

**EUROPEAN
HEALTH PARLIAMENT**

EUROPE'S NEXT GENERATION OF HEALTH

Policy recommendations by the **Next Generation**

6th edition
2020–2021

#ReInventHealth

Recover, Reinvest, Reinvent: Shaping a European Health Union



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The next generation of EU health leaders

The European Health Parliament (EHP) is a Brussels based movement connecting and empowering the next generation of European health leaders to rethink EU health policies. Along with its partners: Johnson & Johnson, European Patients' Forum, EU40, College of Europe, Young European Leadership, Porter Novelli, Euronews and Mavence the EHP provides the next generation of European leaders with the connections, knowledge and platform they need to build a healthier and more innovative Europe.

The EHP answers Europe's need for fresh ideas in health. Health systems are facing immense pressures to adapt their spending and other resources to match changing demographics, rising disease burdens, stronger patient empowerment and modern technologies.

The EHP believes that the solutions required must come from the young European health leaders who influence the policies that will ultimately concern their generation as they age.

That is why the EHP was created in 2014. The initiative connects promising young professionals and challenges them to develop solutions for European health policy that are both innovative and actionable. Each year the EHP convenes a diverse group of 60 young professionals representing all healthcare sectors. Participants work together for six months to develop policy recommendations that address today's most pressing European health issues, which are picked in cooperation with the European Commission. EHP participants are selected for their contribution to and potential to lead in European health policy and come from a range of educational and occupational backgrounds.

This was the first fully virtual edition of EHP. As always, it brought together dynamic young people from across the continent to solve our most pressing health challenges, but this time they managed yet another hurdle of having all their sessions held online. Get ready to see what some of Europe's brightest young health leaders have devised!



Table of contents



Forewords



**Telemedicine and
Patient-centred Care**



**European Health
Data Co-operation**



**Resilient
Supply Chains**



**Health and the
Green Transition**



**Healthy
Economies**

Forewords



Stella Kyriakides
European Commissioner



Seán Byrne
EHP6 President



Zeger Vercouteren
Johnson & Johnson



Alessandro Da Rold
EU40



Olivier Costa
College of Europe



Anna Koj
Mavence Brussels



Lorraine Baldwin
Porter Novelli



Pauline Kühlwein
Young European Leadership



Michele Calabro
European Patients' Forum



Gardenia Trezzini
Euronews

I welcome the Recommendations by the European Health Parliament

The pandemic has negatively affected all of us on a personal, national, European and global level. Now is our chance to work together to chart a new path for health policy in the EU, in the form of a strong European Health Union.

I am glad that the importance of telemedicine and the need to share health data were highlighted within the European Health Parliament recommendations. We have seen an exponential increase in the volume of telemedicine consultations in the last year. We need to implement technology in our policy in order to make healthcare more accessible to everyone, more sustainable and encourage research and innovation. If telemedicine is to become an integral factor in our healthcare systems, patient data will be a key issue. Our forthcoming European Health Data Space proposal will play a key role in empowering citizens with access to their own digital data, which could facilitate a rise in more virtual interaction with healthcare professionals through telemedicine.

To eliminate inequalities in access to healthcare we must also make sure that we have resilient and sustainable global supply chains. Our new Pharmaceutical Strategy is an opportunity for us to ensure and reinforce the strategic autonomy of our pharmaceutical sector and ensure access and affordability of essential medicines for our citizens.

Healthy citizens are the basis for strong economies and societies. The pandemic has shown us more than ever how important it is to have sustainable and resilient healthcare systems that deliver for all citizens. Our ambitious and standalone EU4Health Programme will make €5.1 billion available to support the process of building the healthcare systems of tomorrow, and enabling them to deliver better care for patients across the EU. Integrating digital health solutions is a key part of our vision in this regard.

People across the EU expect us to deliver much more in the future, in every area of health. This year we have witnessed what the European Union is capable of achieving when working closely together, when we are coordinated and united.

Now is the time to move from ad hoc solutions to structural ones. I am confident that we can come out stronger from this crisis, and that we have the opportunity to build a strong European Health Union, a more secure, better-prepared and more resilient EU that can truly protect the health of our citizens.



**Stella
Kyriakides**

European Commissioner
for Health and Food Safety



To reinvent health is no simple mandate. Living in a time of transition, our world is unrecognisable and experiencing great challenge. As Europe stands at the precipice of societal change, the sixth cohort of the European Health Parliament (EHP6) dared to venture ahead, to offer a path through uncharted terrain.

"Be disruptive: think youth; think patient; think sustainable" – from the outset we have been encouraged to break the mould. Contemplating health within the context of a green and digital transformation presented a novel opportunity to shape the future well-being of our society.

The coronavirus pandemic has illustrated the need to utilise our scientific and technological advancement: to rapidly develop treatments or to provide continuity of care through telemedicine. We are moving towards widespread digitalisation, allowing us to leverage digitalised systems and artificial intelligence to augment our decision-making capabilities in every aspect of health, from the supply-chains which deliver medicines, to the prognoses by healthcare professions.

Access to coherent information empowers citizens to make informed decisions about their health, and is a key focus found in each theme explored by EHP6. A focused

effort at the EU-level to coordinate health through several initiatives (the European Health Union, EU4Health and more) can improve a holistic culture of healthcare centred on patients and their healthcare experience. Equally importantly, support for healthcare professionals underpins the reinvention of healthcare systems, so that they may work in an environment conscious of their well-being.

Playing an active role and disseminating ideas borne from the youth perspective is a humbling but powerful experience. In particular, I am delighted to introduce the Committees, and their Chairs and Vice-Chairs. Shaping the policy recommendations which follow, a group of individuals more dedicated to healthcare will be hard to identify. Their curiosity, determination and passion is demonstrated in each of the five focal topics of EHP6:

- » **Telemedicine and Patient-centred Care:** Simone Mohrs, Lars Stollenwerk
- » **European Health Data Co-operation:** Verena Kaip, Candice Altmayer
- » **Resilient Supply Chains:** Giulia Colombo, Cornelia Flood
- » **Health and the Green Transition:** Angela de Ruijter, Marianne Chagnon
- » **Health Economies:** Gonçalo Pinto Mendes, Sophie Millar

Forming bonds in an entirely digital setting is no easy feat, and yet this new generation of future healthcare leaders shares an experience with 60 peers from across Europe and have made life-long connections.

As you read through the recommendations which follow, I invite you to do so with open minds. Embody the disruptive spirit we have in considering what direction healthcare should take – be reflexive in questioning the healthcare system we have, and move to construct a meaningful culture of health that benefits all citizens.



**Seán
Byrne**

EHP6 President



2021 has already been, undeniably and once again, an extremely challenging time for our established healthcare and economic systems. But above all, 2021 has been, undeniably and once again, an extremely challenging year for *people* – who are, in the end, at the centre of everything else. This is then also the time that politics and policy together with all stakeholders around, need to respond to the real needs and face the true opportunities to make courageous changes that bring us all a step forward. In this context, the 6th edition of the European Health Parliament (EHP6) has lived through a historic time, witnessing a series of changes at the policy level, with the first steps being made towards a European Health Union, the development and approval of the EU4Health programme, the establishment of HaDEA and the conversations around expanding the remit of the ECDC and EMA among many other milestones.

Whilst these are major indicators of changing times, many of the ongoing challenges are, unfortunately, not easily tackled; it will require a common effort, and we will be battling through many of the effects of the COVID-19 crisis and subsequent crises this triggered for the years to come. This is why now, more than ever, making sure that young voices are not only involved, but also leading the policy agenda, is essential.

The decisions made today will have an impact on how the tomorrow works, and for that reason the youth perspective will be primordial to ensure a sustainable recovery. Equally as important, though, is

ensuring that we take a step further, using the learnings to not only overcome but also improve – creating innovative approaches to potential future challenges through the out-of-the-box thinking that complicated situations like the one we are living unlock. Whilst acknowledging the reality that we're living is key, we have to be forward-looking, and apply the learnings we take in a future-proofed manner. We need to take on the 'false' excuses that for too long have held us back and expose where and where not national sovereignty is not providing a better response to the needs of the people of Europe.

EHP6 has once again succeeded at capturing this notion. Moving for the first time to an all-virtual setting to ensure that the voices of young leaders in the healthcare sector would continue being heard despite the restrictions, I am proud to present the outcomes of yet another successful edition of this important initiative.

The theme of "Recover, Reinvest, Reinvent: Shaping a European Health Union" mirrors the willingness of the European Union to come out stronger from this crisis, putting healthcare at the core of the policy agenda, moving away now more than ever from the view that this is solely a national matter. Our chosen theme has been underpinned by 5 topics that will be key in the process of moving forward together to come out stronger and more united: Telemedicine and Patient-centred Care; European Health Data Co-operation; Resilient Supply Chains; Health and the Green Transition and Healthy Economies.

If anything, the importance of working together under a common union has been reinforced through the challenges experienced in recent months, which did not understand of borders, countries or regions. With 60 participants from all the healthcare sectors and all over Europe, EHP has lived up to this, developing a series of policy recommendations that focus on the common good for all the European citizens.

Not only are the recommendations developed by this cohort forward-looking; so has been their way of working. EHP6 participants have managed to adapt internal processes to make EHP a more dynamic, engaging initiative, opening the space to the broader healthcare community. With outstanding initiatives such as the newly-introduced #EHPChats – a live event on Twitter that brought together a wide range of healthcare stakeholders to participate in a conversation about self-care; or the #VaccineChamp website – to tackle vaccine hesitancy, with a series of activities such as a competition, this year's cohort has gone above and beyond to adapt to the new realities and make EHP more engaging than ever.

To all the outstanding *EHPers* that have made this edition's policy recommendations a reality: you are the present and the future. Look to the past but don't get stuck on it, because what really makes you exceptional is your way of applying the learnings to make the world a better place for the generations to come.



**Zeger
Vercouteren**

**Worldwide Government Affairs
and Policy Vice President,
Europe, Middle East & Africa
and Global Supply Chain
Johnson & Johnson**



If there is one thing that is clear from the past year, it is that crises can significantly affect our state of being in ways that we are only beginning to understand. This is especially true with regards to our health – the COVID-19 crisis has upended all our systems of stability and normalcy. “Challenge” is an understatement – the world has been impacted in ways that it has never dreamed of. However, we have also been resilient. We have faced the challenges of the past year in solidarity and with empathy. We have come to realise that healthcare, especially in regards to our mental health, has been of the utmost importance – and continues to be.

We see this type of solidarity within the European Health Parliament, which brings together over 60 talented young health professionals in shaping future European innovations. The EHP has shown time and time again that its strength lies in the diversity of thought – bringing young professionals from a variety of backgrounds fosters valuable discussion

for EU health policies. By focusing on protecting our health, tackling the topic of disease, and considering innovation in technologies, the EHP provides an inspiring setting and a great point of reference for leading policymakers and organisations alike.

We at EU40 – The Network of Young MEPs recognise the value of democratic participation, with an eye of regard for young people. The work of the EHP is essential in bringing fresh voices into the conversation at the European level, whilst also providing the opportunity for young professionals to network and learn valuable insight. EHP continues to give us the chance to connect young MEPs with health sector specialists, further contributing to a future, healthier Europe. We are proud to be a part of an initiative which for years has boasted participants from a variety of sectors and nation states, and look forward to the presentation of the EHP6 recommendations.



**Alessandro
Da Rold**

Managing Director
EU40



Last year, the COVID pandemic has hit hard the European Union (EU), demonstrating cruelly that the importance of public health for European societies has been too long undervalued. Since, a consensus has emerged on the need to support public health structures and social protection systems, and to develop strategies at EU level to fight efficiently new threats like the COVID. The pandemic has also hit dramatically the economy, requesting Member states and EU institution to agree on an unseen recovery plan, and on ambitious budgetary perspectives.

In the last 18 months, new European policies have emerged and the true nature of the EU has evolved – opening the possibility to finally consider it as a Welfare state. Those changes have been decided under the pressure of events: now, it is time to organize a broader debate on the topic. Gathering a group of young professionals and post-graduate students to confront their views, experiences and ideas in the frame of the EHP is a way to contribute to the reflection on the future of EU health policy. Indeed, since 2014, the EHP project has been successful because all participants and conveners

are convinced that it is the responsibility of citizens, media, private companies, higher education institutions and civil society organisations to contribute to the EU policy-making.

The College of Europe, which has been preparing graduate students for leadership functions in European affairs since 1949, is most grateful to its partners (Johnson & Johnson, Euronews, European Patients Forum, EU40, Mavence, Porter Novelli and Young European Leadership) for this unique opportunity. For us, initiatives like the EHP are fundamental: our mission is not only to equip our students with the best knowledge and skills, but also to confront them with concrete experiences of collective work and negotiation, and to encourage them to develop their critical thinking.

We are very proud of the College students who worked enthusiastically within the EHP, on top of their very demanding study programme and research duties. I hope that the analyses and proposals of the Sixth EHP will help EU policy makers to shape the future of European public health.



**Olivier
Costa**

Director of European political
and governance studies

College of Europe



We live in a world challenged ever more often by extremely complex and multifaceted issues. To craft adequate solutions, and often even to properly frame the questions we need to answer, it is crucial to build bridges and to bring together people from across various professional realities.

The EHP is a prime example of how this can be done. It also proves the value of having diverse voices contributing to the policy debate, and to building policy recommendations – which you will appreciate when reading through this report.

Mavence has been a proud partner of the European Health Parliament since 2017, helping to select the young professionals that would then go on and shape these very recommendations, and, together the other partners, supporting the participants throughout the whole programme.

In these times, so heavily marked by the Covid-19 crisis and the resulting impact on our health, personal and professional lives, the level of knowledge, dedication and professionalism that we have witnessed from the participants of the EHP has been truly encouraging.

This 6th EHP edition has been unique and challenging on many levels, but it has also been a great success – showing the commitment of the young professionals passionate about health to contributing to a better future.

I would like to congratulate all the participants on this wonderful achievement and wish them great success as they continue their professional journey.



**Anna
Koj**

**Managing Director
Mavence Brussels**



The COVID-19 pandemic is a pivotal moment for the future of healthcare. While vaccination programmes continue to scale up around the world and we cautiously move from crisis response towards recovery and reform, this is a critical moment to reimagine healthcare and build resilience in our health systems. The importance of research, development, and innovation has been underpinned by new diagnostics and technology to develop COVID-19 vaccines.

In less than two years, EU health policy developments have advanced considerably as part of efforts to build a robust European Health Union. The new Pharmaceutical Strategy for Europe, the new Industrial Strategy, Europe's Beating Cancer Plan and the EU4Health programme seek to address existing challenges, prepare for future pandemics, build healthy economies, and ensure resilience whilst facilitating continued innovation.

The policy recommendations devised by this year's EHP members reflect the number of paradigm-shifting transformations expedited by the pandemic. Focusing on telemedicine and patient centred care, European health data co-operation, resilient supply chains, the green transition, and healthy economies, these recommendations highlight the inextricable link between our health and functioning economies.

The EHP is a unique platform that brings together Europe's next generation of health leaders who work diligently to develop innovative and disruptive perspectives to confront the most urgent health issues facing societies today.

It is a privilege to support this passionate and enthusiastic group of young professionals in their advocacy efforts to shape a European Health Union.



**Lorraine
Baldwin**

Senior Vice President
Porter Novelli



As the NGO for Youth Empowerment, the perspective of the young Europeans is always in the spotlight for Young European Leadership (YEL). The current COVID-19 pandemic, being no exception.

It is common knowledge that the last year has been a demanding one for the entire world population but highlighting the youth in Europe. For those, it has more than likely been the most challenging year of their lives. Many young Europeans had to put their life plans and hopes on hold and were left with complete uncertainty as to when this would change.

All of us are living during history in the making.

However, it might have been a long overdue appointment with history that showed how overused most health systems have been. The lack of education surrounding the importance of a functioning health system in the population, became impossible to ignore.

It is important to remember – each member of this year's European Health Parliament (EHP), is part of the workforce

of the future who will have to deal with the consequences of the pandemic. Time and again, such catastrophic situations present rare opportunities. Tremendous investments will be made by the EU to fund the recovery of the EU. Those investments require very careful consideration, as these will be the building blocks and define what matters in the future.

Now is the time to invest in a more developed and future-oriented healthcare system. Now is the time to invest in better education for the entire EU population.

From our numerous experiences, YEL know that behind each developed policy recommendation is a personal story from young and ambitious people who want to make a change. They are committed to ensuring that our health future is better than it has been in the past. There is no better time than right now to get the attention of policy makers on recommendations for health.

Young European Leadership are proud to be partnering with the EHP, to create this great opportunity.

This will prove that diplomacy and youth engagement, cannot be significantly slowed down by the pandemic, as there have been so many innovative and creative ways to make this year's EHP edition quite special as always. The aim will also be to create an environment where likeminded people can discuss and support each other in their ideas on sustainable solutions for the health sector.

Finally, I do hope you all keep in mind that every member of this year's EHP are still young, but already mature enough to make a significant impact – to be passionate about issues and dedicated to creating solutions and work towards achieving health objectives for this generation and future generations, to enable Europe to lead by example.



**Pauline
Kühlwein**

Delegation Director
& VP Strategy

Young European Leadership
(YEL)



The last 18 months have undoubtedly proved to be amongst the most challenging and exhausting years for healthcare at a global level. The ongoing COVID-19 pandemic continues to expose several known and unknown weaknesses of our health and care systems. It continues to have a particularly strong impact on the most vulnerable, for instance on patients experiencing disruptions of access to healthcare and healthcare services, additional stress, anxiety, and social isolation.

National, European, and international institutions have responded to these ongoing challenges with several important initiatives and policies. At the EU level, initiatives such as the European Health Union and new EU4Health Programme, have the potential to pave the way for what we all hope are more collaborative, connected, stronger and resilient health and care systems. However, such initiatives will have to be shaped and implemented around the real needs of Europeans.

In this context, and especially as a former member of the EHP myself, I am extremely glad to introduce the recommendations from this year's cohort. The recommendations address a series of fundamental issues in a comprehensive, concrete, and innovative manner. Telemedicine, health data co-operation, stronger supply chains and the transition to person-centred, healthier, and greener economies are undoubtedly all fundamental ingredients of the complex recipe to move beyond the crisis without simply restoring the pre-COVID-19 status quo.

As the European Patients' Forum (EPF), we welcome the attention dedicated to elements such as co-creation, patient empowerment, health literacy, increasing trust and access to care, all very much integral parts of the work of this year's cohort.

In addition, I would also like to congratulate the EHP6 members for engaging with and securing

endorsements from an impressive range of key stakeholders, including Members of the European Parliament, international organisations, patients and civil society representatives, as well as academics and experts. This is excellent, as it both strengthened the recommendations and secured support for their future dissemination beyond Brussels. This year's cohort must be applauded for tackling the additional challenges of connecting in a completely virtual environment and embarking in new efforts, such as the EHPchats on Twitter or the #VaccineChamp initiative.

To conclude, EPF is once again proud to be a partner of the EHP initiative which brings together brilliant young professionals to discuss and propose innovative ideas to improve healthcare – an endeavour that is needed now more than ever.



Michele Calabro

Policy Adviser

European Patients' Forum
(EPF)



As Europe's leading international news channel, Euronews cultivates and promotes a pan-European perspective where all views and voices are welcome. Our mission is to empower people across the continent – and beyond – to form their own opinion. In a similar vein, the European Health Parliament brings together a variety of participants who, through a collective effort of debate and reflection, propose solutions to public health challenges.

Following last year's successful partnership, where Euronews and EHP worked together to overcome the challenging circumstances of the pandemic, we decided to join forces once again to bring our audiences health-related stories told from a different angle.

As media partner, Euronews hosted a live debate on YouTube centred on the future of healthcare. Moderated by Euronews' science correspondent Jeremy Wilks, the conversation examined the rise in telemedicine and the potential medical applications of artificial intelligence. Dr. Seán Byrne, President of the European Health Parliament, took part in the debate alongside five other healthcare experts.

We're happy to provide the EHP with an additional platform to drive the conversation around the nascent EU's health policy. With its 12 distinct cross-platform language editions, Euronews is available in over 400 million homes across 160 countries, including 67% of homes in the EU and the UK, and reaches over 140 million people every month. Our YouTube channels have more than 10 million subscribers and register an average of 125 million views every month.

The EHP recommendations are a good example of bottom-up policymaking, designed by and for citizens, and serve to draw attention to the trends that are poised to shape our post-pandemic world. The COVID-19 crisis has altered nearly all aspects of our lives and has challenged long-established socio-economic models. Employment, workspaces, gender equality, sustainability, innovation and technology have all acquired a new significance and must be part of the conversation to rethink and rebuild our healthcare systems.



**Gardenia
Trezzini**

**Brussels Bureau Chief
Euronews**



Committee for Telemedicine and Patient-centred Care

The COVID-19 pandemic accelerated the use of telemedicine as an innovative way to support patients, reduce pressure on inpatient care, and maintain access to routine services. The deployment of telemedicine needs to be strengthened to make it a sustainable, alternative solution for patient-centred care and to create a more resilient health system which is able to cope with sudden changes.

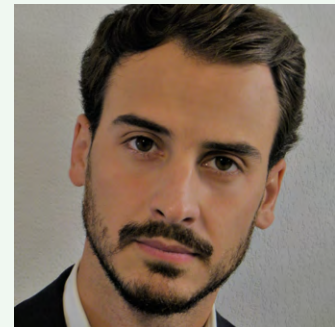


Committee for Telemedicine and Patient-centred Care

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Executive Summary

The Telemedicine and Patient-Centred Care Committee offers 10 policy recommendations, with the aim to design an accessible, flexible, and secure use of telemedicine for a more resilient health system with the patients' interest at its core:

Creating legal certainty through a coherent regulatory and policy framework:

1. National competent authorities to create a legal framework for telemedicine
2. Member States to develop, implement and evaluate national strategies on telemedicine
3. European Commission to develop a communication on telemedicine

Investing in digital health literacy and skills and incentivising telemedicine deployment:

4. Establishment of a European Digital Health Telemedicine Ecosystem (EDTE)
5. Fostering the implementation of local health literacy and skills initiatives
6. European Commission to link national hospital innovation networks to the European Digital Innovation Hub
7. European Commission to review HCPs' harmonised minimum training requirements under Directive 2005/36/EC
8. Streamline initiatives to support continuous professional development

Improving trust and awareness by facilitating co-creation processes and enabling the uptake of telemedicine quality labels:

9. Stimulate co-creation and patient empowerment to ensure trust and alignment with citizens' and HCPs' needs
10. Establish a quality label for telemedicine solutions to build trust and awareness for citizens

- ▶ Executive Summary
- Introduction
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Introduction

The COVID-19 pandemic has accelerated the use of telemedicine as an innovative way to support patients, reduce pressure on inpatient care, and maintain access to routine services. This has facilitated patients' access to diagnosis, treatment, and support from, potentially, anywhere at any time. However, for telemedicine to be a sustainable alternative or a complementary patient-centred tool to in-person care, quality and infrastructure have to improve, thus ensuring equity in access to services.¹ The following elements need to be addressed:

- » legal clarity and guidance;
- » incentives for the deployment of telemedicine and digital health skills and literacy;
- » trust and awareness by facilitating co-creation processes and enabling the uptake of telemedicine quality labels.

Policy environment

According to the Commission Communication COM/2008/0689, telemedicine can be defined as “the provision of healthcare services at a distance – can help improve the lives of European citizens, both patients and health professionals (HCP), while tackling the challenges to healthcare systems”.² While clear guidance and legal certainty are prerequisites for realising its full potential, the current regulatory framework is still fragmented,³

touching on multiple Directives⁴⁻⁷ and Regulations.^{8,9}

Widespread adoption of telemedicine before COVID-19 faced several challenges, including well-defined reimbursement mechanisms, coherent governance structures, resistance to change and slow adoption of new technologies, particularly from HCPs.^{1,10} With a low acceptance by HCPs and patients,¹¹ policymakers had little incentive to amend existing regulations. There has been an immediate need for telemedicine with the COVID-19 outbreak and, to that effect, social distancing practices. As governments were not fully prepared, they had to reactively adapt the legal and health system over a short period of time. This resulted in uncertainties for all the stakeholders involved. Moreover, it had a massive impact on care provision, particularly for patients suffering from mental health and chronic diseases requiring regular consultations.¹²

An innovation-friendly environment is essential for telemedicine to be used by patients and HCPs. The healthcare industry and national governments play an important role in making telemedicine solutions available. While a top-down approach with European Union (EU) funding mechanisms is vital to ensure equal access across the EU (EU4Health,¹³ Digital

Europe Programme¹⁴ and Horizon 2020¹⁵), bottom-up approaches through digital leaders and interconnected innovation units in hospitals and hubs within Member States¹⁶ are essential to further identify targeted needs on the ground.

Telemedicine can be considered supplementary to face-to-consultations as it can facilitate access to care in remote areas and improve the quality and effectiveness of the services.^{17,18} In particular, people with rare diseases report that telemedicine could be considered as a trade-off between seeing HCPs face-to-face which involves better human contact and using remote consultations to save time and have access to the best specialists across the globe or enable multidisciplinary consultations.¹⁹ Nevertheless, this is only achievable if certain conditions are met: citizens and HCPs have to be digitally literate²⁰ and are equipped with the right digital skill sets.²⁰ Additionally, equitable and reliable digital health service infrastructures²¹ need to be in place to allow all stakeholders to make informed decisions. Local initiatives should consider the needs, preferences and interests of citizens and HCPs.

In line with this, trust in telemedicine is essential. It can be improved¹¹ by ensuring the co-creation of telemedicine solutions with patients and HCPs and the introduction of independently verified quality labels.

Executive Summary

► Introduction

Recommendations

Conclusions

Acknowledgements

Endorsements

References



Recommendations

The following pages lay out recommendations to decision-makers to ensure citizens' access to flexible and secure telemedicine for a more resilient health system, with patients' interest at its core. These recommendations aim to inspire debates to ensure an innovative European Health Union.

Creating legal certainty through a coherent regulatory and policy framework

For telemedicine to become a sustainable option in the national health system, the regulatory framework in which telemedicine 'fits' and operates should be clearly defined. Strategies need to be established at the appropriate level, promoting the role of telemedicine in the broader context.

National competent authorities to create a legal framework for telemedicine

Legal certainty is central in healthcare and technology, whereas telemedicine stands at the crossroads. On its own, it does not have a well-established framework.³ While the Member States have been adapting to new medical technologies and continuously updating their policy framework, telemedicine legislation lags behind.²² A telemedicine framework needs to be aligned to existing EU and national regulations, such as the Medical

Device Regulation, the In-vitro Diagnostic Regulation, and the Software as a Medical Device Regulation. Besides, it has to determine the legality of telemedicine services, data governance and reimbursement schemes,¹¹ including defining what types of telemedicine services can be used by which groups of HCPs and patients or can be prescribed. Regulatory telemedicine classifications have to be understandable and recognisable by patients and healthcare professionals. It has to be noted that not all consultations are fit for telemedicine. While physiotherapy is considered the least appropriate for telemedicine, sessions with a psychologist would be considered the most appropriate.¹⁹ Additionally, in line with existing EU and national legislations, such as the General Data Protection Regulation, the framework has to take into account the protection of personal data as well as medical liability issues from providing care remotely or soft- or hardware malfunctions. Harmonised approaches in the interpretation and application of GDPR for telemedicine solutions would be a positive development.²³ Simultaneously, patients have to be educated to consent to the use of specific telemedicine solutions.

Clear reimbursement schemes are one of the highest priorities of patients.²⁴ As reimbursement frameworks differ widely across the EU, telemedicine access should not

be limited by the reimbursement schemes in place. Public reimbursement models should be updated to ensure clear funding pathways that are efficient and digitally friendly.²⁵ Existing models can serve as best practice examples.²⁵ European coordination would be of added value to ensure continuous healthcare provision across the Member States. European citizens deserve to have legal certainty on how their data and aspects of their care are managed. Providing legal clarity to the industry enables structures for innovation and development.

Member States to develop, implement and evaluate national strategies on telemedicine

To maximise the potential of telemedicine, stakeholders need to create synergies in a strategic vision, outlining how it fits in their health ecosystem and what is being done to strengthen it. Strategies must outline the existing legal framework and its current scope, maximising clarity and awareness of opportunities for patients, HCPs and industry. It should consider the evaluation of telemedicine within the broader healthcare context,²⁶ including the various stages of a patient's journey and taking stock of European forums such as the eHealth Network.²⁷ It should leverage telemedicine to further enhance cross-border healthcare and

Executive Summary

Introduction

► Recommendations

Conclusions

Acknowledgements

Endorsements

References



Recommendations

resilience of national health systems as part of the European Health Union and the National Recovery and Resilience Plans.

After consultation with relevant stakeholders, governments can steer the activities and set strategic priorities which the industry is incentivised to meet.²⁸ This way, needs-based solutions will be identified and developed more effectively, linked to meet the needs of patients, HCPs and other relevant stakeholders along the patient's journey.

European Commission to develop a communication on telemedicine

Considering the limited EU competencies in health and the fragmentation of EU legislation on telemedicine on the one hand – and on the other, opportunities linked to digital transformation and cross-border healthcare, including patient's rights – EU level guidance is urgently needed for national and regional policymakers to ensure citizens' access to flexible and secure telemedicine.

Building on the 2018 European Commission communication on digital transformation,²¹ the European Commission should develop a communication on telemedicine, taking stock of its intended actions and lay out a

roadmap for telemedicine implementation by involving the eHealth Network and the eHealth Stakeholder Group. Additionally, it should consider the outcome of the evaluation of the Directive 2011/24/EU, as telemedicine greatly affects patients' access to safe and high-quality care in another EU country and the cooperation between national healthcare providers.²⁹ An accompanying Staff Working Document should provide an overview of Member States' strategies and collect best practices from relevant stakeholders.

Investing in digital health literacy and skills and incentivising telemedicine deployment

While a sound regulatory framework provides legal clarity, it does not assure the availability and accessibility of telemedicine. The development and deployment of patient-centred solutions need to be incentivised for health systems to cope with the increasing demand for high-quality healthcare, accelerated by the digital transformation. Citizens and HCPs have to be digital health literate and possess adequate digital health skills matching a patient's journey and HCPs' specialisation to navigate the increasingly digitised health system and telemedicine solutions.

Establishment of a European Digital Health Telemedicine Ecosystem (EDTE)

To increase the availability of telemedicine and create an innovation-friendly environment, stakeholders have to overcome many hurdles, such as issues surrounding cost-efficiency, interoperability between tools, funding, non-transparent and inadequate IT infrastructure.

The proposed European Digital Health Telemedicine Ecosystem (EDTE) will advance funding schemes to maximise availability at all stages. The EDTE will foster a common framework that can be then transposed and replicated in the Member States. It includes the establishment of standards and guidelines for telemedicine practice (both IT and health practices), laying a foundation for faster deployment of telemedicine services on a large scale, incentivising its wide adoption, also in the context of cross-border healthcare. A key feature of the EDTE is its co-creation approach, including the involvement of patients and HCPs at all stages. Finally, the telemedicine solution has to facilitate patient-centred care provided by HCPs and health outcomes along the different stages of the patient journey.

Executive Summary

Introduction

▶ Recommendations

Conclusions

Acknowledgements

Endorsements

References



Recommendations

Fostering the implementation of local health literacy and skills initiatives

To fully exploit and benefit from telemedicine, citizens and HCPs need to be knowledgeable about the solutions, possess digital skills, and be empowered to manage their health and provide high-quality healthcare. While COVID-19 accelerated citizens' digital health literacy, there is still a digital health literacy and skills gap that needs to be filled in local, regional and national contexts.

In line with the recommendations of the European Health Data Co-operation Committee, an Action Plan for digital health skills and literacy is needed on the EU level. The Action Plan should be accompanied by a detailed roadmap tracking progress on national, regional and local health literacy initiatives. Initiatives must be promoted that consider the various social context of the population (i.e. ageing, vulnerable groups), outlining access to digital healthcare along the patient journey. The implementation of national communication strategies should be adapted to the local context, outlining how citizens, irrespective of their level of education or age, can acquire digital skills and improve their literacy, enabling them to access the health service they need.

European Commission to link national hospital innovation networks to the European Digital Innovation Hub

To utilise local hospital innovation and business development units' potential to expose HCPs to digital health solutions and hands-on learning experiences, regional and national level networks for these units should be established and strengthened. On the national and EU level, these networks should also be linked to the Digital Innovation Hubs,³⁰ focusing on testing before investing and skills and training, enabling the exchange of best practices across regions and countries.

European Commission to review HCPs' harmonised minimum training requirements under Directive 2005/36/EC

With the prerequisite that digital solutions are embedded in normal care pathways, HCPs should have the right set of digital skills to improve health outcomes and support interdisciplinary working. The scope should be defined to match the various medical specialities across the EU, including general and technical digital skills and those that directly affect the HCP-patient relationship (digital communication, collaboration and promoting digital health literacy). General digital skills range from data protection and IT safety to legal and ethical consideration using

digital tools. Technical skills include the use of telemedicine and artificial intelligence and clinical decision support.³¹

The need to include e-health (electronic communication with patients and professionals, telehealth) in Annex V Point 5.2.1 of Directive 2005/36/EC³², adapting the minimum knowledge, skills and training subjects for nurses responsible for general care has previously been examined.³³ Therefore a wider assessment has to be carried out by the European Commission in consultation with HCPs and social partners with a view to reviewing harmonised training requirements of HCPs covered under the Directive. This exercise and revising the medical curricula of future HCPs will ensure that professionals are equipped with the right digital skills to provide high-quality care.

Streamline initiatives to support continuous professional development

Continuing professional development (CPD) and life-long learning (LLL) of the current HCPs should be in line with the scope mentioned above. CPD should be offered to all HCPS, considering the ageing workforce, various education levels, and during the professionals' working time. When developing training modules, interdisciplinary and interprofessional collaboration needs to

Executive Summary

Introduction

➤ Recommendations

Conclusions

Acknowledgements

Endorsements

References



Recommendations

be taken into account within the real-world learning environment: most HCPs retain knowledge 70% by learning at the workplace, 20% when exchanging information from colleagues and only 10% during formal learning.³⁴

On the EU level, existing initiatives, such as the New Skills Agenda, Pact for Skills and Digital Europe Programme, acknowledge the digital skills gap in the sector, allowing for an exchange between EU stakeholders. However, at the national level, these initiatives are too complex for individual stakeholders to reach their full potential and, therefore, have to be streamlined to make a real impact at the local level.

Improving trust and awareness by facilitating co-creation processes and enabling the uptake of telemedicine quality labels

Stimulate co-creation and patient empowerment to ensure trust and alignment with citizens and HCPs' needs

Despite the technological progress in the medical field, the actual use of telemedicine remains below its potential, fuelled by a lack of trust.³⁵ Patient trust in healthcare solutions can be increased by improving co-creation and prioritising patient empowerment.

Co-creation helps improve trust and support the development of needs-based tools. Research has shown that compliance to treatment significantly increases if patients are actively involved in their health management.³⁶ When telemedicine is being developed through public-private partnerships, industry stakeholders should provide a detailed plan on how patient and HCP co-creation processes are incorporated in the various stages when applying for financial support and their plans for co-creation in deployment. Key elements to include when developing patient-empowering solutions are health literacy, patients' engagement, shared decision-making, self-management, patients' control over their health status, experience-sharing and communication with HCPs.³⁷ Including these elements and criteria would be a great incentive for industry stakeholders to actively engage patients and HCPs, which will also increase their trust and adherence.

Establish a quality label for telemedicine solutions to build trust and awareness for citizens

Trust and awareness in the telemedicine solution are key factors for equity access to healthcare. Trust can be built and further strengthened through certified quality labels, as successfully showcased by European labels

such as the EU energy labels³⁸ and the EU Nutri-Score nutrition label.³⁹

Building on the Horizon Europe priority “digital tools for citizens empowerment and for person-centred care”,⁴⁰ it is essential to develop a European label that encompasses not only mHealth applications, but telemedicine solutions as a whole. The top-down approach provides a common EU framework, demonstrating that the solutions' safety and quality standards meet the needs of European citizens. The label can also be used as an incentive to support the industry in developing innovative, co-created solutions. It can provide clarity about potential areas for improvements, including what standards still need to be met. Lastly, this will drive cross-border uptake of telemedicine solutions as quality assessments will not need to be replicated.

The EU label is supplemented by national initiatives and best practice sharing supported by a European framework that facilitates the standardisation of the labelling process at the national level.

Executive Summary

Introduction

▶ Recommendations

Conclusions

Acknowledgements

Endorsements

References



Conclusions

The COVID-19 pandemic has seen telemedicine and patient-centred care take centre stage and has created a pivotal momentum in the European health arena. These recommendations are based on, and supplemented by, considerations of existing programmes and policies. To further advance the range of comprehensive healthcare provision, future recommendations should also consider telemedicine practices alongside home-based care to ensure a more resilient health system. This will create a more trusting and intimate environment for the patients.

The overall key requirement for making telemedicine a European success are the right incentives for all stakeholders in the health ecosystem. Although incentives may take different shapes in different healthcare systems across all stakeholders, collaboration with motivated citizens and targeted educational strategies are fundamental. These recommendations represent a step forward to favour a widespread implementation of a sustainable and patient-centred telemedicine.

- Executive Summary
- Introduction
- Recommendations
- ▶ Conclusions
- Acknowledgements
- Endorsements
- References



Acknowledgements

The Telemedicine and Patient-Centred Care Committee would like to thank the following individuals/organisations for the contribution to the work of the Committee during the past months. The final policy recommendations are a result of essential feedback and discussion between the committee members and experts in telemedicine and patient-centred care. Their contribution does not necessarily imply endorsement of the specific policy recommendations:

- » **Michael Strübin**, MedTech Europe
- » **Sara Roda**, Standing Committee of European Doctors
- » **Shannon Altimari**, GSK
- » **Anna Kole, Jessie Dubief, Erwan Berjonneau**, EURORDIS

"The COVID-19 crisis has shown that it is possible to make leaps towards a digital transformation of health and care in a very limited time frame. With face-to-face care heavily restricted during the pandemic, telemedicine has undoubtedly helped preserve access to and continuity of care. However, the recent past has also laid bare the limits of remote care, and added to concerns that some services constitute low value care. As we move closer to controlling the pandemic, the European Health Parliament's Telemedicine and Patient-Centred Care Committee's recommendations are timely. The focus on legal certainty, digital health literacy and skills, and citizen involvement, is especially relevant, given that structural barriers to the wider and appropriate use of telemedicine still remain, and are difficult to tackle in the short term. Whatever path countries eventually take, the elements discussed in this report merit consideration."

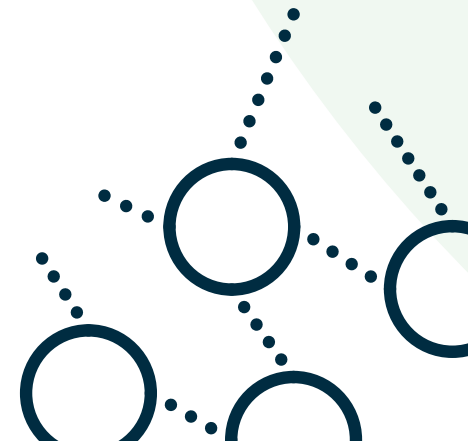
Tiago Oliveira Hashiguchi, OECD

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Executive Summary
Introduction
Recommendations
Conclusions
» Acknowledgements
Endorsements
References



**Committee for
Telemedicine and
Patient-centred Care**



Endorsements



Kateřina Konečná

*Member of the European Parliament
(GUE/NGL, Czechia)*

"I am very happy to endorse the European Health Parliament's recommendations on Telemedicine and Patient-Centred Care. The policy recommendations are thorough, comprehensive and would be very useful for the European Parliament's future work. Only with a strong and close coordination, the EU will be able to overcome current crisis. In the COVID-19 pandemic, telemedicine has proved that it is a very valuable service for patients. The EU, together with Member States, should finally recognise the added value of telemedicine and start work on the common framework for it."



Sibylle Reichert

*Executive Director
Association Internationale de la Mutualité (AIM)*

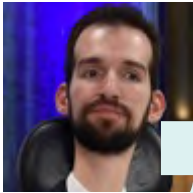
"AIM health insurance funds and not-for-profit health mutuels are pleased to endorse the policy recommendations of the European Health Parliament's Telemedicine and Patient-Centred Care Committee.

The coronavirus crisis has shown how important technologies in the health sector are. Teleconsultations were deployed in record time. Although remote consultations should be complementary to physical contact with the healthcare provider, they are a safe way to follow up on chronic diseases and to ask for prescriptions. It is important that areas of application and/or patient groups that could benefit from telemedicine are identified. The reimbursement process for health applications should be facilitated and a framework for teleconsultations, as well as a reimbursement mechanism, needs to be defined. Digital health literacy must be promoted and integrated into mobile health plans of the Member States to ensure accessibility to telemedicine care for all and help citizens acquire digital literacy skills."

- Executive Summary
- Introduction
- Recommendations
- Conclusions
- Acknowledgements
- ▶ Endorsements
- References



Endorsements



Stelios Kypouropoulos

*Member of the European Parliament
(EPP, Greece)*

"The last 2 years we are facing as a humanity an enormous challenge for our health which threatened the economic and social stability. The ongoing COVID-19 pandemic revealed our weaknesses in our health care systems across Europe and the need for common policies and actions. On the one hand, at the outbreak of the crisis we were faced with different perspectives and political decisions among European countries for the management of this health crisis, from which we, of course, had our winnings and losses.

On the other hand, the pandemic enforced us to work together and act as a union with solidarity, determination and equality. The European Union invested in vaccinations' research programmes with 2.7 billion euro in order to help the scientists to develop the proper vaccine for the fight against COVID-19.

Also, as European Parliament we helped to design the most promising recovery package in the history of Europe. We have the Next Generation EU and especially the EU4Health programme, which plans to mitigate the adverse effects of COVID-19 in the following years, build quality and resilient health care systems. EU4Health will focus its activities on developing the quality healthcare standards at a national level of EU members and improve the infrastructure for telemedicine. We hope that by doing so, we will prevent future major cross-border health threats or another pandemic. The programme will also limit Europe's dependence on essential medical supplies, devices, and equipment from third countries.

We really need movements like the European Health Parliament (EHP) to connect and empower the next generation leaders to plan innovative and sustainable EU health policies. We need to build a common healthcare pillar in the Union in order to protect European citizens and secure the prosperity in the continent from similar future challenges."

- Executive Summary
- Introduction
- Recommendations
- Conclusions
- Acknowledgements
- ▶ Endorsements
- References



Endorsements



Kristine Sørensen

Founder

Global Health Literacy Academy

"Telemedicine expands opportunities for outreach; leaving no one behind is one of the biggest challenges we face in our fast-forward accelerating world."



Dr David Somekh

Network Director

European Health Futures Forum (EHFF)

"As the Telemedicine and Patient-Centred Care Committee quite rightly points out, the pandemic has dramatically increased the use of telemedicine as a vehicle for therapeutic relationships between citizens and healthcare professionals. In that light, EHFF believes the Committee has accurately identified three key policy drivers to allow consolidation of this potential gain, namely, the need for a coherent regulatory framework across the Member States, investing in digital skills for both parties referred to above (HCPs need to learn techniques to compensate for the differences between tele-presence and face-to-face communication and significant numbers of citizens will need to be supported in gaining confidence in using the medium in this context). Finally, the issue of trust is something that comes up repeatedly in respect of new digital tools and needs to be addressed. Indeed, the Committee's points within several of the recommendations on the importance of co-production are important and well-made. Despite our awareness of the effectiveness of solutions, especially in the digital field, that are genuinely co-produced, rather than having been granted only token input from end-users, unfortunately genuine co-production is not yet the rule and still needs to be encouraged."

Executive Summary

Introduction

Recommendations

Conclusions

Acknowledgements

► Endorsements

References



**Committee for
Telemedicine and
Patient-centred Care**

Endorsements



Marta Branca

Secretary General

European Hospital and Healthcare Employers' Association

"The average age of the healthcare workforce is increasing. At the same time, health workers are suffering through a stressful situation due to the increasing needs of the population and the demand for high-quality and personalised care – which is often not balanced out by an adequate supply of health workers, with various situations of health workforce shortages and geographical maldistribution. This imbalance between supply and demand has been exacerbated during the COVID-19 pandemic.

Digital health solutions and digital technologies in general can be an effective opportunity to mitigate health workforce shortages by enabling more widespread healthcare, closer to patient needs, with a predictive approach. However, if the development and deployment of digital solutions is not accompanied and supported by a strategy to develop and upgrade the digital skills of the current and future health workforce, health workers risk being subjected to further frustration, with negative consequences on their mental health and wellbeing, and consequently on their retention and productivity.

We therefore endorse and support the committee's recommendations, with specific reference to: recommendation 2.4 concerning the request for revision of EU Directive 2005/36/EC for the introduction of specific requirements on e-skills in the university curricula of health professionals; and recommendation 2.5 concerning the request to the EU to support e-skills development and updating programmes within the Continuing Professional Development and Life-Long Learning systems of the Member States."

- Executive Summary
- Introduction
- Recommendations
- Conclusions
- Acknowledgements
- ▶ Endorsements
- References



Endorsements



Nicole Denjoy

*Secretary General
COCIR*

"We should not be blindsided by the increased use of telemedicine solutions during the COVID-19 crisis. Instead we should build upon the experience gained and ensure that we take the right steps to structurally integrate telemedicine into our health systems for it to keep delivering value long after the pandemic. We strongly believe the recommendations from the Telemedicine and Patient-centred Care Committee will help to create such a sustainable environment, one where patients will play a more central and empowering role in their care process."



Catarina Baptista

Board Member at Hospital Cruz Vermelha – Portugal

"The recommendations emerging from the work of the Telemedicine and Patient-Centred-Care Committee of the European Health Parliament are in the best interest of all member states and each European citizens. The COVID-19 outbreak urged telemedicine solutions but also exposed asymmetries that need to be addressed. This set of 10 recommendations is a valuable guide for policy and decision making leaders, as it highlights what needs to be done to open the way for full adoption of telemedicine, for both citizens and healthcare professionals. Members states need to assure access to flexible, quality and secure solutions through the development of a comprehensive regulatory framework and the Committee advises on the role of the EU paving this strategy. All stakeholders have to be aligned in improving literacy and supporting continuous innovation to meet citizen's needs. 2021 is the year of recovery plans and patient-centered telemedicine can surely contribute for a healthier EU."

- Executive Summary
- Introduction
- Recommendations
- Conclusions
- Acknowledgements
- ▶ Endorsements
- References



Endorsements



Prof Dr Jefferson Gomes Fernandes

Director, Education Program, International Society for Telemedicine and eHealth (ISfTeH)

Vice-President, Brazilian Association of Telemedicine and Telehealth (ABTms)

"Scientific and real-world evidence has demonstrated the numerous benefits of telemedicine. The COVID-19 pandemic has exponentially accelerated its use worldwide. The ten policy recommendations for telemedicine by the European Health Parliament are a fundamental milestone for the dissemination of the responsible use of telemedicine, that is, with safety and quality. The applicability of these recommendations is not restricted to Europe only, but serves as a reference for all countries that seek to offer their citizens and health systems an efficient and necessary method of health care."



Micaela Seemann Monteiro, MD

Chief Medical Officer for digital transformation, CUF – Hospitais e Clínicas

Former Director of the National Telehealth Center & SNS24, Shared Services for the Portuguese Ministry of Health

Member of WHO's Roster of Digital Health Experts

"European societies and their health systems face enormous challenges – equity and sustainability are at their forefront. New, integrated and scalable healthcare models are needed that deliver continuous, close, personalised, value and outcome-oriented care. An intelligent and efficient use of resources is critical to success. We will not achieve these ambitious goals without the help of data and new technologies – digital health and telemedicine being an important part of it.

The COVID-19 pandemic brought unprecedented attention to the potential of telemedicine. Many who were unconvinced of its value and had even been wary of its use, tried it out realising that it was an opportunity to provide or receive safe care.

But the importance of telemedicine goes far beyond being a substitute for temporarily unavailable face-to-face care. It is more than just a supplement to traditional care. It is an important element of the hybrid patient journey that is under construction. This is a patient journey where remote and face-to-face, digital and human care touch points complement each other. It will improve the health and well-being of every citizen, enhance the citizen's and healthcare professionals' experience and increase the efficiency needed to achieve sustainability.

The European Health Parliament's Telemedicine and Patient-Centred-Care Committee stresses the importance of a concerted European approach in this field and presents sound and workable recommendations to achieve success. Congratulations!"

- Executive Summary
- Introduction
- Recommendations
- Conclusions
- Acknowledgements
- ▶ Endorsements
- References



Endorsements



MD Daniel Ferreira

Clinical Director at Hospital da Luz Digital Clinical Center

"The unavoidable and ongoing digital transformation in healthcare has started long before the COVID-19 pandemic, but was certainly boosted by it, and is here to stay for the future. It has clearly demonstrated the benefits of Telemedicine as an excellent complement to conventional presential medical care, in the best interest of the patient's needs and wishes.

The current **Policy Recommendations of the Telemedicine and Patient-Centred-Care Committee of the European Health Parliament** constitute a valuable guidance that should be carefully considered by all stakeholders interested in implementing and supporting Telemedicine programs, always ensuring that rigorous eligibility criteria for the practice of Telemedicine are followed and that safety, privacy and quality of all doctor/patient interactions are warranted."



Dimitar Kókov

Founder & CEO at Tellocare

"I consider the points addressed essential for the future of telemedicine. There will have to be very clear legislation, that defines which platforms can be used for teleconsultations, since what happens today is the misuse of social platforms for this purpose. This reality puts the user's privacy in danger, as well as putting the health professional in a situation of non-compliance with the GDPR. This has been one of Tellocare's biggest struggles in recent times but without objective legislation we can hardly achieve the goal of making telemedicine safer. I also consider it important to implement an environment that allows the exchange of clinical information more easily and with less bureaucracy between various national health entities and also between Member States."

- Executive Summary
- Introduction
- Recommendations
- Conclusions
- Acknowledgements
- ▶ Endorsements
- References



References

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Executive Summary
Introduction
Recommendations
Conclusions
Acknowledgements
Endorsements
➤ References



Committee for European Health Data Co-operation

The need to transform Europe's health data ecosystem is clear. Leveraging health data offers great potential for fostering effectiveness in healthcare systems, boosting research and innovation, improving diagnosis and decision-making, reducing inequalities, and empowering citizens to access personalised care.



Committee for European Health Data Co-operation

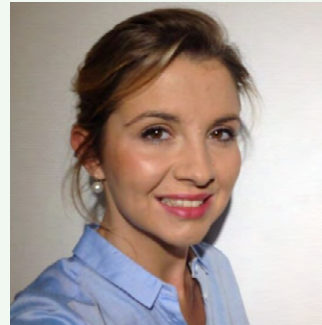
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Mario Villani



Executive Summary

The Committee on European Health Data Co-Operation calls attention to the fragmented health data ecosystem in the European Union (EU), and highlights the urgent need to ensure better coordination and interoperability of healthcare systems to effectively improve research, policymaking, and health outcomes for all European citizens. To foster the deployment and adoption of new technologies at scale, EU policies must also build people's trust in data-powered technologies such as Artificial Intelligence (AI). Targeted attention should be given to the empowerment of all stakeholders, both by ensuring citizens' control over their own data as patients, and by encouraging healthcare professionals to utilise digital health solutions in practice.

With the aim to unlock the transformative power of data in healthcare, the Committee first recommends that EU policymakers build a reliable, secure and agile health data ecosystem supported by a trustworthy and accessible European Health Data Space (EHDS). Secondly, the Committee recommends that the EU actively promote the development of digital health skills towards citizens and health care professionals (HCPs), including the ability to access health information, digital health literacy, and citizens' trust and understanding of emerging technologies.

In developing its recommendations, the Committee conducted a thorough literature review and numerous stakeholder interviews. We identified gaps and roadblocks, exploring potential solutions to enhance EU data use and co-operation to overcome fragmentation within the healthcare sector.

Build a reliable, secure, and agile health data ecosystem

- » **Establish a clear governance framework** – Harmonisation of GDPR interpretations, data standards, and legislation of emerging technologies such as AI is imperative. Without clarity in governance we risk impediments to citizens' trust and the deployment of new technologies.
- » **Consolidate and secure a health data sharing infrastructure** – Infrastructures enabling data exchange are key. Cross-border electronic health record (EHR) exchanges, European Reference Networks (ERNs), FAIRification of data and accessible cloud services will facilitate the digital transformation, but our data infrastructure must have adequate protections against cyberattacks.
- » **Create a trustworthy and accessible European Health Data Space** – The EHDS has unlimited potential to unlock the potential of health data. Combining the potential of all European data spaces, the EHDS can facilitate research through secondary use of data, and also allow citizens to easily access and manage their health data. Building dynamic consent models and establishing interoperable standards can seamlessly bring patient data together.

- » Executive Summary
- » Introduction
- » Approach
- » Recommendations
- » Conclusions
- » Acknowledgements
- » Endorsements
- » References



Executive Summary

Empower stakeholders to benefit from health data sharing

- » **Ensure citizens' involvement and education** – Targeted policies should aim to increase societal approval and citizens' ability to use data-powered technologies, including education and communications efforts such as a Digital Health Literacy Strategy (DHLS) and the creation of a citizens' forum. Special focus should be given to accessibility and the development of a bottom-up approach.
- » **Focus on digital skills for healthcare professionals** – HCPs have the potential to gain the most from digitalisation and to become powerful advocates of its use. Building HCPs digital skills must be interwoven in their education throughout their entire careers.
- » **Engage all key stakeholders** – Expanding the network of data experts and creating accessible and standardised toolboxes for European data use will enhance efforts to transform our digital ecosystem.

We invite you to read our full recommendations to learn more about our vision to reinvent Europe's health data co-operation.

- » Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Introduction

The COVID-19 pandemic underlined the importance of timely access to health data. For research, policymaking, and to improve health outcomes in the EU, data is a key enabler of the digital transformation of health and care systems.¹ Leveraging health data offers great potential: for innovation of new products and services; improving diagnosis and decision-making; fostering productivity and effectiveness in healthcare systems; reducing inequalities and empowering citizens to take control of their health and access personalised healthcare.²

While the pandemic has increased public awareness of the benefits of health data sharing, it has also highlighted a lack of coordination and interoperability among Member States.³ To tackle this, in its 2021 Work Programme, the European Commission announced its intention to deliver concrete results in the area of health data.⁴ A core goal is to increase the accessibility,

availability, and affordability of high-quality healthcare through the creation of a EHDS.⁵ The development of a suitable 'space' within which data can be shared operationally serves to harness the immense potential health data can offer.² A clear regulatory framework can implement transparent protection of citizens' interests and rights, in particular with regard to sensitive primary data collection, while promoting research and innovation through secondary use of health data.

Building people's trust in the use of data-powered technologies, including AI, is key. Without trust we risk neglecting the benefits the digital transformation of healthcare has to offer. To allow the deployment and adoption of new technologies at scale, EU policies must ensure citizens' control over their own data as patients and empower healthcare professionals to utilise digital health solutions in practice.

Executive Summary

▶ Introduction

Approach

Recommendations

Conclusions

Acknowledgements

Endorsements

References



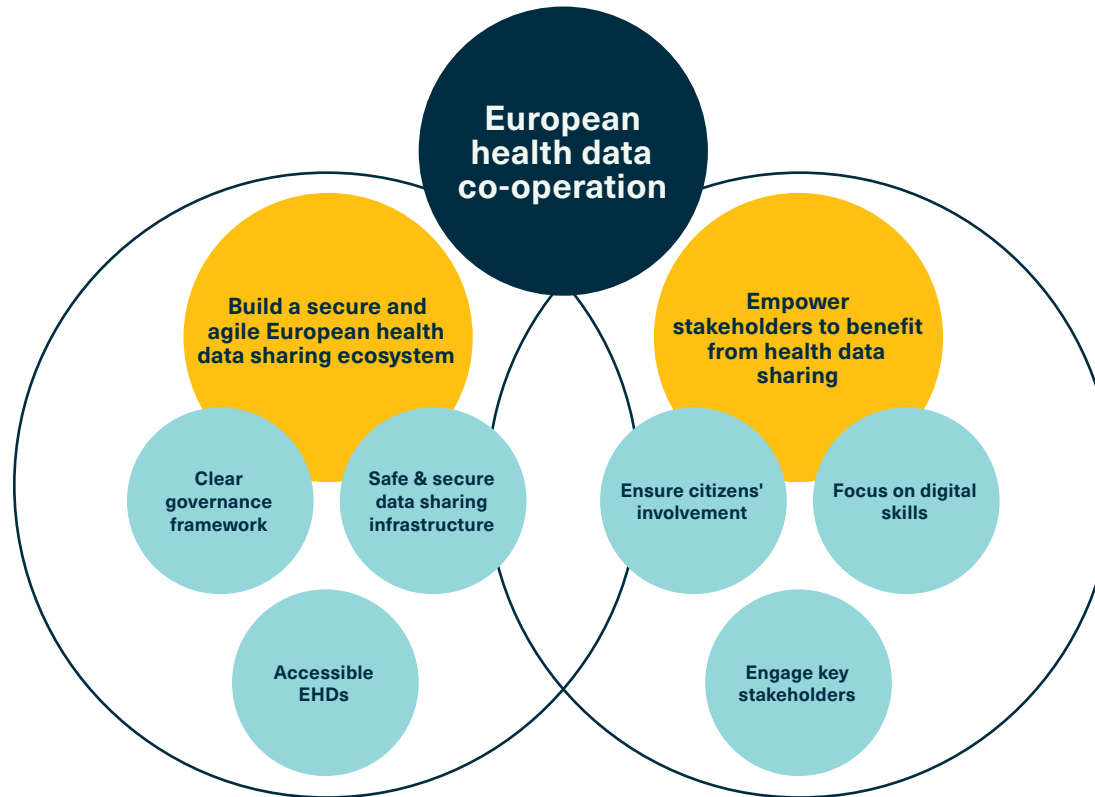
**Committee for
European Health
Data Co-operation**



Approach

The recommendations of our Committee are based on an extensive literature review and interviews with key stakeholders. Our analysis of relevant literature was focused on gaining a deeper understanding of the issues surrounding health data co-operation at EU-level. This allowed us to develop a critical outlook on the current state of EU health data regulation and to dive deeper into various topics, such as interoperability, legal implications, digital literacy, and AI.

The expert interviews conducted provided us with insights from academic, industry and patient advocates, as well as with national healthcare providers. Each stakeholder shared with us their unique perspective and provided us with an up-to-date view of the topic at hand. On the basis of our research and interviews we identified gaps and roadblocks and explored potential solutions to enhance data use and co-operation in Europe, to unlock the potential of innovation and overcome fragmentation within the healthcare sector.



- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Recommendations

The Committee calls attention to the fragmented European health data ecosystem. Our findings demonstrate the urgent need to ensure the coordination and interoperability of EU healthcare systems to support research and innovation, as well as to meet the future needs of European citizens and HCPs.

To deliver on the potential health data can bring to healthcare in Europe, the Committee first recommends for EU policymakers to build a reliable, secure, and agile health data ecosystem supported by a trustworthy and accessible EHDS. Secondly, we recommend for the EU to actively promote the development of the skills needed to unlock the potential of data-powered health tools towards citizens and HCPs, including the ability to access health information, digital health literacy, and citizens' trust and understanding of emerging technologies such as AI.

Building a reliable, secure and agile European health data sharing ecosystem

Establish a clear governance framework

Although seen as a gold standard for data privacy globally, in Europe the General Data Protection Regulation (GDPR) is often perceived as a barrier to data sharing. Our stakeholder interviews and research suggest this need

not be the case. To allow for an interoperable European health data sharing ecosystem, persistent disparities in Member States' interpretation and implementation of the GDPR must be resolved. Moreover, clear and consistent legislation on emerging technologies (e.g. AI) in healthcare is needed.

Align interpretations of the GDPR – Previous EHP recommendations have called for the introduction of a Code of Conduct covering primary and secondary use of health data.⁶ We reiterate the potential clarity such a Code could offer and draw particular attention to existing European Data Protection Board (EDPB) guidelines, which clearly demonstrate the potential for flexible data use in line with the GDPR.⁷ We recommend for the European Commission to adopt clear guidelines on GDPR interpretation in the specific field of health data. Such guidelines should make use of case studies and offer sample interpretations of the GDPR.

Establish a minimum set of common EU data standards – We recommend that the proposed European Data Innovation Board under the Data Governance Act establish a minimum set of common EU data standards for European Health Records (EHRs), based on best practice, and develop a GDPR compliance certification system for European health data.⁸ This system should take the European Union Agency for

Cybersecurity (ENISA) procurement guidelines for cybersecurity in hospitals into account.⁹ In order to enhance European health data co-operation and cross-border healthcare, semantic and technical interoperable systems are crucial, which underline the necessity to establish common European concepts and data models, as well as coding terminologies, standards, and technical guidelines.

Evaluate and harmonise existing legislation towards emerging technologies – Emerging technologies such as AI, the Internet of Things, and robotics bring new opportunities to the healthcare system, yet legal uncertainty remains a barrier to adoption of AI. European businesses identified liability for potential damages (33%), strict data standards (33%), and regulatory challenges (29%) as major external barriers in rolling out AI solutions.¹⁰ While AI solutions are bound to the same EU legislation (fundamental rights such as data protection, product safety and liability frameworks, etc), several aspects of AI (e.g. explicability) leave areas of ambiguity, which should be resolved in pending legislative proposals.¹¹ Fragmentation of regulation and implementation is also increasing costs and impeding pan-European solutions.¹²

The Commission's Strategic Foresight Initiative should include an evaluation of existing EU legislation to identify if emerging technologies are sufficiently covered or whether updates

Executive Summary
Introduction
Approach
► Recommendations
Conclusions
Acknowledgements
Endorsements
References



Recommendations

are needed in-line with Better Regulation.¹³ In this evaluation and updating process, the Committee recommends to:

- » Cross-check and avoid duplication with other legislation (e.g. medical device regulation),
- » Harmonise regulation at the EU-level and ensure Member States are invested in the standardisation of interpretation, implementation, and certification,.
- » Ensure inclusive policymaking by involving all relevant stakeholders and sector representation, specifically including patient groups for the healthcare sector.

Technology is rapidly evolving, and this trend is expected to continue in upcoming years. The Committee recommends to periodically repeat this evaluation and updating process to ensure an agile policy lifecycle.

Clarify EU Certification on Artificial

Intelligence – The lack of a framework on AI at European level is driving further fragmentation across Member States.¹¹ The Committee therefore commends the 2021 Commission proposal for a Regulation on a European Approach to AI.¹⁴ We also recommend for the new regulatory framework to follow the recommendations of the AI High Level Expert Group (HLEG). The Committee supports the pilot and consultation approach taken this far, as well as the framework's principles of being

risk-based and not prescriptive in nature.^{10,11}

The Committee wishes to highlight the need for all current and future regulatory frameworks to take into account the many particularities of the healthcare sector and to include a dedicated analysis of regulatory needs for AI in healthcare. To make the AI framework most relevant to healthcare, the Committee recommends to:

- » Conduct a mapping exercise to explore reusability of deliverables from existing requirements (e.g. from medical device regulation, national frameworks, standards organisations);
- » Set up a stakeholder group including patients, physicians, industry, in order to co-create policies, to improve future compliance to the framework and to actively shape the long-term strategy for AI;
- » Ensure the framework requirements for high-risk application or voluntary labelling outputs to be communicated in plain understandable language and usable format to patients and doctors, in order to build trust.

We believe a certification scheme for trustworthy AI in healthcare could help foster citizens' and HCPs' trust and facilitate producers thanks to clear requirements, given it does not duplicate or conflict with existing certifications in the health data domain.

Build a consolidated & secure health data sharing infrastructure

Establish common principles for the development of health infrastructures

– Considering the ENISA guidelines,⁹ we recommend the European Commission establish principles for a common approach to invest in and develop secure European health infrastructures. This common approach will be underlined by a framework with guidelines for regular security checks on both sides, system engineering in the early deployment stages, and for health data processors. Targeted support to the health IT workforce will in turn increase trust in the security of health data infrastructure and foster the update of health data sharing.

Prepare for potential cyberattacks – The EU should develop a preparedness strategy setting clear incident management guidelines in the event of cyber threats to healthcare systems.¹⁵ As part of the NIS directive, Member States define national security strategies and a Computer Security Incident Response Team (CSIRT), which should take on this responsibility.^{16,17} Malicious network traffic and outdated operating systems are the highest cybersecurity risks for healthcare providers, and efforts must be made in order to proactively defend against breaches at local level. In this regard, the EU may also consider a higher level of security for sensitive data (e.g. genomics).

Executive Summary

Introduction

Approach

► Recommendations

Conclusions

Acknowledgements

Endorsements

References



Recommendations

Facilitate the usage of cloud services for healthcare providers and data processors

– We recommend building European cloud-based data storage solutions for health data, with appropriate security safeguards for risk mitigation. Therefore, we also recommend the European Commission provide health data encryption guidelines and the endorsement of data encryption tools to enhance and facilitate the usage of cloud systems in the health sector.

Further develop and promote the European EHR exchange format and create a European patient ID

– The Commission has adopted the recommendation of implementing a European EHR exchange format, which will be developed by a Joint Coordination Process, with input from industry representatives, health professionals and patients representatives.¹⁸ We encourage this step forward and recommend establishing a permanent committee, consisting of the aforementioned stakeholders. This committee should oversee the continued development and interoperability of the European EHR exchange format, but also of necessary datasets to be prioritised, such as: laboratory results; medical imaging reports; and hospital discharge reports. Moreover, the creation of the European EHR exchange format should foresee establishing a EU-wide unique patient ID, linked with the citizen's eID number.¹⁹ The Commission's proposed Digital Green Certificate to facilitate movement during the COVID-19 pandemic should feed into this objective.

Strengthen the European Reference Networks (ERNs)

– As highlighted by the European Court of Auditors in 2019,²⁰ the ERNs set up by the 2011 cross-border Healthcare Directive have provided European patients with valuable advice, and are widely supported by EU stakeholders such as patients' organisations, doctors and healthcare providers. However, the Commission needs to provide a clear vision for their financing and how to develop and integrate them into national healthcare systems.²⁰ ERNs constitute a best practice for both cross-border healthcare and digital health. Thanks to the development of the web-based Clinical Patient Management System (CPMS), doctors can share data on rare disease patients. It improves access to appropriate care and provides a platform for knowledge sharing and training. Within the EU4Health programme, the financing of ERNs should be strengthened, and budget access procedures should be simplified to allow for the deployment of research through ERNs and to improve citizens' access to treatment.

Focus on data quality and establish

awareness about FAIR data – To allow interoperability and enhance overall data quality, we recommend implementing a holistic European framework in order to classify health data and assess their quality to assure an accurate, complete, reliable, relevant and timely production of datasets. Moreover, we recommend promoting FAIRication (Findable, Accessible, Interoperable, Reusable) of health

data amongst healthcare providers and industry through workshops and sharing best practices.²¹

Create a trustworthy and accessible European health data space

Expectations are high with regard to the Commission's ambition to create a reliable and patient-centred EHDS.²² The EHDS should not only facilitate research through secondary use of data, but also allow citizens to easily access and manage their health data. Moreover, the EHDS should be 'future-proof' and agile enough to allow interoperability with the other EU-wide common data spaces announced in the 2020 European strategy for data⁵, as well as with indicators such as patient-reported outcomes. We recommend to:

Create an overarching entity to ensure interoperability with all EU data spaces

– We recommend the creation of an EU entity creating a link to the other strategic data spaces announced by the Commission, and in particular the common data spaces on the European Green Deal, agriculture, energy and skills, as they directly relate to citizens' health and well-being. Interoperability should also be ensured for indicators measuring patients' experiences such as the OECD's PaRIS survey.²³ This entity would oversee national nodes who provide data connections to the EHDS. This decentralised agency shall set 'gold standards'

Executive Summary

Introduction

Approach

► Recommendations

Conclusions

Acknowledgements

Endorsements

References



Recommendations

for interoperability across Europe and oversee the implementation of interoperability standards by national entities.

Accelerate the expansion of eHDSI/ MyHealth@EU services – The eHealth Digital Service Infrastructure (eHDSI) builds the foundation for cross-border health services and the EHDS, starting with the deployment of services providing patient summaries and e-prescriptions in 2018. However, as of 2021, only 22 Member States have implemented it.^{24,25} This is not enough to effectively sustain the ambition of the EHDS. Therefore, we recommend setting up an EU fund with three objectives. Firstly, financing the infrastructure development needed, attracting remaining MS and allowing the Commission to control the usage of the EU fund by each beneficiary, as well as setting deadlines in the development of infrastructures in order to accelerate the full entry into force of the eHDSI for the wave four (2021-2022). Secondly, to integrate the eHDSI into the EHDS in a primary use of data branch which will enable the EHDS to be a unique centre of health data exchange and thirdly, to enable accessibility for citizens to their entire personal health data via the use of a unique Patient ID via the eID initiative. This fund could be managed by the newly created Health and Digital Executive Agency (HaDEA).

Ensure all data stored within the EHDS is automatically available for secondary use – Health data should only be accessible within a secured research environment provided by the EHDS. Researchers should be able to access data without the risks posed by creating a local copy. Such a research environment, accessible to governmental institutions (e.g. Ministries of Health, ECDC) and trusted affiliates, would allow coordinated responses to common health challenges by utilising data prediction techniques or AI applied to public health. This would permit more responsive policymaking, such as adapting expenditure to areas with persistent health inequalities.

Subdivide data areas within the EHDS – In order to handle the fragmentation of data (EHR records, research data, patient-reported outcomes etc.) and the diversity of stakeholders, we recommend creating subdivisions of the EHDS with different possibilities of access and reusability. This would also allow smaller initiatives with fewer data sets ease of access to their datasets, and thus promote growth of the EHDS and encourage further data sharing.

Link data collection to Horizon Europe – In the EHDS pilot phase, collection of data from EU-funded research under the Mission structure of Horizon Europe, namely the Mission on Cancer, could provide an initial source of data.²⁶

Over time this could be extended to all areas of Horizon Europe, with a particular focus on health-related projects to feed into the EHDS.

Create a citizen-centric European Health Data App – To fully achieve the ambitions of a citizen-centric EHDS, individuals need to know when their data is being processed and what the potential applications are. This can be realised with the creation of a centralised European application, that may be accessed thanks to eIDs. The application should bring together national health systems' EHRs and supplementary real-world data which individuals may choose to upload and create a link with the EHDS and complementary to "MyHealth@EU"/eHDSI. The latter may be achieved through the use of smart EHR (S-EHR)/FHIR-based communication protocols. This allows individuals to access and self-manage their data and enables information of every data access request. Moreover, the application should give accessible explanations on the purpose of health data processing. In this way, the individual has the option to give dynamic consent. Additionally, it can provide tailored educational content on health data, data anonymisation and citizen's rights, as well as facilitate patient surveys. We recommend working with designers, patient representatives and civil society organisations (CSOs) from the beginning to ensure success.

Executive Summary

Introduction

Approach

► Recommendations

Conclusions

Acknowledgements

Endorsements

References



Recommendations

Promote transparent and informed consent

– To increase trust and understanding related to secondary use of data, consent forms should use plain language, and be in formats accessible to people with disabilities and low literacy. With regard to health data, centralised consent records and the ability to opt out of part or all secondary data usage could permit patients to easily provide consent to secondary use. This should not require an intermediary to process consent if such health records can be stored in an EHDS-affiliated database.

Empowering stakeholders to benefit from health data sharing

Ensure citizens' involvement and education

To ensure the adoption of data-powered solutions at scale, European citizens should be aware of the far-reaching potential of health data sharing. The EU should implement targeted policies in this respect, including education and communications efforts to help earn citizens' trust.

Establish a Digital Health Literacy Strategy at EU Level

– We call on the European Commission to adopt a Digital Health Literacy Strategy (DHLS) to enhance citizens' digital health skills and help bridge health inequalities through digital tools. The DHLS would:

- » Use health literacy surveys to identify target areas and audiences and include specific initiatives and indicators for socially disadvantaged groups that traditionally face barriers to accessing healthcare (e.g. migrants, elderly population, individuals with low socioeconomic status, people with disabilities, and other vulnerable groups),
- » Include the development of clear, common, and accessible definitions of digital health tools in all EU languages, including definitions of health data, AI or Electronic Health Records; Have a bottom-up structure, spearheaded by local champions in their communities,
- » Support concrete actions such as the creation of 'buddy' programmes to encourage peer-to-peer support by patient organisations. Citizens living with a disease would guide newly diagnosed patients, thus enhancing their health literacy and guiding them through the use of digital health tools,
- » Centre around success stories where data sharing and new technologies have improved people's health and led to innovative solutions.

Establish a citizens' forum on digital health

– in the context of the Conference on the Future of Europe, we recommend for the EU to allow citizens, patients, HCPs and CSOs to contribute to a more interoperable digital health ecosystem through the creation of a citizens' forum. Based on the Scottish and Irish 'citizen assemblies', it would aim to find a workable balance between ensuring citizens' trust and protection whilst reaping the benefits of health data sharing.^{27,28} The current Data Governance Act proposal makes no mention of CSOs' vital role in shaping the future digital transformation and the EHDS. A citizens' forum, such as an Observatory on Digital Health, would provide a wide variety of citizens with the chance to contribute to this process, providing real-time feedback on EU health data policy.

Focus on digital skills for healthcare professionals

HCPs also have a key role to play in the development of digital health literacy. They should be empowered and incentivised to both interact with digital health tools and clearly communicate to patients their rights and the implications of the use of emerging technologies such as AI. The Committee therefore supports the Commission's Pact for Skills and the focus of its 'health ecosystem' on the healthcare workforce, and on the development of digital skills.

Executive Summary

Introduction

Approach

► Recommendations

Conclusions

Acknowledgements

Endorsements

References



Recommendations

Put digital skills at the core of medical education – Together with Member States and European universities, the EU should promote changes in healthcare professionals curricula to include greater knowledge on digital health, data sciences and emerging technologies.

Require credits in digital health literacy for regulated professionals – HCPs bodies within the EU should require regulated professionals to obtain a set number of credits in digital health literacy. Development of such courses should include the expertise of patients, industry, governments, and medical societies.

Engage all key stakeholders

Fund training for expert data stewards and creation of incentives – The EU and national authorities should fund training for expert data stewards, who can advise stakeholders in each Member State on how to manage data in-line with FAIR standards and provide advice on preparing data for secondary use, as recommended in the EURORDIS-led Rare 2030 foresight project.²⁹ Moreover, it needs to be underlined that the adoption of digital health tools and data-driven solutions requires deeper changes. Insurance companies also play a decisive role to ensure the uptake of digital tools, as the time spent by HCPs to enhance

a patient's understanding and usage should be duly reimbursed. We strongly believe that incentives through reimbursement mechanisms are key to enhance the uptake of new technologies at a local level. Digital tools and data sharing must add value for HCPs – whether through benefiting their clinical practice, improving their reputation for innovation, or simply saving them time and energy.

Create a European Health Data Standard Toolbox – In order to unlock the potential of innovation and to overcome fragmentation within the sector, a European Health Data Standard Toolbox providing all stakeholders with the necessary open standards and guidelines should be created. This measure shall be accompanied by an educational programme and guidance for implementing and using the standards, and to support and empower the health IT workforce. Supportive and efficient IT departments are absolutely key to the development of a successful EHDS. Moreover, ongoing EU programmes involved in health data and interoperability should be aligned (e.g. InteropEHRate, Smart4Health, Trillium-II, Euro-CAS, EHDEN, PIONEER).³⁰⁻³⁴ When appropriate, we should optimise the use of the knowledge and expertise developed thanks to these projects and upscale their role.

Organise 'hackathons' to drive stakeholders' involvement – The Committee recommends the extension and promotion of European-wide activities (see IHE 'Connectathons')³⁵ to engage healthcare providers, industry and students/universities in implementing, testing, maintaining and further development interoperability standards.

Further support National Contact Points for eHealth (NCPeH) participating in eHDSI tests – The Committee encourages the Commission to further support NCPeH by providing guidelines and tools to facilitate the performance and management of eHDSI test activities. This measure aims at empowering healthcare IT providers to gain further expertise on EU interoperability standards and to implement them at a faster pace, thus building a strong fundament for further developments in the sector as well as establishing trust and societal awareness.

Executive Summary
Introduction
Approach
➤ Recommendations
Conclusions
Acknowledgements
Endorsements
References



Conclusions

European health data co-operation is at a crossroads and travelling in the right direction. An increase of funding for digitalisation of healthcare systems at EU and national-level is coupled with an affirmation of support at political level, demonstrated by several legislative initiatives and programmes at EU level which underpin the overall digital transformation.

In our recommendations we call on the EU to take charge in coordinating crucial areas necessary to leverage data use in the future, namely increasing trust and understanding among citizens, and developing a concise, agile framework for governance and operability. The foundations for the future of European data co-operation are well established, it is time to build on them.

- Executive Summary
- Introduction
- Approach
- Recommendations
- ▶ Conclusions
- Acknowledgements
- Endorsements
- References



Acknowledgements

The Committee on European Health Data Co-Operation would like to thank the following individuals for their invaluable contribution, support, and guidance throughout the past few months. This policy brief is a result of essential discussions between the Committee and digital health experts, as well as the hard work, collaboration, and dedication of all Committee members.

- » **Birgit Bauer**, Patient Expert & Digital Health Entrepreneur
- » **Luca Marelli**, Senior Research Fellow at KU Leuven
- » **Paul Nemitz**, Principal Adviser on Justice Policy at the European Commission
- » **Tino Marti**, eHealth Project Officer at the European Health Telematics Association (EHTEL)
- » **Hannelore Aerts**, Data Quality Programme Manager at the European Institute for Innovation Through Health Data (i~HD)
- » **George Crooks**, Chief Executive Officer at the Digital Health & Care Innovation Centre

- » **Michael Strübin**, Digital Health Director at MedTech Europe
- » **Anne-Sophie Lapointe**, Rare Diseases Project Manager at the French Ministry of Health
- » **David Somekh**, Network Director at the European Health Futures Forum
- » **Robert Bauchinger**, Chief Digital Officer at the Hospital Group OÖEG, Upper Austria

Executive Summary
 Introduction
 Approach
 Recommendations
 Conclusions
 ▶ Acknowledgements
 Endorsements
 References



Committee for
 European Health
 Data Co-operation



Endorsements



Mr. Vytenis Andriukaitis

Former European Commissioner for Health and Food Safety

"My past experience in the field of public health in EU policy-making allowed me to commend the EHP analysis of this very complex area. I see very ambitious, thoughtful and appropriate recommendations. We all know that health data co-operation is vital speaking about possibilities to develop new horizons in areas of personalised medicines, in areas of cross border healthcare and in building better co-operation between different stakeholders in European Reference Networks or in areas of Health Technology Assessment. I hope that European Commission will see those recommendations and conclusions as a very informative source for future activities in the area of health data co-operation."



Nick Schneider

Head of Division, New Technologies & Data Use, German Ministry of Health – in his own capacity

"I appreciate that the European Health Parliament has selected the topic of health data sharing in this year's report – the ongoing SARS-CoV-2 pandemic showed us that sharing of health data can indeed save lives. The call for a European Health Data Space – well described as a reliable, secure and agile health data ecosystem – from the European civil society is helpful for European and national policy makers. It confirms the urgency for a secure space to access and share health data for healthcare, research and innovation, which has been highlighted by the German EU-Presidency in 2020. The support of health care professionals is imperative for the European Health Data Space to become reality."

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Endorsements



MEP Eva Kaili

EL, S&D

"The European Health Data Co-Operation Committee recommendations summarize thoroughly the key elements that the European policy on health data should include. Most importantly as EU legislators we must ensure that people have trust in any data collection system powered by Artificial intelligence and that they rest assured that their health data – as sensitive personal data – are not shared by any entities such as insurance companies, without their consent. It is of paramount importance that citizens have control over their data. I will be very glad to continue this fruitful dialogue with the EHP in order to transform these valuable recommendations into EU legislation."



MEP Axel Voss

DE, EPP

"The pandemic made the need for European health co-operation abundantly clear, whether it was regarding contract tracing, locating resources such as free urgent care beds or data exchange for developing the COVID vaccine. However, data exchange can be a life saver beyond the pandemic, to speed up research on other diseases and unburden medical professionals. That is why initiatives like the ones by the European Health Parliament are the vital step towards enhancing co-operation on the European level for the good of all citizens."

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Endorsements



Robert Madelin

Former Director General at the European Commission and Chairman at FIPRA

"My health and digital past in EU policy-making, and my present work in MedTech and telehealth, all combine to make me a firm believer in the vital need for a drive forward on health data as part of the post-pandemic campaign to recover better. I am very pleased to see the ambitious goals set out here: first and foremost, the need to focus and accelerate the work on health data. I am also encouraged to see the case made for 'more Europe', in terms of an overarching agency to drive interoperability and common quality as between the various data spaces now being conceived and prototyped. I expect such suggestions to be controversial in some quarters, but I am confident that this is the right approach."



Prof. Dr. med. Mathias Goyen

Chief Medical Officer EMEA at GE Healthcare

"I applaud the European Health Parliament and its committee for European Health Data Co-Operation for developing a very comprehensive set of recommendations around the use and the governance of health data in Europe. The Coronavirus pandemic has shown to us the value of the digital transformation of healthcare, but it has also laid bare in many places the shortcomings of the fax machine to manage a healthcare system.

Europeans are increasingly embracing digital health technologies. Policy-makers across the continent need to create the right governance frameworks that build trust in how health data is handled and that bring new innovative medical technologies to the market. The recommendations of the young leaders of the European Health Parliament fill me with confidence that the current and next generation of health policy shapers in Europe will usher in an era of precision health that helps healthcare systems be better, more integrated, sustainable and delivering higher patient care and satisfaction."

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Endorsements



Birgit Bauer

Patient Expert & Digital Health Entrepreneur

"In my opinion as a citizen and woman living with a chronic disease for years now, this paper and the recommendations this great group provides are most valuable and important to be realised. I hope that the Members of the Commission will find them useful, valuable, and as meaningful as I do. Good data management can bring a lot of benefits to all European citizens, to healthcare systems and last, but not least, to us patients. It means better care, better services, faster diagnosis and hope for those who have to wait for help because there is no therapy option available."



European Health Futures Forum

"The European Health Futures Forum commends the EHP for its meticulous analysis of this complex area.

We believe that the recommendations made, although undoubtedly ambitious, represent a thoughtful and appropriate approach to the topic. We hope that Commission policymakers will find them to be of value and supportive in helping to bring about the changes necessary in this area to maximize the potential benefits that we all know that good data management can bring."

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Endorsements



Digital Health & Care Innovation Centre

"The Digital Health & Care Institute, Scotland's national innovation centre for digital health and care, welcomes this report and endorses the recommendations that are set out. If Europe wishes to maximise the benefits that next generation digital tools and services can bring to health and wellbeing of its people there requires to a supportive and enabling regulatory environment alongside digital infrastructures focussed on serving the needs of the citizen allowing data to flow seamlessly and securely to where it is needed in a fully consent driven manner."



Prof. Elmar Kotter

European Society of Medical Imaging Informatics (EuSoMII)

"The European Society of Imaging informatics (EuSoMII) fully supports EHPs meticulous analysis of the complex field of Europe's health data ecosystem. The recommendations made represent a thoughtful and ambitious approach to the topic. Both the analysis and the recommendations are in line with the analysis of EuSoMII. Many of the topics addressed in the document are also discussed elsewhere in different places. EHPs analysis, however, contains the most important thoughts and recommendations in one document. This statement is definitely worth reading for all involved in the domain."

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Endorsements



Nicole Denjoy

Director General, COCIR

"The digital transformation of health and care is creating huge opportunities for the provision of care and as a key driver for new innovations and insights that will lead to better health outcomes, for instance through EHRs which are currently not widely used across Europe. The Committee on European Health Data Co-operation's recommendations rightly reflect the need for a trusted framework and meaningful involvement of all stakeholders in order to facilitate access to high-quality health data that will ultimately benefit patients and society. COCIR shares the view that European Commission and Member States should closely work together. This will be instrumental to realise the full potential of a European Health Data Space."

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



References

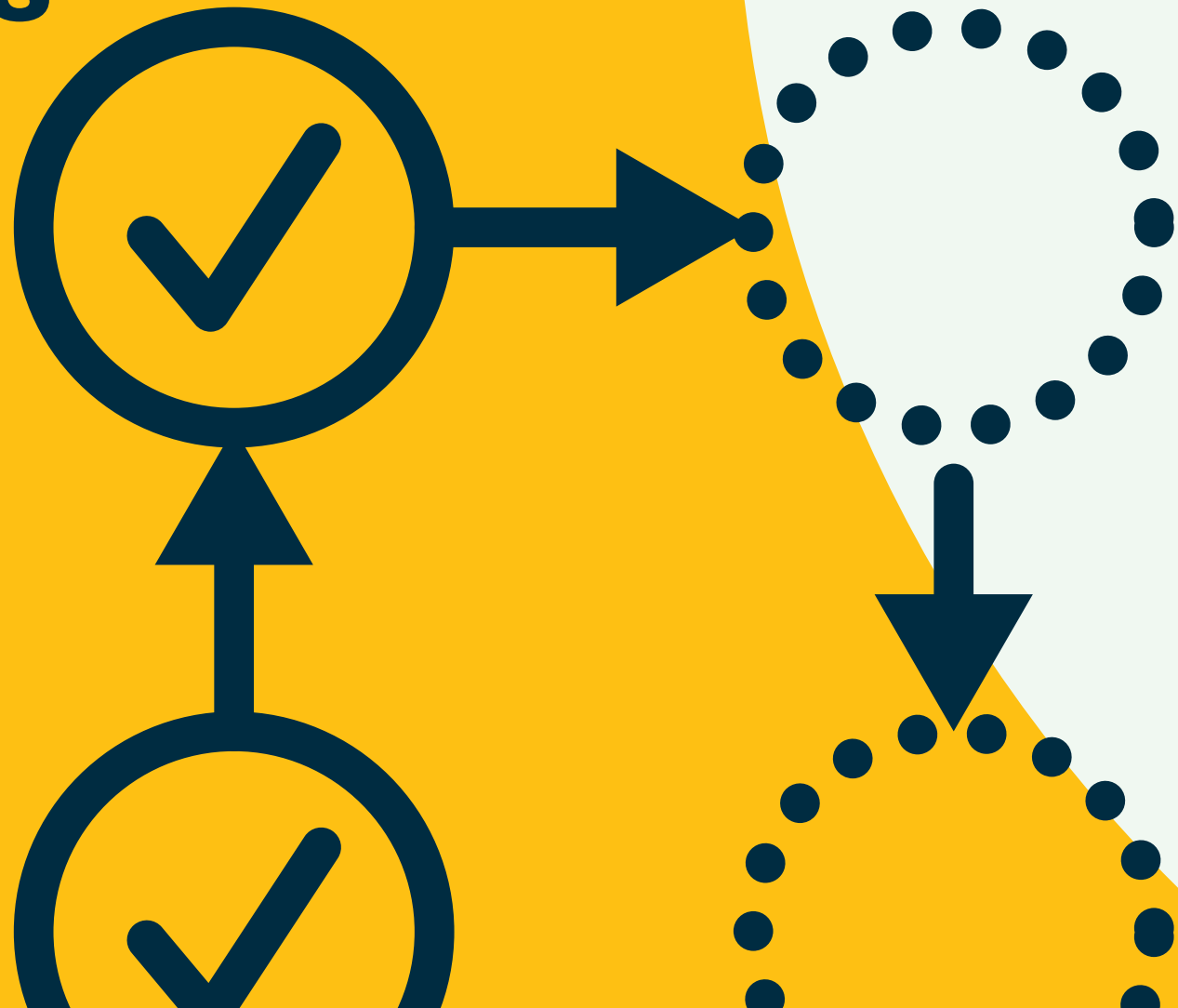
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Executive Summary
Introduction
Approach
Recommendations
Conclusions
Acknowledgements
Endorsements
➤ References



Committee for Resilient Supply Chains

The COVID-19 pandemic has exposed governments and healthcare systems to unprecedented challenges, shed the light on a foundational weakness in our healthcare systems and tested the resilience of global supply chains. At the same time, global supply chains and the value chain stakeholders, alongside European and national decision-makers showed their ability to flexibility and rapidity in their responses to the pandemic.



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Executive Summary

Building on the lessons learned from the pandemic and on Europe's recent commitment to set up a new policy framework (e.g. EU4Health, EU Pharmaceutical Strategy, EU Health Union Package), our recommendations aim to address the identified vulnerabilities of supply chains and propose a range of measures to strengthen the pharmaceutical, vaccines and medical devices supply chains, enabling trade networks and policies, ensuring solidarity amongst EU Member States, strengthening production facilities, and actively managing and mitigating supply disruptions.

Recommendation I: Remove obstacles to the movement of medicines and medical devices

- » Promote an open trade regime for essential products
- » Enhance World Trade Organisation (WTO) negotiations to broaden the scope of the Zero for Zero treaty and turn it into a binding agreement for a wider group of countries
- » Foster sustainability of supply chains – based on circularity – to enhance their resilience

Recommendation II: Establish a resilient EU transport network, to ensure that patients can timely access their treatment, wherever and whenever needed

- » Enhance cooperation and close dialogue amongst supply chains stakeholders and Member States (and beyond) to ensure access to and availability of medicines, vaccines and medical devices
- » Support the development of a harmonized risk assessment system of global pharmaceutical supply chains
- » Create the appropriate policy framework to ensure continuous uninterrupted transport of all essential medicinal and pharmaceutical products, vaccines, medical equipment and medical devices

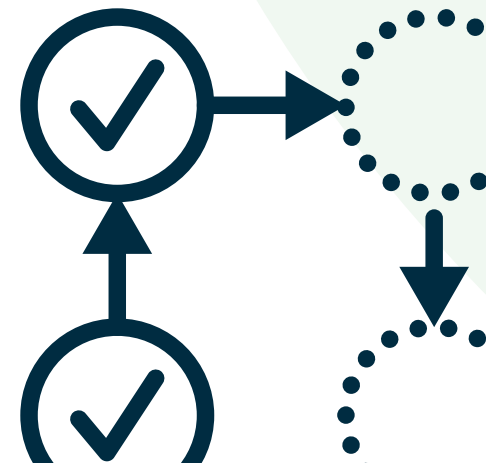
Recommendation III: Establish a sustainable and resilient procurement strategy and strengthen the existing European industrial base for essential medicines and medical devices

- » Establish legally binding requirements for sustainable and resilient public procurement of healthcare products that include environmental and social aspects as well as support the diversification of supply
- » Strengthen existing European high-standard production facilities for vaccines, essential medicines and medical devices, including production of their starting material
- » Establish an EU-level stockpile at bulk level for the prepositioning of essential medicines and medical devices for EU pandemic preparedness

- » Executive Summary
- » Introduction
- » Recommendations
- » Conclusions
- » Endorsements
- » References



**Committee for
Resilient
Supply Chains**



Executive Summary

Recommendation IV: Ensure the development of an Early Warning System to support a common response to the risk of shortages of medicines and medical devices

- » Merge the Single Points of Contact (SPOC) and the industry single point of contact (iSPOC) networks into a single alert system
- » Expanding the scope of the early warning system beyond medicines (for human or veterinary use) to include essential medical devices

Recommendation V: Promote an EU-level solidarity system in case of shortages of medicines and medical devices and for EU pandemic preparedness

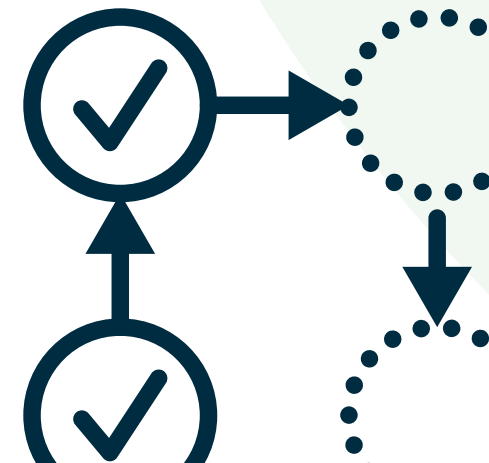
- » Review and update the Solidarity Clause of the Treaty of the Functioning of the European Union to include health threats
- » Boost transparency along the supply chain between stakeholders and towards the European institutions to ensure patients' access to medicines and medical devices, and ultimately improved patient health outcomes and positive benefits for healthcare systems

Recommendation VI: Boost the digitalisation of the global supply chain for improved outcomes for all stakeholders, citizens, patients and healthcare systems

- » Enhance harmonised implementation of ePrescriptions across EU Member States and the mutual exchange and information sharing
- » Introduce Electronic Product Information (ePI) for all medicines and medical devices
- » Maximise healthcare professionals' and patients' access to information and increase health literacy with the introduction of barcodes on packaging containing educational video and audio facilities

These recommendations are intended as a constructive contribution to discussions on how to improve the global supply chains, to ultimately ensure timely access to medicines, vaccines and medical devices to all EU citizens, wherever and whenever needed.

- » Executive Summary
- » Introduction
- » Recommendations
- » Conclusions
- » Endorsements
- » References



Committee for
Resilient
Supply Chains



Introduction

Citizens and patients in Europe and around the world benefit from and depend on medicines (including vaccines) and medical devices that are sourced and made in globalised, complex supply chains. Global supply chains evolved over the last decades as a consequence of variations in innovation, price pressures, material and labour costs, and differences in regulatory requirements and incentives such as subsidies from the public sector. Today, global supply chains have developed to become an integral part of European healthcare systems and have made them more economical and more efficient.

Consisting of a complex interplay of production steps, a plurality of actors involved, as well as regulatory and quality requirements to be fulfilled, flexibility, agility, reliability, responsiveness and security are required across the entire supply chain.

In Europe, we expect medicines to be available for patients in pharmacies and authorised selling points, in hospitals, and in vaccination centres, and doctors to have equipment on hand whenever and wherever it is needed. When COVID-19 spread across the globe, the global population suddenly became aware of the necessity and importance of supply chains, a topic that had thus far been reserved to experts. Being hit by the pandemic and scrambling to provide citizens, patients, and healthcare professionals with the medicines, protective

equipment, and care they needed, European governments had to realise that a supply chain is only as strong as its weakest link.

Having the right policies in place to build a more robust supply chain can help ensure the continued availability of quality medicines and medical devices. During the pandemic, the European institutions responded with a number of ad-hoc measures to absorb the shocks of the COVID-19 outbreak that included a sudden spike in demand for and resulting shortage of products needed to tackle its spread. These measures included guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak,¹ guidance to ensure continuous flow of goods across the European Union via green lanes,² and transparency and authorisation mechanism for exports.³ The urgency of the pandemic has also led the EU and its Member States to invest in the development, production and distribution of new vaccines, to embark on joint procurement negotiations and agreements, and to accelerate marketing authorisation and access processes. For instance, the urgency to fight a global pandemic has sparked discussions on the need for equitable access to efficient and safe vaccines globally, as no one is safe until everybody is safe.

The pandemic also prompted the European Commission to introduce measures with a

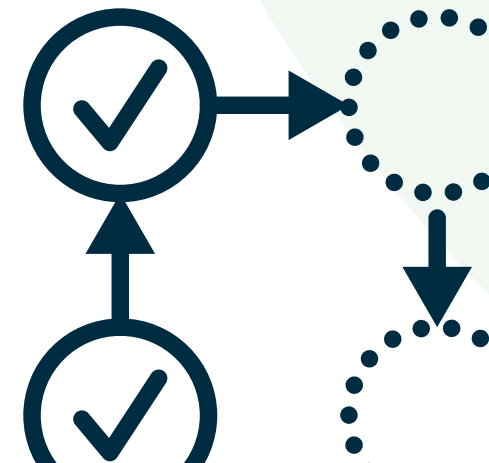
more long-term perspective, including more investments in health in the EU4Health programme,⁴ along with the EU Pharmaceutical Strategy⁵ and the European Health Union,⁶ amongst others, which include elements for increasing the resilience of supply chains, mitigating shortages, and addressing the issue of medicines availability, accessibility and affordability as a whole. The ultimate objective remains to ensure that patients can access medicines and medicinal devices whenever and wherever needed. The EU is also aiming to be better prepared for future pandemics or disruptive events, for example with a reinforced European Medicines Agency⁷ and the EU response package.⁸

More needs to be done to ensure strong supply networks and to establish more resilient, agile and sustainable supply chains that guarantee access and availability of medical products to all European citizens in need.

The following set of recommendations addresses the identified vulnerabilities of supply chains and proposes a range of measures to strengthen the supply chains, deepening trade networks and broadening trade policies, ensuring solidarity amongst EU Member States, strengthening production facilities, and actively managing and mitigating supply disruptions.

Executive Summary

- ▶ Introduction
- Recommendations
- Conclusions
- Endorsements
- References



**Committee for
Resilient
Supply Chains**



Recommendations

Pillar I: Remove obstacles to the movement of medicines and medical devices

The COVID-19 pandemic has exposed Member States to unprecedented challenges and tested healthcare systems' resilience. It has highlighted the need for a collective response from the international community to reinforce preparedness for future crises from a trade policy perspective.^{9,10} In the early stages of the outbreak many countries encountered difficulties in delivering essential goods and services to their population, and trade policy has been a key element in governments' responses. An open and free flow of trade is essential to allow the proper functioning of the global supply chain.

One example is the COVID-19 vaccines rollout, where vaccines (final product) are produced only in a small number of countries but need to be shipped across the whole globe to ensure significant proportions of the human population are immunised.^{11,12}

Promote an open trade regime for critical products¹³

Free Trade Agreements (FTA) with EU trading partners, including ambitious provisions on transparency, crisis-preparedness and mutual

cooperation in the pharmaceutical market, are a key step to maintain an open trade regime and ensuring the free flow of goods – and thus to avoid jeopardising the functioning of the global supply chain could be jeopardised. Building on the EU-led initiative for a multilateral agreement on trade in healthcare products,¹⁴ we call for reinforced cooperation with non-EU countries and the private sector to scale up production and support timely access to medicines.

A stable, agile, and rule-based trading framework shall support the opening up to new markets to diversify sources of supply and developing cooperative systems for fair and equitable access to critical products.¹⁵ We believe the EU should continue supporting global efforts to monitor critical supply chains and work on identifying strategic dependencies to keep the global supply chain functioning and undisrupted.

Enhance World Trade Organisation (WTO) negotiations to broaden the scope of the Zero for Zero treaty and turn it into a binding agreement for a wider group of countries

Tariff and non-tariff barriers pose great obstacles and customs delays to the free movement of medicines and medical devices.

Trade should ease circulation worldwide to better address global demand.¹⁶ The World Trade Organization (WTO) 1994 non-binding agreement on Pharmaceutical Products (Zero for Zero Agreement) was last updated in 2010 and its scope does not cover all pharmaceutical products and medical devices. To ensure a continuous and smooth update process, we believe a negative list system should be put in place. With such a system, all products – including medical devices and active pharmaceutical ingredients (APIs) – would automatically qualify for zero tariffs, unless stated otherwise. For instance, at present APIs do not automatically qualify for zero tariffs and must be formally added to the list of eligible products (positive list).

As the value of pharmaceutical trade outside the Zero for Zero scope continues increasing (20.7% increase between 2006 and 2013), and some of the non-signatories' countries are keeping extremely high barriers (over 8%),¹⁷ its scope should go beyond the current coverage (66% of trade in health products), including additional medicinal products,^{18,19} and broadening its membership. This will lead to reduced costs and delays in products delivery.²⁰

Executive Summary

Introduction

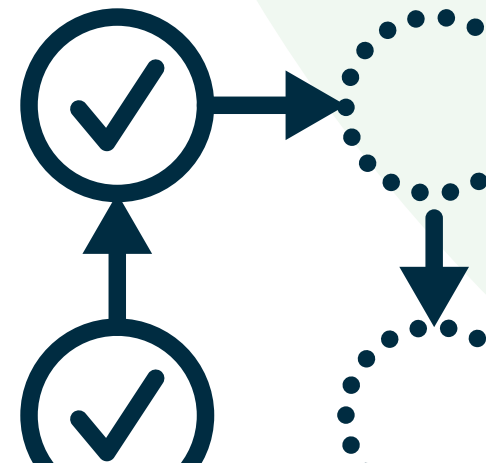
► Recommendations

Conclusions

Endorsements

References

Committee for
Resilient
Supply Chains



Recommendations

Foster sustainability of supply chains – based on circularity – to enhance their resilience

We call for a trade policy promoting sustainability standards, responsible business conduct, greater transparency, and traceability, based on circularity. Sustainable supply chains have proven to be more resilient and more adaptable, performing better in the long term.²¹

Pillar II: Establish a resilient EU transport network, to ensure that patients can have timely access to treatment, wherever and whenever needed

The transport of medicines and medical involves considerable risks linked for instance to temperature control (e.g. vaccines), quality and safety, and security against counterfeit products, as well as the involvement of many different players. The COVID-19 pandemic has heavily disrupted transport and highlighted the importance of a collective and coordinated approach to cross-border transport²² to ensure smooth functioning of global supply chains.²³ We should build on the lessons learned to create European transport network that can successfully support the continuous supply of medicines and medical devices.²⁴

Building on the words of European Commission President Ursula von der Leyen: “We have to keep cross-border transport of supplies flowing, in particular that of medical products”,²⁵ we call for the EU to:

Enhance cooperation and close dialogue amongst supply chain stakeholders and Member States (and beyond) to ensure access to and availability of medicines and medical devices

Solidarity amongst countries and stakeholders plays a crucial role,²⁶ and we call on Member States to refrain from closing borders within the EU, which would obstruct the movement of medicines and medical devices. It is crucial to ensure the good functioning of EU Single Market. The pandemic has demonstrated that no country can be truly self-sufficient and independent from goods and services of other countries across the globe,^{27,28} and only by building and maintaining constant cooperation can we ensure timely access to medicines to patients.²⁹ We call on the European Commission to play an active coordination role in ensuring constant cooperation and close dialogue amongst supply chain stakeholders and Member States, for instance via an ad-hoc task force.

Support the development of a harmonised risk assessment system for global supply chains³⁰

We support the European Commission's position, in recognising that maintaining the functioning of the Single Market is key to avoiding shortages. Free circulation of critical products such as medicines, medical devices and medical equipment in particular should be guaranteed at all times via intensive cooperation and close dialogue.³¹⁻³³ According to EU Good Distribution Practices Guidelines, pharmaceutical manufacturers are required to conduct a risk-based selection process for their transport partners to better plan the transport of pharmaceutical products, by foreseeing potential risks and avoiding them when possible.³⁴

Risk assessment of global delivery routes can ensure more transparency and safety across the supply chain, allowing better evaluation of the capabilities of supply chain stakeholders. This will also lead to better and more solid relationships amongst supply chain partners, increasing information sharing and enhancing flexibility in the response, especially in case of disruptive events.

Executive Summary

Introduction

➤ Recommendations

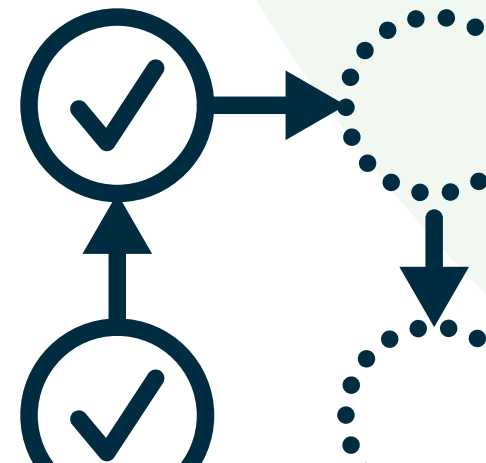
Conclusions

Endorsements

References



**Committee for
Resilient
Supply Chains**



Recommendations

Create the appropriate policy framework to ensure continuous uninterrupted transport of all medicinal and pharmaceutical products (including vaccines), medical equipment and medical devices

Lastly, we believe that transportation of products, from APIs to medicines, vaccines and medical devices, should always be a key priority. We call on the EU to build on lessons learned from the pandemic³⁵ and recognise that continued and uninterrupted transport services for medicines and medical devices are vital.

We call on Member States to put in place the necessary measures to guarantee the smooth movement of goods everywhere, and at all times. These may include measures such as the active removal of any potential transportation barriers, harmonised risk assessment of global supply chains, removal of unnecessary restrictions to air cargo transport.

Pillar III: Establish a sustainable and resilient procurement strategy and strengthen the existing European industrial base for critical medicines and medical devices

Sustainability standards are crucial to contribute to robust supply chains. For this reason, we call on the European institution to:

Establish legally binding requirements for sustainable and resilient public procurement of healthcare products that include environmental and social aspects as well as support the diversification of supply

In 2014, the EU adopted a new Directive on Public Procurement (2014/24/EU)³⁶ to create opportunities for sustainable procurement of medicines and medical devices for public authorities, hospitals and healthcare systems. While the Directive removed some legal barriers for stakeholders implementing sustainable and more resilient public procurement practices in terms of suppliers' environmental and social impact, it is not a requirement for public stakeholders to implement these tendering practices.³⁷ In addition, greater emphasis should be placed upon guaranteeing that a supplier can reliably and securely supply the procured

products by proving their global supply chains are sufficiently diversified; this can include, for example, independence from single sources or single regions in the world, and provide for spare capacity in times of unforeseen spikes in demand.

We therefore suggest updating of the Directive 2014/24/EU to a regulation requiring public procurement processes to select suppliers based on environmentally sustainable, socially responsible and reliable supply aspects.

Strengthen existing European high-standard production facilities for vaccines, critical medicines and medical devices, including production of their starting material

The COVID-19 pandemic and the resulting global health crisis have shed the light on some weaknesses of the European healthcare systems and on the supply of urgently needed medicinal products and particularly their starting material (e.g. APIs). Some medicines were suddenly in heavy demand prompting the European Commission to issue guidance on their optimal use and rational supply.³⁸ At the same time, by investing in innovation, enhancing regulatory standards, financial and environment sustainability, the EU can create a robust supply chain.

Executive Summary

Introduction

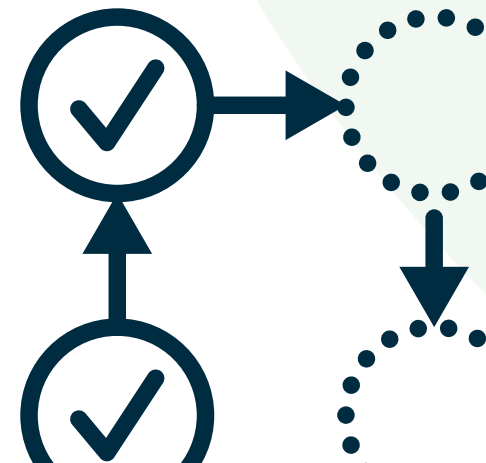
▶ Recommendations

Conclusions

Endorsements

References

**Committee for
Resilient
Supply Chains**



Recommendations

In order to ensure future resilience in supply, the EU should first identify and study areas of vulnerability in essential medicines and medical devices supply chains. As a second step, based on the identified vulnerabilities, the EU could consider strengthening its existing high-quality and high-standard industrial base to ensure manufacturing capacity to produce critical products in Europe when necessary. This could be achieved, for example, by having facilities that produce at e.g. 30% and when a crisis hits, flex capacities up quickly, when appropriate. This way, the EU can produce a buffer level of stock in emergency situations in case supply from global supply chains is interrupted.

Establish an EU-level stockpile at bulk level for the prepositioning of essential medicines and medical devices for EU pandemic preparedness

A European governing body and industry stakeholders (e.g. manufacturers and wholesalers) will (a) identify specific medicines or medical devices that are 'pandemic essential'; and (b) determine if those medicines/devices can be kept in stocks at bulk level in geographically strategic locations across Member States. This would ideally be managed as Public Private Partnerships by industry stakeholders.

These prepositioned products can be used as buffer stocks to absorb shocks produced by sudden increases in demand, and while local production in 'idle' European manufacturing facilities is being ramped up. The combination of these elements will strengthen European supply, making it more resilient, agile and sustainable.

Pillar IV: Ensure the development of an Early Warning System to support a common response to the risk of shortages of medicines and medical devices

Building on the lessons learned from the pandemic, we call on the European institutions to put in place a system which would inform supply chain stakeholders in real time of the risks of supply disruptions and allow appropriate action to be taken to mitigate shortages of medicines and medical devices.

Merge the Single Points of Contact (SPOC) and the industry single point of contact (iSPOC) networks into a single alert system

In 2016, the EMA and Heads of Medicines Agencies (HMA) created an HMA/EMA task force on the availability of authorised medicines to cope with disruptions in the

supply of medicines for human and veterinary use.³⁹ Several groups and documents subsequently followed – among them, the EU Single Points of Contact (SPOC) Network⁴⁰ (April 2019). In April 2020, influenced by the EU pandemic response and together with an EU steering group on shortages,⁴¹ an iSPOC network was created: a fast-track monitoring where pharmaceutical companies report supply disruptions by pharmaceutical companies, to help prevent and mitigate supply issues. The reporting obligation will only enter into force with the regulation on a reinforced role for the European Medicines Agency in crisis-preparedness and management for medicinal products and medical devices.⁴²

As described above, there have been substantial efforts made by the European Commission and the EMA to tackle the risk of shortages of medicines and medical devices in the EU. In addition to these efforts, we recommend merging of the SPOC and the iSPOC networks to create a single overarching alert system managed at EMA level and incorporating all Member States authorities as well as manufacturers of medicines and essential medical devices. The network should require obligatory reporting of supply disruption by a manufacturer in a systemic manner and should be applied continuously and beyond emergency situations.

Executive Summary

Introduction

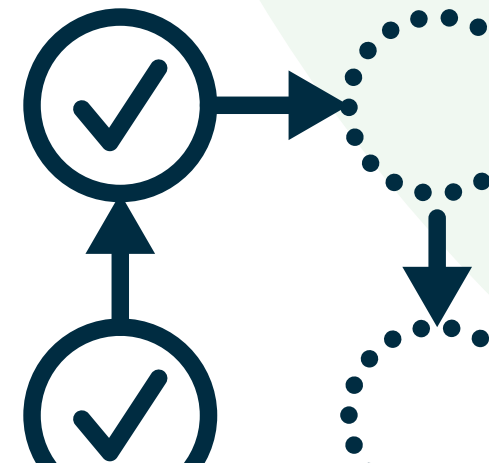
▶ Recommendations

Conclusions

Endorsements

References

Committee for
Resilient
Supply Chains



Recommendations

Expanding the scope of the early warning system beyond medicines (for human or veterinary use) to include essential medical devices

We also call on European institutions and the EMA to define a list of essential medical devices that should be covered by the single alert system and for which manufacturers would be obliged to report any foreseen and encountered supply disruptions.

Additionally, the single alert system could be modified to become an EU-level cloud system connecting pharmacists and other dispensing healthcare professionals in Member States. It would provide information about shortages in each Member State and offers solutions when a medicine or medical device is in shortage (e.g. if substitution is possible, a pharmaceutical alternative is available in a given country). This system could also grant connected stakeholders' access to information on whether another Member State has available stocks which could be imported to alleviate supply disruption; it could therefore function as the basis of a shortages solidarity system within the EU. A key first step to ensure the appropriate functioning of such a system is to have a common definition of shortages.

Pillar V: Promote an EU-level solidarity system in case of shortages of medicines and medical devices and for EU pandemic preparedness

Jean Monnet once said: "People only act in a state of necessity and usually only recognise necessity in a situation of crisis."⁴³

Review and update the Solidarity Clause of the Treaty of the Functioning of the European Union to include health threats

The Treaty of Lisbon states that one of the founding values for the EU is solidarity.⁴⁴ The solidarity clause in the Treaty of the Functioning of the European Union covers disasters such as terrorist threats and natural and man-made disasters⁴⁵ and does not yet include serious threats and disasters to human health, such as pandemics. The current health crisis resulting from the global spread of COVID-19 has shown us that solidarity is key to tackling the crisis efficiently and saving as many lives as possible, for example by moving patients across borders to hospitals with free beds and staff capacities or sending healthcare professionals to places in need.⁴⁶

Boost transparency along the supply chain between stakeholders and towards the European institutions to ensure patients' access to medicines and medical devices, and ultimately improving patient health outcomes and positive benefits for healthcare systems

Additionally, we believe that transparency is critical. Data and information-sharing on production capacity (especially in times of crisis), on stock and national demand levels etc. should be enabled in the best possible way and as appropriate.

Greater transparency along the global supply chain can contribute to building solid and agile international and multi-stakeholder collaboration, which will allow the needed flexibility and rapidity of response in case of shortages, major health threats or other disruptive events.

Executive Summary

Introduction

► Recommendations

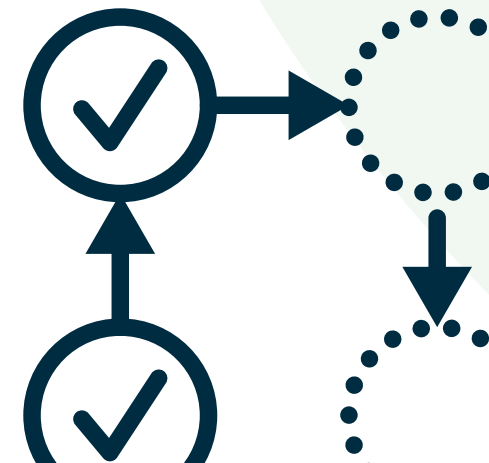
Conclusions

Endorsements

References



**Committee for
Resilient
Supply Chains**



Recommendations

Pillar VI: Boost the digitalisation of the global supply chain for improved outcomes for all stakeholders, citizens, patients and healthcare systems

New digital technologies can contribute to improving treatment and care for patients, as they are a key enabler for efficient healthcare systems. Enabling digital transformation in healthcare is and should continue to be an EU priority,⁴⁷ and digitalised supply chains can play a key role.

Enhance the harmonised implementation of ePrescriptions across EU Member States and encourage mutual exchange and information-sharing

The use of ePrescriptions in the EU is based on the Directive 2011/24 on the application of patients' rights in cross-border healthcare.⁴⁸ ePrescriptions can contribute to greater and more effective communication along the supply chain, which is needed to build strong provider-patient relations and to ensure information-sharing between Member States. The ongoing pandemic shed light on the importance of harmonised implementation of cross-border electronic information for an appropriate and timely response to patients' needs.

Close collaboration between industry players and hospitals, as well as an increased understanding of the challenges and opportunities of the ePrescriptions' implementation are crucial for the functioning of eHealth Digital Service Infrastructure (eHDSI).⁴⁹ The ultimate objective is to facilitate patients' access to medical products and health services across Europe. We recommend building on the successful examples of the use of ePrescriptions in countries like Croatia, Estonia and Finland.

For this purpose, we believe more investments from Member States are needed to boost implementation of ePrescriptions at the national level and to reach a harmonised European framework. In this context, we call on the European Commission to develop a common ePrescriptions implementation toolkit.⁵⁰ The toolkit shall include: an assessment of implementation status in each Member State, best practice examples from the Member States already using ePrescriptions; suggested plans for a transition to ePrescriptions in support of doctors and pharmacies at the national level; and a methodology for enhanced interoperability⁵¹ between Member States, including how to best manage communication with all stakeholders along the supply chain.⁵²

We believe that ePrescriptions will ultimately lead to improved health outcomes for patients, reduced costs, strengthened coordination between EU Member States and enhanced resilience of supply chains.

Introduce Electronic Product Information (ePI) for all medicines and medical devices

Directive 2001/83/EC/article 58⁵³ defines the cases in which a package leaflet needs to be included in, or on the outer of the packaging of all medicinal products. The labelling and packaging provide up-to-date information on the medicine to healthcare professionals and citizens across Europe. At present, patients and healthcare professionals rely in some cases on possibly outdated paper information, or electronic information from unreliable sources. Furthermore, the current language requirements in the EU limit the flexibility to move products easily between Member States, especially in emergency situations.

Building on the flexible labelling and packaging requirements introduced in response to COVID-19,⁵⁴ we advocate for the introduction of ePI – summary of product characteristics (SmPC), labelling and package leaflet (PL) – for all medicines and medical devices (existing

Executive Summary

Introduction

▶ Recommendations

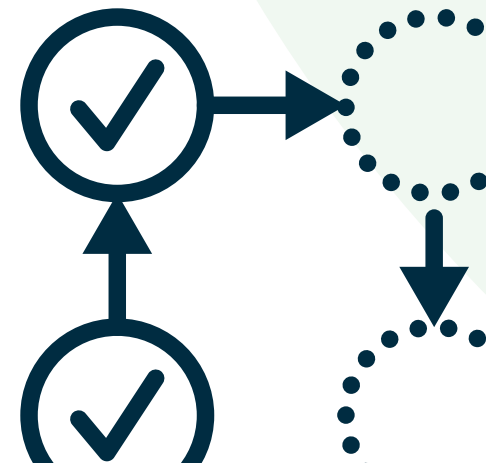
Conclusions

Endorsements

References



Committee for
Resilient
Supply Chains



Recommendations

and new products). Ultimately, this will lead to greater production capacity, better distribution and reduced transport and storage costs. In the long term, ePI should fully replace the paper package leaflet (when possible and meeting patient safety concerns), thus helping to increase availability of medicines across Member States, especially in crisis situations. This will ultimately contribute to strengthening the global pharmaceutical supply chain and ensure timely access to medicines and medical devices for all patients.

Maximise healthcare professionals' and patients' access to information and increase health literacy with the introduction of barcodes on packaging containing educational video and audio facilities

We call for the European Commission to play a central role in the implementation of barcodes and/or alternative technology to ensure the portability of product information. It will enable easier and better access to information for healthcare professionals and patients, via screen readers and mobile applications. Additionally, we call for the enhanced use of existing 2D serialisation codes for medicines.

This refers to the process of assigning a unique code to the packaging of each medicine and printing it on the packaging itself. The technology should facilitate ePI as open data, ensuring that healthcare professionals and patients can always access key information, regardless of whether they have the packaging or the container.

We believe that benefits for healthcare professionals and patients can be maximised by complementing ePI with video and audio facilities to improve health literacy. More specifically, this could include the implementation of alert systems in case of significant leaflet update(s), interface with support functions to actively monitor the patient's health condition, controlled vocabulary to standardise information, patient-friendly translations of information, audible product information formats and high screen contrast for users with different kinds of visual impairments as well as for users with difficulties in reading and writing.⁵⁵

Executive Summary

Introduction

▶ Recommendations

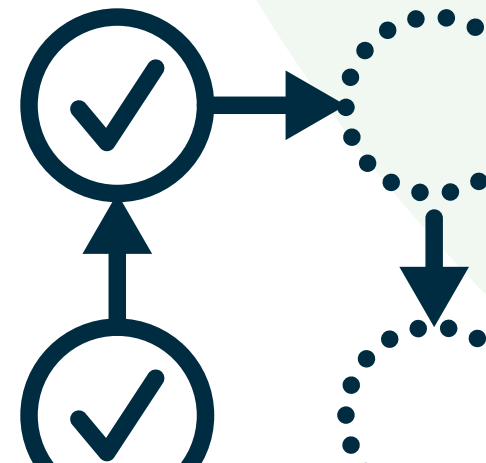
Conclusions

Endorsements

References



Committee for
Resilient
Supply Chains



Conclusions

Recent developments, and particularly the COVID-19 pandemic, have demonstrated that it is more important than ever before to harness the potential of resilient and sustainable global supply chains. Unilateral actions can threaten access to critical medicines, vaccines, medical equipment and medical devices. Building on the lessons learned from the pandemic, it became even more clear that closer collaboration between Member States and stakeholders along the value chain is needed. A greater understanding of the complexity of the global pharmaceutical and medical devices supply chains, and the fundamental role that each stakeholder plays is essential to build more and more resilient and sustainable supply chains in the future.

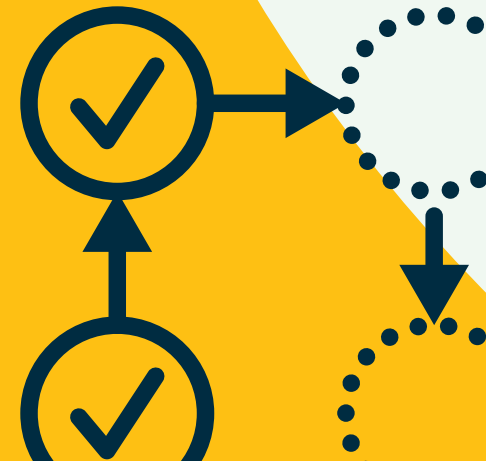
With the ongoing discussions around the Pharmaceutical Strategy for Europe⁵⁶ and the EU Health Union,⁵⁷ we believe that the EU holds the keys to become a leader in the pharmaceutical sector, being able to ensure a strong European voice in the world. Building a resilient and sustainable global pharmaceutical (including vaccine) and medical devices supply chain is a critical step to safeguard timely access to essential products to all patients across Europe. It will ultimately contribute to eliminate health inequities and build a better life for European citizens.

We believe that our proposed solutions and recommendations will equip the EU with the necessary measures to boost resilience and sustainability in the global supply chain. We call upon the EU to assess and incorporate our policy recommendations, for instance in the structure dialogue on security of medicines supply and the following legislative proposals that will stem from it, in order to further support patients, citizens, stakeholders, healthcare systems and institutions, while addressing short- and long-term challenges in the correct functioning of the global supply chain.

- Executive Summary
- Introduction
- Recommendations
- ▶ Conclusions
- Endorsements
- References



**Committee for
Resilient
Supply Chains**



Endorsements



Francesca Colombo

Head Health Division, OECD

"The recommendations of the European Health Parliament's Resilient Supply Chains Committee are insightful and well-crafted. COVID-19 has highlighted important vulnerabilities and unexpected shocks in the supply chains for all types of medical products – ranging from personal protective equipment to essential medicines. Some of these vulnerabilities predate the crisis, as highlighted by pre-existing, widespread shortages of certain medical products, as well the concentration of both production capacity and sources of core ingredients necessary for the manufacturing of medicines such as antibiotics. It is now both timely and crucial for countries in Europe and beyond to identify how best to respond and adapt health, trade and industrial policies to ensure reliable and diversified global medical supply chains, avoiding the temptation to resort to unnecessary export restriction. Making medical supply chains more sustainable and resilient will prevent deaths and benefit economies."



MEP István Ujhelyi

S&D, Hungary

"The COVID-19 pandemic showed us that new health crises can emerge at any time, because virulent diseases and health threats do not respect borders; however, they do require a coordinated response and cross-border cooperation. The pandemic has highlighted the need for EU resilience, the medicine shortages in Europe and the EU's dependency on outside countries for the production of many pharmaceutical ingredients and medicines. Additionally, the COVID-19 outbreak has accelerated the debate about supply chains, which are vulnerable in Europe. The response which was given by the EU showed that our European community is much stronger together, but when it comes to future crises, we should be more prepared.

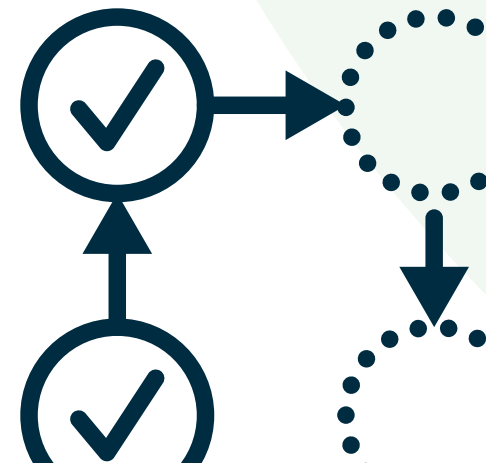
We need better data-sharing, greater access to data, enhanced cooperation and digitalisation of the medicine supply chain and we require a well-functioning HERA and a real European Health Union as well.

European health and healthcare changed a lot in the last year and a half, and are still changing. The ideas of the European Health Parliament's Resilient Supply Chains Committee are fresh, energetic, and youthful, and this is what Europe really needs. Their work is essential, and their commitment is unquestionable, therefore it's an honour to endorse the recommendations of the experts of the Resilient Supply Chains Committee."

- Executive Summary
- Introduction
- Recommendations
- Conclusions
- ▶ Endorsements
- References



**Committee for
Resilient
Supply Chains**



Endorsements



MEP Sara Cerdas

S&D, Portugal

"As we are moving forward from one of the biggest crises our society has faced, lessons need to be learned and the future needs to be prepared. Supply chains are a key area in healthcare provision and need to be addressed in order to be more resilient, not only during a crisis, but also at all times. We need to ensure that no one is left behind and inequalities in access and affordability are tackled all the way along the value chain. Transparency and solidarity will be core values to ensure this fundamental right to proper treatments and medicines. These recommendations from the European Health Parliament's Resilient Supply Chains Committee are a step further in the right direction."



Monika Derecque-Pois

Director General, European Healthcare Distribution Association (GIRP)

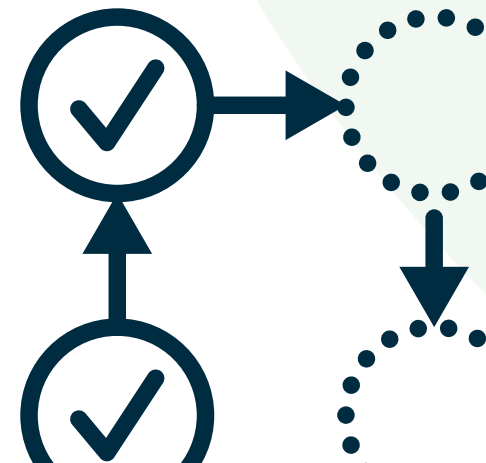
"The COVID-19 pandemic and crisis has exposed vulnerabilities across supply chains in an unprecedented manner and made us all aware about their lengths, complexities, dependencies, and risks. Ensuring the continuity of supply and the availability of medicines, medical devices and other healthcare and medical products for patients, whenever and wherever they are needed, is a highly complex endeavour.

A strong commitment from politicians, policymakers, legislators, regulators, and all supply chain stakeholders to collaborate in order to find solid and long-lasting solutions is a pre-requisite. It is therefore my pleasure to endorse the report and recommendations of the European Health Parliament's Resilient Supply Chains Committee, which takes a holistic approach in its suggestions to improve the resilience of supply chains and comes at a perfect time to feed into the discussions at European level."

- Executive Summary
- Introduction
- Recommendations
- Conclusions
- ▶ Endorsements
- References



**Committee for
Resilient
Supply Chains**



Endorsements



Kasper Ernest

Secretary General, Affordable Medicines Europe

"The necessity to develop a pharmaceutical strategy that truly answers the concerns of European citizen has become more important than ever. As highlighted by the COVID-19 pandemic, the right to equal access to medicines for all will be a key issue in the years to come.

The recommendations proposed by the European Health Parliament's Resilient Supply Chains Committee to tackle this issue point to many innovative, creative and efficient key solutions. They should be taken in consideration in order to guarantee healthy living for everyone, now and in the future."



Johan Styrud

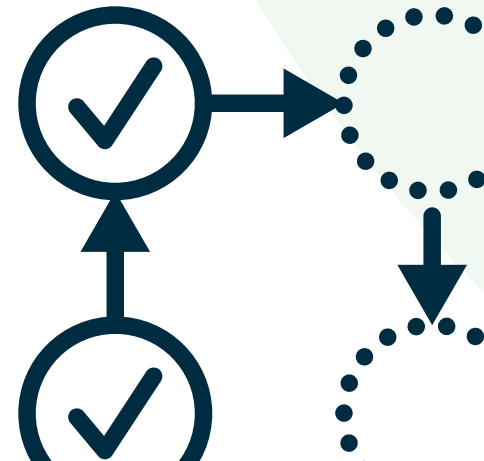
President, the Stockholm Division of The Swedish Medical Association

"COVID-19 has shown the importance of resilient supply chains. Without reliable access to both medicines and medical supplies healthcare systems cannot keep citizens safe from various threats against public health. The Resilient Supply Chains Committee is proposing actions on a broad variety of topics to secure future crisis preparedness within the EU with the patient in the spotlight. I am happy to endorse the recommendations from the European Health Parliament's Resilient Supply Chains Committee – the only way forward is together."

- Executive Summary
- Introduction
- Recommendations
- Conclusions
- ▶ Endorsements
- References



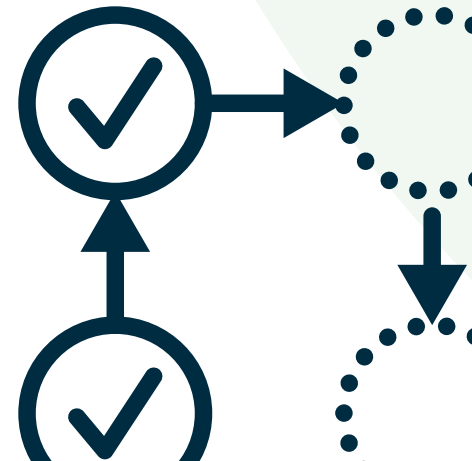
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- Executive Summary
- Introduction
- Recommendations
- Conclusions
- Endorsements
- ▶ References



Committee for Resilient Supply Chains



Committee for Health and the Green Transition

THE VIRTUOUS CIRCLE: CO-BENEFITS OF PROTECTING THE PLANET AND HUMAN HEALTH

More and more people are starting to ring the alarm, as awareness on environmental issues and their relation to health increases. Multiple examples exist of environmental issues affecting citizens' health, air pollution for instance. On the other hand, we also know that making a healthy choice can affect the environment in a very positive way, such as being mindful when consuming food or other goods or going to work by sustainable transport.



Committee for Health and the Green Transition

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Executive Summary

The recommendations provided by the Committee on Health and the Green Transition are about things that we all do in our daily lives. They build upon several pillars from the Green Deal for which some critical gaps still exist and therefore can be improved. We urge European policy makers to empower European Union (EU) citizens in their decision making, resulting in a positive impact for both our health and our planet Earth by:

Empowering societies and their citizens to take concrete steps towards healthy and sustainable diets:

- » EU-wide dietary guidelines on healthy and sustainable diets
- » Moving towards a harmonised nutritional and environmental label for food products
- » Farms above the city – rooftop-gardening

Empowering citizens to be knowledgeable and protected when consuming (other) goods:

- » An educational journey towards a toxic-free environment
- » Not a pill for every ill
- » Limit intellectual pollution to limit environmental pollution

Empowering citizens to think sustainable and healthy when using transport:

- » Encourage biking policies
- » Promote public transport
- » Moving towards an Electric Vehicle battery remanufacturing ecosystem in the EU

The recommendations you will find in this paper are impactful, relevant, realistic and add great value to tackling today's environmental, health and even economic issues. Our planet's alarm is going off, and it is time to be healthy and take action!

- » Executive Summary
- » Introduction
- » Recommendations
- » Conclusions
- » Acknowledgements
- » Endorsements
- » References



Introduction

In 1969, Apollo 11 captured some extraordinary pictures of our planet earth thereby transforming our view on the planet and its limits. Currently, our increased understanding of climate change is transforming our view on the boundaries and determinants of human and environmental health. Our personal health relates to our behaviour, local environmental exposures, and healthcare access. While population health requires the life-supporting 'services' of our planet Earth such as supply of food, water, and comfort, all of which are provided by climate stability. More and more people are ringing the alarm, especially the younger generation who is very much aware of the consequences of our behaviour and the threats to the environment resulting from it.

As an example, it is estimated that already 400,000 premature deaths are attributable to air pollution each year in Europe.¹ The overall annual cost of health impacts and mortality from air pollution are approximately € 1.3 trillion within Europe. Additionally, cardiovascular diseases (CVDs) exacerbated by a lack of healthy diets and by a lack of physical activity causes another 1.8 million deaths in the EU each year, representing 37% of all deaths. CVDs cost the EU € 210 billion per year.² Next to air pollution, other environmental hazards are linked to health issues, e.g. disease outbreaks related to drinking-water are registered even in the most economically developed countries

indicating that unsafe water remains a public health issue throughout the European region.⁵²

The COVID-19 pandemic clearly showed its impact both in terms of health and the environment. Individuals are becoming more aware of their personal health and the link to environmental issues. Many countries experienced a lockdown and witnessed the positive effects on the environment and the decreased level of air pollution in cities. In addition, most travel movements during the pandemic are strongly discouraged in the majority of EU Member States which therefore emphasizes the often unnecessary environmental impact that people made via emissions before the pandemic.

Health and the environment are linked in many ways. It is obvious that protecting the environment would prevent many deaths and diseases, such as the ones linked to air pollution or floods. On the other hand, activities enhancing health would also greatly benefit the environment, such as being more careful about what to eat, being mindful when it comes to the use of digital resources and using active transports.

Now is the time to make a change and encourage policy developments that benefit both human health and environmental health. Therefore, the aim of the policy recommendations of the Committee on Health

and the Green Transition is to have a healthy population to protect the planet and vice versa.

The policy recommendations you will find in this paper are about all things we do in daily life: eating, consuming other goods, and transporting ourselves. The starting point for the recommendations is the following five pillars from the Green Deal:

- » From Farm to Fork: a fair, healthy, and environmentally friendly food system
- » Accelerating the shift to sustainable and smart mobility
- » Mobilizing industry for a clean and circular economy
- » Building and renovating in an energy and resource efficient way
- » A zero pollution ambition for a toxic-free environment

The recommendations have been established by literature research and consultations with various experts within the field of interest.

Many actions have already been put in place, however there are some critical gaps that are still to be addressed for improvement. Our recommendations include actions that can be executed at EU and national level, but also at local and individual level and address both short- and long-term solutions. Empowering EU citizens will positively impact both our health and our planet Earth.

Executive Summary

► Introduction

Recommendations

Conclusions

Acknowledgements

Endorsements

References



Recommendations

EU-wide dietary guidelines on healthy and sustainable diets

As identified in the EU's Farm to Fork (F2F) strategy, current food consumption patterns are unsustainable from both the health and environmental points of view. Since 1980 the obesity rate has tripled³ with currently more than 50% of Europeans overweight and more than 20% obese.⁴ Diet and weight-related diseases account for 25% of all deaths in Europe⁵ and are major drivers of healthcare spending. At the same time, our food system is

responsible for more than 30% of greenhouse gas emissions, most of which are linked to meat and dietary livestock.⁶ Furthermore, over 50% of antibiotics (relative to the Population Correction Unit) are used for livestock,⁷ which plays a predominant role in the development of antimicrobial resistance. This scenario suggests that moving to plant-based diets, including a decrease in the consumption of processed food, can not only reduce the risks of non-communicable diseases and of antimicrobial resistance, but also the environmental impact of our food system.

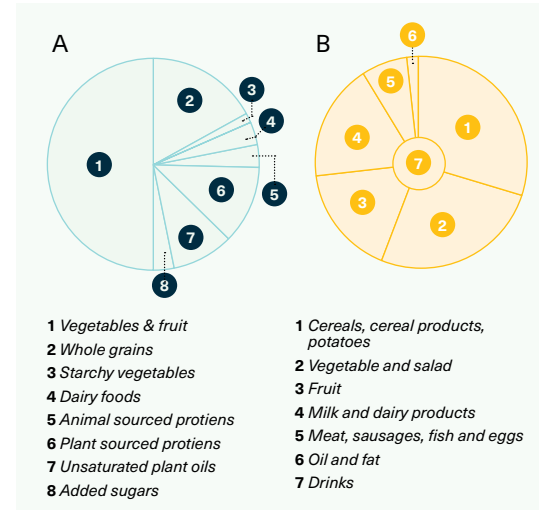


Figure 1: Comparison between the food chart recommended by the EAT-Lancet commission on sustainable and healthy diets and the German Nutrition Society. A. Food-recommendation chart of the EAT Lancet Commission with animal sourced protein and dairy products representing each around 4% of total ideal food consumption. B. Food-recommendation chart of the German Nutrition Society with dairy products representing approximately 20% and animal sourced proteins around 6-8% of total ideal food consumption.

Create EU-wide and concrete food guidelines on sustainable and healthy diets following the best available evidence as ascertained by the EAT-Lancet commission (figure 1A)⁸ and the WHO.⁹ While the Farm to Fork strategy currently in place aims to spur a shift to a healthy and sustainable diet, it crucially does not specify its implications. Therefore, we suggest the development of an EU-wide food

- Executive Summary
- Introduction
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References

EMPOWER SOCIETIES AND THEIR CITIZENS TO TAKE CONCRETE STEPS TOWARDS HEALTHY AND SUSTAINABLE DIETS

HEALTH EFFECTS	ENVIRONMENTAL BENEFITS	ECONOMIC IMPACT
<ul style="list-style-type: none"> Less obesity-related diseases Less non-communicable diseases (NCDs) Such as cardiovascular diseases, type 2 diabetes Less cancers Mental health improvement Increase of social cohesion 	<ul style="list-style-type: none"> Less CO₂ emissions Less pollution of land and water E.g. phosphores, chemicals such as herbicides and pesticides Increase of biodiversity Less flooding and heat islands 	<ul style="list-style-type: none"> Savings in healthcare Circular economy benefits Good quality food production saves money and creates value via a circular fair price food economy Fair wages and working conditions



Recommendations

guideline consisting of predominantly plant-based, non-processed foods from sustainable agriculture and including precise quantitative references of the recommended amount per food category (Example from the EAT-Lancet Commission: 0-14 g/d beef and lamb; 0-14 g/d pork; 300-600 g/d vegetables (figure 1B)⁸). Up until now, EU-wide guidelines have been deemed not feasible by the European Food Safety Authority (EFSA) due to 'country specific availability of food products' and 'cultural characteristics'. Yet, in the past decades eating habits have changed drastically converging towards similar eating patterns (e.g. fast-food globalization). This experience shows how dynamic food systems and preferences are. Therefore, this also suggests they are liable to change and improve from an environmental and nutritional point of view if clear guidelines and effective policies are in place.

The EU and its Member States should inform citizens about the change in dietary recommendations. This can be achieved by organizing public campaigns and integrating the new guideline, proposed in recommendation 1, in health education programmes of schools and universities.

The EU should incentivise Member States to align the meals served in schools, universities, and public institutions with the new EU-food guidelines on healthy

and sustainable diets. Acceptability among citizens will be achieved by implementing recommendation 2 and through a gradual transition: as part of its EGalim policy,¹⁰ France has, for example, introduced a mandatory vegetarian meal once per week in schools (or every day if different menus are proposed).

Moving towards a harmonized nutritional and environmental label for food products

The use of nutritional and environmental labels guides consumers towards healthier and more sustainable diets.¹¹ In addition, the consumption of healthy and sustainable diets enables the preservation of the environment by reducing the climate footprint of the EU-food system.¹² In this context, we welcome the initiative defined in the F2F Strategy to positively influence consumers' food choices by introducing a nutritional labelling. We suggest the below actions to assist the European Commission (EC) to reach the F2F Strategy objectives and to go even further.

The EC should develop complementary nutritional and environmental scores and harmonise their use in food produced and distributed in Europe. The nutritional score should be based on the food guidelines suggested in recommendation 1 adding to the Nutriscore¹³ the degree of processing and the

origin of proteins with only those from plants receiving positive points. The environmental score should depict the environmental impact of food products throughout their life cycle. These two scores would serve as the basis for developing a new nutritional and environmental food label. To ensure compliance of the food industry, auditing on the implementation of both labels at EU level is needed. Also, national authorities should be encouraged to monitor consistently the proper implementation at national level and impose penalties in case of non-compliance.

Establish an EU Platform that guides and advises the EC on the development and establishment of the recommended nutritional and environmental labels. The platform should be composed of policymakers at the EU and national levels, stakeholders from the food sector, experts from the scientific community and representatives of consumer associations, ensuring thereby the development of realistic scores and a smooth implementation of both labels. The platform will act as a space to share the latest scientific evidence, best practices in the implementation of the EU law and, in the long term, improve EU food labelling requirements towards healthier and more sustainable food choices.

Promote educational campaigns at European and national levels to increase awareness

Executive Summary

Introduction

▶ Recommendations

Conclusions

Acknowledgements

Endorsements

References



Recommendations

among consumers on the difference between the nutritional and environmental labels proposed in recommendation 4, compared to other existing labels related to environment, such as organic and ecologic labels.

Rooftop-gardening: farms above the city

Urban green spaces have been associated with many health and environmental benefits, but their expansion collides with the considerable competition over land use and property in urban areas. In light of these facts, rooftop gardens are still an underexploited solution. Rooftop gardens and green spaces are associated with increased physical activity, improved mental health and a reduction in cardiovascular diseases.¹⁴ This method of urban greening also increases biodiversity, reduces urban heat islands, reduces the risk of flooding and, not least, contributes to curbing of greenhouse gas emissions.¹⁵ Combined with urban agriculture, rooftop gardening could provide up to 90% of the vegetables needed for urban dwellers, thereby improving food security as well. In addition to the European Forum on Urban Agriculture 2020-2024, an EU-funded research project aimed at developing better knowledge, deployment and policies in this field should be the first concrete steps undertaken for its roll-out. This networking platform wants to combine rooftop-gardening

with other types of urban agriculture, in order to support the development of sustainable urban food systems.

Develop community-based rooftop gardens on all public institutions with suitable roofs.

Community-based rooftop gardening promotes social inclusion and can enhance the acceptance of plant-based diets, thereby contributing to the transition towards the new food guidelines mentioned in recommendation 1. Developing community-based rooftop gardens will also make this technology known to citizens and encourage them to transform their own rooftops into gardens.

Develop a legislative framework for companies and private households to incentivise the installation of their own rooftop gardens.

The framework should include diverse methods ranging from financial incentives to using nature conservation laws.

Create a cross-cutting fund for the financing of the previous two recommendations.

Policies on rooftop gardens involve many areas ranging from agriculture, sustainable development, health and prevention, climate action, science and technology all the way through to employment and social rights; this renders it an attractive policy measure but also makes resource allocation more difficult.

Green and Digital Transition are terms that go hand in hand. They are part of ongoing European discussions, especially of the Green Deal pillars on 'building and renovating in an energy and resource efficient way' and 'a zero-pollution ambition for a toxic-free environment'. Likewise, they are also intrinsic to the third United Nations' Sustainable Development Goal of good health and well-being. The following recommendations complement the ongoing strategies, address gaps that still exist and add to solutions of our increasingly digital daily lives.

An educational journey towards a toxic-free environment

Most companies use chemicals in one way or another. They are essential for our way of life and our economy, but they must be managed safely so as to protect human health and the environment.¹⁶ 84% of Europeans are worried about chemicals, present in products for daily use, affecting their health and ninety percent are worried about the environmental impact of these products.¹⁷ As well as pointed out in the Chemicals Strategy for Sustainability (CSS),¹⁸ there is a need to extend the principles of open data and the relevant transparency on chemicals. Additionally, the Sustainable Product Policy Initiative is also moving towards availability of information on chemical content and safe use. Nevertheless, there is still

Executive Summary

Introduction

▶ Recommendations

Conclusions

Acknowledgements

Endorsements

References



Recommendations

EMPOWERING CITIZENS TO BE KNOWLEDGEABLE AND PROTECTED WHEN CONSUMING (OTHER) GOODS



HEALTH EFFECTS

Less risk from polypharmacy or pharmaceutical side effects

Less consumption of contaminated water or food

Less respiratory disease from production emissions

Less risks of serious illness such as cancers, skin allergies and mental health



ENVIRONMENTAL BENEFITS

Less waste, emissions and water pollution from production and packaging

Less chemicals from natural excretion and improper disposal

More biodiversity from less contaminated lands and waters

Faster identification of harmful products for the environment



ECONOMIC IMPACT

Less costs of (pharmaceutical) production, purchasing and disposal

Support digital transition of economy and society

room for improvement at citizen level, from production to the end of life of products. These recommendations aim to allow consumers, key actors as well as waste operators to make choices based on transparent information.

Establish an EU 'Single Database Platform' that consumers can easily access to obtain transparent information beyond the labels while buying consumer goods. Create a comprehensive and accessible platform, supported, and maintained by the European

Commission, to ensure that sufficient, open, and appropriate information is made available at citizen level. Companies will be key actors on keeping the platform alive through providing data related to both sustainability and health. The language used in this platform should be friendly, clear and simple. It will be mainly developed for consumer goods sector products, according to their relevance for citizens. This platform could be connected with existing EU platforms (SCIP, IPCheM). It will also serve as a supplement to existing

information provided by some companies at their own websites in addition to bringing consumers more in-depth data beyond logos and green labels.

Organise an International day for non-toxic environments on an annual basis. Set up a 'European Day for a Toxic-Free Environment' in coordination with public institutes, industry, scientific institutes, and non-governmental organisations to promote a common understanding on the link between most common toxic pollutants and health, to raise awareness of the main sources of pollution in our environment and to engage more citizens, healthcare professionals and professionals in industrial sectors to act towards a toxic-free environment. Capitalize on digital tools: create a website with aggregated-contents and an 'all-in-one toolkit' to encourage and facilitate implementation across member countries and rely on networks to deliver messages to boost the launch of this initiative. By strengthening the understanding of citizens about sources of the main exposure to chemicals, latest evidence on chemicals' impacts on health, possible solutions under investigation or practical tips to implement, actions will be encouraged. Both the younger and older generation will change consumer habits as a result of the COVID-19 pandemic.¹⁹ Therefore, creating an European day for non-toxic environments starting today will be a great opportunity.

Executive Summary

Introduction

▶ Recommendations

Conclusions

Acknowledgements

Endorsements

References



Committee for
Health and the
Green Transition



Recommendations

Not a pill for every ill

With the number of citizens aged over 85 years across Europe growing,²⁰ so too will the reliance on pharmaceuticals expand accordingly, especially those prescribed and dispensed for chronic conditions. Patient Information Leaflets (PILs) will accumulate in homes eventually ending in landfill. Active pharmaceutical ingredients inadvertently enter the environment throughout the lifecycle of a medicinal product, whether via the natural excretion of medicines (30% to 90% of an oral pharmaceutical dose can enter the environment as an active substance through natural excretion²¹), improper disposal of medicines (5 to 10% of pharmaceutical substances found in the environment²²), and via effluents from manufacturing facilities (about 2% of pharmaceutical substances found in the environment²¹), resulting in potential risks to both environmental and human health.²³

Lastly, 50% of unused medicines within EU Member States are not collected leading to not only pharmaceutical waste, but considerable monetary loss as well which is estimated to be € 350 million per year in the UK alone.⁵

Utilize a person-centred care approach when prescribing pharmaceuticals, allowing healthcare professionals and patients to work together for a healthier patient

lifestyle.²⁴ Prescribers should feel empowered to prescribe preventative or non-medical measures according to the patient's individual needs and to de-prescribe medicines that no longer add value to the patient. National health institutions should encourage continuous professional development, including concrete and periodic actions for healthcare professionals encompassing both the principles of person-centred care and how this aligns with reducing environmental impacts of unnecessary pharmaceutical prescribing. Person-centred care requires commitment at governmental level to fully integrate it as part of their national healthcare strategy. These measures will reduce the risk of harm to patients from overuse of medicines, and more prudent prescribing which lowers consumption of medicines will ultimately reduce the amount of pharmaceuticals entering the environment through natural excretion.

Combat improper pharmaceutical disposal by educating patients of the appropriate collection and disposal method in their country.²⁵ The proper method of collection and disposal of medicines should be discussed with the patient at the time of prescribing and then again at the time of dispensing. The use of repetitive messaging from qualified healthcare professionals in this way will provide a secure base for a natural change of habit over time.²⁶ This inexpensive and easy to apply method of

patient education should be encouraged at governmental level in order to make it possible to establish a national infrastructure to support both the healthcare professionals and patients to gain knowledge on the proper disposal of medicines. The European Commission can support this strategy by providing a database containing information on the proper collection and disposal of medicines within each member state.

Amend the EU wide legal framework to allow for a QR code and URL link to be placed onto all medicines dispensed. In the longer term, this could serve as an alternative to a traditional PIL, thereby reducing excessive paper wastage. Although Member States hold primary responsibility for delivery for their own health services, the European Commission's Directorate for Health and Food Safety (DG SANTE) can propose legislation to allow for the elimination of traditional paper PILs and transition to a more digital future. The use of this digital technology also has the benefit of providing greater accessibility to real time up to date patient information. This recommendation aligns with the EU4Health goal of a post COVID-19 greener, more digitised Europe²⁷ whilst also falling under Pillar 3 of the EU's Digital Health and Care initiative as it empowers citizens to take greater control of their own health management through digital services.²⁸

Executive Summary

Introduction

► Recommendations

Conclusions

Acknowledgements

Endorsements

References



Recommendations

Limit intellectual pollution to limit environmental pollution

Digital technologies are huge polluters. Firstly, greenhouse gas emissions arise from the use of digital applications such as social networks (4% of the world's greenhouse gases).²⁹ Secondly, digital technologies create intellectual pollution. Social networks are designed to capture the time of their users, resulting in algorithms that aim for their users to stay online as long as possible, 'stealing' their time and selling their 'brain availability' while pushing advertisements. It has deleterious effects on the brain and causes addiction, anxiety and depression. The younger generations, who have not known a world without social networks, are the most exposed. The COVID-19 pandemic exacerbates the problem.³⁰

Create a tax framework for the 'time well spent' on social networks. 'Time well spent' is an expression promoted by Tristan Harris (co-founder of the Centre for Humane Technology) and means that technology should be used intentionally and with care. To limit environmental and intellectual pollution, the EC should create a framework that obliges social network companies to pay taxes based on the time spent on the platform by their users, thereby minimizing their time spent on social networks, resulting in less addiction to these platforms. The money generated by the tax

could be reallocated for preventive purposes in a broader sense. This tax framework could be implemented as part of a directive in the same way that was done on device energy efficiency.³¹

Transport is the largest contributor to climate change: it represents almost a quarter of Europe's greenhouse gas emissions.³² Transport is also the main cause of air pollution in cities and directly affects individuals' health (e.g. mortality, respiratory diseases, and cancers).³³ Each year, approximately 400,000 premature deaths in Europe are due to air pollution.³⁴ Road traffic is the core of the problem; studies show that a reduction of one third of car trips would result in a 25% reduction in pollution and a 36% reduction in carbon monoxide emissions.³⁵ Solutions towards sustainable transport are therefore needed. For short distances, biking must be encouraged. Longer distances could be best bridged by public transport or electric vehicles. The following recommendations aim to foster sustainable mobility based on the European Green Deal and local initiatives.

Encourage biking policies

In addition to the issue of pollution caused by the use of personal cars, it is estimated that 30% of adults are insufficiently active during the week which led to an obesity prevalence of 20% in the EU.³⁶ Physical inactivity is estimated

to cost a country about € 150-300 per citizen each year.³⁷ Active mobility, including biking and walking, would therefore address both environmental and health issues.³⁸ Furthermore, there is great potential for active travel in European countries given the fact that half of all car trips cover distances shorter than 5 km.³⁹ They could be undertaken by foot or by bicycle, if this could be done safely. This requires policy developments to provide safe and appropriate conditions for these behavioural changes.

To develop safe and appropriate biking infrastructure such as definite cycle tracks, traffic signs, bike-sharing systems.⁴⁰ A population will only be encouraged to cycle in a secure environment. The EU should encourage local authorities to develop the necessary infrastructure to ensure cyclists' safety, thus further encouraging European citizens to use bikes rather than cars. Platforms and forums to share best practices could be implemented, as well as EU funding opportunities if appropriate.

To encourage behavioural changes. This could be achieved with bike-promotion campaigns which will help shape the narrative that biking is good for your health and the environment, but is also a safe and easier means of transport. For instance, European campaigns could be launched to promote the use of bikes, together with Member States so

Executive Summary

Introduction

► Recommendations

Conclusions

Acknowledgements

Endorsements

References



Recommendations

EMPOWERING CITIZENS TO THINK SUSTAINABLE AND HEALTHY WHEN USING TRANSPORT



HEALTH EFFECTS

Fewer diseases

E.g. respiratory, cardiovascular, obesity, cancers

Less fatigue

Mental and physical health improvement

Less traffic injuries and deaths

Healthier people in battery producing countries



ENVIRONMENTAL BENEFITS

Less air pollution/CO₂ emission

Less urban heat islands

Less noise

Increase of biodiversity

Lowering waste from batteries



ECONOMIC IMPACT

Less traffic congestion and traffic accidents

Less maintenance and road infrastructure renovations

Enabling people to live longer and healthier

that each country may adapt the campaign and its content to local practices. It should be emphasized how active mobility enables people to live longer and healthier.

To set financial incentives to encourage and reward biking. Increasing biking would also have positive economic effects.⁴¹ Indeed, it would have indirect economic benefits of several billion Euros by reducing car accidents and traffic congestion, and by reducing the impact on road infrastructure and its follow-

up maintenance.⁴² Encouraging biking would therefore have an enormous impact on national economies. The promotion of cycling could also be encouraged at individual level. For example, the taxation system enabling company cars could also involve the use of bikes, including electric bikes, as a sustainable alternative and making it just as financially interesting for employees. Organisations or companies could also create challenges with discounts or incentives per number of km, in partnership with sports applications.

Promote public transport

To ensure a healthy and sustainable Europe, the use of public transport in urban areas must increase. Driving into cities causes particularly elevated costs on the environment and on public health.⁴³ To promote sustainable transport from door to door, railways and buses must become more attractive. Co-modality allows residents to combine walking, biking, driving, and public transportation towards a greener and healthier urban environment.⁴⁴

Raise awareness. Residents should be aware of how their choice matters. Two sets of measures contribute to encourage the use of public transport. First, residents need to be addressed individually. A personalised public transport map with evidence of the benefits for health and the green transition shall be sent by targeted advertising. This invitation to act should be complemented by an app where public transport users could measure how much they contribute to public health and environmental protection, as well as participate in challenges and games. Secondly, public transport must be labelled as beneficial for public health and the environment. The Commission's action plan on rail transport foreseen for 2021 should motivate citizens to opt for public transport. Moreover, the European Climate Pact must encourage bottom-up initiatives. Collaborating with the

Executive Summary

Introduction

► Recommendations

Conclusions

Acknowledgements

Endorsements

References



Recommendations

European Committee of the Regions (CoR) and the Council of European Municipalities and Regions (CEMR) would help to reach local stakeholders.

Incentivize the use of public transport. Raising awareness is necessary, but not sufficient. Three priorities help to incentivize residents to use public transport in urban areas. First, public transport must offer a densely developed route network into the city. Where infrastructure costs for tram, light rail, or metro are too high, eco-friendly bus lines can provide an economical alternative. Secondly, cheap season tickets or zero-fare transport would motivate more residents to use public transport. Fuel or congestion taxes could aim to compensate for the loss of income from the lower fares. Thirdly, investments in 'park and ride' infrastructures outside the city would facilitate connections to the bus or rail system. City tolls and reduced parking spaces incentivize the use of the 'park and ride' system. Public transport must be a priority when implementing the instruments of the European Green Deal and of the European Regional Development Fund for the period 2021-2027. Likewise, the European Investment Bank (EIB) should increase its investments in public transport.

Moving towards an EV battery remanufacturing ecosystem in the EU

The use of Electric Vehicles (EVs) is expected to increase over the upcoming decades and so is the demand of their batteries.⁴⁵ The growing demand of EVs and their waste could counteract the lowered CO₂ emissions and toxic pollutants levels already achieved by a decrease in the transport share of combustion engine vehicles.⁴⁶ Consequently, the number of EV lithium batteries ready to recycle is expected to rise 700-fold and we should be prepared to catch the massive wave. These end-of-life EV batteries can provide a significant amount of valuable secondary raw materials.⁴⁷ We must avoid that green transition for cars means going from one environmentally polluting substance to another, while ignoring negative health repercussions (i.e. cancer, thyroid damage or vision impairments) and human rights violations linked to improper raw material extraction.

Make the EV battery economy circular and sustainable. This can be done by tackling environmental and human health and rights violations from substandard conditions during the extraction of cobalt, lithium and nickel, and through reuse or recycling of EV batteries.⁴⁸ This should be reached in Europe by, firstly, investing in innovative batteries designed for recycling and containing a minimal of critical materials (i.e. low-cobalt batteries).

Secondly, by establishing proper conditions and infrastructure for secondary use of end-of-life batteries in energy storage. Thirdly, by investing in novel EV battery recycling processes (including hydrometallurgical and direct recycling) and creating designated enterprises for energy-efficient and emission neutral recycling of these batteries.

Adapt EU policy on sustainable batteries and increase the minimum required level of recycled materials in new batteries. Under idealized recycling conditions, an 80% lithium and 95% of nickel and cobalt recycled content is possible.⁴⁹ The European Investment Bank's € 2 bn cut of yearly investments from unsustainable initiatives should be reallocated to technological gaps necessitating innovation.^{50,51}

Additionally, a legal policy framework in the EU allowing secondary use and recycling of EV batteries should be provided. This cause would further benefit from guidelines, intended for citizens, on the disposal of antiquated EVs and retrieval of end-of-life batteries.

Continuous incentivization and support of innovation concerning green energy sources, alternatively to electricity, within transport industries. Exploring more labour-friendly and non-depletable sources beyond our current greenest solution, such as wind and solar energy, could further enhance sustainability in the automotive sector.

Executive Summary

Introduction

► Recommendations

Conclusions

Acknowledgements

Endorsements

References



Conclusions

Our recommendations provide policymakers with tools to strengthen sustainability policies in order to improve both human and environmental health. Awareness on environmental issues and their relation to health has increased in recent decades, and the COVID-19 pandemic has only served to emphasise this. Young European health professionals call upon their policymakers to rethink sustainability policy in order to empower Europe's next generation.

These policy recommendations show that we do not necessarily need to sacrifice strong economies for a healthier environment or for a healthier population. The only way forward is to get everyone involved: the EC, national governments, industries, and citizens. We need to go sustainable in all activities as far as possible in our daily lives – from eating, consuming other goods and making use of transport – in order to achieve the goal of having a healthy population which protects our planet and vice versa. There is no second chance. There is no Planet B. Our planet's alarm is going off, and it is time to be healthy and take action!

- Executive Summary
- Introduction
- Recommendations
- ▶ Conclusions
- Acknowledgements
- Endorsements
- References



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- » **Francesca Racioppi**, Head of WHO European Centre for Environment and Health, Bonn
- » **Dr. António Marques Pinto**, EEHYC Executive Board
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Executive Summary
Introduction
Recommendations
Conclusions
» Acknowledgements
Endorsements
References



Committee for
Health and the
Green Transition



Endorsements



Scott Brady

Climate Programme Manager at Health Care Without Harm (HCWH) Europe

"Through the delivery of the Green Deal and by setting its increased climate ambitions in law, the EU has signalled its intentions to build a greener, more equitable world for its citizens. However, there is still much to be done in aligning policies on human and planetary health, and the recommendations in this report lay out a sensible route to achieving that. Health Care Without Harm Europe is, therefore, delighted to endorse these recommendations."



Brando Benifei

Member of the European Parliament (S&D)

"I applaud and fully support all the European Health Parliament for these policy recommendations about the crucial link between health and the environment. The planet and the health of human beings are linked by a clear relationship of dependence: the more we pay attention to our way of life, the more we will live in a beautiful and clean environment. Things can be changed, and politics is where this can best happen. The key word that must drive our future is 'sustainability'. Our lives need to be sustainable from our basic daily moments: eating, moving, working, studying, or having fun. I will work as hard as I can so that the European Union and the European Parliament can play a key role in making sure that all European States and the international community undertake this unavoidable change."

- Executive Summary
- Introduction
- Recommendations
- Conclusions
- Acknowledgements
- ▶ Endorsements
- References



Endorsements



David Somekh

Network Director European Health Futures Forum (EHFF)

"A healthy society in a healthy planet is one of the fundamental pillars of the concept of the wellbeing economy, a concept that itself is drawing more and more interest in the European policy space as well as elsewhere in the world. As stated in this paper, the relationship between better health and looking after the environment is very well established by the available data. The cross-cutting theme of empowering citizens to enjoy and contribute to better health that runs through these recommendations is a worthy one, whether by providing better information, more environmentally friendly infrastructure or more responsible industry practices. The paper acknowledges that the Commission's approach to improving the sustainability and resilience of our societal systems is going in the right direction but offers useful additional observations which could catch the attention of policy makers."



António Marques Pinto

European Environment and Health Youth Coalition (EEHYC)

"It gives me great pleasure to endorse the endeavours and recommendations of the Committee on Health and the Green Transition of the European Parliament. The environment is changing at a progressively level with frightening consequences. Although most recent scientific evidence shows that its impact on people's health is fast and strong, it is imperative to state that this current trail is not predetermined. On the contrary, and since it is affected by choices that governments, stakeholders, and citizens can make, it is a question of strength of will and determination to bend society towards sustainability. By addressing a range of topics within the Environment and Health thematic, namely Food Systems, Non-Toxic Environments and Transports, this work constitutes a must-read guide for any policymaker. Not only does it offer detailed and comprehensive policy directives that take into account the intricacy of actions essential for a supranational, i.e. European approach, it also provides concrete innovative proposals for improving health effects and environmental benefits, always taking into account their economic impact. With the increasing public awareness of the environmental health hazards, I am more than confident that this committee's reflections and suggestions will get strong scrutiny in the near future."

- Executive Summary
- Introduction
- Recommendations
- Conclusions
- Acknowledgements
- ▶ Endorsements
- References



Endorsements



Karen Vancluysen

Secretary General, POLIS Network

"As a network of cities and regions working together towards transport innovation, we are aware sustainable transport plays a major role in improving the health of cities and its citizens. Increasing the share of active travel in cities brings many health benefits, not only by integrating physical activity into people's lives, but also by reducing air and noise pollution, and improving road safety. Promoting walking and cycling, in combination with public transport, and cutting transport-related emissions is vital to cope with the environmental challenges we are facing and move towards healthier mobility ecosystems. We support all positive steps towards this goal and welcome the initiative of the European Health Parliament and its recommendations to empower citizens to favour sustainable and healthy mobility options."



European Cyclists' Federation (EECF)

"We welcome the inclusion of cycling within the European Health Parliament report on Healthy Green transitions. Prioritizing active modes of transport like cycling should be a key component of improving the health of European citizens, as well as overcoming environmental and sustainability problems in our cities. It is important that cycling is safe and comfortable, and the improvement of cycling safety we set in motion a multiplier in improving public health. Not only do we reduce fatalities and injuries of cyclists themselves, but we also reduce 3rd party fatalities and injuries to other road users, and we make the roads look and feel safer to encourage other people cycling. We thus promote healthier active lifestyles and I turn again making roads safer. We believe that creating safe environments for cycling should also be considered a key public health investment as well as providing effective actions to improve our environment and urban environment. We call for more funding of cycling infrastructure; better motor vehicle speed management including 30 kph as default in urban areas; safer vehicles; and better urban planning that prioritizes walking, cycling, and public transport in urban areas; and we fully endorse the policies laid out by the European Health Parliament."

- Executive Summary
- Introduction
- Recommendations
- Conclusions
- Acknowledgements
- ▶ Endorsements
- References



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Executive Summary
Introduction
Recommendations
Conclusions
Acknowledgements
Endorsements
▶ References



Committee for Healthy Economies

More than a milestone, COVID-19 must be a turning point for our society. The pandemic has highlighted many of the existing challenges in our societies and healthcare systems in particular, but it also gives us the possibility to rebuild. Our goal as the Healthy Economies Committee was to ensure that Europe has in place the necessary tools and conditions to do so: better, smarter, more innovative and more efficiently.



Committee for Healthy Economies

Chair

Gonçalo Pinto Mendes

Vice Chair

Sophie Millar

Members

Paul Carty

Anna Chachaj

Sandra Gillner

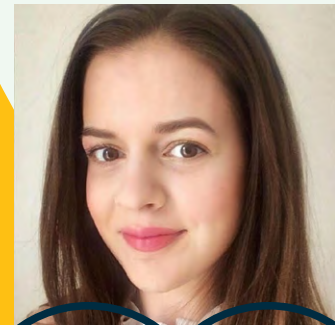
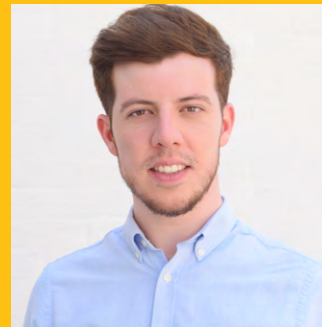
César Gimeno Rodriguez

Jacob Petersen

Thomas Tasios

Bruno Venâncio

Karolina Walsh



Executive Summary

By protecting and enhancing the health of all populations, we can increase productivity, thus promoting stable and generalised economic growth, and feeding a virtuous cycle that propels an economy of well-being. As stated by the Finnish Presidency of the Council of the EU in 2019: “while people’s wellbeing is a value in itself, it is also vitally important for the Union’s economic growth, productivity, long-term fiscal sustainability and societal stability”. Health can, therefore, only be seen as an investment, never just a cost. Now more than ever, we need decision-makers to see health as a priority. We must make healthy living a constant for all if we are to create a healthy economy for all.

To this aim, the Committee conducted an extensive literature review, which was complemented with several interviews with key stakeholders. Based on the knowledge gathered, we propose the following pillars of recommendations:

1. To **improve healthcare systems**, we propose that integrated care be implemented to allow for more coordinated care with a focus on long-term planning and taking full advantage of EU funds. Moreover, it is essential to promote health literacy and education, enabling self-care.

2. As for **enhancing access to healthcare for marginalised communities**, we suggest implementing training courses for healthcare professionals (HCPs) against subconscious bias to improve treatment and facilitate patients’ willingness to be treated. In many cases, these patients do not know how to access healthcare services, therefore, promoting communities’ awareness of the healthcare services available to them is key. However, this is not enough. Decision-makers need to actively consider them in their activities, as such, they require appropriate data in regards to marginalised communities, especially during crisis situations.

3. To evolve the **future proofing of the European workforce**, we propose investing in individuals’ multi-disciplinary skill sets to allow for flexible adaptation, particularly during emergency settings, while ensuring roles and associated tasks are appropriately established. Concurrently, the work load remuneration and reward must be balanced and adaptive to workers, including enabling access to telework.

We would like to invite you to read our full recommendations below to better understand our positions and proposals for Europe to establish itself as a world leader in health and beyond.

Image 1: People’s wellbeing and economic growth are interdependent and mutually reinforcing¹



Image 2: The economics of wellbeing – components of well-being that contribute to long-term economic growth¹



Introduction

Above all, COVID-19 has shown us how deeply intertwined health and the economy are: a healthy economy requires a healthy workforce.² The pandemic has intensified societal challenges and put the health of the world's population at risk. We were not prepared to deal with such a threat, and existing problems have been amplified. The demographic changes³⁻⁵ and the increase in non-communicable, chronic diseases witnessed over the last decades,⁶⁻⁸ combined with the COVID-19 pandemic resulted in a perfect storm. Many who were not directly affected by the disease have seen their health deteriorate, due to the cancelling and postponement of medical appointments and procedures.⁹⁻¹¹ Simultaneously, patients continued to face issues regarding accessibility, availability and affordability.

With people's lives at risk, governments were forced to undertake measures to try to curb the spread of the virus (i.e. lockdowns) which put the economy in severe distress.¹²⁻¹⁵ With businesses struggling and personal incomes contracting, global GDP in 2020 shrunk by 4.3%, according to the World Bank,¹² leading us into "the deepest global recession in decades", despite governments' best efforts to avoid and mitigate this situation.¹⁶ In this new context, the differences within our societies are being highlighted, and the gap between different

strata is quickly growing, as the rich get richer and the poor get poorer.^{17,18} We have also seen a much quicker adoption of digitalisation, including in health, thus allowing patients to be seen more easily by their doctors,^{19,20} although this is still not widespread. It also pushed society towards teleworking, something, which, up until now, seemed quite far away as a standard policy, but which was essential to ensure business continuity during lockdowns as much as possible.^{21,22} This shows how embracing innovation and new technologies helped the world keep a larger proportion of the population safe, while still keeping the economy (at least partially) running.

The profound connection between health and the economy was already known. We have studied the connections between economic prosperity and demographic trends (e.g. life expectancy has a positive correlation with gross national product per capita and with public expenditure particularly in health care),²³ but the COVID-19 pandemic was the first time we all felt it simultaneously, individually and as a society. Hence, we must ensure we can provide quality, equitable and affordable health care to all individuals, in order to maintain a capable workforce. In doing so, we can drive sustainable economic growth. Ensuring employees' health, in all senses of the word (physically and mentally), we can improve

productivity, thus, accelerating economic recovery.²⁴ In fact, the introduction of vaccines in early 2021 has already allowed us a glimpse of the economic effect they can have.²⁵ We must make healthy living a constant for all if we are to create a healthy economy for all.

Within the Healthy Economies Committee, we identified the areas where efficiency could be improved to deliver better health conditions to individuals and transform those into a more dynamic economy. Our recommendations, touch upon the reorganisation of the healthcare system and the promotion of healthier practices, as well as ensuring equitable access to healthcare, especially for marginalised communities.²⁶ Additionally, we looked into the new work practices brought about by COVID-19 (e.g. teleworking) and how employees' general wellbeing and productivity can be improved.

Further below you will find not only our recommendations on these various topics and how we reached them, but also additional approaches we took to engage with stakeholders and society, in particular our digital campaign, #VaccineChamp.

Executive Summary

▶ Introduction

Approach

Recommendations

Conclusions

Acknowledgements

Endorsements

References



Approach

In our path towards defining recommendations, we implemented a design-thinking strategy. We identified key issues affecting Europe and took a deep-dive to try to find their roots. From looking at Europe's healthcare systems and its economy, we found the common thread: people. We realised one cannot thrive without the other and thus, looked into how to make sure the individual, patient or not, had the necessary conditions to grow and promote an economy of wellbeing.

After an extensive literature review, we discussed amongst ourselves the main issues facing Europe's economy and healthcare systems. We conducted interviews with key stakeholders from all levels (technical and political), backgrounds (academia, patients, healthcare professionals, authorities) and jurisdictions (regional, national and European), to debate and confirm our findings. Through this, we gained an enhanced perspective on national and European contexts, which we used to brainstorm possible solutions. Finally, we underwent a second round of interviews in order to examine and evaluate them. This also included a live Twitter debate on self-care organised under the name of #EHPchats.

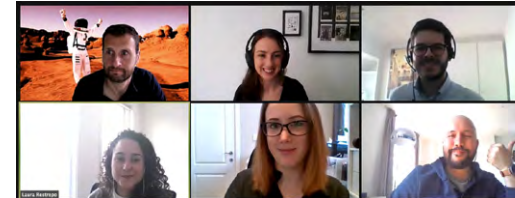
#EHPchats

#EHPchats was a novel way for our Committee to engage stakeholders and collect their feedback, while taking advantage of the full power of social media (see image 3). The Healthy Economies Committee invited **Lars Münter, Karolina Walsh, Vintura, AESGP, and Appetite for Life 'Apetyt Na Zycie'** as guest contributors to discuss on Twitter in real-time and publically the theme of self-care (see image 4). Moderated by Committee Vice-Chair Sophie Millar, this event took place on 2 April 2021 using the hashtag **#EHPchats**. It served for our Committee to gather input from stakeholders present, as well as from any members of the public who wished to participate in the debate. This model of Twitter debates provided us with extremely relevant data and perspectives that fuelled our recommendation in Pillar 1 on the issue of self-care, alongside literature research and follow-up discussions with the guest contributors.

Image 3: Social media metrics for #EHPchats initiative



Image 4: Some of the #EHPchats contributors in a virtual meeting debrief



#VaccineChamp Campaign

One of the main topics highlighted in the Healthy Economies Committee's mandate was the importance of vaccination to overcome the current pandemic. Lack of understanding and knowledge on how vaccines work play a big part in undermining the general population's confidence in vaccines, as does the increasing spread of mis- and dis-information online. A feeling which has been growing as of late, both for recommended and mandatory vaccination.²⁷⁻³¹

Health literacy is a significant component behind vaccine hesitancy and we felt from the start that we needed to do more. That it was necessary to interact with people directly. As such, in collaboration with the EHP partners and the other EHP Committees, we launched a website (<https://healthyeconomies.wixsite.com/vaccines>) compiling trustworthy

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Approach

information on vaccination, in particular regarding COVID-19 vaccines (see image 5). This included national resources for all 27 EU Member States. The intent is to facilitate access to these resources and, thus, address health literacy on vaccines.

To increase engagement with the website, on 12 April 2021 we launched a social media campaign, allowing individuals to feature their own stories around vaccination (vlogs, blogs or quotes) on the website itself and share them through their social media accounts. Given the remit of the EHP, but also the specificities of how youth was affected by this pandemic,³¹ we are targeting younger generations in particular. People across Europe were invited until 14 May 2021 to submit their stories to our website and enter a competition to participate in the final EHP plenary in June 2021.

At the time of writing (6 June 2021), on Twitter alone, **#VaccineChamp** has reached **207 mentions from 85 unique users, and our website has had 1,075 site sessions from 773 unique visitors** (see image 6).

The campaign has been shared all over the world, from Malaysia to San Francisco, with a dense concentration in Europe (see image 7).

Image 5: Social media post on the EHP account regarding the #VaccineChamp campaign



Image 6: Social media metrics for #VaccineChamp initiative

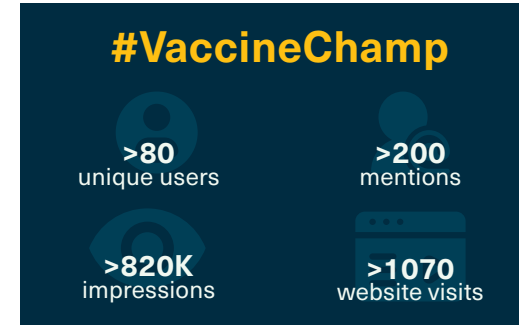
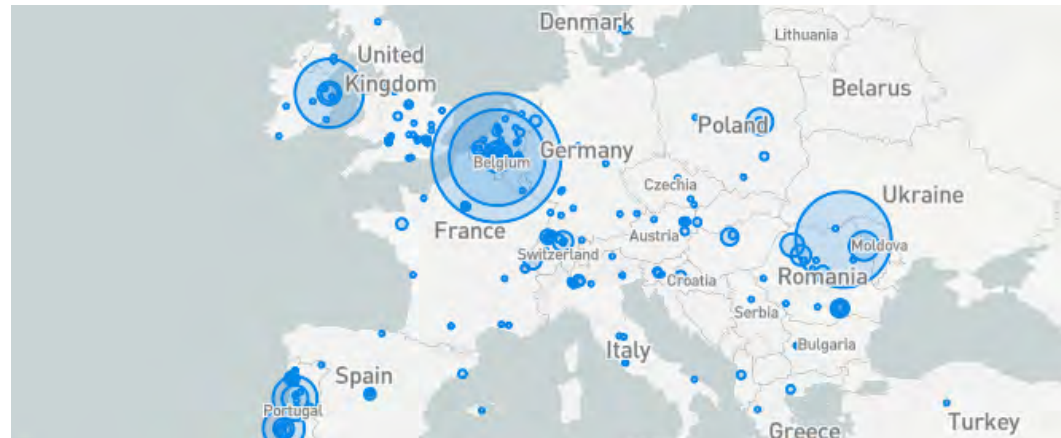


Image 7: #VaccineChamp Website traffic by location (data as of 30 April 2021)



- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Recommendations

Rethinking health and care system design to serve the next 100 years

The basis for our healthcare systems was established nearly a century ago. Since then, many things have changed, from the diseases we are fighting to our knowledge of the human body and how to treat it. Yet, the structure of our healthcare systems has remained the same. If Europe is to embrace the future and use COVID-19 as an opportunity to grow, our healthcare systems and how we approach health are one of the main areas to look into.

Invest in health literacy and include health education in the school syllabus across Europe, and expand the scope of practice of community pharmacists to support self-care

Self-care, which complements and supports regular care, enables individuals to appropriately manage a wide range of common health issues, thus **empowering patients to take ownership of their health** (see image 8). In doing so, it strengthens our society, saving time and unnecessary burden on HCPs, who can then focus on providing better care for those with more complex conditions who cannot treat themselves. Self-care is enabled by basic health knowledge, community action and resources, and enhances the effect of health promotion efforts. In addition, prudent

Image 8: Social media post by AESGP during the #EHPChats initiative, highlighting the importance of self-care



use of antibiotics and knowledge about over-the-counter (OTC) products and hygiene products allows people to single-handedly protect and improve their health and quality of life in the most efficient way possible. In this, **community pharmacists frequently play a crucial role** in advising people and guiding them throughout life or the patient journey.

The **economic value of self-care comes from reducing or even avoiding indirect costs**, for example from preventing unnecessary GP or Emergency Department visits. During the COVID-19 pandemic, when most of us stayed at home, self-care's relevance became even more evident, as it became our first line of defence.³² Looking at a national case, for example in Italy, 1.7 billion euros could be saved annually by increasing access to self-care products that can be used to manage

self-treatable conditions and that are available OTC in other EU countries.³³ In other situations, appropriate care for in-home patients can cost much less (even more than 50% in some cases) than hospital care (Data provided from: Appetite For Life). Self-care can thus **reduce the social costs of disease** while positively affecting mental health and quality of life of patients, their families and care-givers.

Health education should be included in the school syllabus across Europe and include health (and digital) literacy to guide more informed choices by the leaders of tomorrow (see image 9). Nearly half of Europeans have inadequate or insufficient health literacy.³⁴ Furthermore, 80% of Europe's health budget is spent on treating largely preventable chronic diseases, while only 3% is spent on prevention.³⁵

Image 9: Social media post by Vintura during the #EHPChats initiative, highlighting the importance of education and health literacy



Executive Summary
Introduction
Approach
➤ Recommendations
Conclusions
Acknowledgements
Endorsements
References



Recommendations

Health education would enhance the population's confidence in self-care, embed a healthcare culture, and help build trust in self-care by HCPs. This would not only promote healthy behaviours and self-care, but would also contribute to, for example, antimicrobial resistance stewardship and enable the next generation to better understand the healthcare system's structure and how to use it wisely. Given the rise of digitalisation, in particular in the healthcare ecosystem, it is also crucial to invest in digital literacy. The EU4Health programme³⁶ should focus its increased budget allocation on prevention towards investments in health and digital health literacy, supported by the European Health and Digital Executive Agency.

The scope of practice for community pharmacists should be expanded across Europe to support patients in self-care.

Pharmacies are the most widely distributed healthcare facility in Europe and have the potential to become true self-care hubs, therefore, the involvement of pharmacists is key for self-care and will help ease pressure from an already overloaded system. Beyond OTC products, pharmacists should be able to prescribe certain prescription (Rx)-only medication. This can be achieved by passing legislation allowing pharmacists to become non-medical prescribers (e.g. through specific training/certification via a master's degree in

pharmaceutical sciences or a specific post-graduation course) or, alternatively, by setting exceptions for dispensing certain Rx-only-medicines. Administration of vaccines can also be delegated to pharmacists, who often already have training in anaphylaxis treatment and cardiopulmonary resuscitation (CPR). Successful implementation of these services can already be observed in some member states.

Use EU funding instruments to strengthen primary care and correct the implementation gap in enabling integrated healthcare systems and budgets at regional level

The design and operation of health and care ecosystems have remained largely unchanged in the previous century. **Acute, hospital-centred services are no longer adequate** or appropriate to deal with the care delivery required to address issues such as the ageing population and increasing prevalence of chronic diseases. Health ecosystems must be connected, people-centred, and focused around values and outcomes that matter to patients.

COVID-19 has demonstrated undeniably that health is wealth, and that there is no wealth without health. **We must rethink the way we consider health expenditure. Not as a cost,**

but an investment, with high return through better health outcomes, higher productivity and employability, and reduced costs of treatment in the long run. Lack of investments in health literacy and prevention leads to many EU citizens having to struggle with chronic diseases and adds huge costs to EU healthcare systems. We need to see beyond annual budgets, and embed a long-term perspective into the evolution of health and care systems. We need to take the bold responsibility to consider the next 100 years to truly optimise and enable healthy economies for the future.

A transition to **integrated care and overcoming fragmentation of services is needed** in order to secure the future provision of healthcare. The integration of services and strengthening primary care has indeed been a repeated theme within the European Commission's European Semester 2020 Country Reports,³⁷ but **technical enablers, including digital and telemedicine, have been lacking.**

Simply considered, successful integration between general practitioner (GP) practices and pharmacies, i.e. primary care, and acute hospital admissions, involves proactive management of chronic or complex cases thereby reducing planned and unplanned hospital visits. This may in itself **aid in preparedness and resilience** towards future

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Recommendations

pandemics as health services may be better managed, freeing up resources and capacity in hospitals.

There is consistent reporting that financial factors hinder the successful implementation of integrated care, specifically the lack of integrated budgets.^{38,39} A siloed and fragmented approach (wherein each compartment of the healthcare system i.e. hospitals, primary care, medical providers, other services etc. contains its own individual budget) limits the opportunities for smart and sustainable investing, and better lifecycle and patient pathway management. Integrated financing may allow for **improved coordinated care**, and thus have a knock-on effect in **improving patient experiences, outcomes, hospital admissions, and associated costs.**

There is a need for long-term budget cycles which no longer consider, for example, treatment expenditure in isolation, but, instead, a holistic environment where incentives may be aligned within the whole healthcare system to ultimately accommodate and promote optimal patient outcomes.

However, as put by Cheetham and colleagues, integrated financing 'is not a quick fix'.⁴⁰ Successful implementation requires a context

of additional autonomy at local/regional level to adapt policies.

It requires **bold action and long-term thinking** from authorities in Member States who should be **supported through EU financing instruments** such as Cohesion policy funds, the new resilience programme within the multi-annual financial framework (MFF), and the EU4Health programme. Efforts should also be supported by the new European Health and Digital Executive Agency and be directed at enabling structural changes and providing sufficient resources and capacity to implement models of integrated care and financing.

The European Commission should promote standardisation and constant improvement of care by creating a European benchmark of healthcare services/hospitals

Some European countries have in place a benchmarking system,⁴¹⁻⁴⁴ by which specific indicators are collected at hospital level and analysed in order to reflect and compare the status of care provided in each hospital and, in some of those countries, even at individual service level within hospitals.

Without having to expand its mandate on health, the European Commission can enlarge

its assessment of healthcare systems. By **defining common criteria and methodology to collect and analyse data from each individual hospital across Europe**, the Commission can develop a benchmark of health services, not only at country level, but at European level. This evaluation should always allow for data to be put into context, not only in terms of the circumstances of each institution (e.g. number of beds, number and type of services offered, size, age and socio-economic status of the population served, etc.), but also in terms of time, to allow institutions to view their progress and analyse trends. Such results should be made public so that people can see and choose where to go when in need, which may in turn drive efficiency and upgrading. Besides including clinical and effectiveness indicators, this project could also serve as a boost to better defining and applying Patient Reported Outcomes. The Standard Sets developed by the International Consortium for Health Outcomes Measurement (ICHOM) can provide an important starting point to identifying the indicators most relevant for each disease area.⁴⁵

Having a European-wide evaluation of healthcare services will promote competition. By allowing each hospital and national health Ministry to have more visibility on how their institutions compare to similar ones across

- Executive Summary
- Introduction
- Approach
- ▶ Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Recommendations

Europe, organisations will be pushed to **improve and share best practices**. Thus, allowing for **harmonisation of care across Europe**. Bringing us closer to a European standard of care for health services and ensuring that Europeans have the same quality of care, regardless of the country or institution.

Reducing inequalities of healthcare access in marginalised groups

Marginalised groups include (but are not limited to) people experiencing homelessness, traveller and Roma communities, ethnic minorities, asylum seekers, migrants and undocumented migrants, sex workers and people with substance or alcohol addiction.⁴⁶

Health inequalities occur when systematic, avoidable differences in health exist between population groups, often arising from conditions in which people are born, grow, live, work and age. Marginalisation is associated with an increase in health vulnerability and deprivation, ultimately leading to a disproportionate distribution of health across social strata.⁴⁷ During times of international health crisis, the individual needs of marginalised groups may be overlooked or neglected, potentially exacerbating pre-existing health inequalities

and inequities.^{48,49} The Healthy Economies Committee has developed recommendations that we hope will enable EU Member States to reduce the prevalence of health inequalities which arise from marginalisation.⁵⁰ For all recommendations, it is crucial that marginalised communities are meaningfully involved in the development, implementation and evaluation of policies, programmes and services that will impact them.

It is well documented that good health status improves economic situation both on the individual as well as on the state level as it impacts labour market outcomes and affects individuals' well-being.⁵¹ Therefore, we identified building awareness of health inequalities and their reduction as one of the key elements of sustainable development of the European economy.

The Commission should establish a skills training component for healthcare professionals to fight unconscious bias and establish social contact with marginalised groups early in medical careers

The **healthcare access of marginalised groups can be impeded by unconscious bias** among HCPs that stems from stereotyping and limited contact with these groups.⁵²⁻⁵⁴ To ensure the provision of appropriate healthcare

to marginalised groups, it is essential that HCPs possess specialist knowledge of the cultural diversity and unique health risks in these groups. In addition, often there is not sufficient knowledge or awareness of diseases that are not widespread in the European Union.

There is a clear need for **HCP training** that: (1) **bridges knowledge gaps** that lead to social bias against vulnerable groups; and (2) enables HCPs to **build the behavioural skillset to demonstrate compassion and empathy** for the individual needs of these marginalised groups. Standardised training should be developed and incorporated as a core component of medical training programmes.

Promote awareness of pathways that facilitate healthcare access for marginalised groups and avoid the emergence of a digital healthcare divide

At the same time, marginalised groups can be deterred by the prospect of navigating complex health systems and by the potential for incurring costs for receiving appropriate healthcare. Tailored communication and outreach strategies (such as **improving health literacy and championing the role of health navigators** from devolved local organisations) should be implemented to eliminate these potential barriers to access.⁵⁵⁻⁵⁷

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Recommendations

As telehealth solutions gain prominence, it is imperative that EU policy-makers **prevent** the emergence of a **digital healthcare divide**. Best-practice sharing around capacity-building of marginalised communities, trust-building by ensuring data protection and privacy should be endorsed by the Commission. Importantly, digital tools should be developed and evaluated based on their value-added for those at the least-connected end of the spectrum rather than the best-connected end.

Guidelines and minimum requirements should be established for governments to update and disaggregate available health data to adequately represent the situation of marginalised groups, while including them in EU risk assessments

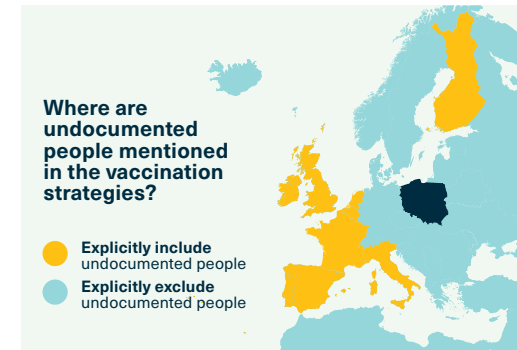
A lack of up-to-date healthcare data on marginalised groups is an EU-wide problem.^{58,59} **Without an evidence base** taking into account all members of society, **policy makers will inevitably fail to design equitable and representative healthcare systems**, particularly when the effects of the COVID-19 pandemic on those groups remain unclear.

As data-sharing in the health domain is a growing trend between member states, governments should be required to contribute

with **data** which is adequately **updated and disaggregated**. This is a vital tool to **identify systematic shortcomings of healthcare systems**. Better data collection will facilitate policy response and evaluation in the event of international health emergencies.

The Commission is proposing the establishment of the European Health Emergency Preparedness and Response Authority (HERA) to enable adequate EU preparedness in the event of health emergencies. Despite recommendations from EU bodies to address marginalised groups in national vaccination strategies – prioritisation and vaccination strategies have been decided on a Member State basis with differing outcomes (see image 10).⁶⁰ **Risk assessments performed in the context of HERA should take into consideration marginalised groups**, since these groups become even more vulnerable and at-risk during health emergencies.^{61,62} Ultimately, marginalized groups may need to be prioritized when taking measures to address public health crises. Including these groups in risk and threat assessments can support Member States' decision-making and help tackle health inequities. Care of marginalised groups must be taken up at national level, rather than just locally.

Image 10: Map entitled “Where are undocumented people mentioned in the vaccination strategies?”⁶⁰



Executive Summary
Introduction
Approach
➤ Recommendations
Conclusions
Acknowledgements
Endorsements
References



Recommendations

Ensuring a healthy future workforce

According to estimates from the International Labour Organisation, **4 out of 5 workers have been affected by the COVID-19 pandemic around the world.**^{21,63} Changes that were predicted to happen over decades, such as digitalisation, are happening much faster. Rather than 'getting back to normal', this presents a **unique opportunity to 'build back better'** and pave the way to a **fairer, more robust and resilient economy** and to futureproof the way we work. Therefore, we propose the following recommendations:

Mobilise a resilient workforce for the future through a stronger emphasis on transferrable skills and inter-European mobility of high-skilled professionals

A resilient workforce requires transferable skills to be at the centre of staff training, thus, it is essential to ensure **flexibility in redesigning roles and the associated tasks**, in order **to take advantage of the skillset of each professional**. A stronger focus on cross-functional knowledge and training would also allow for an easier redeployment of personnel should the need arise (e.g. during a pandemic). Specific support for reskilling and defining clear career paths is particularly important

in the industries most affected by the immediate crisis, as **continuous professional development in the form of life-long learning** is crucial to keep staff motivated.^{64,65}

As always, when implementing human resources policies, it is essential to ensure proper **communication** between employee and employer, in order to allow for recognition of the value of any changes and shifts in key priorities as well as adequate coordination. This concerns particularly potential changes to an employee's functions and role within the organisation. Such occasions require a transparent and flexible leadership.

While striving to maintain a stable and self-sufficient workforce, EU Member States should further **encourage the learning of best practices** to foster transferrable skills, and **facilitate professional exchanges between different countries** to increase the experience and international exposure of workers. This requires the establishment of more accurate mechanisms to account for the number of professionals leaving (e.g. retirement, moving abroad), and of employment policies that consider these phenomena.

Assess the impact of new modalities of work and promote adequate compensation for workers, in line with health and working conditions

Due to the unprecedented situation caused by the **COVID-19 outbreak**, millions of workers have been required to maintain their level of activity under **new modalities of work**, such as working from home or teleworking.^{66,67} According to Eurofound data, 48% of employees worked partially from home and 34% solely from home.⁶⁸ While the pandemic may have brought about better working conditions for many (e.g. saved time from commuting), it has also led to stretched schedules and increasing difficulties to conciliate work and family life. Teleworking is also having an impact on the mental and physical health of workers.

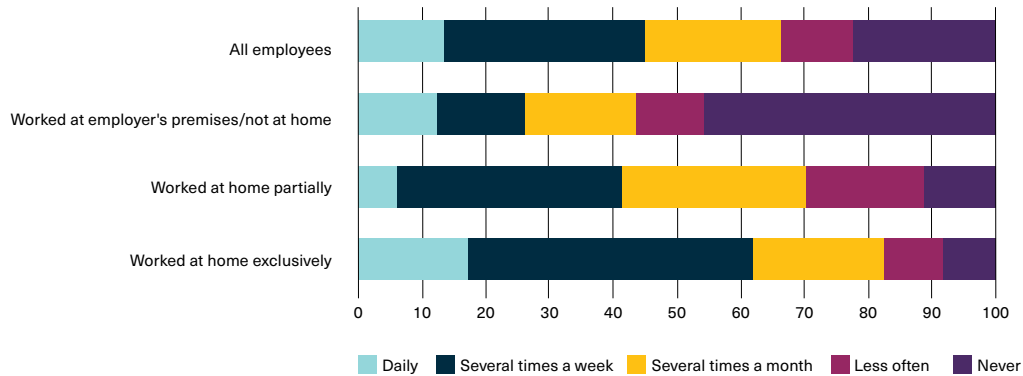
Workers increasingly value their work-life balance, but struggle to keep the two spheres separated. A mix of teleworking and physical presence at the office would be the preferred solution for the majority^{68,69} (see image 11). Therefore, employers should consider and **give staff the possibility to opt for the modality of work of their choice**. We support the European Parliament's recommendation and the European Commission's efforts to establish a **'right to disconnect'** and a series of accompanying rights in order to protect the

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Recommendations

Image 11: Preference regarding regularity of working from home if there were no COVID-19 restrictions, by teleworking status, EU27 (%)⁶⁸



workers' mental health from the consequences of the "always-on" culture that is flourishing with teleworking.⁷⁰

Monitoring and providing funding to **evaluate the effects** of the new working modalities on mental and physical health should be encouraged. It would allow for a proactive regulation of working conditions that is based on evidence rather than on short-term observations, and that takes into account the different impact between men and women in light of the traditional distribution of roles within the household. Thus, employers should work closely with governments to ensure that economic incentives are implemented based on in-depth research.

Adequate mechanisms should be ensured to **offer proper compensation**, particularly in emergency situations, such as additional holidays or time off, payments for overtime and adequate incentives to cover for the additional expenses incurred while working from home.⁷¹ Moreover, to ensure that no individual suffers financial losses when sick or caring for others, **appropriate and harmonised sickness pay conditions** should be established across Europe, thereby allowing for correct disease control and prevention to be implemented.⁶³

Finally, as less work-related diseases equal healthier, happier and more productive workers, emotional wellbeing must be supported too. **Mechanisms for prevention**

and reintegration of employees affected by conditions like **anxiety, depression or burnout** should be established, and these conditions should be recognised as **occupational diseases**.

- Executive Summary
- Introduction
- Approach
- ▶ Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Conclusions

COVID-19 has made Europe pay attention to health. Governments understood that, given the epidemic, it was not possible to relaunch the economy without first securing the population's health. Now, we need to make our leaders understand that that is always true, not only during crises. As per The Tallinn Charter: "Investing in health is investing in human development, social well-being and wealth".⁷² It is the lever that can propel European economy to a state of constant and sustainable growth. One that is based on principles of environmental sustainability, innovation and digitalisation.

Through our recommendations, we wish to help Europe establish health as a priority. We believe that health and care systems can be improved, that they can reach more people and that individuals themselves can become sources for promotion and prevention of their own health. We must make health and healthy living a constant for all if we are to create a healthy economy for all.

- Executive Summary
- Introduction
- Approach
- Recommendations
- ▶ Conclusions
- Acknowledgements
- Endorsements
- References



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- › **Roberta Savli**, Director, Healthcare Systems and Strategy, European Federation of Pharmaceutical Industries and Associations (EFPIA)
- › **Lars Münter** of Self-Care in Europe, Nordic Health 2030 and the Danish Committee for Health Education
- › **Laura Restrepo**, Consultant from Vintura
- › **Baz Amesz**, Partner from Vintura
- › **Luis Rhodes Baiao**, Governmental and Public Affairs Manager, Association of the European Self-Medication Industry (AESGP)
- › **Alix Marchal**, Communication and Member Services Manager, Association of the European Self-Medication Industry (AESGP)
- › **Marek Lichota**, CEO of Appetite for Life "Apetyt Na Zycie"
- › **Álvaro Almeida**, Member of the Portuguese Parliament and Associate Professor at Faculdade de Economia da Universidade do Porto
- › **Carlos Alberto**, President of the Board of Administration of Centro Hospitalar do Tâmega e Sousa, Portugal
- › **Adalberto Campos Fernandes**, former Portuguese Minister of Health and Associate Invited Professor at Escola Nacional de Saúde Pública, Universidade Nova de Lisboa, Portugal
- › **Eurico Castro Alves**, President of the Portuguese Association of Hospital Administrators and of the Portuguese National Health Convention
- › **Rikke Siersbaek**, Centre for Health Policy and Management, Trinity College Dublin, the University of Dublin
- › **Radost Zaharieva**, Policy Officer, European Public Health Alliance
- › **Sebastien Delfosse**, Director People & Culture Northern Europe, ManpowerGroup
- › **Simone Mohrs**, Policy Officer, Hospeem – European Hospital & Healthcare Employers' Association
- › **Ivana Cattaneo**, Executive Director, Oncology Policy and Healthcare Systems, Novartis Oncology Region Europe
- › **Rosen Dimitrov**, Public Affairs Manager, Novartis

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- › Acknowledgements
- Endorsements
- References



Endorsements



António Maló de Abreu

Member of the Portuguese Parliament

It was with great interest that I was able to review the proposals formulated by the Healthy Economies Committee, chaired by Dr. Gonçalo Pinto Mendes, within the scope of the 6th edition of the European Health Parliament.

Indeed, the issues addressed are of the utmost importance and timeliness. I should highlight the assertiveness of the recommendations made to improve health systems and the qualifications of health professionals, without neglecting the protection of the most disadvantaged communities. In short, it is an ambitious and demanding approach, but it is also valued for its strong humanising concern, without which, after all, we would not have modern and universal health systems.



David Somekh

European Health Futures Forum Director

I applaud the proactive approach by this group in putting together their #VaccineChamp campaign and their innovative means to collect expert views via their #EHPchats approach.

In respect of their main recommendations, it is evident that they recognise the vital role of education and training in bringing about desired change. Whether it be tackling health literacy as a key factor in improving self-care and ultimately supporting the effectiveness of primary care services or training for health professionals to be aware of problems in supporting underprivileged or marginalised groups of people, or improving workers skill sets.

Better education of citizens and professionals is necessary but not sufficient. The group also recognises (perhaps because they have wisely used a design-thinking approach) that for the inclusion of previously marginalised groups for the ultimate benefit of all, additional measures need to be put in place over and above education, to ensure they do not remain neglected, and there are some recommendations addressing this.

I commend the recommendations in this paper overall: well done.

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Endorsements



Ivana Cattaneo

Executive Director, Oncology Policy and Healthcare Systems, Novartis Oncology Region Europe

COVID-19 has shown there is no wealth without health. The only way to protect our people and economies against future health threats is to improve the long-term sustainability of our healthcare systems in Europe. And the recommendations of this report show a potential way forward in that direction.



Eduardo Barroco de Melo

Member of the Portuguese Parliament

Having been presented with the conclusions of the Healthy Economies Committee on the sixth Editions of the European Health Parliament, I offer my general support to these ideas. I find the three pillars to be aligned with the major issues on healthcare for the foreseeable future. The design of healthcare systems should prioritize access for marginalised groups and must answer the needs of citizens regardless of their socioeconomical situation. At the same time, involving citizens in a better healthcare system means being able to make them a part of their own healthcare, by providing better information to them and enhancing health literacy. And this cannot be done without understanding that this collective effort cannot be undertaken without a skilled and adequately rewarded workforce.

The recommendations stated in this document constitute a great effort to set out an overarching plan towards a more collaborative and efficient understanding of how economies can become healthier, especially in the post COVID-19 pandemic future.

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Endorsements (Pillar 1 Endorsement: Rethinking health and care system design to serve the next 100 years)



Roberta Savli

Director, Healthcare Systems and Strategy, European Federation of Pharmaceutical Industries and Associations (EFPIA)



Elisabeth Dupont

International Diabetes Federation-Europe (IDF Europe)

The focus on the role of pharmacists is a very interesting one and too often overlooked. Expanding the scope of practice for community pharmacists would greatly benefit people living with diabetes for whom self-management is the norm.



George Valiotis

Executive Director, European Health Management Association (EHMA)

The European Health Management Association congratulates and endorses the European Health Parliament calling for these challenging recommendations to be taken forward to improve healthcare across Europe.



Bart Torbeyns

Executive Director, European Diabetes Forum (EUDF)

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Endorsements (Pillar 1 Endorsement: Rethinking health and care system design to serve the next 100 years)



Jurate Švarcaite

Director General, The Association of the European Self-Care Industry (AESGP)

Definitely, future-proof healthcare systems will need to provide greater empowerment to citizens to manage their care and to be knowledgeable enough to be comfortably on the driving seat of their healthcare decisions. As acknowledged in the European Health Parliament recommendations, leveraging health literacy will help us as a society to achieve better healthcare outcomes. This needs to be done in strict coordination with healthcare professionals and both at the compulsory education level as well as by providing adults and the elderly with tools to keep themselves up to date. Self-care is becoming a greater part of our lives and responsible self-management is not only convenient but it also helps in reducing the burden of disease and unnecessary pressure on the health systems. The healthcare continuum we are shaping for tomorrow needs to be more people-centred, seamless in the transitions of care and more prevention oriented, as that is recognised as the most effective way to face future challenges.



Laura Restrepo *(Consultant)* & Bas Amesz *(Partner)* at Vintura

We, in Vintura, strongly believe that self-care is important for the sustainability of healthcare systems and we are happy to see this topic included in your recommendations.

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Endorsements (Pillar 1 Endorsement: Rethinking health and care system design to serve the next 100 years)



European Alliance for Value in Health

The European Alliance for Value in Health welcomes the approach taken by the European Health Parliament to take a long-term and integrated perspective on health funding and investments, focusing on the outcomes that will ultimately matter for people and patients. The Alliance would welcome working with the EHP going forward to further exchange views on how to best implement a value-based and person-centred approach in health systems.



Marek Lichota

Chair of The Intestinal Failure Patients Association 'Appetite for Life' (Apetyt Na Zycie)

Standardised and value based homecare services for patients with chronic conditions should become one of the pillars of the future healthcare system in the EU.

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Endorsements (Pillar 2 Endorsement: Reducing inequalities of healthcare access in marginalised groups)



PICUM
PLATFORM FOR INTERNATIONAL COOPERATION ON
UNDOCUMENTED MIGRANTS

Michele LeVoy

Director, The Platform for International Cooperation on Undocumented Migrants (PICUM)

Too often being undocumented means facing insurmountable barriers in accessing health care. The pandemic has shown beyond doubt that we all suffer when our health systems exclude people and do not adequately address their realities and needs. We welcome the European Health Parliament's very timely and concrete proposals on how to achieve more equitable access to health care in Europe for everyone, regardless of their residence status.



International Committee on the Rights of Sex Workers in Europe (ICRSE)



Rikke Siersbaek

Centre for Health Policy and Management, Trinity College Dublin, the University of Dublin

Stigma is a hugely important barrier for populations experiencing social exclusion and vulnerability when accessing and engaging with healthcare services and practitioners. For that reason I welcome the European Health Parliament's recommendation to include skills training to combat subconscious bias among healthcare professionals and to arrange for contact with marginalised groups during training. Both of these measures will go a long way toward providing healthcare professionals with the skills, knowledge and familiarity needed to provide quality healthcare to population groups who are often from very different backgrounds than themselves in respectful, equitable ways.

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



Endorsements (Pillar 3 Endorsement: Ensuring a healthy future workforce)



Diane Coyle

Professor of Public Policy, University of Cambridge



William Cockburn

Head of Prevention and Research Unit, European Agency for Safety and Health at Work



Sébastien Delfosse

People & Culture Director, Northern Europe, ManpowerGroup

- Executive Summary
- Introduction
- Approach
- Recommendations
- Conclusions
- Acknowledgements
- Endorsements
- References



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Executive Summary
Introduction
Approach
Recommendations
Conclusions
Acknowledgements
Endorsements
▶ References



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