ELF Briefing
January 2022

Science, not Fiction

Summary

Welcome to the future! From robotics and biomedicine to quantum computing, what long seemed like science fiction is now science reality. How can Europe ensure an innovation-friendly environment to stay at the forefront of progress? What is on the horizon in the fields of software, hardware, medicine, and biotechnology? Forward-looking policies will keep Europe at the cutting edge while ensuring new technologies are embedded in European values.

Francesco Cappelletti
Research Fellow,
European Liberal Forum

Matei Stefan
Research Assistant,
European Liberal Forum

Part 1

Digital Innovation

Executive Summary[1]

To science, from fiction

Sci-Fi is becoming a reality. Half a century ago, 5G, AI, dark matter, observing black holes were theories, or in some cases, fantasies. Thirty years ago, we could not have imagined choosing a computer to buy based solely on its aesthetics, while today we have connectivity, small devices and services that could have been hardly imagined 20 years ago. The forefront of this technological development, spearheaded by artificial intelligence, next-generation networks, quantum computing and automation, will have an unprecedented impact on our societies.

While Europe remains at the vanguard of innovation, its unique tradition based on liberalism, human rights, values and a human-centred approach has enabled us to be the de-facto regulator at the global level for new and future technologies. Overall, the European Union and its Member States can compete globally with high technological value and cutting-edge solutions. Reflecting on our future is more necessary than ever; shaping it means taking part in innovation and not letting it slide by.

In this context, this policy brief aims to guide liberal policymakers so that Europe can succeed in its goal of digital sovereignty, made strong thanks to a flourishing internal digital market, and supported by regulation shaped around the individual.

Context: The Digital Revolution and Europe

What European citizens are witnessing is a re-evolution, not the first nor the last in human history, where technology has the role of shaping the future and the way in which society and our lives are organised. This digital revolution is running ahead of us, to the point where it is often difficult to understand its impact on our own future. On the one hand, the digital revolution is a worldwide phenomenon. When it comes to the digital market, however, Europe

1 This policy brief is the result of an elaboration of the Policy & Research Unit of the European Liberal Forum (ELF) based on the online event held on 3 June 2021, "Science not Fiction: Digital Innovation". All the thoughts expressed in this paper are the result of the elaboration by ELF.

is lagging behind China and the United States (technological "production" and "digital" champions at a global level, respectively).

On the other hand, Europe is setting up ambitious programmes for its digital future, such as: Horizon, Digital Europe, the Recovery and Resilience Facility. These recent proposals provide a unique opportunity enabling investment in both technology and sustainability.

While technological development advances at pace, European regulators are trying to catch up with the digitalisation of our societies. Europe can be proud of some recent successes that have had a real-life impact on citizens, such as the GDPR or the Roaming regulations, along with the newly proposed DSA/DMA, Cybersecurity Act, and Artificial Intelligence Act. Overall, Europe's digital transition plan is built on a precise set of pillars such as skilling and re-skilling, shared infrastructure (5G/6G), cybersecurity, digital industry and businesses, new technology (quantum computing, chips sovereignty). More importantly, the European approach based on values has been the driving force of this regulatory process, safeguarding fundamental rights and privacy while ensuring transparency and accountability.

Policy alternatives: what's needed most?

Regulating without stopping innovation

A common approach to regulation is the essence of the European Union. However, it is essential not to limit innovations by overregulating them: whenever a regulation comes too early, it somehow limits "creative innovation". This may result in having one hand tied behind our backs, affecting the businesses of the internal market and international investors, confining the global digital competition. Bearing in mind that the Union is composed by 27 Member States, regulatory processes should consider the potential of all states and improve the exchange of best practices inside the Union. Also, to be ready for global competition, relations with third parties should be based on transparency and reciprocity.

Fostering business scaling-up by avoiding fragmentation

The EU's Internal Market comprises a large economy, with potential investors, easy access to capital, and highly innovative projects. However, the Digital Market is still fragmented, and the implementation of different rules within the Member States can be detrimental to the whole digitalisation project, especially since fragmentation is still present.

A long-term and bold strategy

In the long term, Europe must compete globally in the field of new technology and digitalisation. This goes hand in hand with the development of a thriving digital ecosystem, by finding regulatory procedures that allow for bold choices in technological advancements. Favouring digital champions and high-value projects means having a long-term strategy that leaves the market free to

flourish. A clear direction, for all of Europe, will allow it to take advantage of talent and excellence. This can be achieved thought smart regulation, adaptive and experimental behaviour and the capacity of enabling "curiosity first".

Change of mindset

Shaping our digital future might also imply a change of approach. Overall, the EU's approach towards innovation has been "curiosity last, total security first". In this sense, the regulatory framework can be improved, but the mindset must be changed. It is of utmost importance to spread the idea that Europe is – or can be – an enabling environment for creativity and innovation, and thus capable of attracting investments.

What is necessary then, is a shift of mindset. This can have different meanings and has to do with the European effort to involve entrepreneurs in a creative manner, in the process of innovation. In this sense what is needed for Europe is to be more open, support a free market, and foster cooperation. Politicians can play a fundamental role and contribute to shifting the current mindset towards "forward looking" strategies and programmes to support these developments.

Thinking ahead: skills

Europe is a hub for creative talents and highly skilled professionals in the field of technology. Nonetheless, it is essential to be realistic in the future: what has been taught today will be old in two or three years. Instead of teaching specific skills, it is more important to teach how to approach learning. Since the amount of information out there is enormous, the mind should be adaptable. Finally, creating talent means being able to gather a blend of different knowledge and experiences.

Policy Recommendations

Leading on innovation is the key to the success of the EU. Nature and the sources of innovation are changing, and the real challenge will be innovating without posing limitations on science. The next waves of innovation will probably focus on deep technology, AI, quantum computing or tele-transportation. Disruptive innovations appear in all fields and come from sources other than only research and science, be it from entrepreneurs, end-users, citizens, or students. Europe should be able to spread the message that innovation is coming from inside the EU.

Science and innovation should not be fictional: this means understanding technology as it is, a neutral efficiency engine capable of catapulting humanity into the future. But it does not understand values or ethics. Technology is a tool that needs a telos.

Thus, Europe must maintain the uniqueness of its approach based on the rule of law, values, human dignity, freedom, human rights, and democracy by advancing creativity of innovation, a flourishing market and a future-proof regulatory framework.

To do so, and for the policymakers to help to turn fiction into science, making Europe ready for the digital world, the following dimensions and recommendations must be considered:

Common rules and values:

- Achieving smart regulation: we should accelerate the procedure of regulations (to catch up with technological development) and have a broad general scope [and]
- avoiding hard regulation where possible, using soft regulations whenever it can work [to]
- create regulation collaboratively with a system of actors, such as the European Commission, European Parliament and the Council of the EU, who should be discussing thoroughly with different stakeholders, civil society organisations and not rushing into regulation too fast [so that the]
- regulatory process must be bold and at the same time systemic and adaptive [this can be achieved through]
- fostering an experimental dedicated playground where regulations are tested in the field and then refined. This can also help identify new talents that are ready "to play" with these regulations.

Internal Market and Business:

- Favour projects that aim to identify and foster digital champions.
- Remove internal market fragmentation and regulatory burdens for high technological value projects [through]
- supportive policies that can facilitate scalability inside the EU for companies to be able to compete globally.

Skills and investments:

- Being able to direct investments in both talent and skills, and a new generation of innovators to foster the transfer of new technology from research to market [also by]
- Implementing multi-disciplinary teaching and computational thinking
- Securing technological sovereignty of Europe in strategic sectors such as quantum computing, deep tech, next generation of network, cybersecurity, chips sovereignty, etc.

Pan-European Ecosystem:

The creation of a "Pan European Innovation Ecosystem" might represent a feasible solution to exchange best practices, gather talent and skills, and be a strong market force. This implies collaboration between:

- EU Institute of Technology
- EU Innovation Council
- EU innovation Ecosystem programme
- EU University alliance

Part 2

Hardware and Industry

Executive Summary[2]

To science, from fiction

Innovation drives and shapes many areas of life. Embracing it means greater power, speed and facility in the digital domain, but also in our industrial, agricultural, educational and healthcare systems. From reusable space rockets and self-driving cars to new renewable energies and delivery drones, hardware dreams are slowly becoming a reality. Techniques and materials that did not seem possible a decade ago are now being developed by industries and universities.

As drivers of progress, liberals need to keep their eyes on the horizon and look beyond to see what science will be bringing us next. We will be able to see that only by understanding and further developing today's hardware advancements. Faced with global competition, we need to facilitate the creation of an innovative environment in which all sectors have everything they need to succeed right here in Europe.

This brief invites a thoughtful, future-oriented discussion on hardware, a practical and vital aspect of our lives that is sometimes overlooked. It is important to understand what pieces of hardware will predominate in our daily lives over the next decades, how to utilise hardware innovation in and for Europe's digitalisation, and to tackle the challenges posed by climate change, while also achieving a balance between regulation and innovation.

Context: the world of hardware

In order to tap into Europe's immense potential when it comes to hardware innovation, Europe needs to look not only at what is in front of it, but rather develop and adopt a future- oriented vision. A vision that will place Europe at the forefront of the new wave of innovation that is unfolding - a new wave characterised by a focus not only on digital start-ups, but on digital *and* hardware start-ups. Europe lost in the start of the innovation race around

2 This policy brief is the result of an elaboration of the Policy & Research Unit of the European Liberal Forum (ELF) based on the online event held on 29 September 2021, "Science not Fiction: The World of Hardware". All the thoughts expressed in this paper are the result of the elaboration by ELF.

20 years ago, when digital start-ups and the dot com revolution occurred. However, it should not dwell on that to play catchup with China or the US, instead, it should focus on the future and play on its strengths, such as industrial processes/production – which started in Europe and for which the Union has great potential.

Robots and AI:

The effort to make machines more intelligent has been at the centre of this new wave of technological hardware innovation. As the robotics industry finds itself at a turning point and is undergoing the same transformation that the computing world did roughly 40 years ago, we note an increased reliance on robots and AI in many areas: service industry, automotive, agriculture, health care, customer service, amongst others; while innovations such as self-driving cars, 3D printers, service robots or delivery drones have become a reality.

The COVID-19 pandemic has accelerated some trends: increased digitalization (e-commerce, industry 4.0, AI, machine learning, 5G), increased uncertainty (supply chain disruptions, trade and political uncertainty, natural disasters) and labour shortages that affect manufacturing activities in many countries (resulting from changes the demographic structures).

Industrial AI and robotics are part of the solution to address these trends in the most efficient way. It is expected that AI-operated robotics will enable European companies to realise tangible productivity gains as they move towards digital manufacturing. Aside from helping the transition to digital, robots will also transform industrial jobs – making them cleaner, safer, less repetitive and less alienating, and will do so not by copying human abilities or replacing humans, but by integrating into the environment, understanding natural language and working alongside humans as a colleague would do. Today, it would be unthinkable for some that in a few decades robots could be as familiar in the workplace as a laptop, but that might well be the reality.

Proper environment for innovation:

Innovation needs to be grounded on an open and enabling environment where innovators receive support to bring forward their creations. There are several prerequisites for fostering innovation: the ability to access funding, availability of support structures, and the existence of the right level of skill, talent and know how.

Regarding funding, we observed initiatives that see European banks running financing programmes for start-ups and SMEs, and that is a step in the right direction. But overall, the investment in new ventures, either by banks or by venture capitalists isrelatively low compared to other regions of the world. With some projects, especially where start-ups or SMEs are concerned, investors are not willing to take big risks and invest into new initiatives. A shift in mindset is much needed so that Europe can renounce its ‘safety first, curiosity last’ mantra,

and steer itself towards forward-looking projects that can lead Europe to more tech and industrial sovereignty.

An ideal innovative environment is one where start-ups and entrepreneurs have the possibility to receive funding, are encouraged and supported to establish their business and to be part of the innovation race. Added to this, a suitable environment for innovation consists of close cooperation between the private sector and universities – which we have seen happening more and more often. Moreover, tax breaks and reductions could be offered to companies entering the market and those who commit efforts to create innovative technologies.

Innovation does not happen without knowledge. As such, the ability to attract and retain international talent is paramount. Going beyond attracting foreign talent, the EU needs to nurture and develop skills for young entrepreneurs or students; it is vital that in every technical area Europe has access to highly capable, well-trained individuals.

Relationship between regulation and innovation:

Regulation will play a vital role in Europe's pursuit of becoming an innovation hub. What is needed is a reliable regulatory framework that fosters innovative projects and does not kill innovation. Legislatures will have to create a wide legal framework, that allows for coherent strategies and legal certainty for both companies and consumers. Recently, there have been talks of creating legislation aimed at completing the digital single market and at creating harmonisation at a rules-based level. Discussions are being held on how to regulate the digital single market, the e-commerce sector, block-chain, and AI. While implementing these regulations, the EU should be cautious as to not create over-regulation and more red tapes that, in turn, could dampen innovation.

Moreover, people need to be educated on new innovations, as we know some may foster negative ideas about technological innovation. We want consumers to trust the product, and it is the responsibility of the companies to educate the consumer in this direction. If companies communicate to the consumers on how new technologies could impact their lives, people will become much more comfortable with innovative technologies.

Climate-conscious innovation:

Just creating amazing technologies is not enough, we need to protect the environment at the same time. To do that, new technologies need to be harnessed and developed reliably up to the point where they can be used as tools to fight climate change. For instance, use of carbon capture technology, of geothermal drilling, and the integration of other renewable sources of energy would help solve pressing climate and energy issues. Coupled with tech resources, better collaboration across sectors is a 'must' to reach climate

goals. The idea is to create a pan-European ecosystem with strong ties between stakeholders, and where people are enabled to mingle and collaborate.

Conclusion and Policy Recommendations:

Retaining and enhancing its technological autonomy is a major goal of the EU. There is an intense global competition going on, and if Europe wants to cement its position as an economic and political power, it needs to create a sound environment where innovators can operate, and become industry and innovation leaders, rather than followers. Otherwise, if this monopoly of hardware innovation is left to other countries that do not share the same values as the EU, Europe will depend on these countries and will receive new products much later, under conditions set by the vendor countries. This dynamic will disempower the EU in many areas and will reduce its overall control and ambitions of technological strategic autonomy.

What should not be forgotten is that all technological and industrial innovations should be for the improvement in the lives of people and for the protection of the environment. If Europe makes the right choices and achieves an economic recovery that brings automation and industrialisation back to the centre of Europe's competitiveness globally, three opportunities will arise:

- EU will be able to achieve tech sovereignty
- EU will have the potential to reach climate change and sustainable development goals
- EU will become a leader of the new tech innovation wave and establish itself as the world's powerhouse for start-ups

Part 3

Biotechnology and Medicine

Executive Summary[3]

To science, from fiction

The final part of the Science, not Fiction 3 trilogy goes into depth on the importance of medicine and biotech sectors in society, how the COVID-19 pandemic has shaped the European healthcare landscape, and what steps should be taken next in order to foster an innovative-friendly legislative and operational framework.

The COVID-19 pandemic has shown first-hand what integral cross-border collaboration between various stakeholders could lead to: the incredible achievement of rolling out a vaccine, with minimum or no risks at maximum speeds, like never seen before. This event constituted a grand achievement and made us wonder what more could be further achieved if Europe focuses more of its resources towards medicine and biotechnology.

Recent advancements in biotechnology have brought us biosensors, bioprinting of drugs, tailor-made organs, nanobots and innovative treatments using human genome sequencing. These are incredible achievements; we should not stop there but should discover other new technologies that would make our lives and health treatments better. It is vital to keep up the momentum and capitalise on the rapid development of COVID-19 vaccines and their innovative spillover, for example, into new mRNA methods.

Context: The Biotech and Medicine sectors in Europe:

Europe is home to a rich innovation ecosystem where start-ups, world-class research institutions, top universities and many small mid-sized pharmaceutical and biotech companies interact to make the pharmaceutical industry a key competitive industry for the EU. This sector ranks at the top in regard of R&D investment and in the creation of high-skilled jobs that could not easily be

3 This policy brief is the result of an elaboration of the Policy & Research Unit of the European Liberal Forum (ELF) based on the online event held on 18 November 2021, "Science not Fiction: Biotechnology and Medicine". All the thoughts expressed in this paper are the result of the elaboration by ELF.

delocalized, making it a critical source of long-term growth.

Nonetheless, in the context of medical innovation, Europe significantly lags the US, while other regions, such as China, are rapidly catching up. We have seen challenges in scaling up pre-clinical and clinical research to deliver innovative medicines as well as the establishment of a favourable regulatory framework that enables innovative medicine and technologies to be developed at a quicker speed. Moreover, leading companies in the biotech industries have slowly but systematically moved their headquarters from Europe and chosen to scale-up in the US.

The COVID-19 pandemic has shown first-hand the importance of the biotech sector, and how its innovation can save lives and allow for better, more suitable patient treatment. Europe's top biotech companies – CureVac, BioNtech and Valneva – have played a critical part in the development and licensing of innovative vaccines at record speed and by leading the global revolution in mRNA technologies. Despite this fact, and despite Europe being a science hub, EU has not yet come up with a long-term vision for the sector.

One of the new technologies that receives increased attention is gene therapy. Gene therapy relates to the next generation of medicines that target the underlying cause of a genetic disorder at cellular level. Gene therapy can drastically improve the treatment for patients with hemophilia A, hemophilia B, and Duchenne muscular dystrophy (DMD). This technology does hold great promise, but it should be noted that it is not an appropriate treatment option for all patients with certain rare genetic disorders.

Healthcare rules and regulations at a European Level:

As gene therapies are considered Genetically Modified Organisms (GMOs), the use of this technology falls under the European GMO legislation, as implemented in each EU Member State. The GMO legislation is complex, and every gene therapy clinical trial needs to comply with its provisions. The sophisticated and complex requirements of the legislation may push away certain initiatives and may render Europe a less attractive region to run clinical gene therapy trials.

The European Commission has recently decided to temporarily exclude potential COVID-19 treatments and vaccines from certain GMO requirements due to recognition that such complexities may invite delays to clinical developments during the pandemic. Following this decision, now could be a good time for the European Commission to reconsider the scope of GMO legislation in view of gene therapy trial and thereby make Europe more accessible for developing this technology.

It is clear that if we want to have an innovation-friendly business environment in the near future, a certain type of regulation needs to be implemented. We have

seen the issuance of the Medical Device Regulation (MDR), which repeals the Medical Device Directive (MDD). However, with the new MDR which supports MedTech companies in meeting regulatory requirements, a new set of barriers have been presented: many companies feel overwhelmed in the process of transitioning from the current Medical Device Directive (MDD) to the new MDR.

As a response to the COVID-19 pandemic, a new instrument brought forward by the Commission is the "Health Emergency preparedness and Response Authority", or HERA: a tool to strengthen the European Health Union for better EU preparedness and response to serious cross-border health threats, by enabling rapid availability, access and distribution of necessarily countermeasures. While the initiative is laudable, it is unclear to what extent HERA will be able to tackle anything beyond Covid in the near future and what the budget will be.

Digital transformation of the healthcare market is a worthy objective to be pursued by stakeholders. DiGA, the German Fast-Track Process for bringing Digital Health Applications to Market is an example of national regulatory framework that facilitates the transition to digital, shares best practices and addresses barriers to bringing digital devices to markets.

An innovation-friendly environment:

Innovation initiatives require political will and a desire to cooperate between actors with different competences. Stakeholders throughout Europe need to make sure to include all sides of the "knowledge triangle" in the equation, so that innovation can happen at the intersection of research, education and business for the benefit of citizens and patients. The pandemic has shown the value of having an ecosystem for MedTech and pharmaceuticals where a number of small and midsized companies can collaborate, and even partner with larger companies where necessary, to develop innovative therapies or prophylactics.

Biopharmaceutical innovation can only be achieved through a collaborative approach and through partnership with policy makers and stakeholders to create proposals and solutions. Enhanced collaboration across stakeholders is paramount because it allows risk sharing for innovative investments; enables investments that can both save lives and lead to cost savings for the future; and strengthens incentives to succeed in creating preventive measures of this kind.

The European healthcare system must evolve as it is currently not ready for drugs that are given as one-time treatments with potentially transformative and long-term clinical effects. That is why key actors operating within the healthcare sector need to partner up to facilitate new payment models, including value-based and risk-sharing agreements, that connect the reimbursement with how well these one-time treatments, such as GTx medicines work for patients.

In order to facilitate R&D in the space of rare and ultra-rare orphan diseases, an innovation-friendly environment that includes OMP and IP regulations is needed. These regulations should reward successful innovation of potentially transformative drugs for patients with rare or ultra-rare diseases.

All in all, to encourage innovation across the healthcare sector, an incentive framework should be created and strengthened to account for the inevitable setbacks and hurdles faced especially by smaller and medium-sized companies. It is critical to address these challenges and to create and maintain a strong incentive ecosystem where partnerships and collaboration between various stakeholders – mid- and small-sized biotech companies, large pharmaceutical corporations, top universities and policymakers – can be realised. Adjacent to harnessing the potential of new innovative treatments, national regulatory and access pathways need to be flexible and favour an early, iterative exchange among EMA, HTA bodies, insurance companies and payers.

Investing in education is a prerequisite for innovation:

If countries are interested in promoting an innovation-friendly environment, they should not only invest directly in innovation. They should also focus on establishing a cultural, social, and institutional environment that is able to promote innovation, and retain the right talent.

Key recommendations relating to investment for innovation

- As raising funds is a lengthy and difficult process for most start-ups, especially for those looking to operate in multiple markets across Europe, the creation of a public-private co-investment programme to allow financing for European health SMEs and to connect scientists and entrepreneurs with venture capital investors or corporate investment firms could come in handy.
- Improve the leadership and medical culture of the medical community in the identification and R&D of innovation, as well as bolster the continuing medical education available to healthcare professionals on implementing and using innovative products and services (digital and data literacy).
- There is a lack of digital skills and competences in the public sector. To address the large gap in digital skills amongst healthcare workers, a holistic digital education could be embedded into medical curricula that could facilitate a combination of technical and medical education at medical facilities, combining technical know-how and best pedagogic practices with a strong focus on challenge-based learning.
- Education should target precision medicine, health data, leadership and change management. In addition, concepts such as willingness to take risks (innovation requires risk-taking due to the uncertainty of outcomes relating to technological advances), readiness to accept change, long-term orientation, openness to new information, organisational learning

and leadership should proactively be embedded into the mindsets of individuals working in biotechnology and healthcare sectors.

- Education is important in order to develop the next generation of health innovators, entrepreneurs and leaders and to educate and skill them in view of supporting the technological challenges (AI, biotherapies, genomic etc.) and societal challenges (pandemic, aging population) that will make European health systems more efficient and sustainable. These challenges can be solved only with a transversal European approach.

About ELF

The European Liberal Forum (ELF) is the official political foundation of the European Liberal Party, the ALDE Party. Together with 47 member organisations, we work all over Europe to bring new ideas into the political debate, to provide a platform for discussion, and to empower citizens to make their voices heard. Our work is guided by liberal ideals and a belief in the principle of freedom. We stand for a future-oriented Europe that offers opportunities for every citizen. ELF is engaged on all political levels, from the local to the European. We bring together a diverse network of national foundations, think tanks and other experts. In this role, our forum serves as a space for an open and informed exchange of views between a wide range of different EU stakeholders.

A liberal future in a united Europe

/europeanliberalforum
@eurliberalforum
#ELFevent

liberalforum.eu

Copyright 2022 / European Liberal Forum (ELF) EUPF.

This publication was co-financed by the European Parliament. The European Parliament is not responsible for the content of this publication, or for any use that may be made of it.