

**IMPACT**  
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Welcome, and thank you all for being here. A special thanks to the Government of Germany for hosting this meeting, *and* in such a beautiful venue.

I think the occasion definitely calls for a celebratory applause – to mark the birth of the taskforce to combat medical counterfeiting, and the beginning of a very rich and inclusive public partnership.

In less than one year we've established an action-based coalition and come up with a comprehensive package of measures. This is a tribute to all of us. It demonstrates that we are committed to the goal of ensuring ethics-based, effective and safe medical supply systems for the populations of all countries.

Since the February meeting in Rome, the coalition has reached several milestones. We have established the IMPACT Secretariat at WHO. We look forward to seeing this grow exponentially from the small team it is now and to accomplish this we need the input of all stakeholders. We have mapped out and agreed on IMPACT's functions and objectives. We have set up five working groups with specific mandates and we have all pledged our commitment, which is enshrined in the Rome Declaration.

Let me spell out why we have made those commitments. And I will use the most recent estimates to do so.

- Many countries in Africa, parts of Asia and parts of Latin America have areas where more than 30% of the medicines on sale are counterfeit.
- In other developing markets the figure is around 10%.
- Many of the former Soviet republics have a proportion of counterfeit medicines which is above 20% of market value.
- Medicines sold by rogue Internet sites are counterfeit 50% of the time.
- True enough, most industrialized countries with effective regulatory systems and market control have an extremely low proportion of counterfeits – somewhere in the range of 1% of market value or just under – but many of the rogue web sites I mentioned are selling their wares in those very countries.

These new estimates, elaborated by our partners IFPMA, PSI and the OECD, are the figures we will use from now on. They are not as dramatic as the over 10% global figure used in the past, but we all know the scale of the human tragedy behind these numbers for patients unlucky enough to have encountered counterfeits, and for their families. Underscoring all our activities and actions is that human aspect, which we should keep in mind at all times. And remember,

just like other health concerns, we must evaluate the situation based on region and not by one global number.

Getting back to our achievements. Each of our five Working Groups has already initiated a number of activities. Let me quickly go through the progress made since Rome in those areas and **OUTLINE** the **NEXT** steps:

**In the legislative area**, we've collected and revised existing information and come up with a set of **guiding principles** to propose to countries. These should serve as a basis for strengthening national legislation to deal with medical counterfeiting, and legal sanctions against counterfeiters and any other actor involved in the supply and distribution of such products.

Those guiding principles are founded on three main points:

1) The idea that we must all use a common definition of counterfeit medicines.

We propose that the WHO definition be adopted. One key aspect of that definition is the 'deliberate and fraudulent' nature of the crime. This facilitates the necessary distinction between counterfeits, which are **ALWAYS** substandard, and other substandard products, which are not necessarily counterfeit.

2) The extent of responsibility. We all agree that those directly involved in the manufacture and trade of counterfeit medicines, chemicals and packaging materials should be held accountable and punished. But we must also define the responsibility of exporters, importers, distributors, wholesalers and retailers who may not be aware of the counterfeit status of the merchandise, but whose duty it is to check its quality. The working group will look at this issue and agree on legal instruments to discourage and punish negligence at all stages of the pharmaceutical supply system.

3) Penalties: In many countries, including the one I know best, counterfeiting a T-shirt receives much harsher penalties than counterfeiting a medicine. The laws are designed to protect trademarks but we must make sure that the objective is to protect the people's health. **IMPACT** will work at assuring this.

Our next step in this area should be to develop models for best practices and good governance.

I would like to see a time in the near future when counterfeiters are viewed as the 21<sup>st</sup> Century pirates of the high seas – unsafe in any harbour. Essentially, the laws would make them unwelcome in any nation.

**In regulatory implementation** Indonesia, Mali and Vietnam have developed projects aimed at improving their capacity to combat counterfeit medicines on national soil.

Vietnam and Indonesia are looking at strengthening national coordination between regulatory, police, customs and provincial authorities as a first step to

implement comprehensive measures. Indonesia and Mali are developing awareness-raising campaigns for the general public.

IMPACT has committed to support the Government of Panama to reform and strengthen its regulatory system and in so doing prevent the recent dramatic diethylene glycol poisoning and similar events from happening again.

We have approached the health authorities of India and China proposing to jointly develop an alert system for importing countries receiving counterfeit products. That information will help China and India investigate the cases at the source.

WHO has developed a data collection tool to identify the weaknesses in national drug regulatory systems. This tool will be expanded to look at the transparency of regulatory processes, post-marketing control and licensing of distribution and retail outlets. It will use indicators to measure problems. The relevant working group will seek partners to join WHO in this endeavour. Our aim is to have the new tool ready, after field testing, by the second half of 2007.

In **enforcement**, WHO and Interpol are having fruitful discussions on the secondment of an Interpol official to join the IMPACT Secretariat at WHO. With Interpol we are also developing training initiatives to help customs officers improve their capacity to detect counterfeit medicines and coordinate with their counterparts in other countries.

Let's train customs agents to essentially sniff out counterfeits just as we sniff out narcotics at borders. We need to use hi-technology to accomplish this.

And so let's talk about technology.

In **technology**, a draft document outlining current technologies to prevent or detect counterfeit medicines has reached an advanced stage and will be finalized as a "dated working document" at this meeting. Technologies keep changing and we need to keep abreast of new developments. For this reason the document will be regularly updated by the working group and will never be issued as 'final'. Each dated version will be made publicly available in a 'simplified' format in order to avoid precious information from becoming intelligence for counterfeiters.

IMPACT has challenged companies to submit proposals on systems combining serialization and mobile communication technologies to query remote databases. The working group is assessing the feasibility of these proposals and will initiate a pilot study. We need to draw upon the technologies that people in all nations are accustomed to, for example cell phones. While in Mozambique several months ago I noticed a young child in tattered clothes, looked as if he was malnourished, but he had a cell phone. Let's work with the people of nations and with technologies that they are familiar with to solve the counterfeits problem.

In the first quarter of 2007 IMPACT will organize an international meeting where companies will present anti-counterfeiting technologies to national regulatory authorities, pharmaceutical manufacturers and distributors. Our aim is to identify the most promising approaches and field test them. IMPACT needs manufacturers, wholesalers and national authorities to volunteer and take the lead in guiding and supporting the development of innovative approaches.

With the pro-bono support of companies that use Internet monitoring technology, IMPACT is receiving reports on rogue Internet sites selling medicines of uncertain origin. We will release these findings once the data has been consolidated.

Using those figures, IMPACT is developing a strategy to involve internet service providers, major courier services, customs, postal police and others to put an effective barrier to the abuse of the internet for the criminal sale of medicines.

IMPACT and AIFA have started a project to purchase selected medicines from Internet sites that do not reveal their physical address. The objective is to collect information to arrive at an accurate estimate of counterfeit medicines offered by rogue sites.

In **communication**, IMPACT, Mali and Venezuela are in the writing phase of a short film aimed at showing that counterfeit medicines affect everybody and are everybody's problem. The film, 2-3 minutes long, will tell the story of a customs officer whose child dies of malaria after treatment with a counterfeit medicine.

We shall do more such work, targeting internet users as well as other audiences around the world by forging partnerships with TV and radio networks, whose responsibility it is to inform the general public. We are currently seeking media partners to work with us on a pro bono basis. We look forward to distributing public service announcements regarding this issue.

IMPACT needs to develop appropriate strategies to communicate risk to health professionals, the public, enforcement officers, elected officials and governments without eroding the public's trust in the health system. We must base our messages on accurate data and improve information exchange by building on existing initiatives such as the web-based Rapid Alert System WHO developed with Australia and the Philippines. Information is the basis for communicating risk and advocating for additional resources for regulatory and enforcement work.

We are also putting together a website with a map of the world whereby anyone can go online and touch a country and learn about any reported cases of counterfeit medicines which have been documented. Hopefully this will go live within the first six months of 2007.

And lastly, I hope everyone has received the bumper stickers and buttons which will help us "brand" the issue of combating counterfeit medicines. I hope to see

the day when just the “exclamation point in the shape of a pill” is recognized worldwide as to signify the need to eliminate counterfeit medications.

I think I have been speaking long enough. As you can see I am enthusiastic about our success, our vision, our determination. And I also realize that I am speaking to the converted and many of you are veterans of this issue.

This morning we shall formalize the establishment of OUR taskforce. We will choose a Chair and a Vice-Chair, who will help ensure the functioning of IMPACT. We will choose the working group chairs, whose task it is to coordinate the groups’ discussions and actions. I trust you will all continue to inject the same commitment, the same energy, the same passion, you’ve demonstrated so far into our programme of work to ensure that IMPACT produces results and that we keep riding on the momentum initiated last February, in Rome.

On that note, I would like to remind you all that commitment and hard work will only take us so far. Resources are also needed and I take this opportunity to appeal to governments and organizations to devote more resources to this effort.

When we gather for the closing session tomorrow, we shall hear and learn what the working groups have decided. What we expect is a clear road map of actions for the coming months and an outline of the resources needed, including possible funding sources. I turn to all the nations, all Member States to help support this initiative by providing the resources we need to move IMPACT forward. I believe that we should have future meetings of the entire IMPACT group, as well as the subgroups, in different parts of the world and we should work with all the regions where the meetings take place to highlight this concern and present the steps we are all taking to solve this problem.

This is the least we can do for patients all over the world. Let’s not forget that at one time or another everyone here can end up in the patient’s shoes. And I am sure that we would all expect the institutions represented by IMPACT to work hard to make all treatment safe and effective, whether it is for ourselves, our local neighbours or our global neighbours.

Thank you very much.