



**Council of Europe European Directorate for the Quality of Medicines and HealthCare (EDQM)
and the Directorate General of Human Rights and Legal Affairs, Criminal Law Division
UN Internet Governance Forum (IGF), Sharm El Sheik, 15-18 November 2009
Workshop “Medicines on the web – risks and benefits”**

1. Introduction

The workshop, co-organised by the Council of Europe EDQM and the Criminal Law Division, dealt with health protection of the internet user from counterfeit medicines and other illegal offers of pharmaceuticals and healthcare products via the internet through empowerment of the internet user, establishment of best practices and regulatory policies, and, where necessary, legal instruments for combating counterfeiting of medicinal products and similar crimes threatening public health, where necessary.

The quality of medical counseling and pharmaceutical products obtained via the internet cannot be taken for granted; the above products could entail considerable risks. Moreover, criminal activities concerning the production, distribution, and use of medicines and healthcare products (including counterfeit and illegal medicines and healthcare products) are widespread and the internet is frequently misused for these purposes.

The Council of Europe aims at counteracting the advertising and selling of illegal medicines and healthcare products via the internet through a comprehensive strategy¹ comprising specific policies² and legal instruments, improving patient information, the quality of healthcare that can be obtained online.

The Council of Europe is preparing an international binding legal instrument against counterfeiting of medical products and similar crimes involving threats to public health, a Council of Europe convention³. The convention is expected to be adopted in 2010 by the Council of Europe Committee of Ministers.

The focus of the draft convention is on public health protection from counterfeit medical products and medical products which are manufactured or distributed without proper authorisation and/or in breach of safety standards.

As is the case for a number of other Council of Europe conventions, and considering the global dimension of pharmaceutical crimes, this Convention could be open for participation by non-member states, giving to the convention a potentially universal vocation. The impact of the draft convention will be complemented by existing Council of Europe international treaties in the field, namely the conventions dealing with international co-operation against cybercrime and corruption.

¹ http://www.coe.int/t/information/society/health/EDQM_en.asp

² Resolution ResAP(2007)2 on good practices for distributing medicines via mail order which protect patient safety and the quality of the delivered medicine. In: <https://wcd.coe.int/ViewDoc.jsp?id=1179467&Site=CM>

³ European Committee on Crime Problems: http://www.coe.int/t/e/legal_affairs/legal_co-operation/steering_committees/cdpc/Meetings/1List_of_meetings.asp#TopOfPage
Draft convention (9 November 2009):
http://www.coe.int/t/e/legal_affairs/legal_co-operation/steering_committees/cdpc/Documents/CDPC%20Plenary%20meeting,%2012-16%2010%202009/New%20Addendums/CDPC%20_2009_15Fin%20E%20Draft%20Convention%20ADDENDUM%20III%20%2009%2011%2009.pdf

Disclaimer: the enclosed version of the text is a draft - the Committee of Ministers will be invited to formally adopt the convention.

2. Key conclusions

The key conclusions drawn by the workshop participants are the following:

All medicines must be safe and of suitable quality and must be provided with an appropriate quality of pharmaceutical care, regardless of which pharmacy dispenses them.

The benefits consumers and patients expect from the availability of medicines on the Net include being able to choose from different offers, competitive prices of medicines and healthcare, anonymity if they suffer from diseases which are likely to lead to stigmatisation, and convenient access.

However, to date, patients have not uniformly benefited from medicines on the Net because they have difficulties finding information and because producers have shortcomings in providing it to them. Often, medicines obtained outside of regulated and legitimate supply chains, including certain offers via the Web, pose significant health risks due to substandard quality of products and pharmaceutical care and to criminal conduct.

Initiatives are required to:

- provide better access to balanced information,
- improve medication-related health literacy,
- verify information on medicines on the Web,
- set standards in a participative manner for the presentation of specific information on the Web.

In particular, information about medicines on the Net should be unbiased and user friendly, including valid information that is easy to read and easy to find.

Public health authorities have an important role as regards consumer education and empowerment, verification of Web information content and accessibility, setting standards and cooperation across borders to contain risks.

Legal offers of pharmaceutical services through the Internet should be regulated at the international level to ensure that they are safe and effective. Council of Europe standards for good practices for distributing medicines via mail order, which protect patient safety and ensure the quality of the delivered medicines and healthcare products, can serve as a model.

International criminal legislation is needed to deal with potential public health risks resulting from criminal activity in this area and especially those arising through Internet trade and the growing market of counterfeit medicines and other healthcare products.

The Council of Europe is preparing an international legally binding treaty, a convention against counterfeiting of medical products and related crimes involving threats to public health, which will also be open to participation by non-member states beyond Europe. It is expected to be opened for signature in 2010.

The UN IGF is invited to consider hosting a future Internet health action framework.

3. Conclusions presented by the workshop moderator, Mr Hugo Bonar, Enforcement manager, Irish Medicines Board

The Council of Europe workshop raised the dangers of buying medicines from the internet through unreliable websites, compromised confidentiality of patients, unknown legitimacy of medicines, the variation of quality of health and product information, and medicines in foreign language labeling.

It emerged from the discussions that all medicines need to be safe and of appropriate quality, regardless of the pharmacy from which they are obtained. This should also apply to the quality of pharmaceutical care activities. Mr Paul Zickler, MD, Canadian International Pharmacy Association (CIPA) stated that "...there was definitely a need for access to safe and affordable medications internationally. When conducted legitimately and with the proper regulatory oversight, distance-based

pharmacy care can provide this access. Several jurisdictions currently license and regulate the practice of international medicine to ensure that appropriate safety standards are in place...”.

In order to enjoy the benefits of safe and affordable medications by mail order trade/internet/international pharmacy which is as safe the workshop concluded on the following:

1. Prescription-only medications should only be dispensed at a distance by licensed pharmacists from a regulated and authorised facility providing pharmacy services and pharmaceutical care activities.
2. No dispensing of medicines without prior face to face interaction with a licensed physician providing an original valid and verifiable prescription.
3. No shipping of narcotics and restricted medicines via mail order across borders.
4. Only medicines with a known source and distribution history should be traded.
5. There should be only licensed suppliers that can be audited.
6. Operators of mail order /internet/international pharmacy must have a good understanding of the risks and the benefits in order to be able to mitigate the risks so that the benefits can be reaped by the patient/consumer.
7. A system for aftercare, including recourse for the patient, and a tracing system of medication should be established.
8. The dispensing pharmacy should be regulated and responsible for the quality of its operation, services, and pharmaceutical care activities. A pharmacy dispensing a product to a patient across a border should respect the respective legislation of the country of destination.
9. There should be a rapid alert system for defective or counterfeit medicines and a recall system based on internationally agreed protocols.
10. In mail order trade, the following principles should apply: the receiving state is responsible for the public health of that state and not that of the supplying state or a commercial entity.
11. The consumer should have the right to buy medication that he can afford from other states that guarantee the quality, efficiency and safety of the product. The medication should be dispensed from pharmacies that are licensed, subject to inspection and that are staffed by licensed pharmacists.

The workshop recognised consumers’ and patients’ legitimate needs and expectations which are to

12. The benefits of buying medication on the net are privacy, convenience and availability. In addition the consumer can compare prices easily from a variety of products to choose from. The consumer will be more likely to be compliant with his medication if he can afford them. This means that he will not increase his risk of morbidity/mortality through left out doses.

The workshop expressed concerns that

13. currently, patients do not enjoy sufficient access to medicines on the net due to inequalities in access to medicines and shortcomings in information transfer from producers to patients.

The workshop called for initiatives (see 14.-19.) and provisions (see 20.) such as

14. increasing medication- related health literacy of consumers;
15. giving consumers and patients better access to objective, accurate and transparent information without imbalanced advertising;
16. establishing verified web sites, overseen by regulators, patients associations, and professional boards;
17. involving patient advocacy organisations as regards relaying medicines’ information;
18. taking responsibility for controlling and eliminating the risks of misleading and wrong information to consumers⁴;
19. working out collaboratively formats for the contents of the web sites between producers and distributors, patients’ advocacy organisations and regulators;
20. providing for a necessary legal and regulatory framework to be adhered to by pharmaceutical manufacturers/mail order trade/E-pharmacies, and government regulators.

⁴ IAPO policy statement on patient information. In: <http://www.patientsorganizations.org/showarticle.pl?id=1070>

The workshop urged increased efforts of public health authorities as regards

21. fostering of partnership with internet service providers, and professional associations;
22. offering reliable and unbiased product information;
23. designing web sites that are user friendly, including valid information easy to read and easy to find;
24. educating and empowering the consumers through promoting balanced independent medication related information;
25. consumer protection through cyber inspectors in charge of establishing and supervising conditions for sale and distribution and through focal points for international co-operation.

Underlined by several panellists, the workshop emphasised that

26. The liberty to choose freely from the offers on the internet requires well informed citizens.
27. Legal offers of pharmaceutical product services through the internet would need international regulation in order to become safe and effective.
28. The Council of Europe standards for good practices for distributing medicines via mail order, which protect patient safety and the quality of the delivered medicines provide a model⁵ for good regulatory practices in mail order trade in medicines that protect the patient and the quality of the distributed medicines.
29. The workshop invited the UN IGF to host a platform for a future internet health action framework: patients' advocacy organisations, bodies of health professionals; e-commerce, national governmental bodies and the relevant regulators and international organisations such as the WHO and the Council of Europe should be involved.

With a view to protecting people and health systems from criminals abusing the internet for intentional criminal conducts, the workshop invited the UN IGF

30. to recognise that international criminal legislation is needed to cater for the potential public health risks resulting from these crimes and especially those arising through Internet trade and the growing market of counterfeit healthcare products;
31. to support the Council of Europe in preparing and implementing in Europe and beyond the first international legally binding treaty, a Convention on counterfeiting of medical products and similar crimes involving threats to public health. The future Convention will also be open for participation by other states beyond Europe and is expected to be opened for signature in 2010.
32. The future Convention⁶ could serve as a model for other regions to participate or to adapt according to local conditions and to use in conjunction with the Council of Europe's Cybercrime Convention to ameliorate some of the worst risks to the patient and to tackle crimes emerging from the abuse of the Internet.
33. The following intentional acts will be criminalised by the future Convention:
 - the manufacturing of counterfeits,
 - the supplying or offering to supply of, and trafficking in counterfeits,
 - the falsification of documents,
 - the unauthorised manufacturing or supplying of medicinal products and the placing on the market of medical devices without them being in compliance with the conformity requirements.

⁵ Resolution ResAP(2007)2 on good practices for distributing medicines via mail order which protect patient safety and the quality of the delivered medicine. In: <https://wcd.coe.int/ViewDoc.jsp?id=1179467&Site=CM>

⁶ European Committee on Crime Problems: http://www.coe.int/t/e/legal_affairs/legal_co-operation/steering_committees/cdpc/Meetings/1List_of_meetings.asp#TopOfPage
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5. Agenda

Moderator: Mr Hugo K. Bonar, Enforcement Manager, Irish Medicines Board, member of the Council of Europe Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP), Ireland
The moderator will contribute to setting the scene for topics 1 and 3.

1. Medicines on the Web – Risks and Benefits

Setting the scene: Mr Paul Zickler, CIPA (Canadian International Pharmacy Association), Canada
Questions and discussion

2. Can Consumers and Patients benefit from Medicines on the Web?

Setting the scene: Mr Kin-ping Tsang, International Alliance of Patients Organizations (IAPO), President, Retina Hong Kong and Mr Griffith Molewa, Manager Law Enforcement, National Department of Health, South Africa
Questions and discussion

3. Policies and Legal instruments that support Patient safety and Cyber-security

Setting the scene: Dr Nico Kijlstra, Health Care Inspectorate, Ministry of Health, Welfare and Sport, Vice-Chairman of the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH), the Netherlands

Questions and discussion

Conclusions