

Opinion of the European Economic and Social Committee on 'Health safety: a collective obligation and a new right'

(2005/C 120/10)

Procedure

On 28 January 2004, in accordance with Rule 29(2) of the Rules of Procedure, the European Economic and Social Committee decided to draft an opinion on: 'Health safety: a collective obligation and a new right'.

The Section for Employment, Social Affairs and Citizenship, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 22 September 2004. The rapporteur was **Mr Bedossa**.

At its 412th plenary session of 27 and 28 October (meeting of 27 October 2004), the European Economic and Social Committee adopted this opinion by 164 votes to 3, with 7 abstentions.

1. Introduction

1.1 For the citizens of Europe, medical safety - which is one of the basic aspects of public health - means that they have an enhanced right to care from the competent authorities (even on occasions when bio-terrorism is involved) and that, on this basis, they exercise their new right to be kept informed in a transparent way of the decisions taken by these authorities.

1.2 Safety and healthcare systems are two terms that people normally associate with each other, albeit subconsciously, even though the concept of public health is still exposed to downward sociological pressures and to medical customs geared to performing diagnoses and individual therapy.

1.3 At a time when the upheavals experienced in Europe clearly show that health risks are no longer a purely medical matter but have erupted into the social and political arena, defining a safe health strategy has become the responsibility of all, particularly political leaders: from now on, citizens must be certain of having such guarantees.

1.4 Health safety does not start from nothing, it enriches and complements the traditional areas of public health, particularly epidemiology, it draws its support from reflection and systems developed to monitor drugs, and achieves dominance as the iatrogenic effects of all medical practices are discovered.

1.5 A health safety-based approach is no different from a medical approach. It proceeds by stages, it is a series of choices based on probabilities at a given moment, dictated by an assessment of the cost/benefits ratio and the risks involved. The quality of health safety mirrors the quality of the healthcare system.

1.6 Health safety is based on a medical approach and on the urgent need for a health safety methodology and a genuine commitment to public action. The field of health safety is, of course, much broader because it goes hand in hand with constant medical innovation.

1.7 The concept of health safety has to evolve, especially when acts of bio-terrorism are to be feared, for example; it cannot stand still: a balance has to be struck between striving for absolute safety, which is unobtainable, and negligence or positive abstention. The growing effectiveness of the health system prompts the need for health safety, though one should not forget to draw comparisons with the poorest countries, whose only current problem is first to acquire the basics of a public health system.

1.8 In the EU, which is richer and well versed in spreading risks, the thing to do now is to get health safety taken into account on an institutional basis. To discuss health decisions and make them public it is necessary to use all the means available, so as to offer the EU's citizens other alternatives than panic or dissimulation; this is how the EU will become a mature democracy as regards public health.

2. Historical background to the EU's approach

2.1 Before the Maastricht Treaty of 7 February 1992 on the European Union, references to health policies in Community texts were only peripheral. The Treaty of 25 March 1957 establishing the European Atomic Energy Community (Euratom) contained specific provisions on protecting the health of the population against the dangers of ionising radiation.

2.2 However, in the Treaty of Rome of 25 March 1957, 'health protection' appeared only in Article 36, which stated:

2.2.1 'The provisions of Articles 30 to 34 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.'

2.3 The insertion of an Article 118A into the Single European Act in 1986 extended the powers of the Community institutions by enabling the European Commission to make proposals in the field of health, based on the need for a 'high level of protection.'

2.4 Another indirect reference to health protection could be found in Article 130R of the Treaty of Rome, added by the Single European Act, which stipulated that action by the Community relating to the environment should aim, among other things, to 'contribute towards protecting human health.'

2.5 The Treaty on European Union radically changed the prospects for European integration as regards health, since it introduced a Title X entitled 'Public Health', under which 'The Community shall contribute towards ensuring a high level of human health protection.' Under Article 129(4) the Council, to achieve its objectives, may adopt either incentive measures, provided for in Article 189B, or recommendations.

2.6 Similarly, the concept of health protection appears in other articles of the Treaty on European Union, since Article 129A, concerning consumer protection, mentions measures to protect the health and safety of consumers.

2.7 A precise legal framework, which would be improved in Article 179 of the draft Treaty establishing a Constitution for Europe, will allow the European institutions to deploy their activities as regards public health:

- '1. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.
2. Action by the Union, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover:

- (a) *the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education ...*'.

2.8 The new structures set up (e.g. the European Agency for the Evaluation of Medicinal Products) can have an even greater impact if the European institutions are engaged in a policy of increased cooperation with non-EU countries and the major international organisations, particularly the World Health Organisation, the Council of Europe, the Organisation for Economic Cooperation and Development, the International Atomic Energy Agency for radiation protection, the Office of the United Nations for Drug Control and Crime Prevention for drug addiction. This cooperation must be continued.

3. The principles of health safety

3.1 *The health decision*

3.1.1 Medical decisions are taken against a background of uncertainty: uncertainty about pathology, the effects of treatments and their respective risks; imperfect medical information for the patient about the options for further examinations and health equipment; a lack of precision in medical questioning dominated by emotion or concern; and clinical examinations that by their nature are only approximate.

3.1.2 A medical act is often the result of a series of decisions based on probability and taken in a situation of uncertainty: the more choices and decisions are involved in a diagnosis or treatment, the greater the risk, or even the probability, of making an error, although such an error may not necessarily be culpable.

3.1.3 In each medical act or decision there is an element of the imponderable, a hazard that cannot be controlled in the present state of scientific knowledge, an unavoidable statistical risk which is part and parcel of medical science.

3.1.4 The lack of health safety has human causes: a mistake or non-culpable error by the practitioner, and factual causes: risks that are known but are statistically inevitable, given the state of scientific knowledge, and unknown risks, which are always possible.

3.1.5 It is impossible to talk about health safety without mentioning these basic features of medical decisions. When health or life is at stake, it is often difficult to agree to ask only for the possible. However, there is no medical activity without risks, because life is not without risks.

3.2 Risk/benefit ratio

3.2.1 The same observations apply to health safety decisions as to medical decisions, and inaction is a decision in the same way that action is; failure to do anything can be reprehensible.

3.2.2 It is a question of weighing the therapeutic risk against the risks of spontaneous evolution. The irrational denial that risk exists in health-related matters is just as irresponsible as negligence.

3.2.3 The culture of the risk/benefit ratio is far removed from the concerns of a European society which has managed to substantially reduce natural risks.

3.2.4 In order to assess the health safety of an act or product, it is important to use a risk scale that makes it possible to determine the minimum risk rather than zero risk. Five criteria should be applied in this risk/benefit ratio:

- degree;
- reality of the situation;
- frequency;
- duration;
- necessity.

3.2.5 It is therefore up to the public authorities, exposed to converging or contradictory pressures of public opinion and producers of health care, to decide, in conditions of uncertainty, whether to adopt the most pessimistic – and hence the most conservative – hypothesis in terms of public health or to opt for the most plausible estimate.

3.2.6 Moreover, health decisions sometimes have to be taken in a crisis situation. The authorities then have to deal simultaneously with a spate of problems, the malfunctioning of certain systems and deeply divergent views on the decisions to be taken.

3.2.7 To avoid having to improvise when faced with an urgent situation, it must be possible to count on tried and tested procedures for evaluation, monitoring and intervention. This requires analysis of previous crises and a health safety methodology.

3.2.8 Regardless of the scientific and medical safeguards, ultimately the assessment of the risk/benefit ratio frequently involves a deep conviction.

4. Medical factors of health safety

Five key factors are involved here.

4.1 Health monitoring

4.1.1 As epidemiologic monitoring is an essential component of public health protection, it is necessary to establish specific arrangements for health monitoring through a European centre in order to ensure health safety (see point 6.3).

4.1.2 The purpose of health monitoring is to identify medical accidents and iatrogenic pathologies, to determine the unforeseen or undesirable effects of the use of therapeutic protocols, to carry out checks and analyse the findings and to evaluate the effectiveness of health intervention procedures; in short, all the activities necessary for health safety.

4.1.3 At international level, efforts have been made to advance health monitoring by establishing information exchange and alert procedures under the auspices of the WHO and the European Union.

4.1.4 Multilateral texts exist on organising cooperation at all levels, in all areas of specialisation and on all continents. They enable the rapid implementation of health measures designed to ensure the maximum level of health safety.

4.2 Choice of therapeutic strategies

4.2.1 The quality and safety of the choice of the therapeutic strategy depend primarily on the current state of science, and therefore on practitioners' knowledge of it.

- The first factor as regards improving this knowledge is obviously medical and pharmaceutical research and the advances in therapeutics or diagnostics which result from it.
- Initial medical training is the second key factor for health safety as regards the choice of strategy, initial training which is adapted to advances in science and in the organisation of the health system.
- The third aspect is continuing medical training: the assimilation of the latest data is, as in all high-tech risk sectors, one of the determinants of safety.
- The final element contributing to the safety of therapeutic choices is medical evaluation, which has become the link between research, training and the day-to-day work of members of the health professions.

— Medical evaluation can be defined as the body of quality control procedures in the health system.

— The evaluation of diagnostic and therapeutic techniques and strategies involves ensuring the evaluation of the tools placed at the disposal of health professionals: medical technologies, diagnostic methods, medicines and a package of procedures and services.

— The WHO defines this evaluation of quality, and consequently of the quality of this care, as follows:

‘A process which makes it possible to guarantee each patient the range of diagnostic and therapeutic acts whereby he can achieve the best possible results in terms of health, in accordance with the current state of medical science, at the most cost-effective price for an equivalent result, with the least iatrogenic risk and with a view to the greatest satisfaction in terms of procedures, outcome and human contacts within the health system.’

— Finally, the evaluation must define benchmarks, i.e. draw up recommendations based on a more or less broad consensus within a college of physicians or associations of experts (‘consensus conferences’) so as to arrive at some guidelines.

4.3 *Performance of health care and medical acts*

4.3.1 Compliance with obligations is monitored by all the authorities concerned and there is a large and uniform body of case law which specifies the obligations of health professionals and defines the concept of conscientious, attentive health care that conforms with current scientific knowledge.

4.3.2 Clearly, the performance of medical acts depends on health safety arrangements, which vary considerably according to the nature of the acts and the existence of ‘natural’ risks.

4.3.3 Comparing the difficulties inherent in the performance of acts, i.e. leaving aside statistically avoidable – albeit marginal – risks, is the only way to establish the health safety conditions to be observed. This is a kind of a risk/benefit analysis which makes it possible to set a standard health safety level which is both accepted and expected.

4.4 *Organisation and operation of healthcare structures*

— Health safety is largely determined by the quality of the organisation and operation of the healthcare system.

— Health safety imposes an obligation of resources on all public or private establishments, resources which are provided for by regulations and subject to special authorisation. The healthcare system must be able to meet the needs

of the people and provide health services under the best safety conditions.

4.5 *Use of health products*

4.5.1 Health products used for prevention, diagnosis and treatment are subject to strict laws and regulations, known as ‘topical regulations’ and governing:

- medicines;
- medical devices;
- products of human origin;
- laboratory agents;
- legal basis of human body products and elements used for therapeutic purposes.

4.5.2 The health regulations applicable to these products provide a genuine safety chain.

5. **Proposals – EESC recommendations**

5.1 *The administrative aspects of health safety*

5.1.1 The public health institutions of the EU Member States have yet to take account of health safety principles.

5.1.2 Health safety is not the result of some equation or formula; it is based on the spirit of precaution and contradiction.

5.1.3 Health safety calls for cross-border awareness campaigns and initiatives. We must resist the illusion of some Maginot line that can effortlessly seal off the next epidemic. Health risks are unpredictable, infinitely varied, and generally appear unexpectedly. Behaviour towards the illness changes, viruses mutate, infectious agents renew themselves or hide.

5.2 *Clearly recognised powers*

5.2.1 Given the lack of any specific legal instruments for public health protection, some European Union countries have tended to skirt around the problem, sometimes employing dubious practices, often involving improper use of social security regulations, because this enables them to mix up health and economic issues in the same debate. While it is legitimate to appreciate the cost of healthcare and to make the most rational use of the limited resources available, it is nevertheless dangerous to confuse the two issues.

5.2.2 It is one thing to acknowledge the effectiveness, quality and safety of a product or a therapy; it is quite another to decide that it is to be made available under national health-care schemes. The problems involved in public health decision-making are compounded by the fact that there are several competing authorities.

5.2.3 Establishing the areas of competence means establishing responsibilities and, consequently, establishing the health authority that will take up the moral, administrative and/or legal burden. This responsibility can only be fully exercised as long as there are no shortcomings or ambiguities in the relevant texts that might lead to disagreement or action that could distort the choices that need to be made.

5.3 *A recognised health administration*

5.3.1 At European level, public health administration is inadequate and has very weak legal support. It also lacks medical legitimacy, owing to the scarcity of resources. All that must be improved.

5.3.2 The public sector can only be effective if it has real legitimacy, and a health administration can only fully exercise its health safety role if it is endowed with this dual legitimacy, i.e. it must be recognised by the official authorities of every EU country, and of course by the general public, i.e. consumers.

5.3.3 For the sake of scientific, medical and technical credibility, more resources and first-rate technical staff are needed, as is cooperation between all the European and national institutions.

5.3.4 Five basic tasks have been identified. These involve recommending, supervising, checking, appraising and evaluating.

5.3.5 The establishment of a European public health network is evidence of the willingness of all European authorities to pool public health players and make existing national health vigilance instruments more consistent and effective.

5.4 *The need for expertise from outside the administration*

5.4.1 Regardless of the technical and scientific excellence of health safety services, the traditional and respected principle of the contradictory must, of necessity, be applied to health safety efforts.

5.4.2 Involving independent experts fulfils the objective of making the most eminent specialists available to the European authorities, thus making it possible, through dialogue, to refine

and supplement information upstream of the decision-making process.

5.4.3 In the most sensitive or technical areas, it would even seem essential to call on third-country experts of international repute. By opening up to international experts, a consensus could be achieved in all the countries concerned, thus avoiding any time lags that might be universally detrimental (i.e. to patients and stakeholders of all kinds).

5.4.4 This could enable the debate to rise above any particularities of national healthcare culture or practitioner training methods.

5.5 *Separate roles for experts, decision-makers and managers*

5.5.1 Health policing powers, which are, in fact, the prerogative of decision-makers (whether to authorise, whether to ban) can only be legitimately exercised if all the information relating to the public health problem in question is taken on board.

5.5.2 This always involves an appraisal of the benefit/risk ratio. This cannot be solely scientific, and it must not be imposed by the manager or by a stakeholder who has some material or intellectual interest in its being disseminated.

5.5.3 Clarification of the roles of expert and decision-maker ensures transparent links between experts and managers. A strict code of conduct must be declared and respected. This is not always taken as read, particularly when the problem is very technical; in such cases there are very few experts and they have often established links with the relevant institutions or companies.

5.5.4 Transparency, which must be the hallmark of health safety decision-making, requires each expert to declare to the health authorities any links he might have with agencies, companies or individuals affected by his professional opinions.

5.5.5 The European Community has started to outline these procedures: rolling out transparency procedures, as called for by the experts themselves, ensures that the experts' opinions are as objective as possible.

5.6 *Transparent decisional procedures*

5.6.1 As with innovation in general, new health risks tend to upset accepted ideas and habits.

5.6.2 The intellectual approach must be the same, i.e. 'to listen to the silence'.

5.6.3 Regardless of the quality of the vigilance system established, the risk of collective blindness cannot be ignored.

5.6.4 Public debate is crucial. Patients and doctors from beyond the panel of experts should be able to make their voices heard, ask the questions that worry them, and sound the alarm.

5.6.5 The debate must be organised properly, so as not to give unnecessary cause for alarm.

5.6.6 This 'health pluralism', which is crucial to improving our chances of avoiding new tragedies, will require more transparent decision-making procedures. Without prejudice to medical or industrial confidentiality, the experts' findings and reasons for health decisions must be made public.

5.7 *A code of conduct for health safety communication*

5.7.1 Despite being made available to a wide audience, there are some basic aspects of public health communication that are even more evident in the field of health safety.

5.7.2 Communicating about these issues often means communicating about illness or death. Transparency and restraint must be the key words when organising this delicate task of the health system.

5.7.3 Transparency is essential to ensure confidence and to avoid the distress that would be caused by revealing information that might seem sensational because it appeared to be surrounded in secrecy.

5.7.4 Health authorities and institutions must comply with this, just as a doctor has to inform his patient. Given the risks involved for everyone's health, the 'duty of truth' is essential.

5.7.5 However, this moral obligation is accompanied by a duty of restraint. Since it is often released in a hurry, information must be comprehensible and scientific, and must take care not to be conflicting, sensational or alarmist. It requires common working rules for the media, health professionals, patients' associations and the public authorities. Causing panic or cover-ups are not alternatives.

5.8 *Routine communication*

5.8.1 Patients are always inclined to scrutinise health information particularly closely.

5.8.2 There is a distinction to be drawn between the type of information intended for doctors and that intended for the general public.

5.8.3 The former benefits from the scientific background of its target group, which has its own channels: courses, conferences, symposia, and professional and industry associations.

5.8.4 On the other hand, communication intended for the general public cannot assume –without risking being misunderstood or causing panic – that the public has the medical knowledge needed to grasp the scope of the information provided. It has to find a balance between, on the one hand, the need for information about new or traditional therapies, and on the other, the risks connected with misinterpreting the information.

5.8.5 The information thus released could lead to unnecessary or exaggerated public panic or, conversely, unfounded hopes of new therapies. It is part and parcel of public health education, which contributes directly to the effectiveness of health policies, risk prevention, and a pro-active healthcare system.

5.9 *The communication crisis*

5.9.1 In a health emergency or serious danger to public health, communication has to deal with three requirements:

- First of all, the amount of information released must be proportionate to the health risk.
- Secondly, it should be remembered that information is not just intended to increase public awareness, but also to secure behavioural change. Information therefore needs to achieve its goal, i.e. prevent or contain the accident without giving undue cause for alarm and ensure that the public know what is going on and that the press avoid printing alarmist and sensationalist stories.
- And thirdly, crucial information must be given with the different target audiences in mind, and the order in which they need to be informed.

5.9.2 Whatever the scenario, the press plays a decisive role in the success of crisis communication. The media must sometimes accept the fact that they cannot release information to the general public until health professionals have been fully informed. So, there is also a need to provide training for specialist journalists who are capable of understanding what is happening and communicating correctly on health safety matters.

5.9.3 This is difficult since, for example, calculating undesirable effects, their origin, the impact of the media on the notification rate and overall risk assessment involves difficult, complex analyses, whereas the public expects to be informed immediately in simple, emotional language.

6. Conclusion

6.1 Through becoming aware of the successive public health crises which have shaken the world over the past two decades (AIDS, contaminated blood, SARS, legionnaires' disease, bio-terrorism through the threat of anthrax), the EESC proposes to hold regular high level European congresses on public health.

6.2 The aim of these conferences will be to discuss what collective measures should be taken, provide precise information on these crises, produce coordinated responses, assess the threats of risks from outside, help speed up diagnoses and provide adequate responses.

6.3 The EESC recommends that the future European health monitoring centre in Stockholm be given as of now an extensive and reinforced mandate to draw up targeted and regular reports on public health and have the necessary measures taken

by the EU countries, in accordance with the subsidiarity principle.

6.4 The EESC considers that it is the ideal place for alerting and raising the awareness of European civil society.

6.5 The EESC asks that all the parties concerned adopt an active attitude towards public health: an overall view of the crises in public health should enable all experiences to be shared at a time when such crises are global issues.

6.6 The EESC considers that a grand information policy must be promoted at European level, involving specific training for all the actors and organs of the press that have a particular stake in the matter.

6.7 The EESC would point out that its recommendations are interlinked and require a strong commitment by the EU countries to implement them; they include:

- boosting administrative capacities, with cross-border linkage and administration recognised and allowed everywhere;
- legal powers and the instruments to support them;
- transparent decision-making procedures and stricter ethics, shared by all, regarding communications on health safety;
- more cooperation and worldwide networking between all surveillance and monitoring bodies (the European Union, the World Health Organisation, the Organisation for Economic Cooperation and Development, the Council of Europe, and large national organisations such as the USA's Centres for Disease Control and Prevention in Atlanta).

Brussels, 27 October 2004.

The President
of the European Economic and Social Committee
Anne-Marie SIGMUND
