

Explanatory Memorandum to the MANIFESTO FOR A EUROPEAN HEALTH UNION

What is the Explanatory Memorandum about?

The Explanatory Memorandum has been prepared in order to assist the reader of the Manifesto and contribute to an informed debate on it. It does not form a part of the Manifesto.

It explains what the Manifesto is calling for and provides background information on its development.

The paper is best read alongside the Manifesto. It is not, and is not intended to be, a comprehensive description of the Manifesto.

Overview of the Manifesto

The Manifesto addresses three issues:

It calls on the political leaders of Europe in the framework of the Conference on the Future of Europe to commit to creating a European Health Union (EHU).

It invites the people of Europe to engage in building a health policy that contributes to the long-term sustainable development of the European Union (EU). Commitment to progress should not be framed just by the necessity to fight COVID-19 within the framework created by existing European Treaties. Rather it should be framed by the necessity to show the people of Europe that our Union is there to protect us all. The pandemic has created a window of opportunity to take strong public action to build a Union where the lives and health of everyone matters.

The Manifesto sets out a vision of a EHU (with goals, policies, measures, principles) developed by the signatories of the Manifesto. We need to build a EHU where all people are as healthy as they can be throughout their lives.

Health in European Policy

I. EU Member States are committed to health via the Constitution of the World Health Organisation, European Treaties, the European Charter of Fundamental Rights, and the Sustainable Development Goals. The list of main Legal provisions is as follows:

- a) Art. 168 of the Treaty on the Functioning of the European Union (TFEU) states that “A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.”
- b) Art. 191 of the TFEU states that “Union policy on the environment shall contribute to pursuit of the following objectives: preserving, protecting and improving the quality of the environment; protecting human health; prudent and rational utilisation of natural resources; promoting measures at international level to deal with regional or worldwide environmental problems, and, in particular, combating climate change.”

- c) The preamble to the European Charter of Fundamental Rights states that “the Union is founded on the indivisible, universal values of human dignity, freedom, equality and solidarity.” Art. 35 states that “Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices.”
- d) Art. 34 of the European Charter of Fundamental Rights states that “The Union recognises and respects the entitlement to social security benefits and social services.”
- e) Art. 41 of the European Charter of Fundamental Rights confers “the right of every person to be heard, before any individual measure, which would affect him or her adversely is taken.”
- f) The WHO Constitution recognises: “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being...”
- g) Under the UN Convention on the Rights of the Child, Art.12 states that the Parties “shall assure to the child... the right to express those views” and in Art. 24 “shall take appropriate measures to ensure the provision of necessary medical assistance and health care to all children.”
- h) The EU and all Member States are obliged to implement United Nations Development Programme (UNDP) Sustainable Development Goals (SDGs). SDG 3 commits signatories to “ensure healthy lives and promote well-being for all at all ages.” SDG 3.8 commits signatories to “achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all.” Various SDGs commit the signatories to environmental goals including SDG6, SDG11, SDG12, SDG13, SDG14 and SDG 15. All those environmental goals are closely related to health and interlinked with Paris Climate Agreement and the EU Green Deal agenda.
- i) Under the International Convention on Economic, Social and Cultural Rights all Member States are obliged to progressively realise the goal “to support the right to health through allocation of “maximum available resources.”

II. The SARS-CoV-2 pandemic has shaken Europe. The experience of the pandemic has shone light on the weaknesses of existing mechanisms for collaboration among Member States and with the European institutions. Collectively, Europe was slow to act and the response was severely fragmented, with Member States often pursuing their own national objectives to the detriment of Europe as a whole. An obvious example was the scramble to procure scarce supplies of personal protective equipment. In response, the European Commission (EC) President, Dr Ursula von der Leyen, called for a EHU in her September 2020 “State of the Union” address. “For me, it is crystal clear - we need to build a stronger European Health Union,” she said. The Manifesto supports this initiative and invites the people of Europe to take an active role in creating a EHU.

The people of Europe must respond to the call for new EU competences in the field of health, supported by a strengthened understanding of how many other areas of EU policy impact on health. The challenge is not to make the EU responsible for all matters in health; that would be a great mistake. Rather it is to find the best way to enable cooperation among the EU and its Member States, enabling them to act more strongly and more effectively in both “normal”

and “pandemic” times. Progress in achieving this will go hand in hand with actions mapped out in other policy initiatives such as the social market economy, the Green Deal, and the digitalisation agenda. This progress must first and foremost build on the EU Pillar of Social Rights and the commitment of the EU and its Member States to the SDGs.

A EHU would promote healthy living and working standards, and well-being for all people of all ages. The EHU would achieve a high degree of synergy with measures implementing Social Europe, the Green Deal, Universal Health Coverage, and policies to protect and promote health and prevent disease. The EHU will help Europe prepare for future threats to health with stronger crisis preparedness mechanisms.

III. What are the specific actions, mechanisms & instruments of the European Health Union?

The scope of EHU actions is potentially vast. Some proposals as identified by various stakeholders include:

- a) Strengthen European health agencies, their competences, budget and staff (ECDC, EMA, EU HTA) and ensure better cooperation among them and with other EU agencies (EFSA, EU-OSHA, EEA, ECHA, EMCDDA, JRC) in health-related issues;
- b) Establish an EU equivalent of the US Biomedical Advanced Research and Development Authority (EU BARDA), explore the potential to create a fully integrated European Health Agency, and strengthen further European health research;
- c) European policies on key areas of public health (such as the AMR Action Plan, vaccination strategy, cancer screening programme) could be developed further, including harmonisation measures;
- d) Strengthen legislation on cross border threats (e.g. AMR), embedding a “One Health” approach in European policies. The EC should strengthen networks of European experts on infectious diseases and zoonoses, including EU centres of excellence;
- e) Establish the proposed Health Emergency Preparedness and Response Authority (HERA), drawing on lessons from the Union Civil Protection Mechanism. The response could be strengthened by a health solidarity clause that works in a similar way to the EU civil protection clause;
- f) Support innovations in health system reform in Member States;
- g) Consider stress testing of Member States’ healthcare systems and an EU Directive for Minimum Standards for Quality Healthcare;
- h) Share responsibility in “care and cure” in the areas of rare cancers and rare diseases. Explore the feasibility of a European Health Insurance Fund for Rare Diseases;
- i) Increase the mandate and scope of the European Reference Networks, developing them as legal entities and assisting them to take advantage of developments in digitalisation and Artificial Intelligence. Full implementation of the Cross-Border Healthcare Directive and the Clinical Trials Regulation is essential;
- j) Establish an EU Global Health Policy and incorporate an enhanced health dimension in the EU Neighbourhood Policy;
- k) Strengthen the EU representation, with the status of a legal entity, in the WHO, and promote multilateralism at global level;

- l) Set out a legal basis to strengthen health considerations in areas of EU competence such as the internal market and fiscal governance. The responsibility for health cannot be secondary to economic and industrial policy. The role of public health experts and health lawyers must be strengthened;
- m) Mandate the EC to monitor the European health workforce and support pan-European solutions related to healthcare workforce shortages;
- n) The EU mandate on joint procurement should be expanded and strengthened, with greater enforcement of provisions on transparency. Measures that recognise the particular features of the pharmaceutical sector are needed in the Public Procurement Directive;
- o) Revision of the Transparency Directive on pricing of medicines. Health sovereignty must be restored, taking back control of medicine and vaccine production in Europe, a robust Pharmaceutical Strategy and a European Resilience Strategy should be developed;
- p) Harmonise vaccination schedules across the EU and work with the WHO on this process across the whole European region;
- q) Create a pan-European e-vaccination passport for EU residents, placing a priority on children;
- r) Work for common digital and eHealth standards across Member States. Procedures for standardisation and data sharing in a European Health Data Space should be considered;
- s) New legislation on health and safety in the workplace should be considered, including a new Directive on work related musculoskeletal disorders and on mental well-being in the workplace;
- t) Develop a new and stronger EU health strategy that implements a Health in All Policies Approach, pushing EU health policies out of silos created by economic and political considerations, fostering implementation of the 2019 Council Conclusions on the Economy of Well-Being. A paradigm shift from an “illness system” to a “well-being system” should be strengthened;
- u) Explore the feasibility of a European Observatory on Health and Well-Being and Charter on Health and Well-Being;
- v) Develop broad public health guidelines that address the main risk factors and strengthen measures to prevent NCDs.

A EHU is emerging. We are looking to a multi-sectorial and multi-dimensional cooperative model of a EHU that combines local, regional, national, and European shared rules in Health. The EC’s competences on Health are currently restricted. While Article 168 of the Treaty on the Functioning of the EU provides a basis for the EU’s policies, it also leaves health policy as the responsibility of the Member States. The EC may only complement, coordinate, and encourage cooperation or sometimes supplement it. Many argue for a Treaty change. For example, Margaritis Schinas, the vice-president of the EC told reporters (on 28 May 2020): “If the moment is right, it will happen.”

There are many initiatives related to the idea of a EHU within the European Parliament. The EC is working hard on the EHU. Their efforts are greatly welcomed. On 11th November 2020, the Commission Communication “Building a European Health Union: Reinforcing the EU’s resilience for cross-border health threats” proposed the “first building blocks for a European

Health Union”, based on existing Treaty competences. Legal services of the Council, European Parliament, and EC strictly follow the Treaty obligations and limits.

How a EHU will actually evolve and what it will look like will depend on the political process. This is in the hands of the people of Europe. The road forward can be seen in three different scenarios.

IV. Different scenarios can be envisaged to achieve the health and well-being of all Europeans:

- a) Measures to make progress in health concentrate on what can be done with existing legal, financial, and managerial instruments, upgrading already functioning institutions, and improved implementation of already agreed policies;
- b) Fine tuning of existing instruments of health policy in parallel to the development of secondary legislation and establishment of new institutions that can create added value for European health. The scenario does not foresee amendments to the European Treaties;
- c) Europeans decide that in addition to “a” and “b”, a “c” is needed, where the status of health policy in the European Treaties is strengthened, with provisions for a EHU incorporated into the TFEU, giving the European Union explicit competence in health policy in very concrete areas, while preserving the principle of subsidiarity as a core.

All three scenarios have their own advantages and disadvantages. None are perfect and none can be implemented immediately. According to the vision of Robert Schuman expressed in 1950, “Europe will not be made all at once, or according to a single plan. It will be built through concrete achievements which first create a de facto solidarity”.

The former EC President Jacques Delors lamented that the lack of solidarity in response to an earlier pandemic was a mortal danger to the EU. The solidarity he sought is what a EHU would deliver.

Health is a political choice, and it requires a strong political will, passion, and ambition. From this point of view a scenario “c” is, of course, the most ambitious. The best choice would be to adopt this scenario. By opting for scenario “a” or “b” Europeans would restrict the benefits they would obtain from deeper cooperation on health. The existing Treaty constrains what can be achieved. Let us be bold and inspired by another, paraphrased, call by Robert Shuman: “People’s health cannot be safeguarded without the making of creative efforts proportionate to the dangers which threaten it.” We cannot miss a once in a generation opportunity to place health at the centre of our European Union.

[Actions that will follow the publication of the Manifesto](#)

- The Manifesto in English will be available on #EuropeanHealthUnion #EUHealth4All #EUHealthManifesto and Websites of the European Health Forum Gastein (EHFG) and the European Institute of Health and Sustainable Development (EIHSD).
- All comments on the document are welcomed and will be collated and presented to institutions working on the design of a EHU.
- The text of the Manifesto will be translated into all official EU languages and presented to national parliaments of Member States for consideration.

- European NGOs, if they see it reasonable, will be invited to support calls for a EHU to be placed on the agenda of the Conference on the Future of Europe.

On behalf of signatories of the Manifesto for a European Health Union