



## PANDÉMIES, ÉTHIQUE, SOCIÉTÉ



### ***Are EU ethics guidelines possible and desirable for public health emergency situations?***

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#### **The primacy of member states' competence in the domain of public health**

In the field of epidemics, which logic justifies some actions that have been carried out? On one hand political decisions advocate strong embedding of fundamental ethical values. On the other hand, we may collectively have to take measures – in case of emergencies, of threats to public health – that contradict some of these values.

What is really possible with regards to political power in terms of public health? The European Union has some specific power in the field of public health, but quite a limited one. It is for example related to the circulation of biological materials, blood derivatives and public health actions that have a specific pan-European significance and value. Epidemics are typically a matter that justifies a strong response at the scale of the European community. The consequences of the spread of an infectious agent are not country limited.

Looking at the recent history of the European institutions, we can notice that member states seem to prefer addressing epidemics individually. But, at the same time, the European institutions were much more called upon to find some sort of parallel actions for public health security. The big move about epidemics was the decision to set up a European agency dedicated to the control of infectious diseases.

What is the philosophy underlying the current evolution? It can be characterized as a will to increase the ethics power in launching proactive actions. This is certainly a positive trend. Nevertheless, when

dealing with public health the specific legal nature of the EU and the subsidiarity principle complicate the setting up of a common policy at the European level.

### **Dealing with collective values and individual rights**

Nevertheless, a significant political shift can be perceived. It was first expressed with emphasis. During the German presidency, head of EU Member States signed a common Declaration on the policy dimension of the EU. The focus of a major common declaration was on values: solidarity, peace, justice... Notice that they were all collective values. And they have to be understood as key elements to pave the way for a new political process of the EU.

A major document related to the protection of fundamental rights was adopted in Nice in 2001: the European Charter of fundamental rights. The current Lisbon Treaty, under ratification, will attribute a legal value to this document. In the domains of public health and infectious disease prevention, it was clear that the reflexion on values could not be disconnected from the consideration of individual rights.

### **The difficulty to provide an ethical framework to deal with emergencies in public health**

Mentioning the SARS epidemic brings up very pragmatic matter. When it happened, the European Union started financing research trials under the EU framework programme for research.

The EU regulatory frame on clinical trials (EC/2001/20) requires the trials to go through an ethical review. EU funded SARS trials, following the above regulatory frame and the ethics rules adopted in the EU Research Programme, had then to go for the approval of ethics committees in the countries where the trials took place, opening then difficulties in using common ethics standards in the different countries involved in SARS projects. The need of having shared methodologies for ethics committees in emergency situations and epidemics often materialize in multi-centre research or clinical trials.

In the field of emergency, what is ethics' function? Some experts advocated that ethics should remain a matter of interpretation (flexibility and case by case approach) rather than a matter of compliance with specific norms. In fact, when we deal with public responses to emergency situations such as epidemics, we do not need theoretical views, but rather something pragmatic solutions to be immediately implemented. At this point, in this matter, subsidiary should rule.

To say it differently, in Europe, the current legal system does not allow the establishment of a reference EU ethics frame to use in public health. That's why the European Commission is supporting a lot of initiatives with interlocutors such as EU Countries, WHO, UNESCO, Council of Europe, in order to capitalize on expertise on emergencies situations while leaving EU Member states decisions on what specific ethics rules should be applied in their own countries.

## **When ethics has to be pragmatic**

In the case of SARS, the ethical frames of other countries (such as China) had to be taken into account. When Europe gives financial support to programs or initiatives, ethical criteria have to be fulfilled. The action of the European Union had to take into account those of authorities whose legality lied outside its borders. And legal mechanisms to negotiate with these authorities were lacking at that time. The main question was: which minimal ethical basis has to be shared?

The SARS epidemic raised the issue of minimal standards sharing, particularly in the case of Asia. Off course, monitoring the implementation of such standards is not an easy task.

Considering both ethics and epidemics, the European Commission supported some initiatives. These initiatives followed a “minimum values sharing philosophy”, which can be depicted from the European Charter of fundamental rights and reinforced by a mechanism of capacity building of ethics committees in the involved countries. For example, what was at stake by supporting the African poverty disease platform was the building of capacities to act and to react, in front of public health emergencies. In many areas, this policy of capacity building in centres of responsiveness was conducted in partnership with the WHO. In the field of ethics, only minimum guidelines in local ethics committees have been applied. Considering global issues responsiveness, minimum standards have been again implemented in specific centres, rather than general guidelines.

## **We won't avoid major debates to go further in the European ethical reflexion related to emergencies in public health**

The reality of the European action in public health has nothing to do with what it is in other areas. Security must be mentioned. In issues such as biometric passports, surveillance technologies, biosecurity and defence, general guidelines can theoretically be established at the European level. Nevertheless, in such matters, a serious debate on values (individual rights, holistic approach...) can not be bypassed.

Undoubtedly, when security issues are debated (counterterrorism actions, priorities setting...), major tensions can occur between member states and European institutions. Respect of fundamental human rights is at stake, but implementing provisions to achieve this goal are complex to be identified and shared by all actors involved.

At the European level, some positive progress has been obtained with the creation of the Stockholm agency. It can help dealing with dilemmas opposing the necessity to act effectively and the respect of human rights in epidemics and emergency situations. But we have to notice that this new agency has to act with respect to the powers of other ones (for example in the areas of market access regulation for pharmaceutical products or food consumption regulation).