Falsified and Substandard Medicines: Current Challenges and Long-Term Solutions - a Public Health Perspective

Proceedings of the Seminar

October 15, 2010

Intercontinental Hotel
Geneva, Switzerland
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An event organized by IBSA (India, Brazil and South-Africa)
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Introductory Note

Medical products of compromised quality, safety and efficacy (QSE) pose significant health risks, represent a serious challenge to global health and call for a comprehensive strategy at national, regional and international levels. In spite of the gravity of the problem and its direct threat to public health, the lack of reliable empirical data on the prevalence and impact of substandard, spurious, falsely-labeled, counterfeit and falsified medicines hinders decision-making processes on the efficient allocation of resources and result-oriented plans of action. Hence, to identify concrete and effective solutions to address this issue, it is crucial to promote debate and improve understanding of all aspects related to medical products of compromised QSE.

Along with enhancing comprehension of this complex matter, there is a strong need to foster discussion about measures focused on the promotion of access to safe and efficacious and affordable medicines and other medical products. Trade of substandard, spurious, falsely-labeled, counterfeit and falsified medicines is encouraged when quality affordable medicines are not available. The systematic access to affordable, safe and efficacious medicines of assured quality reduces the risk of fraudulent activities.

To this end, the strengthening of national regulatory agencies, both in terms of surveillance capacity and regulation, should be the primary concern of international organizations like WHO. Drug regulatory authorities need to rely on enforcement mechanisms when medical products of compromised QSE are detected. However, enforcement without adequate regulatory and surveillance capacities can be counterproductive if authorities do not have the competence to assess drug quality.

The seminar “Falsified and Substandard Medicines: Current Challenges and Long-Term Solutions - a Public Health Perspective”, held in October 2010, in Geneva, was an opportunity to debate this critical issue of the health agenda. The event gathered specialists, policy makers, scholars and the public in general to present their views and exchange ideas on the prevention of falsified medicines from the standpoint of public health.

The Seminar was able to: i) enhance the understanding of the challenges posed by medical products of compromised QSE and their impact on public health; ii) help identifying positive options and concrete solutions for improving access to quality, safe,
efficacious and affordable medicines; iii) discuss concrete policies aiming at discouraging production and trade of medicines of compromised QSE.

The transcripts of the presentations of the guest-speakers have the purpose of keeping record and sharing with a larger audience the richness of the debate.
Speakers’ Biographies

Anand Grover

Mr. Anand Grover is the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health appointed by the United Nations Human Right Council. A practicing lawyer in the Bombay High Court and the Supreme Court of India took up his functions as Special Rapporteur on 1 August 2008. Mr Grover is Director of the Lawyers Collective HIV/AIDS in India, having offices in Mumbai, Delhi, and Bangalore which he co-founded in 1981 with Ms. Indira Jaising. The Unit dealing with HIV/AIDS was established in Mumbai in 1998.

He serves as member of various renowned health boards. He was a member of the drafting group of the International Guidelines on Human Rights & HIV/AIDS and is currently a member of the Reference Group on Human Rights to Peter Piot, Executive Director, UNAIDS. He is a National Advisory Board Member of International AIDS Vaccine Initiative, a member of the World Care Council, a member of the Board of the International Council of AIDS Service Organizations (ICASO), a member of the National Board of AVAHAN, the India AIDS Initiative of Bill and Melinda Gates Foundation, a member of the Core Group of NGOs representatives in the National Human Rights Commission of India and the member of the National Advisory Board on HIV and AIDS set up by the Prime Minister of India.

Mandisa Hela

Mandisa Hela is the Registrar of medicines at the Medicines Control Council of South Africa, a body responsible for the regulation of medicines. She has been involved in the pharmaceutical policy area for more than 15 years. She has represented South Africa at several international forums on matters relating to pharmaceuticals. She is a past chair of the national essential medicines Committee of South Africa. She is currently involved in a project to harmonize regulatory standards in the South African Development Community (SADC). Miss Heal is passionate about access to safe, efficacious quality medicines. She is a pharmacist by profession and holds a Masters degree in Public Health.
**Frederick Abbott**


Prof. Abbott is also the legal counsel for India in the ongoing WTO consultations with the European Union on the drug seizure issue.

**Sisule F. Musungu**

Mr. Musungu is the President and a founding member of Insensate (Geneva) and the Managing Director of Insensate Consulting (Nairobi). His research and policy work focus on governance and the development dimensions of innovation, access to knowledge, intellectual property, international trade and health policies and laws. He is also a human rights researcher with a particular interest in socio-economic and cultural rights. Sisule, who holds law degrees from the University of Nairobi (Kenya) and the University of Pretoria (South Africa), also has affiliations and/or holds a range of other positions including being a Member of the UNITAID Proposals Review Committee (PRC) and the Chairman of the Board of Directors of Health Action International (HAI) Africa.
**Michelle Childs**

Michelle Childs is Director of Policy Advocacy for the Campaign for Access to Essential Medicines, part of the independent medical humanitarian organization Médecines Sans Frontières (MSF). The purpose of the Campaign is to improve access to existing medical tools (medicines, diagnostics and vaccines) and to stimulate the development of urgently needed better tools for people in countries where MSF works. This includes addressing patent and other barriers to access and promoting new models to stimulate innovation and access.

Previously she was Head of European Affairs at Knowledge Ecology International (KEI), working on Access to Medicine and Access to Knowledge issues and an adviser to the UK Stop Aids Campaign. Prior to that Michelle was Head of Policy Research and Analysis at the Consumers' Association UK Europe's largest consumer organization which included teams covering health and information policy.

As part of her work there she held a stakeholder review of NICE (National Institute for Clinical Excellence) She has been a personal adviser to the Director General of the Office of Fair Trading UK, and a consultant to the Hong Kong Telecoms Regulator. She started out working as a lawyer (solicitor) in the Commercial Litigation Department of a London law firm handling a range of disputes including IP. She holds a law degree LLB *(Hons.)*.

**Erika Veiga**

Specialist in Regulation and Health Surveillance, International Affairs Unit, ANVISA. Pharmacy-Biochemistry Graduate, Faculty of Pharmaceutical Sciences, University of São Paulo. Master in Bromatology, Faculty of Pharmaceutical Sciences, University of São Paulo. Law Graduate, University of São Paulo. Ongoing Master in Bioethics, University of Brasilia.

**Sangeeta Shashikant**

Sangeeta Shashikant is a Legal Advisor to and Coordinator of Third World Network Office in Geneva. She actively follows negotiations pertaining to intellectual property and public health that takes place in the various international organizations in Geneva. She
has also written extensively on discussions ongoing in the World Health Organisation especially on the issue of influenza virus and benefit sharing in the context of pandemic preparedness and on the issue of counterfeit medicines.
Welcoming Remarks

Permanent Representative of India, His Excellency Ambassador Gopinathan Achamkulangare

Thank you very much Ambassador Matjila for those warm words of welcome to which I would like to add my own to all of you for responding so enthusiastically to our invitation.

Medical products of compromised quality, safety and efficacy, QSE, for short pose significant health risks and represent a serious challenge to global health. The treat from them is growing particularly in poorer countries with weak regulatory mechanisms and poorly monitored distribution networks. In spite of the gravity of the problem, the lack of reliable empirical data on the prevalence and impact of substandard spurious falsely labeled counterfeit and falsified medicines hinders decision making processes and result oriented plans of action. No doubt the global community has had a long standing interest in combating medical products of compromised QSE.

Dating back to the 1988 World Health Assembly resolution 41.16 however; it was only earlier this year that the World Health Assembly decided to set up and Intergovernmental Working Group to examine the role of WHO in ensuring the availability of quality, safe, efficacious and affordable medical products as well as the role of WHO in the prevention and control of medical products of compromised QSEs.

The Working Group will also examine the relationship of WHO with the international medical products anti-counterfeiting task force or IMPACT which has been in the center of many acrimonious debates in WHO.

Access to medicines is a key element in our goal of full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, ‘Right to health’ for short. Access to medicines is influenced by several factors such as availability, pricing, health delivery systems, intellectual property encumbrances, health insurance schemes and demonstrates health regulations.
For the poor, price can be an absolute barrier to access. Access to medicines is not possible unless affordability bridges the gap between availability and access. The deliberate confusion created by some interest groups of by conflicting the concept of counterfeiting which has a specific meaning in relation to intellectual property law, with issues concerned with the quality, safety and efficacy of medicines has further confounded the issue.

The Doha Declaration on Public Health in 2001, rightly clarified that the TRIPS does not and should not prevent members from taking measures to protect public health. The declaration stressed the need for effective use of intellectual property regime and if the flexibility in the TRIPS agreement for public health objectives.

What causes us concern is that simultaneously efforts are being made to circumscribe the very same flexibilities which the Doha Declaration extolled and that unilateral trade and political pressures are being brought to bear on countries which use flexibilities such as compulsory licensing. And they have serious concerns about the numerous seizures of generic drug consignments at some ports in the European Union, which have resulted in a denial of access to efficacious and affordable generic medicines to several developing countries including the least developed countries.

We are further concerned about the TRIPS-Plus trends initiated by some developed countries in free trade agreements, multilateral organizations and pre-lateral agreements like the Anti-Counterfeit Trade Agreement or ACTA.

The Special Rapporteur on the Right to Health, whom we have the privilege of having in our midst today, in his report of the Human Health Council last year has highlighted that such TRIPS-Plus initiatives impede access to medicines, circumscribe the flexibilities available in the TRIPS agreement, negate they Doha Declaration on public health and nullify many of our collective efforts to achieve the Millennium Development Goals.

As brought out eloquently by the Special Rapporteur in his report, while access to medicines is a public health issue, no discussion can be complete without addressing the related question of intellectual property rights. IPRs have a direct impact on access to medicines and the right to health since they are connected with pharmaceutical products.
There is no denying that we are committed to respecting our TRIPS obligations however; the closest choice we have to make is whether IPRs should be a part of the problem or should become part of the solution.

This seminar which Brazil, South Africa and India have the privilege to organize intends to look at current challenges and long-term solutions to address the issue of falsified and substandard medicines.

It also seeks to enhance the understanding of the challenges posed by medical products of compromised QSEs and their impact on public health. To help identifying positive options and concrete solutions for improving access to quality, safe, efficacious and affordable medicines and to discuss concrete policies aimed at discouraging production and trade of medicines of compromised QSEs.

We are indeed privilege to have a panel comprising the Special Rapporteur on the Right to Health, international legal experts, health professionals, civil society and most importantly a discerning audience.

We hope that the presentations and discussions that follow will provide constructive inputs for meaningful discussion and further consideration of these issues during the Intergovernmental Working Group meeting on QSE scheduled for December.

Two words in the end, firstly we had invited the India Pharmaceutical Alliance to be present here and make a presentation, but unfortunately for reasons beyond our control they have not been able to do so. They have sent us a presentation which we are making available at the back of the room.

Just to introduce the subject let me mention that, generic drugs are an inseparable element in the metrics of access to medicines. Over 95% of WHO’s list of essential medicines are generic. To have a comprehensive discussion at the seminar we had invited Mr. DG Shah, Secretary General of the India Pharmaceutical Alliance who also I think is currently the president of the International Association of Generic Manufacturers. The umbrella organization which, the IPA is the umbrella organization of India’s leading generic manufacturers.
According to a UNITAID’s study released last month, Indian generic manufacturers supply more than 80% of donor funded AIDS medicines to developing countries. The Médecins Sans Frontières figures tell a similar story. As I have said early Mr. Shah is unable to join us but has sent the presentation, copies of which are available at the back of the room.

On a personal note, I want to convey my apologies not only to the Ambassadors of Brazil and South Africa and to the panelist and all of you in advance because I have to now go and subject myself to torture in the Committee of Elimination of Discrimination against Women, so I have to leave, leave you in the safe hands of the Ambassador of Brazil and South Africa.

Thank you very much.
Permanent Representative of South Africa/Chairperson, His Excellency Ambassador Jerry Matthews Matjila

Ambassador, thanks for those opening remarks. I am sure the audience appreciates the context and the main reasons why we convene this. Now to break the India rhythm, I am not going to ask Grover to take the floor. I am going to make a few remarks and then I will introduce the panelist.

It is a special pleasure to be here, as combating falsified and substandard medicines is very relevant to South Africa and to Africa. I am therefore hoping that the outcome of our deliberations today will include innovative and sustainable solutions to the challenge of falsified substances as medicines. And I will go further and argue and urge all of us to extend remedial strategies to include “in vitro” diagnostics and related devices.

South African is faced with a terrible burden of diseases: HIV/AIDS, TB and other communicable diseases, non-communicable diseases, injuries and violence. Coupled with this, there are unacceptable levels of unemployment and poverty. The latter impacts directly on social determinants of health. This vision is further aggravated by the global economic crisis. Does this means we must moan or despair? I mean to say it very emphatically: no. Access to health care and essential medicines is a human right.

The government of South Africa has identified four health-related goals for the next five years: 1) increasing life expectancy; 2) decrease in maternal and child mortality; 3) comparing HIV/AIDS and TB; and 4) strengthening health care system. South Africa has also made commitments to introduce a national health insurance. I do not know who is going to fund it.

Transcript not revised by the speaker.
A common threat running through all these goals is the access to medicines. Strengthening the primary health care approach has been identified as one of the strategies to meet these goals.

Three years ago we celebrated the 30th Anniversary of Alma-Ata Declaration, which not only advocated for the strengthening of health systems for the primary care approach, but also: i) call for equity and social justice; ii) emphasize the importance of prevention; iii) acknowledge the importance of the Social Determinants of Health; and iv) advance the notion of expenditure on health as an investment rather than consumption. These principles still hold true today. Health for all and social justice imply access for the rich and the poor, access for rural, access for peri-urban and urban citizens, developed in developing countries alike.

Illness is not invited nor can it be wished away. It often strikes at the most inopportune moment. Our democratic principles, and our core values of Ubuntu, our commitment to people’s first principles implies that every citizen must be treated with dignity and in the case of medicines, must have access to essential medicines.

Pharmaceuticals are a significant cost-driver in healthcare in our continent. Cost containment efforts are a reality in most countries including our own, and health care budgets are squeezed. Affordability of medicines is therefore critical. Sharper instruments are necessary to assess affordability medicines and to ensure sustainability of services. To mitigate these challenges, South Africa adopted the pro-generic medicine policies as early as 1996, two years after democracy. We also amended the relevant piece of legislation to facilitate implementation of TRIPS flexibilities we all fought so hard to attain.

Our region is currently engaged in efforts to harmonize regulations of pharmaceuticals, improve medicine procurement practices, strengthen domestic legislation to enable implementation of TRIPS flexibilities and strengthen human resource capacity. Key is the need to implement TRIPS articles 31b, in a manner that benefits countries with little or no manufacturing capacity. Falsified and substandard medicines compromise these noble efforts.
Combating falsified medicines is not an easy task as we all know. It is the right thing to do anyway. There are opportunities too with a joint obligation to society, to ensure availability of safe, efficacious, quality and affordable medicines all of us.

We have an obligation to society to deliver the right medicines at the right time with the right prices. We have an obligation to make our sick society informed of discussions regarding their choices.

The demand for health care is infinite and therefore requires privatization. In today’s exercise we need to identify the three following; essentials must do’s, expected to do’s and lastly desirable can do’s. We hope that, as the Ambassador of India was saying, our deliberations will be fruitful in tackling this program.

Now I have managed to break the Indian rhythm, so I am with your support, I would then like to start to introduce the panel one by one. The Ambassador of India has already given to you sort of who’s around the table. We tried to look at the broadest participant of panelists from different regions, different expertises in dealing with this issue and I am so delighted that most of the colleagues are here, Ambassadors representatives are here also.

Now, the first panelist and I think we are on time, is Mr. Anand Grover. Mr. Grover is the Special Rapporteur on the right to the enjoyment of the highest attainable standard of physical mental health, appointed by United Nations Human Rights Council, a practicing lawyer in the Bombay Higher Court and the Supreme Court of India. He took up his function as Special Rapporteur on the 1st of August, 2008. Mr. Grover is a Director for the Lawyers Collective HIV/AIDS in India, having office in Mumbai, Delhi, Bangalore, which he co-founded in 1981 with Ms. Indira Jaising. The Unit dealing with HIV/AIDS was established in Mumbai in 1998.

He has a very illustrious CV, so it will take me a couple of hours to read it through. I have a great pleasure therefore asking Mr. Anand Grover to address the panel.
Mr. Anand Grover, Special Rapporteur on the right to the enjoyment of the highest attainable standard of physical mental health

Thank you very much, the Hon’ble Ambassador from South Africa. I don’t have a prepared speech; neither do I have a PowerPoint. The Honorable Ambassador from Brazil was kind enough to invite me on Monday when we were together in another meeting. As usual I could not say no to her. I agreed to her suggestion to address this meeting, and frankly I am very happy that India, Brazil and South Africa have taken the initiative to hold this meeting on falsified medicines. In fact I have been prompting them on a number of occasions to actually take this initiative. So I am happy that this initiative is actually taken off in Geneva. As I happened to be here, I am able to have a conversation with you. I want to put some issues before you on falsified medicines. Hopefully there would be a lot for interaction on this issue.

As you know the Special Rapporteur on the Right to Health, has got a long title. I don’t know why they love giving long names but I would hazard a guess and venture to suggest that it must have been Indian lawyer who had a hand in this formulation. But Excellencies I don’t represent India, I am an independent Rapporteur, It is in that spirit I am making these remarks.

There is paucity of time. So I don’t want to take too much of it. Let me make a few remarks.

Internationally, the right to health has been recognized as an enforceable right, but as you know, historically, in contrast to civil and political rights, which are immediately enforceable, economic social and cultural rights are progressively realizable. With respect, I would submit that this artificial distinction was born out of cold war politics, a modus vivendi arrived at between the so-called socialist states and the so-called capitalist states. Be that as it may, this artificial distinction has been torn asunder by domestic courts of, India, Brazil, South Africa, significantly the very countries that have taken initiative to hold this meeting today. The right to health in the IBSA countries and a host of others in Asia, Africa and Latin America is immediately enforceable. Unfortunately, the right to health is not recognized in some domestic jurisdictions. Of note is the United States, where a lot of people agree with the notion of the right to health, but as you know, the government and courts do not recognize it. I hope that this will change in the coming decade.
Coming back to the main issue of falsified medicines. I must tell you that we had a meeting on Monday. At that meeting, there was a question raised by a participant whether access to medicines is part of the right to health. There is no doubt and cannot be a doubt that access to medicines is part and parcel of the right to health, internationally as well as domestically. In that context, obviously, falsified or counterfeit medicines are a very important role in that sense that if you have so many counterfeit medicines they will impact the right to health adversely.

But I want to draw your attention to the fact that the debate on falsified medicines has started because there is a push, as the Honorable Ambassador from India said, to conflate or confuse counterfeit or falsified medicines with genuine generic medicines. You have seen the examples of that.

But I want to take you back. Please appreciate the whole issue of TRIPS and TRIPS-plus. In 1995, when the TRIPS Agreement was signed, a large number of governments, including the Indian government, thought that, and I say this with utmost respect, all the troubles are over. They thought, “We have signed the TRIPS Agreement and now we don’t have to think about it anymore.” Why were we wrong? Why was the Indian government wrong? Because, they didn’t realize that, and I want to emphasize this, the MNC pharmaceutical companies have always had a very long-term agenda and the agenda is to have the same patent law, the same intellectual property law, all over the world, whether you are in the US or in India, you must have the same law. By getting the developing countries to sign the TRIPS Agreement, they had only achieved part of their agenda. The rest of it still had to be fulfilled. That is why after the signing of TRIPS, there has been a push for TRIPS-plus measures, and it was only much later that we realized the game of the MNC pharmaceutical companies.

They could not do achieve the TRIPS plus agenda in the TRIPS Council. So they have resorted to bilateral and multi-lateral Free Trade Agreements (FTAs). All the FTAs, whether US, European or Japanese, are all pushing for TRIPS-plus measures. Why? This is the question that needs to be asked. It actually helps us to be very honest and candid. What is the purpose of having these TRIPS-plus measures? Pertinently, all the FTAs have the same things, patent term extension, patent linkages and data exclusivity, enforcement measures, investment measures, arbitrations tribunals for the breach of the FTAs etc. These provisions only help a selective group of MNC companies to make super or unconscionable profits. If the profits are unconscionable, why do we countenance these measures? For example; as we have discussed at another meeting on Monday this week, what are the profits that have been made by these MNC pharma companies, are they reasonable profits? These are monopolies in a free liberalization era. Monopolies are antithetical to liberalization but they are very much around. What are the profits that they make? Does anybody know whether they are 10%, 20%, 100% or 1000 or 5000%. The
MNC pharmas don’t tell you how much profits they make. So studies have been done in the United States to find out. They show that to get a blockbuster drug (from a few candidates to a successful one on the market), it can cost anywhere from 800 million USD (according to the Industry study, Tufts study) to 200 million USD (Congressional Budget Office study) to 100 million USD (Public Citizen study). Most of the companies do not innovate, but have very good marketing skills start making money in the first year itself. Take the example of Gleevec, an orphan drug invented with funding by the National Institute of Health, ultimately marketed by Novartis AG. For clinical trials it must have cost them less than USD 400 m USD (taking the high-end of the studies figure). It appears from the figures that in the first year turnover for Gleevec alone for Novartis was 1 billion USD. This is the situation that you have.

Pharmaceutical companies are pressurizing, I use the word very advisedly, governments of developing countries to get FTAs with TRIPS-plus provisions adopted. There are a lot of studies done which show such pressures were used even in the least developed countries, in West Africa, which adopted TRIPS-plus measures before 2005, though as you know they have to be TRIPS-compliant only in 2016. This is the state of affairs.

So what we are looking at? This is a political issue. Let me say it very clearly. The whole purpose of the MNC game plan is that generic industry should actually be humbled. India happens to be the home to the largest generic industry in the world. They supply, according to the latest study, about 89-93% of the anti-retrovirals to the developing countries, which are funded by the Global Fund on HIV, TB and Malaria.

The India-EU FTA is the most dangerous thing in this context. If the EU succeeds in getting what they want, we can say good-bye to a lot of the access to medicines in the developing countries and I want to note this because last week they have concluded some of the parts of the agreement. Unfortunately, in this the era of transparency the India-EU FTA negotiations completely lack transparency and participation. The only participation is from the industry who would be the beneficiaries under the Agreement. This is antithetical to human rights. I told a representative of the European Commission the other day that they very good at promoting human rights but when it involves their pharmaceutical companies, Human Rights are the last thing on their agenda. But unfortunately, to be very honest, the European Commission does not even listen to the European Parliament. It appears that the European Parliament has actually cautioned the European Commission about going for TRIPS-plus measures in the developing countries but to no avail. There is a recent study by a European NGO which outlines that the India-EU FTA is actually being goaded, aided and abetted, and again I am using my words advisedly, by the European industry and sections of the Indian industry who are pro-multinational. No other people have any role in it. It is a case of a complete lack of transparency and a complete lack of participation.
So this is the context. But what about falsified or counterfeit medicines? Is there a really a huge problem of falsification of drugs? Or are we actually responding to a red herring? I think it is very important for us to respond because deliberate confusion has been put forth and we can see this in a country like Kenya. Every time this debate takes place, you would be surprised to know, very coincidentally, I would imagine, the Kenyan press is full of those reports of a large number of seizures of falsified medicines. Are there any studies to tell us the extent of falsified medicines? Yes, there are. Fortunately, the Indian government, was prompted into doing a study on spurious drugs in India. It was imagined to be a huge problem. What does the study show? You would be shocked.

According to this official study of the Government of India\textsuperscript{2}, it was revealed that in the respective years the percentage of spurious drugs: substandard drugs, were as follows respectively, 2003-04 (6.3%: 0.3%), 2004-05 (7.5%:0.29%), 2005-06 (7.3%:0.35%), 2006-07 (6.4%:0.16%). Now does this indicate that it is such a huge problem that you have to have an international agreement on it? I would respectfully submit that you have to look into these issues, who are we aiding, who are we supporting? According to the Kenyan activists, the Kenyan Anti-Counterfeit Act directly impinges, and adversely, on the right to health. And we have to stop such laws. I am an independent Special Rapporteur. Fortunately, I can say what I want to say. Fortunately, I have based my statements, though they may appear to be a bit extreme to some, on solid data. In my first report on TRIPS, patents and access to medicines where I have outlined how developed countries, are actively pursuing TRIPS-plus measures which directly impact the rights under the international covenants because it aids and helps their multinationals companies and of course it helps some of the local industrialists but not the people of the developing countries. It is our duty to ensure that the rights of people of the developing countries, particularly their right to health, is respected. This should not become an empty formality and certainly should not be sacrificed at the altar of development with interest of only few being satisfied. Thank you very much.

\textsuperscript{2} \textit{Report on the country wide survey of spurious drugs}, Central Drugs Standards Control Organization, Directorate of Health Services, Ministry of Health, Government of India, 2009, New Delhi
Understanding health risks related to falsified medicines and the role of health authorities in preventing them: the South African Experience

Mandisa Hela, Manager, National Regulation Authority, Department of Health, South Africa

His and hers Excellencies, all dignitaries, all protocol observe, friends and colleagues and I see many friends in the room. I was asked to share the South African experience on this important topic and I think it is something that is worth pondering and thinking about. Because falsified and substandard medicine in the context of public health, whether it is 10%, whether it is 1%, whether it is 2%, it is still important. We can not afford to lose one life, one life is one life too many. However, having said so, we do subscribe to the notions that we express by the previous speaker that the true flexibilities, access to health care and conflation of IPR issues with public health issues is a no.

Nevertheless, from a public health perspective, I repeat one life lost is one too many. That is the outline of the presentation, what are falsified medicines? It is an old problem. Attribute is a crook physician in the first century, AD who noted the thing with the remedies that they used that day. That this high valued thing called medicine was falsified as far back as then.

In South Africa we have defined it in legislation and I have put counterfeit medicine in parenthesis, deliberately because probably, we need to pause and think whether we should continue calling it counterfeit medicine or we should call it falsified medicine as a principle, in order to do away with the confusion. But I can not change the law, that is the way it is written and it was written many years ago. It means a medicine in respect of which a false representation has been made with regard to its contents, its identity or source, by any means including its labeling and packaging and I will expand on this as I continue with the presentation. It implies we are fully misleading.

What is a source? In our context source includes the manufacturer, the active pharmaceutical ingredient which we call API manufacturer that is the actual chemical, the

3 Transcript not revised by the speaker.
country of manufacturing, the registration certificate holder, or license and certificate holder, who is the packer, who is the final product releasing laboratory. All of these types are important because that is part of who is the foundation of registration of the medicine, which is part of the foundation of market authorization of a medicine. However, this definition does not include good manufacturing practice violations, things that will happen any day through mistakes, through carelessness and through not willfully misleading.

What is deliberate falsification in our book? It is things that do not have an inactive; it is things where we have substituted something with something else. I will show you an example shortly, of incorrect levels of API and so on. And people do these things willfully to gain money and to dupe the public.

There is also falsification of the regulatory process, which is not actually a violation, but outright falsification. People will use alternative or additional sources of API without an authorization by the regulatory authority, people will change the formula or manufacture and procedure of actives without authorization, people will change recipients at their will without authorization and where records of the data on which registration is based are suspect.

What are the health risks? From a public health perspective, it obviously leads to increased morbidity and mortality, due to ineffectiveness, toxicity, instability and the list is long. Obviously, it compromises health policy because we are discussing access to quality, effectiveness and safe medicines and if you do these things our health policies will be compromised because we are married to that as government. Then we have to look for other alternatives, often far more expensive, we know the cases where there has been substandard and falsified malaria treatment for instance and people have, we have had to move to commodities which are far more expensive than what we used before with the Chloroquines and we definitely just cannot afford it from a developing country perspective. It leads to loss of confidence in the health system and health care professionals because I mean, I am citizen and I go to a provider and I get a medicine that does not make me better, in fact makes things worse for me. Do I still have confidence in that system; will I have confidence in that health professional? I cannot and therefore I will question who is the regulator in this country, how come there are
things like that in the market, what is their role, healthy forsaken their stewardship on my behalf?

Obviously, the increased burden on regulators, health workers, customs, police and everybody that is involved and most importantly some of these things that are done have a wider impact on the population. For instance, if we compromise the efficacy of vaccines or antibiotics, that has an impact on the health of the community. And lastly, there is an adverse environmental impact because these things are often disposed in a very compromising way that has an impact on the other determinants of health, such as safe water, equality and so on. As for citizens, they could be sick for longer, they could need to extended rehabilitation, could be deaths, increased adverse events that would otherwise be very minimal, and then economic loss for the patient and their family, out of sickness and out with their loved one, who is the breadwinner.

Now I want to speak a little bit about what I meant by a regulatory related process falsification. This may result in changes of the physic-chemical characteristics of the active ingredients. The particle size, the melting point, the crystal form, all of those things that are listed there, may have an impact on quality and safety. They may have an impact on whether the drug is dissolved in the gut and is absorbed as it should be.

Secondly, there may be a compromise of the integrity of bioequivalence with the innovative product. Let me explain what I mean there. When we register a generic we will compare its bioequivalence with an innovative product and therefore generic companies do not have to do clinical trials to establish anything. That has already been established and we can not subject people to an unnecessary clinical trial - that is unethical. And therefore we will take the data that the generic company prints, compare it with what we know from innovator publisher, and then see whether there is equivalence. And that equivalence determines the rate of, and extent of absorption, the rate and extent of release of the API. Now, if you compromise these things, there is going to be a little bit of a problem willfully. And therefore these things, that are done willfully, do compromise the integrity of generics and generics are absolutely beautiful drugs, absolutely good drugs, but if you do a little bit of little things behind the back, it does give a wrong impression about generics which should not be.
The role of health authorities is to uphold the constitution, as the first speaker has said, including the bill of rights. He has spoken at length to that, as well as, access to information creating and enabling environmental policy and legislation, responsiveness to needs and investing in human resources.

What are the further rules of the authorities? Now I will speak a little bit about the South African experience. We will only allow into our market medicines that have been registered by our own authority. We license manufacturers including the exporters and importers, distributors, wholesalers, pharmacies, everybody.

There is a vertical distribution of medicines from manufacturer or importer to the wholesaler, to the distributor, to the pharmacy, to the hospital, patient and it does not jump a step. We do not allow import and export by wholesalers, because we have found that is where a lot of diversion and untidy things happen.

We also do not allow a wholesaler to sell to another wholesaler, because we lose the track of where this medicine that went from point A supposed to go to point C and has gone in between. We have only four designated ports of entry for the importation of medicines, which makes it easier for us to manage them. We also have in transit shipment of medicines and raw materials to other countries in the region and that is allowed.

It needs collaboration between customs, the regulator authority, law enforcement officers, who track the consignment. We do allow bonded warehouses, where things can be kept that are meant to be in transit, however, in a bonded warehouse there should not be any manipulation of stock, no repackaging. We have somebody called the responsible pharmacist, who is controlling the supply chain throughout these multiple entries. This person is licensed, as such by the professional body, which licenses professionals and therefore if this person does anything wrong, he or she will be held accountable.

We introduced a transparent pricing system, whereby it is published single exit price for every product, whoever in the country knows that this medicine that is called A should be sold at such and such a price. It is very clear and transparent and there is a register for that. Of course people can discount a little bit below that however, if you are now found
something that should have been $5 according to the register that is $1 you should to begin to ask questions, where is it coming from and why and we have to got reasonable inspections.

Now, we also have relationships and a formal Memoranda of Understanding with the police; the special investigations unit of the Department of Trade and Industry, Customs, Justice. Moreover, we have Memoranda of Agreement with other stringent regulatory authorities outside South Africa, as well as regionally. We have a strong cooperation with WHO, pharmaceutical industry organized formations as well as the professional bodies, as mentioned earlier.

The types of falsification we have encountered are through imports; some things are repackaged and manufactured locally. There is diversion of suspect consignments to neighboring countries, which have weaker regulatory systems, and then they come back to South Africa, or are exported elsewhere, with a stamp that says they have gone through South Africa.

We have found that there is diversion of suspect goods with two countries including our own for trade zones including our own because the customs regulation is a little bit weaker than in the other ports. Passengers carry things in suitcases; people will hijack delivery vehicles with expired stock that is going somewhere and redo something to it.

We have had a few examples in South Africa. In 2004, the famous case, which was a store room that contained everything that could be wrong. There were innovative products that were stolen, duplicated and repackaged. They were outright falsified items that had been manufactured, in an approved site in India, repackaged in Pakistan and delivered for South Africa via Lesotho that has very little regulatory capability.

A similar case was called Valli and fairly recently we had sample cases of a which is a fairly inane, little ointment that was shipped to South Africa, the culprits were captured and arrested then they reshipped sample to Lesotho, a neighboring country and diverted to South Africa and sold to countries.
Fairly recently, we had the case of Grantham, where the customs staff and special investigations people found that these people had brought in a packing machine and they alerted us and we all worked together. In the premises we found that the active was salicylic acid, not acetylsalicylic acid which is what the powder should have contained.

As there are many cases, I will not go through them all. In 2009, and this does not happen with pharmaceuticals, but only last year we had a herbal medicine that was adulterated with sibutramine through mainly Internet sales which we heard about this week. And as Abbot has withdrawn, there have been the sale of sibutramine globally and there is a supposedly inane herbal medicine for slimming, for women being adulterated with sibutramine.

I just cited an example of falsifying the regulatory process. When we go to verify, by equivalence data during a clinical practice inspections, you get what you want to look at the raw data on the basis of which you made the decision to register and to find that the source data is not there, we have been told it has been swept away during a monsoon, it was destroyed in a fire, it was kept many miles away, we say okay bring it, it comes three months later, generated by the same analyst, using the same pen and this was a study that was supposed to be taken three years, so there are things that people do.

We still have identified a couple of gaps. Generally, we do not pay attention to exports, as we all assumed that. The responsibility for quality resides with the recipient or the importing country. Can we do more? In our situation, we are aware that our neighbors do not have very strong regulatory capacity and we still have to do these things.

I think we need to pause and think. Penalties are often not deterrent. Internet sales and one thing that bother me is that, we are active in our approach, instead of being proactive. And, there is adequate funding and human resources and most importantly in adequate education of the public and health professionals. Those African children should be kept healthy.

In conclusion, I think we need the multiplicity of complementary initiatives. I think we need a common accepted and understood definition of falsified medical products. That is a key. This must be globally understood and asserted, it is a public health issue, nothing
to do with IPR. We need to strengthen surveillance and have information sharing and other systems. Strengthening regulatory systems and have resources to do that. I want to illustrate a few things on.

I am sorry; I must show you this one. Thank you. Now that is a picture of how these things are manufactured and those are the current powers alluding to and those untightened and unhygienic conditions or registering script, those from South Africa will see that, that looks like the genuine Grantham the one that they put acetylsalicylic acid in and that is the heat and ventilation and air conditioning system and these things. That is where they are discarding the original packaging and most importantly the waste disposal and what does it do for the environment. Through cooperation with customs we have found that there are people crooks that enter the country every three months to do watch and we have begun to trail them and working together we are beginning to catch them.

Thank you.
Good morning, it’s a pleasure to be here with you today. I first want to thank the ambassadors. I am greatly honored by their invitation.

The Special Rapporteur, Mr. Grover, presented an excellent overview of the situation in this area, then we had a wonderful presentation regarding the specifics of the problem with substandard medicines, from South Africa. I think maybe the most important single thing I can note at the outset of my presentation is simply the audience in this room. I know many of you personally. Here in Geneva I wouldn’t say it’s a collection of friends because there are too many interested stakeholders in the room to suggest that, but certainly a group of expert colleagues representing some of the greatest levels of expertise in this area. So there is very little I think that anyone on the podium can tell the people in this room that they don’t already know. I think that the objective then is to bring together some concepts and philosophical premises of the discussion we are going to have and that is what I will try and do in a few brief minutes this morning.

I think we can presumably start with the premise that no one on the podium and no one in this room is here to promote the availability of substandard or falsified drugs. We are all here with a shared common objective to provide populations with high quality safe and effective medicines and we are really here this morning discussing some of the details about how best to accomplish that objective. We know that each of the intellectual property rights used to regulate the pharmaceutical sector has both restrictive and permissive characteristics. In every country with a long history of implementing intellectual property laws in the pharmaceutical sector there is a history of balancing in this area.

New medicines are subject to the grant of exclusive rights in patent allowing an originator pharmaceutical company a temporary right to exclude others from entering into the market. But it is open to potential competitors to challenge the validity of the
As recognized in the TRIPS Agreement, intellectual property rights are private rights. They are granted to a person, in most cases they can be granted to a corporation. It is the responsibility of that person to enforce their intellectual property right through an action in the civil courts or as appropriate through an administrative authority. The process of enforcing an IPR in a civil court typically involves a defense by an alleged infringer. This allows the judge or the administrative authority to study the evidence and balance the interest of the parties. In the case of civil enforcement of patents, in the case of a challenge to the validity of a pharmaceutical patent, a judge may decide that it should not have been granted in the first place. With respect to each form of IPR there is a legal contest between the person asserting an exclusive right and the person against whom the right is invoked. The results of the contest are judicially determined based on evidence.

With respect to the TRIPS Agreement there were two sets of interests involved: that is, mercantile business profit-oriented interests and, in the pharmaceutical area, public health interests and objectives. The results of the TRIPS Agreement were transformative in the sense that each country was required to adopt and apply a fairly harmonized level of intellectual property protection, including pharmaceutical patent protection. The TRIPS Agreement was also transformative in that it introduced a new type of border regulation into the GATT-WTO trading system. One in which IP right holders would be entitled to prevent the entry of certain IP protected goods into free circulation by patent, the basis on which it is granted. Pharmaceutical companies that seek to abuse their rights are subject to remedial action by competition authorities. In all events, when the patent term expires generic producers can enter the market. The brand names of drugs are protected by trademarks, but generic producers may market the same drug under a different brand name. There is an international nomenclature system, INNs, that provide a generic identifier that is open to everyone for their use. National and sub-national jurisdictions adopt generic substitution laws to control the market power of the pharmaceutical brand name owners. Pharmaceutical industry copyright owners can protect unique forms of designing and explaining their products, but the science in medical literature, including drug information leaflets, is not protected by copyright against third party use. Regulatory data protection may preclude registration by a generic drug maker for the same drug for a limited term, but when the term expires the generic producer may rely on the originator regulatory submission at least in the sense of seeking approval for a bioequivalent drug.
initiating procedures with customs authorities. Mandatory border measures were limited to trademark counterfeit and copyright pirated goods. The TRIPS Agreement also allows each country to apply its own principle of exhaustion.

It is fundamentally important to recognize the difference between IPRs regulation and trade regulation that was previously embodied in the GATT. When a customs agent applies a tariff rate to an imported good, or limits an import based on a quota, he or she is acting on behalf of the government with a governmental interest. In the absence of corruption, the tariff rate is relatively transparent and fixed by law. A quota is a matter of internal customs administration.

Intellectual property rights are different; they are invoked by private right holders, including for our purposes pharmaceutical originator companies. When the originator company lodges a complaint based on an IPR with a customs authority, the customs authority has limited capacity to determine whether the IPR is valid and should be enforced. The customs agent is typically acting on the basis of a piece of paper, showing local registration of an IPR or some reference to an IPR registration number, along with a description of the pharmaceutical product. Although the TRIPS Agreement says there must be sufficient evidence to support a seizure, customs authorities do not have the time, training or capability of investigating an IPR claim on which a request to act is made.

Significant implications flow from the way border measures are designed to operate. It is relatively easy for an IPRs holder to block the importation of drugs at the border, at least temporarily, and to shift the financial and administrative burden to a generic producer to challenge the blocking before a court or administrative authorities. In other words, IPRs holders have a power to control the importation of products by potential competitors which is not available to those without IPRs protection.

Touching again on something that Special Rapporteur Grover mentioned before, the problem with the TRIPS Agreement and pharmaceuticals is that we cannot assess the situation in a vacuum. The pharmaceutical industry, like most industries, is highly competitive. The actors with the power to do so fairly consistently have demonstrated a willingness to use IPRs to obtain commercial advantage beyond the legitimate scope of
their rights. At the macro level, shortly following entry into force of the TRIPS Agreement, a large group of originator companies banded together to sue Nelson Mandela’s new government in South Africa for authorizing parallel importation of medicines. A practice which every genuine expert in TRIPS, including those at the WTO Secretariat, opined was permissible. Developing countries are routinely threatened with trade sanctions or withdrawal of investment when they exercise or threaten to exercise rights to grant compulsory licenses clearly allowed under the TRIPS Agreement. The government of India was sued for violating the TRIPS Agreement when it amended its Patents Act, when it was apparent to any knowledgeable observer that a suit based the TRIPS Agreement could not be pursued as a matter of the Indian constitutional treatment of treaties. But these are macro problems at the international level. They are only part of the reason to have concern over the counterfeiting issue.

As pharmaceutical originator companies face key patent expirations over the next several years and have not found replacements for their new drug pipelines, they are aggressively pursuing market share in the generics sector where they have previously been willing to cede ground to developing country producers. A recent study by the European Commission Competition Directorate found what had previously been found by the Federal Trade Commission in the United States, that originator companies are routinely using strategies involving weak patents to artificially block generic companies from entering the European market, just as those strategies were used in the United States. Now more attention is being paid to emerging markets where incomes are rapidly rising. A marketing strategy that is routinely being used is to cast doubt on the quality of drugs being offered by developing country producers, both those drugs manufactured locally and those imported from countries such as India. This use of negative marketing strategies isn’t a secret. A year ago at the annual meeting of the International Generic Pharmaceutical Association, this was one of the most consistent concerns expressed by generics manufacturers, large and small, that is the use of negative marketing campaigns coming from the major originator actors.

The strategic use of IPRs arose again recently in the context of seizures of generic drugs in transit through airports in the Netherlands, and here I don’t speak entirely as a disinterested observer. As the program notes, I have been working with the Indian Government in consultations with the European Union on this matter. Again we had a situation where mercantile interests in IPRs were expressed as an overextended or
hyperextended view of the rights of patent holders. It was up to individuals and the policy community, those interested in access to medicines, to make strong objection. To the credit of the originator companies I would say that in reaction to those objections they essentially conceded that this was not something within the ordinary purview of patent holders, to seize generic drugs as they move through airports in transit. Commissioner de Gucht in talks in Brussels has recognized that this was one country acting essentially without the mandate of the European Union and undertaking these actions, and the latest draft of the ACTA in fact takes patents out of the border measures provisions. So are we are moving in the right direction in this area, but only because people were paying attention, and another effort at overextending the use of intellectual property rights protection has been brought back into balance. The international IP system is regaining its balance, we hope.

So we return then briefly to this issue of counterfeiting. I don’t think anyone really has an objection to use of the term counterfeiting in its specific historical context, which is the application of an identical trademark to essentially identical goods, and the right of protection traditionally afforded to a trademark holder in this area. As Special Rapporteur Grover noted, the problem is that efforts are being made to extend the concept of counterfeiting well beyond what we thought of as counterfeiting historically as a matter of intellectual property rights law. The draft ACTA isn’t an anti-counterfeiting agreement. It is an intellectual property rights broadly agreement. We see particularly, and I expect that Sisule Musungu will address this in detail, we see African legislation being introduced and/or adopted that takes the concept of counterfeiting and the concept of intellectual property rights protection far beyond anything that was contained within its ordinary historical context. That type of extended push is what causes the reaction to the use of the term counterfeiting, because it no longer means what we thought of as counterfeiting. It means a broad panoply of intellectual property rights which raise real potential problems for the protection of public health and the free movement of medicines in international commerce.

It does seem tempting to turn the issue of quality, safety and efficacy regulation over to the major and very well funded pharmaceutical companies because they perhaps have the manpower along with customs authorities to police certain parts of the market. But as a practical and real long-term solution, this is going to have very poor consequences for access to medicines in general. It is essentially turning regulation over to the regulated
industry. A lot of time, attention and money are going to be needed to build up regulatory authorities so that they can adequately deal with this problem. But I think it’s in everyone’s best interest, or at least in the interest of public health globally, to devote time and attention to that build up.

Thank you.
Thank you very much Ambassador. Let me also begin by thanking the three Ambassadors of India, Brazil and South Africa for inviting me to make this presentation. As Mr. Grover have also argued before that developing countries in particular should take leadership in defining issues around enforcement of intellectual property because these issues affect them and they should be in the leadership to do this. Today my topic might be a little broader than what I am going to say partly because of time and partly because of what other people have already said. I will speak about regulatory capacity and access to medicines in Africa and focus primarily on the Kenyan legislation and some of the developments going on in Africa.

The Kenyan Anti-counterfeiting legislation and other legislative proposals in the East African region has consistently come up in the ongoing debate both at WHO and in other forums. So let me begin by saying what is obvious, it is true, I think, that in the last ten years or so efforts to improve access to medicines in Africa have achieved quite a bit of success in terms of improving the situation. We have seen increased funding for medicines specifically and investments in health systems. We have also seen what I would call an enlightened approached to intellectual property rights. All these developments have made the availability of generic medicines more widespread and we have figures in some countries like Kenya where about 90% of the medicines, at least in the public sector, are generic medicines.

Overall, of course economic growth and development have improved the ability of people in many African countries to either buy insurance cover, which includes medicines, or to afford medicines out of pocket. This is important because we still have in Africa a situation where most of the population gets medicines through out of pocket purchases as opposed to public supply or insurance cover. The overall improvement in economic terms has therefore helped people be able to afford medicines. But the situation remains grim; according to the WHO for example, 72% of deaths in the African
region are due to communicable diseases compared to 27% in all other WHO regions combined. At the same time deaths related to non-communicable diseases are also increasing at a very rapid rate. So the situation despite the improvements remains grim. Therefore, the need for safe and affordable medicine in Africa cannot be gainsaid and the need to tackle, as a corollary, falsified, substandard, spurious and related medicines is a real challenge and that has already been illustrated by those who have spoken before me.

There are two approaches on the table for addressing this problem. The first approach is what I call the anti-counterfeiting approach to addressing questions around falsified medicines. As Ms. Hela already pointed out, the problem of ensuring access to safe and high quality medications is not new either in Africa or anywhere else. This at least in Africa has been a constant concern since the independence of these countries. In the recent past however there have been strong arguments which have been made by governments, some industry actors that anti-counterfeiting laws, and I’ll come to what that means shortly, are a better or an effective way of tackling falsified and substandard medicines. This approach using the terminology of anti-counterfeiting has captured the imagination of politicians and the general public, and as a result we are already seeing a number of legislative activity based on the anti-counterfeiting approach. We see this in Kenya where the law is in force, in Malawi where the law is being considered and Nigeria where the law is being considered, in Tanzania where there is regulations that are in force, in Uganda where the law is being considered, in Zambia where there is a draft law which might have passed already and in the East African community as a region, all these are based on a similar approach. Of course we have also seen the African group seeking action at the WHO in some cases along the same lines.

So what is the basic characteristic of the anti-counterfeiting approach that seems to have captured the imagination of people in Africa or those operating in Africa? So you will hear Presidents, President Museveni of Uganda, President Kibaki of Kenya, talking about anti-counterfeiting activities including particularly using examples related to medicines. What does this do? The basic characteristics of that approach and if you look at the Kenyan legislation which is the most clear of all of the laws in the region, is that it focuses on criminal enforcement of intellectual property including with respect to goods in transit. That is the first characteristic; the focus is on criminal enforcement. Secondly, unlike what the TRIPS Agreement does, there is no threshold for establishment of criminal liability. What do I mean? Under the TRIPS Agreement countries are required to
introduce criminal enforcement where there is intentional trademark counterfeiting on a commercial scale. Those are two important thresholds and they are thresholds for a reason. One, is standard rules in criminal law that you cannot be accused of a criminal act when there is no intention to knowingly commit a crime what lawyers call *mens rea*. Two, commercial scale, because the focus is on the people who are trying to make money, do business out of fraudulent activities. That is why the TRIPS Agreement has those two thresholds. The Kenyan law and other proposed laws like the East African Community proposed law do not have these thresholds because of the way counterfeiting is defined.

In fact the use of the term counterfeiting is intended to cover all form of intellectual property infringements including trademarks, copyrights, patents, plant varieties, and industrial designs, all of that essentially. Of course in relation to medicines, the biggest challenge relates to the inclusion of patents and that is a longer discussion which Fred Abbott has already touched. But that is an important characteristic of these laws. The anti-counterfeiting approach also designates health and regulatory inspectors as anti-counterfeiting inspectors. So the health and drug regulatory inspectors have an additional responsibility to enforce intellectual property, all the forms of intellectual property in cases where they might be related to medicines. That is another characteristic. And finally an important characteristic is that these laws introduce certain presumptions as regards evidence. So for example if an inspector makes an allegation regarding counterfeiting the law says that it is presumed to be correct until disproved. The general approach in criminal law is that you must prove a case against as someone, a prima facie case, before they are put to their defense. Those are the basic characteristics of the law. I will not go to analyze what each of those means at this point there is no time for that but I think that’s what we should discuss.

There is a second and different approach in the same jurisdiction, that is Kenyan for example and many of the other jurisdictions in Africa. This approach was used before the anti-counterfeiting rhetoric, and I use the word rhetoric, deliberately. This is not to suggest that people who are concerned with the proper enforcement of intellectual property are wrong, but I am using the word rhetoric to refer to cases where we are dealing with medicines. So as earlier noted the challenge has been there for a long time, we might have a bigger challenge because of population growth and all that but the framework, there was a framework to deal with falsified, substandard, and spurious medicines in Kenya before the Anti-Counterfeiting Act. There are at least 11 legislations
and I have left out about eight other legislations that have relations to addressing these problems, but just at least 11 legislations that existed before the Anti-Counterfeiting Act. The first is the Dangerous Drug Act, second Food, Drugs and Chemical Substances Act, third HIV AIDS Prevention and Control Act, fourth the Malaria Prevention Act, the Medical Practitioners and Dentists Act, Narcotic Drugs and Psychotropic Substances Act, the Penal Code Pharmacy and Poisons Act, Prevention of Organized Crimes Act, Public Health Act, Standards Act, Use of Poison and Substances Act. All these laws still exist in the Kenyan legal system, all of them provide for criminal sanctions for a wide range of activities related to falsified medicines or dealing with adulterated food, drinks including alcohol, all of that. This legal framework existed before and still exists.

A number of questions therefore arise in a country like Kenya. Does using the term counterfeit to describe all forms of IP infringement and as a rallying call to address health and safety questions help or hinder public health efforts to address falsified medicines. I think we need to think about this because the anti-counterfeiting approach, as I have suggested, seems to imply that anti-counterfeiting laws are a silver bullet to solving these problems and that all the other 11 legislations, in Kenya for example, are irrelevant. Two, if we look at the example of Kenya, is it a lack of legislation and criminal sanctions or there is another problem? As I said earlier at least 11 legislations with criminal sanctions were existing before the Anti-Counterfeiting Act. Does adding a single act with a few more criminal sanctions solve the problem? That is something we need to debate. Three, what are the regulatory implications of designating health and drug regulatory inspectors as anti-counterfeiting inspectors responsible for IP enforcement. If you look at the literature from WHO and others one of the problems that we face in Africa in this area is lack of human capacity, lack of resources. These people who are responsible for dealing with falsified medicines are already overstretched. What are the implications of adding an additional function to them when in fact the resources are going to another agency, they are not being added for them, they are going to another agency, what are the implications of this particular approach?

Finally, which ties to the first question, what empirical or other evidence do we have for example to determine that what more than 11 legislations could not achieve can be achieved by one legislation? Those are at least four broad questions that I think we need to think about when we are thinking about how do we solve this problem in Africa and
what is the right approach? There is a combination of approaches as has been suggested but we need to think carefully.

Let me finish by saying that in respect with the Kenyan law, there is a constitutional challenge to that law based on the definition. A number of HIV/AIDS activists have gone to the Constitutional Court and said to the court that by defining counterfeiting to include all forms of intellectual property infringement, the impact of that law will be to affect the supply of generic medicines which will directly affect their possibilities of living. So they have challenged on the basis that it will compromise their right to life. The Constitutional Court has made an initial decision on this question and has said it agrees with them and has suspended the application of law with respect to medicines. The court feels that the definition is so broad that it can be used against generic medicines and therefore the court believes that they have made a case that there is a possibility that their right to life will be infringed. Since that decision Kenya has changed its constitution. In the new constitution there are a range of new things that will be used to determine whether that law is constitutional. One additional thing is that previously Kenya did not have the right to health in its constitution. The new constitution has a right to health. The new constitution also has a range principles relating to legislation and public administration which will be used to determine whether the law is constitutional or not. I think in end if the Kenyan Constitutional Court finds that law as unconstitutional the implications are huge, the implications are huge both for the public health community and the intellectual property community. For the public health community there will be a public assumption that the arguments made about the government solving the problem of falsified medicines were not well founded and the public will lose confidence in the government’s ability to solve this problem. That is for public health people who might not have been involved in this law but they will be affected because in the public eye it is the government, it’s the same thing, whether you are public health or intellectual property is irrelevant. For intellectual property people the implications might even be broader. Efforts for intellectual property enforcement will be significantly delegitimized. That is already happening in Kenya because of what the Constitutional Court has said already. Thank you very much Mr. Chairman.
Access to Safe, Effective and Affordable Medicines: the MSF Experience

Michelle Childs, Director of Policy Advocacy, Médecins sans Frontières

Thank you Mr. Chairman and I would like to thank the Ambassadors of India, Brazil and South Africa for inviting MSF to speak here. What I have been asked to talk about is our experience as a medical humanitarian organization, primarily working in developing countries on access to, securing access to safe, effective and affordable medicines.

What I first want to talk about is the context. Then I will discuss our approach to securing QSE and also to try and pull out some of the experiences that we have had and witnessed in the countries where we work. I will also discuss a few of the challenges and end with possible solutions. Some of this is reflected in the speeches that we have heard before, so I will skip over some of this in the interests of time.

I think the first thing is really to think about the context in relation to access to medicines. Before 1990 most of the drugs were produced in Europe and then they were exported. Less than 5% of the drugs were generics.

Today we are seeing a growth of alternative supply particularly from China and India but this also has to be rapidly updated because we are also seeing production in African countries, in Uganda and also in Tanzania.

We are seeing the growth of the alternative pharmaceutical industry in developing countries. We are also experiencing the growth of generic prescription and its use worldwide, 50% of generic prescriptions are generics, but in developing countries we are talking about 80-90%. I think this is important because it is really a reflection of why we have this concentration and on how you manage QSE because it is a mixture of both the commercial and practical realities of these changes.

So you know against the background of a more complex environment what are we getting? Well, the benefits of course for us as an organization and for many developing
countries is that the generic production from India and elsewhere has provided us with low cost adapted quality assured generics.

We saw 80% of the antiretrovirals that we use to treat people living with HIV from Indian generics and it is not really just because they are lower price although it was Indian generics that lowered the price from 10,000 to initially 365 for the first line treatment and now it is much lower than that. But also, because they have adapted those medicines for the population of developing countries. They created the first fixed dose combination which combines many pills into one, so you can take one in the morning and one in the evening and they also created pediatric formulations because in the west you do not get many children with HIV. There are a lot of them in developing countries and there was no incentive for the big pharmaceutical companies to really focus on that. We still need more pediatric formulations but at least the generics started looking at this.

We also have the big movement of donors such as PEPFAR and the Global Fund and others coming in to take advantage of these lower costs and also to fund drug treatments. They also bring with them their own requirements for how these drugs are imported and stored. But it does also create real issues particularly for countries that rely on imports and have no or limited drug regulatory authorities. They have to deal with a number of different ways of importation and multiple donor systems and this is a real issue.

The WHO has said that there are only about 20% of countries who have fully operational drug regulatory authorities, 30% have none or very limited. We also heard about the conflicting interests here, I think both for the originator and generic drug companies, there is an interest in fighting fake drugs because it damages the reputation of their branded goods, but I think, they also have an interest in ensuring that there is a focus on criminal behavior rather than focusing on their own manufacturing and storage issues.

So I would also support what Professor Abbott said, that there is a real danger in handing over to the companies what should be regulated and the rules in this area, because they also have this conflicting interest. We have heard also that from the originators the use of the terms counterfeiting and IP enforcement is also used to limit generic competition.
From our point of view what is concerning about the IP enforcement measure is not just that it obviously have this affect of limiting generic competition but more importantly it skews the approach to dealing with quality and safety and efficacy and it also takes much needed resources from the problem to be either becoming patent police or trademark police. Now if you are looking at trying to source and supply medicines and to assure QSE, you really need to be looking at the whole of the circuit. MSF we do all of this which looks at the needs, looks the order, we’re involved in the procurement, the reception, the storage, the distribution and the dispensation which gives us an overview.

But what you actually find is that in a number of countries or in a number of approaches you have different organizations doing different parts of this and it can be actually very difficult to track and maintain the overall control. So what is our approach to QSE? Well, you know we take a public health approach. I mean our main responsibility is to ensure that the medicines that we provide and that we use in our programs are safe, of assured quality, are affordable and effective and that is particularly, because in a number of countries where we work, they have very weak or no drug regulatory authorities and so we have to take this responsibility.

We devoted resources and procedures to achieving this and resources are key here, you know we can talk about legislation, we can talk about magic bullets but actually it comes down to the reality of the resources that you put, such as, human resources and financial resources.

We have in practice limited experience of what people call fake or counterfeit medicines, as they are defined under the TRIPS Agreement that is fraudulent exact copies of packaging. We have had an experience of that we report it, but in our experience in over 70 countries the overwhelming problem is not this copying of the branding of the packaging, it is actually the full scope of substandard medicines and it is a far greater problem than I think is currently recognized in these debates around IP and counterfeiting.

So how do we actually go about procuring medicines? Well, partly it is historical, I mean we have procurement centers based in Europe partly because we were started by French doctors so it is a historical issue, but also because we are an emergency organization we
also need to stockpile medicines. Conflicts and natural disasters do not happen when pharmacies are open, so we need to be able to have these stocks.

We also have our own sort of slightly complicated, sorry I will just go back to this, supply chain. So basically, we generally buy our drugs directly from the manufacturers, sometimes we will get them from wholesalers and distributors and then they will go to our storage centers in Europe.

We have a validation process when we are purchasing drugs which I will go into with a little bit more detail where we approve the site and we validate the product. But what I also like to point out is that we also store in a number of African countries, either for use in those countries or to transit and use in other countries where there is not the possibility of having stable storage facilities. And that is why we are also concerned about over-broad IP provisions because we store in the EU, we are concerned that the EU customs regulations could affect our ability to store and transit, because we need to import medicines and other medical products into Kenya and other African countries. We are also concerned about the Kenyan legislation.

And one point which I do not think has been brought up, it is not just a question of the breadth of the definition, which could potentially capture generics, but it is also the chilling effect of the remedies. If you have an over-broad definition, plus what is increasingly being seen as criminal penalties for infringement, the risk profile might change. So if we are importing a medicine and there is a risk of somebody accusing us of infringement, which is often a commercial tactic, and before the risk for us was whether we would have to pay a fine, now the risk could be even before this is fully tried, since members of our staff could be imprisoned. So it really does change the risk profile.

So when we go through our procurement system we basically base our choice of drugs on the WHO recommendations, which is from the essential drugs list. And I think it is really important to think about where you get guidance for the drugs that you need. We also have other essential drugs that we need because they are not all on the WHO’s list.

We only purchase qualified drugs and that is either we rely on the WHO pre-qualification system. Although that has its limits, because it is only for a certain number of drugs,
drugs registered in highly regulated countries, or what we call MSF qualified drugs where we actually carry out a qualification procedure.

We also may purchase directly from local markets, there is where an importation is restricted by governments. It occurs often for good reasons and we respect the rights of governments to require registration and obedience to their rules, but in those cases if we cannot rely on previous validations that we have done, our pharmacists will actually go in and check the sources, to give recommendations to the field teams working in those countries about which drug sources they should use. A risk benefit analysis is done if in emergencies a full assessment cannot be carried out.

As I said we do this two-step validation process and we either rely on the inspection of the WHO's GMP audit and we also do a product assessment. Once we have done this and I think, it is important to point out that, when we carry out an assessment and when we choose providers, we do not just do it on price, we do it on this assessment of not just quality but their ability to deliver in the terms and the requirements that we need.

This is really a sort of just pictorial of what we have said. I think the point is that we not only rely on pieces of paper, which are important like the WHO’s qualification and GMP, but we also go and inspect the producers, and the reason why we do that is, to check if there are cases where both originators and generics will change their production lines and standards depending on where they are sending their drugs.

So what are some of the issue that we have found, if we think that substandard are a real concern? Now a number of you may have seen this article which is in the Journal of Tropical Medicine & International Health, where basically a number of my colleagues looked through the literature and also brought together some of the experience that we have had in looking at substandard medicines in resource pool settings.

I will not go through all this slide, but I think what is important is that, there are often myths about this; one of them is that the origin of the product is always a developing countries and that is not the case. There are also myths that there is only one form of substandard and what we are really talking about here is, I think as Ms. Hela has also
pointed out, is a multitude of factors. So you have got contamination and over-concentration and under-concentration.

I will leave these slides because we have not got time to go through all of them, but I would recommend looking at this article, because it does go through some of the countries, origins, as well as some of the problems. So it kind of gives an indication of some of the problems that can be found.

I think Ms. Hela has pointed out what we really have been seeing is a multitude and under-concentration of the active ingredients and over-concentration, no active ingredients, dissolution failures, irregular filing of files, mislabeling. And I think it is important to point out that, this mislabeling is not the mislabeling that people who are pushing IP laws talk about, it is not about copying someone’s brand, it is actually about putting, describing the product in the wrong way. So here you know it was actually a particular drug described in a different way.

This is just to give you a kind of visual idea, because often when we discuss this it is quite difficult to think about what it looks like. For example, if you look at the far side, what you are looking at is a product which has two expiring dates. One is in 2006 and the other one in 2007. So how do you know when this product expires? If you look at the top we have non-stable, anti-TB fixed dose combinations and also a poor packaging. These are the sort of the reality of some of the things we see. So what are the consequences of this? Well, they are fairly obvious, that contamination can cause fatal toxicity.

The level of the active ingredient can lead to an ineffective treatment. It can prolong illness or, in the worst case, can actually cause death. Under-dosing - and this is a real concern of the API - which can also be done by manufacturers who want to lower the cost of their production. Risks promoting drug resistance and if you have a diagnostic that does not work or gives false readings then you are wasting time and the cost on the diagnosis, you will get a false diagnosis and the disease will progress.

So, what have we learned from that? Well, that this issue of substandard drugs is not just an issue from certain countries. The substandard drugs that we have seen are originating
from developed and developing countries. We have seen that the WHO prequalification program is a real driver of quality of medicines for countries with limited drug regulatory authorities. It has really helped the quality in relation to HIV, TB and most of the malarial drugs. But it has its limits because it only applies to certain drugs.

We have also seen that there have been cases of poor compliance with manufacturing standards. In the inspections that we have carried out, we have seen that manufacturers, who passed inspections, adjust their standards to the recipient country. We also think that there is a problem of donors and there is this particular issue for countries which rely on their supplies, which is that quality is not demanded from purchasers. If you are procuring just on price, and do not actually take into account the source of your medicines, then this can lead to substandard.

There is, as I said, limited capacity for technical evaluation in a number of countries. There is also limited ability to follow up after the medicines have been used, which can be an important way of tracing where the problem is.

The reality is though, so is the systems that we apply and also that good regulatory authorities apply. And as Ms. Hela has set out, they are costly, complicated and they have to compete with many other pressing health system priorities in resource-poor countries.

So, what are some of the solutions? Now, we are not immodest enough to say that we have all of the solutions. So these are just some that we put for discussion. First point is that, and I cannot emphasize this enough. Resources are key, but they have to be the right resources to tackle the right problem, and that is why we support the points that other people have raised, we do need independent data collection of what the type of problem is in each country. If they problem it is not really about copying people’s brands, but it is substandard medicines. Therefore you should not be spending your resources on creating IP enforcement policies; you should be spending your resources on strengthening your drug regulatory system.

There is not only one solution; all stakeholders have a role to play. The most important factor as we all know is to strengthen the drug regulatory authorities. We and others have been talking about this for a very long time, but the reality is that there has been a lack of
political willingness from National Governments and to extent donors, to support the strengthening of drug regulatory authorities. It is also important that they are independent, both financially and politically, so that they can carry out their public health function. Moreover, I think there is also a concern, because people are looking for quick fixes. I think Sisule was saying this, you can hold out an IP law as a way of protecting it, but we all know that the longer term solutions need to be focused on.

There is some good news. I mean, there are a number of regional initiatives, particularly in Africa where they are looking at sharing resources and harmonizing some of their drug regulatory authorities. This is going to take some time, but it is an important objective to be supportive. We think that donors have a real responsibility to have clear quality assurance policies and apply that to the assessment of the medicines and to the manufacturers. We also think, because there are these intermediaries, and because procurement agencies and distributors are so important in a number of donor-dependent countries, that there should be a pre-qualification system for procurement agencies and distributors to ensure that they are following a quality assurance system.

It is also important that the good manufacturing guidelines are adhered to and put in place. I support the point that Ms. Hela said about sharing information and also sharing resources. You could look at some of the success stories that we have heard from some of the African regulators, we have recently got together to discuss this issue with. Well-performing quality controlled labs could be held out as leaders and could be applied for a sub-regional approach.

It is also important that you and we review anti-counterfeiting legislation. We believe that only willful trade marking actually shows a real public health effect. So that if someone is exactly copying the brand, then there is no other real purpose in that fraud, and they are trying to cover up the fact that there is probably not a real medicine underneath that. But the reality in medicines is that civil trademark disputes, which are also covered under this legislation, would be very common in medicines, primarily because both the originator and the generics abuse the international naming system. So they will use sound alike names, which are a cut of the general generic name. We also know that there is an increased protection in the shape and color of pills. So this type of civil trademark disputes we are likely to see more and more often, and they should be resolved in the courts because they do not have a public health effect.
The cost of IP enforcement, as I think others have talked about, for quality, safety and efficacy can be huge if they are wrong and Sisule has talked about some of these problems in Kenya and you know, just for us, it really does have a practical effect. Generally we are concerned about our ability to continue to import and store in Europe, although the EU is moving in the right direction, they said they will remove patents, they have not done it yet. They have said nothing about trademarks. So we think the drugs could still be caught.

In Kenya, again there is recognition that it needs to be changed, but at the moment, we have to advise our people in Kenya that there is this risk and we are making alternative arrangements. I think one of the final points that I make and one of the really important ones is that access to affordable medicines is a key part of the fight against counterfeit medicines. We have heard Sisule say and we know that 90% of people in developing countries have to pay for their medicines out of pocket. If you are desperate and you need medicines, it is not affordable for you and someone comes and offers you the hope that they will give you a cure and it is cheap, then you will take it. It is therefore really important that this is seen as a key part of the fight so that we close down the market for counterfeiters.

Thank you very much.
Good morning. First of all I would like to thank you for the invitation. My name is Erika Mattos da Veiga. I work at ANVISA, at the International Affairs Unit, and I am here speaking not only on behalf of the institution itself, but especially on behalf of the technical units, which implement the provisions and policies I will now present to you.

As a starting point I would like to mention some events that have changed the health surveillance framework in Brazil. Between 1997 and 1998, Brazil experienced the main crisis of the health surveillance system. And I should stress that it was a crisis of the health surveillance system and not a crisis of falsification of medicines, because according to our legislation any intentional act that exposes public health to threats and risks is punished with the same strict laws as the falsification itself. During this crisis, isolated cases made clear that our health surveillance framework at the time was not good enough to prevent this kind of goods to reach the final consumer.

Changes have been made in our domestic legislation in order to respond to this problem. The main change was the inclusion of two new articles in our criminal code. I would like to point out that, in Brazil, the act of falsifying medicines and other medical products is not a violation of civil law, but also a serious criminal offence, punishable with 10 to 15 years of or deprivation of liberty. Additionally, law 9,695/98 entered into force in 1998 and provided for that falsification of medicines is a crime with no correctional benefits for the convicted person. Thus, Brazil implemented a strict regime of prosecution and punishment of convicted persons.

Besides these changes regarding strengthened legislation and enforcement, our national policy on medicines is aimed at ensuring quality, efficacy and safety of medicines. In Brazil, we take the view that not only falsified medicines expose the public to threats, but also every single medicine that is not produced in compliance with the best manufacturing practices.
Another important change in our legislation is the publication of Ordinance 802/98, by our Ministry of Health, which established the safety criteria for the distribution and production of medicines. These criteria relate to the reliability and security of packages, which must have security seals to ensure that there will not be any violation of the packages, as well as the use of a reactive ink to guarantee the authenticity and origin of the medicines.

Additionally, we have another Ordinance, issued by the Ministry of Health that establishes rules for procurement and a compulsory notification to the head of surveillance system and the police in cases of falsification and even suspicion of falsification. There are other legal instruments that ensure good manufacturing practices, aimed at strengthening the pharmaceutical sector including its reliability among the population and the authorities.

Last but not least important, ANVISA was created as a consequence of the crisis I have mentioned before. This body was created in 1999 and here in this picture you can see our headquarters in Brasilia, our capital city. ANVISA is in charge of the coordination of our National Health Surveillance System that I will now present to you.

The National Health Surveillance System is part of our Unified Health System, so-called in Brazil the “SUS” and here in the picture you can see all the institutions that compose the system.

As you may know, the SUS is a universal system, which means that every single Brazilian citizen has the right to be covered by it. Another core principle is that the SUS is integral in nature, which means that there is no discrimination of products or services to be provided to the beneficiaries, as long as the medicines are properly registered with ANVISA and provided by the government. The third principle is equality. In other words, every Brazilian citizen has the right to be assisted on an equal basis, with no discrimination on the grounds of race, age, sex or even the health condition.

As mentioned the National Health Surveillance System is part of the SUS, and regarding our surveillance system, it is important to underscore that it is composed of three levels: (a) the national level is represented by ANVISA, the institution where I work; (b) There
is also the state level. Brazil has 26 states, in addition to the Federal District, that have been divided in five regions which are very different between themselves and (e) there are more than 5000 municipalities. Thus, another principle of our health surveillance system is the decentralization of those levels which are extremely important when considering the continental dimensions of our country.

If you want an effective health surveillance system, it is important to guarantee that even in very isolated areas there will be a civil servant or an expert able to identify events that expose the population to health risks or threats. That is the reason why the option was to work in three levels, to ensure that the system will be adapted to the specificity of each part of our country.

Now that I have presented an overview of our framework, I would like to stress some points related to our domestic policies. When considering falsified medicines, Brazil always focus on public health, as it is understood that the falsification of medicines is primarily a public health issue and not intellectual property rights issue.

ANVISA plays an important role in setting measures and actions for our government in order to guarantee the efficacy, quality and safety of the medicines we have in our market.

There are two types of ANVISA measures. The first one is related to prevention and is constituted of actions that I have already mentioned, such as: regulation, communication and information sharing, education, and monitoring/investigation. The second type is the combat of the falsification itself, which is implemented through joint actions in coordination with other national government bodies.

The National Plan of Action was launched in Brazil in 2001 and was elaborated by the National Committee for the prevention and combat of falsified medicines. It was defined five main areas of action in Brazil.

The first one concerns capacity building that is extremely important if you bear in mind that we have three levels of action and that it is imperative to ensure that even in isolated areas there will be an expert able to identify a falsified medicine or any other kind of
medicine that was not produced in compliance with the rules. The second main area is norms setting, third inspection, fourth information sharing and education, and finally the last one technology that will be used to ensure the traceability system within our country.

When considering norms setting, ANVISA is responsible for the improvement of our domestic legislation regarding, as I mentioned before, good manufacturing, distribution and importation practices in order to guarantee that no spurious or falsified medicine or even ingredients will reach our market. It is also worth mentioning the storage, manipulation, dispensation and prescription of medicines.

I should stress that these two last actions are related with rational use of medicines that in our point of view has to do with the safety of our market. If you do not have a proper pharmaceutical environment, where people have access to medicines with an appropriate dispensation system and with the prescription of a doctor or a physician, it is more likely that there will be problems related to the access to dangerous products.

And, again, addressing the prevention and combat of falsification, I should emphasize that, for us, it is much more effective not to recall a falsified product that is already in the market, because in this situation the public has already been exposed to the risk.

It is more efficient to strengthen the distribution and productive chains, in order to create a health surveillance system that is able to identify and to recall these products before it reaches the market or even to prevent the production or importation. Therefore, it is very clear that there must be an integrated approach of this issue with the main activities related to public health, not to private rights.

All the measures that I have mentioned are in accordance with WHO’s guidelines issued in 1999. And also bearing in mind that the falsification of medicines and all the health products is mainly a public health issue, ANVISA fosters and contributes to the integration of all government bodies implicated in this matter.

It is important for us that all the sanitary authorities of all three levels, not only the federal level, work together with customs and police forces in an articulated manner, in
order to prevent, and not only to combat the crime of falsification. In this regard, ANVISA signed an agreement with our Minister of Justice.

I shall now present some examples of our actions. Between 2008 and 2009, ANVISA took part in 58 joint operations and investigations together with our police forces, and again, I would like to highlight that, in Brazil, falsification is a criminal offence that is punished with imprisonment.

Moreover, ANVISA has a legal instrument that regulates the commercialization of medicines on the Internet. In our country, only domain names hosted in “br.com.br” are allowed for this purpose.

ANVISA has also made clear the importance of sanitary inspections, not only where the medicines are produced, but also in the distribution sites and pharmacies, aiming at the enforcement of good distribution practices in coordination with local sanitary authorities since, as I mentioned before, our country is vast and has different regional realities.

Another type of measure mentioned before was dissemination of information and education on the rational use of medicine. It is important to have awareness raising campaigns, in order to inform the general public that they are exposed to risks and to enable them to identify medicines that are not original or even retailers that are not certified by ANVISA.

In Brazil, there is also a system called NOTIVISA, a system of notification in health surveillance that is integrated by 208 hospitals named “Chain of Sentinel Hospitals”. Through this system, health care professionals can notify problems related to medicines and other health products such as side effects that have been identified, a suspected product that may be falsified or may not have been produced in compliance with good manufacturing practices.

We have moreover ANVISATENDE, namely a communication channel through which the population can denounce risks and suspected goods. I would like to inform that, as from 2012, we will have another system, which will allow the visualization of the
package’s seals. It will have a unique identification number and that will guarantee the authenticity of the medicine.

It will work in the following manner: the unique identification number will be one of the compulsory pieces of information to be available in the electronic invoices of the pharmaceutical sector.

And finally, to conclude, I would like to stress that in Brazil the crime of falsification is understood primarily as a crime against public health and not against private rights. The prevention is important, as important as the combat itself. Measures to protect public health should not be distorted by private or trade interests and in our point of view no TRIPS-Plus measures should be adopted to combat the falsification of medicines and other medical products.

Thank you very much.
Thank you, Mr. Ambassador, for your kind introduction. Let me start by thanking the three Ambassadors from India, Brazil and South Africa for the invitation to contribute to this discussion.

My presentation has two parts. First I will highlight some of the gaps that need to be filled to actually enable effective public health action against compromised medicines while in the second part of my presentation I intend to briefly outline measures that we should focus on and the role of certain actors in this regard. Professor Abbot has made a very important observation when he first started. What is the basic premise? And we mustn’t lose sight of this basic premise. We are not disputing that there is a problem of compromised medicines being sold particularly in developing countries. It is also not in dispute that we need public health oriented measures to deal with this problem.

Now having said this if we look back at what we know about this problem we would realize that actually we know very little about the problem we are trying to deal with. This has been mentioned repeatedly. Reliable empirical data on the nature and the extent of the problem is virtually nonexistent. The most often cited statistics is from WHO which estimated at one time that more than 10% of the global medicines market is comprised of counterfeits and up to 25% of medicines in developing countries are counterfeits. Since then it has emerged that these statistics cannot be supported. In fact WHO in its recent report at the World Health Assembly concurs that no reliable and sound data exist on this issue. But if you look at news reports, law articles, WHO fact sheets, government task force reports you will find statistics of counterfeit medicines being bandied around all the time.

On the issue of statistics two prominent US based academics Professor Kevin Outterson and Ryan Smith point out not only that evidence about counterfeit drugs is anecdotal rather than empirical but that the only comprehensive collection point for global data on
counterfeiting is the Pharmaceutical Security Institute, a trade organization created by security directors of 14 global company drug companies that do not make their data available to the public. They also point out that the terms fake and counterfeit have included a wide range of drug products from those resulting in criminal acts of homicide, to placebos, to safe and effective drugs from other countries.

This brings me to the next point. When we speak of “counterfeit medicines” this term means different things to different people and there is true confusion as to what the term actually really represents. It has been mentioned repeatedly - the confusion of issues in relation to the counterfeit terminology but let me just touch on it briefly so that we understand how this term is being used in different contexts. Professor Kevin Outterson and Ryan Smith present this confusion very descriptively as “the good”, “the bad” and “the ugly”.

There are many countries that actually use “counterfeit” in the context of IPRs, to refer to all sorts of IP infringement including patent violations. Now we may argue that it may not be wise to do so (i.e. for “counterfeit” to mean patent violations) but there are countries that actually define it as such. Thus a medicine may be perfectly safe and effective but its use may violate certain IPR laws and in some jurisdictions they term this as a counterfeit. Now this drug which is called the “good counterfeit” for the purpose of illustration cannot be equated with contaminated, toxic and other types of unsafe drugs.

The health sector is concerned with bad counterfeits, medicines manufactured with the aim of intentionally defrauding consumers, medicines containing inadequate or no active ingredients or use contaminated materials. Now this trade deserves enhanced criminal sanctions but note that applying these same criminal laws to good counterfeit, and I am going to come to the ugly drugs, would actually be a mistake and a misallocation of resources.

The health sector is also concerned with ugly counterfeits and MSF has pointed out the prevalence of substandard medicines. Now these are products that do not meet standards set by national drug regulatory authorities due to certain acts including negligent acts for instance they do not meet certain labeling standards as a result of poor storage
transportation facilities. You find that the drug does not meet certain standards. Now these drugs are legitimate but they must not be equated with bad counterfeit drugs.

Finally, as we are going through the different ways the term “Counterfeit” is used, it is important to recall that the only multilaterally agreed definition of “Counterfeit” is in the TRIPS agreement wherein “Counterfeit” is defined as referring to a specific category of trademark violations.

The reason I have shown these slides and gone through the good, bad and ugly is to show that the term counterfeit is used in many different contexts in different ways. I think what is most worrying for those in the public health community is that numerous emerging anti-counterfeiting initiatives, I mean many of you have heard of ACTA, the Anti-Counterfeiting Trade Agreement, claim that they are dealing with public health issues but they actually use the term “Counterfeit” to deal with IP infringement and enforcement issues. These initiatives have got nothing to do, absolutely nothing to do with issues of quality and safety. We have also heard from Sisule the problem of anti-counterfeiting legislation in Africa.

So from a public health standpoint: this confusion and lack of clarity raises a fundamental question: Is this terminology mess in the interest of public health?

I think this is a very important question and an equally important question that has also been raised by Sisule is: Will it facilitate or hinder our ability to better understand the nature and extent of the problem and to take targeted measures to deal with the problem of compromised medicines. For instance, if we want to gather reliable data on counterfeit medicines, how do we do that if the same term means different things in different context? It would be impossible to actually get reliable data.

In addition as mentioned by Sisule the effect of this confusion on public health is already noticeable in many parts of the world. For instance in several African countries anti-counterfeiting legislations have been or are in the process of being enacted. Of course the given the rational is always that it is to protect the public from unsafe or poor quality medicines. But if you look at the legislation it’s all about IP enforcement and protecting
the rights of IP holders. In fact such legislations through their erroneously broad definition of counterfeit make every generic pharmaceutical a counterfeit.

So I would argue that what is in the interest of public health is firstly to have clarity about concepts used, for instance when we refer to spurious, substandard, falsely labeled, falsified, what do we mean, we need to have clarity. This clarity is important as the sanctions will defer depending on the intent factor and so would measures adopted to address the problem. As we determine such concepts it is also important to acknowledge certain concepts such as “Counterfeit”, already have multilaterally agreed definitions.

This brings me to the second part of my presentation, what aspects should we focus on for effective action against compromised medicines and the role of certain actors in this regard?

First, as I have mentioned we need to generally undertake comprehensive market surveillance and we need to collect reliable impartial empirical data based on an agreed methodology on the nature, causes and the extent of the problem of proliferation of compromised medicines. This is a crucial aspect to inform policy making and allocation of resources. Market surveillance will provide us with the basic facts necessary to truly understand the threats to our drug supply and to actually separate public relations and scare mongering campaigns from genuine threats to public health. For this purpose I believe WHO should be the natural coordinator to undertake this initiative.

Secondly, we need clarity of concepts. Again, WHO would be the most appropriate fora to facilitate intergovernmental discourse so we can emerge with an improved lexicon to describe specifically the different aspects of compromised medicines?

Third, if you look at the way action is taken against counterfeit medicines or compromised medicines in recent years, there seems to an increased focus on enforcement action particularly action by customs and police and often to the extent of sidelining the drug regulatory authorities. This matter is further compounded by the fact that international organizations such as the World Customs Organization and Interpol, appear to be dealing with the issue of compromised medicines in the context of IP enforcement. For instance, Interpol’s 2008 annual report explains its IP crime activity as
follows “the intellectual property crime program focuses increasingly on counterfeit goods especially medical products which pose a threat to the health and safety of consumers”.

The focus on enforcement is based on *ad-hoc* short-term measures. It does not address the root causes, primarily high prices of medicines and the problem of weak regulatory capacity.

On the issue of high prices on medicines, I think we have to acknowledge that so long as there is a demand for affordable medicines, a demand that is not being satisfied there will always be an incentive for selling compromised medicines. So we need to address this issue. A related point to this is that we need to take accompanying measures to improve generic production of quality medicines in developing countries so that countries become more independent in supplying their own medical needs.

On the issue of weak regulatory capacity, according to the 2003 WHO paper, only about 20% of countries have fully operational medicines regulatory bodies. While over the years this percentage may have increased or decreased, it is a fact and we need to deal with it. Drug regulatory authorities are often the weakest national authorities and they actual lack the necessary facilities, financial and human resources. Ignoring this fact and just simply stressing on enforcement including provision of harsher penalties, broader criminalization is unlikely to be productive in the long term.

We have to look at how to strengthen capacity of national drug regulatory authorities as it is the main authority that will ensure the quality, safe and effective medicines are available on the market. Other agencies would not have the required expertise and providing penalties would have a limited effect if the Drug Regulatory Authority has limited implementing capacity.

What has interestingly been pointed out is that countries already have laws in place. We have a lot of laws to deal with the problem of compromised medicines, we also have significant penalties, the problem often is the capacity to actually implement and take measures in the context of Drug Regulatory Authority.
So a major focus has to be on building capacity of Drug Regulatory Authority and the issue is how do we ensure that it has the facilities and the technology for example, it would need mobile testing labs, it would need equipment and laboratories for testing at the ports, it would need human and financial resources to carry out this task and to this end. I think it would be useful to actually develop a comprehensive up to date mapping of the state of affairs with regard to drug regulatory authorities in developing countries. This would be very useful in determining the capacities, identifying the gaps and facilitating solutions. In this regard WHO member states have got a very important role to play to make sure firstly that WHO takes all the necessary steps to facility access to more affordable medicines, to promote production of generic medicines of quality in developing countries and thirdly to strengthen regularity capacity. I would like to stress that this is not a role that we can outsource or WHO can outsource to organizations or initiatives outside of WHO. WHO is tasked in coordinating, it is the international coordinating authority on health and so it has to undertake this task and any such initiatives has to be taken inside of WHO.

With regard to enforcement agencies, they also have a role to play but their role is more of a supportive role to the functions of the Drug Regulatory Authority and not substituting the role of the Drug Regulatory Authority. It is worth noting that if you have a strengthened Drug Regularity Authority, this Drug Regulatory Authority would actually ensure that it is sufficiently empowered to take the necessary action and has all the support it needs from the other agencies. I think it is very urgent to actually undertake a thorough review of how other organizations such as the World Customs Organization and Interpol actually undertake measures with regard to compromised medicines because wrongful measures would actually have a chilling effect on suppliers of generic medicines.

Finally and fourthly, we need to probably explore types of cooperation and information sharing that can be had between importing and exporting countries. For instance it could be envisaged that medicines that are to be exported would be notified to the importing country government which would then verify the quality and safety of the medicines upon receiving the medicines.

I will end my presentation by saying that the recent decision of the World Health Assembly to establish a working group is a step in the right direction as it will allow
member states to unpack the issues surrounding compromised medicines and address some of the issues that I have raised with regard to data, concepts and also the necessary measures that WHO should undertake and provide strategic direction to WHO from a public health perspective.

Thank you very much.
Closing Remarks

Permanent Representative of Brazil, Her Excellency Ambassador Maria Nazareth Farani Azevêdo

I think we achieved our objective, which was to raise awareness about the seriousness and complexity of falsified medicines. We did have a very good discussion on sustainable solutions too, not only about problems but about solutions and we also held an open and constructive debate here today.

Let me read to you something that I read last week which was very inspiring for this meeting: a very small excerpt in an article published by Robert Naiman. The article discusses if Brazil should lead on access to essential medicines. Its main message is that Brazil and countries like India and South Africa, emerging countries, should take the lead to discuss the flexibilities on the TRIPS, to talk about access to medicines because, when we talk about these things, we were talking about lives. And there is one excerpt in his article that I liked very much: he contends that political violence draws our attention in a way that economic violence does not. If you deny someone lifesaving medicines you kill them as surely as if you dropped a bomb on their house. But if you drop a bomb many people will notice, it will be on the headlines. This is a silent war. We are talking here about lives and I liked what Ms. Hela mentioned: one life lost is one life too many.

Well, the task that my colleagues have given me it is not an easy one. I will not summarize this meeting because I run the risk of being unfair. Thus, I prefer to share with the speakers and audience what I have learned during this discussion. Firstly, I agree very much with the premises presented by Professor Frederick Abbott, whereby nobody is here to promote the sale of substandard or falsified medicine and I guess that nobody is here either to promote the sale of any medicine, in spite of the human right of everyone to highest attainable level of health. That is what South Africa, Brazil and India will promote. We were the locomotives behind the resolution at the WHA that created our intergovernmental group to discuss falsified medicines. But this is not something that should oppose rich and poor, nor oppose those who are healthy and those who are sick. It should neither oppose generic industry against branded medicine.
This has to be something that should unite all of us and I think our fight here is a fight for life and as we fight, as we wage that fight, we have to do that in accordance to the commitments we have made. We all have agreed under TRIPS. It was clear from the debates that no one should do away with TRIPS, or that we should do away with our commitments to respect patents. We have to do it in a balanced manner. However, we cannot go on saying that profit comes before health. This is the message learned during this seminar. Substandard and falsified drugs are a problem of both developed and developing countries, of both generic and branded drugs. Independent data collection is needed, political technical independence to fight this problem is essential to address this challenge. Price of medicine is a key aspect in fighting falsified medicines, but competition is important, so is the production of generic medicines in developing countries.

Access to medicines is an integral part of the right to health. Falsified medicines hamper the enjoyment of this right. TRIPS-Plus is being pursued in bilateral agreements for the continuation of patents. This only helps a selective group of persons or a selective group of companies; this does not help health in the world. So, pursing vulnerable poor countries to draft laws that do not have a health perspective in the area of falsified medicine is not the way forward. If this attempt prevails, we can say goodbye to pharmaceutical industries in developing countries. I guess we can say goodbye to many lives too. One life lost is one life too many.

In Brazil, the crime of falsification of medicine is one against public health, not against private rights. There may be good, bad and ugly counterfeit. The confusion over the term counterfeit does not help public health. Empirical and reliable data is crucial to address the problem of genuine public health and compromised medicine. Lately, the focus on enforcement has taken the center in the fight against compromised medicine. Is it the right way to go? Or should we have a more health oriented perspective? It is crucial to strengthen health regulatory authorities everywhere as they are the ones to identify falsified and substandard medicines. Enforcement agencies have a role to play, but their role should be supportive of health authorities in this area. Our fight is for lives. One life lost is one life too many.

I hope that this exercise has helped us, governments, civil society and industry, because we will be involved in a way or other in the deliberations of this intergovernmental
group. We will do our best, Brazil, India and South African to write some sort of outcome of this meeting.

Thank you.