



THE CONSTITUTIONAL IMPLICATIONS OF EUROPEAN PUBLIC HEALTH POLICY

A Study of the EU Response to the Influenza H1N1
Pandemic

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Abstract

This study looks at the response to the influenza A H1N1 pandemic within the institutional context of the EU. The focus is on what happens in practice in case of a health emergency in the EU, regardless of limited legislative basis in the area of public health. The institutional dynamics of actors on the European level and the policy they produced in response to the influenza A H1N1 are assessed in light of European constitutional principles. This shows the constitutional implications of the European response a public health emergency.

Introduction

In April 2009 a new strain of influenza virus first became apparent in Mexico.¹ It is likely that this influenza strain originates in pigs from Asia that were carried to North America.² In Europe, the first vaccines became available in the fall of 2009. As of 21 March 2010, worldwide more than 213 countries and territories have reported over 16,931 deaths due to the influenza A H1N1.³ These are only the laboratory confirmed cases.⁴

Not long after the influenza A H1N1 started disappearing from the news and it turned out that the virus was not a lot more deadly than a seasonal influenza,⁵ questions were raised into how this pandemic was handled.⁶ Most Member States started seeking to off-load the large supply of vaccines ordered.⁷ Speculations were made that through informal structures of cooperation and expert committees in the EU and the WHO, the pharmaceutical industry has pushed for the declaration of a false pandemic,⁸ so that they could recoup the billions of investments in researching and developing vaccines for the avian influenza scares in 2006 and 2007.⁹

The Parliamentary Assembly of the Council of Europe has instigated a review of the role of experts within the WHO that declared the pandemic. At the same time MEP's in the European Parliament are seeking an official inquiry into how the

¹ See M Lacey & D.G. McNeil, 'Fighting Deadly Flu, Mexico Shuts Schools', in *NYT* 24 April, 2009.

² The flu is a mutation of four types of influenza one that is found in humans, one in birds and two strains that are more common in pigs. See European Centre for Disease Control *Threat Assessment Human cases of swine influenza without apparent exposure to pigs, United States and Mexico* of 24 April 2009; also see from The European Surveillance Network for Influenza in Pigs by K. Van Reeth, *Influenza: variations on an old theme*, available at: <http://www.esnip.ugent.be/page6/page6.html>.

³ The Influenza A H1 N1 is also called the Mexican flu, or Swine Flu: see K. Bradsher, 'The Naming of Swine Flu, a Curious Matter,' *NYT* April 28, 2009.

⁴ WHO Pandemic (H1N1) 2009 - update 93, available at http://www.who.int/csr/don/2010_03_26/en/index.html

⁵ World Health Organization *Comparing deaths from pandemic and seasonal influenza* (22 December 2009), shows the relativity of comparing the death toll of seasonal and pandemic influenza: Pandemic influenza data is based on laboratory confirmed cases, whereas, seasonal influenza data is based on estimation models.

⁶ See Medical News Today, Swine Flu False Pandemic, Questions in Europe, 14 January 2010.

⁷ <http://www.euractiv.com/en/health/eu-governments-seek-offload-flu-vaccines/article-188534>

⁸ Ibid. supra note 6

⁹ Brian O'Connell, 'Street Talk: Investments in Avian Flu Soar, Companies and global governments open their pocketbooks to prevent a pandemic, in 19 *BioPharm International* 5 (May 1, 2006).

influenza A H1N1 was handled, specifically to name and shame those experts within the European public health authorities that might have had undeclared conflicts of interest.¹⁰

Generally the seriousness of these allegations with regard to the EU role in handling the influenza A H1N1 pandemic, at least illustrates that regardless of the limited EU legislative basis, European public health policy can have a significant impact in the lives of Europeans. Health risks such as HIV/Aids, BSE and SARS and the increasing effects of European internal market law on public health issues, over the years have strengthened the European competences for adopting legal measures in the area of public health.¹¹ In constitutional context here the question is often asked, generally, how the European internal market can be balanced with a European social model.¹²

This is not the focus of this paper however. It is taken for granted that the EU has limited competence for creating public health policy, and looks at what happens in practice, regardless of legislative basis. This means that the study attempts to look at the role of public health policy within the political system of the EU, which functions and allocates values through constitutional principles, beyond the scope of the European internal market.¹³ In this perspective, European public health policy is not only viewed in relation to the principles of the internal market, but rather it is assessed in light of European constitutional principles.¹⁴ Since handling a public

¹⁰ See Euractiv, EU to pump €18m into flu research (10 March 2010) at <http://www.euractiv.com/en/science/eu-pump-18m-flu-research-news-323230>.

¹¹ T. K. Hervey and J.V. McHale, *Health Law and the European Union* (Cambridge University Press: Cambridge, 2004).; also see E. Mossialos, G. Permanand, R. Baeten and T.K. Hervey (eds), *Health Systems Governance in Europe, the Role of European Law and Policy* (Cambridge University Press, 2010).

¹² In this perspective, the harm that European economic policy can have for individuals and the health systems of the Member States needs to be “corrected” or “cushioned” on the European level by health policy, see *ibid.* at 2.

¹³ S. Hix, *The political system of the European Union* (Palgrave Macmillan: 2005).; also see D.M. Curtin, *Executive Power of the European Union. Law, Practices and the Living Constitution* (Oxford University Press: 2009).; also see L.F.M. Besselink, 'The Notion and Nature of the European Constitution after the Lisbon Treaty' in J. Wouters, L. Verhey and P. Kiiiver (eds), *European Constitutionalism beyond Lisbon* (Intersentia: Antwerp, 2009). at 162.

¹⁴ Although the European Union is largely the result of integrating European markets, it is hardly disputed that overtime that within the structures of European governance and law constitutional principles have become increasingly entrenched: see generally M. Longo, *Constitutionalising Europe: Processes and Practices* (Aldershot: Ashgate, 2006).; and see F. Snyder, 'Unfinished Constitution of the European Union: Principles, Processes and Culture' in J.Weiler and M.Wind (eds), *European Constitutionalism beyond the State* (Cambridge University Press: 2003).

health emergency has the potential to have a deep impact in the lives of Europeans, a study of the constitutional implications of the role of the EU in this regard, is a starting point for assessing the legitimacy of EU health emergency policy. The specific question is: *what are the constitutional implications of the European response to the influenza A H1N1 health emergency?*

In order to illustrate how the EU can create far-reaching emergency health policy, regardless of legislative basis, in the first part of this paper the evolution of the EU health emergency architecture is presented in historic context (I). The second part turns to how this European health emergency structure works in the European institutional context (II). Here the question is: who the actors are that shaped EU public policy response to the Influenza A H1N1 pandemic and how did they interact? Specifically with regard to the emergency vaccine authorisation procedure, part II looks at the interplay between formal and informal practices within the European public health emergency framework. In the last part these findings are taken from the European institutional order, to the more abstract European constitutional order (III). The third part turns to the implications of the response to the influenza A H1N1 in light of European constitutional principles.

PART I HISTORIC CONTEXT: THE EVOLUTION OF THE EU HEALTH EMERGENCY ARCHITECTURE

Introduction

This part turns to the development of the European public health emergency structure. It is the nature of public health emergencies to transcend national borders. Already at the time of the Black Death in the second part of the 14th century, the disease would spread through the trade routes. Now with intense air traffic, diseases can spread more rapidly than ever. This is the reason that already from 1851 onwards the World Health Organization is a main player in regulating public health emergencies and the International Health Regulations from the WHO are leading in terms of coordinating international public health emergency responses.¹⁵ The main political actors for the protection of international public health are the Member States to the WHO. Nevertheless, the EU claims exclusive and shared competences for

¹⁵ See International Health Regulations (2005) 2nd Edition, WHO, 2008.

some aspects of health emergencies. The development of European public health competence is related to recent health emergencies, such as legionella, SARS, BSE, and Anthrax, that have created and impulse for policy response on the European level. Within this development of European public health policy, the institutional context in which formal and informal actors and practices shape the EU health emergency structure can be understood.

1) Health Emergencies as Impetus for European Public Health Policy

On the European continent, the first public health measures relate to the supply of clean drinking water to cities and developing public health works such as sewerage systems.¹⁶ Later with the increased understanding of communicable diseases such as whooping cough, typhus fever, scarlet fever and syphilis, public health became a true policy fields for the bureaucrats of the renaissance.¹⁷ About a hundred years later came the realization that public health architecture could be an instrument in strengthening the political and economic power of the state. Keeping the population healthy meant having a strong workforce.¹⁸ Interestingly, the current European health objectives are also tied in to economic objectives, in the context of the Lisbon Agenda, and the 2020 Agenda.¹⁹ In Europe spending on health care makes up a share of 7,6 percent of the total GDP and a healthy population is an “economic priority”.²⁰

A) European Competence for Public Health

For a long time there was no legislative basis to make public health policy on the European level. In the founding treaties of the 50s, no competence for health

¹⁶ See G. Rosen, *A History of Public Health*, John Hopkins University Press. (1958 1rst ed.) 1993 at 30.

¹⁷ *Ibid.* at 75.

¹⁸ *Ibid.* at 90.

¹⁹ The Healthy Life Years indicator, a measure of years lived in good health, is one of the European Structural Indicators of the Lisbon Agenda see Commission Communication (COM(2003) 585 final).

²⁰ Commissioner Markos Kyprianou, responsible for Health and Consumer Protection on *The European Voice* conference ‘Health care: Is Europe getting better?’: “In Europe health can be seen as a productive factor in a competitive economy(...) if the costs of ill health are so high, improving the population's health must become an economic priority.” Brussels, 20 January 2005 (SPEECH/05/24); and see *Europe in Figures - Eurostat Yearbook 2006-07* (Luxembourg: Office for Official Publications of the European Communities, 2007) p. 108.

legislation was made for the European legislator.²¹ The only envisioned European measures regarding health, were provisions on social security for workers to ensure their free movement (Article 51 EEC, now Article 48 TFEU).²² Article 2 of the EEC Treaty formulated as one of the Community objectives to raise the standard of living, which means that health legislation at the time could have been taken on the basis of Article 235 EEC (Article 352 TFEU), however this never happened. Instead, public health was tied in with market regulation, such as Directive 65/65 on pharmaceutical products. This directive was adopted in response to the Thalidomide tragedies in the early 60's, which caused the death and deformity of thousands of children across Europe.²³ Also in the area of the safety of food, already in 1962 the Community adopted measures for the protection of public health, on the basis of internal market provisions.²⁴

The Single European Act in 1987 provided in Article 100a (3) that a '*high level of protection of health*' should be considered when proposing internal market measures. However, as an attempt to integrate health concerns with economic legislative measures, this provision failed, as the consideration of social concerns was excluded by subparagraph 2 of Article 100a EEC. This last provision was added under pressure of the UK, which did not want to loose authority over social policy and public expenditures. Nevertheless, even without legislative basis, European public health policy was already in the 70's created with relation to cancer and HIV/Aids and merely based on 'the Treaty establishing the EC'.²⁵ The rapid international spread of the HIV/Aids virus created a rational need for European cooperation in

²¹ Competence in the European legal order is a central prerequisite for European institutions to formal legal power to act. The founding treaties, the Treaty on the Functioning of the EU and the Treaty on European Union, only grant this power to act in specific areas, see P. Craig & G. De Burca, *EU Law: Text, Cases and Materials 4th ed.*, (Oxford University Press, 2008) at 98.

²² See, what is now Regulation (EC) No 883/2004 of the European Parliament and of the Council on the Coordination of Social Security Systems (O.J. L166, 30/4/2004)., implemented by Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security system (O.J. L 284/1).

²³ See T. K. Hervey and McHale, *supra* note 11 at 49.

²⁴ O' Rourke, *European Food Law* (Bembridge: Palladian Law Publishing, 1999) at 3.

²⁵ See Decision 88/351/EEC Europe Against Cancer Programme of the council and Representatives of the Governments of the Member States meeting within the Council. O.J. 1988 L160/52; also see the Europe Against Aids Programme, Decision 91/317/EEC of the Council an Ministers of Heath of the Member States O.J. 1991 L175/26; also see T. Hervey & McHale, *supra* note 11 at 73.

the area of public health. Nevertheless, a formal legal basis for health was only introduced in the amendments made by the Treaty of Maastricht.²⁶

The Treaty of Maastricht in 1992 introduced Article 129 EC (now Art 168 TFEU) on health in the EC Treaty. Here the legislative incentive might well have been that Member States wanted to limit competence creep by providing clear competence boundaries in the area of health.²⁷ On the other hand, some Member States viewed the introduction of a legal basis for European health legislation as a formalization of actions that had already been taken in the field of public health.²⁸ Article 129 EC Treaty provided that: *'The community shall contribute towards a high level of human health protection by encouraging cooperation between Member States and, if necessary, lending support to their action'*²⁹ However, as the activities in the internal market impacted on public health as well, Article 129 EC also provided for a "mainstreaming" health into other policy areas. This meant that regard should be given to the effects on public health issues of other community activity.³⁰ Nevertheless, harmonization of public health was explicitly excluded in Article 129 EC. This meant that policy directly based on this article had to use multi-level coordination as its instrument for implementation.³¹

The Treaty of Amsterdam in 1997 was adopted after bovine spongiform encephalitis/Creutzfeldt-Jacob disease (BSE), which prompted the adoption of a rather critical report by the European Parliament on the role of the European executive in taking public health measures.³² The outcome of the BSE crises is the

²⁶ The Treaty on European Union (TEU), signed in Maastricht on 7 February 1992, entered into force on 1 November 1993 (OJ 1992 C 191).

²⁷ See T. Hervey & Mc Hale supra note 11 at 73; see further S. R. Weatherill, 'Competence creep and competence control' (2004) 23 *Yearbook of European Law* 1-55.

²⁸ Ibid.

²⁹ The actions of the EU were to be directed to specific areas such as major health challenges, research into these diseases and their transmittance and the provision of information and education on health. These areas of activity outline that action on the basis of Article 129 EC was mostly to be directed toward public health rather than health care entitlements for individual citizens.

³⁰ Ibid; also see A.P. Van der Mei, *Free Movement of Persons within the European Community: Cross-Border Access to Public Benefits* (Oxford: Hart Publishing, 2003).

³¹ Article 129 EC formally granted the Commission the power to recommend and promote measures for coordination. The Council and the Parliament were given the power to formulate "incentive measures" in accordance with the co-decision procedure, or they could make recommendations on the basis of a proposal of the Commission. See Art 152 EC, ex Art 129 EC.

³² Resolution of the European Parliament on the report of the Temporary Committee instructed to follow up the recommendations on BSE (19 February 1997) (R4-3135/97). The European Parliament even considered dismissing the European Commission entirely. Jacques

strengthening of the health provision in the Treaty. Therefore, Article 152(4) (a) (b) creates the possibility for harmonisation of Member States regulations of quality and safety of organs and substances, veterinary and phytosanitary measures which have as their direct objective the protection of public health.³³ Nevertheless, the subsidiarity principle in section 5 of Article 152 EC still strictly bordered off the general leeway for the European legislator to harmonize national law and to develop a horizontal health policy.

With the ratification of the Treaty of Lisbon, public health in Article 9 TFEU, becomes an overarching objective of the Union, which should be taken into account when defining or implementing EU policies or activities. This means that public health is no longer supplementing internal market provisions alone. It has become a self-standing objective for all Union policies. In this sense it is recognition that not only internal market measures can have a public health impact, but all Union activities. Moreover the list of the EU public health policy objectives in Article 168 TFEU now includes –on top of improving public health, preventing physical *and mental illness* and diseases– *monitoring and early warning*, and *combating cross-border health threats*. As an implementation mechanism the “Open Method of Coordination” has been formalized with the ratification of the Lisbon Treaty.³⁴ Nevertheless the old principle of subsidiarity of Article 152(3) EC is firmly reinstated in Article 168(7) TFEU. Article 152 EC and the new Article 168 TFEU signify, that in the area of public health the European Union has been able to establish a reasonably stable competence.

2) The Evolution of the European Health Emergency Structure

The first warnings from Mexico that a new influenza virus was found, which had mutated from and birds and pigs to a virus that affected human health, were disturbing to public health officials. In the case of the 2003 SARS (Severe Acute

Santer, then president of the European Commission, in turn promised that from now on public health would be at the ‘forefront of development of Europe’.

³³ H.D.C. Roscam Abbing, ‘Volksgezondheid in het Verdrag van Amsterdam, een beknopte analyse’, *Tijdschrift voor Gezondheidsrecht* 1998, at 75-80.

³⁴ The Open Method of Coordination (OMC) constitutes a flexible form of cooperation, which has especially been important, and developed in the context of the implementation of the Lisbon agenda, but also in many other politically sensitive policy areas such as health. See K. Armstrong & C. Kilpatrick, ‘Law, Governance, or New Governance? The Changing Open Method of Coordination’ 13 *The Columbia Journal of European Law* (2007), at 649-679.

Respiratory Syndrome) in Asia 774 of the 8096 people infected deceased.³⁵ This is a large percentage, in comparison, the Spanish flu in 1918 to 1919 killed millions, but had an actual mortality rate of 2,5 % with respect to the amount of people that were infected with it.³⁶ Nevertheless, had there been flu medicine at hand, it is probable that the outbreak would not have been as widespread and cause as many lives.

A) *Communicable Diseases*

The first involvement in communicable disease monitoring of the European Union developed in the context of an exchange of letters with the WHO in 1972.³⁷ Over time, specifically in the area of communicable diseases, cooperation increased over the 90's between the WHO and the Communities and also within the Community itself.³⁸ In this context the 2005 the revised International Health Regulations (IHR's) are adopted with intense involvement of the European Commission.³⁹ An important impulse in this regard was the international health risk posed by the SARS virus in 2003. This means however, that currently, the governance of health emergencies –specifically also communicable diseases– is divided between the international, European and Member State level.⁴⁰

³⁵ See WHO Communicable Disease Surveillance and Response, *Severe Acute Respiratory Syndrome (SARS): Status of the Outbreak and Lessons for the immediate future*, 20 May 2003 at 3; also see WHO Severe Acute Respiratory Syndrome (SARS) - multi-country outbreak - Update 6 March 2003.

³⁶ See Viroj Wiwanitkit, *Bird Flu: The New Emerging Infectious Disease*, (New York: Nova Science Publishers, 2008) at 2.

³⁷ Exchange of letters between the European Communities and the World Health Organisation laying down the procedure for cooperation between the two organizations (82/725/ECSC, EEC, Euratom) (O.J. L 300, 28/10/1982, 20-22).

³⁸ Exchange of letters between the World Health Organisation and the Commission of the European Communities concerning the consolidation and intensification of cooperation (2001/C1/04) O.J. C1/7

³⁹ See World Health Assembly, *Global Health Security: Epidemic Alert and Response*, (WHA 54.14) May 21, 2001; and World Health Assembly, *Revision of the International Health Regulations*, (WHA 56.28) May 28, 2003.

⁴⁰ The IHR'S now form the legal basis for the responsibilities of Member States to the WHO. This means that when there is a public health risk, defined as events 'posing a serious and direct threat to the health of human populations' The WHO can make binding recommendations with regard to international public health measures such as travel restrictions and bans on trade to be taken by Member States, however, there is no enforcement mechanism. Nevertheless, there is a dispute resolution procedure. As to cooperation with the EU, Article 57 of the IHR prescribes that 'states that are members of a regional economic integration organization shall apply in their mutual relations common rules in force in that regional economic integration organization.' This means that in case the WHO would make a recommendation, the EU would have to act collectively, on initiative of the Commission.

In the EU, the more encompassing competence for public health policy in Article 152 EC with the adoption of the Treaty of Amsterdam in 1997, increased possibility for formalizing otherwise informal networks for surveillance and control of communicable diseases. In 1998 the first European network for epidemiological surveillance and control of communicable diseases in the Community was set up with Decision 2119/98.⁴¹ This European Network for Communicable Diseases over time became to cover two pillars. The first pillar is the surveillance network, which is set up to track and monitor diseases and includes at least 15 disease specific networks in the EU.⁴² Within these disease specific networks the WHO and the EU collaborate, such as in the area of Euro HIV and in the European Programme for Epidemiology Training (EPIET). The second pillar is formed by the European Early Warning and Response System: This system alerts public health authorities in Member States and the Commission on outbreaks with greater than national dimensions, requiring European coordination.⁴³

In 2001, after the terrorist attacks, the Health Council meeting adopted the first Health Security Programme.⁴⁴ On the basis of this programme a Health Security Committee and a Health Emergency Operations Facility was put in place, under auspice of the Commission.⁴⁵ In 2003 the institution of a separate Health Threats Unit within the DG-SANCO supplemented the health emergency structure. This unit became responsible for terrorism surveillance and early warning of biological, chemical, and radiological threats within the European Union, but also for the threat of communicable diseases. In 2005, the European Centre of Disease Prevention and Control is established. This EU agency, seated in Stockholm Sweden, especially provides expert recommendations and advice, and has an important role in the

⁴¹ Decision 2119/98/EC of the European Parliament and of the Council, of 24 September 1998, setting up a network for the epidemiological surveillance and control of communicable diseases in the Community.

⁴² Many of these DSN's already existed in the 90s, however at the beginning of 2000, the Commission proposed to progressively place all communicable diseases under one EU surveillance network, see Commission Decision 2007/875/EC of 18 December 2007 amending Decision No 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions.

⁴³ Commission Decision 2000/57/EC amended by Commission decision 2008/351/EC.

⁴⁴ See Programme of Cooperation on Preparedness and Response to Biological and Chemical Agent Attacks (Health Security), (G/FS D (2001) GG) 17 December 2001.

⁴⁵ Ibid.

implementation of the IHR's.⁴⁶ The Public Health Executive Agency, now also implementing consumer policy, was created on 1 January 2005 in order to implement the EU Public Health Programme, in which communicable diseases are an important objective.⁴⁷ In 2006 the mandate of the Health Security Committee was formally extended from a mandate in the area of health threats from attacks in which biological and chemical agents might be used to the more generic preparedness for health emergencies and influenza preparedness and response.⁴⁸

B) Influenza Preparedness: International Cooperation and Science

Most Member States have had pandemic preparedness plans for many years.⁴⁹ Influenza, moreover, as of 1999, is one of the disease specific networks under the European Early Warning and Response System.⁵⁰ However, with regard to surveillance, a European Influenza Surveillance Scheme as a collaborative project was already established in 1996.⁵¹ In 2004, in light of the threat of a pandemic, with spread of the SARS and Avian influenza, the Commission identifies influenza as a priority area within the Community Network for Communicable Diseases. European policy in this regard is developed in WHO context, whereby the stage of influenza pandemic planning is firstly assessed in the different European countries.⁵² Secondly,

⁴⁶ Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control.

⁴⁷ The EAHC now implements the EU Health Programme, the Consumer Programme and the Better Training for Safer Food initiative. In 2008, the agency's mandate was prolonged and expanded to include actions in consumer protection and training for safer food. See <http://ec.europa.eu/eahc/about/about.html>.

⁴⁸ See Communication from the Commission to the Council on transitional prolongation and extension of the mandate of the Health Security Committee in view of a future general revision of the structures dealing with health threats at EU level (COM (2006) 699 final).

⁴⁹ http://www.ecdc.eu.int/Health_topics/Pandemic_Influenza/Pandemic_Planning.html; and see http://www.ecdc.eu.int/Influenza/National_Influenza_Pandemic_Plans.php.

⁵⁰ See Conference Preparedness planning in the community: Influenza & other health threats (Brussels, 27 November 2001) http://ec.europa.eu/health/ph_threats/com/Influenza/influenza_conference_1.htm; also see http://ec.europa.eu/health/ph_threats/com/comm_diseases_networks_en.htm; and see the outline of the European Influenza Surveillance Scheme at <http://www.eiss.org/html/introduction.html>.

⁵¹ There is a EISS coordination centre, which under the auspice of the ECDC manages a common database, initiates efforts to standardize and harmonize the data and surveillance activities, and communicates findings for the network. See J. C. Manuguerra, A. Mosnier, W. Paget, 'Monitoring of influenza in the EISS European network member countries from October 2000 to April 2001' 6 *Eurosurveillance* 2001 at 127-135.

⁵² See Commission Communication on Pandemic Influenza Preparedness and Response Planning in the European Community (COM(2005) 607 final).

the influenza preparedness plan of the WHO, published in 2005,⁵³ becomes the model for national influenza preparedness plans, supported through the ECDC by EU guidelines.⁵⁴ Within the European Health Emergency structure for instance, the Commission itself also used these guidelines to update the three alert phases it had before, to six, in accordance with the WHO system.⁵⁵

In the following years, harmonization and coordination of influenza preparedness plans was facilitated through the work of the ECDC.⁵⁶ As a result, influenza preparedness plans on Member State level have become more coherent and coordinated with the WHO recommendations on influenza preparedness.⁵⁷ Nevertheless differences remain, especially in the area of border control issues, antiviral drugs and vaccines.⁵⁸ These are vital elements as each health care system only has limited resources; therefore these issues inherently are politically sensitive and more difficult in terms of international cooperation.

a) Science of Pandemic Influenza Planning

The historic development of the European health emergency structure shows that on the basis of cooperation a rather elaborate framework for handling a communicable disease has been developed. This is related to the role of science as a basis for

⁵³ See the WHO checklist for influenza epidemic preparedness (WHO/CDS/CSR/GIP/2005), available at http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_GIP_2005_5.pdf.

⁵⁴ Generally the objective of these plans to make sure that essential services are maintained, and disease transmission is curbed, minimize socio-economic consequences of a pandemic, hospitalizations and deaths, see *ibid*.

⁵⁵ However, the WHO and the Commission are both empowered to recognize a pandemic. The Commission can recognize a pandemic independently acting under the decision establishing the network for communicable diseases (Decision 2119/98/EC).

⁵⁶ The ECDC has organized workshops and country visits and created an assessment tool and indicators http://www.ecdc.eu.int/Health_topics/Pandemic_Influenza/pdf/Assessment_Tool_060913.pdf. In this regard the agreement is made between the ECDC and the WHO EURO, that the Commission would assess pandemic plans within the EU while the WHO EURO would do the same outside the EU.

⁵⁷ In 2007 it was measured that in comparison to 2005, more EU Member States now have an early containment strategy, and countries have similar approaches as to priority groups in their population for giving vaccines. See Mounier-Jack S, Coker RJ. 'How prepared is Europe for pandemic influenza? Analysis of national plans', 367 *Lancet* 2006 at 1405-1411.

⁵⁸ See Centre for Disease Prevention and Control (ECDC), 'Pandemic influenza preparedness in the EU' (2007), available at: http://www.ecdc.eu.int/pdf/Pandemic_preparedness.pdf; but see Nicoll A, Kaiser R. Limitations of recently published review of national influenza pandemic plans in Europe 11 *Euro Surveill* 2006.

creating health emergency policy:⁵⁹ Through the Public Health Programmes and the European Research programmes, significant research funds have been invested over the years in influenza specifically and communicable diseases generally.⁶⁰ Coordination in this respect is facilitated through the adoption of similar case definitions for particular health threats,⁶¹ or by making public health data comparable diagnosis, scientific risk evaluation and risk management.⁶² As of today, ECDC has published more than 30 documents on Influenza A H1N1 including several scientific publications, guidelines for public and healthcare workers, and guidance dedicated to policy makers.

However, what makes the role of science especially important is the involvement of a significant number of scientific experts, expertise agencies and committees in identifying health threats, advising on response measures and what action should be taken. It is some of these experts and agencies that are now subject of a possible investigation by the European parliament, which illustrates at least to some extent the political influence these various actors have had in the response to the Influenza A H1N1. Therefore the next part turns to how the European health emergency structure works in the European institutional context: it looks at the dynamics and interaction of the actors that shaped the influenza A H1N1 public policy response. Specifically it addresses the emergency vaccine authorisation

⁵⁹ See the Royal Society London publication 'Pandemic influenza: science to policy' (2006), available at: <http://www.royalsoc.ac.uk/document.asp?id=5574>

⁶⁰ For instance, already from the middle of the nineties, the Union has been invested in dissemination knowledge on communicable diseases through a weekly journal *EuroSurveillance*, which over the years has gained a wide reach. As of March 2007, *EuroSurveillance* has been published by the European Centre for Disease Prevention and Control (ECDC) in Stockholm, Sweden.

⁶¹ For instance, the Council resolution in response to the influenza A H1N1 outbreak, calls for the use of all Member States of a case definition of the new influenza virus to be adopted by the WHO and the European Center for Disease prevention and Control, amending Commission Decision 2002/253/EC, which lays down case definitions for reporting communicable diseases across the European Union, see Council Conclusions on Influenza A H1N1 infection, 30 April 2009.

⁶² See for instance the increased funding and development by the Commission on initiatives that aim to increasing the comparability of health data. Decision 2002/253/EC (amended by Commission decision 2008/426/EC) in this respect lays down the definitions for reporting communicable diseases to the Community network; also see for instance the technical guidance documents of the ECDC to serve as a guideline for the influenza A H1N1 case definition updating the 2002/253/EC Decision is so that it integrates clinical, laboratory and epidemiological criteria as well as three case classification definitions to be used in all Member States, covering cases under investigation, probable cases (those showing flu-like symptoms and likely exposure to the disease) and laboratory confirmed cases.

procedure as one of the most important examples of countermeasures to the influenza pandemic.

PART II INSTITUTIONAL CONTEXT: THE EUROPEAN HEALTH EMERGENCY STRUCTURE IN ACTION

Introduction

There are numerous institutions and actors involved in European public health policy. As the historical outline has shown, the main political actors in Europe are the Member States, the WHO and the European institutions. However, more particular, public health authorities, European agencies such as the European Center for Disease Control, the European Medicines Agency and the European Food Safety Agency, the Health Security Committee, expert committees, pharmaceutical companies and the medical community are of enormous importance. The historic context in which the European health emergency developed also shows that the broadening of European competence overtime has made a difference in the EU's ability to address public health emergencies. However, in the context of ever deepening globalization, the serious international threat of public health emergencies, has also been an impetus for creating European cooperation in this regard. In this part, the study turns to the institutional context in which the response to the influenza A H1N1 Pandemic took place. By examining the institutional dynamics within which actors responded to the influenza A H1N1 the question is addressed how, regardless of the limited legislative basis, it was possible to develop rather binding and effective public health strategies, that directly affect European citizens.

1) The Actors

The coordination of a European public health emergency falls under the responsibility of Directorate-General SANCO of the European Commission. This Directorate General is divided into two Directorates, one for Health and one for Consumers, each represented by a commissioner. The Directorate for Public Health is

organized in seven units.⁶³ Unit C3 “Health Threats Unit” is especially invested in health threats such as influenza. The Network for Communicable Diseases is implemented with help of a regulatory comitology committee.⁶⁴ This means that if the Commission would want to propose measure in the area of communicable diseases that exceeds its implementing power, the Committee can refer the Commission decision to the Council.⁶⁵ This committee consists of representatives of the Member States and is chaired by a representative of DG SANCO.

The set up of the European Centre of Disease Control (ECDC) in 2004, strengthens the Network for Communicable Diseases. The Centre has to provide independent scientific advice in order to improve the existing networks under the network for Communicable Diseases, such as the Early Warning and Response Network and the Surveillance networks. Under this unit the Commission organizes the Network for Communicable Diseases.⁶⁶ This agency, has no regulatory powers,⁶⁷ however it does have the task to coordinate the networks that are part of the Network of Communicable Diseases (Art. 3d) and to carry out risk assessments.

The Commission Health Emergency Operations Facility⁶⁸ and the Health Security Committee (HSF), put in place by the Council in 2001, are founded on Article 152 EC Treaty and Decision 211/98/EC on the European Network for Communicable diseases in the European Union.⁶⁹ It also has its basis in the Public Health Programme, which outlines European objectives for the response to a public health crisis.⁷⁰ The HSC provides a setting in which emergency decisions can be

⁶³ See the public health website of the Commission at: http://ec.europa.eu/health/index_en.htm

⁶⁴ (C19700) Committee on the decision to set up a network for the epidemiological surveillance and control of communicable diseases Generated by the Comitology Register on 29/04/2010.

⁶⁵ See Council Decision, Laying down the Procedures for the Exercise of implementing powers conferred on the Commission (1999/468/EC) Article 5.

⁶⁶ Decision 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community; also see Regulation(EC) 851/2004 of the Parliament and of the Council, establishing a European Centre for Disease Prevention and Control (OJ L142/1)

⁶⁷ See *ibid*, at r. 6.

⁶⁸ The Health Emergency Operations Facility is located in Luxembourg and is used for the management of alerts and emergencies notified by Member States. During an emergency situation the response of the Commission, Member States, and Agencies residing under the Commission including the liaison with international organizations such as the WHO are coordinated from this facility.

⁶⁹ See *ibid*. **Error! Bookmark not defined.**

⁷⁰ See the current public health programme, Decision No 1350/2007/EC of the European Parliament and of the Council establishing a second programme of Community action in the

taken on the European level, that surpasses the Early Warning and Response System which is part of the Network for Communicable Diseases in cases where responsibility for action is actually exclusively with the Member States. The Member States representatives in the HSC are authorized by their health ministers to make coordinated decision and commitments with respect to responding to major health threats.⁷¹

However, representatives of D-G SANCO and other relevant Commission services and agencies, such as the European Center for Disease Control and the European Medicines Agency are also part of the HSC. Experts can be invited to the meetings and there are working groups that reside under the HSC. Within the EU institutional structure, the HSC is an informal EU Committee and relies on scientific and technical support on the European Centre for Disease Control.⁷² The HSC has to assess this scientific advice, also that provided by other agencies, such as the European Medicines Agency and assesses the political social and economic implications European health emergency decisions would have.⁷³ The Health Security Committee also provides advice on decisions to be taken in the Council or in the Commission.

A) What Should Happen in Case of an Emergency?

In case of a public health emergency, under coordination of the HSC, its task is to provide ongoing information to the Commission and the Member States. In order to do so various tools have been set up to gather and disseminate information. These systems allow public health authorities in Member States and the Commission to receive and trigger an alert as well as exchange information regarding events that might affect public health at EU level and the coordination of measures.⁷⁴

The Commission has outlined that it is authorized to declare a pandemic on the basis of decision No 2119/98/EC on Communicable Diseases.⁷⁵ However, it is questionable that this is part of the implementation authority of Article 7 in this

field of health (2008-13) (O.J. L 301/3).

⁷¹ See Communication from the Commission to the Council on transitional prolongation and extension of the mandate of the Health Security Committee in view of a future general revision of the structures dealing with health threats at the EU Level, COM (2006) 699. Also see Health Council of February 2007.

⁷² Ibid.

⁷³ See *ibid* at 5.

⁷⁴ Such as the rapid alert system.

⁷⁵ See *ibid*. 66.

Decision. The main purpose of the Decision is setting up a network and establishing cooperation (Art 1) whereas the declaration of a pandemic has further reaching implications on Union level, such as with regard to the authorization of vaccines, than foreseen in the communicable diseases decision. The Commission nevertheless can declare a pandemic independently of the WHO. The Commission does use the WHO 6 phase alert system. If the level is raised to 6 (pandemic), the European emergency architecture, also with respect to the authorization of pandemic vaccines, becomes operational.⁷⁶

2) The Response to the Influenza A H1N1 Pandemic

After the outbreak of the new strain of influenza became apparent in April 2009, following notifications by the WHO and the US and Mexico European coordination was primarily led under auspice of D-G SANCO. On June 11, 2009 the WHO raised the pandemic alert Phase 6, which reflects the fact that influenza A H1N1 had spread to multiple parts of world. The declaration of a pandemic is significant in terms of the spread of the virus, not in terms of its severity of illness caused by the virus. The Commission in turn, activated the Health Emergency Operations Facility for a daily monitoring of the spread of the influenza H1N1. The emergency facility was on-duty 24/7 and brought daily reports on the epidemiological situation and what measures should be implemented and what information should be put forward to the public.⁷⁷ The Health Security Committee oversaw the early warning and response and surveillance systems linking the Member States, the Commission and relevant players to ensure a rapid and effective response by the EU. Moreover there was permanent contact with Member States, the ECDC, the WHO and Public Health Departments and Centers in the world through the Global Health Initiative Channel.⁷⁸

⁷⁶ See DG SANCO's The Commission Health Emergency Operations Facility,; For a Coordinated Management of Public Health Emergency at EU Level (2007) in which the former EU 3 level emergency structure was still outlined.

⁷⁷ See EU Factsheet April 2010, Pandemic H1N1 2009.

⁷⁸ The Global Health Security Initiative (GHSI) is an informal, international partnership among countries to strengthen health preparedness for pandemic influenza, amongst other public health threats. This network was an initiative in November 2001 of Canada, the European Union, France, Germany, Italy, Japan, Mexico, the United Kingdom and the United States. The World Health Organization serves as an expert advisor to the GHSI. The network is made up of the Public Health Agency of Canada, Health and Consumer Protection

On the 30th of April 2009, on the basis of the advise of the European Centre for Disease Control, the Health Security Committee adopts a legally binding case definition, specifically for the Influenza H1N1. This meant that Member States were obliged to report incidences of the influenza in accordance with this definition through the EU Network for Communicable Diseases. This decision is implemented by the Commission on the basis of its implementing powers under the Communicable Diseases Decision from 1998, on the basis of a Comitology procedure.⁷⁹ The Council, on that same day, welcomes this work of the WHO and the ECDC and the Health Security Committee on the common case definition and providing technical guidance of what should be done in terms of prophylaxis and treatment regarding persons that have been infected, or have been in contact with infected persons, which is based on the advise hereto from the HSC. The Council conclusions also outline that with regard to curbing the spread of the pandemic, Member States should take 'all appropriate measures' with regard to travel (bans) on the basis of the advise of the HSC and the European Centre for Disease Control, together with the WHO.⁸⁰

On the 12th of July, the Commission decides that in case of a communicable disease with an EU dimension, where tracing of personal contacts of infected persons is necessary, the Member States need to collaborate through the Early Warning and Response System and exchange information. The legislative basis for this decision is first of all the Communicable Disease Decision, but also the public health exception with regard to the protection of personal data in Article 8(3) of Directive 95/46/EC and Article 10(3) of Regulation EC 45/2001, inasmuch as the exchange of data takes place between recognized health professionals.⁸¹ The patients in this regard should be informed on the fact that their contacts are being traced, unless 'this proves

Directorate General of the Commission, Ministère de la Santé et des Solidarités of France, The Federal Ministry of Health of Germany, The Ministry of Health of Italy, Ministry of Health, Labour and Welfare of Japan, Ministry of Health of Mexico, Department of Health of the UK, Department of Health and Human Services of the USA and the WHO

⁷⁹ Commission Decision of 30 April 2009 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council COM(2009) 3517)

⁸⁰ See Council Conclusions on Influenza A/H1N1 infection 30 April 2009, Luxembourg - Council of the European Union, employment, social policy, health and consumer affairs.

⁸¹ Moreover, Article 23 (1) of the WHO IHR's also provides that the WHO may require state parties to exchange data on passengers traveling and tracing contact of infected patients.

impossible or involves a disproportionate effort'.⁸² The Commission in this regard bases its authority on the implementation of Decision 2119/98/EC on Communicable Diseases and the Comitology procedure in Article 7 of that Decision.

On 12 October 2009 the Council decides on a strategic approach to the outbreak of influenza A H1N1 on the basis of a Commissions Communication on the pandemic.⁸³ It is firstly recognition the informal cooperation measures that had taken place in the context of the Health Security Committee. For instance the decisions on agreements on school closures, symptomatic individuals traveling and on target and priority groups for vaccination. In this context the Council also recognizes the importance of the Strategic Advisory Group of Experts (SAGE) on immunization in WHO context, with regard to their vaccination strategy.⁸⁴ Especially with regard of information of public health risks, it is agreed that the advice of the European Centre for Disease Control and the WHO in this regard would be leading. Moreover, in terms of information and communication of the public it reinforces the role of the Health Security Committee. ⁸⁵ By that time, three vaccines had already been authorized by the Commission, on the basis of the fast track procedure for pandemic vaccines by the EMEA. Vaccinations generally were the primary focus of the influenza A H1N1 strategy to curb the spread of the pandemic.

3) Vaccines

The EU and Member States share the responsibility of authorizing vaccines and pharmacovigilance. On this basis, the Member States developed a shared strategy on priority groups for vaccination, within the Health Security Committee on 25 August 2009.⁸⁶ With respect to allowing influenza vaccines onto the European market, on

⁸² Commission Decision of 10 July 2009 amending decision 2000/57/EC on the early warning and response system for the prevention and control of communicable diseases under Decision 2119/98/EC of the European Parliament and of the Council (2009/547/EC).

⁸³ Communication from the Commission Pandemic (H1N1) 2009 (COM (2009) 481); see further {SEC(2009) 1188}, {SEC(2009) 1189}, {SEC(2009) 1190}, {SEC(2009) 1191}, {SEC(2009) 1192}.

⁸⁴ This expert group is currently under investigation by the Parliamentary Assembly of the Council of Europe, since it is suspected that its advise might have been relied on too heavily by the WHO executives, especially in light of some conflicts of interest within the pharmaceutical industry of its members.

⁸⁵ Council Conclusion on Pandemic (H1N1) 2009 – A Strategic Approach, Luxembourg, 12 October 2009.

⁸⁶ EU Health Security Committee (HSC) / Early Warning and Response System (EWRS)

the European level, the central authorization procedure would be mandatory. However, at the same time national authorities can also approve vaccines. In that case the mutual recognition regime would apply for distributing the vaccine across the EU. On this basis, in the European context, the EMEA scientifically assesses vaccines, and the Commission decides ultimately on authorization.⁸⁷

In case of an influenza pandemic however, this process can be sped up once a pandemic is declared. In this case there are scientific and regulatory processes that are specially designed for a pandemic. Once a pandemic has been declared, a central conditional marketing authorization may be granted on the basis of less comprehensive data in terms of safety and efficacy compared the regular authorization procedure, if this happens in order to fulfill unmet medical needs and there is sufficient proof of a positive risk-benefit balance.⁸⁸ In the case of the influenza H1N1 pandemic, for this reason “rolling review procedure” has been adopted by the European Medicines Agency, to allow for a faster review of vaccines.⁸⁹

In order to speed up the development of vaccines even more, the Commission as part of the general health emergency structure, already in 2007 approved some influenza vaccines as pandemic mock-up dossier under exceptional circumstances. These are used as prophylaxis in case of influenza. What this means is that less of the virus antigen is needed when combined with adjuvant monovalent influenza vaccines: if there is an influenza pandemic, since the “general” part of the medicine was already approved by the Commission, the process of approving the specific vaccine for the pandemic would be much faster. Where usually the process may take up to 210 days, in this case the procedure only has to take 70 days.⁹⁰ Once enough data has been gathered to show that the vaccine’s benefits outweigh its risks, the

HSC/EWRS Statement on Influenza A(H1N1) 2009: target and priority groups for Vaccination 25 August 2009.

⁸⁷ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

⁸⁸ Article 14(7) Regulation EC 726/2004; Commission Regulation (EC) 507/2006 These authorizations however only have a validity of one year and need to be backed up with extra scientific data and may have to be involved in to specific additional obligations in the area of collecting data for pharmacovigilance

⁸⁹ In his regard the EMEA has developed specific technical guidelines www.emea.europa.eu/htms/human/pandemicinfluenza/vaccines.htm.

⁹⁰ See *ibid*

company is obliged to make a formal application to the European Medicines Agency, so that the vaccine can be authorized for use.⁹¹

A) Limited Civil and Administrative Liability for the Influenza A H1N1 Vaccine

Vaccines can thus be authorized using this emergency procedure and can get “temporary approval” after the receipt of application, even before the full procedure of scientific and regulatory assessment has been completed.⁹² In this case marketing authorization holders, manufacturers and health professionals are not subject to civil or administrative liability for the use of a vaccine, as long as the vaccine is used in response to a declared pandemic.⁹³ The conditions under which the authorization scheme is allowed has to be either based on the recognition of the high level of the threat the WHO and/or on the basis of 1998 Decision on Communicable Diseases.⁹⁴ The shield for administrative and civil liability applies also when the unauthorized vaccines is being used beyond the conditions for use (for instance for other age groups) and for pandemic vaccines that have been approved by national authorities. In case of the influenza H1N1 vaccines, this process of conditional authorization by the European Medicines Agency is eventually adopted for most of the first vaccines that were distributed and given to millions of Europeans.⁹⁵

Access to a vaccine; being part of a priority group that has first access to influenza medicine; having personal contacts traced and medical files shared among public health authorities across the EU; being screened for symptoms of the disease by aircraft personnel or closing schools, are all measures that have a potentially deep impact in the lives of Europeans. The fact that no administrative or civil liability is

⁹¹ See *ibid.* supra note 83.

⁹² See Commission Regulation EC No 507/2006 of 29 March 2006 on the Conditional Marketing authorization for medicinal products for human use falling within the scope of Regulation No 726/2004 of the European Parliament and of the Parliament.

⁹³ Article 5 Directive 2001/83/EC

⁹⁴ See *ibid.* supra note 88

⁹⁵ Five vaccines have been authorized on the basis of these procedures, available for use H1N1 influenza pandemic Focetria, Pandemrix, Celvapan, Arepanrix, Humenza, Certain effects that might be seen with pandemic vaccines have been classified as ‘adverse events of special interest’. These effects have been seen with some vaccines in the past and need to be monitored very closely. Even if not caused by a pandemic vaccine, any cases of these adverse events will need to be reported to companies and to regulatory authorities for assessment as a matter of urgency. They include problems affecting the nervous system, anaphylaxis (severe allergic reactions) and vaccination failure.

possible for the authorization and distribution of a vaccine that has not been checked in accordance with standard safety procedures, and that all this is based on an emergency structure that in a European institutional context is rather informal, potentially has some significant constitutional implications.

PART 3 CONSTITUTIONAL IMPLICATIONS OF THE EUROPEAN RESPONSE TO THE INFLUENZA A H1N1 PANDEMIC

Introduction

The measures adopted in response to the influenza A H1N1 pandemic on the European level, show that European public health policy affects Europeans directly. Public health law pertains to the management of health risks of a population at large (public health *policy*). In this sense, it establishes a the fundamental balance between government intervention in the management of risks to the public and individual rights, but it is also the field of law that pertains to how and what political choices are made with regard to public health priorities.⁹⁶ Looking at the institutional dynamics in which the influenza A H1N1 measures were adopted, using comitology, the Health Security Committee, the different agencies, experts, the WHO the Member States, the Council and the Commission, one wonders if this emergency structure is legitimate? In the context of the EU the question of legitimacy in legal terms can be assessed with reference to European constitutional principles. In this regard the central question for this next part is: What are the constitutional implications of the European response to the influenza A H1N1 pandemic?

1) Constitutional Principles in Europe

Generally, constitutionalism refers to both legal procedural safeguards to unbridled government power and the safeguarding of fundamental rights.⁹⁷ The institutional and constitutional set up of the EU is the result of a complex history of integration,

⁹⁶ See L.O. Gostin, *The Theory and Definition of Public Health*, in *Public Health Law: Power, Duty Restraint* (University of California Press, 2008).

⁹⁷ J. Habermas, 'Why Europe Needs a Constitution' in R. Rogowski and C. Turner (eds), *The shape of the new Europe* (Cambridge University Press: 2006); M. Tushnet, *The New Constitutional Order* (Princeton University Press: 2004; also see J.H.H. Weiler 'A Constitution for Europe? Some Hard Choices' 40 *Journal of Common Market Studies* 4, 563-580 (2002).

constitutionalisation and constitutional construction.⁹⁸ The Treaty on the Functioning of the EU⁹⁹ and the Treaty of European Union¹⁰⁰ form a constitutional basis for the institutional structure of the European Council, the Council of Ministers the European Parliament, the Commission and the Court. And through this institutional order the European Union exerts power and resources on European citizens and Member States,¹⁰¹ through instruments, institutional and legal restraints and processes through its own particular European constitutional set-up.¹⁰² This particular constitutional set-up sets the EU apart from other international organisations. Already in the landmark case *Van Gend and Loos* in '62, the European Court of Justice referred to the EU as a 'new legal order of international law for the benefit of which the states have limited their sovereign rights'.¹⁰³

Within this legal order neither the Member States nor the Union (former EC) institutions can avoid review of the conformity of their acts with the 'constitutional charter', the EU encompasses 'a Community based on the rule of law'.¹⁰⁴ Moreover, the legal order of the EU is also binding on EU institutions and Member States with respect to fundamental rights.¹⁰⁵ The Court in this respect has played a significant role in conferring a constitutional status on the political and institutional structure of the EU. In a historical perspective then the conceptualization of the nature of the European constitutional order is not found in (a) revolutionary constitutional moment(s).¹⁰⁶ It is the product of constitutional sedimentation, a living organism that is shaped through constitutionalisation of institutional practices, integration and formal treaty revisions.¹⁰⁷

From an internal, normative perspective, the constitutional order of the EU is structured by constitutional principles such as a separation of powers, the principle

⁹⁸ M. Longo, *Constitutionalising Europe: Processes and Practices* (Aldershot: Ashgate, 2006).

⁹⁹ Treaty on the Functioning of the EU (O.J. 115/49).

¹⁰⁰ The Treaty on European Union (O.J. 115/15).

¹⁰¹ See P. Mair 'Popular Democracy and the European Union Polity ' C-05-03 *European Governance Papers* (2005).

¹⁰² *Ibid.*

¹⁰³ *NV Algemene Transporten Expeditie Onderneming van Gend & Loos v. Netherlands Inland Revenue Administration* [1963] ECR 1 .

¹⁰⁴ *Case 294/83 Les Verts v. Parliament* [1986] ECR 1339, para. 23.

¹⁰⁵ Article 6 (2) TEU.

¹⁰⁶ L.F.M. Besselink, 'The Notion and Nature of the European Constitution after the Lisbon Treaty' in J. Wouters, L. Verhey and P. Kiiver (eds), *European Constitutionalism beyond Lisbon* (Intersentia: Antwerp, 2009) at 162.

¹⁰⁷ D. Curtin, 'The Sedimentary European Constitution: The Future of 'Constitutionalisation' without a Constitution' in I. Pernice and E. Tanchev (eds), *Ceci n'est pas une Constitution - Constitutionalisation without a Constitution?* (Nomos: 2009).

of the limited powers, implied power, supremacy and direct effect and subsidiarity, non-discrimination, respect for fundamental rights, respect for national identities and respect for general principles of law.¹⁰⁸ These principles in the context of the European political system are straddled by three overarching principles, the rule of law, democracy and fundamental rights, including fundamental freedoms (Article 2 TEU).¹⁰⁹

A) The Rule of Law

Article 2 TEU refers to the rule of the law as one of the founding principles of the Union. Although there is some inherent ambiguity on the precise meaning of this principle, in the context of the Union, the rule of law more generally means that the Union is bound by legal rules.¹¹⁰ In this first sense, principle of the rule of law means that legal acts of European institutions and actors with (delegated) European public powers, not only with respect to the adoption of legal measures, but also with respect to implementation, have to be in conformity with European legal rules and procedures. This “administrative legality” is the basis of a number of legal procedural doctrines. For instance, the EU can only act in those areas where it has exclusive, shared or complementary, supporting or supplementary competence to act (Articles 2a-2e TFEU).¹¹¹ In the second sense, the rule of law also extends to the principle of judicial process or the right to due process. With regard to judicial review Article 263 TFEU is central in that it allows for judicial review of procedural aspects of treaty amendments, secondary EU law and procedural and substantive implementing acts. However due process also includes the concept of administrative review, whereby the exercise of public power of EU actors is checked through administrative supervision and public accountability, which takes place through different processes across different sectors on the European level.¹¹²

¹⁰⁸ F. Snyder, 'The Unfinished Constitution of the European Union: Principles, Processes and Culture'

¹⁰⁹ Compare M.P. Maduro 'Europe's Social Self: "The Sickness Unto Death"' 2 *conWEB – webpapers on Constitutionalism and Governance beyond the State* (2000).

¹¹⁰ B. Tamanaha, *On the Rule of Law, History, Politics, Theory* (Cambridge University Press: 2004).

¹¹¹ See Protocol on the exercise of shared competence (C306/158).

¹¹² M. Asimow 'The Many Faces of Administrative Adjudication in the European Union' *Administrative Law Review* (2008).

a) EU response to Influenza H1N1 in light of the principle of the Rule of Law

Public health policy is an example where europeanization does not necessarily takes place as a resultant of constraining Member States competence but by interplay of national and European actors and pressures.¹¹³ Indeed, with regard to public health there is only limited competence in Article 168 TFEU. The objective of the 1998 Decision on Communicable Diseases was merely to facilitate cooperation in this area, and not to provide a mechanism in which Member States would transfer some of their authority and responsibility for public health measures to the European level. In order to respond to health threats, nonetheless the Member States in 2001, after the terrorist attacks did want to create an emergency structure. Therefore the informal Health Security Committee was put in place. This Committee, as the response to the influenza A H1N1 shows, has become the central actor in terms of responding to health threats.

The decisions taken in this committee have the status of multilateral international agreements, as each of the Member States representatives in the HSC has been given the authority to make decisions. They represent their respective (ministerial) health departments. In terms of its working methods, the role of experts within the Committee and oversight, there are no formal procedures, as it is not a formalized Committee in terms of for instance the comitology committee in the context of the Network of Communicable diseases. The implication is that the Health Security Committee, in an emergency situation can create and propose measures that have a deep impact in the lives of Europeans without legal constraints. It is unclear according to what rules the HSC decides, besides that it weighs the political, social and economic impact of the expert advice that is given by the ECDC, the EMA and other experts, that also take part in its deliberations.

As to the decisions taken by the Commission in response to the influenza A H1N1 through the comitology procedure in the context of the 1998 Communicable Diseases decision, the question is how it was possible that these decisions could not be regarded as being outside the scope of implementation of the Decision from 1998. For instance it is hard to see how a decision to screen the contacts of particular patients with other people, falls within the Decisions' objective of setting up a network on Communicable diseases.

¹¹³ See M.A. Pollock, 'Theorizing EU Policy-Making' in H. Wallace, W. Wallace and M.A. Pollock (eds), *Policy-Making in the European Union* (Oxford University Press: 2005). at p. 40.

The most poignant implication of looking at the European response to the influenza A H1N1 in the context of the principle of the rule of law is the decision to declare a pandemic. Where the Commission and the regulations on conditionally authorizing vaccines outline that this declaration should be based on the 1998 Communicable Diseases Decision, there no provision in this decision to that effect. *How* the Commission, through what procedure, in accordance with what *checks*, can declare pandemic is actually unclear. The policy documents in this respect seem to point out that there has to be scientific agreement to this effect and that there should be coordination with the WHO. However, who, and where the wider implications of such a declaration are carefully deliberated is not clear. At the same time, declaring a pandemic has made possible that millions of European have received a vaccine that was only conditionally approved for distribution. Moreover, since the possibility for bringing a civil or administrative suit in case of medical complications as a result of one of the influenza vaccines is impossible, both on a national and European level, access to justice is barred in practice with regard to one of the main counter measures (a vaccine) to the influenza A H1N1 pandemic.

B) The Principle of Democracy

The Union is founded on the constitutional principle of democracy (Article 2 TEU). democracy within the European political system has a dual nature. On the one hand Member States are represented in the Council, whose representatives are democratically elected on the national level. On the other hand European citizens (Article 9 TEU) are represented directly by the European Parliament. In the context of the European constitutional order the concern is that the transfer of legislative powers from the Member States to the EU is not matched by an equivalent degree of democratic accountability and legislative input by the European Parliament, or any other democratically representative body.¹¹⁴ Democratic legitimacy with regard the Council in this sense is problematic. Its democratic legitimation is derived from delegation, in that it consists of delegates of national democratically elected governments.¹¹⁵ However at the European level it forms rather the executive centre

¹¹⁴ A. Heritier, 'Composite Democratic Legitimation in Europe: the Role of Transparency and Access to Information' MPI Collective Goods Preprint No. 2001/6

¹¹⁵ See J. Shaw, A. Wiener, The Paradox of the 'European Polity' in M G Cowles, M. Smith (eds.), State of the European Union 5: Risks, Reform, Resistance, and Revival, Oxford

together with the Commission.¹¹⁶ These are not directly accountable to the national parliaments nor to the European Parliament and often decisions are taken in secrecy. In this view an increased role for the European Parliament is the immediate compensation for reduced competencies of national parliaments by the expansion of unchecked executive power on the European level.¹¹⁷

a) EU response to Influenza H1N1 in light of the principle of democracy

The response to a health emergency is typically a responsibility for the executive branch of government. It is part of the responsibility of public authorities that are mostly represented by health departments. The reason is of course that it is too risky to wait for a parliamentary legislative procedure. The same goes for the response to the influenza A H1N1 at the European level. Decisions were taken with regard to passenger screening, school closures, contact tracing and vaccine authorisation. This took place, mostly within the institutional context of the Commission, but with later affirmation of the Council. Now the question is to what extent these decisions were democratically legitimized. In other words, were the actors in some way representing an electorate, and is it possible to hold these actors to public account afterwards?

The Member State representatives in the Health Security Committee are principally representing their Health departments at the Member State level. However at the European level, they are acting as a quasi-formal institutional decision maker. At the same time this body is also compiled –to what extent is not clear– of experts from either Member States or European agencies. In what way these experts exert influence in the decision making of the HSC is not clear either, as there are no formal procedures by which this body works, since its nature remains informal. Nevertheless Member State representatives are subject of oversight by their national health departments, which are checked by the national parliaments.

The question is however to what extent this democratic oversight is practicably realizable. The emergency decision-making takes place in Brussels and is often based

University Press, 2000; also see generally D. Curtin, *The Constitutional Structure of the Union: A Europe of Bits and Pieces* 30 *Common Market Law Review*, (1993) 17-69.

¹¹⁶ D.M. Curtin, *Executive Power of the European Union. Law, Practices and the Living Constitution* (Oxford University Press: 2009).

¹¹⁷ See A. Follesdal and S. Hix 'Why There is a Democratic Deficit in the EU: A Response to Majone and Moravcsik', 44 *Journal of Common Market Studies* 3, 533-562.; also see broadly D. Curtin, a 'Comment on Rittberger and Lord', in B. Kohler-Koch, B. Rittberger (eds.) *Debating the democratic legitimacy of the European Union*, (Rowman and Littlefield Publishers, 2007).

on lengthy expert reports. Moreover at the European level, the Parliament has no formal role to look into the decision-making of the HSC as it is an informal committee. Nevertheless there is a current initiative by some MEPs' in the Europe Parliament to look into the role of experts and undeclared conflicts of interest that might have led to an over-exaggeration of the severity of the Influenza A H1N1 causing inter alia Member States to order a lot more vaccines than they needed.

C) Fundamental Rights

Article 6 TEU provides a general guideline on the status of fundamental rights in the EU.¹¹⁸

1. The Union recognises the rights, freedoms and principles set out in the Charter of Fundamental Rights of the European Union of 7 December 2000, as adapted at Strasbourg, on 12 December 2007, which shall have the same legal value as the Treaties (...)

Importantly, this implies that the Charter, which holds fifty-four provisions on fundamental and social rights, will obtain the status of primary law, in contrast with the proclamation in Nice in 2000, where it was given the status of an inter-institutional agreement.¹¹⁹ The principle of adherence to fundamental rights has developed firstly in the case law of the ECJ, where with the increasing powers and supremacy of European law, the ECJ started referring to fundamental rights by referring as 'general principles of community law' drawing on the European Convention of Human Rights and the constitutional traditions common to Member States.¹²⁰

a) EU response to Influenza H1N1 in light of Fundamental Rights

With regard to the outbreak of a communicable disease generally the infringement of

¹¹⁸ The Treaty on European Union (O.J. 115/15).

¹¹⁹As the declaration to the Lisbon Treaty refers to the case law on supremacy of Union law, it will mutatis mutandis also apply to the provisions of the Charter, see for an in-depth analysis here J. Rochère, 'The Protection of Fundamental Rights in the EU: Community of values with Opt-Out?' in I. Pernice and E. Tanchev (eds), *Ceci n'est pas une Constitution - Constitutionalisation without a Constitution?* (Nomos: 2009).

¹²⁰ F. G. Jacobs, 'The European Convention on Human Rights, The EU Charter of Fundamental Rights and the European Court of Justice: The impact of European Union accession to the European Convention on Human Rights' in, I. Pernice, J. Kokot, C. Saunders (eds.): *The Future of the European Judicial System in a Comparative Perspective* (Nomos 2006).

individual rights can lie in counter measures: these may restrict movement of people and goods, they can have a direct impact on social and economic life and can have a legal impact in many ways. Especially when one considers that countermeasures could include quarantine, selective immunization of a predefined group and the requisition of property and medical facilities. Counter measures can even warrant law enforcement actions in order to enforce public health measures.¹²¹ Counter measures then immediately affect the fundamental and constitutional balance between the protection of the population at large and the rights of the individual. This connection between government, health and fundamental rights is widely established in international legal instruments and national constitutions.¹²²

The main counter measures in response to the influenza A H1N1 related to the authorization of vaccines, passenger screening, possible school closures, information exchange on specific patients and contact tracing. In many of these cases, fundamental rights could come into play with regard to the right to privacy as a result of exchange of information.¹²³ Much of the medical dossier of patients is part of the confidential relationship between the patient and the doctor. However, this personal medical information was exchanged on patients across the EU through the Early Warning and Response System. Although a public health emergency is an exceptional situation, the extent of the information exchange in this regard is not clearly outlined and bordered off within the European emergency structure.¹²⁴

Nevertheless also in the context of social rights the response to the influenza A H1N1 has some implications. For instance the decision to prioritize certain groups for vaccination has implications with respect to the equal right to access health care, as in Article 35 of the Charter of Fundamental Rights of the EU. Although it might reasonably make sense from a risk management perspective to prioritize certain

¹²¹ See Technical guidance documents on generic preparedness planning, Commission interim document April 2005 at 35-37.

¹²² See Universal Declaration of Human Rights 1948, Article 25; European Social Charter 1961, Articles 11 and 13; International Covenant on Economic, Social and Cultural Rights 1966, Article 12; Convention on the Elimination of all forms of Discrimination against Woman 1979, Article 12; Convention of the Rights of the Child 1989, Article 24; European Social Charter 1994 (revised), Articles 11 and 13, Convention on Human Rights and Bio Medicine 1997, Article 3; also see A. den Exter and H. Hermans eds. *The Right to Health in Several European Countries* (The Hague: Kluwer, 1999); also see T. Hervey, 'The "Right to Health" in European Union Law', in T. Hervey & J. Kenner (eds.) *Economic and Social Rights under the EU Charter of Fundamental Rights*: (Hart Publishing, 2003) at 193.

¹²³ See T. K. Hervey & J. V. Mc Hale, *Health Law and the European Union*, (Cambridge University Press, 2005) at 21.

¹²⁴ See *supra* at page 15.

groups for vaccination, these types of decisions at the same time also have constitutional implications. The same goes for instance for a decision on school closures in the context to the right to education.

Conclusion

When the response to the influenza A H1N1 pandemic is analyzed in the context of European constitutional principles, it shows that the role of the EU in public health has significant constitutional implications, regardless of actual legislative competence. Although formally much of the cooperation that takes place can be labeled under national responsibility, the European institutional structure provides a forum in which executive actors can make decisions that have far reaching implications for the rights of European citizens.

In historic context the European framework for public health emergencies has developed in tandem with the increasing risk and incidence of the spread of communicable diseases and biological terrorist attacks, that is facilitated through an ever-increasing integration of global and European movement of persons and trade. The growing reliance on science-based policy in the area of public health has made recommendations of agencies such as the ECDC and other international expert committees, increasingly important.

The European institutional context in which actors from national public health authorities, experts and European actors respond to the influenza H1N1, works for a large part on the basis of cooperation and a reliance on expert scientific advice regardless of the limited legislative public health basis. Significant in this respect is the lack of a formal European procedure through which a pandemic may be declared, allowing for the activation of a formalized process of conditional authorization of the distribution of vaccines to millions of Europeans, without any possibility for later administrative or civil liability.

Clearly the nature of a health emergency warrants a certain executive discretionary competence in order to respond swiftly. However, at the same time, as the countermeasures to health emergency can impact individual rights to the extent we have seen in response to the influenza A H1N1, one would expect proper procedures and checks in place within the emergency structure. European Member States remain reluctant to transfer competence for health policy over to the European

level. At the same time a health emergency warrants European cooperation. The result is that the response to the influenza A H1N1 to a large extent is orchestrated within the institutional context of the European Union, on the basis of informal cooperation, far removed from the national parliaments, yet also without European institutional oversight.