

Aim of the seminar

- Is there a problem? Yes
- Do we need action? Yes
- Is there commitment? Yes

Internal organisation CoE

- 1 Council of ministers
- 1 Partial agreement
- 1 Public health committee
- 1 Expert committee on pharmaceutical questions
- 1 Ad hoc working group on counterfeit medicines

Terms of reference expert committee on pharmaceutical questions

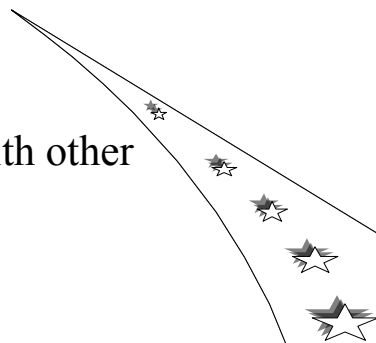
- 1 To contribute to the improvement of public health by promoting the safety, quality and effectiveness of medicines and their appropriate use in society.

Resolution concerning the pharmacist's role in the framework of health security

- 1 Counterfeit medicines pose real threats. In order to combat these dangers, the authorities, manufacturers, wholesalers, pharmacists and intergovernmental and non-governmental organisations must co-operate.

The problem of counterfeit medicines

- 1 What is the difference with other counterfeit products?
- 1 public health risk
- 1 trust of patients
- 1 highly regulated



Safe and Secure

Prevent unreliable products from invading the system



Prevent genuine products from leaving the regular distribution system




The actions

- Legislation
- Implementation and control
- Co-operation
- Exchange of information
- Public health challenges
- Training and awareness

Legislation

- 1 European directive on medicinal products: registration, GMP(incl. API's), GDP
- 1 European Commission: counterfeiting is a criminal offence; intellectual property
- 1 Illegally produced health care goods: criminal offence: sufficient penalties
- 1 Harmonize legislation: Harper report
- 1 Council of Europe: convention
- 1 WHO conventions and schemes

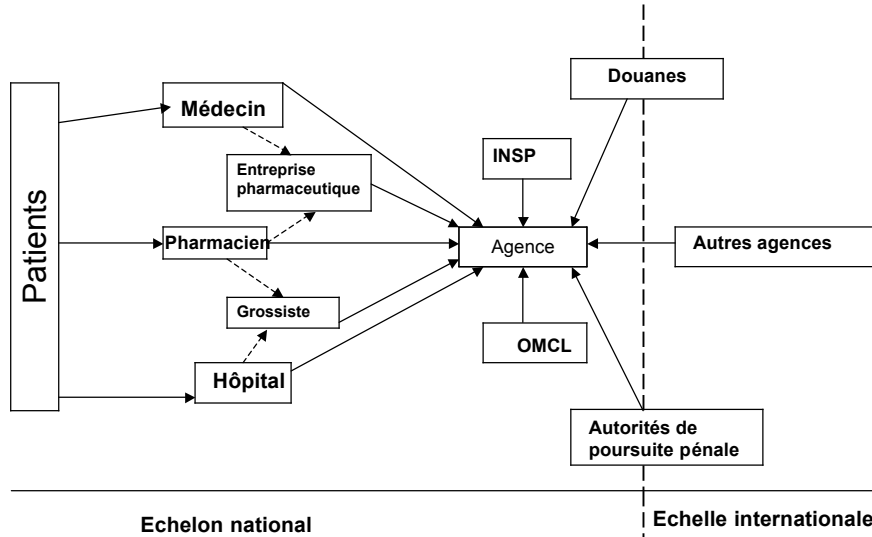
Implementation and control

- 1 Inspections of manufacturing and wholesaling: PIC/S
 - 1 Competent authorities: agreement on inspections of the legitimate channel
 - 1 Competent authorities: priority to counterfeit
 - 1 Code of conduct for industry
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Co-operation

- Political awareness
- (semi) permanent forum: CoE
- Co-operation between health authorities and enforcement authorities: forensic pharmacy
- Exchange of information between all stakeholders
- Implementation of Integris

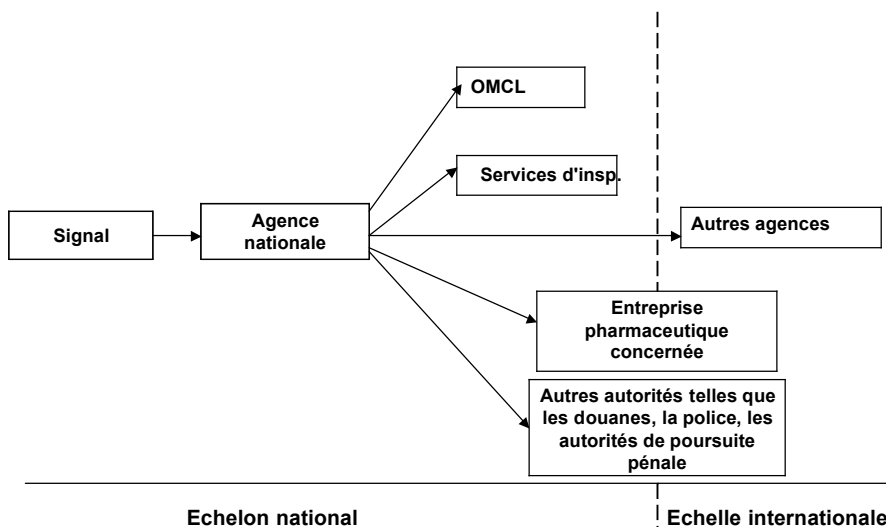
Possibilités d'annoncer les contrefaçons: 1. Signaler les soupçons



Council of Europe Seminar on
Counterfeit Medicines 21 - 23
September 05

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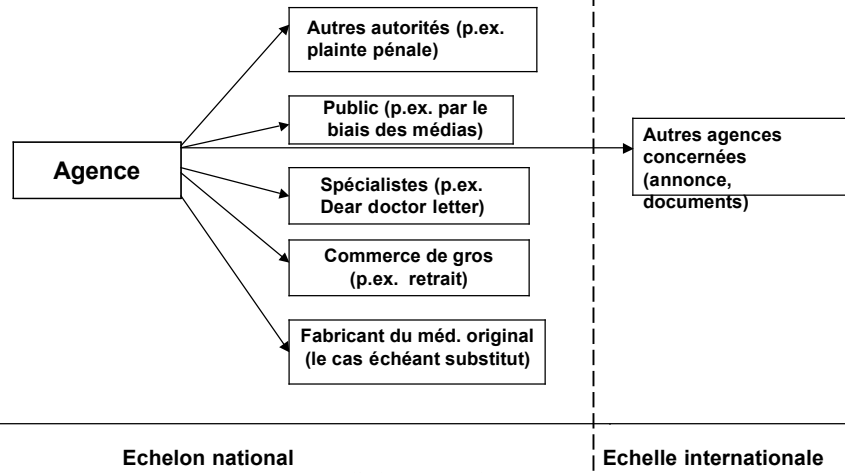
Possibilités d'annoncer les contrefaçons : 2. Définir la marche à suivre



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Possibilités d'annoncer les contrefaçons : 3. Prendre des mesures (la contrefaçon est avérée)



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Public health challenges

- Include counterfeit in vigilance system
- Identify target groups of patients
- Recall: up to patient level

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Training

- 1 Inspectors, manufacturers, wholesalers, customs officers, police
- 1 Council of Europe: outline training plan
- 1 Country specific training needed
- 1 Expert groups

Awareness raising

- 1 public and health care professionals
- 1 dilemma: awareness versus unjustified mistrust: risk communication
- 1 freedom of choice versus public health protection

Actions within the Council of Europe

- 1 drawing up a final document of this seminar including the recommendations: October 2005
- 1 approval by the expert committee on pharmaceutical questions: October 2005
- 1 approval by the public health committee: November 2005
- 1 resolution by the committee of ministers

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

Mr Chairman, Ms Hansen, Ladies and Gentlemen,

The American writer Scott Fitzgerald once said “No grand idea was ever born in a conference”.

I do not agree at all.

The economist John Kenneth Galbraith once said: “Meetings are indispensable when you don’t want to do anything.”

I do not agree either.

Looking round the audience, I am reassured to see about the same number of participants that I had the pleasure to greet on day one of the seminar – a good sign !

I can read in your faces enthusiasm and commitment. Enthusiasm about the ideas raised at this conference, and commitment to do something.

I took note with great interest of some of your excellent presentations and the bouquet of conclusions. The facts, full-hearted appeals, and the snapshots left a lasting impression on my mind.

They say that a picture may say more than a thousand words. No lecture could tell you more about the need for regulatory norms and legal requirements of good manufacturing practice than the slide show which took us midway into a counterfeiter's messy and chaotic place of illegal work: obvious for all viewers, no product of reproducible, desired therapeutic properties can result from such process. Moreover, medicines sensitive to heat, cold or humidity could be destroyed when produced or packed in this way, and harm patients through their loss of potency or through toxic by-products. It goes without saying that such environment does not know aseptic or sterile handling procedures.

Many experts highlighted the ambiguous role of the Internet, where innumerate offers for information or products including medicines are poured like water through a mesh without any effective means of large scale controls.

We also have to assume some link between organised crime groups and counterfeit goods. Intellectual Property Crime is becoming a preferred choice of funding for a number of terrorist groups. As the presenters made clear, a dark shadow of a profitable crime, poorly penalised, difficult to detect and to prove, is reaching out to us if we do not engage in a concerted multisector co-operation to counteract. “Counteract the counterfeiters”, let me remind you, Ladies and Gentlemen, is the title of this Seminar.

You, the experts, have now taken all these jigsaw pieces and worked them in laborious workshops and evening sessions into a complete picture of proposals for actions and instruments. The conclusions of the 12 thematic workshops were merged into a comprehensive and conclusive set of recommendations on the 6 themes of the seminar.

Ladies and Gentlemen,

Our programme objectives were high. At the end of this seminar, we have to ask ourselves whether we did achieve the goals.

Creative and sound proposals have been made in a cooperative atmosphere between many experts from different sectors and different member states of the Council of Europe and beyond.

However, as emphasised by many of you, nothing can be achieved if we do not breathe life into these papers produced when we go back to our everyday work.

Rightfully so, you may ask me about the possibilities of the Council of Europe to take action and possible further steps.

As a political international organisation of 46 European member states with competency in standard setting, legal co-operation and policy formulation, the Council of Europe claims an active role to play in the fight against medicines counterfeiters and the containment of these absolutely unacceptable risks to patients and consumers, to the entire society. This is in line with the core values which unite the member states and bring about this Organisation, namely the protection of human rights, democracy and the rule of law.

This is underpinned by a proven track record of our some 200 conventions and many more policy recommendations offered to governments.

The Council of Europe puts at the disposal of member states and stakeholders the competencies and flexible and effective working methods of its services, in particular in the political, legal and public health fields.

Let me confirm here, that we will take your expert conclusions and your repeatedly voiced appeals for co-operation very seriously. The concerned services in the Council of Europe will study the Seminar conclusions with a view to initiate the political negotiation process on their possible implementation in the member states of the Council of Europe. This can neither be a one-off nor a one-sided exercise: so we highly appreciate the desire of all participants to continue following and actively supporting this work which is only at its beginning.

It is very important for us that the Russian Federation, the country that will chair the Committee of Ministers of the Council of Europe from May to November next year, is going to put the issue of combating the phenomenon of counterfeit medicines on the agenda of the priorities of its Chairmanship. An important follow-up activity is being planned in Russia.

So, let's engage now in the challenging task of transforming a good beginning into a fruitful outcome.

I would like to close by expressing my sincere gratitude to all the member states and private stakeholders for their voluntary contributions, which were indispensable for the organisation of this seminar, and which enabled a balanced representation of Council of Europe member states.

Ladies and Gentlemen,

I started by saying that I see enthusiasm and commitment in your faces. That is true. But it is only half the truth, Because, I also see in your faces the reflections of the hard work you have been doing here over the last few days.

I would like to thank all of you wholeheartedly for the effort and energy you put into this seminar. I would in particular like to thank some key figures in the preparation and management of this seminar, and I would like to ask you to please come forward and accept a small token of appreciation for your work to improve patient and consumer safety.

Mr Bonar, Chair of the organising committee and of seminar day 1,

Mr Duneton, Chair of seminar day 1,

Mr Ten Ham, Chair of the ad hoc Group on counterfeit medicines and of seminar day 2, and

Mr Dietschy, Chair of seminar day 3 and of the preceding pharmaceutical seminar.