford them?



For the last time woman, the complete dosage will cost you Sh3,450. Take it or leave it.



Shrewd business men will seek to get rid of life saving generics off the shelves so that they can make extra money from desperate citizens.



Things get out of hand at Masumbuko as the residents confront Mheshimiwa Tumbo demanding an explanation for his support of bad laws that will affect them negatively. They jeer and curse him for attempting to remove generics and thereby leaving them at the mercy of foreign investors who sell them very expensive medicines.



Sensing danger, Mheshimiwa Tumbo seeks counsel from his adviser, who tells him his move to get rid of generic medicines was ill-advised. But the investor would hear none of it.

Quite! You know well that the only way to grow the economy of Masumbuko is to ensure that people pay for the services they get. This cheap business of generics will not take you anywhere. I know it is a bitter pill to swallow, but as I told you at the beginning, we have tried it back home in Europe and it has worked....

Now I see it clearly. These guys set me up and I beleieved every single thing they told me,. What an idiot I have been!

Wo..wo..wo.. cool it mister, I am here to provide a solution to Mheshimiwa's predicament



Leave him alone!
I don't want to hear any more of your lies. I have known nothing but trouble since I first met you. I'm going back to see my electorate, and when I come back, I WANT YOU OUT OF MY FACE! You and you bunch of lying buddies.

No need for that hostility buddy, let's talk aout this

I am glad you agreed to see me on such a short notice Mtetezi. I need your help on this.

No problem Mheshimiwa. I am happy to serve the people of Masumbuko



Mheshimiwa Tumbo requests for an urgent meeting with Mtetezi to discuss this issue.

DID YOU KNOW?

- 1 Access to essential medicines is guaranteed under the constitutional right to life and the right to health.
- 2 Intellectual property rights is a barrier to access by making essential medicines prices high resulting from monopoly/lack of competition and remittance of royalties.
- 3 The Government bears the responsibility of ensuring access to essential medicines in Kenya.
- 4 The bulk of medicines currently being used in public and private health care system to combat diseases such HIV and AIDS, TB and malaria are generic.
- 5 Access to generic medicines can be impeded by laws, policies and trade agreements requiring the protection and enforcement of intellectual property rights beyond international standards.
- 6 Big pharmaceutical companies through their respective governments are using political, legal and economic pressure on developing countries to impede access to generic medicines.
- 7 The entire world is in agreement that intellectual property rights should not be a barrier to access to essential medicines including generic medicines.
- 8 All stakeholders including community members, civil society, private sector, and international community have a role to play in ensuring access to affordable medicines.

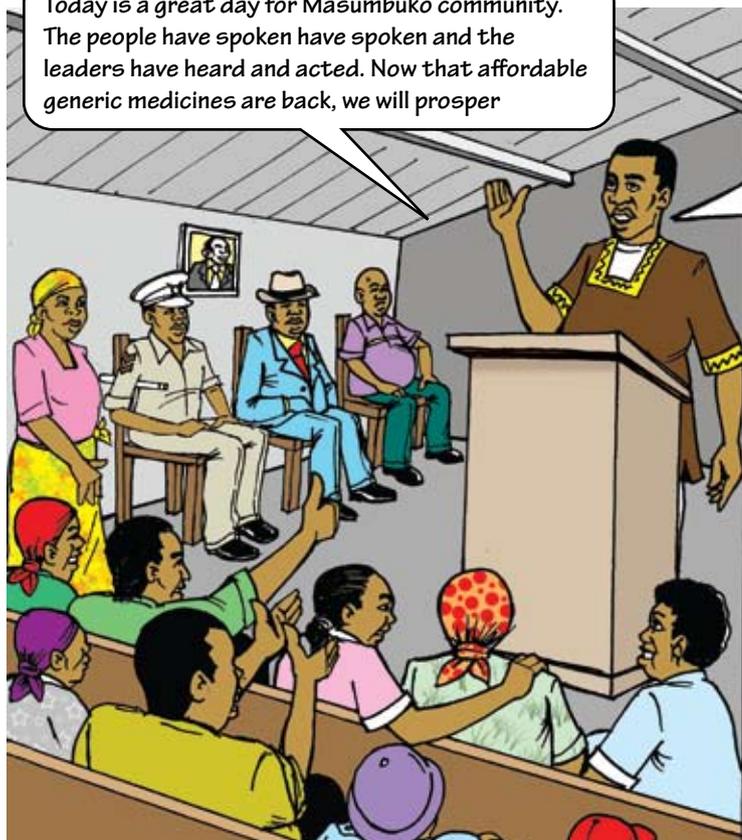
Generic medicines are safe, quality and efficacious and are similar to branded medicines.



Their greed discovered, the greedy 'investors' are sent packing. At the airport to see them off are Bwana Mtetezi and his army of Masumbuko residents.



Today is a great day for Masumbuko community. The people have spoken and the leaders have heard and acted. Now that affordable generic medicines are back, we will prosper



Take Action Now

As Community Members you must:

- Educate yourself on issues relating to intellectual property and access to essential medicines by accessing relevant information available online or elsewhere
- Raise awareness in your community on the issues relating to intellectual property and access to essential medicines
- Take action by for example petitioning your member of parliament and other policy makers in government to guarantee access to generic medicines
- Report cases where essential medicines cannot be accessed in your health facilities to ALP and other relevant institutions
- Participate in campaigns organized to promote generic medicines
- Enforce your right to health and right to life before a court of law

Take Action Now

As Civil Society Organizations, you must:

- Initiate intellectual property and access to medicines programmes in your communities
- Collaborate in campaigns to improve access to medicine situation in Kenya
- Be the voice of the voiceless



Take Action Now

As Members of Parliament and other Policy Makers, you must:

- Familiarize yourself with the flexibilities under the TRIPS Agreement
- Oppose any laws, trade agreements or policies that impact negatively on access to essential medicines
- Support laws, trade agreements and policies that impact positively on access to essential medicines

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Generics make up
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90%
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<http://ipsnews.net/news.asp?idnews=54657>

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