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- Alpha-1 Plus Belgium
- Cystic Fibrosis Europe (CF-E)
- European Federation of Allergy and Airways Diseases Patients’ Associations (EFA)
- European Lung Foundation (ELF)
- European Pulmonary Fibrosis Federation (EU-PFF)
- European Respiratory Society (ERS)
- Lung Cancer Europe (LuCE)
- Pulmonary Hypertension Association Europe (PHA-E)
- Tuberculosis European Coalition (TBEC)

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Executive Summary

The European Lung Health Group (ELHG), a group of nine European level non-profit organisations gathering 179 member associations across 34 European countries, outlines in this document how improving lung health can lead to healthier, stronger, more resilient societies.

It begins by looking at the burden of lung disease in Europe and the consequences of poor lung health. It then sets out three areas for EU action on improving lung health: prevention, research & innovation, and care, looking at the pressing challenges of climate change and health emergencies. After taking stock of current – fragmented – EU action on lung health, it puts forward suggestions of concrete short-term actions for the European Commission and the EU ecosystem, which would set the ball rolling for the EU to support transforming lung health, thereby alleviating pressure on healthcare systems, stimulating European economies, and improving our overall wellbeing.

“A strong policy towards lung health will improve and save millions of lives, lessen the strain on Europe’s ailing healthcare systems, and better prepare the bloc for future health crises.”

European Lung Health Group
Lung health: Europe’s Achille heel

Our lungs are at the core of everything we do. If we stop breathing, everything else stops. The average European will breathe in and out 20,000 times a day, processing more than 7,000 litres of air a day. The quality of those breaths of air tells an accurate story of our well-being.

The burden of lung disease is huge in the EU and worldwide. Even before COVID-19, lung diseases were some of Europe’s biggest killers, despite many of them being preventable or manageable. Current measures to increase awareness and prevent risks show limitations, as countries have been unable to contain disease progress. The World Health Organisation (WHO) estimates that 87 million people live with a lung condition in the European Region¹ and 1 in 8 deaths in the EU are due to respiratory diseases².

The respiratory system is a vulnerable part of our health. While people have minimal control over the quality of air they breathe, they must keep breathing to be alive. Diseases of the lung and the respiratory system can be highly debilitating, affecting life as a whole and leading to comorbidities such as cardiovascular disease and obesity. Yet lung and respiratory diseases (chronic, rare, and infectious) remain Europe’s Achilles heel.

Lung disease covers a wide medical spectrum (more than 40 different conditions)³, which ranges from common infectious diseases (such as tuberculosis, pneumonia and severe acute respiratory syndrome (SARS), caused by influenza and coronavirus) to non-communicable diseases (NCDs) (such as respiratory allergies and asthma, chronic obstructive pulmonary disease (COPD), bronchiectasis and lung cancer), to those classified as rare and ultra rare respiratory diseases (alpha-1, idiopathic pulmonary fibrosis, pulmonary hypertension).
Eurobarometer data underlines that most people in the EU think that respiratory diseases are a serious problem in their country. Tackling these diseases, and therefore addressing lung health, relies on early diagnosis and timely intervention, as well as ensuring access to the right treatments. It also requires a multidisciplinary approach to lung health which focuses not only on symptom management but holistic care; one that also places a strong emphasis on preventative measures – including increasing health literacy, strengthening overall, lifelong health to prevent infection and promote research into the most pressing challenges.

But lung health is important not just for patients and carers; it affects the whole society. People in Europe are exposed to a multitude of external factors that impact lung health across their lifetime; the air a European breathes in interacts with the airways and may well result in disease years down the line. Lung health, particularly in childhood, is an important factor in the current health of a child, and in predicting its future health. Action for healthy lungs is crucial in improving the overall wellbeing of the population in the EU. Having healthy lungs means we can breathe, work, and play – and be better prepared for future health crises.

The total societal cost of poor lung health in Europe is 611 billion EUR. Improving lung health is one of the most effective ways of alleviating the strain on EU health systems, improving quality of life, and stimulating the EU economy. By acting on the three pillars of action outlined below (prevention, care, research & innovation), EU policymakers can support EU citizens to keep breathing and improve lung health.
Preparing for the challenges of tomorrow

Lung health is – and will always be – a determining factor in the overall health of our societies. However, the need to tackle poor lung health in a targeted, holistic manner has never been more urgent. With the unfolding permacrisis, the disease burden is likely to increase.

The SARS-CoV-2 pandemic unveiled the limits of healthcare systems and Europe’s lack of lung health awareness and preparedness against airborne transmission crisis. The EU has stepped up to the plate in improving Europe’s and the global health security architecture. It has structured a European Health Union with a coordinated, harmonised and solidary emergency framework to help Europe’s health systems become more resilient and prepared for future health crises.

Respiratory infections pose a recurrent threat in the region. As Europe sees increasing incidence of influenza and respiratory syncytial virus (RSV), the EU has quite rightly identified pathogens from respiratory RNA viral families as a priority health threat⁹ and is taking steps to better monitor prevalence¹⁰ and bolster development of medical countermeasures.

But addressing prevention in the broader context of lung health will be crucial to ensuring actual preparedness. Pro-actively investing in public health measures as well as monitoring and planning, will mean that everyone – including, but not limited to those with pre-existing conditions – is better protected, equipped and resilient against respiratory health threats.

Future viral pandemics are not the only imminent threat to public health; climate change is also making the whole population even more vulnerable. Climate change is affecting human health by exacerbating existing respiratory conditions and exposing otherwise healthy people to risk factors that can cause their lung health to deteriorate. Extreme weather events such as increased temperatures, heatwaves and storms, pollen counts, as well as environmental hazards like wildfires and floods, are impacting the quality of the air and contribute to worsening respiratory issues that can become chronic and lethal.

Respiratory care is essential during emergencies. Disruptions in access to healthcare services due to health and total emergencies further compound the challenges faced by individuals with lung-related conditions – for example by reducing access to critical medicines, medical devices and specialists. The combination of these factors underscores the urgent need for comprehensive efforts to address climate change and protect respiratory well-being. Lung experts and patients can help design safe and scalable care pathways, ensuring patients receive treatment and support.
What the EU is doing to improve lung health

The EU competence when it comes to acting on public health matters is shared with its Member States, with the latter being the main drivers of change in defining and delivering national health services and medical care. However, the EU has a role in complementing the national policies by means of European public health strategies. Based on this, the EU established its EU4Health programme for 2021-2027 in response to the Covid-19 pandemic and as a means to start paving the way for a European Health Union. Some of the initiatives adopted as part of EU4Health programme are the ‘Europe’s Beating Cancer Plan’ and ‘A comprehensive approach to mental health’, both examples of health strategies within the competences of the Union in the area of public health. Finally, Commission cross-cutting priorities such as the Green Deal, coupled with the focused emphasis on One Health, as well as digitalization, are paving the way for more integrated preventative and clinical action on lung health.

There are nine main policy areas where lung health policy is being decided at EU level, namely one health, public health, health crisis preparedness and response, energy efficiency, zero pollution, climate mitigation and adaptation for prevention, health systems, medical innovation for care, and research.

The European Lung Health Group has conducted a comprehensive mapping of these actions, which is outlined in Annex 1. The main findings show that responsibility for lung health is divided among vastly different departments, working on policies that are interlinked but with no unifying plan. Investment in lung health (notably under the Healthier Together initiative – see graph), while higher than in previous years, remains insufficient to unlock society-wide benefits and solid progress to reach the NCD and sustainable development goals (SDGs) targets.
How the EU can transform lung health: three Pillars of EU Action

Improving lung health in Europe can alleviate the strain on EU health systems, improve quality of life, and stimulate the EU economy – as well as make sure we are better prepared for future crises. The Treaty on the Functioning of the EU (TFEU) sets out the EU mandate to act on health in several articles: Article 168 (protection of public health), Article 114 (single market) and Article 153 (social policy).

We call on the European Commission to step up its action on lung health by adopting a holistic approach – working across Directorates-General (DGs) – and by increasing its ambition through more investment, research and action. The members of the European Lung Health Group stand ready to work with the Commission, and all EU institutions and agencies, as well as the Member States, to realise this ambition.

The increased investment in tackling non-communicable diseases (NCDs) under the Healthier Together Initiative is a turning point, especially in reducing the immense burden of chronic respiratory diseases, although the resources it allocates to lung health fall short. The planned review of tobacco control legislation and the Beating Cancer Plan will be key in reducing the prevalence of lung cancer and COPD. However, lung health is not just a result of lifestyle and disease. Addressing lung health as an integral part of overall health will open doors to strengthening health systems and tackling societal problems of climate change and crisis preparedness.

The European Lung Health Group has identified three pillars for EU action on lung health: policies to protect lung health (prevention), policies to reduce health inequalities and improve respiratory disease (care), and policies for imperative care and technological development for respiratory (research and innovation).
### TABLE 1. Areas of EU action to improve lung health in the long term

<table>
<thead>
<tr>
<th>PREVENTION</th>
<th>CARE</th>
<th>RESEARCH &amp; INNOVATION</th>
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</thead>
</table>
| • Improve lung health by implementing **safer air quality standards**, both indoors and outdoors and especially in highly populated areas¹¹  
• **Eradicate smoking** to lower the toll of preventable deaths stemming from respiratory diseases such as lung cancer and COPD'  
• Work with Member States to improve **early screening** rates across Europe, especially for lung cancer and rare diseases of the lung  
• **Raise public awareness** around lung health, including by improving health literacy (especially for children) and increasing knowledge of respiratory diseases to improve symptom detection, but also destigmatising certain lifestyle behaviours  
• **Reinforce crisis preparedness**, ensuring that both health systems and people are equipped to respond to future respiratory viruses such as COVID-19  
• **Reduce carbon emissions** in line with the Green Deal, to prevent climate disasters that exacerbate lung disease, such as heatwaves and wildfires | • **Work with Member States** and stakeholders to develop national lung disease programmes to ensure **correct and early diagnosis** of lung diseases, leading to better disease management, preservation of lung health, and cost savings  
• Support healthcare systems and require market rules to right **inequalities in access**, ensuring people across Europe get the right treatment at the right time  
• Encourage Member States to adopt a **life-course immunisation approach** to reduce the burden of respiratory infectious diseases on patients with vulnerable lungs  
• Bolster provision of **multidisciplinary care** and long-term therapy to reduce lung disease hospitalisations and the considerable associated costs  
• Reduce the burden on patients and on healthcare systems by **empowering people to self-manage**, especially through personalised plans and digital solutions  
• Work with Member States to ensure **greater specialised knowledge** on respiratory illnesses, to improve clinical guidelines and patient reported outcomes  
• Establish **centres of excellence and registries** for lung disease at the Member State level reinforced by relevant European Reference Networks | • Drive innovative **research to tackle respiratory disease morbidity and mortality**, particularly on lung health biomarkers, disease severity and personalised medicine, and ultimately towards finding cures  
• Protect the next generation through novel, **tailored and accessible treatments for children** with lung health issues  
• Ensure the development of **novel vaccines for infectious respiratory diseases** to allow for an effective response and reduce hospitalisations and preventable deaths  
• Enable tackling rare respiratory diseases through **reinforced European Reference Networks** that provide improved data and evidence sharing, including via patient focused digital solutions  
• Fully integrate and reinforce the role of respiratory registries and biobanks in any research to address lung health  
• Invest on **environmental health research** to inform prevention policies and improve buy-in of public health interventions perceived as restrictive |
Recommendations for EU action on lung health 2024-2029

Short-term

In the short-term, the ELHG recommends the European Commission to take the following steps, with the support of the respiratory community we represent:

**PREVENTION**

- Work with all stakeholders (such as the ELHG) to raise public awareness of the prevalence of lung diseases and the benefits of good lung health, and to disseminate information about prevention and management, via a pan-European campaign;
- Collaborate with colleagues within and across EU institutions and agencies to ensure lung health is embedded in all policies – including climate change and emergency preparedness;
- Fully integrate the air quality dimension into One Health, drive efforts to monitor aeroallergens and aeropathogens, and prevent airways disease.

**CARE**

- Assign an expert or expert group the authority to oversee lung health across EU policies and act as coordinator for future work, either within the Commission or under the EU Health Policy Platform;
- Learn from and develop a blueprint for cross-sectoral, targeted health plans (such as the Beating Cancer Plan and the Mental Health Strategy), which can be applied to other key disease areas in the future, specifically in lung health;
- Enable a dedicated formal forum to discuss lung health within the European Commission, in the form of a Coalition, a thematic network in the EU Health Policy Platform and with regular updates with the Steering Group on Health Promotion and Prevention;
- Ensure that recent funding for lung health (for example, under the chronic respiratory diseases strand of the Healthier Together initiative) is – at a minimum – maintained in the next health budget, to respond to the incidence and prevalence of respiratory diseases and their cross-border dimension.

**RESEARCH AND INNOVATION**

- Undertake a holistic Impact Assessment to review current EU action addressing lung health and to evaluate the impact of increased investment and research in lung health on Europe’s societies and economies.
Medium and longer-term

In the medium and longer-term, we propose the following strategies to improve lung health in Europe:

**PREVENTION**

- Streamline lung health awareness, reinforcing the healthy ageing efforts and highlighting healthy growth and development, through lung function testing in childhood;
- Support the dissemination of standardized information on the prevention of risk factors for respiratory disease, such as public health measures to increase health literacy and using the potential of digitalization.

**CARE**

- Invest in regional pilot programmes that standardize key diagnostics e.g. screening and lung health test programmes, enabling early disease detection initiatives and learning at EU level;
- Encourage investment and adoption of tools for respiratory disease self-management, integrating digital technology;
- Conduct capacity building programmes to enhance healthcare workers’ skills in managing respiratory emergencies and patients with chronic diseases during acute events.

**RESEARCH AND INNOVATION**

- Set improving lung health and respiratory care as a novel EU public health mission, basic, multidisciplinary and translational research;
- Prioritize development of supporting medical countermeasures for pathogens and environmental hazards affecting health.
Conclusions

Our vision is of a Europe in which people are healthier, health systems are agile and resilient, societies are better prepared for crises, economies are competitive, and quick and affordable treatment is available everywhere. We believe we share this vision with the European Commission – but we see a missed opportunity in better addressing lung health as a whole in order to make this vision a reality.

The COVID-19 pandemic both drew public attention to the vulnerabilities of respiratory health and prompted the EU to be more ambitious in strengthening our health systems, notably under the European Health Union. It also set important precedents with targeted action plans such as the Beating Cancer Plan and the mental health strategy, and is set to make significant strides in addressing lung health through initiatives like Healthier Together.

However, tackling cross-cutting issues requires a comprehensive approach and joined-up policymaking that encompasses all aspects of lung health. The current climate crisis, exemplified by heatwaves, floods and wildfires across Europe, and the threat of future pandemics, underscore the need for urgent action. Finally, work to prevent lung diseases and adopt national lung health plans is closely linked with WHO/Europe initiatives, such as strengthening and digitalising health systems, tackling climate change and ensuring crisis preparedness, thus offering hope for multiple co-benefits.

The European Lung Health Group stands ready to collaborate with the European Commission and Member States to take better care of citizens’ lung health, and to realise this vision of a healthier, stronger Europe.

“We believe the EU has a genuine capacity to work horizontally, facilitating best-practice sharing, providing support for structural reforms and ensuring stakeholder engagement. This work would form a foundation to build out a more ambitious and targeted action on lung health towards the horizon 2030.”

European Lung Health Group - BREATHE Vision for 2030
# Annex 1. EU initiatives improving lung health

## Prevention

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<th>EU initiative</th>
<th>Status</th>
<th>Responsible EU service</th>
<th>Objective and impact on lung health</th>
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<tbody>
<tr>
<td><strong>Healthier together – EU Non-Communicable Diseases (NCD) Initiative</strong></td>
<td>Adopted by European Commission June 2022</td>
<td>Directorate-General for Health and Food Safety</td>
<td>To support Member States in their work to tackle NCDs by addressing the leading causes of avoidable premature deaths in Europe and improving citizens’ health and wellbeing.</td>
</tr>
<tr>
<td><strong>Directive 2014/40 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products</strong></td>
<td>In force, applicable since May 2016. Revision expected in 2024.</td>
<td>Directorate-General for Health and Food Safety</td>
<td>Sets out the rules on the manufacturing, presentation and sale of tobacco and related products, while ensuring a high level of public health. Contributes to de-normalisation of tobacco use, which causes a great deal of respiratory diseases.</td>
</tr>
<tr>
<td><strong>Directive 2011/64 on the structure and rates of excise duty applied to manufactured tobacco (Tobacco Taxation)</strong></td>
<td>In force, applicable since January 2011</td>
<td>Directorate-General for Taxation and Customs Union</td>
<td>Lays down principles and minimum rates of excise duty on manufactured tobacco across the EU. Contributes to de-normalisation of tobacco use, which causes a great deal of respiratory diseases.</td>
</tr>
<tr>
<td><strong>Directive 2003/33 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products</strong></td>
<td>In force, applicable since May 2003</td>
<td>Directorate-General for Employment, Social Affairs, and Inclusion</td>
<td>Regulates tobacco advertising and promotion in the printed media, as well as the tobacco-related sponsorship. Contributes to de-normalisation of tobacco, which causes a great deal of respiratory diseases.</td>
</tr>
<tr>
<td><strong>Council Recommendation of 30 November 2009 on smoke-free environments</strong></td>
<td>In force, proposal for revision (adoption TBC)</td>
<td>Directorate-General for Health and Food Safety</td>
<td>Aims at protecting EU citizens from second-hand smoke exposure in public spaces. It safeguards the right to clean air, crucial for lung health patients, as well as the overall population, to not increase the risk of developing respiratory conditions.</td>
</tr>
<tr>
<td><strong>Council Recommendation 2023/0125 on stepping up EU actions to combat antimicrobial resistance in a One Health approach (AMR)</strong></td>
<td>Adopted by the Council 1 June 2023</td>
<td>Directorate-General for Health and Food Safety</td>
<td>Aims at fostering the prudent use of antimicrobials, recommending concrete targets on AMR and antimicrobial consumption in the human sector. Antimicrobials are key medicines for respiratory patients.</td>
</tr>
<tr>
<td><strong>A European One Health Action Plan against Antimicrobial Resistance (AMR)</strong></td>
<td>Initiative adopted June 2017</td>
<td>Directorate-General for Health and Food Safety</td>
<td>Aims to prevent antimicrobial resistance to existing medical countermeasures.</td>
</tr>
<tr>
<td><strong>Directive 2010/31 on the energy performance of buildings</strong></td>
<td>In force. Proposal for recast Directive on the energy performance of buildings, currently in inter-institutional dialogues</td>
<td>Directorate-General for Energy</td>
<td>Promotes the improvement of energy performance of buildings, taking into account outdoor climatic and local conditions, as well as indoor air quality requirements. It can contribute to achieving better indoor air quality. Long-term exposure to polluted indoor air can result in the development of respiratory diseases and aggravate existing symptoms.</td>
</tr>
<tr>
<td><strong>Communication 2021/82 from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions on adaptation to Climate Change – the new EU Strategy on adaptation to Climate Change</strong></td>
<td>Adopted by the European Commission February 2021</td>
<td>Directorate-General for Climate Action</td>
<td>Proposes a set of adaptation measures to climate change, taking into account the effects of COVID-19, together with the latest unprecedented climate disasters (e.g. heatwaves, forest fires, droughts).</td>
</tr>
<tr>
<td><strong>Regulation 517/2014 on fluorinated greenhouse gases (F-Gases)</strong></td>
<td>In force. Proposal for revision by European Commission, awaiting final official endorsement before publishing in the official journal.</td>
<td>Directorate-General for Climate Action</td>
<td>Contributes to EU’s commitment to reduce greenhouse gas emissions by 2030. Foresees a sharp curve down of around half per cent of the F-Gases volume used on metered dose inhalers (MDIs) in Europe, impacting the lives of respiratory patients dependent on MDIs.</td>
</tr>
<tr>
<td><strong>Directive 2016/2284 on the reduction of national emissions of certain atmospheric pollutants</strong></td>
<td>In force, applicable since July 2018, to be reviewed by end of 2025.</td>
<td>Directorate-General for Environment</td>
<td>Aligns with international commitments to achieve air quality objectives, mitigate climate change impacts, while contributing to reducing health-related costs of air pollution.</td>
</tr>
<tr>
<td><strong>Proposal for Regulation 2022/0365 on type-approval of motor vehicles and engines and of systems, components and separate technical units intended for such vehicles, with respect to their emissions and battery durability (Euro7)</strong></td>
<td>Proposal adopted by European Commission, awaiting vote in European Parliament to enter inter-institutional dialogue</td>
<td>Directorate-General for Environment, Industry, Entrepreneurship and SMEs</td>
<td>Aligns with international commitments to achieve air quality objectives, mitigate climate change impacts, while contributing to reducing health-related costs of air pollution.</td>
</tr>
<tr>
<td><strong>Proposal for a Regulation on non-road mobile machinery circulation on public roads</strong></td>
<td>Proposal adopted by the European Commission, awaiting vote in the European Parliament for draft report.</td>
<td>Directorate-General for Environment, Industry, Entrepreneurship and SMEs</td>
<td>Sets out the requirements for the EU type approval and placing on the market of non-road mobile machinery intended to circulate on public roads.</td>
</tr>
<tr>
<td><strong>Directive 2022/431 amending Directive 2004/37 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work</strong></td>
<td>In force, applicable since April 2024</td>
<td>Directorate-General for Employment, Social Affairs &amp; Inclusion</td>
<td>Aims at protecting workers against risk to their health and safety arising from exposure to carcinogens, mutagens or reprotoxic substances at work, including the prevention of such risks. Such exposure is detrimental to the population, as it can increase the risk of developing respiratory diseases.</td>
</tr>
<tr>
<td><strong>Directive 2009/48 on the protection of workers from the risks related to exposure to asbestos at work</strong></td>
<td>In force. Process of revision finalised in October 2023, awaiting signature of act and publication in official journal</td>
<td>Directorate-General for Employment, Social Affairs &amp; Inclusion</td>
<td>Protects workers from activities in which they are exposed to asbestos fibres in various products. Such exposure is detrimental to the population, as it can increase the risk of developing respiratory diseases.</td>
</tr>
</tbody>
</table>
## Environment and Climate Action

Regulation 2021/783 establishing a Programme for the dissemination of innovation, laying down its rules for participation and – the Framework Programme for Research and Horizon Europe (EU4Health) financial framework for the years 2021-2027 [In force since January 2021 until 2027]

Regulation 2020/2093 on medical devices [In force since May 2020]

Regulation for a Regulation 2022/0216 on standards of quality and safety for substances of human origin intended for human application [In force, applies as of January 2025]

Regulation 2021/2282 on health technology assessment (HTA) [In force, applies as of January 2025]

Directive 2011/24 on the application of patients’ rights in cross-border healthcare (establishing European Reference Networks) [In force, applicable since October 2013]

Regulation 2022/2371 on serious cross-border threats to health [In force since January 2023]

Proposals for a Regulation 2022/0140 on the European Health Data Space [Inter-institutional dialogue]


Council Recommendation of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases [Adopted by the Council on 7 December 2018]

### Objective and impact on lung health

- **Proposal for a Regulation 2023/0131 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency (EMA)**
  - **Status**: Proposal adopted at the European Commission level, currently draft report at the European Parliament level
  - **Responsible EU service**: Directorate-General for Health and Food Safety
  - **Objective and impact on lung health**: Sets specific rules on top of the ones in the Directive for medicines authorised at EU level, in particular the most innovative ones. It sets out the rules on coordinated management of critical shortages and security of supply of critical medicines.

- **Proposal for a Directive 2023/0132 on the Union code relating to medicinal products for human use**
  - **Status**: Proposal adopted at the European Commission level, currently draft report at the European Parliament level
  - **Responsible EU service**: Directorate-General for Health and Food Safety
  - **Objective and impact on lung health**: Sets all the requirements for authorisation, monitoring, labelling and regulatory protection, placing on the market and other regulatory procedures for all medicines authorised at EU and national level.

- **Regulation 2017/745 on medical devices**
  - **Status**: In force since May 2020
  - **Responsible EU service**: Directorate-General for Health and Food Safety
  - **Objective and impact on lung health**: Provides the rules on placing on the EU market, making available, and putting into service the medical devices for human use and their accessories.

- **Regulation for a Regulation 2022/0216 on standards of quality and safety for substances of human origin intended for human application**
  - **Status**: Proposal adopted at the European Commission level, currently inter-institutional dialogue
  - **Responsible EU service**: Directorate-General for Health and Food Safety
  - **Objective and impact on lung health**: Ensures the safety of patients undergoing blood transfusion, transplantation and medically assisted reproduction. Vital piece of legislation for lung health patients, such as alpha-1 patients.

- **Regulation 2021/2282 on health technology assessment (HTA)**
  - **Status**: In force, applies as of January 2025
  - **Responsible EU service**: Directorate-General for Health and Food Safety
  - **Objective and impact on lung health**: Contributes to improving the availability for EU patients of innovative technologies in the area of health, such as medicines and certain medical devices.

- **Directive 2011/24 on the application of patients’ rights in cross-border healthcare (establishing European Reference Networks)**
  - **Status**: In force, applicable since October 2013
  - **Responsible EU service**: Directorate-General for Health and Food Safety
  - **Objective and impact on lung health**: Establishes the rules for facilitating access to safe and high-quality cross-border healthcare in the Union, ensuring patient mobility.

- **Regulation 2022/2371 on serious cross-border threats to health**
  - **Status**: In force since January 2023
  - **Responsible EU service**: Directorate-General for Health and Food Safety
  - **Objective and impact on lung health**: Delivers a strengthened framework for health crisis preparedness and response at EU level addressing the weaknesses exposed by the pandemic.

- **Proposals for a Regulation 2022/0140 on the European Health Data Space**
  - **Status**: Inter-institutional dialogue
  - **Responsible EU service**: Directorate-General for Health and Food Safety
  - **Objective and impact on lung health**: Increased digital access to and control of EU citizens electronic personal health data, at national level and EU-level.

- **Communication 2021/44 from the European Commission to the European Parliament and the Council Europe’s Beating Cancer Plan**
  - **Status**: Adopted by European Commission, February 2021
  - **Responsible EU service**: Directorate-General for Health and Food Safety
  - **Objective and impact on lung health**: The EU’s strategy to improve cancer prevention, treatment and care.

- **Council Recommendation of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases**
  - **Status**: Adopted by the Council on 7 December 2018
  - **Responsible EU service**: Directorate-General for Health and Food Safety
  - **Objective and impact on lung health**: Sets out actions to be undertaken by Member States and the Commission regarding vaccination plans, strengthening vaccine supply and communication and education regarding vaccination.

### RESEARCH & INNOVATION

<table>
<thead>
<tr>
<th>EU initiative</th>
<th>Status</th>
<th>Responsible EU service</th>
<th>Objective and impact on lung health</th>
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</thead>
<tbody>
<tr>
<td>Regulation 2020/2093 laying down the multiannual financial framework for the years 2021-2027</td>
<td>In force, applies as of January 2021 until 2027</td>
<td>Directorate-General for Budget</td>
<td>The EU’s budget 2021-2027.</td>
</tr>
<tr>
<td>Regulation 2021/522 establishing a Programme for the Union’s action in the field of health (EU4Health Programme)</td>
<td>In force, applies as of January 2021 until 2027</td>
<td>Directorate-General for Health and Food Safety</td>
<td>EU funding programme to improve and foster health to reduce disease; to improve health emergency preparedness and response; to improve access to medicinal products and medical devices, and to strengthen health systems.</td>
</tr>
<tr>
<td>Regulation 2021/695 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination</td>
<td>In force, applies as of January 2021 until 2027</td>
<td>Directorate-General for Research and Innovation</td>
<td>EU funding programme to develop, promote and advance scientific excellence; to generate knowledge and support the access to and uptake of innovative solutions in European industry; to foster all forms of innovation. It has a specific Health cluster.</td>
</tr>
<tr>
<td>Regulation 2021/783 establishing a Programme for the Environment and Climate Action (LIFE)</td>
<td>In force, applies as of January 2021 until 2027</td>
<td>Directorate-General for Environment</td>
<td>EU funding programme to contribute to the shift towards a sustainable, circular, energy-efficient, renewable energy-based, climate-neutral and - resilient economy, in order to protect, restore and improve the quality of the environment, including the air, water and soil, and restore nature and halt biodiversity loss</td>
</tr>
</tbody>
</table>
Annex 2. EU agencies relevant to lung health

<table>
<thead>
<tr>
<th>Name</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (EMA)</td>
<td>The European Medicines Agency (EMA) is a decentralised agency of the European Union (EU). It is responsible for the scientific evaluation, supervision and safety monitoring of medicines.</td>
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<tr>
<td>Regulation 2022/123 on a reinforced role of the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices</td>
<td>Strengthen the role of the EMA, allowing the EMA to closely monitor and mitigate shortages of medicines and facilitate the faster approval of medicines that could treat or prevent a diseases causing a public health crisis.</td>
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<tr>
<td>Regulation No 851/2004 establishing a European Centre for disease prevention and control (ECDC)</td>
<td>The European Centre for Disease Prevention and Control (ECDC) is a public health agency of the European Union (EU), with the aim to protect over 500 million people from infectious diseases that are mainly caused by parasites and germs (such as viruses, bacteria and fungi).</td>
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<tr>
<td>Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response authority (HERA)</td>
<td>The Health Emergency Preparedness and Response (HERA) department's mission is to prevent, detect, and rapidly respond to health emergencies. HERA, created in the aftermath of the COVID-19 pandemic, will anticipate threats and potential health crises, through intelligence-gathering and building the necessary response capacities.</td>
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<tr>
<td>Regulation (EU) 2019/126 establishing the European Agency for Safety and Health at Work (EU-OSHA)</td>
<td>In charge of the occupational safety and health, contributing to the European Commission’s Strategic Framework on Health and Safety at Work 2021-2027, and other relevant EU strategies and programmes.</td>
</tr>
<tr>
<td>Commission Implementing Decision 2021/173 establishing the European Climate, Infrastructure and Environment Executive Agency (CINEA)</td>
<td>Plays a key role in supporting the EU Green Deal through high-quality programme management (e.g. Horizon Europe, LIFE programme).</td>
</tr>
</tbody>
</table>

References

European Lung Health Group

The European Lung Health Group (ELHG) is an informal group of nine European level patients’ and healthcare professionals’ organisations gathering 179 member associations across 34 European countries.

Our mission centres around bringing together know-how to support our organisations in empowering patients with lung diseases, improving early diagnosis, optimising multidisciplinary care, progressing quality of life, and research. At the European level, we reinforce the messages of our organisations to strive for better care, increased patient participation and improved prevention, to reduce fragmentation of knowledge and voices around lung health at the European level.

Support the #KeepBreathing campaign

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@EuroLungHealth  @europeanlunghealthgroup

Members of the European Lung Health Group