Creation of a better medication safety culture in Europe: building up safe medication practices

Recommendation of the Council of Europe

Expert Group on Safe Medication Practices

About the Council of Europe

- the continent's oldest political organisation, founded in 1949
- distinct from the 25-nation European Union
- 46 countries, including 21 countries from Central and Eastern Europe
- Parliamentary Assembly, grouping 315 representatives from the 46 national parliaments.
- Committee of Ministers, organisation's decision-making body, composed of the 46 Foreign ministers
- headquarters in Strasbourg, in north-eastern France

Council of Europe' role in health protection of consumers

46 member states treaty

Committee of Ministers

Council of Europe Recommendation Rec(2006)7 of the Committee of Ministers to member states on management of patient safety and prevention of adverse events in health care

19 member states treaty

Partial Agreement in the Social and Public Health Field

Public Health Committee (CD-P-SP)

- Convention on the elaboration of a European Pharmacopoeia
  - European Directorate for the Quality of Medicines (EDQM)
- Committee of Experts on Pharmaceutical Questions (P-SP-PH)
  - Expert Group on Safe Medication Practices

Council of Europe initiatives for improving patient and medication safety

- **20-22 October 1999** - pan-European Seminar Strasbourg
  "The pharmacist at the crossroads of new health risks: an indispensable partner for their management"
- **21 March 2001** - Council of Europe Resolution ResAP(2001)2
  of the Committee of Ministers concerning
  the pharmacist's role in the framework of health security
- **21–22 November 2002** - Council of Europe Expert Meeting
  Medication safety Den Haag, The Netherlands
- **November 2002** - Establishment of the Committee of Experts
  on Management of Safety and Quality in Health Care
  by the Public Health Committee
- **April 2003** - Establishment of the Expert Group on Safe Medication Practices by the Committee of Experts on Pharmaceutical Questions
- **24 May 2006** - Council of Europe Recommendation Rec(2006)7
  of the Committee of Ministers to member states on management
  of patient safety and prevention of adverse events in health care
- **16 October 2006** - Approval
  by the Committee of Experts on Pharmaceutical Questions
  of the report of the Expert Group on Safe Medication Practices

Promoting safer medication practices in Europe

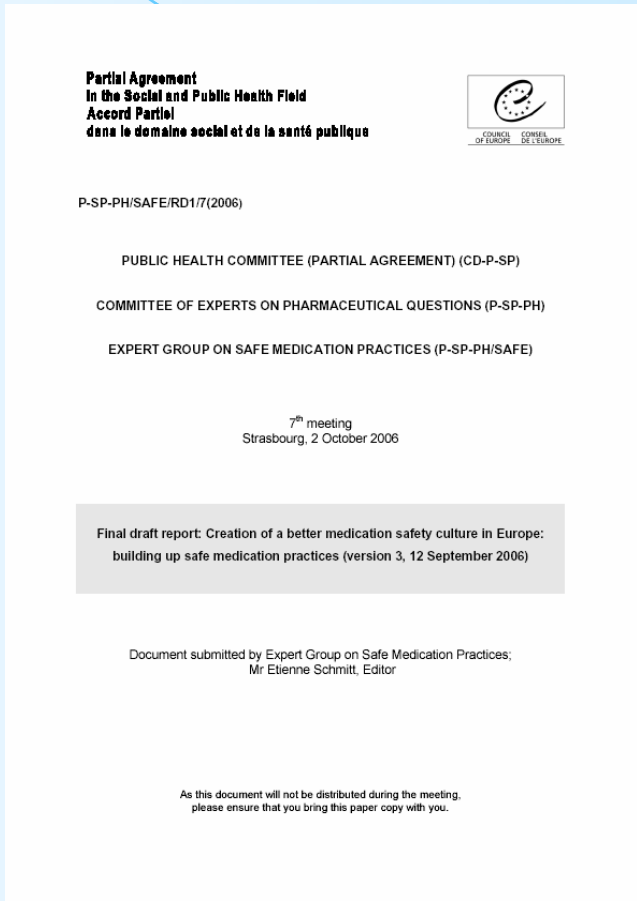
- European Union:
  - Project SIMPATIE “Safety Improvement For Patients In Europe”
  - Luxembourg Declaration on Patient Safety (5 April 2005)
  - No safe medication practice initiatives announced
- Council of Europe:
  - Strong cooperation between the Committee of Experts on Management of Safety and Quality in Health Care and the Expert Group on Safe Medication Practices
  - Adoption of common glossary of terms related to patient and medication safety
  - “Medication safety, a specific strategy to promote patient safety” is a full part of the Recommendation Rec(2006)7: Appendix E
  - Report of the Expert Group on Safe Medication Practices “Creation of a better medication safety culture in Europe: building up safe medication practices”

Aims of the Expert Group on Safe Medication Practices

- to enhance awareness and recognition of medication errors
  awareness of medication errors across the European countries and
  recognition of medication errors as an important system-based public health issue;
- to provide guidance
  for reducing medication errors and preventable adverse drug events
  in all the processes of the medication use-system,
  both in hospital and ambulatory care settings,
  based
  – on reporting, analysing and active learning from the medication errors
  – on evidence-based strategies already recommended
- to help
  European Health Authorities,
  governments and regulatory agencies,
  pharmaceutical companies,
  organizations and professional societies,
  health care professionals and patients,
  in selecting top safety practices to implement both at national and local levels,
  building-up Europe-wide standards for safe medication practices

Challenges to the Expert Group on Safe Medication Practices

- the lack of information on medication errors occurring in European members states
- the great variation in the different European countries regarding:
  - medication regulations
  - clinical practices
  - medication uses procedures
  - organizational cultures



Partial Agreement
in the Social and Public Health Field
Accord Partiel
dans le domaine social et de la santé publique

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

P-SP-PH/SAFE/RD1/7(2006)

PUBLIC HEALTH COMMITTEE (PARTIAL AGREEMENT) (CD-P-SP)

COMMITTEE OF EXPERTS ON PHARMACEUTICAL QUESTIONS (P-SP-PH)

EXPERT GROUP ON SAFE MEDICATION PRACTICES (P-SP-PH/SAFE)

7th meeting
Strasbourg, 2 October 2006

Final draft report: Creation of a better medication safety culture in Europe: building up safe medication practices (version 3, 12 September 2006)

Document submitted by Expert Group on Safe Medication Practices;
Mr Etienne Schmitt, Editor

As this document will not be distributed during the meeting, please ensure that you bring this paper copy with you.

Report structure

- **Introduction**: scope of the report
- **Chapter I**:
  how to prevent errors by learning from medication errors
- **Chapter II**:
  how to measure and evaluate medication safety
- **Chapter III**:
  how the design of medicine products used in Europe can be developed to improve the safety of these products in use
- **Chapter IV**:
  methods for improving safe medication practices
- **Chapter V (or Part II)**:
  how drug information practices contribute to medication safety

Preventable adverse drug events in Europe

Incidence in European hospitals

- 0.4 - 7.3% of admissions
  Spain: 1.4% 19.9%
- admissions caused by preventable ADEs
  - **medicine:** **23.1% - 70.6%**
    (0.9%-4.7% of admissions)
    Spain: 4.7% 70.6%
  - **intensive care:** **44.3% - 60.9%**
  - **geriatrics:** **30.1% - 79.6%**
  - pediatrics: unknown
  - **multicenter studies:** **47.0% - 72.0%**
  - **emergency admissions:** **32.0% - 66.9%**
    Spain: 66.9%
  - **visits to emergency units:** **37.9% - 46.8%**
    Spain: 43.3%
- 59% of post discharge ADE are preventable

Costs

- 3,000 € per preventable adverse event (Spain)
- 3,700 € per drug related hospitalisation (Germany)
- national annual cost estimates:
  - 400 million € (Germany)
  - 706 million € (UK, 72% preventable)
  - 636 million € (France, 38% preventable)

Medication errors in Europe

European direct observation studies (administration error rates without wrong-time errors)

a – traditional floor stock or ward stock system

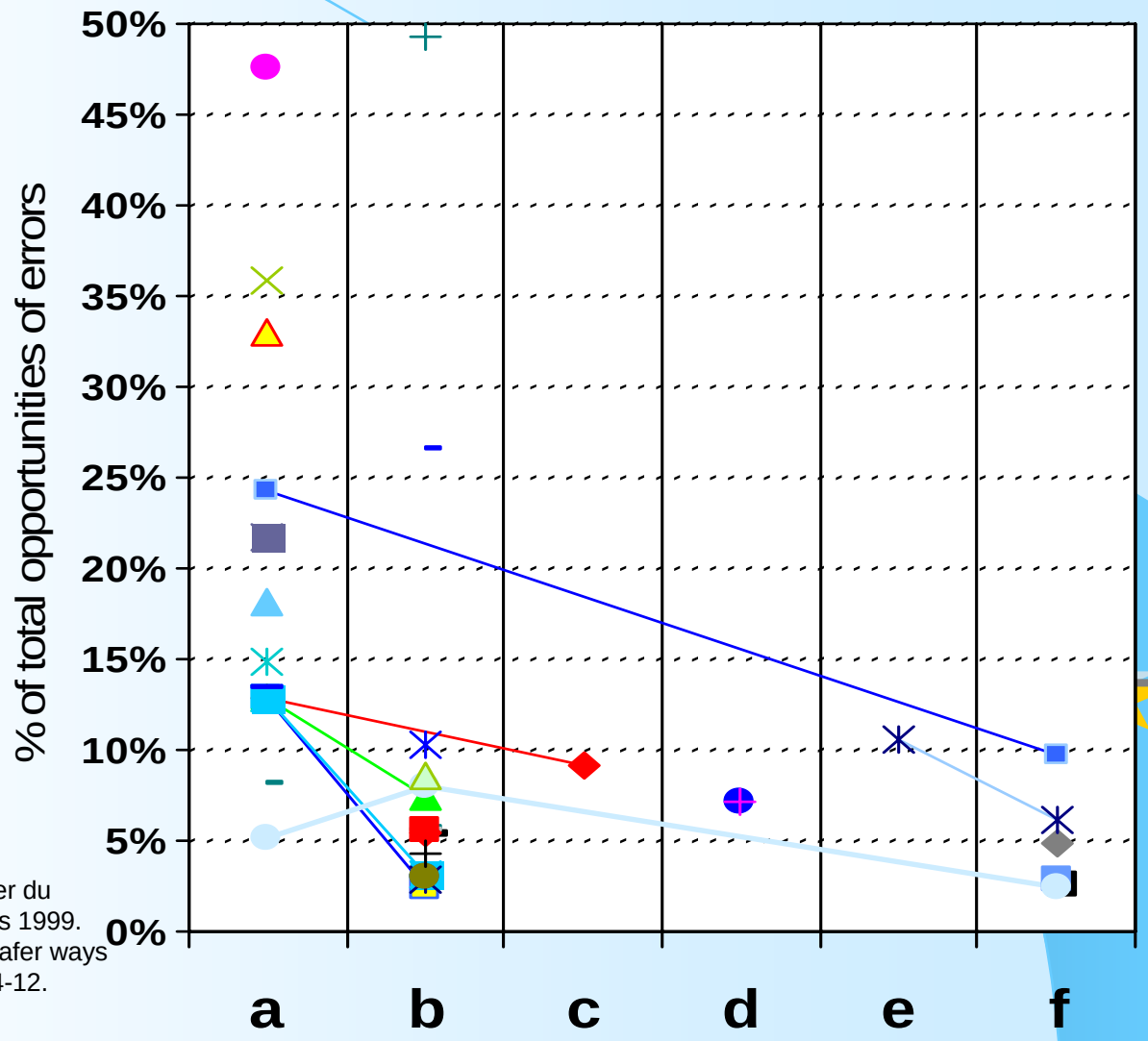
b – UK ward stock system with original prescription

c – ward stock + patient prescription system

d – individual patient prescription distribution system

e – unit-dose drug distribution manual system

f – unit-dose drug distribution computerised or automated



Updated from Schmitt E.
Le risque médicamenteux nosocomial: circuit hospitalier du médicament et qualité des soins. Masson Editeur, Paris 1999.
Unit-dose drug distribution systems: old-fashioned or safer ways for pharmaceutical care? Eur Hosp Pharm 2000; 6(1):4-12.

Learning from medication errors

European Healthcare Organisations and other related stakeholders are recommended to:

- establish **medication error reporting systems** (MERS) including primary care as well as hospital settings at local, national and European levels
- delegate the responsibility for the management of local medication use systems in both primary and secondary care to **multidisciplinary safe medication practices committees**.
- establish a recognised **national focal point for safe medication practices**, in a collaborative and complementary way with pharmacovigilance systems
- use a **common terminology** concerning patient harms from medicines and promote a **common taxonomy** to facilitate the sharing of safety information in Europe

Sharing information on analysed errors at a European level

European Health Authorities should:

- build a **European network of national MERS**;
  - mandate the co-ordination between MERS to a permanent network pertaining to the Council of Europe, further as a structure belonging to the European Directorate of the Quality of Medicines;
- ensure that all **medication error reports** related to its relevant missions, such as naming, labelling, packaging, advertising of medicinal products, **are shared with** the European Medicine Agency and national **regulatory agencies**;
- ensure that all medication error reports related to the recommended International Nonproprietary Names (INN) are shared with the World Health Organisation (**WHO**) **INN Programme**.

Assessing the safety of medication practices

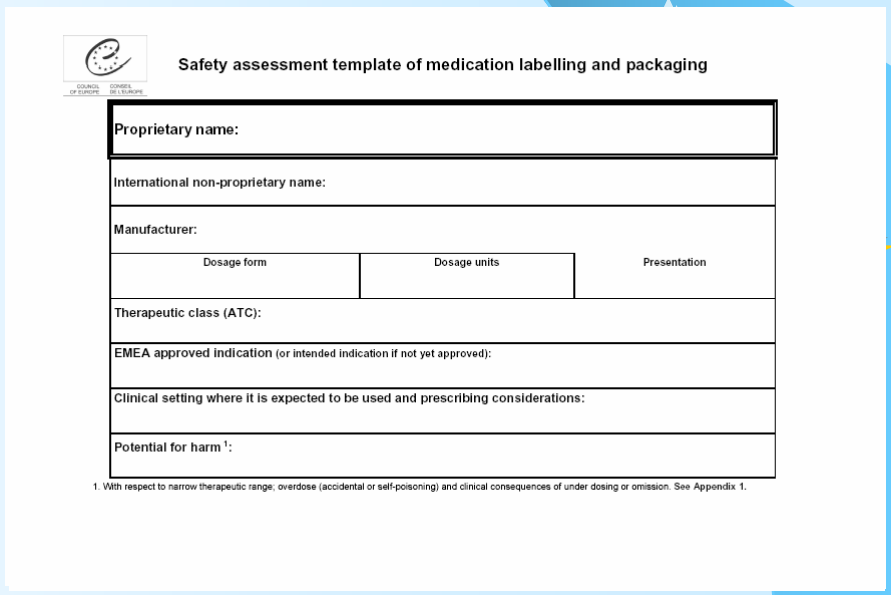
European Healthcare Organisations and other related stakeholders are recommended to:

- use systematically appropriate **methods** to detect medication incidents that are occurring and evaluate the effect of safe medication practices and initiatives intended to minimise risks
- use **self assessment tools** designed to help identifying opportunities for improvement and enabling a comparison with the aggregate experience of demographically similar sites
- establish an **annual safe medication practice report** enabling them to summarise and prioritise their medication risks
- ask National Centers for Safe Medication Practices to publish **annual reports** helping to identify risks of medication errors and methods that have been used effectively to manage these risks

Improving the safety of European medicines: naming, labelling and packaging (1)

European Medicines Agency, National Medicines Agencies and other related stakeholders are recommended:

- **Prior to marketing authorisation**:
  - to take into account the need for **good design** to minimise the risks of medication errors when using medicine products in practice
  - to require that packaging and labelling be subject to human factor assessment and **user testing** to be undertaken by the manufacturers
  - to use a **template** designed to systematically assess the potential risk of the different components of the medicines packaging:
    - outer packaging,
    - immediate packaging,
    - delivery devices,
    - diluents or
    - secondary containers, and
    - package design



Safety assessment template of medication labelling and packaging

Proprietary name:		
International non-proprietary name:		
Manufacturer:		
Dosage form	Dosage units	Presentation
Therapeutic class (ATC):		
EMEA approved indication (or intended indication if not yet approved):		
Clinical setting where it is expected to be used and prescribing considerations:		
Potential for harm [1]**:**		

1. With respect to narrow therapeutic range; overdose (accidental or self-poisoning) and clinical consequences of under dosing or omission. See Appendix 1.

Improving the safety of European medicines: naming, labelling and packaging (2)

European Medicines Agency, National Medicines Agencies and other related stakeholders are recommended:

- **During post-marketing monitoring**, to support national centres for safe medication practices which should:
  - identify problems related to poor naming, labelling and packaging and drug information that occur with medicines in the day-to day use
  - work closely with National Medicines Agencies and manufacturers to respond appropriately and timely to resolve any problems detected
- to coordinate their actions at European level

Improving the safety of naming of European medicines

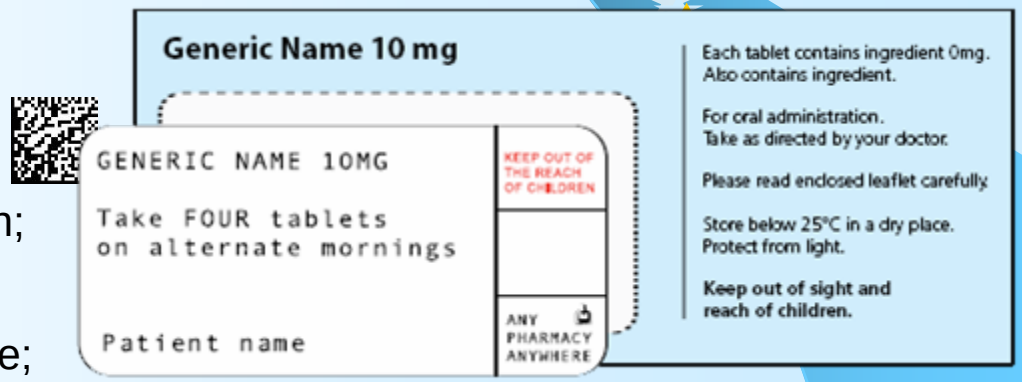
European Medicines Agency, National Medicines Agencies and other related stakeholders are recommended:

- to establish standardised procedures for assessing the risks of all proposed trademark names including:
  - a risk assessment and evaluation by the manufacturers, for possible sound- or look-alike confusion with existing marketed medicines, including user testing
  - a review of the risks of proposed trademark names by the medicine agencies as a part of the normal marketing authorisation application
  - publication of official assessment criteria for trademark names
- to promote the use in practice of INNs instead of trademark names:
  - assessment techniques incorporated by the WHO INN Programme and national nomenclature committees including INNs safety review by health care practitioners and patients
  - systematic comments of proposed INN during the 4 month objection period by the National Centres on Safe Medication Practices
  - management of the confusion between INNs by:
    - submitting a proposal for substitution to the WHO INN Programme
    - using of both the INN and the trademark name as an additional safety barrier

Improving the safety of labelling of European medicines

European Medicines Agency, National Medicines Agencies and other related stakeholders are recommended to:

- to require design features for packaging and labelling of medicine products including:
  - large font sizes;
  - use of Braille system;
  - use of clear descriptions for the dosage strength;
  - prominence of the INN name;
  - data matrix bar code;
  - relevant use of colour and design;
  - clearly presented ‘essential information’ on at least three surfaces of the medicine package;
  - avoiding non-important information and the use of other languages than the official language where the product is marketed
- to require the pharmacists dispensing medicines for ambulatory patients to put a dispensing label on the medicine package when it is dispensed, and the drug companies to allocate space for a dispensing label



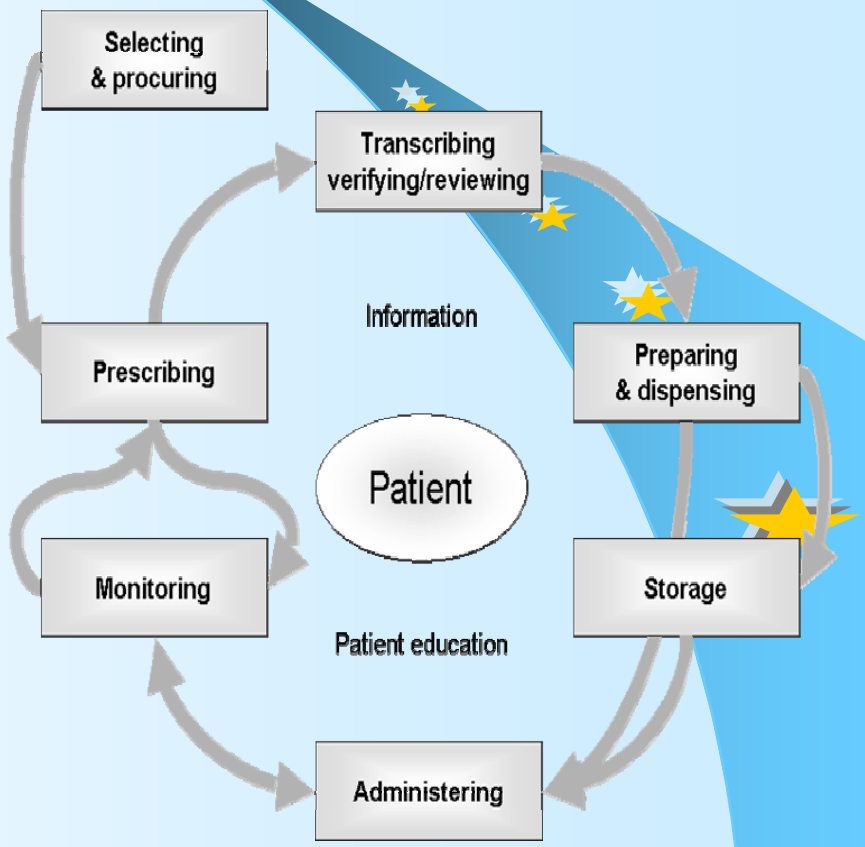
Improving the safety of packaging of European medicines

European Medicines Agency, National Medicines Agencies and other related stakeholders are recommended to:

- assess the adequacy of the package design to drug delivery and administration
- provide medicines in unit-dose presentations, ready to use, and ready to administer
- require complete and unambiguous labelling of every single unit of all licensed medicines

Improving the safety of the medication use system

- Understanding the use of medicines as a complex system
- Using the knowledge of human factors engineering
- Establishing a strategic plan for medication safety
- Creating a culture of safety



Some recommended actionable safe practices

European Medicines Agency, National Medicines Agencies and other related stakeholders are recommended to:

- ask prescribers to evaluate the patient's total status and review all existing drug therapy before prescribing new or additional medications
- obtain **reconciliation** of drug histories at every transition of care in which new medications are ordered or existing orders are rewritten
- restrict **high-risk drugs** storage and establish adequate controls to ensure the safe use of these products
- carry risk assessment of the safety of pharmaceutical products when organizations are selecting them for **purchase and procuring**
- minimise the preparation of complex and high risk injectable medicines in the clinical area by procuring presentations of ready to use or **ready to administer** injectable products

Making medication use safer

European Healthcare Organisations and other related stakeholders are recommended to:

- include multidisciplinary medication practice procedures in undergraduate, induction and refresher training for all healthcare staff who have responsibility for medicine use
- develop multidisciplinary teams to develop working procedures that describes safe medication practices
- promote the key role of complete and appropriate interpersonal and interdisciplinary, oral and written communication between healthcare professionals and patients, particularly at the key stages of prescribing, dispensing, counselling and transfer of information about a individual patients' medicines between organizations
- enable pharmacists to review, on a regular basis, medication orders and the patient health record before medication are dispensed and/or to identify and correct medication errors. and to discuss problems with the prescriber, if needed.

Safer drug information practices

European Healthcare Organisations and other related stakeholders are recommended to:

- consider the quality of drug information as important as the technical quality of drug therapy: all information supports (SPCs, PILs, IT based supports) should be user tested before approval
- meet patient's and health care practitioners' needs; taking into account specific needs of special groups, such as the elderly, children, disabled, immigrants, low literacy people
- educate health care professionals to communicate about medicines with patients in an empowering way to involve them in their own care as active partners and experts of their disease/symptoms
- educate health care professionals and patients to use drug information sources and to distinguish between commercial and balanced information
- strictly regulate content and dissemination of drug information to patients and forbid direct-to-consumer advertising for prescription drugs, even by indirect ways

Conclusion

Protecting the safety of health care is a part of European citizens' rights. Building-up safer medication practices is the way for protecting them from any harm caused by medication errors occurrence.

Beyond everyone' capability to implement these recommendations at national and European levels,
the aims of the Expert Group on Safe Medication Practices were:

- to encourage collaboration between parties in order to improve quality of medication use and patient safety
- to foster the development of a safe medication practices agenda shared at European level

A Network of European National Safe Medication Practice Centres is a pragmatic approach for sharing information concerning medication errors, reporting methods, analysis, safer practice solutions, and evaluation of these solutions.