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Public Health Diplomacy

A Legal Perspective

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This paper explores the issue of health diplomacy from three perspectives. The first is the debate on health as a national or an EU competence; the second is the definition of what health diplomacy was and is; finally, it explores what this might mean for the future post COVID-19. In its conclusion, the paper raises the question of the need for global political leadership in the future as the failure of cooperative action and the undermining of multilateral institutions during the current pandemic are deemed to have contributed to the weak global response to COVID-19.

EU Health Competence

Health is a shared competence in the EU, i.e. shared between the institutions of the EU, especially the European Commission, and the Member States. The EU has a limited right to act in the field of public health but has no role (other than monitoring) in the provision or delivery of healthcare, which remains a national competence, thereby placing the Member States in the driver's seat.

The Commission's competence has grown over the years since the Maastricht Treaty and is now set out in **Article 168 TFEU** since the Lisbon Treaty in 2007 (previously in Article 152). This article confers competence in a number of specific health policy areas such as food safety, veterinary and plant health, measures on human organs and blood, and animal health and welfare.

EU legislation relying on Article 168 TFEU confers strong powers in the protection of food safety and animal health. The emphasis on these two policy areas is a consequence of the food safety scandals in the 1990's, in particular, BSE (or Mad Cow Disease) which caused the deaths of hundreds of thousands of cattle, and its human equivalent CJD, from which hundreds of people died. The fact that there was an acknowledgment by the UK in 1996 of a causal link between the two diseases created significant political pressure for remedial action.

EU Food Safety Powers

The clarity and strength of the Treaty powers conferred on food safety and animal health has brought considerable benefit. This EU legislation is arguably the best and safest in the world. Following the White Paper on food safety published in January 2000, four months after the setting up of the first health Directorate General in the Commission, extensive legislation was enacted in the European Parliament and Council. The most important was the General Food Law (178/2002) which established the European Food Safety Authority (EFSA) and the basic principles of food law. This was followed by more than 80 other legal measures over the following years. It is EFSA's function to provide the scientific advice to the European Commission which then introduces the necessary legislation to ensure adherence to the advice and controls to ensure compliance.

This scientific/legal structure is supported by the work of the Food and Veterinary Office (FVO), located in Ireland since 1997, carrying out inspection, surveillance and controls wherever food is being produced for the EU Single Market. This robust safety system removes non-compliant food from the market and bans the importation of such food from outside the EU.

To reinforce this safety regime, the EU joined as a full member, the Codex Alimentarius Commission (CAC), a UN body established by the World Health Organisation and the FAO, for the purpose of draw-

ing up an international code of Food Safety. Although not initially intended as such, compliance with this code has become the de facto requirement for global trade in food.

All of this has been achieved by building on the Treaty competence contained in Article 152 of the Amsterdam Treaty in 1999, which was renumbered Article 168 in the Lisbon Treaty in 2007.

EU Powers in Human Health

In contrast to these powers in food safety and animal health, Article 168 limits EU competence to "incentive measures" designed to protect and improve "human health" and specifically excludes "harmonisation of the laws and regulations of the Member States". It is this provision which, in the area of human health (unlike in animal health) contains the limitation of precluding the Commission from initiating legislation by Directive, which is the normal route for the enactment of legislation with the European Parliament and Council for the harmonization of national laws. This reflects the view held over the years that in public health particularly as it relates to human health, there has been a desire to proceed on an intergovernmental basis rather than by use of the "community method" where the EU has the leadership role with the Member States. This is the legal position which has existed since the setting up in 1999 of the new health and food safety department/Directorate General in the European Commission, then named DG SANCO, now called DG SANTE reporting to Commissioner Stella Kyriakides.

So, the question is whether the exclusion of harmonisation in Article 168 adversely affected progress in the development of human health policies. Certainly, DG SANCO was apprehensive that it would, and so in 2001/2002 expressed its concern, following which the European Commission made submissions to the Convention on the Future of Europe, seeking to put human health and pandemic preparedness on a Treaty footing to enable the EU to initiate harmonization of legislation on infectious diseases. Unfortunately, this request was unsuccessful. It should be said that in 2013, Decision No 1082/2013/EU on serious cross-border threats to health was established to provide a limited legal framework for EU level of coordination on health security but which excluded harmonisation.

Nonetheless, the Commission was not deterred by this limitation. From its inception DG SANCO had an ambition to introduce anti-tobacco legislation requiring Member States to introduce controls into their laws on cross border advertising and sponsorship and also on the production, marketing and sale of tobacco products. As this would have called for harmonisation of national laws, Article 152 alone could not have been the legal base. So, it was decided to add a second legal base contained in Article 95, the legal base for the regulation of the Internal Market.

Following a legal challenge by some Member States in the European Court of Justice, it was decided by the Court that the proposed legislation was lawful as its purpose was to regulate and harmonise the existing cross-border trade in tobacco. The legislation could not have imposed rules on purely national trade, for example by attempting to ban advertising in cinemas, as this would not have had a cross-border dimension. One of the main consequences of this court decision was the banning of tobacco advertising and sponsorship of motor racing teams in Formula 1 racing in the EU, which ultimately had the effect of ending it worldwide.

One further example of the effect of enhancing the narrow legal base in public health occurred following a series of judgements of the Court of Justice in the Kohl/Decker cases, where Mr Kohl and Mr Decker, two Luxembourg nationals were refused reimbursement by their social insurance fund, one for the cost of spectacles purchased in Belgium and the other for dental treatment provided in Belgium. The Court found in their favour in holding that the refusals offended EU law on the freedom of goods in one of the cases and the freedom to provide services in the other. Then the Watts case extended this right to in-hospital care, with conditions.

These findings on the rights of citizens under the EU Treaty compelled the EU institutions to introduce a directive giving effect to these Treaty Rights as in the tobacco cases. The **EU Cross-Border Healthcare Directive** required the addition of the Internal Market legal base, then contained in Article 95 (post Amsterdam Treaty Article 114) as the proposal required the harmonisation of the national laws of the Member States, which, as I have already stated, was excluded from the health legal base in Article 152. This legislation received some publicity in Ireland as Irish citizens availed of it when they travelled to Belfast for cataract and hip replacement operations.

These hugely important cases, consistently approved by the Court of Justice, recognised the possibility of a dual legal base for a directive, thereby extending the competence for health-related cases where appropriate.

The ECDC

However, the Commission's plans for a European Centre for Disease Prevention and Control (ECDC) could have fared better. This initiative was introduced by the Commission in response to the SARS epidemic in 2003. It was established by law in 2004 and although its progress was fast, its resources were inadequate. Its mission was to act as a dedicated surveillance network for the detection of communicable diseases. (This was permitted under the existing health competence). However, it did not have the same impact as EFSA, whose opinions on food safety were capable of being enacted into legally binding provisions. Opinions from the ECDC were not.

EU4Health Regulation

It is important to stress here that the **EU4Health Regulation** introduced by the Commission to the European Parliament in March 2021 proposes to give the ECDC greater powers and a new budget of over €600 million. I will return to this later.

Towards Effective Public Health Diplomacy

Following the experience gained from the application of the rigour associated with food safety and animal health, an effective health diplomacy should identify policies and actions that will ensure: scientific evaluation, a rules-based response, adequate controls, surveillance, compliance and enforcement.

What might this mean in the future post COVID?

In November 2020 in the European Parliament, the President of the European Commission when introducing a new proposal for a new European Health Union said "Europe needs to give a higher priority to health". Part of the **European Health Union** contains the **EU4Health** programme which has a fund of €5.1bn over 7 years. It is structured around a number of strands including:

1. Cross-border health threats
2. Reinforcement of Europe's national healthcare systems (to lay the foundations for more resilient national health systems)
3. Driving the digitalising of health (national electronic health records)
4. Strengthening disease prevention, diagnosis and treatment (funding for national genome sequencing centres)
5. Cross cutting priority on cancer support in Europe's Beating Cancer Plan.
6. Increasing the budget for the ECDC from €68m to over €600m
7. Upgrading the European Medicines Agency (EMA), EFSA and the Euro Chemical Agency.
8. Establishing HERA (the Health Emergency and Preparedness-Response Authority)

This was followed in March 2021 by the agreement between the European Parliament and the Council of Ministers on a new **Regulation on Serious Cross-border Threats to Health (COM/2020/727 Final)**, which set out a comprehensive legislative framework to govern action at Union level on preparedness, surveillance, risk-assessment and early warning and responses. It replaces the Decision No 1082/2013/EU mentioned earlier.

This comprehensive legislation is based on Article 168 (5) of the Treaty and therefore does not provide for the harmonisation of national legislation. Consequently, it would probably preclude the possibility of certain measures such as harmonisation of rules on the movement of goods, coordinated movement of people and maybe lockdown in a pandemic. It should be noted however that the legislation also invokes the subsidiarity principle by stating the Union is to take action to support, coordinate or supplement that of the member states, without superseding their competence in these areas.

The Conference on the Future of Europe is likely to discuss such matters and if it were considered that this posed a problem, it could be resolved by Treaty amendment. The Conference might also consider that the current competences for health in the Treaty were inadequate and make a recommendation to amend or completely recast them thereby creating the need for Treaty amendment.

In the event of a treaty amendment being recommended, it would then need to be considered whether an amendment to the Irish Constitution would be necessary, thereby requiring a referendum. This would require the advice of the Attorney General.

The World Health Organisation (WHO) Report

The report of the Independent Panel for Pandemic Preparedness and Response, co-chaired by Dr Helen Clark and former President Ellen Johnson Sirleaf, which was set up by the WHO to investigate the outbreak of COVID-19 and why it became a global health and socio-economic crisis, was published on 12 May 2021. One of the report's recommendations is the establishment of a new global surveillance system. **This is likely to be a relevant issue for consideration on EU Treaty Change by the Conference the Future of Europe**.

Recommendation

The European Commission is well aware of the growing importance of precision or personalised medicine in the future diagnosis and treatment of disease. Therefore, the EU4Health Programme concentrates on such initiatives as the digitalisation of health and the strengthening of health promotion and disease prevention. Funding for both these initiatives will focus on electronic health records and the setting up of genome sequencing centres. While Ireland has some pockets of excellence, it does not have a genome sequencing centre as many other countries do. This is significant as the report notes that the sharing of the genome sequence of the novel Coronavirus on an open platform quickly led to the most rapid creation of diagnostic tests in history. Ireland is also deficient in electronic health records, although currently there may be some progress being made on these issues. The €5.1bn EU4Health budget will be available for applications for such projects. The legislation itself should be examined to identify the procedures for such applications. (See Regulation on the establishment of a Programme for the Union's action in the field of Health for the period 2012 – 2027. (COM (2020) 405 FINAL). (Chapters II and III).

As the Conference on the Future of Europe begins and societies start to re-open following COVID-19 restrictions, the European Union, national governments and citizens should be aware of what health diplomacy is, and what it could mean for the future of the EU.

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