

## Position Paper

# Treaty Change for a European Health Union

The COVID-19 pandemic has revealed weaknesses in the division of powers (competences) between the European Union (EU) and its Member States (MS) that limit the ability to harness the benefits of acting together in the field of health. In this position paper we first outline the EU's current health powers, second, we hypothesise the benefits of expanding the EU's legal basis for health, taking a health perspective which – counter-intuitively – could actually enhance the power of the MS rather than that of the EU. Last, we indicate what changes to the current legal text could enable the EU to achieve more in the field of health, while safeguarding MS' autonomy.

### Current legal health powers for the EU

Unlike many national jurisdictions, where power lies at the top and is delegated downwards, power in the EU is presumed to lie with the MS except where it is granted to the EU through the treaties. Where this happens, the EU is given competence to create laws on behalf of MS that provide for the economic benefits associated with a single European market and the movement of people, products, services, and capital within that market. These harmonised laws either set EU-wide standards for a wide range of economic activities or ensure that MS recognise each other's standards, making the benefits of European economic integration available to all. However, the EU has never been just a market: it also has law-making powers to support a range of policy objectives, including progress in social and environmental development, in areas such as agriculture, fisheries, criminal justice, and energy. In other fields, such as economic and monetary policy, employment, or education, the Union has powers to support MS' action to achieve greater cohesion, again to seek to bring the benefits of European integration to everyone within the EU.

At this time, powers granted to the EU to promote and protect health are limited. The EU is obliged to 'mainstream' health in all its policies and activities (Articles 9, 168 Treaty on the Functioning of the European Union (TFEU)). However, it has limited competence to harmonise laws that set standards of quality and safety of medicines, medical devices, substances of human origin such as blood; and to set animal and plant health standards that are directly aimed at protecting human health. For every other area of health, the EU must either shoehorn the desired law into its internal market powers (used, for example, to set standards for tobacco products) or adopt 'incentive measures' that do not harmonise laws.

This is no longer good enough. The pandemic has shown that the MS must endow the EU with competences in a broader range of health matters if we are to maximise the benefits of EU membership. The current TFEU leads to a situation where EU policies with major implications are led by those responsible for agriculture, the internal market, or enterprise (in the Council and the Commission), where those with interests that may be damaging to health, such as manufacturers of harmful commodities, may have disproportionate influence. In contrast, the influence of the health community is focused on national and sub-national jurisdictions. This explains to some extent the 'defensive' nature of Article 168 TFEU, which prohibits harmonisation of measures affecting both

public health and healthcare. This resistance by national health organisations against EU action is easily understood as there are large differences in the organisation of healthcare and its quality among EU MS. In addition, health gain is only one goal of a health system. It also serves to protect against catastrophic expenditure and redistribute resources. However, as many observers have noted, the EU's limited competence in health has not stopped EU law from encroaching on health policy through other fields. In fact, viewing health as an ancillary objective of other policy agendas disempowers health representation at EU level.

### **Health as a central objective and empowerment of national health representatives and civil society**

In all fields of policy in which MS confer powers to the EU, use of this power is delimited by the principle of subsidiarity (Art 5 (3) TEU), whereby Union action is only permissible where the desired outcome is one that the MS acting alone could not achieve. This political discussion must be informed by clarity about what the objective of the conferred power was and if that aligns with the objective of the law that is under discussion. Herein lies an important opportunity for gaining greater benefits of a European Health Union through a stronger legal basis.

Broadening and sharing competence in health in the TFEU would potentially empower health representation at national and EU levels in matters concerning health. Currently the ordinary legislative procedure (Art 294 TFEU) applies only to the few areas of EU policy where laws on health may be harmonised (medicines, blood and its derivatives, and animal & plant health), or where 'incentive' measures (meaning funding) are used to tackle cross-border health threats. Generally, harmonisation of national health law is prohibited (Art 168 (5)(7) TFEU).

Procedurally, this has meant that decisions affecting health have been taken within internal market or other non-health fora, such as the Competitiveness Council, attended by economic affairs ministers. Currently there is no singular Council configuration for health. To the extent that it is discussed, it is part of the EPSCO Council that meets in a health configuration as an add on to its meetings on social policy. If the health competence were expanded, the likely institutional change would be to create a health-specific Council configuration to support the expanded competence, a matter which can be decided by the European Council (Art 16 (6) TEU j. 236 TFEU). Furthermore, we would expect that the Commission would not initiate health legislation as part of other sectors, such as was the case in the famous Services Directive Proposal including health, which was initiated in the Internal Market DG.

Substantively, having a stronger health competence would ensure a more nuanced political discussion on the application of the provisions of Article 5(3) on subsidiarity and proportionality. As the Court has reiterated, the existence of a legal basis does not mean that the EU has become all-powerful to determine the law in that field, rather it means that an assessment of EU added benefit and the proportionality of EU action must be undertaken. This assessment of whether legislation is appropriate for reasons of health is different when health is ancillary to other policy objectives. This means, on the whole, that one counter-intuitive effect of a stronger EU power in the field of health can be that MS' health ministries and the attached health communities will have a more powerful role in determining whether EU legislation does or does not meet the test of subsidiarity. Similarly, health would be in the 'driving seat' of health policy in the Commission.



## Annex: Legal text with proposed amendments

### Preamble Treaty on European Union (TEU)

DETERMINED to promote economic and social progress for their peoples, taking into account the principle of sustainable development and within the context of the accomplishment of the internal market and of reinforced cohesion and environmental **and health** protection, and to implement policies ensuring that advances in economic **and social** integration are accompanied by parallel progress in other fields,

### Article 3 TEU

1. The Union's aim is to promote peace, its values and the well-being of its peoples.
2. The Union shall offer its citizens an area of freedom, security and justice without internal frontiers, in which the free movement of persons is ensured in conjunction with appropriate measures with respect to external border controls, asylum, immigration and the prevention and combating of crime.
3. The Union shall establish an internal market. It shall work for the sustainable development of Europe based on balanced economic growth and price stability, a highly competitive social market economy, aiming at full employment and social progress, and a high level of protection and improvement of the quality of the environment **and human health**. It shall promote scientific and technological advance.

It shall combat social exclusion and discrimination, and shall promote social justice and protection, equality between women and men, solidarity between generations and protection of the rights of the child.

It shall promote economic, social and territorial cohesion, and solidarity among Member States.

It shall respect its rich cultural and linguistic diversity and shall ensure that Europe's cultural heritage is safeguarded and enhanced.

4. The Union shall establish an economic and monetary union whose currency is the euro.
5. In its relations with the wider world, the Union shall uphold and promote its values and interests and contribute to the protection of its citizens. It shall contribute to peace, security, the sustainable development of the Earth, solidarity and mutual respect among peoples, free and fair trade, eradication of poverty and the protection of human rights, in particular the rights of the child, as well as to the strict observance and the development of international law, including respect for the principles of the United Nations Charter.
6. The Union shall pursue its objectives by appropriate means commensurate with the competences which are conferred upon it in the Treaties.



#### Article 4 TFEU

1. The Union shall share competence with the Member States where the Treaties confer on it a competence which does not relate to the areas referred to in Articles 3 and 6.
2. Shared competence between the Union and the Member States applies in the following principal areas:
  - (a) internal market;
  - (b) social policy, for the aspects defined in this Treaty;
  - (c) economic, social and territorial cohesion;
  - (d) agriculture and fisheries, excluding the conservation of marine biological resources;
  - (e) environment;
  - (f) consumer protection;
  - (g) transport;
  - (h) trans-European networks;
  - (i) energy;
  - (j) area of freedom, security and justice;
  - (k) **European Health Union** common safety concerns in public health matters, for the aspects defined in this Treaty.
3. In the areas of research, technological development and space, the Union shall have competence to carry out activities, in particular to define and implement programmes; however, the exercise of that competence shall not result in Member States being prevented from exercising theirs.
4. In the areas of development cooperation and humanitarian aid, the Union shall have competence to carry out activities and conduct a common policy; however, the exercise of that competence shall not result in Member States being prevented from exercising theirs.

#### Article 6 TFEU

The Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States. The areas of such action shall, at European level, be:

- (a) ~~protection and improvement of human health;~~
- ~~(b) industry;~~
- (c) culture;
- (d) tourism;
- (e) education, vocational training, youth and sport;
- (f) civil protection;
- (g) administrative cooperation.

#### Article 9 TFEU

In defining and implementing its policies and activities, the Union shall take into account requirements linked to the promotion and achievement of a high level of employment, the guarantee of adequate social protection, the fight against social exclusion, and a high level of education, training and protection of human health.



## Article 168 TFEU

1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.
2. ~~The Union action shall define and implement a European Health Union.~~
3. The ~~European Health Union~~, which shall complement national policies, shall be directed towards ~~protecting~~, improving ~~public and promoting human~~ health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. ~~The European Health Union shall be based on principles of equality, efficiency and respect for human rights. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.~~

~~The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.~~

4. ~~The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives of the European Health Union through adopting measures for the approximation of law, regulation or administrative action in Member States, and incentive measures, designed to protect and improve human health.~~
5. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to ~~build capacity to withstand health threats~~, improve the complementarity of their health services in cross-border areas ~~Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. and cross-border health problems.~~ The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.

~~3. The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.~~

~~4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:~~



~~(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;~~

~~(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;~~

~~(c) measures setting high standards of quality and safety for medicinal products and devices for medical use.~~

~~5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross border health scourges, measures concerning monitoring, early warning of and combating serious cross border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.~~

6. The Council, on a proposal from the Commission **and after consulting the European Parliament**, may also adopt recommendations for the purposes set out in this Article. **The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.**
7. Union action, **which shall be based on the principle of subsidiarity**, shall respect the responsibilities of the Member States for the ~~definition of their health policy~~ **and for the organisation and delivery of health services and medical care. The Union shall support the capabilities of Member States to promote health equality, reduce unmet medical needs, and strengthen the interoperability of their health systems.** The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. ~~The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.~~