Introductory Speech of

Director Georgette Lalis

WHO IMPACT International Conference "Developing Effective Legislation to Combat Counterfeit Medical Products"

Lisbon
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Dear Professor Vasco Maria[1],

Honourable Member of the Parliament of Columbia Mrs. Moreno Piraquive[2]

Honourable Member of the Parliament of Mexico Mr. Saro[3]

Dear Doctor Reggi[4],

Ladies and Gentlemen,

"Counterfeit drugs kill", "Counteract the counterfeiters", "Putting an end to drug counterfeiting", – these recent vigorous warnings from WHO, the Council of Europe and the European Parliament highlight a serious public health concern.

We are confronted with a global problem as confirmed by recent figures from WHO:

According to WHO figures between **10 and 30%** of medicines used in many **developing countries** such as Africa, parts of Asia and Latin America are counterfeited. In many of the former Soviet Republics, counterfeit medicines represent 20% of the entire market value and thus reach a similarly alarming level. As counterfeiters frequently target medicines against life-threatening

[1] Prof. VASCO MARIA President of INFARMED (Portugese Medicines Agency)
[2] MRS. ALEXANDRA MORENO PIRAQUIVE Senator from Columbia (Member of Parliament)
[3] MR. ERNESTO SAROSenator from Mexico (Member of Parliament)
[4] DR. VALERIO REGGI leads the IMPACT Secretariat at WHO and is the only WHO participant at the conference

diseases, such as AIDS, malaria and bacterial infections, this situation represents a real danger to the health of patients in these countries.

For **developed countries**, the WHO estimates that where effective regulatory systems and supervision exist**, less than 1% of the market value** of medicines is counterfeited.

In the past, most counterfeit medicines identified on the European market belonged to the category of "**life-style**" drugs. However, most alarmingly we have received recent indications that lifesaving medicines such as medicines used to for the treatment of cancer and heart-related diseases have and will continue to be targeted. In addition, the European Commission has become aware of the existence of counterfeited medical devices, which may equally impair patient health.

European customs have noted an increase of seized counterfeit medicines at European customs borders of 380% in 2006 compared to 2005. The main source-countries identified were India, the United Arab Emirates and China.

These facts clearly demonstrate that counterfeiters are unscrupulous and plan their criminal business without any respect for human lives.

The European Commission has a key responsibility for preparing harmonised legislation for the European Community, covering the 27 Member States, and for establishing international cooperation.

The legal framework of the European Community has been amended to protect intellectual property rights and to strengthen customs action. Member States and the European Parliament are currently bringing forward discussions on specific legislation on criminal measures aimed at ensuring the enforcement of intellectual property rights. EU-wide penalties are foreseen as a major step to combat counterfeit medicines.

Our efforts against counterfeiting medical products inside the Community reflect, of course, the crucial importance of **cooperating with all partners** both

at regional and at international level, and IMPACT provides for an excellent platform to do so. The G8 leaders have expressed their support for the WHO Task Force at their meeting in Germany in June 2007.Vice President Verheugen has expressed his full support to the WHO's Medical Products Anti-Counterfeiting Task Force "IMPACT", as it provides for a unique opportunity to exchange best practices and help each other in detecting and fighting counterfeit medicinal products *and* medical devices.

An effective international fight against counterfeit medical products should be based on comparable principles vested in regional and national legislation. The European Commission has therefore decided to support WHO's project to develop specific principles and elements for legislation to minimise the risk of counterfeit medicines to reach patients. We consider this conference to be a major event that will allow to agree on such principles and promote them for implementation.

Let me focus on specific principles of particular importance:

We think it is important to reach a common understanding on what should be considered a **counterfeit medical product**. Quality defects of legitimate and authorised medical products should not be confused with counterfeiting.

Governments have the key responsibility to define the **obligations of all business partners** involved in the marketing, importation, manufacturing, distribution and supply of medical products from the manufacturer to the patient. Appropriate resources for strict supervision and enforcement are necessary to ensure that legal requirements are complied with.

Counterfeiters search for any gap through which they can enter their products into the supply chain. It is therefore of high importance that governments monitor their regulatory systems for any gaps. Specific attention should be given to the **import and export of products and the transit** via ports and free zones. We are aware that in the past counterfeiters may have transited medicinal

products via the European Union and falsely given the impression that these products were manufactured in compliance with the high requirements of the European Community.

Full traceability of medical products throughout the whole distribution chain from the manufacturer to the retailer should be one of the key future objectives. There are numerous ways through which such an eager objective may be achieved. At a global level it is important to note that different products and regions may need different technical solutions.

At this point I would like to mention that in the field of technologies, the European Commission has launched an initiative on **RFID – Radio Frequency Identification Systems**. In a consultation in 2006 on this technology the pharmaceutical sector was identified as an area which could benefit from RFID applications. However, we heard concerns from various stakeholders that the technology needs further development before it can be effective in preventing counterfeiting and affordable for health care systems.

Sales of illegal medical products over the **Internet** are an area of particular concern. According to WHO data more than 50% of medicines purchased through internet websites that conceal their address are counterfeited. Although it is difficult to map the highly complex business structures of criminals using the Internet it is important that the principles for legislation address this area as far as possible. Moreover, cooperation structures of regulatory authorities, police and customs must be enhanced and any activity in this area must be accompanied by appropriate awareness-raising methods. I understand that IMPACT has established separate working groups on these topics. To ensure sustainable cooperation and awareness-raising governments should consider implementing appropriate strategies.

In the past one of the supporting factors for counterfeiters has been the fact that **sanctions** were relatively low. In the future, clear sanctions vested in national legislation should provide for sufficient deterrent effects for criminals.

Beyond the specific challenge of counterfeiting, there is one additional important aspect of equal access to high-quality medicines in developed and developing countries, namely that of so-called "**double standards**". The current legislation in developed countries often sets standards for medicines sold on the home market, but not for those produced which are intended to be exported to third countries. This is also true for the European Union. We find this difficult to accept. We have therefore asked IMPACT to define specific obligations and responsibilities which could be enshrined in our legislation.

I would like to encourage the participants of this conference to engage in the discussions on the principles for legislation with a view to agree to them by the end of this conference.

The international activities should, however, not stop at this point. We consider important that WHO, through IMPACT, takes a key role in supporting adherence to these principles and in promoting and monitoring their implementation throughout the countries and regions involved. WHO should initiate a revision and amendment should future experiences demonstrate the need for this.

The European Commission is currently developing a strategy to prevent counterfeiting and is considering enhanced harmonised legislation for pharmaceuticals and medical devices in this respect. Tailor-made activities within the European Community must be coherent with, and complement actions at the international level. We have foreseen that our work will sufficiently take into account the results of IMPACT and in particular the outcome of this conference and we envisage to present concrete results for the European Union for pharmaceuticals in 2008 and for medical devices in 2009.

This said, I wish you a fruitful discussion over the next days.

Thank you very much for your attention.

Note: Only actual speech given is valid.
