

THE PRECAUTIONARY PRINCIPLE IN THE MANAGEMENT OF EPIDEMIOLOGICAL EMERGENCIES: FROM *AD HOC* RESPONSE MEASURES TO ADVANCE PLANNING POLICIES

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Summary

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- 3. The three tests of legitimacy in the Italian experience of case law: science-based inquiry, proportionality, temporary duration
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The pandemic as a tsunami-like event

- Italy was the first European country to face the pandemic
- It is important to remember that the Italian population is approximately 60 million
- During the last year, about 2 million people fell ill with Covid-19 (around 4% of the entire population)
- About 85,000 people have died so far
- We can think of the pandemic as a tsunami-like wave of changes not only on the medical, economic and social levels, but on a legal level as well

A flood of legal acts

- **4** resolutions passed by the Council of Ministers (Italian cabinet) that declared a state of emergency
- **20** prime ministerial decrees (DPCM – Decree of the President of the Council of Ministers)
- **30** provisional measures having the force of law (decree-laws)

National government levels

- **15** ordinances from the extraordinary commissioner for the implementation and coordination of Covid-19 measures
- **50** other civil protection ordinances
- **40** ordinances and decrees from the Ministry of Health
- Various ordinances and decrees from the Ministry of the Economy, the Interior, Infrastructure and Transport, Labor, Economic Development, Education, Agricultural Policies, Civil Service, Justice, the Environment, and Foreign Affairs

Regional and local government levels

- ordinances from the presidents of the various Italian regions
- local ordinances and other urgent ordinances of the municipalities

International law and European law

- January 30, 2020: Emergency Declarations of International Significance
- Directive 2020/739/EU on placing Covid-19 among the biological agents that can cause infectious diseases

Specific areas of law affected by the pandemic

- labor law
- contract law
- bankruptcy law
- tax law
- family law

But mostly:

- public law
- administrative law
- administrative trial law

Main issues in public law

- the relationship between government and parliament
- the relationship between the prime minister and individual ministers
- the organization of work in the Italian parliament
- the division of responsibilities between the state and the regions with reference to health care
- the relationship between nation states and the European Union
- the role of local authorities
- the reliability of state relief programs
- the system of funding initiatives

Main issues in administrative law

- the relationship between science and politics
- digitalization
- the management of extraordinary powers
- administrative procedures and their simplification
- the governance of the national territory
- administrative bodies of a technical-scientific nature
- the environment
- immigration
- the prison system

Main freedoms affected by the pandemic

- the freedom of movement
- the freedom of assembly
- the freedom of worship
- the freedom of economic initiative

Main rights affected by the pandemic

- the right to health;
- the right to education;
- the right to privacy

Prominent role of the precautionary principle and the prevention principle

- Among the principles that have been discussed during the pandemic, a prominent role is played by the precautionary principle and the related principle of prevention
- Public health emergencies represent the laboratory in which the precautionary principle first emerged (e.g. during a cholera outbreak in the St. James district of London)

The St. James cholera case, 1854

In 1854, a deadly cholera epidemic broke out in London. City health officials were baffled: accepted knowledge (e.g. Royal College of Physicians) stated that cholera was spread by air. Contact avoidance measures were ineffective. Dr. John Snow, a physicist, observed that several deaths were linked to a certain water source. He hypothesized that the spread of the disease was linked to the water from a particular fountain. Despite uncertainty, authorities prohibited the water supply to that source. Cases of cholera decreased almost immediately, and the disease was soon completely eradicated. Thirty years later, in 1884, Koch demonstrated that cholera was not spread by air, but rather through a vibrio (i.e. bacteria) contained in water. It was therefore confirmed that Dr. Snow had been correct.

Links between health and the environment

- The precautionary principle has become the cardinal principle of the pandemic because it provides clear rules of conduct when administrations are faced with risk scenarios
- The most important rules regarding these principles come from environmental law; these rules are general in nature and they apply to the field of health and safety law, as well as to other areas

Article 191 of the Treaty on the Functioning of the EU

- *Union policy on the environment shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should - as a priority - be rectified at source, and that the polluter should pay*
- There is an evident link between health and the environment
- *Union policy on the environment shall contribute to pursuit of the following objectives: — preserving, protecting and improving the quality of the environment, — **protecting human health**, — prudent and rational utilisation of natural resources*

Article 301 of the Italian Environmental Code

- Legislative decree n. 152 of 2006
- Paragraph 1: *“In application of the precautionary principle referred to in Article 174, paragraph 2, of EC Treaty, in case of dangers, even if only potential, for human health and for the environment, a high level of protection must be ensured”*.

Art. 301 par. 2

- Par. 2 “*The application of the principle referred to in paragraph 1 should occur only after the risk in question has been identified by a preliminary objective scientific evaluation*”.

Art. 301 par. 4

- Par. 4 “*preventive measures at any time, pursuant to Article 304, must be:*
 - a) proportional to the level of protection to be achieved;*
 - b) non-discriminatory in their application and consistent with similar measures already adopted;*
 - c) based on an examination of the potential benefits and costs;*
 - d) updatable in the light of new scientific data”*

The precautionary principle in the pandemic

- The current situation undoubtedly meets those criteria as administrations on various levels find themselves managing an emergency caused by a virus about which very little is known
- Administrations around the world are now confronted with the *dangers, even if only potential, for human health and for the environment (art. 301, par. 1)* caused by the virus

Proliferation of technical bodies

- The Technical-Scientific Committee (*Comitato Tecnico Scientifico*, CTS) was established on the basis of art. 2, paragraph 1 of the order of the Head of the Department of Civil Protection, n. 630, from 3 February 2020
- The CTS is made up of experts and qualified representatives of state administrative bodies
- The aim is a *preliminary objective scientific evaluation* of risks in the sense of article 301 par. 2
- In France, President Macron set up a Committee of Experts for Analysis and Research (known as CARE) in order to obtain expert advice on the COVID emergency

Broad discretionary powers

- The application of the precautionary principle legitimizes the use of very wide discretionary powers on the part of the public administration.
- Based on the criteria outlined in art. 301 of the Italian Environmental Code (TUA), administrators must define terms like "dangers, even if only potential, for human health and the environment"; "high level of protection"; and "risk", the preliminary assessment of which must not only be "scientific" but also "objective".
- For the authorities who must apply the law, this leaves considerable room for interpretation, and the same is obviously true for the judges who are called upon to review the relevant acts.

Problems posed by the application of the precautionary principle

- How should existing dangers to human health and the environment be assessed, especially if they are only "potential dangers"?
- What level of public authority is responsible for making the precautionary decisions?
- How can a "high" level of protection be adequately defined?
- What are the differences between the various levels of protection?
- At what point does a possible risk become a probable risk?
- When can a technical evaluation be categorized as scientific, thus legitimizing precautionary measures?
- Does the scientific nature of the evaluation depend on the professional excellence of the person making the assessment?
- Is an isolated scientific opinion sufficient in justifying precautionary measures, or is it necessary to have a certain number of research institutes that share a particular thesis?
- When can a technical scientific evaluation be considered objective?
- Can such evaluations be based on experimental data?

Compatibility between precautionary administrative actions and respect for the principle of legality

- It is precisely in moments when legislators fail to promptly intervene that the precautionary principle is applied; it acts as a principle of closure in the legal system when administrations are left without the necessary network of protections foreseen by the law in the face of a crisis characterized by technical and scientific uncertainty.
- Under truly unfortunate circumstances, this pandemic has provided us with ideal, almost laboratory-like conditions under which the functioning of the precautionary principle can be extensively examined.

Main point: from *ad hoc* responses towards planning and organizational activities

- The proposed solution will be to apply the precautionary principle in a different manner.
- If the use of the precautionary principle has so far been limited to the management of day-to-day government administrative business and the initial response to the crisis, the new suggestion will likely be that, from now on, the principle should be increasingly applied to the spheres of planning and organizational activity.

New administrative organizations

- Advance planning is an absolutely essential part of any responsible protection plan in responding to possible new challenges generated by the pandemic.
- This necessitates having better-structured organizations which are prepared to take administrative action on short notice, rather than making ad hoc administrative decisions once the emergency has already gotten out of hand.

The precautionary principle before the pandemic in Italy: a few questions

- First of all, in a situation that could be characterized as pre-pandemic, we should ask ourselves if actions ascribable to an implementation of the precautionary principle – applied to administrative organization, planning, and above all to the organization of health care – had been thought out in advance.
- And if so, we should ask ourselves whether or not those ideas/action plans were ever implemented.

1999: the WHO plan

- In 1999, the World Health Organization was among the first to point out the need for a pandemic plan with the publication of its "Influenza pandemic preparedness plan: the role of WHO and guidelines for national and regional planning".

2002: the first Italian national plan

- Following the WHO guidelines in 2002, Italy – for the first time in its history – formulated an action plan to face a possible pandemic
- The Italian multi-phase emergency plan for an influenza pandemic was published in the Official Gazette no. 72 of March 26, 2002

2005: EU Communication

- The European Union also subsequently intervened and, with its 2005 publication "Communication on Pandemic Influenza Preparedness and Response Planning in the European Community", it outlined the main responsibilities of member states, the Commission, and other European Community agencies in the event of a pandemic, also including information about the various phases of a possible pandemic.

2005: International Health Regulations (IHR)

- Partially in response to the avian influenza outbreak in 2003, the WHO decided to update its International Health Regulations (IHR) which had been adopted by the General Assembly in 1969 (and later updated in 1973 and 1981). That project concluded with the approval of the so-called "IHR (2005)" which came into effect in 2007.
- In a more recent update in 2014, it was suggested that each member state should have its own pandemic plan.

2006: the Italian pandemic plan

- It was precisely on the basis of such WHO publications that the Italian Ministry of Health approved the "National plan for preparedness and response to an influenza pandemic" in 2006.
- This is the plan with which our administration faced the 2020 pandemic.

Goals of the Italian pandemic plan

- The goal of this plan was to strengthen pandemic preparedness at the national and local levels so that cases of influenza caused by new viral subtypes could be rapidly identified, confirmed, and described in order to recognize the onset of a pandemic in a timely manner.
- Other goals of the plan included minimizing the risk of transmission; limiting pandemic-related morbidity and mortality; reducing the impact of the pandemic on health and social services while ensuring the maintenance of essential services; ensuring adequate training of personnel involved in the pandemic response; guaranteeing the availability of up-to-date and timely information for decision makers, health care professionals, the media, and the public; and monitoring the effectiveness of the interventions undertaken.

No simulation exercises, no revisions, no knowledge, no organization ...

- It is worth remembering some of the statements which were made in that plan back in 2006.
- For example, the authors stated that "the effectiveness of the plan will be evaluated with national and regional simulation exercises in which all institutions potentially involved in the event of a pandemic will participate".
- They also asserted that the plan would be "subject to periodic revisions as the epidemiological situation changes."
- Unfortunately, it appears that the pandemic plan has not been taken into account by the administrations involved in the management of the current health emergency: it is sufficient to observe that it has not been mentioned or considered in the prime ministerial decrees and decree-laws that have appeared in great numbers over the last year.

First conclusion: no preparation

- Italy would have been more adequately prepared for the impact of the pandemic if it had properly (i.e. attentively and completely) implemented the necessary precautionary and preventive principles before the event occurred.

The role of the administrative judges

- To get an idea of the order of magnitude we are speaking about, we can report that approximately two hundred rulings have been made which are directly linked to the management of the health emergency (until the beginning of summer 2020, that number was just over a hundred).
- Some of these rulings are well known among the general public in Italy.

Citizens' health as a primary value

- In one of the countless precautionary rulings that have come down to us this year, the Council of State significantly affirmed that, "although all the measures approved up to this point by national, local and technical governmental political authorities are somehow different in nature and serve various purposes, the common denominator of those measures has demonstrably been that of ensuring, **according to the principle of maximum precaution, the health of citizens as a primary and non-negotiable constitutional value.** The primacy of protecting citizens' health has even compelled authorities to suppress – within limits and in the manner deemed necessary from time to time – the exercise of different rights or freedoms, chief among which is the right to the freedom of movement“ (Cons.Stato, (monocratic decree), III, 26 June 2020, no. 3769).

The Italian system of administrative jurisdiction

- It is worth noting that the pandemic has led to a veritable explosion of precautionary monocratic protection
- In Italy, the code of administrative trial (CPA) was approved with legislative decree no. 104 of 2 July 2010
- Article 4 states that administrative jurisdiction is exercised by the Regional Administrative Courts and the Council of State
- According to article 5, the Regional Administrative Courts are the courts of first instance
- According to article 6, the Council of State is the court of last instance in terms of administrative jurisdiction

Judicial decisions

- Legal measures according to art. 33 CPA

Par. 1. The court issues:

- a) a **ruling** when it defines the judgment entirely or in part;*
- b) an **order** when it takes preliminary or interim measures, or decides on competence;*
- c) a **decree** in cases provided for by law.*

Art. 55 CPA: collegial precautionary measures

- Par. 1. *If an applicant, claiming to have suffered serious and irreparable damage during the time necessary to arrive at a decision on the application, requests the issuance of precautionary measures (...) which appear, in the circumstances, most likely to temporarily ensure the effects of the final decision on the application, the college pronounces with an **order** made in chambers*

Art. 56 CPA: monocratic precautionary measures

- *Par. 1. Before the treatment of the interlocutory application by the college, in cases of extreme gravity and urgency, such as not to allow even a delay until the date the council meets in chambers, the applicant may, with an interlocutory application or a separate application notifying the counterparties, request the President of the Regional Administrative Court, or the section thereof where the application is assigned, to provide for interim precautionary measures.*
- *Par. 2. The president (...) verifies that the notice of application has been delivered to the recipients or at least to the public party and one of the counterparties, and issues a **motivated decree** that cannot be appealed.*

The precautionary principle as a justification for the suppression of rights and freedoms

- From the standpoint of administrative jurisprudence, it is precisely the application of the precautionary principle in protecting the citizens' **right to health** which has justified the suppression of a number of freedoms and constitutionally guaranteed rights.
- An analysis of art. 301 of the Italian Environmental Code (TUA) provides us with general indications that are useful for systematizing these numerous rulings, above all concerning rulings of a precautionary nature which have been approved by administrative judges in applying this principle.

Three tests for precautionary measures

- In accordance with paragraph 1 of art. 301 TUA, precautionary measures:
 - 1) must be based on preliminary, objective scientific assessments (**science-based inquiry**)
 - Beyond this, as provided for in paragraph 4 of the same article, such measures must be:
 - 2) proportional with respect to the level of protection that is being proposed (which also includes a cost/benefit analysis) (**proportionality**)
 - 3) updatable with regard to the emergence of new scientific data (**temporary duration**).

Science-based inquiry: the use of face masks 1/3

- As an example involving the test of science-based inquiry, I would like to show you a recent case in which the use of face masks was contested.
- The Lazio Regional Administrative Court made the following statement in its decision:
- *“The current health emergency involves a risk to public health that is difficult to analyze and manage. It is this fact, among other things, that legitimizes the authorities – who are responsible for managing that risk – in making decisions which are in compliance with the precautionary principle, i.e. on the basis of available scientific evidence, and in consideration of the opinions provided by the scientific bodies specifically appointed to speak on the subject”.*

The use of face masks 2/3

- *“In light of the preceding considerations, and as a result of the summary examination of the precautionary phase, the fumus of the appeal is not evident, given that the applicant is questioning the scientific data on which the contested Prime Ministerial Decree is based. During the present monitoring phase, the applicant has not produced, in turn, scientific data which is evident, unambiguous and unchallenged. The applicant has not adequately explained why the discretion expressed by the contested Prime Ministerial Decree should be considered an example of misrepresentation, irrationality or contradiction, especially considering that the contested act is obviously inspired by precaution”.*

The use of face masks 3/3

- *“The applicant, moreover, does not even describe and demonstrate the specific disadvantages that he would have suffered from the use of masks. From this it follows that the interests protected by the contested act are absolutely prevalent”* (TAR Lazio, sez. I, 04/12/2020 n. 7469).

Proportionality: a restriction of the right to education

- The second case I would like to show you, in relation to the test of proportionality, is about the balance between the right to education and right to health.
- In this instance, a municipality in Campania had issued an ordinance demanding a more restrictive suspension of teaching activities than the one which was ordered at the state level.

A balance between the right to education and the right to health

- The Campania Regional Administrative Court ruled that the municipal ordinance was legitimate. In the balancing of interests, the importance of limiting the contagion prevailed over the personal interest of the applicant, i.e. the ordinary conduct of his professional activity. In reaching the decision, the limited temporal validity of the suspension was also taken into account (TAR Campania, (dec.mon.), V, 27 November 2020, no. 2205).

Temporary duration: restriction of the freedom of economic initiative

- The test of temporary duration was used in another instance to confirm the legitimacy of a state measure which suspended activity in the food service industry.
- The court made its decision "*in light of the brief duration of the contested measure, and in consideration of the fact that the precautionary principle, even if unexpressed, must cover all administrative activity in the present epidemic emergency, therefore assuming a value and importance prevailing over other interests at stake* (TAR Lazio, III quater, (decr.mon.), 13 November 2020, no. 6970).

Balance between the right to health and other rights

- An analysis of administrative case law shows that precautionary measures must be based on scientific data, they must be proportional in nature, and they must be temporary in duration
- In evaluating the judges' rulings, we see that the right to health generally prevails over any other rights or freedoms (it also prevails over the right to privacy)

Three lessons learned?

At this point, we must look to the future and ask ourselves what lessons we will have learned after the pandemic has ended. To that end, we can already summarize three conclusions. In general, Italy, Europe and many other countries require the following:

1. A regulatory model for pandemics;
2. Advance pandemic planning and organization;
3. The implementation of new technologies in addressing pandemics.

A pandemic management model

The first suggestion concerns a blueprint (pre-existing model) which needs to be followed.

- It would be useful to provide a regulatory model (for example, a decree-law) which could be implemented in the scenario of a future pandemic.
- It is important to be equipped with a single clear model, one which is well defined in advance in order to avoid the disorganized, flood-like mass of regulatory acts that have affected the lives of citizens in the last year.
- In such a model, decision-making centers should be clearly identified, interference between competencies should be avoided, and the organizations in charge should be provided with the necessary powers to carry out their work.

Advance pandemic planning and organization

- It will be necessary to create a pandemic plan that will be well known and well understood by public institutions, in schools, and by citizens. Frequent updates to the plan will also be necessary.
- Under the new plan, hospital networks and intensive care units will have to be strengthened and personal protective equipment will need to be stockpiled in sufficient quantities.
- A fundamental space in the plan should be reserved for the improvement and restructuring of basic medical services in our local health care systems.
- It does not seem that the downsizing of hospital services, especially in some regions, has been matched by a sufficient strengthening of local health care structures in Italy, and the coordination between existing structures seems to be lacking.

Implementing new technologies in the health care system

- In this connection, the use of artificial intelligence could be broadly encouraged (think of applications that can carry out diagnostic tests on the basis of x-rays)
- The Electronic Health File (*Fascicolo Sanitario Elettronico*, abbreviated as FSE) should be made bindingly operational
- A mandatory tracking system should be developed – with proper regard for the protection of privacy – which could be employed in the event of an epidemic (in particular with reference to travel)
- The use of new technologies such as thermo scanners or drive-through tests should be envisaged
- The police or the army should be deployed to carry out contact tracing within 24 hours if necessary
- Remote medical monitoring and diagnostic tools should be utilized in order to treat patients in their own homes

The issue of “money”

- Generally speaking, to achieve these objectives, it is not enough to simply announce that funding has been earmarked for ad hoc preventative measures; instead, the money must actually be invested and the measures must be fully implemented.
- Relevant research has also shown that we need to put a stop to the downward trend in public health spending which has been evident in recent years (that trend is probably due to the fact that health care requires more personnel than other sectors) .

Questions

These issues will be of central importance in the coming years. We should ask ourselves:

- Will we succeed in developing a proper regulatory model?
- Will we be able to formulate a pandemic plan and will we be capable of executing it?
- Will the use of new technologies be adequately incentivized?
- Will we create mobile health units that can be deployed, in a manner similar to mobile emergency task forces, when the need arises?
- Will we carefully monitor the need for personal protective equipment, ensuring that a certain supply is always available and that production can be increased on short notice?

The challenge: learning from past experience

- As we have seen, drafting a new pandemic plan is only the first step in preventing future health emergencies.
- Once the details have been decided, the complete implementation of that plan, down to the last detail, is equally important. In Italy, it seems that the real challenge to our system is in applying the principles of precaution and prevention to planning and organizational activities.
- Only the future will tell if we have learned our lesson...