

**Opening speech by Mr Alexander VLADYCHENKO
Director General, DG III - Social Cohesion, Council of Europe**

**On behalf of Ms Maud DE BOER-BUQUICCHIO, Deputy Secretary General of the
Council of Europe**

Mr Chair,

Mr Le Tallec, representing the Mayoress of the town Strasbourg, Ms Keller,

Mr Schreiner, Vice-President of the Parliamentary Assembly of the Council of Europe,

Ms Zapfl-Helbling, Member of the Parliamentary Assembly of the Council of Europe,

Ladies and Gentlemen,

Mr Le Tallec, I am happy to have you with us at the opening of this seminar and would like to refer to the city of Strasbourg as a place offering a welcoming environment to pharmaceutical enterprises.

Mr Schreiner and Ms Zapfl-Helbling have contributed to the seminar's topic in a significant way: Mr Schreiner acted as rapporteur of the Parliamentary Assembly on counterfeiting: problems and solutions in the frame of the Committee on Economic Affairs and Development, chaired by Ms Zapfl-Helbling, which gave rise to the relevant Parliamentary Assembly Recommendation.

Ladies and Gentlemen,

May I invite you to imagine a sixteen-year-old boy who had received a liver transplant and is dependent on adjuvant therapy with high tech, high price medicines to treat his severe anaemia. Imagine that injections administered to him as prescribed do not have the expected therapeutic effect but painful and unusual side-effects. Deeply concerned by the boy's suffering, his family and treating physician are worried and left helpless for a long time – until a seemingly unbelievable crime is being revealed: the medicine was diverted by criminals and repacked in a setting far from being sterile and controlled as otherwise required for medicines. In order to increase profit, the medicine was labelled a multiple of its original low dose before being re-entered into the official distribution chain. The boy had received a counterfeit medicine, which provided much less treatment than intended and had undergone conditions potentially harmful for its quality and hence patient's safety.

Did I entertain you with a fiction made up by a crime and suspense author? No, it is a real story. It happened outside of Europe in a country with high standards for healthcare and pharmaceuticals. Unfortunately such cases also happen in our continent. They are just not widely known. But the situation is changing.

Reports on counterfeit medicines spotted in the legal distribution chain in Western Europe are popping up in newspapers. Most recently a member state's regulatory agency has recalled a batch of counterfeit cholesterol-lowering medicines before being used and harming patients. Public press refers to this recall as the third one in a series of counterfeit medicines since the beginning of 2004 which have entered the pharmaceutical supply chain. These reports shed

some light on dangerous developments in Europe, which experts in the field, member states' officials, European and international organisations and institutions and the private sector tend to voice more and more loudly since a time, until now too often unheard and unthanked.

Let me summarise some facts about counterfeit medicines' situation in Europe:

- WHO estimates that counterfeit medicines make up for 8 to 10% of the European pharmaceutical market, in some countries even up to 12%.
- Experts are convinced that the counterfeiting of medicines is on the rise in Europe.
- Counterfeit medicines often appear so like the genuine product that neither healthcare professionals nor patients can tell the genuine product from the counterfeit before using it. Hence, the patient undergoes the risk of using an ineffective, or less effective and even toxic compound not worth being called a medicine nor worth the price the individual or the health care system pays for it.
- All categories of medicines are profitable targets for counterfeiters – so called life style medicines as well as essential medicines like antibiotics and insulins.
- There is no recognised central reference point in Europe for surveillance, trend analysis and policy recommendations in the field of counterfeit medicines.
- Medicines' counterfeiters can still rely too much on national and international cooperation deficits and information gaps in Europe. Once counterfeiters or their middlemen are prosecuted, often administrative or almost token/non-deterrent fines are spoken.
- Several indicators suggest that organised crime has found a currently lucrative and nearly safe business of counterfeiting medicines to generate resources for other criminal activities. Organised crime puts at stake public health, the health of individual citizens, and aims at creating widespread corruption networks which hinder democratic and economic development and welfare. This also means deprivation of the private sector of its legitimate revenues.

Therefore I call for a multisectorial approach in addressing the problem of counterfeit medicines. It should bring together public sectors dealing with health, law enforcement and distribution, private sectors dealing with pharmaceutical industry and trade, as well as health care professionals.

It is high time for all stakeholders to engage in cooperation in order to protect the patient and the market from counterfeit medicines and to take precautions that uncompromised confidence in medicines and healthcare products can be maintained.

The Council of Europe lends itself as a highly qualified platform to member states and stakeholders to bring forward adequate measures and instruments. The core competencies of the Council of Europe lie within human rights protection, the fostering of fundamental social rights like access to safe and efficient medical treatment. Let's not forget that there is a vital link between good health and the ability to exercise one's own human rights.

Ladies and Gentlemen,

The ancient Chinese general Sun Tzu, who lived 2500 years ago in north-east China was famous for his strategies. Some of them summarised in his “Thirteen commandments of the art of war” could inspire our battle against medicines counterfeiters.

- Take up battle position!

Already in 1999, when the preceding pharmaceutical seminar took place, the Committee of experts on pharmaceutical questions gave an early warning about the risks posed by counterfeit medicines. It anticipated a multisectorial approach to tackling this issue in the Council of Europe Resolution AP(2001)2 concerning the pharmacists role in the framework of health security. This Committee of experts decided in 2003 to set up a multisectorial ad hoc group with a view to develop concrete measures and follow-up.

- Be a leader for others in the fight!

The Council of Europe has the necessary competencies in leading the way in this fight through the responsibility, expertise, experience and ability for cooperation which is derived from its founding principles and core values.

- Act carefully and stick to the facts!

A key to success is to choose the right moment for action with careful preparation. The Committee of experts on pharmaceutical questions has devoted time and resources to look into the counterfeit medicines' situation in Europe within the member states of the Partial Agreement in the Social and Public Health Field and stakeholder associations in the private sector. It has undertaken for the first time to generate actual survey data which complement compendia of case reports and literature reviews to base its measures onto. I would like to thank all respondents who made possible the preparation of this useful report which is now in your hands.

- Act quickly and pragmatically!

Council of Europe working methods and structures allow for great flexibility in the choice of effective working methods and partners across sectors and countries: genuine debates and discussions during this seminar would expedite taking practical effective measures to counteract counterfeit medicines for both public and private partners.

- Be innovative and take initiative!

My wish for this seminar is that the participants identify new modes of co-operation and of exchange of expertise and information in the field of counteracting counterfeit medicines. The seminar programme tries to open up different aspects of the counterfeit medicines issue in legislation and law enforcement, public health practice and multisectorial co-operation, which offers in itself opportunities for addressing the problem. Let us widen existing opportunities within and across this organisation and take further bold initiatives. Whatever different views there are in European capitals today, I strongly believe we should have as our target for the years to come a comprehensive legal instrument to combat counterfeiting.

- Be cooperative !

It is my pleasure to express my sincere thanks to all the co-operation partners in and outside the organisation who have committed themselves to join their expertise and competencies to build an alliance to counteract medicines counterfeiters through effective measures and mechanisms. Namely I would like to thank the European Commission, European Patent Office, US Food and Drug Administration, WHO and within the organisation the Parliamentary Assembly, Directorate General of Legal Affairs, the Directorate for the Quality of Medicines, the Partial Agreement in the Social and Public Health Field and, most important – yourself - the seminar participants from Europe and beyond.

After these introductory glimpses, I would like to welcome you to this pharmaceutical seminar. You are invited to devise through your motivated involvement, open expression of views, conclusions and recommendations on the protection of public health from counterfeit medicines in Europe.

Ladies and Gentlemen,

Let us recall what is at stake if we are talking on counterfeit medicines.

At stake are the very pillars of this organisation, first, the rule of law extending to the legislation on safety and quality of pharmaceuticals and aimed at the protection of citizens. May I remind you in this context that the Council of Europe hosts the Directorate on the Quality of Medicines which is a real cornerstone to the structure of pharmaceutical legislation.

Second, the pillar and core value of vital democracy is threatened by inevitably associated corruption and money laundering. As a response to these threats, Council of Europe has recently launched conventions on the topic of money laundering, cyber crime and corruption.

Third, human rights are at stake which embrace the social right to healthcare of appropriate quality. The Third Summit of the Council of Europe was very strong on this point. The Summit instructed the Council of Europe to intensify the work in this area. I am sure your seminar will be a valid contribution to implementation of this Summit's decision.

I wish you success in your work.

Outline for the draft opening address by Mr Bernard Schreiner, Vice-President of the Parliamentary Assembly and Rapporteur, on the problem of counterfeiting in Europe

Mr Chair,
Ladies and Gentlemen,

I would like to thank you for inviting the Parliamentary Assembly of the Council of Europe to take part in this seminar. The President of the Assembly has asked me to extend his best wishes to you and to tell you that he hopes that your discussions over the next few days will produce practical and clearly defined proposals for all those concerned by counterfeiting in both the public and the private sectors.

As Rapporteur of the Parliamentary Assembly of the Council of Europe, I am pleased to take this opportunity to make a number of more general comments on the problem of counterfeiting in Europe.

A year ago the Assembly adopted a recommendation which underlined the rapidly rising incidence of counterfeiting and the need for better surveillance, control and prevention of the counterfeit-related risks to public health and well-being and the economy. Despite our different social and professional backgrounds, we are all consumers and therefore all concerned by the problem.

What is counterfeiting? First and foremost, counterfeiting is a form of deceit. A counterfeit product is something that has been forged, copied or illegally imitated by the counterfeiter for the purpose of extracting money from credulous or consenting clients, to the detriment of the legal manufacturer.

You have certainly all come across ‘odd’ products that appear suspect because of:

- their price – which is too “cheap”;
- their quality – which is usually bad;
- their appearance - which does not come up to your expectations.

The product may be a watch, an item of designer clothing, a CD bought at a local market or during a voyage, or a forged banknote which you inadvertently accepted.

But there are also counterfeit medicines, toys that do not conform to safety standards, spare parts, foods and common consumer products that are dangerous or potentially so.

Although valuable products have been counterfeited since time immemorial, there has been an increase in this phenomenon over the last few decades. Technological advances and the increasingly frequent relocation of production units to poorer countries with lower labour costs but often inadequate protection of intellectual property rights have transformed once marginal counterfeiting activities into well-organised, highly productive and profitable ‘parallel’ businesses, sometimes linked to criminal networks.

The spread of digital technologies has not only made copying faster and cheaper but also radically improved the quality of the copies, with the result that modern imitations are more and more difficult to distinguish from the genuine article.

It is estimated that counterfeit goods now account for almost 9% of world trade. They can be found in every sector and in every country. The number of counterfeit goods being sold in Europe is steadily increasing. According to the European Union:

- the number of counterfeit goods seized at European borders has increased fourfold over the past five years and is continuing to increase,

- meanwhile, national interests are harmed through the loss of job opportunities (somewhere between 100,000 and 200,000 jobs are lost every year in Europe) and tax revenue, a decrease in GDP of several billion euros and a reduction in investment.

For businesses, counterfeiting is, among other things, unfair competition since counterfeiters are invisible and illicit, and it leads to a devaluation of their products. This also means a gradual drop in sales, market share and profits and, to a certain extent, the amounts spent on research and product development. Small companies are, of course, particularly vulnerable. At a time when economic growth is sluggish, not to say stagnant, in several European countries, counterfeiting is an additional curb on growth, and all-out action must be taken to combat it.

While the general public views drug trafficking and human trafficking with great concern, some people feel less strongly about counterfeiting. The risks that imitation goods pose to the health and well-being of the consumer are generally underestimated and the acquisition of a fake product is still too often seen as a 'bargain'.

Counterfeiters can therefore take advantage of a growing demand for counterfeit products with relative impunity. Counterfeiters do not have to respect quality, fair-trade or safety standards in order to make a profit, nor do they have to provide any after-sales service. Several countries still offer inadequate protection for consumers and it is high time the image of counterfeiting as a harmless activity was challenged. So what can we do to counter this phenomenon?

To date the main action taken by the European Union and other European countries to counter this situation has been in the form of strong customs measures to prevent the entry of counterfeit goods from 'third countries', in particular Asian countries such as China, Hong Kong, Malaysia and Taiwan.

It is now a well-known fact that substantial quantities of counterfeit goods are actually manufactured within Europe. Responses to the problem must therefore come from several levels: international organisations and business associations, the law, industry, companies, law enforcement agencies, regional authorities and consumers themselves.

Harmonising anti-counterfeiting laws and measures throughout the continent continues to be a top priority to ensure that such laws and measures are more effective. The European Union has taken a number of relevant legislative steps:

1. A new regulation to protect intellectual property rights against counterfeiting and pirated goods entering the EU has been applicable in the enlarged European Union since July 2004.

2. It is to be hoped that this regulation will soon be supplemented by a directive, which is already being prepared, on the harmonisation of procedures in member states for combating the counterfeiting of goods within the EU.

3. The agreement on customs co-operation drawn up between the European Union and China in late 2004 is also welcome, given that some 60% of counterfeit goods entering Europe come from China.

Closer multi-sectoral co-operation is required between European countries. Countries that are not members of the EU could align their legislation and law enforcement systems not only with international legal standards but also with EU legislation, as Norway, Iceland and Liechtenstein did through the European Economic Area Agreement that entered into force on 1 January 1994 and as Switzerland did via the bilateral agreement it concluded with the EU.

As regards medicines, there are not enough specific laws on counterfeit pharmaceuticals. In this context, it is also important to underline the need to strike the right balance between intellectual property protection and the needs of society, particularly with regard to patents for medicines that might save lives in developing countries.

Pending the introduction of stronger laws and law enforcement systems at national and EU level, companies and industries should continue to take measures to improve protection for their products and, insofar as possible, their distribution channels.

Our fellow citizens should be made aware of, and given more information on, the problems that counterfeit goods pose for their own safety and for the economy. The competent authorities should also be given responsibility for compiling statistics on the links between counterfeit goods and the accidents or deaths which such products may have caused, particularly in the case of products such as medicines, toys and spare parts.

I trust that over the next few days we will have a fruitful discussion on the subject and that we will succeed in identifying the priority measures that must be taken to put a stop to the counterfeiting of medicines, on the basis of the work carried out by the many European institutions present here today.

Thank you for your attention.

**Opening address by Ms Rosmarie Zapfl
Member of the Parliamentary Assembly and former Chair of the Committee on
Economic Affairs and Development**

Secretary General, Ladies and Gentlemen,

The Parliamentary Assembly is greatly concerned at the speed at which trade in counterfeit goods is growing in Europe. Counterfeit goods pose a threat to the health and wellbeing of European consumers, erode the market for legitimate products, damage the reputation of brand names, distort competition, undermine employment and ultimately reduce tax revenue.

The member states of the Council of Europe must therefore do their utmost to effectively reduce the incidence of counterfeit goods and counterfeit-related accidents and deaths by combating the counterfeiting not only of spare parts, household appliances and food products but in particular of pharmaceutical products, on which urgent action needs to be taken.

Europe must develop a joint policy to help detect and prevent counterfeit-related risks. In order to do this, it is first necessary to inform and involve both industry and the general public. The same applies to the risks related to the uncontrolled sale of medicines and other sensitive products over the Internet.

The Parliamentary Assembly was pleased to learn that the Council of Europe Committee of Experts on Pharmaceutical Questions has already addressed these problems. During summer 2004, the committee published a document on counterfeit medicines on the Internet and came to the conclusion that there is an abundance of information on this subject on the Web but that very little of this information can be considered serious or reliable. The same applies to medicines sold on the Internet: many of them do not conform to the standards applied in our countries and some of them are even counterfeited. Swissmedic, the Swiss authority responsible for monitoring pharmaceutical products, has chosen to warn the public at large by clearly stating that people who buy medicine on the Internet are putting their health at risk.

With a view to preventing the counterfeiting of pharmaceutical products and the risks they pose to patients' health, the Committee of Experts on Pharmaceutical Questions has set up an Ad hoc Group on Counterfeit Medicines, which took the initiative of organising this seminar.

What exactly is the problem? For some years now, counterfeit pharmaceutical products have also been found on the European market. This problem usually concerns expensive medicines which are still under patent, in particular life-style medicines such as Viagra or Cialis, but also medicines which are essential to a specific group of patients, for example new-generation medicines for treating AIDS, or Sandimmun, which inhibits organ rejection following transplantation. The scope of the problem is, however, underestimated in many countries. For instance, in Switzerland alone, a country which is relatively small, two cases of illegal trading have been discovered, each of which involved counterfeit goods worth 15 million euros. In the first case, a Swiss wholesaler illegally introduced counterfeit goods into the German market. In the second case, the Swiss customs authorities blocked a large shipment of AIDS medicine from Africa intended for the EU market. The pharmaceutical industry is also aware of other major counterfeit scandals in Europe, about which we will talk later, and, what is more worrying, there are signs that there may be an organised crime and money-laundering network behind these operations.

Counterfeit pharmaceuticals are of varying quality. In some cases very advanced technology is used, which would seem to suggest that the counterfeiters are anything but amateurs. Others are commodities from countries which sell them at low prices, and they are repackaged and resold in countries where medicines are expensive. Some counterfeit medicines do not contain any active ingredient whatsoever or contain a different one from that indicated. Hitherto unknown active ingredients have even been discovered, for example an analogue of sildenafil, the active ingredient in Viagra. Moreover, some counterfeiters have recently tried to pass off capsules containing these medicines as dietary supplements, under a false declaration, which obviously poses a major risk to the patients concerned. Fortunately, the worst has not yet happened: there are, to date, no counterfeit medicines on the market which are essential to a specific group of patients but which contain no active ingredient. It is important to prevent this happening in future or at least to detect such counterfeit medicines as soon as possible and then take the appropriate steps to protect the patients concerned. One of the specific aims of this seminar is to decide how this can be done.

Who can help solve this problem? The responsibility for solving this problem lies mainly with the medicine regulatory authorities. They cannot turn a blind eye on the grounds that “that which should not be done cannot be done” because – as the pharmaceutical industry is well aware – counterfeit goods are often uncovered only after a great deal of active research. Many regulatory authorities in Europe are not yet fully familiar with the problem or do not have enough relevant information, while others are perfectly aware of the problem and determined to solve it but do not have the necessary legal backing. Given that many major counterfeit cases concern several countries, it is important to settle issues concerning the exchange of information between the various national authorities concerned.

Experience also shows that it is pointless for these authorities to take action on their own. There has to be close co-operation with the customs authorities because it is they who have succeeded in uncovering numerous examples of counterfeiting. It is also necessary to ensure co-ordination with the judicial authorities and the police. It is therefore important that these authorities should, in future, easily be able to exchange information on both a national and an international scale.

There are also other partners who have a major interest in taking action on counterfeiting, in particular the pharmaceutical industry. Its turnover is falling, patents and brand legislation are not being respected, and when a patient suffers from the effects of a counterfeit medicine, the original brand image also suffers. It is also quite clear that the pharmaceutical industry currently has much greater knowledge of counterfeiting than many medicine regulatory authorities. It is therefore important that these authorities and the pharmaceutical industry pool their knowledge in order to guarantee maximum safety for patients. This seminar is also a first step in that direction.

Counterfeit medicines are, as a rule, illegally introduced into legal distribution channels through the wholesale trade. Wholesalers must consequently also become involved in the fight against counterfeiting, in particular by complying with the rules and regulations designed to prevent its development. I am therefore delighted to note that the European section of the Association of Pharmaceutical Full-line Wholesalers is taking part in this seminar and subsequently intends to take the necessary measures to prevent trading in counterfeit goods.

Finally, people working in the pharmaceutical field, in particular doctors and pharmacists, must also help to combat counterfeiting, for they are the ones patients turn to when they have a problem. If a medicine does not have the desired effect, medical staff must also consider the possibility that the medicine has been counterfeited. I was therefore pleased to learn that the fight against counterfeiting has become a major priority for the International Pharmaceutical Federation (FIP) and its President, Jean Parrot. And I am convinced that it will also become a priority for doctors.

Last but not least, it will also be necessary to explain to patients that they are under threat and that the best way of helping the medicine regulatory authorities and other partners to eliminate counterfeit-related risks is to be particularly vigilant.

What are the aims of this seminar? First of all it aims to bring all partners together to exchange the information they have on the subject and identify ways of co-operating in the fight against counterfeiting. It will therefore be necessary to consider what action should be taken to enable effective co-operation and a very rapid exchange of information in case of emergency to ensure that patients come to no harm.

It is therefore important, Ladies and Gentlemen, that we ask ourselves the following questions:

1. What can be done to improve co-operation between the various national medicine regulatory authorities on the one hand and between these authorities and the customs, judicial and police authorities, on the other? What form should co-operation between these authorities and business enterprises take? How can their staff be trained to combat counterfeiting?
2. Given that most counterfeit cases concern several countries, what can be done to sound the alarm at international level in suspicious cases? Who would take charge of operations to solve the problem?
3. What steps would need to be taken to withdraw counterfeit goods from the market and replace them with the medicine essential to certain patients? Such problems could give rise to very sensitive legal issues.
4. How and in what sort of case should the public be informed of existing risks and who should have responsibility for informing them? How should information be co-ordinated at international level, and between business enterprises and medicine regulatory authorities?
5. What can be done to make medical staff and patients aware of the problem, and what can be done to encourage them to report suspicious cases as quickly as possible?
6. What type of legislation needs to be introduced in the different countries to combat counterfeiting, collect and exchange information on this subject, seize suspicious consignments and bring legal proceedings against counterfeiters?

The Parliamentary Assembly of the Council of Europe expects this seminar to not only seek answers to these questions but also put forward concrete proposals for countering the threat posed by counterfeit pharmaceutical products. Given that counterfeiting is a relatively new phenomenon, you are all invited to express your opinions by making clear, well-defined and specific proposals. You should also state whether your proposals require the introduction of

fresh legislation in a particular country and specify the substance of the laws in question. You should make recommendations for improving co-operation and state whether they require the conclusion of international agreements. This seminar could also indirectly aim at defining good practices in combating the counterfeiting of pharmaceutical products. And please do not hesitate to enlist the Council of Europe's services in informing both those working in the pharmaceutical field and the public at large.

This seminar will be fruitful:

- If you manage to make the authorities and stakeholders concerned throughout Europe aware of counterfeiting issues.
- If you propose ways of improving co-operation between the relevant authorities, at both national and international level.
- If you identify opportunities for co-operation between the authorities and the associations concerned.
- If you indicate the shortcomings in the legislation of particular countries, which make it difficult to effectively combat the counterfeiting of pharmaceutical products.
- If you put forward proposals concerning the establishment of an efficient network for the very swift detection of counterfeit products, thereby ensuring that patients do not suffer. In addition to the Official Medicines Control Laboratories (OMCL) in the different countries, the Council of Europe network co-ordinated by the European Directorate for the Quality of Medicine could play a role at this level.

This seminar is a first step in the fight against the counterfeiting of pharmaceutical products. I therefore wish much success to all those concerned. The Parliamentary Assembly will support all your efforts in this field. Thank you for your attention.