



Suggestions for an efficient European fight against a pandemic – legal aspects in the health care sector

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Policy Recommendations

1. In times of crisis, especially a pandemic, national health care systems have to be supported by well coordinated cross-border activities.
2. There is a need of EU-wide standards concerning the storage of medicine, medical devices and protective clothing etc. in order to support the containment of a pandemic. A new and not yet established EU authority, a “European Agency for Health Care Safety“ should be responsible for the efficient control of the implementation of new standards. In addition to this task it should focus on prevention, watch developments concerning health care, analyse the world-wide situation, develop strategies for decision-makers if needed during a crisis and coordinate the member states in case of emergency.
3. The Treaty on the Functioning of the European Union has to be expanded with a new article 168a to create a competence of the EU concerning the fight against a pandemic and to enable the responsible EU agency to act fast on cross-regional level in the event of crisis.

Abstract

Since the so-called „Spanish-flu“, the worst world-wide pandemic in history, which raged in the years 1918-1920, Europe was untroubled by pandemics. Now, exactly hundred years later, nobody exists who can remember this situation. In fact the European health care systems were unprepared in February 2020 when the coronavirus crisis started in northern regions of Italy and rapidly endangered other countries in Europe. A pandemic ignores state borders. Because even in the European Single Market health care systems are in the responsibility of the member states, it was soon obvious that the lack of harmonised standards regarding a pandemic would be an enormous obstacle in the fight against it and this situation unveiled a huge gap in the European cooperation. There is an un-

conditional need for EU-wide standards in the future concerning the storage of always available protective masks, protective clothing, disinfectants etc. in relation to the population. Furthermore it is necessary that the member states coordinate cross-border cooperation in case of emergency in order to prevent the spreading of a pandemic from the very beginning. It will not be sufficient just developing new standards and action plans to combat a pandemic, the new standards also have to be executed effectively, even before the outbreak of a pandemic. Therefore a “European Agency for Health Care Safety“ with a stable legal basis, which can only be achieved by adding a new article 168a in the Treaty on the Functioning of the European Union, is essential.



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Introduction

If anybody just after midnight during celebrations of New Year's Eve 2019/2020 would have said that in a few weeks - prescribed by the state - it would no longer be possible having a party with friends, everybody should wear a face mask, shopping would be impossible in many places, above all travelling in a free Europe would be restricted, everybody would have stated this is a bad joke or maybe this person has drunk too much and in the morning of New Year's Eve he or she should be in line again with reality.

If one would have asked at the same time a politician responsible for civil protection or a head of government in a member state of the EU, whether in this member state would be stored enough face masks and disinfectants and this member state is prepared sufficiently for a pandemic that would break out in a few weeks and would spread very quickly all over Europe, nobody would have taken this person seriously - not even if he or she would have been an expert for civil protection. One would have assured that of course everything is prepared, but there is no danger at all and the last pandemic in Europe occurred exactly hundred years ago.

“In the short term the focus should be on how to avoid or at least minimise the effects of a “second wave“ or a future pandemic.”

Only a few weeks later Europe looks quite different. It is impossible to get on a plane and fly to a destination in a member state, it is even not possible to book a summer vacation without great uncertainty. A virus, introduced from China, causes mass deaths¹ in the middle of Europe, in big, wealthy and

industrialised countries with highly developed health care systems, although they were not affected to the same extent by the pandemic. One reason is the longtime economy measure to reduce costs in the health care system or some states hesitated too long to take appropriate measures, so the number of person who died from COVID-19 is disproportionately high in comparison to the figure of infected person.

Someday scientists finally will have figured out what happened, where the first case of infection with coronavirus occurred in Europe, etc. And some day the courts will have clarified whether negligence was the reason. This is undoubtedly interesting and important in the medium and long term, but in the short term the focus should be on how to avoid or at least minimise the effects of a “second wave“ or a future pandemic.

We quite often hear the flat criticism that “the EU“ has failed in the fight against the coronavirus but this is not true because the member states are primarily responsible for health policy. Only in article 168 paragraph 5 of the Treaty on the Functioning of the European Union² one can detect approaches regarding the fight against a pandemic: “The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse

1) Corona Virus Resource Center der Johns Hopkins University in Baltimore, USA: <https://coronavirus.jhu.edu/> (26.05.2020)

2) <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A12008E168> (26.05.2020)



of alcohol, excluding any harmonisation of the laws and regulations of the Member States.³

“We quite often hear the flat criticism that ‘the EU’ has failed in the fight against the coronavirus but this is not true because the member states are primarily responsible for health policy.”

The last pandemic in Europe occurred exactly hundred years ago. Between 1918 and 1920 demonstrably more people died from the “Spanish flu” than from the First World War which ended just before.⁴ This fact was almost unknown until recently and also was not taught to pupils in history lessons. Even people who are hundred years old today cannot remember this disaster.

Without any doubt one of the greatest achievements of the western civilisation in the last hundred years was that hygienic standards reached such a high level that epidemics seemed to be exterminated forever. But this standard is not automatically secured at such a high level. It must be constantly achieved again by efforts that should not be underestimated. Already relatively small cost reductions, caused by the pressure to save money, represent an enormous risk for the health care in times of exceptional circumstances. The costs for health care increased in the last decade more than the gross national product, which has an impact on policy and budget because the tendency is to expect better performance with less resources.⁵ Furthermore new threatening scenarios are existing: due to the rapidly growing air traffic it is possible to spread a pathogen

globally within a few hours. In addition the danger of bioterrorism should not be underestimated.

Suggestions for procedures in the event of a future pandemic

How is it possible to avoid a repetition of a pandemic in the future? What has to be done on behalf of the EU and its member states?

The greatest threat for a society in the event of a pandemic is a mass disease that affects employees of the rescue, police, fire brigades or public health sector. Regarding health care professions it is impossible to replace staff - not only in the case of doctors - because of their long education. In other words: in the case of a flood disease doctors can also be used for ancillary activities, but unskilled workers are never able to treat patients. Even medical staff is sometimes severely limited or even helpless without assistance of other health professionals because today's medicine is based on teamwork (not least due to the very advanced specialisation).

The most important task⁶ in regard of the fight against the pandemic was almost totally ignored: the comprehensive protection of health care professionals against infection in order to maintain the health system operational. This could be achieved with relatively simple measures: a sufficient quantity of face masks, protective clothing, disinfectants etc. has to be stored and should not be imported (considerably more expensive⁷ and partly in not sufficient quality) from Asia by plane in a media-effective way. Experts can easily calculate the quantity needed to be stored. Since these products are long-lasting but not durable forever it can happen that they have to be disposed unused. At first glance this seems to

3) <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A12008E168> (26.05.2020)

4) The figures are fluctuating very much, so erously it could be about 20m (Goldmann Lexikon, volume 9, page 3853) but due to bad registration systems it could be also 50m world-wide.

5) <https://www.fiskalrat.at/Publikationen/Sonstige.html>

6) It would be desirable that in mid term more person would work in the health care sector but therefore more financial means would be necessary. In this context also demografic development and less appreciation for jobs in health care are relevant factors.

7) The sudden demand was higher than the supply, thus the prices rapidly got up.



be a misuse of taxpayers' money, but it is quite reasonable. Most of the airbags in cars are still unused when the car is scrapped. Should airbags no longer be installed in cars in order to save money? Anyway a smart material management could considerably reduce the rate of waste (for instance for face masks).

“Surprisingly there is little to no meaningful and structured data about frequency, type and consequences of malpractice damages, which makes improvements almost impossible.”

There should be EU-wide standards how much medical material should be stored per 100,000 inhabitants in a member state or region. It is self-evident that acquisition, storage and timely replacement of these goods has to be controlled regarding their durability continuously and any divergence should not remain without consequences. In order to achieve this a new (not yet established) EU authority is needed for security in health care (European Agency for Health Care Safety). This agency should have the necessary competences and penetration rights and it should be independent from national authorities in the member states. Beside unannounced controls of the stock the control of health care institutions concerning cases of malpractice and their rehabilitation could be part of its competences. Surprisingly there is little to no meaningful and structured data about frequency, type and consequences of malpractice damages, which makes improvements almost impossible. The “retrospective damage analysis”, which was introduced at the Vienna General Hospital in the year 2000 - without any legal obligation - is a best practice during twenty years and could serve as a role model for Europe.

The already existing European Centre for Disease Prevention and Control (ECDC)⁸ was in this respect not able to act efficiently because the competences for urgent measures were not transferred. A new and not yet established “European Agency for Health Care Safety” should be provided with

8) <https://www.ecdc.europa.eu/en>

executive powers for the the event of crisis. As for 100 years Europe was untroubled by pandemics, so the wrong opinion prevailed that in a modern highly developed health care system this can't occur anymore. Since the coronavirus crisis this is now out of question and the authorities have to take steps for prevention in the future. As an example for successful European cooperation we can see what the European Union Aviation Safety Agency (EASA)⁹ has achieved with effective work: in some years not a single person died in an accident in the field of commercial air traffic.

“A new and not yet established ‘European Agency for Health Care Safety’ should be provided with executive powers for the event of crisis.”

Such an agency could be legally attacked, because the establishment of an authority with so far-reaching competences is not foreseen in article 168 of the Treaty on the Functioning of the European Union and the EU does not have the competence for this measurement. It is overlooked that the member states determine to what extent they hand over or retain national competences, which sometimes can be a complicated and painful process. Given the drama of the coronavirus crisis and its consequences, which cannot be estimated at all yet but will certainly lead to a recession for several decades¹⁰ (like global economic crisis in the year 1929), there will be a political will to create such a new authority.

When adding an article 168a to the Treaty on the Functioning of the European Union also a far-reaching duty of assistance could be defined for the member states, so it would be obligatory to support a member state in the event of a crisis when help is needed (in the coronavirus crisis it would have been clearly Italy). This would be furthermore a contribu-

9) <https://www.easa.europa.eu/>

10) https://ec.europa.eu/commission/presscorner/detail/en/IP_20_799 (26.05.2020)



tion as well to the strengthening of the European idea. A duty of assistance could include a temporary supply of health care professionals, but also other labor, as well the transfer of patients to other countries and regions in order to avoid the collapse of a national health care system and the sudden stop of the export of personal protective equipment due to national considerations.

“Given the drama of the coronavirus crisis and its consequences, which cannot be estimated at all yet but will certainly lead to a recession for several decades (like global economic crisis in the year 1929), there will be a political will to create such a new authority.”

Certainly enough funds¹¹ would have to be provided for the establishment of such a new authority apart from enough necessary materials and resources (soft- and hardware, updated emergency plans, which should be tested regularly, information brochures etc.), which have been missing at the beginning of the coronavirus crisis. A member state that is not willing to raise the necessary funds must be aware to get confronted with the counter argument that the grants already decided by the EU are certainly much more expensive¹² and nobody knows if they will be sufficient. Compared to the benefit, that maybe cannot be measured in money, these costs are negligible. To put it in a nutshell and following up the introduction of this policy brief: Which politician on New Year's Eve, who would have been able to look ahead, would not have done everything possi-

ble and useful, specially would not have spent money, to restrict the consequences of the pandemic?

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11) An estimation is difficult, but in comparison with other EU recovery packages already decided, it would be less: €5bn EU-wide – but this is a completely personal estimation.

12) A return of investment at a ratio of 50:1 is quite realistic. Empirically the savings are approximately 90 times higher than the costs. The problem is simply that initially mainly costs arise. This can be compared to the process of making a movie, that only generates earnings after it is finished. It is a great challenge to put this across to politicians and managers.



About the author

Dr. Leopold-Michael Marzi studied law at the University of Vienna. 1989-1998 he was working for the Municipality of Vienna in various positions (District Administration, Finance Department of the City of Vienna, Hospital Administration of Vienna). 1998-2016 he was Head of the Legal Department of the Vienna General Hospital. Since 2017 he is Head of Department for Critical Events and Prevention in the Medical Board of the Vienna General Hospital.

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