

**Partial Agreement
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dans le domaine social et de la santé publique**



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TRAINING COURSE

WORKING ACROSS DISCIPLINES AND BORDERS -

BEST PRACTICES TO COMBAT COUNTERFEITING OF MEDICINES AND TO PROTECT
PUBLIC HEALTH

**EXECUTIVE SUMMARY
AD HOC GROUP TRAINING NEEDS SURVEY - DRUG REGULATORY
AUTHORITIES/INSPECTORATES, OMCL, POLICE AND CUSTOMS
AUTHORITIES (2007)**

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Executive Summary

Introduction

The survey on the training needs of health and law enforcement authorities of the Council of Europe member states was commissioned by the Council of Europe Ad hoc Group on Counterfeit Medicines, subordinate group of the Committee of experts on Pharmaceutical Questions, in the framework of its ongoing activity on minimising public health risks posed by counterfeit medicines and other forms of pharmaceutical crime.

The current work programme of the Ad hoc Group on Counterfeit Medicines aims *inter alia* at developing of multisectorial training programmes for member states officials and other stakeholders to combat the public health risk posed by counterfeit medicines and pharmaceutical crimes through transfer of know-how and proven practices. Furthermore, it aims at refining co-operation structures and procedures and the facilitation of international co-operation through supporting a network of single points of contact within the Council of Europe member states.

Objective

An action plan for the above training programmes - which should be needs-based - has been established by the Ad hoc Group on Counterfeit Medicines. A pilot training is scheduled for December 2007. In the context of the above training programmes, the objective of the present survey was to gather essential input for the development of training programmes beneficial for officials of health and law authorities in all 47 Council of Europe member states¹.

Survey questionnaires were sent to drug regulatory authorities (DRA), Official Medicines Control Laboratories (OMCL), and police and customs agencies in May 2007 to find out about key topics of a training programme, specific needs and existing experiences/skills levels, available training plans and resources, risk management procedures, co-operation structures and national/ international liaison persons and partners. The survey questionnaires were sent out by the Partial Agreement Secretariat to existing contacts in DRAs, by the EDQM-OMCL to the OMCL network, via Interpol and WCO to the liaison officers in the Council of Europe member states.

Methods

All questionnaires were had the same structure and the same key questions as far as applicable. Key questions were phrased as closed questions (Yes/No).

A reminder was sent out to all survey participants. Individual respondents were contacted by mail in case further clarification of an information was needed.

¹ Albania, Andorra, Armenia, Austria, Azerbaijan, Belgium, Bosnia & Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Monaco, Netherlands, Norway, Poland, Portugal, Republic of Montenegro, Republic of Serbia, Romania, Russian Federation, San Marino, Slovak Republic, Slovenia, Spain, Sweden, Switzerland," The former Yugoslav Republic of Macedonia," Turkey, Ukraine, United Kingdom

The data were entered and edited using EpiData software, version 3.02 . Missing replies and/or the reply “unknown” were labelled at entry.

In the frame of the evaluation of the survey results, specific criteria for rating priorities for receiving training in and for delivering training by respondent member states were developed. The criteria were based on the survey replies.

The survey was carried out from 1 April to 15 August 2007, data lock point was 20 July 2007.

Results

- The reply rates were 69.23% for the DRA (27 replies/ 39 sent questionnaires), 62.5% for the OMCL (20 replies/ 32 sent questionnaires), 38.30% for the police (18 replies/ 47 sent questionnaires), and 23.40% for the customs authorities (11 replies/ 47 sent questionnaires).
- The contact details of a Single Point of Contact (SPOC) were given in 100 % of the DRA and the OMCL, in 87.5% of the police authorities (6.3% “no”, 6.3% missing”), and in 90,9% of the customs agencies (9,1 % “missing”).

Key results for consideration in the planned multisectorial training programme are summarised in the following paragraph: it is noted that **all results pertain to the respondent authorities. No conclusions are drawn on non-responders.**

- (1) A current training plan for staff involved in pharmaceutical crime is available in 44.4% of the DRA (55.6% “no”), in 46.2% of the OMCL (53.8% “no” replies), in 18.8% of the police authorities (75% “no”, 6.3% “missing”), and in 9.1% of the customs authorities “yes” to 90.9 “no” replies.
- (2) A need for training is expressed in 81.5% of the DRA (11.1% “no”, 7.4% missing), in 69.2% of the OMCL (23.1% “no”, 7.7% is missing), in 75% of police authorities (25% “no”), and in 63.6% of customs authorities (36.4% “no”).
- (3) Training to any agency or organisation to deal with counterfeit medicines and/or pharmaceutical crime is provided in 33.3% of the DRA (66.7% “no”), in 19.2% of the OMCL (80.8% “no”), in 6.3% of police authorities (93.8% “no”), and in 0 % of the customs authorities (100% “no”).
- (4) Trainers to a possible Council of Europe training programme on pharmaceutical crimes can be contributed in 37% of DRA (63% “no”), in 26.9% of the OMCL (65.4% “no”, 7.7% “missing”), in 37.5% of the police authorities (56.3% “no”, 6.3% “missing”), and in only 9.1% of customs agencies (81.8% “no”, 9.1% “missing”).
- (5) Funding of the travel and accommodation cost for the training providers within the own country in case of receiving training is possible in 77.8% of the DRA (18.5% “no”, 3.7% “unknown”), in 69.2% of the OMCL (26.9% “no”, 3.8% “missing”), in 12.5% of the police authorities (56.3% “no”, 18.8% “missing”, 12.5% “unknown”), and in 27.3% of the customs authorities (63.6% “no”, 9.1% “unknown”).
- (6) Funding of the travel and accommodation cost of the staff members in case of receiving training within Europe is possible in 92.6% of the DRA (3.7% “no”, 3.7% “missing”), in 76.9% of the OMCL (19.2% “no”, 3.8% “missing”), in 31.3% of the police

authorities (31.3% “no”, 25% “missing”, 12.5% “unknown”), and in 45.5% of the customs authorities (45.5% “no”, 9.1% “missing”).

Questions (7) and (8) were included in the survey with a view to evaluating the feasibility and acceptability of distant/ online training programmes.

(7) Stable access to the Internet have 92.6% of the DRA (3.7% “missing”, 3.7% was “unknown”), 100% of the OMCL, 81.3% of the police authorities (18.8% “missing”), and 100% of the customs authorities.

(8) Access to telephone conference have 81.5% of the DRA (18.5% “no”), 65.4% of the OMCL (34.6% “no”), 37.5% of the police authorities (62.5% “no”), and only 9.1% (90.9% “no”).

(9) Those respondent member states who wished training identified the following **priority topics of a training programme**:

DRA consider training on a) international and intersectoral (health/law enforcement), co-operation and alerts, b) penal legislation including procedures and securing of proofs, c) tracing counterfeits (medicines and other therapeutical products) in legal/illegal distribution chain (Internet, wholesalers, parallel trade), d) types of counterfeits, types of production, and illegal distribution, e) visual and chemical-analytical identification of counterfeits, f) public health protection and education including media strategies, awareness raising, g) anti-counterfeiting technology, and h) criminal intelligence including links to other (e.g. economic) crimes, desirable.

OMCL wish training on a) chemical-analytical identification of (sophisticated) and counterfeits in general, illegal unknown medicines and available literature, b) sampling and how to present a report, c) information exchange and rapid alert, d) scope of the problem on a global basis.

Police authorities indicated a need of training on a) steroids, counterfeit of lifestyle products, b) identification of counterfeits, production and illegal distribution, c) national and international penal and medicine legislation, d) national health/law enforcement co-operation.

Customs authorities specified the need of training on a) control techniques especially risk analysis, b) tracing counterfeits medicines (imports/exports), trends, methods of concealment, c) lifestyle drugs, means of transport, d) mutual co-operation between international and national organisations, e) criminal investigations cases and legal protection of pharmaceutical patents.

(10) Those respondent member states who delivered training indicated availability of the following **competencies**.

Competencies available in the DRA are a) inspection of supply chain especially parallel traders, inspection technique, general GMP training for inspectors, identification of packaging, risks, internet investigation, b) medicines legislation, penal formation, intelligence gathering, pharmaceutical crime enforcement, enforcement of counterfeit medicines, c) pharmacovigilance and Eudravigilance training, developing quality systems, d) documentation tracking, e) regulations and international co-operation, f)

medicinal and borderline products, cosmetic and medical devices, g) implementation and strengthening of drug regulatory authorities.

Competencies available in the OMCL are a) visual inspections and analytical methods for identifying unknown illegal medicines/counterfeits, b) quality assurance, laboratory testing, sampling, c) identification of steroids (TLC), d) NHR and MS technology, e) Forensic and legal analysis.

Competencies available in police authorities are a) GMP training, b) pharmaceutical crime and counterfeit medicines enforcement, c) tactic operations security intelligence.

Competencies available in customs authorities are a) enforcement and criminal investigation, b) raising awareness, c) identification of counterfeit medicines, routes, production, and distribution.

Conclusions

A clear and need of training on counterfeit medicines and other forms of pharmaceutical crime was voiced by all respondents.

It was noted that the majority of the respondent DRA and OMCL have an overall considerably higher availability of training plans for staff involved in pharmaceutical crime compared with the respondent police and customs authorities respectively. This underlines that DRA and OMCL have a key role in promoting awareness of counterfeit medicines and pharmaceutical crimes with police and customs authorities who are at the forefront of detecting and seizing counterfeit and illegal medicines/ other forms of pharmaceutical crimes.

More DRA and OMCL engage in trans-sector transfer in specific knowledge on counterfeit medicines and pharmaceutical crimes. Action plans for counterfeit medicines and pharmaceutical crime are often absent and suggest a clear need for training.

In general a higher willingness was noted in respondent member states to send staff abroad in Europe for receiving than to fund training providers within the own country.

There was an adequate response from the respondent countries to contribute trainers to a Council of Europe training programme.

Overall, the counterfeit medicines and other forms of pharmaceutical crimes seem to be less high on the agenda for respondent police and customs authorities compared to DRA and OMCL.

The reply rates were high and above the reply rates usually obtained by mailings²: this indicates that the survey method including the preparation questionnaires and follow-up of the mailing was adequate, efficient and supported by established groupings active in the field. The replies were pertinent, comprehensive and timely.

In conclusion, the findings of the survey report support in general the need and feasibility of multisectorial training programmes for Council of Europe member states for example as proposed by the Council of Europe Ad hoc Group on Counterfeit Medicines in its

² Literature reply rates for postal mailings: 10-20% reply rate

strategy paper and it is hoped that the input provided through the survey is adequately considered.