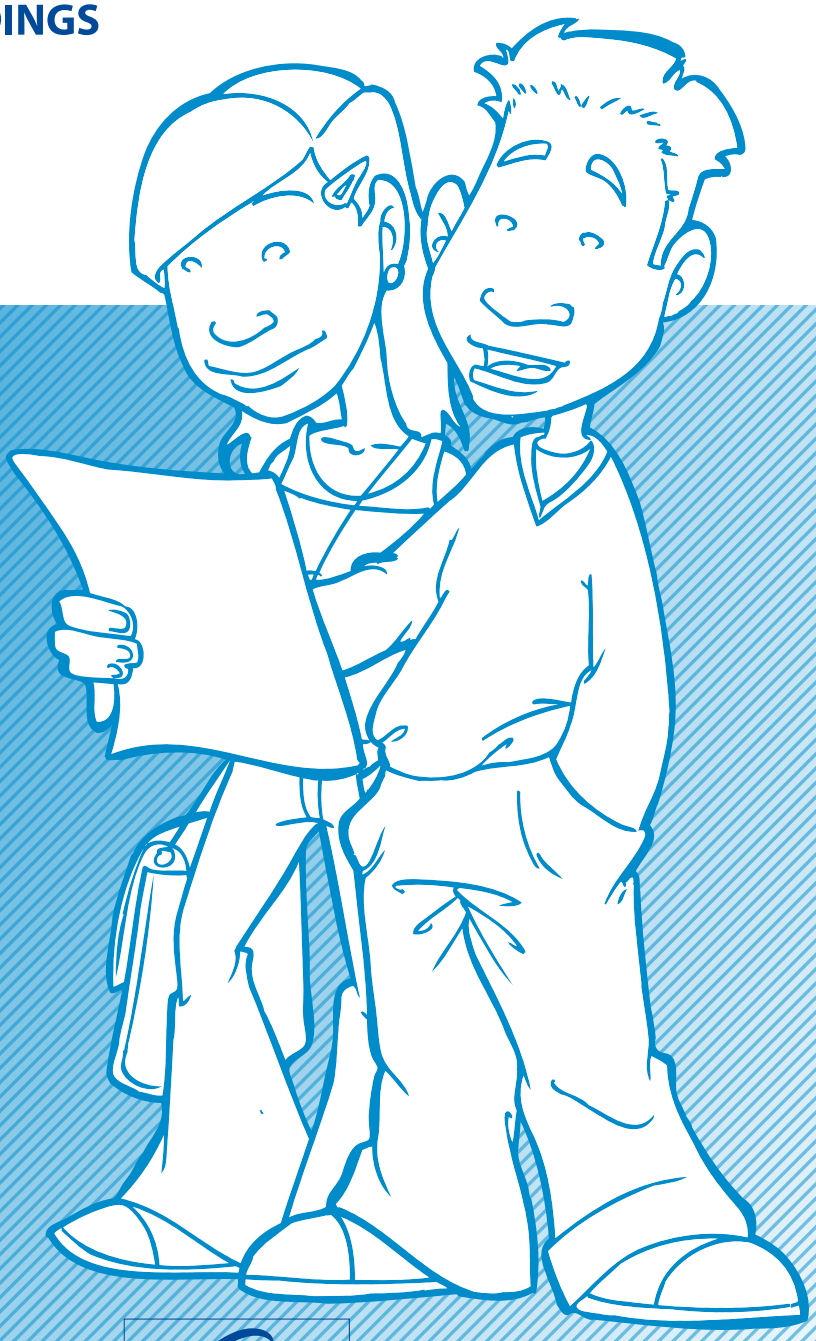
COMMUNICATION ABOUT THE RISKS POSED BY COUNTERFEIT MEDICAL PRODUCTS AND SIMILAR CRIMES

Expert Workshop Proceedings

AIFA, Rome, Italy - 29 November, 2011



AIFA

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Agenzia Italiana del Farmaco
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European Directorate for the Quality of Medicines & HealthCare |EDQM
7 allée Kastner, F-67081 Strasbourg
http://www.edqm.eu | e-mail: info@edqm.eu

Printing Service
Tecniche Nuove, via Eritrea 21, 20157 Milano
Editorial Office: tel. 02.39090264, fax 02.39090255, e-mail: libri@tecnichenuove.com
ISBN 978-88-481-2851-3

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Compiling a book is a complex operation, which requires repeated checking of the text, the figures and the relations between these. Experience shows that it is practically impossible to publish a book free of errors. We are therefore grateful to any readers who point out such errors.

Director of the Publication: Susanne Keitel, Director EDQM
Editor in chief and Coordinating Author: Domenico Di Giorgio
Editorial production: AIFA
Editorial Staff: Domenico Di Giorgio (chief editor), Chiara Prost (editing), Gianpaolo Derossi (graphic design), Marcello Chiavoni, Marta Gramazio, Michael Haldane, Melissa Coutinho, Lynda Scammell, Joanna Groves, Sabine Walser (copy editing of texts).
Cover: Gianpaolo Derossi
Printing: Andersen, Borgomanero (NO)
Printing completed in Italy, October 2012

Expert Workshop:
COMMUNICATION ABOUT THE RISKS POSED BY COUNTERFEIT MEDICAL PRODUCTS AND SIMILAR CRIMES

Agenzia Italiana del Farmaco (AIFA), Rome (Italy), 29th November 2011

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Thanks to Emanuele Cesta, Marcello Chiavoni, Chiara Prost (AIFA) and to all the WS moderators, speakers and participants.

FOREWORD

COMMUNICATION, NETWORKING AND THE SCIENCE BEHIND THEM

The expert workshop on risk communication, organised in the frame of an entire week dedicated to counterfeit medical products and similar crimes, was among the first events AIFA hosted since I took up my mandate as Director General of the Italian Medicines Agency.

A lucky coincidence indeed, for a number of reasons; the study of ***communication*** *and its tools, intersectorial and international* ***networking****, the* ***science****-based approach behind all this and - in general - in the regulatory world, which has been part of the concept fuelling the project, are some of the pivotal points on which I have decided to focus the new mission of AIFA under my term of service.*

Communication *is, in my opinion, one of the most overlooked instruments among those available to drug regulatory agencies; when an incident related to counterfeit medicines occurs, and even more when one wants to prevent such an event, communication becomes paramount. If properly managed and administered through the relevant networks we are part of, benefiting from the cooperation and communication of scientists, the network in itself could become a weapon.*

All AIFA activities, such as those related to anti-counterfeiting, strongly benefit from ***networking****, both at a national and international level. The transparent communication and exchange of information, the mutual support, the sharing of knowledge and science with competent experts between administrations and private stakeholders, is so important in my view, that we have dedicated a whole new line of projects to it, called "Open AIFA".*

Science *in its broadest definition, is in my background, therefore since the beginning I wanted AIFA to consider the means of dissemination through scientific publication to be a priority. I feel it is important to communicate about the significant results of our activities not only in the usual regulatory framework, where an agency is an established and respected entity, but also in the academic and broadest cultural networks, in order to underline the role that all drug regulatory authorities have in fostering the progress of research.*

These proceedings of the expert workshop on "Communication about the risks posed by counterfeit medical products and similar crimes" *that we organised with the EDQM are an attempt to organise facts in a structured manner, based on method: they undoubtedly constitute a publication, but are moreover a joint effort and above all a scientifically inspired regulatory activity.*

> Le savant doit ordonner; on fait la science avec des faits comme une maison avec des pierres; mais une accumulation de faits n'est pas plus une science qu'un tas de pierres n'est une maison.
> *(Henri Poincaré, Science and Hypothesis, 1901)*

> The man of science must work with method. Science is built up of facts, as a house is built of stones; but an accumulation of facts is no more a science than a heap of stones is a house.

Professor Luca Pani
Director General
Italian Medicines Agency – AIFA, Italy

KEYNOTE

Many disciplines have addressed the topic of communication from different perspectives. One key issue concerns the evaluation of the effects of the message that is communicated, to a specific target population, at one point in time. Another element that is, according to me, essential to this reasoning (although rarely considered particularly by practitioners) is related to anchoring interventions and research to strong theories. Let me start from this last point.

Social psychology research has identified theoretical models to explain how people form attitudes toward social objects or toward behaviours. Fishebein and Ajzen's theory of reasoned action (TRA) and its natural development, Ajzen's theory of planned behaviour (TPB), represent milestones in attitudinal research. According to these two models, behavioural intentions are the best predictors of behaviour itself. In turn, intentions are explained by the attitudes towards a certain behaviour (that is, the evaluative disposition toward the behaviour), the subjective norm (that is, the probability that the behaviour will be approved by other relevant individuals), and the perceived behavioural control (that is, the perception that the behaviour is easy to be carried out). Each of these predictors of intention is in turn explained by beliefs related to: the advantages/disadvantages of enacting that specific behaviour; the relevant individuals who will approve that behaviour; the factors that may facilitate or hinder that behaviour. A further predictor of intention is past behaviour.

There are several good reasons why this theoretical model is crucially important for communication interventions. Attitudes and other predictors of intentions are based on beliefs. In particular, if you believe that medicines that are sold online are unsafe, you will probably consider buying online as something bad. On the contrary if you think that buying online enables you to save money and time, you will probably consider this action as something which is good and useful. The more you consider buying (medicines) online as a good thing, the stronger will be your intention of buying online, and as a consequence the probability that you will buy online.

Since their introduction in the late '70, TRA and TPB have been applied to different fields of social and applied psychology, ranging from health habits, to marketing research, to voting as well as to political behaviour. Empirical studies evidenced the scope of these models: all the variables considered can be measured through questionnaires; all hypotheses derived from these theories can be verified by means of statistical techniques such as multiple regression analysis and structural equation models.

It is well known that a prohibition of a type of behaviour is, most of the time, an ineffective means to challenge that behaviour. If institutions really want to change risk behaviours, they must communicate effectively to change the beliefs of those whose behaviours are established. The two theories we are considering may represent a theoretical grounded and empirically sound model to guide communication interventions aimed at changing risk behaviours by providing: a) key theoretical constructs to be made operational and measured; b) a technology on how to develop measurement and assessment instruments; c) a series of stringent criteria on how to verify the effectiveness of the intervention/prevention programs developed.

Professor Claudio Barbaranelli
Professor of Methodology
at the Department of Psychology
Sapienza University of Rome

Section 1
CONCLUSIONS

Break-out Session 1
RISK COMMUNICATION IN A PUBLIC FRAMEWORK: RULES AND PRACTICES

What rules to apply to a risk communication exercise about counterfeit medicines?

FIRST STEP:
IDENTIFY (SELECT AND STUDY) THE TARGET POPULATION

The first step involves identifying the target which may include running surveys or market research, with the support of experts, using an inter-sectorial approach. In the analytical phases, the discussion between experts who deal with communication, risk prevention, pharmacovigilance and with other stakeholders (e.g. patients) is invaluable.

Sharing information about surveys already performed is useful: accordingly, ask your colleagues in other Member States or in the international network (the Committee of Experts on Minimising Public Health Risks Posed by the Counterfeiting of Medical Products and Similar Crimes, for instance), if they have any relevant data.

On performing the exercise, consider that there are at least two specific target audience groups with defined profiles - patients (looking for medicines they usually receive through a legal supply chain) and consumers (looking for solution for their non-medical issues, e.g. prescription medicines bought without a medical need or a medical prescription); both groups have different characteristics.

In order to properly profile your target, you should start with the following preliminary questions:

- Who is the target?
- What are his/her personal characteristics (attitudes, personality traits, beliefs, perceived capabilities)?
- Why is the target using this channel to obtain his medicines/products?

Some general advice that may assist in profiling the target population:

- consider schools as a way of targeting a wide profile of groups, including some patients and consumers;
- educating young people (i.e. future customers/patients) is crucial as young people can often be more easily influenced;
- making schools a target requires that specific skills and certain procedures should be adhered to: a risk-based message may have the unwanted effect of promoting the very behaviour that it is intended to prevent, because people previously unaware of the matter are now alerted to it. Nonetheless, a synergistic effort in the communication strategy between different actors (communicating about different kind of risk: e.g. doping) may foster the creation of positive messages and self-empowerment.

SECOND STEP:
DEVELOP THE MESSAGE

What message should be sent to the identified target population (patients, consumers, school pupils etc.) who order (or who do not at present, but would like to order) their medicines online (from unknown/unreliable sources)?

The risks associated with this activity should be as specific as possible, tailored to the target audience. A general risk will not be taken very seriously.

It should be a proportionate and dissuasive message, as regards the risk you are trying to communicate: you should involve communication experts for a proper evaluation of the message characteristics.

- What beliefs (advice /guidance) are communicated?
- What emotions do they intend to raise?

As a general rule, it is recommended to transmit positive messages (as far as possible – e.g. using legitimate products will protect your privacy, your happiness, your family) and for these to be associated with risk avoidance.

The development of a set of "basic messages" shared at a Council of Europe regional level, to be applied and "endorsed" at a national level considering the different cultural and social peculiarities, would be a commendable goal for the communication group.

Examples of messages to emphasise are as follows: illegal medicines are related to some unknown dangers (the extent of the level of harm they are capable of is unknown), they have long term side effects, the desired effect you believe that they will achieve is not as good as you thought (and buying them is illegal and subject to enforcement, and related to funding other types of criminal organisations and activities).

THIRD STEP:
SELECT WHO SENDS THE MESSAGE AND THE MEDIA THAT SHOULD BE USED

Does it make a difference who the message is sent by? Who is the most effective "carrier"?

In general, physicians (or other health professionals, according to the local social/cultural framework) may be among the most important carriers for the message of risk communication; it is better to involve health authorities, in comparison to stakeholders within the private/industry sectors, as they are perceived to a lesser extent as having a conflict of interest or a hidden agenda, given the financial interests of those involved in pharmaceutical manufacturing.

Authorities should support and/or coordinate risk communication exercises: all other stakeholders could be invited to cooperate.

Use the most appropriate multimedia tools in compliance with the identified message and target (e.g. young people are more likely to use electronic messaging via social networks, whereas older people may be more effectively reached via television, newspaper or radio).

FINAL STEP:
MONITORING AND EVALUATION

The risk communication campaign should have measurable objectives as far as possible: the communicators should first define what changes are expected to be achieved by the message, and how these changes could be measured and followed up.

It is not always easy or possible to measure the impact of a message, but the communicators should try to define the expected changes, and ways of measuring the situation before and after the campaign, involving the proper kind of experts (i.e. market research institutes, psychologists, statisticians, etc).

Measurement methods should be scientifically based, and should consider the short and long term effects of the communication campaign: in some cases, field research may be substituted by case studies or other small-scale studies.

Measurements for monitoring and evaluating impact should also be part of the "in-progress revision" of the communication strategy: the development process of the campaign should consider the evaluation of results and feedback as input for the real time refinement of the message in order to maximise the possibility of having the optimal effect.

Break-out Session 2
RISK COMMUNICATION: PROFESSIONAL STANDARDS, PRACTICE AND TRAINING COURSES

ENSURING PROPER TRAINING AND COMMUNICATION FOR HEALTHCARE PROFESSIONALS ON COUNTERFEIT MEDICAL PRODUCTS AND SIMILAR CRIMES

In order to engage healthcare professionals in the fight against counterfeit medicines, they should receive proper training on communication.

Such training could be integrated in the curriculum of healthcare professionals, especially those involved in the distribution chain of medicines. However, this training should also be integrated in the continuous professional development of healthcare professionals, through different means, such as conferences or guidelines.

It has been recommended that national healthcare professional associations together with the relevant authorities should develop guidelines on counterfeit medical products and similar crimes.

These guidelines could include definitions, terminology and legal concepts about counterfeit medical products and similar crimes. They should then present the related risks and how to prevent these risks (i.e. how to protect the integrity of the supply chain), together with a procedure on how to report suspicious cases (for instance, through a network of single points of contact – SPOCs). These guidelines could be completed by information and advice on communication about counterfeit medical products.

Such guidelines especially if integrated in the standard of practices could be referred to when a suspicious case is encountered by a healthcare professional.

These guidelines could draw healthcare professionals' attention that when they or their patients notice that a medical product has apparently had no therapeutic effect, a strange taste, appearance or a strange effect, they should consider it as a possible case of counterfeit medical products or a similar crime, and report it to the relevant authorities.

[Examples of guidelines can be found in the CD of the book "Counterfeit Medical Products and Similar Crimes – Risk Communication". Ed. D. Di Giorgio. Rome and Strasbourg: AIFA and Council of Europe, EDQM 2011.]

It was also suggested that health professionals should be informed by authorities about suspect cases as soon as they come to the attention of the public. The information sent to healthcare professionals should be sufficient in order to help patients to avoid or

minimise health risks (and be able to relay information to prevent undue panic). Such information should be channelled through the means used for the withdrawal of medical products from the market.

ACTIVITIES AND POTENTIAL ROLES OF HEALTHCARE PROFESSIONALS IN RAISING PUBLIC AWARENESS ON COUNTERFEIT MEDICAL PRODUCTS AND SIMILAR CRIMES

Healthcare professionals, in particular pharmacists should be involved in the planning, carrying out, distribution, and evaluation of public campaigns about counterfeit medical products and similar crimes, through national or regional associations.

It was also mentioned that the inclusion of healthcare professionals in the campaign could be an effective way to lower the cost of the campaign (e.g. they could display the posters free of charge in their shops, pharmacies, offices etc, and the cost could be shared among the different organisations) and could increase the credibility of the message (particularly in countries where governmental authorities' independence or expertise is questioned).

If relayed by healthcare professionals, they will also be able to answer some urgent questions from their patients that may arise from this campaign.

Of course, one of the prerequisites for an effective collaboration with healthcare professionals is to involve them in the preparation of the communication campaign, which may sometimes be connected to their training (see *previous section*).

When a case of counterfeit medicines is discovered, the provision of clear information to healthcare professionals will enable them to relay the same message as the one from the drug regulatory authority, thereby increasing the effectiveness of this message.

IMPROVING REPORTING OF SUSPICIOUS CASES OF COUNTERFEIT MEDICAL PRODUCTS AND SIMILAR CRIMES

In addition to the inclusion of the procedure on how to report this in guidelines for healthcare professionals feedback on the outcomes of this report could be an additional incentive for healthcare professionals to report.

Therefore, authorities should provide information to the individual who reported a suspicious case about the follow-up given to the report and the outcome of this investigation. This feedback would become a learning experience for the healthcare professional who reported this suspicious case (whether this suspicion has been confirmed or not).

It was also suggested to include, as part of the pharmacovigilance report, the origin of the product (e.g. bought in a foreign

country, in a bricks-and-mortar pharmacy, via the Internet, or via illegal sources.).

Break-out Session 3
TWO SIDES OF THE PROBLEM: INDUSTRY AND PATIENTS

WHAT ARE THE COMMUNICATION NEEDS OF PATIENTS AND THE GENERAL PUBLIC REGARDING COUNTERFEIT MEDICAL PRODUCTS?

As regards to the communications needs of patients and consumers, it is necessary to ensure that adequate and appropriate information is available to patients to ensure that their risk of exposure to counterfeit medical products is minimised without causing any undue panic or the erosion of trust in the healthcare system which may lead to patients not taking their medicines correctly or at all.

Patients should have the confidence that they will receive, on the one hand safe, high quality and appropriate medicines and, on the other, accurate, relevant and comprehensive information.

The target of any communication campaign is the end user or patient. Market regulation and monitoring are important, but this should not divert attention from the need for the awareness of patients and consumers about the situation regarding counterfeit medical products and communicating the risk of purchasing counterfeit medical products.

These actions are extremely significant for the purpose of making patients and consumers aware of the dangers of counterfeit medical and similar products and encouraging and empowering them to report any suspicions or concerns to their health professionals and/or the relevant authorities, thereby educating them to be more aware of this issue.

Campaigns and initiatives must be tailored to be appropriate and accessible. This may include consideration of different cultures and knowledge, level of detail needed, risk perception, socio-economic groups, levels of literacy, healthcare behaviour (e.g. buying medicines via the Internet, a market or from a licensed pharmacist) and so on.

What roles do the different stakeholders assume?

Collaboration is key in terms of risk communication, so that stakeholders can provide any technical, scientific and regulatory information, input and advice with patient groups and academia.

Therefore any communication activity aimed at informing patients and consumers should be the result of a collaboration involving not only institutional stakeholders (such as regulatory agencies, national health authorities, enforcement authorities) but

also representatives from patients' and consumers' associations, industry sector (both branded and generic medicine producers) and health professionals.

Moreover, the role and the involvement of front-end operators (like pharmacists and physicians) are crucial for the success of a trustworthy risk communication initiative.

Specifically, it is important to have broad representation and involvement (e.g. through a producers' or consumers' association is better than a single pharmaceutical company or small-sized consumers' groups).

Who should carry out risk communication activities?

Communication campaigns should be developed and carried out by institutional bodies (such as regulatory agencies) in order to guarantee the absolute absence of any conflict of interest.

In the "Internet era", the general public have access to extremely diverse sources of information and the overwhelming quantity of information provided by the web may considerably influence public opinion with respect to risk: the "perception" related to negative signals, supplied by sources that, differing from the official channels, may be considered as untrustworthy, can became the "reality".

That means that, concerning risk communication, we should consider the Internet not only as a multiplier of points of sale, but also as a relevant modifier of user behaviour: a strong influence on the information environment that should be taken into appropriate consideration.

The Internet represents both a big risk and an opportunity, so it is crucial to help patients/consumers to identify illegal web sites.

The participants at the break-out session 3 identified some crucial points to take into account when implementing communication campaigns for patients and the general public regarding counterfeit medicines, well summarised in the article of Ms Kulakowska (see *Section 2*).

The participants further concluded that all campaigns and initiatives must be addressed to patients and the general public, in order to make appropriate information available and to raise the awareness about the dangers of counterfeit medicines.

Collaboration between all stakeholders is considered fundamental when planning any risk communication campaign.

Section 2
PRESENTATIONS

Session theme
IMPACT OF RISK COMMUNICATION

THE ROLE OF RISK COMMUNICATION IN ANTI-COUNTERFEITING STRATEGIES

Gen. Cosimo PICCINNO
Carabinieri for Public Health Safety (NAS), Italy

The dictionary defines risk as: "(Exposure to) the possibility of loss, injury, or other adverse or unwelcome circumstance; a chance or situation involving such a possibility".

For our purposes it is not always easy to translate medical and scientific aspects into simple advice for the general public.

To meet such a need, all communication instruments, both traditional and online, must be prepared and connected.

Health risk communication is a type of technical and scientific communication aimed at helping people to accept or to avoid risks or to identify at an early stage the possibility of an injury by making the message recipients aware of an "informed and watchful concern".

The formulation of messages is essential for giving a correct transmission message of the communication which are in turn the basis for correct comprehension.

Many elements – related to the type of risks – could influence risk perception: on the one hand by reducing risk perception (e.g. knowledge of the phenomenon, trust in institution, controllability and voluntariness), on the other hand by increasing it (the catastrophic potential, experts uncertainty, the knowledge about the victims, attention to mass media information).

The management of a risky situation could be "bidirectional": to calm citizens when a danger is over-perceived, or to increase attention when population underestimates potential risks.

The problem with counterfeit medical products is that risks are quite undetectable or poorly considered or, what is worse, associated with benefits.

Risk communication does not always reach its goal. The reason is that risk assessment is not the result of facts but of individual perception.

Therefore, risk communication about counterfeit medicines should be strengthened in order to achieve the desired results.

INTRODUCTION AND OVERVIEW: RISK COMMUNICATION ON COUNTERFEIT MEDICAL PRODUCTS AND SIMILAR CRIMES

Mr Domenico DI GIORGIO
Italian Medicines Agency - AIFA, Italy

The most frequent illegal products on our market are: fake natural products containing APIs and small parcels shipped through postal services to private address.

International regulation on counterfeit medical products and similar crimes has been strengthened in 2011 with the introduction of two important legal instruments:

1) Directive 2011/62/EU of The European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source;

The directive aims to prevent falsified medicines entering the legal supply chain and reaching patients.

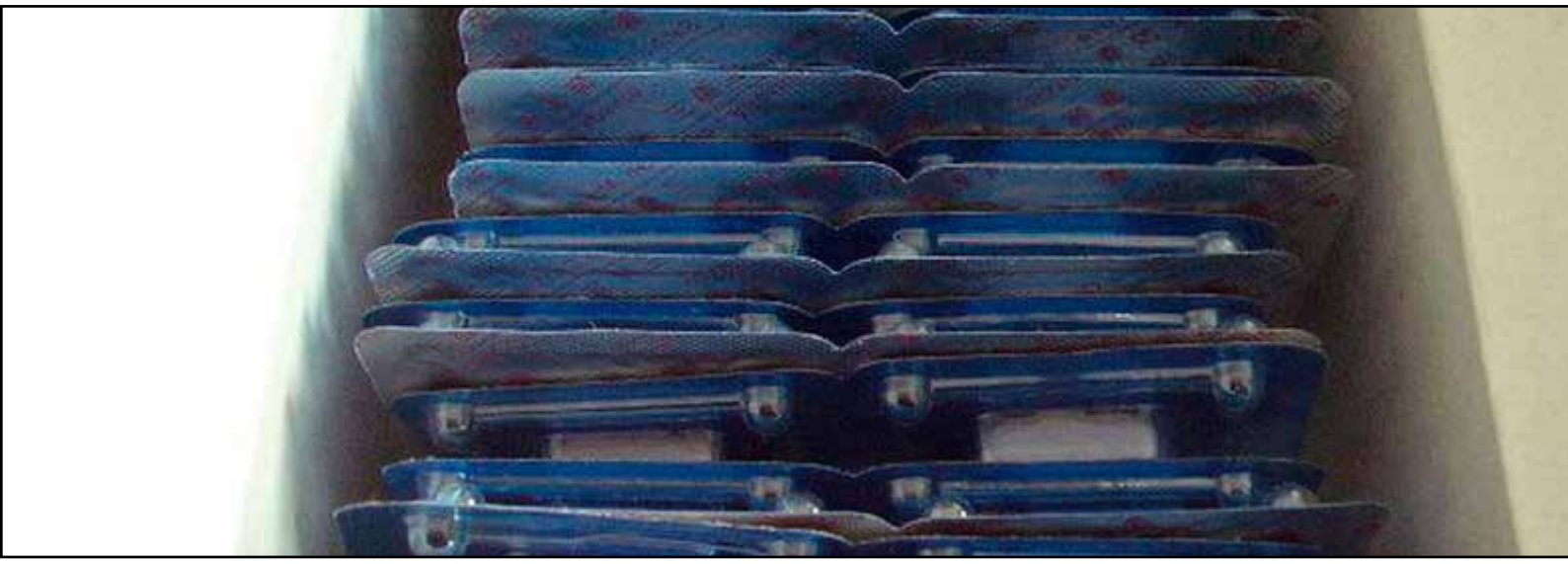
It introduces harmonised safety and strengthened control measures by applying new measures.

2) The **MEDICRIME Convention of the Council of Europe** on the counterfeiting of medical products and similar crimes involving threats to public health.

The EDQM (Council of Europe) gives support to the prevention and follow-up measures included in the Medicrime Convention, assuring:

- multisectorial monitoring mechanism to ensure the effective implementation of the Convention;
- involvement of expert bodies (such as the Committee of Experts on Minimising Public Health Risks Posed by the Counterfeiting of Medical Products and Similar Crimes);
- development of practical tools (eg. Training and investigative schemes, publications);
- fostering intersectorial cooperation.

Dangerous, illegal products on our market
Fake natural products containing APIs like sildenafil and tadalafil: imported as "natural products", sold in non pharmaceutical shops.



Small parcels shipped through postal services to private address: one-tenth of parcels were for local illegal distribution networks (e.g. sex shops, gyms).

Active promotion of the knowledge and use of the MEDICRIME Convention through practical measures and concrete support for national and international legislation, in particular as regards the prevention and cooperation articles, should be a priority of the European Committee on Pharmaceuticals and Pharmaceutical Care and its Committee of Experts on Minimising Public Health Risks Posed by the Counterfeiting of Medical Products and Similar Crimes in line with its terms of reference.

The implementation of the Medicrime Convention is also supported by the EDQM through various initiatives, as outlined below.

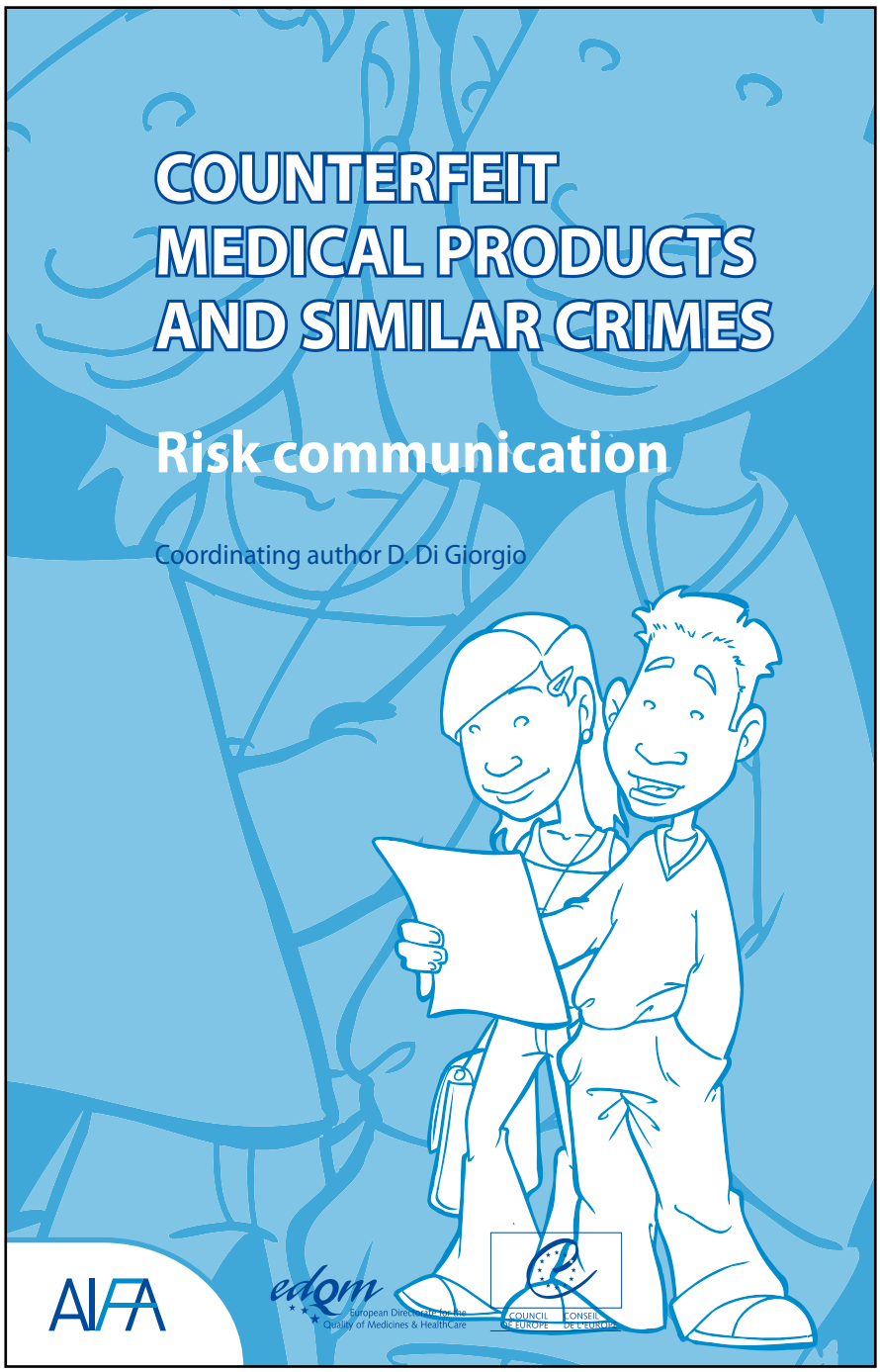
SUPPORTING THE IMPLEMENTATION OF THE MEDICRIME CONVENTION

- Safe access to good quality medical products for human and veterinary use
- Prevention and prosecution of counterfeiting of medical products and similar crimes
- Support for regulatory systems and procedures, drug enforcement, and public empowerment (awareness-raising) for the effective implementation of the MEDICRIME Convention
- Support for the MEDICRIME Convention by developing practical model approaches

In 2011 the Committee of Experts on Minimising Public Health Risks posed by the Counterfeiting of Medical products and Similar Crimes (CD-P-PH/CMED) of the Council of Europe/EDQM, and the Italian Medicines Agency (AIFA) co-published the book "Counterfeit medical products and similar crimes – Risk Communication" with the aim of giving scientific support to the exercises in communication related to the risk campaign represented by counterfeit medical products.

The book was part of a broader publication project which began in 2009 with the first edition of "Counterfeit medicines: facts and practical advice" and was developed in co-operation with the Italian Medicines Agency (AIFA), which also published the first national edition which included specific chapters illustrating the situation in Italy.

The supply of clear and reliable information is a matter of proper communication, which is a science itself. This is why it is important not only the involvement of experts in the pharmaceutical sector, but also from psychologists, journalists and other experts in the field of risk communication.



SETTING UP EFFECTIVE AWARENESS CAMPAIGNS

Ms Ewelina KULAKOWSKA
Expert

Nowadays public campaigns that aim at a change in behaviour, try to imitate commercial campaigns. Most of them, however, are badly targeted, inaccurate, and, in consequence, inefficient. Contrary to well-structured commercial campaigns, they often lack evaluation of results, as well as a continuous and coherent strategy.

A solution to the problem can be found in social marketing. It combines strategies derived from traditional commercial marketing with project management and communication technology, in order to provoke social progress in a planned and structured way. Here are a few of its basic methods that could be kept in mind while preparing such a campaign:

Audience targeting / market research

Market research allows a better definition of the context in which your campaign is going to take place, of your audience's needs, its state of opinion, and its knowledge gaps, of tools you'll choose, costs, available materials, possible partnerships and sponsors.

Targeting the audience means determining precisely the population to reach. The population is composed of many segment groups with their specific concerns, interests, and information needs. It should be segmented (*e.g.* according to demographic, and psychogeographic characteristics), because each population group will respond differently, and different techniques will be required to motivate each of them. Remember that the more precisely targeted the audience is, the more relevant the message will be.

Know who you want to reach...
Audience targeting & market research
- define your audience & its state of opinion
- define relevant tools & strategies

= basis for:
- communication strategies
- work of advertising agencies
- identification of relevant media/events

Objectives

Good objectives will help you state exactly what you want, and how you want to achieve it, enabling you to announce it to others clearly, without misunderstanding. A useful mnemonic used in project management describes an ideal objective as "SMART": **S**pecific, **M**easurable, **A**chievable, **R**ealistic, **T**ime-based.

… and what you want to achieve!

OBJECTIVES (behaviour objectives, knowledge objectives; belief objectives)

- **S**pecific
- **M**easurable
- **A**chievable
- **R**elevant
- **T**ime-based

Setting objectives, and expected short- and long-term effects and results, will serve as a useful guideline for the analysis that will be conducted before, during and after the campaign.

Message conception and delivery

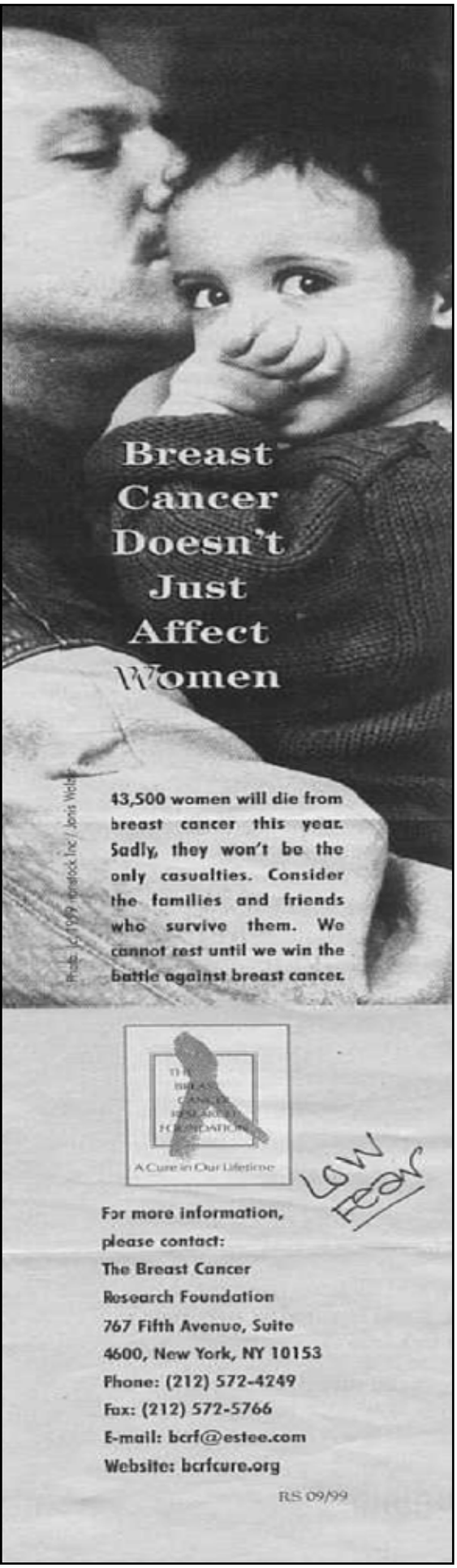
A good message should be coherent, pertinent, easily comprehensible, and convincing. If formed in an inappropriate way, its receivers won't understand or access the information being transmitted, and hence won't know what they're expected to do. This, in turn, will lead to their not taking the action at all, or taking the wrong one.

Remember that you, as an expert, perceive things differently than your public, and that they don't necessarily know the facts that might be obvious to you. Also, various resistance filters, such as fear or guilt, and cultural difference factors, may influence the reception of your message. It is thus necessary to test your message for its comprehension, retention, credibility, and identification - both before and after your campaign.

You should have a few tailored messages for your segment groups, but in parallel, keep a key message as an easily recognisable sign of your campaign. State it in a simple, catchy way, and repeat it frequently. It will help both the public and the journalists to make a quick association whenever they see it.

As different media give different results in terms of communication reach, they should be carefully assessed based on their relevance to the subject, the coverage, and audience. The best media are either the most influential, or the most adapted to the targets, *e.g.* radio is suitable for messages with strong informative content, whereas billboards are powerful but can deliver only short messages.

Each media has different time requirements and different availability - a media plan will help you to check their availability against your campaign's timelines in order to avoid the saturation of information.



...message

Korean advertisements = more emphasis on family integrity, social relationships, and group benefits than advertisements in American magazines (Hann & Shavitt, 1994)

Koreans = more convinced by advertisements with relational terms

U.S. Americans = more convinced by advertisements with individualistic terms (Gregory & Munch, 1997)

Monitoring and evaluation

Measuring effectiveness gives you feedback about the receipt of the message and shows whether it was understood and processed by the target audience. It also serves to prepare the follow-up campaigns, necessary to prevent the audience from forgetting about the issue, and to maintain their level of awareness. Each campaign should be monitored throughout, and evaluated both before (to verify the choice of the channels, strategies, messages, state of opinion, and predictions of impact) and after (immediately after the campaign to measure its impact and effectiveness, a few months later for the retention). To avoid false results, it's important to choose the right time for each step of the evaluation, it should neither be done too soon, nor too late.

Advertising agencies

Remember that advertising agencies are regulated by various legal frameworks which differ from country to country, such as market competition, government procurements, and timeframes concerning campaigns.

To install a satisfactory cooperation with an agency, you'll need to understand your respective businesses. The more you teach them about you and your subject matter, the better job they'll do for you. Give them your time, communicate your needs and goals clearly, answer all the questions, allow them to immerse in your business. By working closely with your agency you'll reduce the time it takes to nail down the right campaign.

Advertising agency and You

- provide wide information
- keep each other regularly informed
- refine your media plan
- explain validation workflow in your institution

Conclusion

The effectiveness of any campaign depends to a great extent on its planning, implementation, monitoring and feedback analysis. Although still underestimated by numerous social communicators, social marketing provides a solid framework for the effective communication process. Let us sum up its importance with a little comparison, which might help for remembering the key steps. In reality, campaigning is like giving someone the perfect gift: having learned the person's needs and taste, the giver will carefully match the gift to the receiver's personality, and choose the best and most adequate wrapping for it. Then, he/she will decide on the best way to deliver it, and when the gift is finally offered, will attentively observe the receiver's reaction.

PROACTIVE AND REACTIVE COMMUNICATION

Marcel MOESTER
Dutch Healthcare Inspectorate, Netherlands

The aim of both proactive (e.g. media campaigns) and reactive communication (e.g. web support to recall systems and enforcement activities) is protecting patients and consumers by communicating risks.

Many governments nowadays give information about the risks and dangers of falsified and other illegal medical products.

There are many factors to consider in communication: behaviour in other areas, financial considerations, personal experiences, level of education, level of information, conceptions and misconceptions, sources of information.

There are many examples of campaigns that are thought to have a high impact, a clever approach or even a regional approach (see for example the Interpol "Proud to be" campaign, *http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Proud-to-be*).

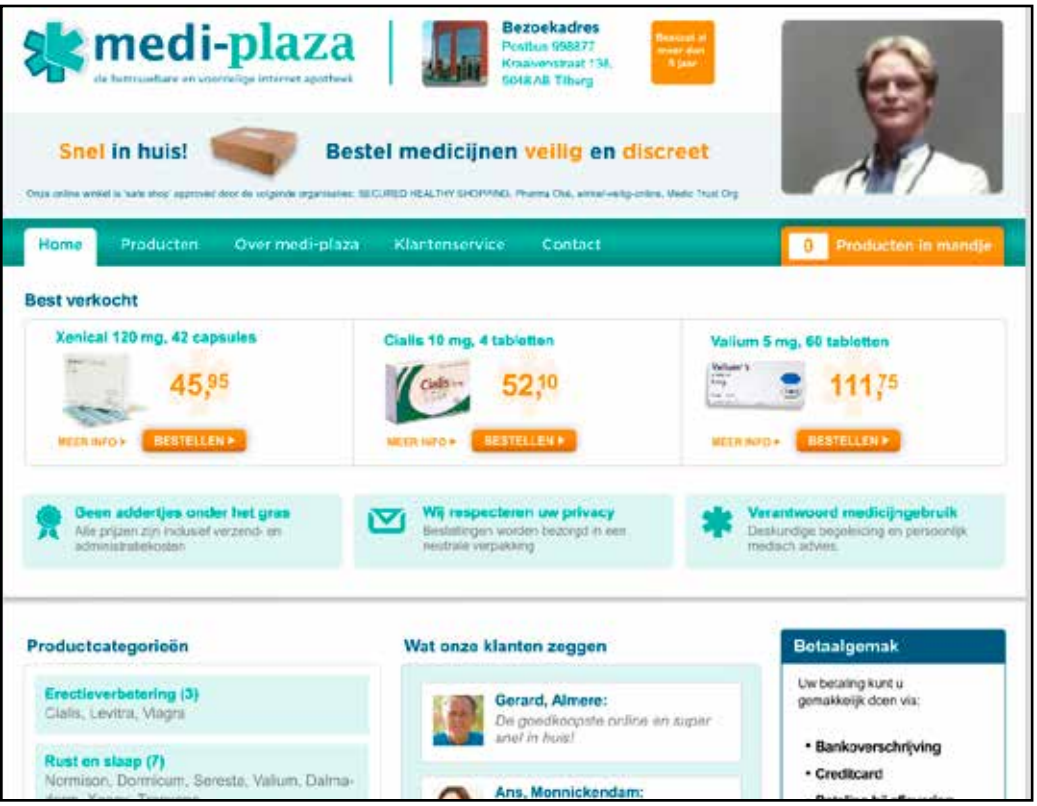
To change the behaviour of people it is essential to understand why they do things, like buying medicines over the Internet; in this area very little research has been done.

High impact
http://www.realdanger.co.uk/history/

Buying from pharmacies presents pros (safe distribution, reimbursement, pharmaceutical care) and cons (embarrassment, cumbersome, intrusive questioning, medication records); non-pharmacy outlets and Internet may be more confortable, e.g. by giving more privacy.

Educating patients and consumers has the goal of teaching responsible behaviour and to make people aware of dangers (message: "be aware of dangers, and trust the system"); giving health education at schools may be considered.

On the other hand, educating healthcare professionals means to encourage them to be aware of signals of harm and of behaviours, and to contribute to education.



Clever approach
www.medi-plaza.nl

The MediPlaza website of the Dutch Ministry of Health, Welfare and Sport is one of the silver winners of the SpinAwards 2012 in the category "Best Website". The jury finds this fake site "a clever and creative idea that took guts on the part of the government. Not the well-known admonishing finger from the government, but learning through experience. The site was made with attention to details in its design, making it a plausible site."

THE POINT OF VIEW OF PATIENTS ASSOCIATIONS

Joanna GROVES
International Alliance of Patients' Organisations (IAPO)

IAPO - International Alliance of Patients' Organisations - is a patient-led global alliance of over 215 organisations which promotes patient-centred healthcare on a cross-border and cross-disease basis. Our full members are patients' organisations and our membership spans over 50 countries and all regions of the world.

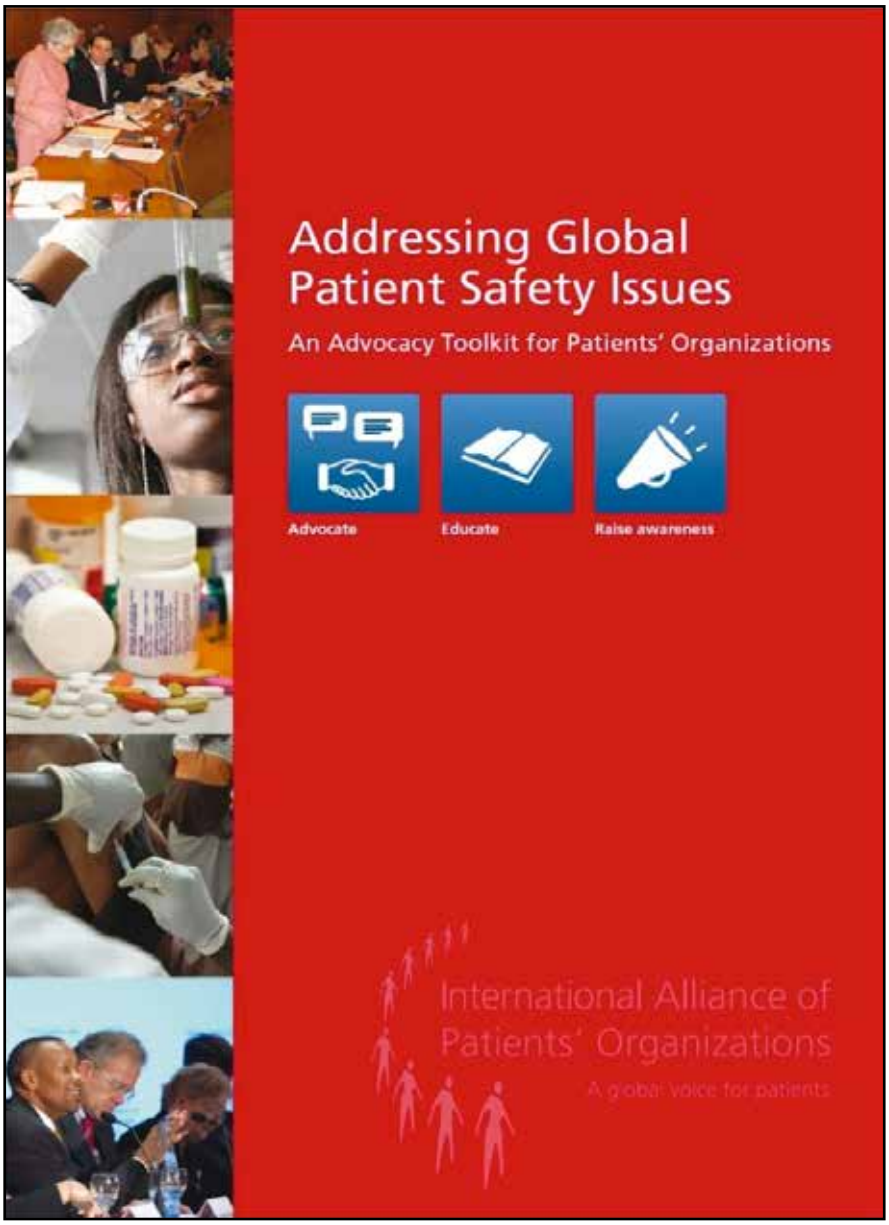
As is increasingly recognised, counterfeit medicines are a global issue and a patient safety issue. Patient safety issues ranging from medical errors and hospital-acquired infections, through to quality and safety of medicines, continue to rate as one of the priority concerns for our member organisations.

Whilst the prevalence of counterfeit medicines and their impact continues to be hard to quantify, the fact that there is criminal intent in the development and sale of these substances and that they are bypassing the regulatory system and therefore their quality cannot be assured constitutes a risk to public health which needs to be recognised and tackled by a multi-faceted and multi-stakeholder approach.

In addition to the direct dangers of counterfeit medicines to patients, they are also posing a threat to the erosion of the public's trust in medicines and the healthcare system with negative consequences such as patients discontinuing their treatment without consulting with their doctor or pharmacist. A further concern for patients is the lack of awareness and understanding by patients and patients groups about counterfeit medicines and how to avoid, identify and report suspected counterfeit medicines.

A global issue for patients
A matter of patient safety
A public health risk
Erosion of trust in healthcare systems
Poor awareness

A 2007 survey in the UK found that some patient advocacy group representatives did not understand the term "counterfeit". Many patients are unaware of the risks of obtaining medicines from unauthorised sources. Many others are aware but there are stronger factors influencing their decision to buy from the Internet or an unlicensed source such as a market stall. These include: cost (patients don't want to or can't pay the price where medicines are out of pocket), stigma and embarrassment about certain conditions (such as sexual and mental health). More widely than the patient community, confusion and disagreement over the term, 'counterfeit'



has been detrimental to efforts to combat counterfeit medicines and prevent patients from harm.

Patients should have the confidence that they will receive access to safe, high quality and appropriate treatments. It is essential that continued efforts are made to ensure patients are not exposed to and cannot access counterfeit medicines.

However, since we cannot currently guarantee all medicines will be high quality and safe, patients should be able to trust that they will receive accurate, relevant and comprehensive information which empowers them to be vigilant regarding their medicines and to have the confidence to discuss any concerns with their doctor or health professional. In terms of communicating the risks of counterfeit medicines, this means that these activities must be based on some fundamental principles of a patient-centred approach to healthcare. These include involving patients and patient groups

in communications activities gaining from the knowledge of, and networks with patient communities.

Risk communication to patients needs to focus on a number of areas:

- Raising awareness of the risks of counterfeit medicines including clarity on what they are, and what they are not and providing data on the prevalence of counterfeit medicines, what is being done to stop their development and sale.
- Communicating the level of risk of purchasing medicines from a licensed source such as a pharmacy compared to an unregulated source such as an unlicensed Internet site, highlighting what the licensed sources are and outlining the regulatory process which ensures that legitimate medicines fulfil safety and quality criteria thereby maintaining and developing trust in medicines and the healthcare system.
- Communicating clearly what patient should be vigilant for - empowering them to ask about their medicines, what they need to know about the medicines they are taking, why they are taking them, what they should feel or expect from the medicine and where the medicine came from and what to do if they are suspicious or have concerns about the appearance or the effect of their medicines – who to speak to, who to report it to and what response they can expect.

Raising public awareness and providing information and advice to patient communities:

- to be aware of the risks of counterfeit medicines;
- to purchase medicines from licensed sources and appreciate the dangers of unregulated sources;
- to be vigilant with medicines and to report differences or worries to health professionals.

In the long term, there needs to be continued and increased investment in increasing all citizens' health literacy levels so that they are active participants in their healthcare. In all communications activities, health literacy principles such as these should be considered and communications will need to be tailored to suit particular audiences and communities of patients. One size does not fit all – people will have different literacy levels, different ways of accessing and processing information and be motivated by different factors.

Health professionals are key allies and they must be fully aware themselves and have access to the necessary information and facts to be able to discuss concerns with patients. Both prescribers and dispensers of medicines have a strong role to play in highlighting how patients can decrease the risk of being harmed by counterfeit medicines. This means that both patients and health professionals

must be able to be open in exchanging information, listening to each other and asking questions.

Through multi-stakeholder initiatives and responding to consultations IAPO has called for and supported a number of actions in the fight against counterfeits.

Communication is a key element which should complement other activities such as law enforcement and regulatory developments. We should review and develop our communications activities but on no account transfer the burden regarding protecting the public against counterfeit medicines to the individual.

Some relevant initiatives

- Patient Safety Toolkit
  - Taking medicines correctly
  - The quality and safety of medicines including counterfeit medicines
- Policy Statements and Guidelines on:
  - Health Literacy *www.patientsorganisations.org/healthliteracy*
  - Patient Involvement *www.patientsorganisations.org/involvement*
  - Patient Information *www.patientsorganisations.org/information*
- Educational and training workshops for patient groups
  - Global Patients Congress
  - African Regional Network Meeting, South Africa, 2011
- Collaboration with EDQM and WHO

To conclude:

- A global problem requires a global solution
- Combating counterfeit medicines requires collaboration and patient groups are a key partner
- Risk communication is a vital component of strategies to raise awareness and inform patients and the public.

Session theme:
LEGAL FRAMEWORK

THE MEDICRIME CONVENTION: LEGAL FRAMEWORK FOR RISK COMMUNICATION

Sergey GLAGOLEV
Roszdravnadzor, Russian Federation

Common troubles of anti-counterfeiting activities

- Imperfect inter-disciplinary cooperation
- Limited effectiveness of suppresing of distant trade and Internet promotion
- Unawareness or delusions of customers
- Underestimation of threats by general audience

Selected "pros" of the Medicrime convention

- Focus on patient and consumer protection
- Aimed at prosecution of offences notwithstanding IP rights violation
- Promotes cooperation and information exchange, risk communication and trainings
- Option of expert support to the Parties from CoE bodies
- Other types of healthcare product may be covered by additional protocols
- Open treaty for non-European states
- May become a model for similar agreements in other regions

Options for risk communications offered by the Medicrime convention

National level

- Information exchange and cooperation of state authorities (representatives of health authorities, customs, police and other competent authorities) art.17 (1)
- Reactive communications and cooperation with private sector, industry and civil society art. 17 (2,3)
- Professional training for relevant specialists art. 18 (3b)
- Pro-active communication (awareness-rising campaign) art. 18 (3c)

International level

- Information exchange through designated single contact points art. 22 (1)
- Consultation within the Committee of parties and options of advise from the expert bodies of the Council of Europe art. 23,24, 25
- Assistance to non-party states in combatting medicrime art. 22(3)

Information exchange and cooperation at national level

Chapter IV – Co-operation of authorities and information exchange

Article 17 – National measures of co-operation and information exchange

Each Party shall take the necessary legislative and other measures to ensure that representatives of health authorities, customs, police and other competent authorities exchange information and co-operate in accordance with domestic law in order to prevent and combat effectively the counterfeiting of medical products and similar crimes involving threats to public health.

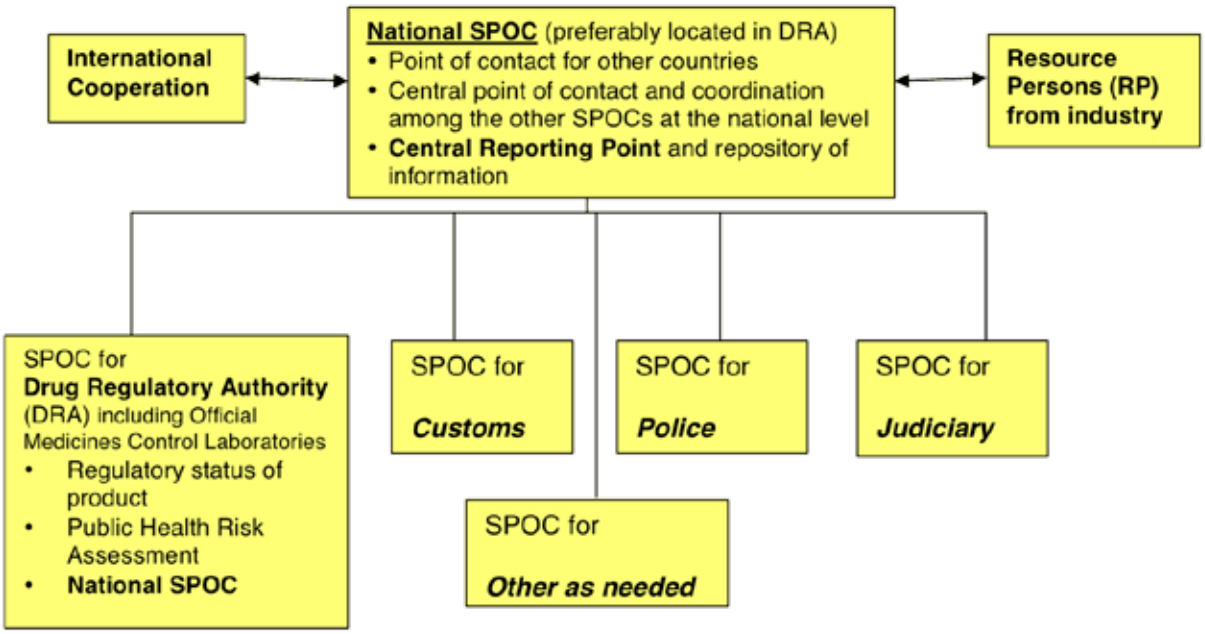
Each Party shall endeavor to ensure co-operation between its competent authorities and the commercial and industrial sectors as regards risk management of counterfeit medical products and similar crimes involving threats to public health.

With due respect for the requirements of the protection of personal data, each Party shall take the necessary legislative and other measures to set up or strengthen mechanisms for:

- receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health;
- making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them.

Each Party shall take the necessary measures to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose. Such units or services shall have adequate resources.

An option of a network of SPOCs (CD-P-PH/CMED model)



International cooperation

- Fully-connected network of national SPOCs
- Committee of Parties serves a ground for consultations and sharing experience
- Council of Europe structures (CDPC, EDQM, CD-P-PH, OMCL) may provide an expert assistance by the request of the Committee of Parties

Inter-regional cooperation

- Similar approaches to regulation and business practices predispose to common crime patterns
- Organized crime often affects several countries sharing the same historical and cultural background
- Parties may explore an option of inter-regional networking
- Training programs are encouraged to be included into assistance program for such states

Preventive measures

Chapter V – Measures for prevention

Article 18 – Preventive measures

Each Party shall take the necessary legislative and other measures to establish the quality and safety requirements of medical products.

Each Party shall take the necessary legislative and other measures to ensure the safe distribution of medical product.

With the aim of preventing counterfeiting of medical products, active substances, excipients, parts, materials and accessories, each Party shall take the necessary measures to provide, inter alia, for:

- training of healthcare professionals, providers, police and customs authorities, as well as relevant regulatory authorities;
- the promotion of awareness-raising campaigns addressed to the general public providing information about counterfeit medical products;
- the prevention of illegal supplying of counterfeit medical products, active substances, excipients, parts, materials and accessories.

Awareness-raising campaigns

- Focus on danger of counterfeiting , risks related to Internet purchases and necessity of reporting
- Strategy and tactics may be defined in consultation with concerned state authorities, industry and civil society
- Local specifics and culture should be taken into account
- Necessity of modern approaches to communication (blogs, banners, viral commercials)
- Internet users should be provided with instructions on authenticity check of supplier's site (an option of publishing positive or negative list of legal Internet pharmacies)

Committee of the Parties

Article 23 – Committee of the Parties

1. The Committee of the Parties shall be composed of representatives of the Parties to the Convention.

Article 24 – Other representatives

1. The Parliamentary Assembly of the Council of Europe, the European Committee on Crime Problems (CDPC), as well as other relevant Council of Europe intergovernmental or scientific committees, shall each appoint a representative to the Committee of the Parties in order to contribute to a multisectoral and multidisciplinary approach.
2. The Committee of Ministers may invite other Council of Europe bodies to appoint a representative to the Committee of the Parties after consulting them.
3. Representatives of relevant international bodies may be admitted as observers to the Committee of the Parties following the procedure established by the relevant rules of the Council of Europe
4. Representatives of relevant official bodies of the Parties may be admitted as observers to the Committee of the Parties following the procedure established by the relevant rules of the Council of Europe.
5. Representatives of civil society, and in particular non-governmental organisations, may be admitted as observers to the Committee of the Parties following the procedure established by the relevant rules of the Council of Europe.
6. In the appointment of representatives under paragraphs 2 to 5, a balanced representation of the different sectors and disciplines shall be ensured.
7. Representatives appointed under paragraphs 1 to 5 above shall participate in meetings of the Committee of the Parties without the right to vote.

Functions of the Committee of the Parties

Article 25 – Functions of the Committee of the Parties

1. The Committee of the Parties shall monitor the implementation of this Convention. The rules of procedure of the Committee of the Parties shall determine the procedure for evaluating the implementation of this Convention, using a multisectoral and multidisciplinary approach.
2. The Committee of the Parties shall also facilitate the collection, analysis and exchange of information, experience and good practice between States to improve their capacity to prevent and combat the counterfeiting of medical products and similar crimes involving threats to public health. The Committee may avail itself of the expertise of relevant Council of Europe committees and other bodies.
3. Furthermore, the Committee of the Parties shall, where appropriate:
   a. facilitate the effective use and implementation of this Convention, including the identification of any problems and the effects of any declaration or reservation made under this Convention;
   b. express an opinion on any question concerning the application of this Convention and facilitate the exchange of information on significant legal, policy or technological developments;
   c. make specific recommendations to Parties concerning the implementation of this Convention.
4. The European Committee on Crime Problems (CDPC) shall be kept periodically informed regarding the activities mentioned in paragraphs 1, 2 and 3 of this article.

The Medicrime convention: the provisions on risk communication

- All types of risk communication are required to be used for prevention and prosecution of offences
- Flexibly in defining the ways of national cooperation
- Right for retroactive risk communication and opportunities of cooperation for civil society and private sectors
- Special focus on awareness rising campaigns
- Continues multi-disciplinary trainings for concerned specialist
- Implementation is facilitated by consultations and sharing the best experiences of the Parties
- Possibilities of scientific advise from the expert bodies of the Council of Europe on the best approaches

COMMUNICATION IN THE AMENDMENT OF THE EU DIRECTIVE 2001/83

Dr Johannes DICHTL
Bundesministerium für Gesundheit, Austria

The Directive 2011/62/EU of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products was published in the Official Journal of the EU on 1st July 2011.

Implementation date for major parts of this directive is 2nd January 2013.

Under the new provisions, better transparency will be achieved by creating a **central database at European Medicines Agency (EMA) level** containing details on:

- certificates of good manufacturing practice and good distribution practices issued by the Member States;
- a list of wholesale distributors for complying with applicable Union legislation (inspection by a competent authority of a Member State);
- registration of importers, manufacturers and distributors of active pharmaceutical substances (APIs).

Union database at EMA

- Common database managed by the EMA on behalf of the Union
- Member States shall enter the certificates of good manufacturing practice and good distribution practices which they issue

Manufacturers will have to inform the competent authority and the marketing authorisation holder immediately, when they are aware that medicinal products covered by their manufacturing authorisation are falsified, or are suspected of being falsified.

Member States shall have a **system** in place which aims at preventing medicinal products that are suspected of presenting a danger to health from reaching the patient.

This system shall cover:

- The receipt and handling of notifications of suspected falsified medicinal products as well as of suspected quality defects of medicinal products
- Recalls of medicinal products by marketing authorisation holders or withdrawals of medicinal products from the market from all relevant actors in the supply chain during and outside normal working hours
- A recall, where necessary with the assistance of health professionals, of medicinal products from patients who received such products

- A rapid alert notification, if a serious risk to public health is assumed, to all Member States and all actors in the supply chain
- Urgent public announcements within 24 hours in order to recall such a medicinal product from the patients containing sufficient information on the suspected quality defect or falsification and the risks involved.

Sale at a distance to the public

- The public should be assisted in identifying websites which are legally offering medicinal products for sale at a distance to the public
- A common logo should be established, the design is to be developed by the Commission
- Websites offering medicinal products for sale at a distance to the public should be linked to the website of the competent authority concerned
- An explanation of the use of the logo should be given, also on the EMA website
- Member states have to provide background information on the risks related to medicinal products supplied illegally to the public by means of information society services on their websites
- Patients' and consumers' organisations are to be kept informed about enforcement activities to an extent compatible with operational needs.

Information campaigns on the dangers of falsified medicinal products aimed at the general public are to be promoted.

Information campaigns
The Commission shall, in cooperation with the European Medicines Agency and Member State authorities, conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal products.

Those campaigns shall raise consumer awareness of the risks related to medicinal products supplied illegally via the Internet and of the functioning of the common logo, the Member States' websites and the Agency's website.

Close cooperation between the Commission and the Member States and support of ongoing work in international forums on the subject of falsified medicines should take place as well as working together with third countries in this field.

Session theme:
EXPERIENCES OF COMMUNICATION IN EUROPE

THE RIVM PROJECTS

Dries DE KASTE
National Institute for Public Health and the Environment (RVIM), Netherlands

At the RIVM, communication is aimed at various target groups: clients at the ministry, professionals (e.g. doctors, pharmacists, healthcare workers), researchers from neighbouring fields of research, journalists, interested citizens, and also RIVM colleagues.

The RIVM staff are being coached in the writing of scientific and journalistic publications, and media training courses are offered to spokespeople. Communication plans and procedures have been developed at the RIVM to provide professional, reliable, authoritative and independent information, also in times of crisis. Such information is distributed from the principle of providing only the facts and interpretations of research that has been conducted under the responsibility of the RIVM; political views are avoided, and full disclosure is given, also in cases of "negative" news.

RIVM is using the following basic principles for external communication:

Basic principles used by RIVM

- to avoid creating a panic, we do not hold back any information;
- we ensure that a reliable professional is available, at all times, to provide information;
- we avoid using scientific jargon;
- we do not provide information which we know is untrue;
- we ensure that spokespeople's messages are in tune with those of organisations that are also involved in the research;
- we maintain a focus on our target groups, by trying to envisage their information needs and by finding striking examples;
- when confronting the press, we make sure that we are not taken by surprise, we prepare well and carefully formulate our key messages, and we prepare a questions and answers memo in advance of the interview;
- we do not use long sentences and make sure that they are to the point.

Within the framework of the pharmaceutical crime project, and after consultation with our client, the Health Care Inspectorate, a number of reports have been published using the RIVM communication infrastructure. These reports describe test results and trends related to products that the inspectorate has sent in for research.

An estimation has been made of the dangers and risks related to the use of these, often illegal, products. Recommendations have been made to the ministries, policymakers and investigation departments to warn consumers against using these products.

Examples RIVM reports (key messages)

- Illegal weight-loss products:
  - Fake medicines are unreliable products (no GMP)
  - Food supplements can have hidden active components
  - Ephedrine which is banned, is replaced by sibutramine
  - Improve monitoring health damage
- Illicit erectile dysfunction products:
  - Often contain experimental medicines (analogues)
  - Risks: overdosing, long term effects unknown
  - Side effects are not reported
  - Trend: PDE5 inhibition combined with other pharmacological principles (delay ejaculation, anti-depressants)

Research results have been widely communicated at a number of different levels. Besides in press releases and interviews, these findings have also been used by the Ministry of Health, Welfare and Sport in warning campaigns to discourage the public from using medication that can be ordered through the Internet.

Results are also extensively discussed in the master class Introduction to Forensic Pharmacy, which is held annually and was developed by the RIVM together with the Health Care Inspectorate and the Department of Pharmaceutical Sciences at Utrecht University. This master class fits in with the communication strategy pursued by the ministry to point out the dangers related to these products to a wide audience, citizens and health-care professionals. This way the use of such products can hopefully be reduced.

THE AIFA PROJECTS

Marta GRAMAZIO
Counterfeit Prevention Unit, Italian Medicines Agency - AIFA, Italy

In the last few years AIFA carried out some communication campaigns and conducted two surveys in order to investigate on the phenomenon of counterfeit of medical products.

In autumn 2009 IMPACT Italia, the national anti-counterfeiting task force, set up an information campaign addressed to the general public and to patients. The campaign started running at same time of the launch of a specific website.

The Italian campaign is an adaptation of the "BE AWARE" message and it was necessary to make some adjustments in order to take into account the specific need and particularities of the Italian market.

As a result, the message has been reformulated in order to focus on the channels which are truly at risk in Italy, that is the illegal channels.

The communication was aimed at patients and we chose pharmacies as distribution points for communication materials.

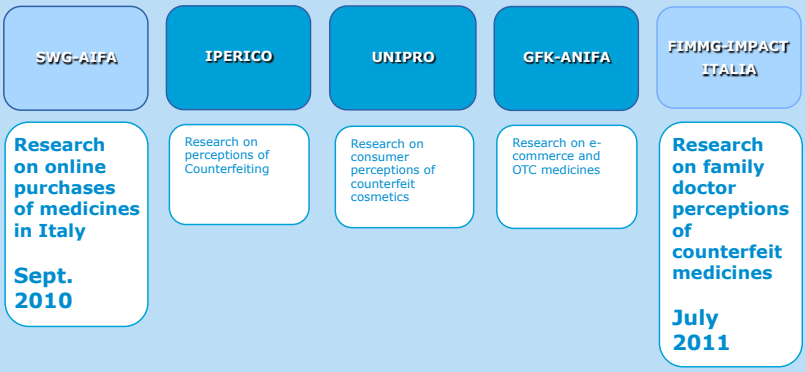
The choice of the two means of information, posters and leaflets, ensured a greater impact of the message in order to achieve the objectives established:

- to inform the public about the risks posed by counterfeit medical products
- to discourage the patients from buying medicines by e-pharmacies and other illegal channels

After the campaign we have evaluated the effectiveness of the tools used.

The results helped us to develop other information initiatives as two surveys subsequently conducted.

Characterisation of the phenomenon of online purchases
After cracking counterfeit research, that has distorted the data of online purchases of medicines, were made 5 market researches shared through the CNAC (National Council Anticounterfeiting) and 4 IT Intelligence Studies.



The first was carried out, in collaboration with a research institute, to investigate online purchases of medicines.

The research was conducted on a sample of one thousand people by Internet interview (CAWI methodology).

The results showed a growing phenomenon, and 33% of respondents viewed online purchases positively because of being cheap, fast and easy to order.

The perception of the risks was low, as 41% of respondents didn't know that in Italy the purchase of medicines via the Internet is illegal.

The results showed that it was necessary to introduce a new communication campaign based on a target strategy to increase risk awareness.

The second survey was conducted – in collaboration with the national association of "family doctors" – in order to investigate their perception of the problem.

An online questionnaire for about 600 doctors was developed, and the results were interesting:

- 40 % of respondents suspect that their patients buy medicines in e-pharmacies
- 28% of the sample suspect that their patients take counterfeit medicines
- 41% of respondents don't know the Italian law on Internet purchases of medicines.

Currently the results have been processed and they will be used for a new communication campaign that will probably be launched in 2012.

In addition to information initiatives, the Italian Medicines Agency (AIFA) has published several books on counterfeit medical products and similar crimes.

The newest publication is on risk communication which has become a regulatory obligation included in the new European Directive 2011/62 which states that national authorities shall carry out or promote information campaigns aimed at the general public, in order to raise consumers' awareness of the danger of falsified medicinal products.

THE INFARMED PROJECTS

Mr Joao Cristovao MARTINS
National Authority of Medicines and Health Products (INFARMED), Portugal

The Portuguese medicines agency (INFARMED) is fully committed to the fight against the counterfeiting of medicines. With this aim INFARMED has a program of activities in the communication area. Examples of this are awareness activities, cooperation with Portuguese speaking countries and ibero-american countries and daily cooperation with customs.

In the field of awareness activities, INFARMED developed different campaigns mainly on the Internet, using social networks and agreements with providers (like Google-PT), to give citizens more information on the risks of buying medicines on Internet.

With the goal of knowing more about the impact of those campaigns and to have better knowledge on the people who uses Internet to buy medicines, a survey was conducted and the results were analysed to improve future campaigns. Additionally, INFARMED supports specialised lectures for healthcare students in different Portuguese universities on counterfeit/falsified medical products.

The exchange of information established between Portuguese customs and INFARMED, on a daily basis, concerning mail packages with medicines, allows us to seize and destroy, every day on average, 129 packs and 1851 units of illegal or counterfeit medicines.

INFARMED/Customs cooperation

Data: 2011/02/01 to 2011/10/31

Total:

3281 parcels with illegal medicines

Daily average:

- 18 different products
- 129 packs
- 1851 units

Training and exchanging information (using Internet facilities) are the main activities within the cooperation between INFARMED and third countries such as Portuguese speaking countries and ibero-american countries.

Cooperation with Ibero-American Countries

EAMI – Falsification group (Chair: Portugal /Chile)

- Survey on national practices concerning falsification of medicines
- Promote the use of the portal EAMI to change information

The implementation of the national SPOC (single point of contact) and SPOCs in the main stakeholders is another aim of the Portuguese cooperation.

Putting the issue of falsified/counterfeit medicines on the agenda of meetings and events organized by INFARMED is one of the better ways of communication with stakeholder in the portuguese market.

CRIMEMEDICINE, THE SWEDISH AWARENESS CAMPAIGN

Ms Monika JOHANSSON

Manager, Chemical Analyses, OMCL, Medical Products Agency, Sweden

"Crimemedicine" was an information campaign by the Swedish Medical Products Agency. It was launched in the autumn 2008 with the purpose of informing people about the risks involved in buying medicines from unknown Internet sites. Internet trading in counterfeit medicines is increasing and the Medical Products Agency was therefore asked by the Swedish Government to launch a public information campaign.

The campaign had a three-tiered approach, a) advertisements in newspapers, b) advertisements on television and c) information on the Internet.

The advertisements in newspapers were offering penicillin, morphine or medicine against heart-problems. The idea was to use the same kind of advertisements that the criminal world would use when offering counterfeited medicine.

The message was:

- Reduced price, get 3 for the price of 2;
- Make your own diagnosis;
- We produce the medicine;
- No expensive clinical trials;
- No prescription needed;
- We deliver to your home;
- It might not contain what you expect, but you have to take a chance to get a low price;

There were also advertisements on TV during the same time period. The advertisements, both in newspaper and on TV, encouraged the audience to visit the Internet website *www.crime-medicine.com* to obtain more information.

A few seconds after opening the homepage of *www.crime-medicine.com* the screen of the homepage disappears and a totally different picture is shown. Information about different aspects of illegal medicine is given including:

- Production of illegal medical products, pictures from a criminal investigation in a factory south of Stockholm.
- Professional information from police, customs and medical authorities.
- Cases, information from hospital of three people who needed medical care after having consumed illegal medicine. One woman, a mother with 4 children, had died.
- Interview with a woman who had bought weight loss pills over the Internet.
- Industry representative on quality failure in manufacturing of counterfeit medicine.

Advertisements in newspapers

Advertisements on TV

Campaign site

- Discussions about economic crime. The criminals earn a lot of money that can be used for other purposes.
- What homepages look like when selling illegal medicine.

The awareness of the risks of buying medicine over the Internet was measured before and after the campaign. Before the campaign, 3% of the Swedish population had bought medicine or similar preparations from "pharmaceutical Internet sites" and 35% would consider buying prescription medicines from "pharmaceutical Internet sites".

Measurements after the campaign showed that the campaign message was understood and appreciated by the public. In slightly more than 3 months about 1˙000˙000 persons have seen the homepage *www.crimemedicine.com* and the homepage counted 430˙000 unique visitors. Very positive reactions were obtained from healthcare institutions and authorities. Awareness of the risks of buying medicines over the Internet had also increased, from 0 to 50%. But, like all campaigns, the message needs to be repeated to keep a high awareness of the risks of buying medicine over the Internet among the public.

THE MHRA PROJECTS

Ms Lynda SCAMMELL
Medicines and Healthcare products Regulatory Agency (MHRA), UK

Outline

- What is the issue?
- Concept
- Objectives
- Methodology
- Participation
- Operational Activity Options
- Results

Internet pharmacy

- Professional Site
- Responsible policies
- Patient Information
- Secure
- Private
- Good value

Rogue pharmacy

- Unlicensed medicine
- Controlled drugs
- Withdrawn medicines
- No prescriptions
- Unregulated site
- No address
- Registered in China
- Hosted in Russia

Concept

Aim

- Global response to a global issue
- International Internet Week of Action (IIWA) involving Medicine Regulators and Law Enforcement Agencies:
  - tackling the **demand**, through raising public awareness
  - tackling the **supply**, through targeting the illegal on-line sale of medicines including unlicensed and counterfeit products
- Protecting public health

Operation Dates

20-27 September 2011 – Operational enforcement activity

29 September 2011 – Press Release

Objectives

- **Safeguard** public health
- **Raise public awareness** of the increased risks in obtaining medicines from unregulated websites
- **Seize** counterfeit and illegal products and remove from the market
- **Disrupt, dismantle** and **close down** websites and businesses acting illegally
- **Identify and investigate** the producers and distributors of counterfeit and illegal medical products and the criminal networks supporting them
- **Prosecute** those responsible where appropriate and seize their assets
- Enhance **co-operation** amongst domestic and international agencies combating the illicit trade of counterfeit and illegal medical products

Methodology

- Focus on the four components required by a website illegally supplying medicines
- Engage specialists on the best way to disrupt the sites
- Engage the media in the most effective way to raise awareness
- Obtain the biggest impact for the minimum cost and effort

Participation

- MHRA – IIWA Secretariat
- 81 countries, 165 agencies
- Participation breakdown by agency:
  - Customs – 72 countries
  - Medicines Regulators – 30 countries
  - Police – 26 countries
  - INTERPOL offices – 37 countries
- Payment providers: PayPal, Visa Europe, Visa Inc, Barclaycard, Western Union and Mastercard Europe

Operational Activity Options

- Public Awareness
- Customs/Postal Hubs
- Website identification and takedown
- Visits/Inspections ('Raids')
- Results Coordination – INTERPOL
- Payment processing facility removal

PANGEA IV Results – International

- **Auction sites** - 606 adverts removed
- **Websites** – 13,495 websites taken down
- **Postal hubs / ports** – 399 postal hubs inspected with 45,519 packages inspected
- **Seized at hubs / ports** – 7,901 packages seized containing nearly 2.5 million doses
- **Types of medicines** - epilepsy, asthma, acne, narcolepsy, breast cancer, cholesterol reduction, contact lenses, skin conditions, antibiotics, anti-histamines, erectile dysfunction, weight-loss, pain relief, hair-loss, human growth hormone, anabolic steroids, antidepressants, skin-lightening creams, sedatives, stomach ulcers.
- **Public Awareness** – 17 campaigns
- **Total - nearly 2.5 million doses, valued at approx £5 million**

PANGEA IV Results – UK

- **Seizures with UKBA** – over 1 million doses of unlicensed medicines worth approximately £2m including over 52,000 doses of counterfeits worth an estimated £100,000
- **Websites taken down** with Metropolitan Police – over 12,800 (plus 600 auction/marketplace/social nw)
- **Visits with Police** – 16 warrants executed, 13 arrests, nearly 100,000 doses seized worth estimated £200,000
- **Additional seizures** – approx £17, 500 cash, computers, phones, correspondence including financial
- **Other criminality** – discovery of stun-gun, crossbow, starter pistol, knuckle-duster, knife and cannabis plants
- **Medicines seized** – epilepsy, asthma, acne, narcolepsy, breast cancer, erectile dysfunction, weight-loss, pain relief, hair-loss, human growth hormone, anabolic steroids, anti-depressants
- **Press coverage** – Press Briefing, BBC 1 O'clock news, BBC Fake Britain, Press Association, Sky News, BBC Radio 4, BBC Radio 5Live, BBC Radio London, BBC Radio Sussex, The Guardian, Daily Mail and more…
- **Total – approx 1.2million doses seized, valued at approx £2m**

THE INDEPENDENT

SATURDAY EDITION

Fake medicine den shut down

Police uncover £30,000 of illicit prescription-only drugs

COURTS

Man imported fake medicines

Fined £10,000 for selling illegal impotence drug

Section 3
SOME RECENT EXAMPLES OF COMMUNICATION

THE SWISS ANTI-COUNTERFEITING AND PIRACY PLATFORM

Ms Ruth Mosimann
Swissmedic, Switzerland

To raise awareness about the health risks of illegally imported medicines, Swissmedic initiated a national awareness campaign together with the pharmaceutical industry and the Swiss Pharmacists' Society. This campaign was carried out under the umbrella of "Stop Piracy", the Swiss Anti-Counterfeiting and Piracy Platform.

The "Stop Piracy" campaign, including videos and a website, was launched on 25 October 2011 with a press conference. The press was informed about the estimated extent of illegal imports and about lab results. Many radio and TV interviews were given - even in the main news - informing about the danger of medicines bought from the Internet. Swissmedic specialists trained pharmacists about the characteristics of illegally imported medicines and how to recognise counterfeits. 760 Swiss retail pharmacies (which is about the half of all Swiss pharmacies) actively participated in the campaign.

In the week of the "Stop Piracy" campaign these pharmacies informed their customers about the possible risks of medicines bought on the Internet, and patients could bring illegally acquired medicines for evaluation. During the campaign, posters were displayed in public places such as the train stations of many Swiss cities.

The campaign against counterfeit medicines included a short film "Illegal medicines have a shady past" and a microsite where it is possible obtain further information. The microsite is accessible on *http://shady-past.ch or stop-piracy.ch*.

FINLAND CAMPAIGNS ABOUT THE RISKS OF COUNTERFEIT MEDICINES

Mr Tom Wikberg
Finnish Medicines Agency, Finland

Here are some examples of materials produced in Finland for campaigns about the risks of counterfeit medicines. The posters are examples of materials produced and used by the customs in Finland to inform the public about the threats of counterfeit medicines.

The poster campaign took place in 2007 and the materials produced were used by customs authorities in Finland to inform the public about the threats of counterfeit medical products.

The claim of the "POSTER child" is "Would you endager his/her life? Do not endager the health and wellbeing of those you love by buying counterfeit medical products. Keep Finns safe – buy authentic medical products!".

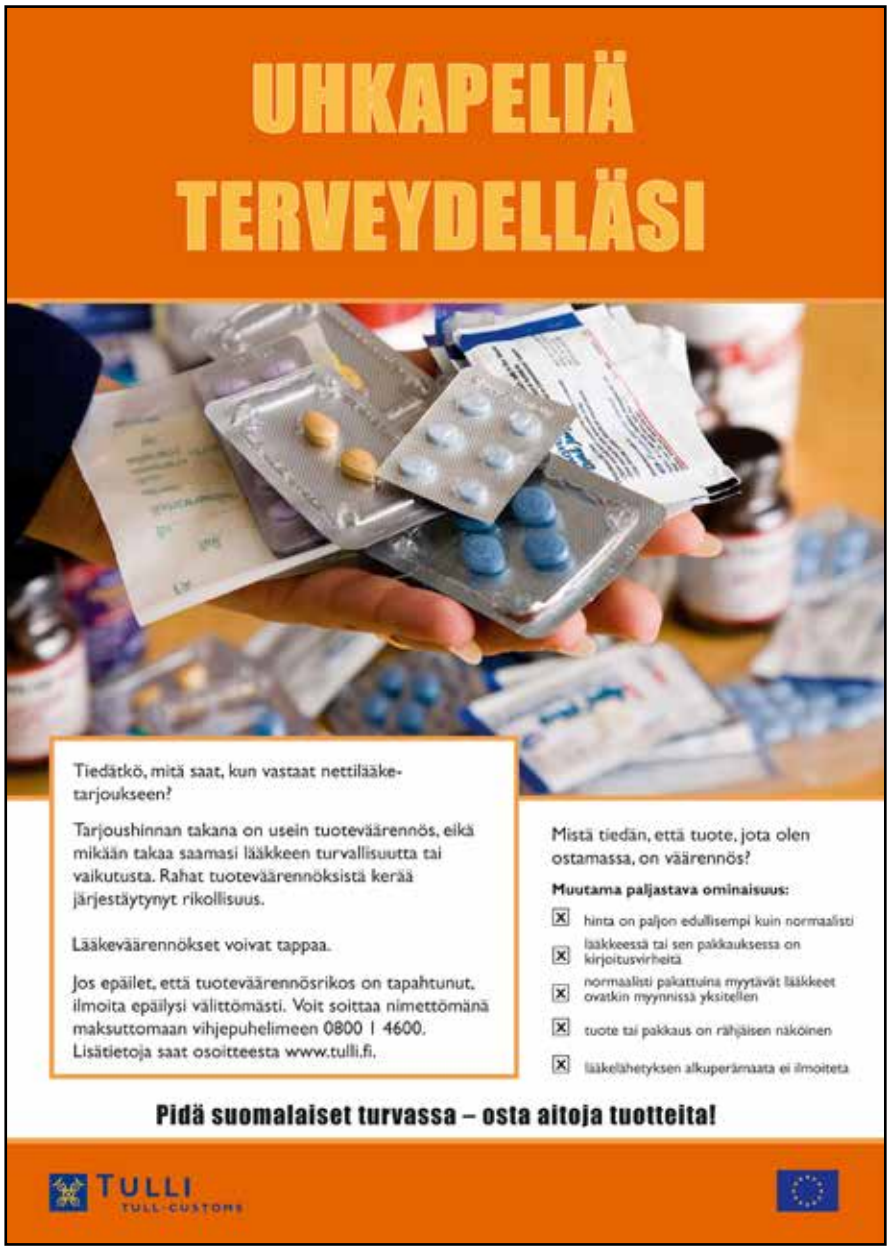
The claim of the "POSTER Medicine" is "Gambling with your health. Keep the Finns safe – buy authentic medicinal products!".

The text explains that organised crime is often behind the counterfeited products. The warning is that taking counterfeit medicines can be fatal.

The target of the campaign was the general public, and posters were displayed at airports, harbours etc. The aim was to make people aware of the phenomenon of counterfeit medicines and list some characteristics of such products (cheap price, spelling errors on package, products are sold in smaller quantities than normal, the packaging is of low quality).

A free phone number was provided in order to report possible counterfeit products.

An Internet campaign was launched by the Finnish Medicines Agency in 2008 under the address *www.vaarennosvaiei.fi*. The video was still online in September 2011. The campaign consists of three short videos where it is possible to change the face of the actor with your own (or your friend's) picture. Additionally there was an information package with questions and answers concerning counterfeit medicines. The message was that counterfeit medicines can often only be distinguished from real ones by visual inspection only.

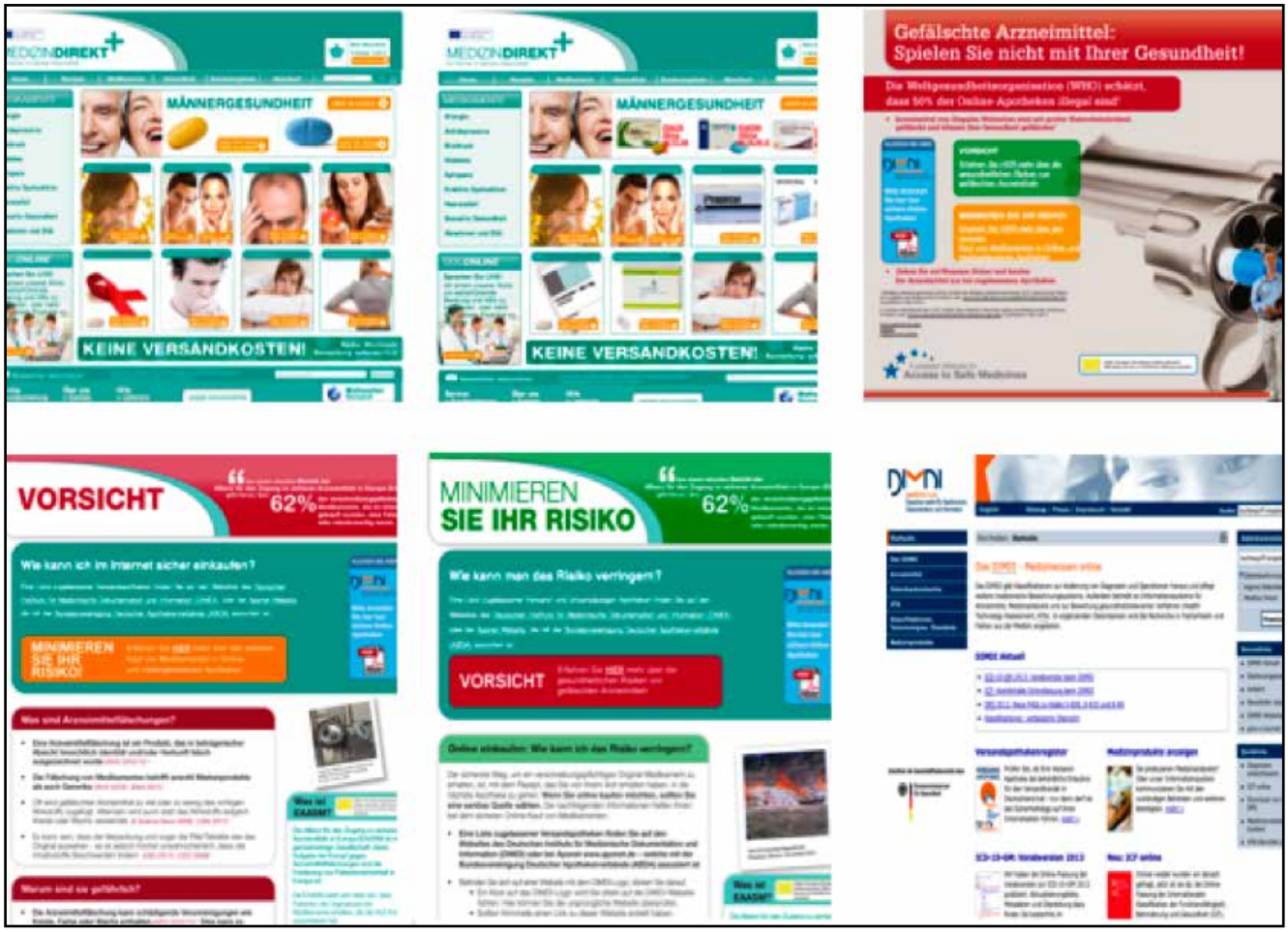


COUNTERFEITING THE COUNTERFEITER, THE EUROPEAN ALLIANCE FOR ACCESS TO SAFE MEDICINES CAMPAIGN

Mr Mike Isles
The European Alliance for Access to Safe Medicines

In 2011, the EAASM created a "fake fake" pharmacy, medizin-direkt.com. Using Google adwords as the main acquisition tool.

Visitors to the website clicked on their medicine or therapy area of choice but, instead of making a purchase, were "sold" information via an audio recording of a "doctor", and information pages (see visuals below). They were then given the option to link to the register of legitimate online and high street pharmacies, held by DIMDI (the German pharmacy body).



The project was a major success, and our website (despite not selling a single pack) became the third highest ranked online pharmacy in Germany. 182,602 unique visitors came to the site. Over 145,000 of those viewed the warning message and in excess of 12,000 were routed through to DIMDI's register. Astonishingly, had the website been selling medicines, it would, by conservative estimates, have generated up to €35 million per annum.

The EAASM will now use the learnings from this project, to develop further patient awareness and education programmes in other European countries. To support the project, the EAASM undertook a major media campaign, and the data from this is included below, together with a breakdown of the project's performance.

The full report is available at *www.eaasm.eu*.

Number of unique visitors	Where	Why is this important?
182,602	Landing pages	Scale of the problem
142,676	Warning page	Key message delivered
16,378	Extra warning information	People want to find out more about the dangers of fake medicines
12,227	DIMDI website where a list of legitimate German online and high street pharmacies are detailed	Behaviour change influenced by people being shown how to buy safely

APPENDIX

PROGRAM

Communication about the risks posed by counterfeit medical products and similar crimes

Plenary session

Welcome address and opening

Professor Sergio PECORELLI, *Chairman of the Board (AIFA), Italy*

Session theme: Impact of Risk Communication

The role of Risk Communication in anti-counterfeiting strategies

General Cosimo PICCINNO, *Head of Carabinieri for Public Health Safety (NAS), Italy*

Introduction and overview: risk communication on counterfeit medical products and similar crimes

Dr Domenico DI GIORGIO, *Director of Counterfeit Prevention Unit (AIFA), Italy*

Proactive and reactive communication

Mr Marcel MOESTER, *Dutch Healthcare Inspectorate, Netherlands*

Setting up effective awareness campaigns

Ms Ewelina KULAKOWSKA, *Expert*

The point of view of patients associations

Ms Joanna GROVES, *International Alliance of Patients' Organisations (IAPO)*

Session theme: Legal framework

The Medicrime Convention: legal framework for risk communication

Mr Sergey GLAGOLEV, *Roszdravnadzor, Russian Federation*

Communication in the amendment of the EU Directive 2001/83

Dr Johannes DICHTL, *Bundesministerium für Gesundheit, Austria*

Session theme: Experiences of communication in Europe

The RIVM projects

Mr Dries DE KASTE, *National Institute for Public Health and the Environment (RVIM), Netherlands*

The AIFA projects

Ms Marta GRAMAZIO, *Counterfeit Prevention Unit, Italian Medicines Agency - AIFA, Italy*

The INFARMED projects

Mr Joao Cristovao MARTINS, *National Authority of Medicines and Health Products, (INFARMED), Portugal*

Crimemedicine, The Swedish Awareness Campaign

Ms Monika JOHANSSON, *Head of Chemical Section, Medicine Agency, Sweden*

The MHRA projects

Ms Lynda SCAMMELL, *Medicines and Healthcare products Regulatory Agency (MHRA), UK*

Break-out session 1

Risk communication in a public framework: rules and practices

Moderator:

Mr Lidwien VERVEIJ, *Ministry of Public Health, Welfare and Sport, Netherlands*

Rapporteurs:

Professor Claudio BARBARANELLI, *Sapienza University of Rome, Italy*

Ms Luisa SALMASO, *Ca' Foscari University of Venezia, Italy*

Support:

Domenico DI GIORGIO, *AIFA, Italy*

Break-out session 2

Risk communication: professional standards, practice and training courses

Moderator:

Mr Luc BESANCON, *International Pharmaceutical Federation (FIP)*

Rapporteur:

Ms Sabine WALSER, *EDQM (Council of Europe)*

Support:

Ms Marta GRAMAZIO, *AIFA, Italy*

Break-out session 3

Two sides of the problem: industry and patients

Moderator:

Ms Joanna GROVES, *International Alliance of Patients' Organisations (IAPO)*

Rapporteurs:

Mr Emanuele CESTA, *AIFA, Italy*

Ms Monika JOHANSSON, *Head of Chemical Section, Laboratory, Medicine Agency, Sweden*

Support:

Ms Rossella MIRACAPILLO, *Italian Consumers Association; National Anti-Counterfeiting Council, Italy*

Ms Chiara PROST, *AIFA, Italy*

Plenary session

Session theme: Approaches to provisions for practices in risk communication and practical assistance for implementation

Workshop conclusions

Moderators:

Ms Ruth MOSIMANN, *Swiss Agency for Therapeutic Products (Swissmedic), Switzerland*

Professor Claudio BARBARANELLI, *Sapienza University of Rome, Italy*

Dr Domenico DI GIORGIO, *Director of Counterfeit Prevention Unit (AIFA), Italy*

AUTHORS' CVs

CLAUDIO BARBARANELLI

Claudio Barbaranelli is Full Professor of Methodology at the Department of Psychology, Sapienza Unversity of Rome. He graduated in Psychology (1989, Sapienza University of Rome), and PhD in Social and Personality Psychology (1996, Padua University).

He has been Fullbright Visiting scholar at Stanford University, and Visiting Professor at the University of Paris, Nanterre, and at the Universidad Autonoma, Madrid.

His main scientific interests are related to: Construction, validation and adaptation of psychological tests; Measurement of personality, attitudes and aptitudes; Self-efficacy and social-cognitive theory; Safety and Security in the workplace; Counterproductive Work Behaviour and Work Stress; Problem Gambling; Structural equation modeling; Analysis of longitudinal and cross-cultural data. He his author of more than 100 publication on International and National scientific journals, of five books and of ten psychological tests.

Selected Papers:

- Bandura, A., Barbaranelli, C., Caprara, G.V., e Pastorelli, C. (1996). Multifaceted impact of self-efficacy beliefs on academic functioning. Child Development, 67, 1206-1222.
- Barbaranelli, C. Caprara, G.V., e Maslach, C. (1997). Individuation and the five factor model of personality traits. European Journal of Psychological Assessment, 13, 75-84.
- Caprara, G.V., Barbaranelli, C., e Zimbardo, P. (1997). Politicians uniquely restricted Personalities. Nature, 385, 493.
- Barbaranelli, C., e Caprara, G.V. (2000). Measuring the Big Five in Self Report and Other Ratings: A Multitrait-Multimethod study. European Journal of Psychological Assessment, 16, 29-41.
- Barbaranelli, C. (2002). Evaluating cluster analysis solutions: An application to the Italian NEO Personality Inventory. European Journal of Personality, 16, S43-S55.
- Barbaranelli, C., Fida, R, Paciello, M., Di Giunta, L., Caprara, G.V. (2008). Multitrait Multimethod's study on the BFQ-C. Personality and Individual differences, 44, 876-886.

EMANUELE CESTA

Dr. Cesta is a legal functionary at AIFA's Quality Product Office. He obtained a law degree in 2000 and became a lawyer in December 2003. He worked in international law firms, practicing in the fields of Protection of personal data, Energy and Environmental Legislation, Aviation, Corporate Law, Pharmaceutical Law and Industrial and intellectual property and IT&C.

In January 2005 he joined AIFA as legal and administrative consultant within the Administrative Affairs Area, coordinating activities to comply with the provisions on workers' safety and security, the protection of personal data, handling of insurance policies, the management of public tenders, over and beyond community threshold, drafting of public contracts and agreements. He was also

appointed as secretary or Member of valuation committees. In March 2011 he moved to the Quality Product Office, providing legal assistance in administrative issues, court procedures and enforcement of national legislation and EU Directives.

DRIES DE KASTE

Dr. Dries DE KASTE obtained his degree as pharmacist from the State University of Groningen, the Netherlands, in 1979. He studied medicinal chemistry at the University of Amsterdam and the State University of Utrecht. In 1990 he received a doctorate for the thesis: "Receptor classification with slightly selective ligands".

He is head of the department for Quality Control and Pharmacopoeia Affairs in the National Institute for Public Health and the Environment (RIVM, Bilthoven, the Netherlands) since 1991 (dries.de.kaste@rivm.nl). This laboratory is an active participant in the network of the Official Medicines Control Laboratories in Europe, coordinated by the EDQM in Strasbourg.

He is team leader of the project Pharmaceutical Crime, commissioned by the Dutch Health Care Inspectorate-Enforcement Unit. In this capacity he provides analytical and forensic support to inspection services and customs authorities.

He is author of 25 publications in international scientific journals and RIVM reports, and speaker on international conferences on the field of forensic pharmacy.

He has been a lecturer since February 2009 of the master class: "Introduction to Forensic Pharmacy" at the University of Utrecht.

JOHANNES DICHTL

Dr. Johannes DICHTL is Deputy Head of the Department Pharmaceuticals and Medical Devices in the Austrian Ministry of Health. He holds a Diploma (1980) and a Doctorate in veterinary medicine (1981).

From 1982 to 1985, he worked as Assistant veterinary surgeon in the Departments of Medical Chemistry and of Pharmacology at the Veterinary Medicinal University of Vienna.

In 1985, he joined the Federal Ministry of Health. His fields of activity comprise meat hygiene, animal welfare, licensing of veterinary medicinal products and most recent, market surveillance of medicines and medical devices.

He has been Austrian CVMP member from 1995 to 2005 and Austrian Delegate to the CVMP Working Parties "Veterinary Pharmacovigilance" and "Veterinary Immunologicals" from 1995 to 2003.He joined the "Ad Hoc Group Counterfeit Medicines" at the Council of Europe in 2006 and participates in the meetings of the Committee of Experts CD-P-PH/CMED until today.

DOMENICO DI GIORGIO

Dr. Domenico DI GIORGIO is Director of the Counterfeit Prevention Unit for the Italian Medicines Agency (AIFA). He holds a PhD (1994) in biochemistry and a BSc (1990) in Chemistry from the University of Rome (La Sapienza).

From 1996 he was senior GMP inspector for Ministry of Health and AIFA and since 2003 he started working on anti-counterfeiting: currently, he is responsible for coordinating the national anti-counterfeiting activities as coordinator of the

national task-force IMPACT Italia and of the "Pharmaceuticals and Cosmetics" working group at the National Anti-Counterfeiting Council.

He is the editor of the books "Counterfeit Medicines: Facts and Case Studies" (CoE/EDQM, 2009), The IMPACT Handbook (IMPACT/AIFA, 2011), "Counterfeit Medicines" (CoE/EDQM/AIFA, 2011), "Counterfeit Medicines: Risk Communication" (CoE/EDQM/AIFA, 2011), and of the related booklet series aimed at the training of the investigators.

He is Chairman of the EDQM/CoE "Committee of experts on minimizing public health risks posed by counterfeiting of medical products and similar crimes" and "European Committee on Pharmaceuticals and Pharmaceutical Care": coordinator and member of the organizing committee of the AIFA-WHO international conference "Combating Counterfeit Drugs" (Rome, 2006); Italian member and Acting Executive Secretariat responsible for IMPACT-WHO; Consultant of the Italian Senate (e-pharmacies and counterfeit medicines).

MARTA GRAMAZIO

Marta GRAMAZIO is an administrative officer of the Counterfeit Prevention Unit for the Italian Medicines Agency (AIFA). She holds a baccalaureate degree (2002) in Communications from the LUMSA University of Rome and a postgraduate (2003) in Healthcare Communications.

Since 2009 she started working on anti-counterfeiting. She is currently a member of the national task-force IMPACT Italia.

She is the co-editor of the books "Counterfeit medicines: facts and case studies" (CoE/EDQM, 2009), IMPACT The Handbook (IMPACT/AIFA, 2011), "Counterfeit medicines" (CoE/EDQM/AIFA, 2011), "Counterfeit medicines: risk communication" (CoE/EDQM/AIFA, 2011), and of the related booklet series aimed at the training of the investigators.

She is coordinator of the online courses for Customs operators and member of the EDQM/CoE Committee of experts on the Classification of Medicines as Regards their Supply. Italian member and Acting Executive Secretariat responsible for IMPACT-WHO; Consultant of the Italian Senate (e-pharmacies and counterfeit medicines). She also participated in the definition of the amendment to European Directive 2001/83.

SERGEY GLAGOLEV

Sergey GLAGOLEV is a chief of the division for monitoring of safety and efficacy of medicines in the Federal Service for Surveillance in the Sphere of Healthcare and Social Development. Graduated from the School of Medicines of the Moscow State University of Medicine and Dentistry in 2002, he attended residency programs in cardiovascular surgery and ophthalmology.

In 2009 he completed professional training on pharmacovigilance. In 2010 he graduated from a fellowship programme in Healthcare management and Public Health of the Moscow State Medical Academy.

In 2005 he joined the expert body of Roszdravnadzor, the Scientific Centre for the Evaluation of Medical Products, as a researcher in the Institute for pre-clinical and clinical evaluation of medicinal products. Later that year he was promoted

to managing specialist of the Roszdravnadzor's division for marketing authorisation of medicines.

Since 2009 he has been senior specialist deputy chief and chief of the division for monitoring of safety and efficacy (DRA's pharmacovigilance office). Throughout his work in Roszdravnadzor he has been involved in international collaboration programmes with the Council of Europe (EDQM, OMCL network, Commission of the European Pharmacopoeia, WHO, IMPACT and national regulatory agencies. He was also a member of the former Ad hoc committee on counterfeit medical product and similar crimes involving threats to public health (PC-ISP) which drafted the Medicrime convention.

As Russian representative to the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH), he lectures at proficiency training for pharmacovigilance units of quality control laboratories and hospitals. He is an author of articles and presentations on regulatory issues of the Russian pharmaceutical market.

JOANNA GROVES

Joanna GROVES is Chief Executive Officer of the International Alliance of Patients' Organisations (IAPO). IAPO is the global group representing patients from all disease areas and all regions of the world. Joanna is responsible for managing and implementing the overall strategy of the organisation as defined by IAPO's Governing Board. Driven by its membership, IAPO focuses on issues that are of importance to patients' organisations regardless of their disease area or geographical location.

Joanna holds a Master's degree in Science and Technology Policy Studies. She joined IAPO in 2004 as Policy & External Affairs Director before becoming Chief Executive Officer in 2007. Prior to joining IAPO, she worked in other nonprofit health organisations including in a policy and research capacity building role for The Welcome Trust's Biomedical Ethics Section. She has a particular interest in how policy is formulated, supporting a stronger role for patient engagement and social and ethical considerations in health policy-making.

MONIKA JOHANSSON

- 1969 - Technical College, Eskilstuna, Sweden
- 1973 - B.Sc. Pharmacy, Faculty of Pharmacy, Uppsala University, Uppsala, Sweden
- 1973 - M.Sc. (Pharm.), Faculty of Pharmacy, Uppsala University, Uppsala, Sweden
- 1981 - Ph.D. Analytical Pharmaceutical chemistry, Uppsala University, Uppsala, Sweden
- 1990 - Post Doc, Cornell University, USA. 1 year
- 1995 - Associate professor, Analytical Pharmaceutical Chemistry, Uppsala, Sweden

Employment

1974 - 1981

Assistant/Research Assistant, Dept. of Analytical Pharmaceutical Chemistry, Uppsala University, Uppsala, Sweden

1981

Chemist, Dept. of Clinical Chemistry, Uppsala University, Uppsala, Sweden, Three month

1981 - 1987

Research Assistant/Research Scientist, Dept. of Pharmacology and Toxicology, Faculty of Veterinary medicine, the Swedish University of Agricultural Sciences, Uppsala, Sweden

1987 -1991

Research Scientist, Dept. of Psychiatric Research Centre, Ulleråker Hospital, Uppsala University, Uppsala, Sweden

1991 – 1994

Senior Scientist, Medical Products Agency, Uppsala, Sweden

1994 - 1996

Director, PMC Contract Research AB, Analytical Services,

Uppsala Sweden

1996 – 2007

Director, Quintiles AB, Analytical Services, Uppsala, Sweden

2007 – to present

Manager, Chemical Analyses, OMCL, Medical Product Agency

Uppsala, Sweden

Membership in professional organisations

Swedish Academy of Pharmaceutical Sciences, Rotary, Glunten, Uppsala

EWELINA KULAKOWSKA

Ewelina Kulakowska graduated from the University of Strasbourg with a double Master's degree in international relations and in communication. After having joined the PR agency Powell Communication Consultants in Manchester for a 6 month period, she returned to France where she has been providing communication consultancy for Hanatsu Miroir, and for Auditive Connection.

Her areas of research have concerned communication in multicultural organisations, and intercultural communication in a Polish-British context. She is the author of the article "Setting Up a Campaign" appearing in the EDQM&AIFA's publication 'Risk Communication' (2011).

JOÃO CRISTÓVÃO MARTINS

Director of the Directorate for the Assessment of Medicines (DAM) INFARMED, I.P and he is a PhD student in Public Health (Health Economics).

Background training

Pharmaceutical Sciences Degree, Universidade (Clássica) De Lisboa

Graduation On Marketing, IPAM - Inst. Port. Administração Marketing Graduation on Economic Evaluation of Medicines, ISEG- Inst. Sup. Economia Gestão (UTL)

Hospital Administration Specialist, Escola Nacional de Saúde Pública- UNL

MBA on Pharmaceutical Business, Universidade Autónoma Lisboa- UAL

Professional Background

July 1997 - September 1998

Pharmacist, Technical director – Community Pharmacy

September 1998 – July 2004

Technical Director, Marketing Director, Quality Systems Director – Pharmaceutical Company

August 2004 - February 2008

General Manager at DLA Farmacêutica -Grupo Azevedos (Distribution and exportation)

National Committees

2004-2007 (trainer)

Good Distribution Practices (GDP) and ISO9000:2000

2001-2004

Member of the Board - National Council for Quality – Pharmaceutical Society

2001-2004

Member of the Working Group of Pharmaceutical Distribution – Pharmaceutical Society

2004-2007

Member of the Board of the Lisbon Regional Department of the Pharmaceutical Society

International Committees

CD-P-PH/PC - experts on quality and safety standards in pharmaceutical practices and pharmaceutical care, CoE | 2008-

CD-P-PH/CMED – experts on minimising public health risks posed by counterfeiting of medical products CoE | 2008-

PC-S-CP – Group of specialists on counterfeit pharmaceutical products – Preliminary draft Convention of the CoE on counterfeiting of medical products and similar crimes involving threats to public health CoE | 2008-2009

Ibero-American Drug Agencies coordinator of falsified medicines working group, EAMI | 2008- 2010

Academic activities

Drug Regulatory Affairs, Professor ULHT

Stock Management, Professor ERISA- Grupo Lusófona

Pharmaceutical Logistics, Lecturer on the PAGEF programme U. Católica Portuguesa

MARCEL MOESTER

Marcel Moester is a senior inspector with almost 30 years of experience with the Dutch Health Care Inspectorate. This inspection service is an autonomous part of the Ministry of Health, Welfare and Sports and involves professionals of medical, psychiatric and pharmaceutical backgrounds.

The pharmacist inspectors mainly supervise the quality and distribution of medicinal products.

Marcel Moester's present duties are inspections of manufacturers and distributors of medicinal products, with a focus on biopharmaceutical production sites. Since 1996 Mr. Moester is a member of the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations. He is also an expert on falsified medicines. In this last capacity he was for many years involved in enforcement of pharmaceutical legislation. Currently he represents the Dutch Healthcare Inspectorate in EU and Council of Europe working groups on combating pharmaceutical crime.

RUTH MOSIMANN

Ruth MOSIMANN is Head of the Unit for Control of Illegal Medicines, at Swissmedic, the Swiss Drug Regulatory Agency. She holds a diploma of pharmacy by the University of Berne (1991). Prior to joining Swissmedic, Ruth worked for the pharmaceutical industry. She worked in development divisions for the international companies Schering-Plough, Novartis and CSL Behring. Ruth had either managerial or project management jobs, but always in the field of clinical supplies which involved packaging and international logistics of products in development. In May 2006 she was hired by Swissmedic as a scientific officer responsible for counterfeits and illegal trade within Switzerland. One year later, a new unit for market monitoring of illegal medicines was created and Ruth was promoted to head this unit. Her unit is active in enforcement against illegal trade, imports of medicinal products, counterfeits and in pharmaceutical expertise in penal cases. Since 2008, she is Vice-Chair of the Council of Europe Committee of Experts on minimising public health risks posed by counterfeiting of medical products and related crimes.

LUISA SALMASO

Graduate in Psychology and postgraduate specialisation in Psychology of Life Cycle at Padua University (Italy). She worked as Psychotherapist for Learning Disabilities, as teacher at school and tutor supervisor at Faculty of Primary Education Sciences of the same University, where she also worked in workshops for undergraduates about Media Education (advertising).

Now she is enrolled in a PhD programme in Educational and Cognitive Science at the University of Venice.

She has been involved in school prevention projects and in researches-projects for Community and Learning Development. She has publications in the indicated areas.

LYNDA SCAMMELL

Medicines and Healthcare products Regulatory Agency (MHRA)

Lynda works as the Senior Policy Adviser on the Enforcement Group of the MHRA.

She has now worked at the MHRA for 20 years – transferring from another Government Department to work as an Investigating Officer when the Enforcement Group had only 4 staff (currently over 40 staff).

Lynda deals with all policy and legislative developments that affect the group and its operational activity.

She was involved in the development of the Medicrime Convention from 2008 onwards.

SABINE WALSER

Sabine WALSER is a pharmacist and holds a doctoral degree in pharmacology, a masters degree in toxicology (1996) and a masters degree in public health (2006). Since 2002, she has worked for the Council of Europe, an international political organisation.

She coordinates programmes of activities carried out by member states focused on public health-oriented policy-making in the fields of public health risk management and prevention from counterfeit medicines and similar crimes, patient-centred pharmaceutical care, the classification of medicines into prescription and OTC medicines, carried out by expert bodies and overseen by senior officials. Within the above mentioned programmes, the Council of Europe activities against counterfeiting of medicines and similar crimes were launched in 2003 by the former Ad hoc group on counterfeit medicines.

As Co-secretary of the concerned bodies, she facilitated the transfer of public health expertise to the drafting of the Council of Europe Medicrime convention, an international treaty in the criminal law field. Since 2008, she has worked for the EDQM (Council of Europe) and is inter alia responsible for coordinating programmes aiming at assisting member states with the practical implementation of national and international legislation through networking, intelligence building and training.

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Counterfeit medical products and similar crimes: risk communication
D. Di Giorgio ed.
Tecniche Nuove, AIFA/EDQM
publishing, 2011
ISBN 978-88-481-2662-5

Counterfeit medical products and similar crimes
Case studies Vol II
D. Di Giorgio ed.
Council of Europe/EDQM
publishing, 2011

Risk communication is an essential element of the strategies and activities used to counteract the risks posed by the counterfeiting of medical products and similar crimes. The internet has introduced new elements in the complex frame of global communication.
Effective risk communication can prevent or reduce harm and encourage the public to adopt appropriate behaviours for avoiding risks.

For that reason the Italian Medicines Agency (Agenzia Italiana del Farmaco - AIFA) and the European Directorate for the Quality of Medicines & HealthCare (EDQM - Council of Europe), organised this expert workshop about risk communication, with the expert support of the Committee of Experts on Minimising Public Health Risks Posed by Counterfeiting of Medical Products and Similar Crimes (CD-P-PH/CMED).

The main objectives of the expert workshop, hosted by AIFA, Rome, on 29 November 2011, were to start a discussion between regulatory and academic experts about the key elements of good practice on how to inform the general public about the risks of counterfeit medical products and similar crimes in an appropriate and balanced way, considering also the provisions for proper communication with patients included in recent international and EU legislation (Council of Europe MEDICRIME Convention, EU Directive 2011/62).

The EDQM is a Directorate of the Council of Europe, an international organisation founded in 1949 that covers almost the entire continent of Europe. The Council of Europe aims to develop common democratic and legal principles based on the European Convention on Human Rights and other reference texts on the protection of individuals.

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Ministero dello Sviluppo Economico

ISBN 978-88-481-2851-3
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