



COUNCIL OF EUROPE    CONSEIL DE L'EUROPE  
Committee of Ministers  
Comité des Ministres

**Resolution ResAP(2007)2  
on good practices for distributing medicines via mail order which protect patient safety and the quality  
of the delivered medicine**

*(Adopted by the Committee of Ministers on 5 September 2007  
at the 1003rd meeting of the Ministers' Deputies)*

The Committee of Ministers, in its composition restricted to the representatives of the states members of the Partial Agreement in the Social and Public Health Field,<sup>1</sup>

Recalling Resolution (59) 23 of 16 November 1959 on the extension of the activities of the Council of Europe in the social and cultural fields;

Having regard to Resolution (96) 35 of 2 October 1996 revising the Partial Agreement in the Social and Public Health Field, whereby it revised the structures of the Partial Agreement and resolved to continue, on the basis of revised rules replacing those set out in Resolution (59) 23, the activities hitherto carried out and developed by virtue of that resolution, these being aimed in particular at:

- raising the level of health protection of consumers in its widest sense, including a constant contribution to the harmonisation – in the field of products having a direct or indirect impact on the human food chain as well as in the fields of pesticides, pharmaceuticals and cosmetics – of legislation, regulations and practices governing, on the one hand, quality, efficiency and safety controls for products, and, on the other hand, the safe use of toxic or noxious products;
- integrating people with disabilities into the community: definition – and contribution to implement it at European level – of a model coherent policy for people with disabilities, which takes account, simultaneously, of the principles of full citizenship and independent living; contribution to eliminate barriers to integration, whatever their nature: psychological, educational, family-related, cultural, social, professional, financial or architectural;

Having regard to action carried out by the Council of Europe over several years for the purposes of harmonising legislation and practices in the public health field, including those with a view to promoting the safety, quality and effectiveness of medicines and their appropriate use in society;

Recalling Committee of Ministers' Resolution ResAP(2001)2 concerning the pharmacist's role in the framework of health security, which, in paragraph 9, drew attention to certain practices related to the Internet, as well as illicit importation and illegal distance sales, that may compromise the guarantee of the quality, safety and efficacy of medicines on the market;

Having regard to the aim of the Committee of Experts on Pharmaceutical Questions (P-SP-PH) to develop a simple user-oriented, easily available and accessible information guide to help citizens to select amongst the

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<sup>1</sup> Austria, Belgium, Bulgaria, Cyprus, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

deluge of information on medicinal products, appropriate modes of prescription and distribution, which resulted in a core message for developing user-oriented guidance<sup>2</sup> offered to Partial Agreement health authorities;

Taking into account that this effort, however, has been and remains insufficient, and considering that:

- Internet trade and mail-order trade in medicines have been growing during recent years;
- criticism of mail-order trade in medicines deals mostly with the dangers of the illegal sale of medicines via the Internet, which may often be counterfeit, whereas the legal trade in medicines via mail order is often overlooked;
- this does not take account of the fact that mail-order trade in medicines is permitted in many countries;
- in December 2003 the European Court of Justice of the European Communities issued a ruling (C-322/01) with implications for the current legislation of European Union member states on mail-order trade in non-prescription medicines;<sup>3</sup>
- pharmacies will, therefore, increasingly make use of the possibility of selling medicines via mail order;
- as a consequence, consumers and pharmacists wanting to supply medicines to patients by mail order are more than ever confronted with questions of the quality of mail-ordered medicines;
- it is, therefore, necessary to proceed with the development and implementation of good practices for the distribution of medicines by mail order to ensure patient safety and quality of medicines and to fulfil the stipulations of Resolution ResAP(2001)2, paragraph 9.

Having regard to Committee of Ministers' Resolution ResAP(2007)1 on the classification of medicines as regards their supply, superseding Resolution ResAP(2000)1 on the classification of medicines which are obtainable only on medical prescription, which recommends to member states, in the absence of uniform legislation on the supply of medicines, to apply the general provisions on the supply conditions of medicines as set out in ResAP(2007)1, to accept its annually revised appendices, to adopt the general provisions relating to minimum information to be included in prescriptions and to supply information on a regular basis concerning the national legal classification of medicines;<sup>4</sup>

Having regard to Committee of Ministers' Recommendation Rec(2004)17 on the impact of information technologies on health care – the patient and Internet, which focuses on the use of the Internet for medical purposes;

Considering that the above recommendation does not deal with adequate quality and safety standards with regards to mail-order trade in medicines, which constitute an indispensable aspect of patients' safety;

Noting that illegal mail-order trade in medicines is constantly increasing leading to a considerable hazard for patient safety, namely the distribution of counterfeit medicines;

Taking into account that mail-order trade in medicines is by and large marketed via the Internet, which is uncontrollable and used as a platform for many illegal offers of medicines, be they for prescription-only medicines or medicines available without prescription, stem from doubtful sources of supply, and be of substandard or uncontrollable quality (for example, counterfeit);

Considering that the only way to protect the public from such illegal offers is to help to differentiate these easily from legal offers which bear a clearly identifiable legal imprint, and that information on a pharmacy website should therefore be understandable, reliable and specific;

Noting that Article 5 of Directive 2000/31/EC on electronic commerce, and the European Commission Communication on quality criteria for health related websites of 29 November 2002 (COM (2002) 667) address the relevant information to be provided for marketing offers on the Internet, but do not deal with quality and safety standards to be used for mail-order trade in medicines;

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<sup>2</sup> [http://www.coe.int/t/e/social\\_cohesion/soc-sp/Health Information Sources.tif](http://www.coe.int/t/e/social_cohesion/soc-sp/Health%20Information%20Sources.tif) – Medicines and the Internet: user-oriented guidance.

<sup>3</sup> European Court of Justice ruling of December 11, 2003 in the case C-322/01 Deutscher Apothekerverband e.V. vs. 0800 DocMorris NV and Jacques Waterval.

<sup>4</sup> [http://www.coe.int/t/e/social\\_cohesion/soc-sp/Health Information Sources.tif](http://www.coe.int/t/e/social_cohesion/soc-sp/Health%20Information%20Sources.tif): – Medicines and the Internet.

Having in mind the current practices and legislation regarding mail-order trade in medicines in the European Union, the European Economic Area and Switzerland;

Considering that quality and safety standards to be applied when carrying out mail-order trade in medicines often differ from country to country, or are sometimes not regulated at all;

Taking the view that patients' safety is paramount, and that, if permitted, mail-order trade in medicines therefore requires clear quality and safety standards with a reliable legal basis, and that member states should for this reason enable the implementation of and further adaptation to the state of the art of adequate regulations;

Considering that such regulations should be harmonised at European level because of their increasing cross-border nature;

Recommends that the governments of the member states of the Partial Agreement in the Social and Public Health Field implement the requirements concerning the standards according to which mail-order trade in medicines can take place safely and maintain patient safety and the quality of the supplied medicines, namely standards pertaining to and as set out in the appendix to the present resolution:

- delivery methods and related responsibilities;
- counselling and information for the patient;
- mandatory notification;
- conditions for sale and distribution;
- exclusion of unsuitable medicines from mail-order trade;
- marketing and advertising;
- handling of prescriptions for mail orders of prescription-only medicines;
- establishment of focal points and their role and contribution to international co-operation;
- measures to follow up on offences.

Each government, however, remains free to adopt stricter regulations.

#### *Appendix to Resolution ResAP(2007)2*

### **1. Scope of application**

This resolution should serve countries which permit, or plan to permit, mail-order trade in medicines as a frame of reference for the criteria and safety standards which should be abided by when such trade is carried out.

### **2. Definition**

"Mail-order trade in medicines" is understood as distance selling of medicines by an authorised person to an individual patient/consumer who ordered them (physical part). Mail-order trade in medicines is by and large marketed via the Internet (virtual part).

### **3. Pharmacy**

As the operation of mail-order pharmacies could greatly benefit, particularly with respect to counselling patients, if it were linked with community pharmacies, mail-order trade in medicines should take place from pharmacies open to the public. Such trade in medicines could also take place from other retailers if they are permitted to sell certain medicines in the member state in question.

### **4. Person responsible for delivery**

Mail-order trade in medicines should be carried out by adequately licensed persons only.

### **5. Delivery**

A quality assurance system for the delivery of the medicines should be established and maintained. This system should ensure:

- a. adequate packaging, transportation and delivery of the medicine ensuring that its quality and effectiveness are preserved;
- b. delivery to the person ordering or an individual nominated by this person;
- c. the possibility to track and trace deliveries.

## **6. Languages for counselling and information**

Patient counselling and information should be, at a minimum, in the language or languages of the country of destination.

## **7. Counselling and medication surveillance**

Counselling of the patient or the recipient of mail-ordered medicines should be provided by e-mail and/or telephone. An adequate level of medication surveillance (for example checking of dosage, interactions and incompatibilities), as required by each national authority, should be maintained.

## **8. Information for the patient**

The patient should be informed about the contact details of the selling pharmacy or another licensed retailer and about the requirement to contact the attending physician if medication-related problems or any adverse effects occur. Medicines delivered should be accompanied by the warning: "Please contact your pharmacy if package or medicine appears unusual, broken or damaged"

## **9. Mandatory notification**

There should be a system in place for notifying adverse effects, interactions, warnings, recalls and quality defects to the patient and by the patient, as well as for taking in-house measures to guard against such risks.

## **10. Conditions for sale and distribution**

Medicines should only be mailed if authorised for marketing and permitted for sale or distribution via mail-order trade in accordance with the legislation of the country of destination.

## **11. Exclusion of medicines**

Narcotics should, as a rule, be excluded from mail-order trade in medicines. Medicines which could be dangerous – when mail-order traded – for any person or the environment, even when properly packaged, and medicines with an expiry date close to time of delivery are not suitable for mail-order trade.

## **12. Marketing and advertising**

Any marketing of mail-order trade in medicines on web pages on the Internet or otherwise should carry the following information:

- a. name of the responsible pharmacist or licensed person;
- b. address and telephone number;
- c. e-mail address;
- d. name of licensing authority;
- e. date of licence and of last inspection;
- f. clearly indicated prices, specifying whether they are inclusive of tax and delivery costs.

### **13. Prescription-only medicines**

Mail-order trade in prescription-only medicines should only take place under the supervision of a pharmacist against submission of a valid prescription. It may also be submitted electronically if properly authenticated.

### **14. Liability**

The pharmacist or any other licensed person providing for mail-order trade in medicines should be responsible for any shipment and be held liable for proper delivery.

### **15. Focal point**

Countries which permit mail-order trade in medicines should establish a national focal point for easy exchange of information on problems arising in this context and adequate co-operation at international level. Units or agencies rather than individuals should be designated as focal points (for example, single points of contact (SPOCs)). Such focal points should particularly serve those persons with complaints related to mail-order trade in medicines and co-ordinate relevant exchanges of authorities.

### **16. Offences**

Countries should provide for adequate measures to follow up on breaches of the safety standards provided to protect patient safety and the quality of the delivered medicine.