

COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

Resolution ResAP(2001)2
concerning the pharmacist's role in the framework of health security

*(Adopted by the Committee of Ministers
on 21 March 2001
at the 746th meeting of the Ministers' Deputies)*

The Committee of Ministers, in its composition restricted to the Representatives of Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland and the United Kingdom, Member States of the Partial Agreement in the Social and Public Health Field,

Recalling Resolution (59) 23 of 16 November 1959, concerning 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, 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 previously carried out and developed by virtue of that resolution, these being aimed in particular at:

- a. raising the level of public health protection in its widest sense, including a constant contribution – in the field of products having a direct or indirect impact on the human food chain as well as in the field of pesticides, pharmaceuticals and cosmetics - to harmonising 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;
- b. integrating people with disabilities into the community: by defining, and contributing to the Europe-wide implementation of, a model of coherent policy for people with disabilities, taking simultaneous account of the principles of full citizenship and independent living; and by contributing to the elimination of all types of barrier to integration, whether psychological, educational, family-related, cultural, social, professional, financial or architectural;

Having regard to the action carried out for several years for the purpose of harmonising legislation in the public health field and, in particular, in the pharmacy sector;

Bearing in mind the measures proposed in Resolutions AP (93) 1 on the role and training of community pharmacists, AP (94) 1 on the rational use of medicines and AP (97) 2 on the development of the function of pharmacists and the adaptation of their initial training, and the need to implement them;

Bearing in mind the proceedings of the Seminar on “The pharmacist at the crossroads of new health risks: an indispensable partner for their management!”, held at the Council of Europe in Strasbourg from 20 to 22 October 1999;

Considering the emergence of new therapies with their associated risks;

Considering that iatrogenic effects, including medication errors, are not only a public health problem but also lead to increased health expenditure;

Considering the growing trend towards self-medication;

Considering the dangers inherent in counterfeit products;

Considering the problems posed by distance sales of medicinal products and the development of this practice through the Internet;

Considering the challenges of new information technologies;

Considering the need to ensure that the application of technological progress benefits the patient;

Considering that pharmacists provide added value both through their scientific and pharmaceutical expertise and in terms of ethics;

Considering the need to promote the pharmacist's role in the management of new health risks;

Considering that community pharmacists are the health professionals most readily accessible to patients and that they help to personalise the delivery of patient care;

Considering that pharmaceutical care helps to reduce iatrogenic risks, including medication errors;

Considering the need to take professional services into account in the remuneration of pharmacists;

Considering that health expenditure must not be curbed at the expense of quality of care;

Considering that regulations need to be adapted to address the emergence of new health risks and the development of the pharmacist's role in their management,

Recommends that the governments of the member states of the Partial Agreement in the Social and Public Health Field take the following principles into consideration for the purpose of adapting their regulations to reflect the pharmacist's developing role in relation to health security, and that they encourage pharmacists, professional bodies, academic institutions, health insurance funds and patients' and consumers' associations to take them into account:

1. With the developments in communication systems and scientific progress, there is a risk of less personal contact. Patients, as of right, should be able to have direct contact with a pharmacist. It is also essential to establish co-operation through networks linking pharmacists, health authorities and other health professionals. Pharmacists must be able to function freely

and dispassionately within these networks. The system under which they are remunerated must be reviewed to reflect the professional service they provide rather than the profit margin or volume of their sales, in accordance with Resolution AP (93) 1 on the role and training of community pharmacists. Pharmacists' basic and further training should include behavioural sciences and communications skills.

2. Health spending cannot be curbed at the expense of quality of care. In order to reconcile quality with the need to keep costs down, the contribution of the pharmacist to quality improvement and cost control should be recognised and the regulatory framework should ensure a role for pharmacists at every stage of the medication chain.

3. One of the pharmacist's basic functions, as an expert in medicinal products, is to help prevent avoidable iatrogenic risks. There are various means of reinforcing the pharmacist's role in this respect. An epidemiological network on medication errors, involving pharmacists and other health professionals, must be set up, with systematic notification. Pharmaceutical care and clinical pharmacy (in hospitals and community pharmacies and in primary healthcare) should also be developed. The pharmacist's role as a supplier of information to prescribing doctors, patients and other health-care providers must be strengthened. In particular, pharmacists must give patients not only oral but also written advice on the proper use of medicinal products.

4. Pharmaceutical care is an essential element in the prevention and reduction of iatrogenic risks and should be implemented systematically. It includes:

- the keeping of pharmaceutical records that contain details of the patient's case-history, medicines supplied, clinical information, available therapeutic and biological results, and recommendations made to the patient;
- the monitoring of prescriptions, particularly in the light of the patient's pharmaceutical record in order to check for consistency and for possible interactions with other medicines;
- the evaluation of patients' overall medication;
- the rationalisation of the advice given to patients: procedures must be developed whereby, in particular, patients will in certain circumstances receive information in writing;
- the systematic exchange of information with other health professionals (via networks).

In order to achieve these tasks, full use should be made of the various information technologies and relevant databases, and it should be possible to access patient profiles and incorporate them in pharmaceutical records.

5. The risks associated with self-medication can be reduced if patients are well informed and pharmacists have an important role in the process. The pharmacist must inform the patient about significant interactions. Moreover the patient must be informed about the risks associated with "borderline" products and medicines available outside pharmaceutical control, both by health professionals and through information campaigns.

Pharmacists must evaluate all patient requests. They must be able to rely on guidelines including criteria for evaluating the patient's condition and offering advice. Pharmacists must,

if necessary, put their opinions in writing and, with the patient's agreement, address them to his or her doctor.

Where a patient record is kept, it should also include information about self-medication.

6. Given the high risks inherent in new therapies, such as gene and cell therapies, it is essential to:

- draw up a set of good practices in co-operation with all the professionals concerned, and monitor their implementation;
- ensure, at every level, that therapeutic protocols are documented in detail and verified;
- set up multi-disciplinary teams that will make the best possible use of their members' different skills;
- establish criteria for deciding when treatment is appropriate, given the dangers and the high cost of such therapies;
- ensure that there is an exchange of information between the relevant health professionals inside and outside hospitals;
- make mandatory the recording of all steps in the research, production and use of pharmaceutical products resulting from genetic engineering.

The pharmacist, as one of the experts in the management of healthcare risks, must be integrated at every stage and play an active role in decision making.

7. As therapies are increasingly used to enable people to exceed their natural capacities, rather than to treat their illnesses, pharmacists must be given a greater role in discouraging such practices. They must make patients aware of the inherent risks, and evaluate their requests in the light of their patient record. Health authorities must organise campaigns to inform people about the dangers of using medicines in this way.

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

The authorities must:

- set up systems of surveillance involving pharmacists at every stage of the medication chain;
- require that a person (as a rule a pharmacist) be made responsible for quality at each stage of the distribution process;
- reinforce the system of inspection of manufacturers' and wholesalers' premises;
- act against uncontrolled importation, distribution and marketing;
- take a cautious approach to the opening of markets and to price-reduction policies.

Manufacturers must:

- develop packaging that makes falsification difficult;
- recognise the need to lodge complaints about counterfeiting as a matter of course;
- when they are victims of counterfeiting, notify the health authorities and those responsible at every stage in the distribution chain.

Pharmacists must take due care in choosing their suppliers.

Patients must be made aware of the inherent dangers of counterfeit medicines.

9. Public health authorities should guarantee the quality, safety and efficacy of medicines on the market. But such guarantees are jeopardised by certain practices related to the Internet, as well as by illicit importation and illegal distance sales.

A specific set of pharmaceutical good practices for the Internet (GIP) must be drawn up. These should, in particular, be implemented by those governments contemplating the sale of medicines by Internet. If necessary, they should guarantee real (as opposed to virtual) contact between the patient and a health professional.

International legislation should be drawn up, or in its absence the legislation of the country of final sale should prevail over that of the country of origin.

With regard to information and advertising, it is necessary to introduce an accreditation system and a quality mark.

Consumers must be made aware of the issues, both individually and through mass information campaigns.

Public health authorities should use the Internet to direct the public to reliable information.

10. In order to optimise patient care, networks should be set up including hospital and community pharmacists and those working in primary healthcare teams, doctors and, where appropriate, health authorities, health insurance funds and universities. They must also facilitate co-operation between professionals inside and outside hospitals.

The primary aim of such networks must be to serve the patient's interests.

It should be ensured that:

- patient retains freedom of choice;
- patient data is confidential and only selected parties have access to it;
- network quality and security criteria are established, and networks are validated and compatible;

- levels of responsibility are determined.

The use of new technology will also make it easier to keep patient records and monitor prescriptions.

11. In order to achieve these aims, the basic and further training of the various practitioners involved must be adapted on an ongoing basis.

Glossary

Borderline product:	product not classified in a defined legal category (medicine, cosmetic product, food supplement, medical device) owing to confusion over criteria concerning its presentation and/or function
Health security:	the security of individuals against all forms of risk associated with choices of therapy, preventive and diagnostic care and treatment, the use of healthcare products, and the actions and decisions of health authorities
Iatrogenic effects:	unexpected reactions, events or accidents that may occur as a result of the specific effects of medicines or as a result of the circumstances of their use, including medication errors
Pharmaceutical care:	the implementation of different processes permitting responsible dispensing of medicinal treatment until tangible results improving the patient's quality of life are achieved
Primary health care team:	multidisciplinary community health team that ensures the first patient's contact with the whole health care system
Self-medication:	pharmaceutical treatment undertaken by the patient on his/her own initiative without medical prescription