

STUDY

Requested by the ENVI committee



EU Public Health Policies

State of play, current and future
challenges



Policy Department for Economic, Scientific and Quality of Life Policies
Directorate-General for Internal Policies
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Abstract

This study provides an outlook on the topics that may shape the ENVI Committee's public health agenda during the new legislature. It describes key public health definitions, principles and concepts, discusses the EU's powers to act on health, and presents an overview of health policy developments and challenges.

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LIST OF ABBREVIATIONS

AGRI	Agriculture and Rural Development Committee
AFET	Foreign Affairs Committee
BUDG	Committee on Budgets
CJEU	Court of Justice of the European Union
Commission	European Commission
Council	Council of the European Union
EMA	European Medicines Agency
ENVI	Environment, Public Health and Food Safety Committee
EU	European Union
IPCC	Intergovernmental Panel on Climate Change
ITRE	Industry, Research and Energy Committee
LIBE	Civil Liberties, Justice and Home Affairs Committee
Parliament	European Parliament
Plenary	Plenary of the European Parliament
REFIT	Regulatory Fitness and Performance
SDG	Sustainable Development Goal
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
UN	United Nations
WHO	World Health Organization

EXECUTIVE SUMMARY

Eurobarometer surveys report that **health is a main concern** of Europeans and a policy area where the European Union has been asked to do more. Nearly 10% of the EU's Gross Domestic Product (GDP) is spent on healthcare. Despite gains in life expectancy, Europeans on average spend between almost a quarter and a fifth of their lives with a disability. More than 1.2 million people in the EU in 2013 died from illnesses and injuries that might have been avoided. The burden of ill-health and premature mortality falls disproportionately on people exposed to socio-economic vulnerabilities.

According to the WHO, **health** is a state of complete physical, mental and social **well-being**, and not merely the absence of disease or infirmity. **Public health** is most commonly defined as the art and science of preventing disease, prolonging life and promoting health through the organized efforts of society. The aim of **public health policy** is to create the enabling conditions for people to maintain their health, improve health and well-being, and prevent ill-health or the deterioration of their health.

In view of a possible strengthened response by the new European Commission to legislative requests from the European Parliament, this paper provides a brief discussion of the **powers of the EU to act on public health**. The discussion demonstrates that the EU can rely on a broad range of relevant legal bases to develop and implement an EU-level public health agenda.

The main aim of this paper is to provide an **outlook on the topics that may shape the ENVI Committee's public health agenda during the new legislature**. A number of public health-relevant procedures that are currently in progress and assigned to the ENVI Committee are listed. Looking forward, the paper finds that most of the overarching priorities highlighted in the Political Guidelines for the 2019-2024 Commission, like tackling climate change, ensuring a just and equality-oriented transition, pursuing a zero-pollution ambition, developing an ethics-based digital future and enhancing the inclusiveness and integrity of policy-making, are closely linked to public health challenges.

The Mission Letter to the Commissioner-designate for Health describes several priorities the new President of the Commission has committed to pursue. These include actions to ensure the **supply of affordable medicines**, an issue that has been high on the agenda during the last legislature. Questions such as the review of the orphan and paediatrics legislation, incentives for biomedical research and development, and medicines shortages will likely be discussed. Tackling **vaccine hesitancy** is another priority highlighted in the Mission Letter, as is ensuring the effective and future-oriented implementation of the two Regulations on **medical devices**, the first of which will apply from 2020.

The Mission Letter instructs to make use of the opportunities offered by **e-health** and prioritises the creation of a **European Health Data Space**. The digital transformation of healthcare and society was also a focus of the previous legislature. Different challenges in this space remain to be addressed, such as the **ethical and equity implications of digitalisation**, m-health, data privacy and ownership, Artificial Intelligence, digital marketing, and the wider implications of digitalisation for health systems, including the evolution of personalised medicine.

The Mission Letter refers to tackling **antimicrobial resistance** (AMR), in particular by ensuring the implementation of the EU One Health Action Plan against AMR and working towards a global agreement on antimicrobials. Other challenges on the agenda include supporting the effective implementation of national AMR action plans, which Member States committed to in the framework of the WHO.

The Mission Letter entrusts the future Commissioner with putting forward a **plan to fight cancer**, consisting of actions at every key stage of the disease, from prevention to palliative care. Challenges related to the prevention of cancers are closely linked to those of the other major **non-communicable diseases (NCDs)** as they share a limited number of main risk factors; notably tobacco and alcohol use, unhealthy diet, lack of physical activity and air pollution. Considering the vast burden of NCDs, a synergistic approach to tackling cancer and other NCDs, as well as **obesity**, may be explored.

The future Health Commissioner will also lead the creation of a **'Farm to Fork' strategy for sustainable food**. Transforming the food system is a challenge, but also an important opportunity considering how the food system affects multiple health dimensions, such as nutrition, food safety, climate, AMR, air quality, chemical safety, biodiversity and socio-economic determinants. **Improving consumer information** on food products, covering themes such as claims and simplified front-of-pack nutrition declarations, is another priority which is deeply embedded within the food and health nexus.

The Mission Letter entrusts the new Health Commissioner with contributing to the 'zero pollution' ambition, foreseeing action on, among others, **endocrine disrupting chemicals (EDCs)** and **air quality**. The mission to address EDCs fits within the wider expectation of an EU strategy on a **non-toxic environment**. Different processes on air quality are ongoing, including on vehicle emissions, the evaluation of the Ambient Air Quality Directives and the implementation of the National Emissions Ceiling Directive.

Promoting **health equity** is a foundation of public health. While most policies in the remit of the ENVI Committee can contribute to this aim, socio-economic policies usually fall under the responsibility of other Committees. The ENVI Committee can however consider its close involvement, which would also be consistent with the European Green Deal's aim to support the most affected. According to the Political Guidelines for the upcoming Commission and relevant Mission Letters, a range of actions can be expected in this domain, including on the **European Semester**, the **European Pillar of Social Rights**, the **Child Guarantee**, as well as action on **gender**, minimum wage, unemployment and work-life balance. Special health focus is also warranted to the **demographic transition**, especially considering the ageing of the European population and that healthy ageing starts from childhood.

Furthermore, the ENVI Committee's engagement on **international trade and investment** agreements and the EU's approach to **global health** may provide significant added value for public health. The same applies to ensuring adequate **funding** allocations in the EU budget for the effective pursuit of health and health equity objectives. This is especially relevant as the current Health Programme will, in the next programming period, be merged into a wider European Social Fund Plus.

The Political Guidelines for the new Commission and the Mission Letters to Commissioner-designates put strong emphasis on **improved policy-making**. The EU is under a legal obligation under the WHO Framework Convention on Tobacco Control to ensure adequate procedures to protect tobacco policy from vested interests. Greater **transparency** will also benefit other areas of public health policy-making. Likewise, the challenge of ensuring adequate structures and procedures to **include the voices of citizens and civil society** in policy-making remains.

Other health policy topics are likely to be raised, including in the wake of the evaluation of the **EU blood, tissues and cells legislation** and following discussions on the renewal or introduction of EU action plans and strategies, such as on the EU **health workforce; HIV/AIDS, tuberculosis and viral hepatitis; drugs; Roma; disability, mental health; alcohol; childhood obesity** and the **8th Environment Action Plan**.

Also, regular reports will be due on various pieces of EU health legislation, notably on **tobacco, cross-border healthcare, professional qualifications** and in the area of **chemicals**.

Furthermore, monitoring the EU's preparedness and response to **cross-border threats to health**, and the effects of **Brexit**, particularly in a 'no deal' scenario, will be important.

Aim

- This paper presents an outlook on the topics that may shape the ENVI Committee's public health agenda during the new legislature.¹
- In doing so, the analysis provides a description of some of the key policy developments and future challenges, drawing, among others, on guidance documents for the new Commission.
- Other relevant health themes and challenges, not mentioned among Commission priorities are identified, ranging from health systems to disease prevention.

¹ Consistent with the scope of this study, food safety, environmental and climate change policies are not included, despite their potential public health impacts.

1. THE SCOPE OF PUBLIC HEALTH POLICY

KEY FINDINGS

This section provides a brief overview of key public health definitions, principles and concepts for a fuller understanding of public health policy. It finds that the aim of public health is to create the enabling conditions to promote health, understood as a state of complete physical, social and mental well-being. Public health policy therefore covers, but also goes beyond issues concerning health systems and healthcare delivery.

Central to the practice of public health is the recognition that health and well-being is shaped by multiple social, economic, political, environmental and biological determinants. The 'Health in All Policies' approach, which seeks to mainstream health in all relevant policy processes, is key to public health policy-making. Public health policies have been found to deliver significant rates of economic returns on investment.

Eurobarometer surveys have consistently found that **health is a main concern** of Europeans and a policy area where the EU has been asked to do more.^{2 3 4} More than €1,000 billion is spent on healthcare in the EU each year, or between 7 and 10% of GDP.^{5 6} Despite gains in life expectancy, Europeans on average spend between nearly a quarter and a fifth of their lives with a disability.⁷ More than 1.2 million people in the EU in 2013 died from illnesses and injuries that might have been avoided.⁸ The burden of ill-health and premature mortality falls disproportionately on people exposed to socio-economic vulnerabilities.⁹ According to the WHO, **health** is "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."¹⁰ **Public health** is commonly defined as the "art and science of preventing disease, prolonging life and promoting health through the organized efforts of society."^{11 12}

The aim of public health policy is to create the enabling conditions for people to maintain their health, improve health and well-being, and prevent ill-health or the deterioration of their health.¹³

The science and practice of public health is founded on the recognition that the health and well-being of individuals and populations, throughout every stage of life, is shaped by multiple social, economic, political, environmental and biological factors. These factors are referred to as the **determinants of health**.¹⁴ The most prominent determinants are highlighted below:

² Eurobarometer (2017) [Two years until the 2019 European Elections](#).

³ Standard Eurobarometer 89 (2018) Spring 2018 [Public Opinion in the European Union](#).

⁴ Standard Eurobarometer 91 (2019) Spring 2019 [Public Opinion in the European Union](#).

⁵ Eurostat (2017) [Member States spent over €1000 billion on health](#).

⁶ OECD/EU (2018) [State of Health in the EU. Health at a Glance: Europe 2018](#).

⁷ Eurostat website [Healthy Life Years Statistics](#).

⁸ OECD/EU (2016) [State of Health in the EU. Health at a Glance: Europe 2016](#).

⁹ [Health Inequalities in the EU - Final report of a consortium](#). Consortium lead: Sir Michael Marmot (2013) European Commission Directorate- General for Health and Consumers.

¹⁰ WHO (1946) [Constitution of the World Health Organization](#).

¹¹ Acheson (1988) Public health in England: the report of the Committee of Inquiry into the Future Development of the Public Health Function. London: HMSO.

¹² Marks et al. (2011) [Strengthening Public Health Capacity and Services in Europe](#). A concept paper. Durham University and WHO/Europe.

¹³ WHO/Europe, [Public Health Services](#).

¹⁴ WHO, [Health Impact Assessment. The determinants of health](#).

- **Social, or socio-economic, determinants of health** are “the conditions in which people are born, grow, live, work and age”,¹⁵ and are shaped by factors such as income, employment and education.¹⁶ Social determinants are linked to **health inequalities** and are largely responsible for **health inequities**, which are inequalities that are avoidable and therefore deemed unfair or unjust.¹⁷ People exposed to socio-economic vulnerabilities are disproportionately burdened by ill-health.¹⁸
- **Environmental determinants of health** refer to the health impacts of environmental factors, ranging from air quality, to occupational health; from chemicals safety, to housing and urban environments; from water quality and sanitation, to levels of noise.¹⁹ **Climate change** poses increasing health risks through extreme weather events, and through indirect impacts on ecological and social systems, such as increased incidence of infections and infectious diseases, nutritional and psychological impacts.²⁰ The fundamental links between human health and the health of the **biosphere**, including the quality of ecosystems and biodiversity, are increasingly being acknowledged.²¹
- **Health system determinants of health** refer to the health impacts of different approaches to organising, resourcing and operating health systems. While the configuration of services can vary from country to country, as they do in the EU,²² an effective health system is one that “delivers quality services to all people, when and where they need them” without causing financial hardship.²³
- **Commercial determinants of health** refer to the health impacts of private sector activities.²⁴ The manner in which commercial activities are carried out, and the role of commercial actors in setting the rules by which society and the economy operate are important factors influencing the health of populations.²⁵ Different corporate practices have been identified that have negative implications for public health policy and public health outcomes.^{26 27}
- **Individual determinants of health**, refer to personal factors that influence health outcomes. Such factors include biological factors, such as genetics, and behaviours, sometimes referred to as ‘lifestyle’ factors.²⁸

This wide scope of health determinants means that many decisions influencing health are taken in policy processes outside the health sector, and that the opportunity to promote health and health equity therefore lies in all sectors of society and how they interact, not just with those that oversee

¹⁵ WHO, [Social determinants of health. About social determinants of health.](#)

¹⁶ UCL Institute of Health Equity (2013) [Review of social determinants and the health divide in the WHO European Region.](#) Final report. WHO/Europe.

¹⁷ WHO, [Health Impact Assessment. Glossary of terms used.](#)

¹⁸ [Health Inequalities in the EU - Final report of a consortium.](#) Consortium lead: Sir Michael Marmot (2013) European Commission Directorate- General for Health and Consumers.

¹⁹ WHO/Europe, [Environment and Health.](#)

²⁰ WHO, [Climate change and human health.](#)

²¹ See for instance: [The Lancet Planetary Health Journal](#) launched in 2017. Planetary health was defined as “the health of human civilisations and the natural systems on which they depend”.

²² European Commission. [Health Systems.](#) European Semester Thematic Factsheet.

²³ WHO, [Health systems.](#)

²⁴ Kickbusch et al. (2016) The commercial determinants of health. *Lancet Global Health.*

²⁵ McKee and Stuckler (2018) [Revisiting the Corporate and Commercial Determinants of Health.](#) *American Journal of Public Health.*

²⁶ University of Bath, [Tobacco Tactics.](#)

²⁷ Swinburn et al. (2019) [The Global Syndemic of Obesity, Undernutrition, and Climate Change: The Lancet Commission report.](#) *The Lancet.*

²⁸ WHO, [Health Impact Assessment. The determinants of health.](#)

health service delivery. The **Health in All Policies (HiAP)** approach, which seeks to systematically mainstream health in all relevant policy processes, is a response to the cross-sectoral nature of public health policy.²⁹ The HiAP principle is codified in the EU Treaties and in the EU Charter on Fundamental Rights.³⁰

A core feature of HiAP is its basis in a human rights perspective, in particular the **right to health**.³¹ The right to the enjoyment of the highest attainable standard of health is protected by a broad range of international conventions, and in particular regional instruments such as the European Social Charter³² and the EU Charter on Fundamental Rights. Children's right to health has been interpreted as "an inclusive right, extending not only to timely and appropriate prevention, health promotion, curative, rehabilitative and palliative services, but also to a right to grow and develop to their full potential and live in conditions that enable them to attain the highest standard of health through the implementation of programmes that address the underlying determinant of health".³³

The degree to which health policies should leverage individual agency as compared to achieving structural changes in living environments is a recurring theme in health policy debates. In general, public health evidence finds structural policies (population-level interventions) to be more effective and equitable compared to approaches that require individuals to change their behaviour.³⁴ For example, the WHO Best Buys and other recommended interventions provide a selection of the most promising, evidence-based policy options to tackle NCDs.³⁵

Public health policies offer significant opportunities for individuals, communities, and the economy. A 2016 systematic review assessed the **rate of return on investment** in public health policies, concluding that such interventions are cost-saving and offer substantial long-term returns, in the range of 14:1.^{36 37}

²⁹ Leppo et al. (ed.) (2013) [Health in All Policies. Seizing opportunities, implementing policies](#). Ministry of Social Affairs and Health, Finland.

³⁰ Articles 9 and 168(1) Treaty on the Functioning of the EU and Article 35 of the EU Charter on Fundamental Rights.

³¹ Office of the UN Commissioner for Human Rights & World Health Organization (2008) [The Right to Health](#). Factsheet 31.

³² Council of Europe, [The European Social Charter](#).

³³ Committee on the Rights of the Child (2013) [General Comment No. 15 on the Right of the Child to the Enjoyment of the Highest Attainable Standard of Health](#), CRC/C/GC/15, United Nations.

³⁴ Adams et al. (2016) [Why Are Some Population Interventions for Diet and Obesity More Equitable and Effective Than Others? The Role of Individual Agency](#) PLOS Medicine.

³⁵ WHO (2017) ["Best buys" and other recommended interventions for the prevention and control of noncommunicable diseases](#).

³⁶ Masters et al. (2016) [Return on investment of public health interventions: a systematic review](#). BMJ Journal of Epidemiology and Community Health.

³⁷ Aspects of the added value of EU action on health policy have been described in a 2019 report by the European Parliamentary Research Service: Lomba (2019) [The benefit of EU action in health policy: The record to date](#). European Parliamentary Research Service.

2. PUBLIC HEALTH AND EU POWERS

KEY FINDINGS

This section provides a brief discussion of the powers of the EU to act on public health. Understanding the legal basis for EU action is important to assess the scope that EU institutions have to develop and implement an EU-level public health agenda. This especially in view of a possible strengthened response by the new Commission to legislative requests from the Parliament.

The discussion demonstrates that, even though the wording of Article 168 TFEU may seem restrictive, it nonetheless mandates the EU to ensure that all its policies and activities adopt a high level of public health protection. Consequently, the EU can rely on a broad range of relevant legal bases allowing for the harmonisation of the laws of the Member States in areas that impact on public health, not least Article 114 TFEU on the establishment and functioning of the internal market.

The EU derives its powers, or competences, from the TEU³⁸ and the TFEU,³⁹ as interpreted by the CJEU. Under Article 5(2) TEU, “the Union shall act only within the limits of the competences conferred upon it by the Member States in the Treaties”. Competences not conferred on the EU remain with the Member States (Article 4(1) TEU).

In relation to public health, the EU has a **shared competence** with Member States on “common safety concerns in public health matters, for the aspects defined in this Treaty” (Article 4(2)(k) TFEU). The EU also has **complementary competence** to “carry out actions to support, coordinate or supplement the actions of the Member States” on the “protection and improvement of human health” (Article 6(a) TFEU).

Article 168 TFEU further defines the scope of EU public health competences. In particular, it allows the EU to engage in a wide range of **supportive and coordination actions** to improve public health, and in particular prevent physical and mental ill-health, and obviate threats to health (Article 168(1), (2) and (6) TFEU). It also calls on the EU to act on global health issues, by fostering cooperation with third countries and competent international organisations (Article 168(3) TFEU). At the same time, however, the article explicitly provides that Member States retain the responsibility to organise their health systems (Article 168 (7) TFEU).

As far as **legally binding measures** are concerned, Article 168 distinguishes two categories of measures. First, it highlights three instances in which the Parliament and the Council can adopt EU-wide standards to address “common safety concerns”, fleshing out Article 4(2)(k) TFEU: (1) measures relating to organs and substances of human origin, blood and blood derivatives; (2) measures in the veterinary and phytosanitary fields “which have as their direct objective the protection of public health”; and (3) measures to regulate medicinal products and medical devices (Article 168(4) TFEU).

Furthermore, Article 168 also allows the Parliament and the Council to adopt (1) “incentive measures” designed to protect and improve human health and combat “major cross-border health scourges”; (2) measures on “monitoring, early warning of and combating” cross-border threats to health; and (3)

³⁸ [Treaty on European Union](#).

³⁹ [Treaty on the Functioning of the European Union](#).

measures with the “direct objective” to address tobacco and alcohol-related harm. However, Article 168 explicitly excludes the adoption of “any harmonisation of the laws and regulations of the Member States” (Article 168 (5) TFEU), preventing the adoption on the basis of this provision of EU wide legal standards (even minimum standards) which would replace existing national legislation to protect public health beyond those addressing “common safety concerns”.

Nevertheless, an isolated reading of Article 168 does not fully reflect the scope of EU powers to pursue an effective public health policy. As highlighted above, **the EU has a duty to ensure a high level of human health protection in the definition and implementation of all its policies and activities.** This is explicitly stated in the TFEU (and Articles 9 and 168(1) in particular) and in the EU Charter of Fundamental Rights (Article 35).⁴⁰ Consequently, while Article 168 itself provides a limited legal basis to adopt binding public health measures, there are several other legal bases that the EU can rely upon to achieve its public health objectives.

In particular, the EU has a shared competence with Member States to ensure the establishment and functioning of **the internal market**. This EU competence is broad and has been frequently used to promote market integration and public health objectives: to promote the mutual recognition of the professional qualifications of health workers; the free movement of medical services; or the approximation of the laws of the Member States on tobacco control or food information and food safety standards.⁴¹

Article 114 TFEU is the most frequently invoked legal basis. When proposing and adopting internal market measures on the basis of Article 114 TFEU, the Commission, the Parliament and the Council must take as a base a high level of health, safety, environmental protection and consumer protection (Article 114(3) TFEU). The CJEU has developed a rich case law on the extent to which the EU can pursue ambitious public health objectives through the process of internal market integration. If, on the one hand, the CJEU has held that Article 114(3) may not be used to “circumvent the express exclusion of harmonisation” contained in Article 168 (5) TFEU referred to above.⁴² It has also ruled, on the other hand, that “provided that the conditions for recourse to [Article 114 TFEU] as a legal basis are fulfilled, **the [EU] legislature cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made.**”⁴³

The same reasoning would apply in other important areas where the EU has been granted the competence to adopt legally binding measures, and most notably:

- **Agriculture and fisheries policy** (Articles 38-44 TFEU)
- **Tax policy** (Article 113 TFEU)
- **Social policy** (Articles 151-161 TFEU)
- **Consumer policy** (Article 169 TFEU)
- **Environmental policy** (Articles 191-193 TFEU)
- **International trade and investment policy** (Article 207 TFEU)

⁴⁰ It should be noted that mainstreaming obligations do not expand EU competence, but help achieve coherence between policies and actions within existing spheres of competence with a view of taking all EU objectives into account.

⁴¹ Garde (2016) [EU law and competence to tackle antimicrobial resistance: What can the EU do?](#) European Public Health Alliance.

⁴² Case C-376/98 Germany v Council and the European Parliament (Tobacco Advertising I) [2000] [ECR I-8419](#).

⁴³ Joined Cases C-154 and 155/04 Alliance for Natural Health [2005] [ECRI-6451](#). Emphasis added.

This section has provided a legal view on both the limits on EU public health competence and the broad margin of discretion that the EU retains to act on public health matters and therefore fulfil its obligation to ensure a high level of public health protection in all its policies and activities.

This is all the more relevant in view of a possible strengthened response by the new Commission to legislative requests from the Parliament, otherwise referred to as “a right of initiative”.⁴⁴

⁴⁴ Von der Leyen (2019) [A Union that strives for more. My Agenda for Europe](#): Political Guidelines for the Next European Commission 2019-2024.

3. ONGOING PUBLIC HEALTH POLICY PROCEDURES

KEY FINDINGS

A number of public health-relevant legislative and non-legislative files are currently assigned to the ENVI Committee in its capacity as both the Committee responsible, and as opinion-giving Committee. The files are at different stages of the policy development process, from preparatory phase to already in Trilogue. The files also cover different legislative procedures, from ordinary legislative procedure, to budgetary procedure, to delegated acts procedure.

The files have, primarily, been selected from those listed in the ENVI Committee's "Work in Progress" portal on the Parliament website [last accessed 6 September 2019]. Files were selected based on their relevance for public health. Procedures with a primary focus on environment, climate change and food safety, despite their potential health impacts, have not been included considering the scope of this study.

3.1. Main ongoing procedures with ENVI as lead committee

3.1.1. Health technology assessment

An ordinary legislative procedure is almost finalised based on a 2018 Commission proposal for a Regulation on Health Technology Assessment (HTA).⁴⁵ The objective of the proposal was, among others, to create a new, mandatory, EU-wide HTA system which would improve the functioning of the single market for health technologies, streamline HTA national processes and accelerate access to new medicines for patients. The ENVI Committee adopted a report in 2018, and the Parliament a legislative resolution in 2019. Negotiations are ongoing in the Council.

3.1.2. Air quality - vehicle emissions

Two active⁴⁶ files on air quality, in particular on vehicle emissions, are currently assigned to the ENVI Committee:

- An ordinary legislative procedure is pending, based on a 2019 Commission proposal for a **Regulation on type approval of motor vehicles (Euro 5 and 6)**.⁴⁷ The proposal seeks to review and adopt 'conformity factors' for the Real Driving Emissions test. Conformity factors allow cars to emit more when driven on the road than when tested in laboratory during type approval. One of the questions this procedure will answer is the degree to which manufacturers will need to demonstrate that their cars meet the legal nitrogen oxides (NOx) emissions limit in driving conditions. The ENVI Committee has not yet drafted a report.
- A regulatory procedure with scrutiny is pending, based on a 2019 Commission proposal for a Regulation addressing, among others, **auxiliary emissions strategies** for heavy duty vehicles,

⁴⁵ European Parliament Legislative Observatory [Procedure 2018/0018\(COD\) Health technology assessment](#).

⁴⁶ Another procedure is marked as ongoing, but has been frozen since 2015: European Parliament Legislative Observatory [2014/0012\(COD\) Reduction of pollutant emissions from road vehicles](#).

⁴⁷ European Parliament Legislative Observatory [Procedure 2019/0101\(COD\) Motor vehicles: type approval with respect to emissions from light passenger and commercial vehicles \(Euro 5 and Euro 6\) and access to repair and maintenance information](#).

and the emissions performance of heavy duty vehicles in the period following a cold engine start.⁴⁸ The ENVI Committee has not yet drafted a report.

3.1.3. Chemicals

A number of files addressing different aspects of chemicals regulation⁴⁹ are assigned to the ENVI Committee:

- A regulatory procedure with scrutiny is pending, based on a 2019 Commission proposal to add several **substances of very high concern (SVHC)** to Annex XIV of the EU Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), which provides for a ‘sunset date’ after which the use of listed substances would be banned.⁵⁰
- A delegated acts procedure is pending, based on a 2019 Commission proposal to amend annexes to the EU Regulation concerning the **export and import of hazardous chemicals**.⁵¹
- Two delegated acts procedures are pending, based on 2019 Commission proposals to amend annexes to the EU Directive restricting the use of certain **hazardous substances in electrical and electronic equipment**.^{52 53}
- Three regulatory procedures with scrutiny are pending, based on 2019 Commission proposals to amend annexes to the EU **Regulation on cosmetic products**.^{54 55 56}
- Several delegated acts procedures are pending, based on 2019 Commission proposals to include certain active substances to Annex I of the EU **Regulation on biocidal products**.⁵⁷ Annex I lists active substances that do not give rise to safety concerns. The active substances currently proposed for inclusion are egg powder;⁵⁸ honey,⁵⁹ vinegar;⁶⁰ *Saccharomyces cerevisiae*;⁶¹ concentrated apple juice;⁶² cheese;⁶³ and D-fructose.⁶⁴

⁴⁸ European Parliament Legislative Observatory Procedure 2019/2749(RPS).

⁴⁹ Procedures addressing the topic of pesticides residues on certain products have not been included, consistent with the scope of this study which excludes food safety issues.

⁵⁰ European Parliament Legislative Observatory Procedure 2019/2773(RPS).

⁵¹ European Parliament Legislative Observatory [Procedure 2019/2771 \(DEA\) Export and import of hazardous chemicals: amending Annexes I and V](#).

⁵² European Parliament Legislative Observatory [Procedure 2019/2792 \(DEA\) Exemption for bis\(2-ethylhexyl\) phthalate \(DEHP\) in certain rubber components used in engine systems](#).

⁵³ European Parliament Legislative Observatory [Procedure 2019/2793 \(DEA\) Exemption for lead in solders used in certain combustion engines](#).

⁵⁴ European Parliament Legislative Observatory Procedure 2019/2724(RPS).

⁵⁵ European Parliament Legislative Observatory Procedure 2019/2728(RPS).

⁵⁶ European Parliament Legislative Observatory Procedure 2019/2779(RPS).

⁵⁷ [Regulation \(EU\) No 528/2012 concerning the making available on the market and use of biocidal products](#).

⁵⁸ European Parliament Legislative Observatory [Procedure 2019/2791\(DEA\) Biocidal products: including powdered egg as an active substance in Annex I](#).

⁵⁹ European Parliament Legislative Observatory [Procedure 2019/2790\(DEA\) Biocidal products: including honey as an active substance in Annex I](#).

⁶⁰ European Parliament Legislative Observatory [Procedure 2019/2789\(DEA\) Biocidal products: including vinegar as an active substance in Annex I](#).

⁶¹ European Parliament Legislative Observatory [Procedure 2019/2788\(DEA\) Biocidal products: including *Saccharomyces cerevisiae* as an active substance in Annex I](#).

⁶² European Parliament Legislative Observatory [Procedure 2019/2787\(DEA\) Biocidal products: including concentrated apple juice as an active substance in Annex I](#).

⁶³ European Parliament Legislative Observatory [Procedure 2019/2786\(DEA\) Biocidal products: including cheese as an active substance in Annex I](#).

⁶⁴ European Parliament Legislative Observatory [Procedure 2019/2785\(DEA\) Biocidal products: including D-fructose as an active substance in Annex I](#).

3.1.4. Drinking water

An ordinary legislative procedure is almost finalised, based on a 2017 Commission proposal to recast the Directive on the Quality of Water Intended for Human Consumption.⁶⁵ The Directive establishes a legal framework to protect people from the adverse health effects of contaminated drinking water. In response to the successful European Citizens' Initiative "Right2Water"⁶⁶ and the follow-up Parliament Resolution,⁶⁷ the recast, among others, emphasises measures to ensure access to drinking water for all, with particular focus on vulnerable and marginalised groups. The ENVI Committee adopted its report in 2018. The Plenary, after votes in 2018 and 2019 adopted a legislative resolution. The file is currently awaiting the position of the Council.

3.1.5. Environmental noise

A regulatory procedure with scrutiny is pending, based on a 2019 Commission proposal to amend Annex III of the EU Directive on the assessment and management of environmental noise.⁶⁸ Annex III deals with the assessment methods for harmful noise effects.

3.1.6. Civil protection mechanism

An ordinary legislative procedure is ongoing, based on a 2019 Commission proposal on the establishment of a budget for the Union Civil Protection Mechanism.⁶⁹ The objective of this mechanism is to provide support for disaster prevention, preparedness, response and recovery. It covers all types of natural and man-made disasters, such as environmental disasters, marine pollution and acute health emergencies, occurring both within or outside the EU. The ENVI Committee has not yet drafted a report.

3.2. Main ongoing procedures with ENVI as opinion-giving committee

3.2.1. Budgetary procedures

Several files related to EU budgetary procedures, with BUDG as the committee responsible, are assigned to the ENVI Committee for an opinion. The size of the EU budget, the objectives pursued by the budget, the types of budgetary allocations envisioned and the conditions for making resources available can all have important repercussions for the EU's impact on, and added value for public health.

- A budgetary procedure is ongoing, based on the 2019 Commission proposal for the EU's **2020 General Budget**,⁷⁰ including a mandate for Trilogue.⁷¹
- A consent procedure is pending, based on the 2018 Commission proposal for the **Multiannual Financial Framework** (MFF) for the years 2021 to 2027.⁷²
- An ordinary legislative procedure is ongoing, based on a 2018 Commission proposal for **Regulation for a reform support programme**.⁷³ This programme aims to enable technical and financial support to Member States for structural reforms to the economy, and national institutional and regulatory frameworks. Its scope includes measures to enhance social

⁶⁵ European Parliament Legislative Observatory [Procedure 2017/0332 \(COD\) Quality of water intended for human consumption. Recast.](#)

⁶⁶ European Citizens' Initiative, [Water is a human right.](#)

⁶⁷ [European Parliament resolution of 8 September 2015 on the follow-up to the European Citizens' Initiative Right2Water](#) (2014/2239(INI)).

⁶⁸ European Parliament Legislative Observatory [Procedure 2019/2783\(RPS\).](#)

⁶⁹ European Parliament Legislative Observatory [Procedure 2019/0070\(COD\) Union Civil Protection Mechanism.](#)

⁷⁰ European Parliament Legislative Observatory [Procedure 2019/2028 general budget: all sections.](#)

⁷¹ European Parliament Legislative Observatory [Procedure 2019/2020\(BUD\) 2020 Budget: Mandate for the Trilogue.](#)

⁷² European Parliament Legislative Observatory [Procedure 2018/0166\(APP\) Multiannual financial framework for the years 2021 to 2027.](#)

⁷³ European Parliament Legislative Observatory [Procedure 2018/0213\(COD\) Reform support programme 2021-2027.](#)

inclusion, social security and welfare systems, public health and healthcare systems. The ENVI Committee has not yet drafted a report.

- A procedure is pending, based on a 2018 Commission proposal to make available **EU own resources based** on common consolidated corporate tax base, the EU emissions trading system and on plastic packaging.⁷⁴
- Multiple **budget discharge procedures** are pending, based on 2019 Commission annual accounts for the 2018 budgets of the European Medicines Agency (EMA);⁷⁵ the European Centre for Disease Prevention and Control (ECDC);⁷⁶ the European Chemicals Agency (ECHA);⁷⁷ the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA);⁷⁸ and the European Environment Agency (EEA).⁷⁹

3.2.2. Common Agricultural Policy

Two ordinary legislative procedures are ongoing on the reform of the EU Common Agricultural Policy (CAP), with AGRI as the committee responsible. Based on 2018 Commission proposals, two draft CAP Regulations are assigned to the ENVI Committee for an opinion; the Regulation on CAP Strategic Plans⁸⁰ and the Regulation amending rules on the common organisation of markets for agricultural products, quality schemes and others.⁸¹

Notable under this reform are the proposal to add “food and health” as a new CAP objective;⁸² the new delivery model based on objectives and indicators; the enhanced legislative status of the ENVI Committee for several provisions under the Regulation on CAP Strategic Plans (associated committee procedure, Rule 54);⁸³ and the proposed inclusion of nutrition and ingredient labelling of wines under the Common market organisation Regulation. The ENVI Committee delivered its opinion in both ongoing procedures. The AGRI Committee adopted reports, which the Plenary has not yet debated. Parliament did adopt an own initiative report in 2018.⁸⁴ Under discussion is how the CAP reform process will be taken forward in the new Parliament session, especially regarding whether, and the degree to which the previously adopted reports may be revisited.

3.2.3. Research - Horizon Europe

Two ordinary legislative procedures are ongoing on the next EU research and innovation programme “Horizon Europe”, with ITRE as the committee responsible. Based on 2018 Commission proposals, the

⁷⁴ European Parliament Legislative Observatory [Procedure 2018/0131\(NLE\) Making available the own resources based on the common consolidated corporate tax base, on the European Union emissions trading system and on plastic packaging waste that is not recycled, and measures to meet cash Requirements.](#)

⁷⁵ European Parliament Legislative Observatory [Procedure 2019/2073\(DEC\) 2018 discharge: European Medicines Agency \(EMA\).](#)

⁷⁶ European Parliament Legislative Observatory [Procedure 2019/2079\(DEC\) 2018 discharge: European Centre for Disease Prevention and Control \(ECDC\).](#)

⁷⁷ European Parliament Legislative Observatory [Procedure 2019/2086\(DEC\) 2018 discharge: European Chemicals Agency \(ECHA\).](#)

⁷⁸ European Parliament Legislative Observatory [Procedure 2019/2069\(DEC\) 2018 discharge: European Monitoring Centre for Drugs and Drug Addiction \(EMCDDA\).](#)

⁷⁹ European Parliament Legislative Observatory [Procedure 2019/2070\(DEC\) 2018 discharge: European Environment Agency \(EEA\).](#)

⁸⁰ European Parliament Legislative Observatory [Procedure 2018/0216\(COD\) Support for strategic plans to be drawn up by Member States under the common agricultural policy \(CAP strategic plans\) and financed by the European Agricultural Guarantee Fund \(EAGF\) and by the European Agricultural Fund for Rural Development \(EAFRD\) 2021–2027.](#)

⁸¹ European Parliament Legislative Observatory [Procedure 2018/0218\(COD\) Common agricultural policy \(CAP\) 2021–2027 .](#)

⁸² Article 6(i) proposal for the CAP Strategic Plans Regulation.

⁸³ European Parliament, [Rules of Procedure of the European Parliament](#), Rule 54 : Associated committee procedure.

⁸⁴ European Parliament resolution of 30 May 2018 on the future of food and farming ([2018/2037\(INI\)](#)).

ENVI Committee is assigned to provide an opinion on the Horizon Europe Framework Programme⁸⁵ and the Specific Implementing Programme.⁸⁶

Horizon Europe's main aims are to strengthen science and technology, foster industrial competitiveness, and implement the SDGs. Key new instruments to promote health under Horizon Europe include the new Missions on cancer; climate adaptation and societal transformation; climate neutral and smart cities; and on soil health and food.⁸⁷ Other features include new forms of partnerships, including the Innovative Health Initiative; and the European Innovation Council.

The ENVI Committee has provided opinions on the Framework Programme and the Specific Programme. In 2019 Parliament and Council reached a partial agreement, covering the Specific Programme's content. The file is pending due to the ongoing negotiations on the EU's overall 2021-2027 long-term budget. Further Trilogue negotiations will take place.

3.2.4. Neighbourhood, development and international cooperation

An ordinary legislative procedure is almost finalised on a Regulation for a Neighbourhood, Development and International Cooperation instrument, based on a 2018 Commission proposal and with AFET as the responsible committee.⁸⁸ The instrument is conceived in the context of the EU's 2021-2027 MFF. It aims to support the EU's external action priorities, providing funding to support responses to global challenges such as regional conflicts, terrorism, economic inequalities, growing migratory pressures, climate change and environmental degradation. The ENVI Committee delivered its opinion in 2018 and the Parliament adopted a legislative resolution in 2019. The file is awaiting the position of the Council.

3.2.5. Data privacy

An ordinary legislative procedure is ongoing, based on a 2017 Commission proposal for a Regulation on Privacy and Electronic Communications (ePrivacy Regulation), with LIBE as the committee responsible.⁸⁹ The procedure was assigned to the ENVI Committee for an opinion in 2017. The Committee decided not to give an opinion.⁹⁰

⁸⁵ European Parliament Legislative Observatory [Procedure 2018/0224\(COD\) Horizon Europe framework programme for research and innovation 2021-2027](#).

⁸⁶ European Parliament Legislative Observatory [Procedure 2018/0225\(COD\) Specific programme implementing Horizon Europe framework programme for research and innovation 2021-2027](#).

⁸⁷ European Commission (2019) [Commission launches work on major research and innovation missions for cancer, climate, oceans and soil](#).

⁸⁸ European Parliament Legislative Observatory [Procedure 2018/0243\(COD\) Neighbourhood, development and international cooperation instrument 2021-2027](#).

⁸⁹ European Parliament Legislative Observatory [Procedure 2017/0003\(COD\) Respect for private life and the protection of personal data in electronic communications](#).

⁹⁰ [Report on the proposal for a regulation of the European Parliament and of the Council concerning the respect for private life and the protection of personal data in electronic communications and repealing Directive 2002/58/EC \(Regulation on Privacy and Electronic Communications\)](#) (COM(2017)0010 – C8-0009/2017 – 2017/0003(COD)).

4. KEY POLICY DEVELOPMENTS AND FUTURE CHALLENGES

KEY FINDINGS

This section provides an overview of EU policy developments and challenges relevant to the public health mandate of the ENVI Committee. Some of the described developments might lead to future (legislative) policy procedures that will be referred to the Parliament. Other developments and challenges may be considered for further engagement on the initiative of the Committee and its Members.

Most of the public health-relevant developments and challenges described below are closely interlinked with the EU's overarching strategic priorities, especially as described in the Political Guidelines for the 2019-2024 Commission, the Mission Letters to the Commissioner-designates, and the Commission's proposed strategic approach to implementing the Sustainable Development Goals (SDGs).

The developments and challenges described also derive from Commission reports and evaluations, calls for action from Council Conclusions and Parliament Reports and Resolutions, from EU action plans and strategies, and linked to key international developments, among others.

4.1. Health Systems

4.1.1. Human medicinal products

Access to medicines. Concerns over the affordability of some new medicines and the challenges they pose for the sustainability of healthcare systems have put medicines high on the political agenda during the past five years. In 2017, the Parliament adopted a Resolution on options for improving access to medicines.⁹¹ In 2016, Council Conclusions were adopted on strengthening the balance in the EU's pharmaceutical systems.⁹² Successive EU Presidencies prioritised access to medicines and several Member States have joined forces in regional initiatives to negotiate together the pricing and procurement of new medicines, such as BeNeLuxAI⁹³ and the Valletta Declaration Group of countries.⁹⁴

Two key medicines-related legislative initiatives were launched during the last mandate: a Regulation on Health Technology Assessment (HTA), still ongoing, and a Regulation for a Supplementary Protection Certificate Manufacturing Waiver,⁹⁵ now completed. Also, evidence was developed on the role and impact of intellectual property (IP) incentives in medicine development,^{96 97} which is important for encouraging an effective and appropriate use of incentives, including in the development of new

⁹¹ European Parliament resolution of 2 March 2017 on EU options for improving access to medicines ([2016/2057\(INI\)](#)).

⁹² Council of the European Union (2016) [Council Conclusions on Strengthening the Balance in the Pharmaceutical Systems in the EU and its Member States](#).

⁹³ [The Benelux Initiative on Pharmaceutical Policy](#) website.

⁹⁴ Council of the European Union, 14574/17, [Meeting of the Employment, Social Policy, Health and Consumer Affairs Council. Pharmaceutical policy in the EU – current state and future perspectives: Exchange of views](#).

⁹⁵ European Parliament Legislative Observatory [Procedure 2018/0160\(COD\) Supplementary protection certificate for medicinal products](#).

⁹⁶ Copenhagen Economics (2018) [Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe](#). Study for the European Commission.

⁹⁷ Max Planck Institute for Innovation and Competition (2018) [Study on Supplementary Protection Certificates](#). Study for the European Commission.

antibiotics.⁹⁸ Ensuring the supply of affordable medicines and an innovative pharmaceutical industry will be major priorities for the future Health Commissioner.⁹⁹

Medicines shortages. Several recent surveys point at increasing concerns about shortages of certain medicines.^{100 101 102} In 2019, the French Ministry of Health published a Roadmap to tackle medicine shortages.¹⁰³ In 2019, the European Medicines Agency's (EMA) Task Force on the Availability of Authorised Medicines for Human and Veterinary Use¹⁰⁴ issued a guidance on the detection and notification of shortages of medicinal products,¹⁰⁵ and a good practice guidance for communication to the public on medicines availability issues.¹⁰⁶ Potential medicines shortages and their causes may require further examination.

Rare diseases and children. In 2017, the Commission launched an evaluation of the EU legislation on medicines for children and rare diseases,¹⁰⁷ focused on the Regulations on Orphan Medicinal Products¹⁰⁸ and on Paediatric Medicines.¹⁰⁹ In 2019, an EU conference was held on rare diseases and children, addressing this evaluation.¹¹⁰ The Commission is expected to publish a Staff Working Document on the evaluation by the end of 2019.

Other developments related to human medicinal products. Other questions related to human medicinal products currently overseen by the Commission's Public Health and Food Safety Directorate General, and often supported by the EMA and its specialist committees, are worth mentioning and monitoring.

These include the areas of **clinical trials**, in particular the implementation of the 2014 Clinical Trials Regulation,¹¹¹ the application of which has been postponed from 2018 to 2020 due to technical difficulties;¹¹² the ongoing development of guidelines and agreements on **good manufacturing and distribution practices**,¹¹³ the activities to tackle **falsified medicines**,¹¹⁴ and **international cooperation** in the sphere of pharmaceuticals.¹¹⁵ It also concerns activities on **pharmacovigilance** following the application of new rules in 2012 to reduce the risk of adverse reactions from medicinal products.¹¹⁶ The latest regular Commission report on pharmacovigilance activities however dates back

⁹⁸ WHO, [UN Interagency Coordination Group \(IACG\) on Antimicrobial Resistance](#).

⁹⁹ European Commission (2019) [President-elect von der Leyen's Mission Letter to Stella Kyriakides](#).

¹⁰⁰ European Association of Hospital Pharmacists (2018) [2018 Medicines Shortages Survey](#).

¹⁰¹ France Assoc Santé (2019) [Enquête CSA pour France Assos Santé : les Français veulent une Europe plus forte et plus protectrice en matière de santé](#).

¹⁰² Ministry of Health, Romania [Medicamente Lipsa \(beta\)](#).

¹⁰³ Ministère des Solidarités et de la Santé (2019) [Lutter contre les pénuries et améliorer la disponibilité des médicaments en France](#). Présentation de la feuille de route 2019-2022.

¹⁰⁴ Heads of Medicines Agencies, [HMA/EMA Task Force on Availability of Authorised Medicines for Human and Veterinary Use](#).

¹⁰⁵ Heads of Medicines Agencies and European Medicines Agency (2019) [Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders \(MAHs\) in the Union \(EEA\)](#).

¹⁰⁶ Heads of Medicines Agencies and European Medicines Agency (2019) [Good practice guidance for communication to the public on medicines' availability issues](#).

¹⁰⁷ European Commission, [Evaluation of the legislation on medicines for children and rare diseases \(medicines for special populations\)](#)

¹⁰⁸ [Regulation \(EC\) No 141/2000 on orphan medicinal products](#).

¹⁰⁹ [Regulation \(EC\) No 1901/2006 on medicinal products for paediatric use](#).

¹¹⁰ European Commission (2019) Report of Conference [Medicines for Rare Diseases and Children: Learning from the Past, Looking to the Future](#).

¹¹¹ [Regulation \(EU\) No 536/2014 on clinical trials on medicinal products for human use](#).

¹¹² European Commission, [Medicinal products: Clinical Trials](#).

¹¹³ European Commission, [Medicinal products: Good Manufacturing and Distribution Practices](#).

¹¹⁴ European Commission, [Medicinal products: Falsified medicines](#).

¹¹⁵ European Commission, [Medicinal products: International cooperation on pharmaceuticals](#).

¹¹⁶ European Parliament Legislative Observatory [Procedure 2008/0260\(COD\)](#) Medicinal products for human use: pharmacovigilance of products.

to 2016, covering the years 2012-2014.¹¹⁷ **Brexit** may affect issues such as medicines shortages, pharmacovigilance activities and other areas (see Brexit section).

The relationship between the **EMA** and pharmaceutical companies was recently investigated by the European Ombudsman.¹¹⁸ It remains to be seen which of the Ombudsman's recommendations will be taken on board by the Agency.¹¹⁹ The leadership of the Agency will change as the mandate of the current Executive Director is coming to an end in November 2020.

4.1.2. Medical devices

Implementation of the medical devices Regulations. In 2017, two Regulations on medical devices were adopted, one on medical devices (Medical Devices Regulation),¹²⁰ and one on in-vitro diagnostic medical devices,¹²¹ with the aim to improve the functioning of the internal market on medical devices and better ensure their safety. The first Regulation will apply from May 2020, the second from 2022.¹²²

The Medical Devices Regulation, among others, establishes new mechanisms for the certification of medical devices, provides for the establishment of a European database on medical devices (Eudamed) and introduces changes to the system of notified bodies, which are bodies designated to carry-out conformity assessment procedures prior to placing medical devices on the market. Currently, there is some debate about whether sufficient notified bodies will be in place by May 2020 to ensure availability of devices.¹²³ Addressing the effective implementation of the medical devices Regulations will be a priority for the new Health Commissioner.¹²⁴ Also notable is that the medical devices portfolio will move back from Internal Market, to the Health Directorate.¹²⁵

4.1.3. Cross-border healthcare

Implementation of the Cross-border Healthcare Directive. The next regular report by the Commission on the implementation of the Directive on the Application of Patients' Rights in Cross-border Healthcare¹²⁶ is due in 2021. The Directive establishes the legal framework for patients to receive health services and information about health services in another Member State, and on the reimbursement of such services.

A 2019 special report by the European Court of Auditors assesses several aspects of the implementation of the Directive, and makes recommendations, among others on the Commission's support for National Contact Points, the cross-border exchanges of health data, and activities in the field European Reference Networks.¹²⁷ Also in 2019, the Parliament adopted a Resolution on the implementation of the Cross-Border Healthcare Directive, with suggestions for improvements.¹²⁸

¹¹⁷ European Medicines Agency, [Implementation of the pharmacovigilance legislation](#).

¹¹⁸ European Ombudsman (2017) [Decision in strategic inquiry OI/7/2017/KR on how the European Medicines Agency engages with medicine developers in the period leading up to applications for authorisations to market new medicines in the EU](#).

¹¹⁹ European Medicines Agency (2019) [EMA takes note of the European Ombudsman's decision on pre-submission activities](#).

¹²⁰ European Parliament Legislative Observatory [Procedure 2012/0266\(COD\) Medical devices](#).

¹²¹ European Parliament Legislative Observatory [Procedure 2012/0267\(COD\) In vitro medical devices](#).

¹²² European Commission (2019) [Transition Timelines from the Directives to the Regulations - Medical Devices and in vitro Diagnostic Medical Devices](#).

¹²³ European Parliament (2018) [Debate: Implementation of the Medical devices and In-vitro diagnostic medical devices Regulations](#).

¹²⁴ European Commission (2019) [President-elect von der Leyen's Mission Letter to Stella Kyriakides](#).

¹²⁵ European Commission, [Medical Devices](#).

¹²⁶ [Directive 2011/24/EU on the application of patients' rights in cross-border healthcare](#).

¹²⁷ European Court of Auditors (2019) [Special report no 07/2019: EU actions for cross-border healthcare](#).

¹²⁸ [European Parliament resolution of 12 February 2019 on the implementation of the Cross-Border Healthcare Directive](#) (2018/2108(INI)).

4.1.4. Vaccination

Vaccine hesitancy. Growing concern about dwindling vaccination coverage rates and outbreaks of vaccine-preventable diseases, such as measles, has prompted increased EU activity to restore trust and increase immunisation.¹²⁹ In 2018, the Commission published a Communication on Strengthened Cooperation Against Vaccine Preventable Diseases,¹³⁰ and launched a Joint Action on Vaccination.¹³¹ In 2018, the Parliament adopted a Resolution on vaccine hesitancy calling, among others, for a comprehensive EU Action Plan to strength action in this area.¹³²

Council Recommendations of 2018 aim to tackle vaccine hesitancy by improving coordination on procurement, supporting research and innovation, and strengthening EU cooperation on vaccine-preventable diseases, while calling on Member States to develop and implement national vaccination plans.¹³³ One of the follow-up actions from these recommendations was the creation of a vaccine coalition of health professionals in 2019.¹³⁴ In 2019, the Commission summarised different actions to be taken on vaccination in a Roadmap towards 2020.¹³⁵ A Global Vaccination Summit with the WHO was held in Brussels in September 2019.¹³⁶ Addressing vaccine hesitancy will be a priority for the future Health Commissioner.¹³⁷

4.1.5. Health workforce

Action Plan on EU Health Workforce. The 2012 Action Plan on the EU Health Workforce will expire in 2020.¹³⁸ A renewal and update of the action plan may be considered in order to reflect learnings from the EU Joint Action on Health Workforce Planning and Forecasting¹³⁹ and the Support for the Health Workforce Planning and Forecasting Expert Network.¹⁴⁰ Issues covered in these initiatives include professional development, ethical cross-border recruitment, workforce retention and ensuring the provision of high quality patient care. Enhanced alignment with the WHO Code of Practice on the International Recruitment of Health Personnel may also be considered.¹⁴¹

Cross-border mobility of health professionals. The next Commission report on the implementation of the Professional Qualifications Directive,¹⁴² which supports the free movement of professionals, including health workers, is due in 2022. This provides an opportunity to consider whether there is need to update the list with evidence of formal qualifications for medical professionals to ensure better mutual recognition of qualifications.

¹²⁹ European Commission, [Vaccination](#).

¹³⁰ Commission Communication (2018) [Strengthened Cooperation against Vaccine Preventable Diseases](#) COM/2018/245 final

¹³¹ [European Joint Action on Vaccination](#).

¹³² [European Parliament resolution of 19 April 2018 on vaccine hesitancy and the drop in vaccination rates in Europe](#) (2017/2951(RSP)).

¹³³ Council of the EU, 2018/C 466/01, [Council Recommendation of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases](#).

¹³⁴ Standing Committee of European Doctors (2019) [A new Coalition for Vaccination brings together healthcare professionals](#).

¹³⁵ European Commission (2019) [Roadmap for the Implementation of Actions by the European Commission based on the Commission Communication and the Council Recommendation on Strengthening Cooperation Against Vaccine Preventable Diseases 2019-2022](#).

¹³⁶ European Commission (2019) [Global Vaccination Summit](#).

¹³⁷ European Commission (2019) [President-elect von der Leyen's Mission Letter to Stella Kyriakides](#).

¹³⁸ European Commission (2012) [Commission Staff Working Document on an Action Plan for the EU Health Workforce](#). European Commission.

¹³⁹ [EU Joint Action on Health Workforce Planning & Forecasting](#).

¹⁴⁰ [Support for the health workforce planning and forecasting expert network](#).

¹⁴¹ WHO (2010) [WHO Global Code of Practice on the International Recruitment of Health Personnel](#).

¹⁴² [Directive 2005/36/EC on the recognition of professional qualifications](#).

In 2020, the Proportionality Test Directive, adopted in 2018, will have to be transposed into national laws.¹⁴³ The Directive aims to ensure that national rules organising access to regulated professions do not constitute an unjustified or disproportionate barrier to the exercise of the free movement of workers and the free movement of establishment of professionals. The Directive accords special status to healthcare professionals, giving discretion to Member States to ensure that a high level of health protection is respected when regulating such professions.

A procedure on the revision of the Blue Card Directive, which aims to provide a streamlined procedure to attract and retain highly skilled non-EU nationals, including healthcare professionals, is currently frozen.¹⁴⁴

Complementary and alternative medicines sector. A sub-group of health workers are active in the complementary and alternative medicines (CAM) sector, which includes a broad group of medical systems, products and practices. The relationship between CAM and the main health systems varies between Member States.¹⁴⁵ Ongoing debates about CAM¹⁴⁶ may warrant further strengthening of the evidence base, especially regarding the effectiveness and health and well-being outcomes of different modalities.^{147 148}

4.1.6. Blood, tissues, cells and organs

Evaluation of EU blood, tissues and cells legislation. In 2017, the Commission published a Road map to evaluate the EU's blood, tissues and cells legislation,¹⁴⁹ in particular the 2002 Directive on Human Blood and Blood Components,¹⁵⁰ and the 2004 Directive on Human Tissues and Cells.¹⁵¹ Blood, tissues and cells donated by humans play an important role in the provision of healthcare services. The evaluation seeks to establish, among others, whether the current provisions are still up to date in view of technological and scientific developments, and whether they provide for adequate quality and safety standards. The results of the evaluation are expected to be published in autumn 2019.

4.1.7. Personalised medicine and genomics

Personalised medicine. Personalised medicine is a developing area of research and practice closely linked to digitalisation (see section Health in the digital era) aimed at improving the effectiveness of treatments.¹⁵² Personalised medicine has been described as "a medical model using characterization of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention".¹⁵³

¹⁴³ [Directive \(EU\) 2018/958 on a proportionality test before adoption of new regulation of professions.](#)

¹⁴⁴ European Parliament Legislative Observatory [Procedure 2016/0176\(COD\). Conditions of entry and residence of third-country nationals for the purposes of highly skilled employment.](#)

¹⁴⁵ [Cambrella: European research network for complementary and alternative medicine website.](#)

¹⁴⁶ Ministère des Solidarités et de la Santé (2019) [Médicaments homéopathiques : Agnès BUZYN suivra l'avis de déremboursement rendu par la Haute Autorité de Santé.](#)

¹⁴⁷ European Parliament Directorate General for Internal Policies: Policy Department A: Economic and Scientific Policy (2017) [Workshop: Complementary and Alternative Therapies for Patients Today and Tomorrow.](#)

¹⁴⁸ WHO (2013) [WHO traditional medicine strategy: 2014-2023.](#)

¹⁴⁹ European Commission, [Blood, tissues, cells and organs: Evaluation of the EU blood and tissues and cells legislation.](#)

¹⁵⁰ [Directive 2002/98/EC on setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.](#)

¹⁵¹ [Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.](#)

¹⁵² European Parliament Policy Department A: Economic and Scientific Policy (2017) [Personalised Medicine - Current Status.](#)

¹⁵³ European Commission, [Personalised Medicine.](#)

Council Conclusions from 2015 on personalised medicine provide a range of recommendations to encourage developments in this area.¹⁵⁴

Genomics. The WHO defines Genomics as the study of genes and their functions, and related techniques.¹⁵⁵ Genomics are important for the development of personalised medicine, better diagnostics and, potentially, the sustainability of health systems. Despite being a health intervention, at EU level genomics policy falls under the EU Digital Single Market. An important EU initiative in genomics is the 1+ Million Genomes Initiative, which was launched in 2018.¹⁵⁶ An overview of national legislation on genomics in the EU was published in 2018.¹⁵⁷

As an evolving area, significant developments are still required in the area of personalised medicine before the opportunities of this approach can be fully exploited. Another challenge is to ensure that developments and research demands in personalised medicines and genomics do not overshadow attention to existing effective health interventions,¹⁵⁸ or compromise individual rights.^{159 160}

4.2. Disease prevention, health promotion

4.2.1. Communicable diseases

The incidence of infectious diseases has decreased in high-income countries over the last century, but recent disease outbreaks have led to renewed attention. A 2018 study for the European Centre for Disease Prevention and Control (ECDC) estimates that the leading communicable diseases, in 2011, led to over 37 million disease cases and 48,000 deaths across the EU. The leading three infectious diseases were influenza, tuberculosis and HIV/AIDS.¹⁶¹

HIV/AIDS, tuberculosis and viral hepatitis. In 2017, the Parliament adopted a Resolution calling on the Commission and Member States to develop a comprehensive EU policy framework addressing HIV/AIDS, tuberculosis (TB) and viral hepatitis.¹⁶² It also urges the EU to play a strong role in dialogue with neighbouring countries in Eastern Europe and Central Asia. The 2014 Action Plan on HIV/AIDS in the EU and Neighbouring Countries,¹⁶³ introduced to support the implementation of the 2009 Commission Communication on combating HIV/AIDS,¹⁶⁴ expired in 2016 and has not been renewed. No action plan exists for the other two diseases. In 2018, the Commission issued a staff working document providing an overview of initiatives to support EU and neighbouring countries' response to the three diseases.¹⁶⁵

¹⁵⁴ Council of the EU (2015) [Council Conclusions on personalised medicine for patients](#).

¹⁵⁵ WHO, Human Genomics in Global Health, [WHO definitions of genetics and genomics](#).

¹⁵⁶ European Commission, [European '1+ Million Genomes' Initiative](#).

¹⁵⁷ Angers et al. (2018) [Overview of EU National Legislation on Genomics](#). European Commission Joint Research Centre.

¹⁵⁸ Coote and Joyner (2015) [Is precision medicine the route to a healthy world?](#) Correspondence. The Lancet.

¹⁵⁹ Kulynich (2017) [Is privacy the price of precision medicine?](#) Oxford University Press Blog.

¹⁶⁰ European Union Agency for Fundamental Rights (2017) [Fundamental rights and the interoperability of EU information systems: borders and security](#).

¹⁶¹ Cassini et al. on behalf of the BCoDE consortium (2018) [Impact of infectious diseases on population health using incidence-based disability-adjusted life years \(DALYs\): results from the Burden of Communicable Diseases in Europe study, European Union and European Economic Area countries, 2009 to 2013](#). Euro Surveillance.

¹⁶² [European Parliament resolution of 5 July 2017 on the EU's response to HIV/AIDS, Tuberculosis and Hepatitis C \(2017/2576\(RSP\)\)](#).

¹⁶³ European Commission, SWD(2014) 106 final, [Action Plan on HIV/AIDS in the EU and neighbouring countries: 2014-2016](#).

¹⁶⁴ Commission Communication, COM/2009/0569 final, [Combating HIV/AIDS in the European Union and neighbouring countries, 2009 - 2013](#).

¹⁶⁵ European Commission, SWD(2018) 387 final, [Commission Staff Working Document on Combatting HIV/AIDS, viral hepatitis and tuberculosis in the European Union and neighbouring countries -State of play, policy instruments and good practices](#).

Drugs. The 2013 EU Drugs Strategy¹⁶⁶ and the 2017 EU Action Plan on Drugs will expire in 2020.¹⁶⁷ A 2016 mid-term evaluation of the current Drugs Strategy found that the strategy and the periodically renewed action plans provide added value to Member States. It also contains recommendations by stakeholders for further improvements. The study further highlights certain issues that could be addressed in a strategy beyond 2020, including the changes in the types of new psychoactive substances available, the changing techniques for trafficking drugs, and the trend of discussing drugs in the context of wider addiction strategies, covering both legal substances, such as tobacco, alcohol and prescription drugs, illegal substances and non-drug related addictive behaviours, such as gambling.¹⁶⁸

Cross-border threats to health. The 2013 Decision on Serious Cross-border Threats to Health¹⁶⁹ provides the framework for EU action related to crisis preparedness and response. Activities focus on the monitoring, early warning and response to cross-border health threats, especially related to, though not limited to, communicable diseases. The approach includes an Early Warning and Response System (EWRS), operated by the ECDC, and a Health Security Committee (HSC) which coordinates responses to outbreaks and pandemics, both within and outside the EU.¹⁷⁰

Topics discussed within the HSC include antimicrobial resistance (AMR), vaccination, joint procurement of medical countermeasures to health threats, such as vaccines and anti-toxins, biological and chemical terrorist attacks, Ebola, the Civil Protection Mechanism and others.^{171 172 173} Developments such as climate change are widely associated with increased risks of infectious diseases and other health threats, such as forest fires.¹⁷⁴

4.2.2. Antimicrobial resistance

A 2018 study estimates that 33,000 people die annually in the EU and the European Economic Area (EEA) due to infections with antibiotic-resistant bacteria.¹⁷⁵ According to a 2019 UN-backed report, if no urgent action is taken to contain the threat of antimicrobial resistance (AMR), it could cause 10 million global deaths annually by 2050.¹⁷⁶ Additionally, the World Bank estimates that by 2030, AMR could push 24 million people into extreme poverty and between 1.1-3.8% of global GDP could be lost due to AMR if left unchecked.¹⁷⁷

Global and National Action Plans on AMR. In 2015, all WHO Member States committed to a Global Action Plan on AMR,¹⁷⁸ which called for the adoption of AMR National Action Plans (NAPs) by mid-2017.

¹⁶⁶ European Monitoring Centre for Drugs and Drug Addiction (2012) [EU Drugs Strategy \(2013-2020\)](#).

¹⁶⁷ [EU Action Plan on Drugs 2017-2020](#).

¹⁶⁸ Balbirnie et al. (2016) [Mid-Term Assessment of the EU Drugs Strategy 2013–2020 and Final Evaluation of the Action Plan on Drugs 2013–2016: Final Report](#) Report for the European Commission.

¹⁶⁹ [Decision No 1082/2013/EU on serious cross-border threats to health](#).

¹⁷⁰ European Commission, [Communicable Diseases](#).

¹⁷¹ European Commission (2019) [Flash report of the Plenary Meeting of the Health Security Committee 3-4 July 2019, Senningen/Luxembourg](#).

¹⁷² European Commission (2018) [Flash report from the Plenary Meeting of the Health Security Committee \(HSC\) 14 December 2018, Senningen/Luxembourg](#).

¹⁷³ European Commission (2018) [Flash report from the Plenary Meeting of the Health Security Committee \(HSC\) 14 December 2018, Senningen/Luxembourg](#).

¹⁷⁴ European Academies' Science Advisory Council (2019) [The imperative of climate action to protect human health in Europe](#).

¹⁷⁵ Cassini et al. (2018) [Attributable deaths and disability-adjusted life-years caused by infections with antibiotic-resistant bacteria in the EU and the European Economic Area in 2015: a population-level modelling analysis](#). The Lancet.

¹⁷⁶ Report to the Secretary-General of the United Nations (2019) [No Time to Wait: Securing the future from drug-resistant infections](#), WHO.

¹⁷⁷ World Bank Group (2017) [Drug-Resistant Infections: A Threat to Our Economic Future](#).

¹⁷⁸ WHO (2015) [Global Action Plan on Antimicrobial Resistance](#).

This commitment was reiterated in subsequent political declarations, including 2016 Council Conclusions calling for a comprehensive One Health approach to fighting AMR.¹⁷⁹ More recently in June 2019, the Council adopted Conclusions proposing next steps for making the EU a best practice region in combating AMR, focusing among others on improving data collection, funding, and supporting Member States to overcome the barriers to NAP development and implementation.¹⁸⁰

European One Health Action Plan. In 2017, the Commission adopted the European One Health Action Plan against AMR,¹⁸¹ and as part of its actions, launched an EU AMR One Health Network to act as a platform for Member States and EU agencies to share AMR developments and good practices.¹⁸² The action plan prompted the Parliament to adopt a Resolution in 2018, calling, amongst others, on the Commission to publish a mid-term and ex-post evaluation of the action plan. It also urged the Commission to be “more ambitious in any future action plan it develops,” including in the use of legislative tools and funding.¹⁸³

The full implementation of the European Action Plan against AMR is highlighted among key public health priorities of the next Commission in the Mission Letter addressed to Commissioner-designate for Health.¹⁸⁴ The Commission has also signalled the importance of its role in advocating for a global agreement on the use of and access to antimicrobials. The Commission issues regular progress reports of the implementation of the European Action Plan, which remains in effect until 2022.¹⁸⁵ The European Court of Auditors is currently conducting an audit on key EU activities to tackle AMR and seeks to provide recommendations on how to improve the implementation of the AMR Action Plan.¹⁸⁶

Animal medicines package. In 2019, two Regulations were adopted addressing antibiotics use in farm animals, one on Veterinary Medicinal Products, with ENVI as committee responsible,¹⁸⁷ and one on Medicated Feed, with AGRI as committee responsible.¹⁸⁸ These Regulations are important milestones in the fight against AMR and will apply from 2022, a process that should be accompanied by the adoption of several delegated and implementing acts.

Pharmaceuticals in the environment. In 2019, the Commission released the Strategic Approach to Pharmaceuticals in the Environment, committing to actions in six areas across the entire lifecycle of pharmaceuticals, from design and production to disposal and waste management. Tackling antimicrobials in the environment is one of the pillars in the fight against AMR.¹⁸⁹

4.2.3. Non-communicable diseases

Non-communicable diseases (NCDs), also known as chronic diseases, encompass a wide variety of physical and mental medical conditions that are not caused by infectious agents. They are by far the

¹⁷⁹ Council of the European Union, 2016/C 269/05, [Council Conclusions on the next steps under a One Health approach to combat antimicrobial resistance](#).

¹⁸⁰ Council of the European Union, 2019/C 214/01, [Council Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance](#).

¹⁸¹ European Commission (2017) [A European One Health Action Plan against Antimicrobial Resistance \(AMR\)](#).

¹⁸² European Commission, [AMR One Health Network](#).

¹⁸³ [Motion for a European Parliament Resolution \(2018\) on a European One Health Action Plan against Antimicrobial Resistance \(AMR\) \(2017/2254\(INI\)\)](#).

¹⁸⁴ European Commission (2019) [President-elect von der Leyen's Mission Letter to Stella Kyriakides](#).

¹⁸⁵ European Commission (2019) [Progress Report 2017 EU AMR Action Plan](#).

¹⁸⁶ European Court of Auditors (2019) [Audit preview: EU action to fight antimicrobial resistance](#).

¹⁸⁷ European Parliament Legislative Observatory [Procedure File 2014/0257\(COD\) Veterinary medicinal products](#).

¹⁸⁸ European Parliament Legislative Observatory [Procedure File 2014/0255\(COD\) Medicated feed: manufacture, placing on the market and use](#).

¹⁸⁹ Commission Communication (2019) [European Union Strategic Approach to Pharmaceuticals in the Environment](#) COM(2019) 128 final.

leading cause of disease and mortality in the EU.¹⁹⁰ Approximately €700 billion is spent each year on treating NCDs across EU countries.¹⁹¹ More than half a million people under the age of 65 die of NCDs in the EU annually.¹⁹² Many NCDs are to a considerable degree preventable or their development can be delayed.¹⁹³

Cancer. The 2009 Commission Communication on a European Partnership for Action Against Cancer includes a target to reduce the burden of cancer in the EU with 15% by 2020.¹⁹⁴ A Mission Board on Cancer was established in 2019 to support the implementation of Horizon Europe, the next EU research and innovation programme.¹⁹⁵ The Political Guidelines for the 2019-2024 Commission refer to the introduction of a European plan to fight cancer,¹⁹⁶ and the Mission Letter to the Commissioner-designate for Health contains as a priority the creation of a “Beating Cancer Plan” to strengthen cancer prevention and care across all stages of the disease.¹⁹⁷

Non-communicable diseases. The WHO classifies cancer as a major NCD, alongside cardiovascular diseases, diabetes and respiratory diseases, as well as mental ill-health.¹⁹⁸ These, as well as other NCDs, share a limited number of main risk factors,¹⁹⁹ namely tobacco and alcohol use, unhealthy diet, lack of physical activity and exposure to air pollution,²⁰⁰ as well as other chemical pollutants.²⁰¹ ²⁰² Obesity also represents an important risk factor for NCDs.²⁰³

In 2018, at the Third United Nations (UN) High Level Meeting on NCDs, governments worldwide, as well as the EU, committed to accelerate action on NCD prevention and control, with a comprehensive review meeting foreseen for 2025.²⁰⁴ In 2016 the Commission established an EU Steering Group on Health Promotion, Disease Prevention and Management of NCDs;²⁰⁵ several Joint Actions relevant for NCDs are either ongoing,²⁰⁶ finalised,²⁰⁷ ²⁰⁸ or upcoming;²⁰⁹ and different EU agencies, such as the European Agency for Safety and Health at Work (OSHA), are pursuing NCD-related priorities.²¹⁰

¹⁹⁰ European Commission Joint Research Centre, [EU burden from non-communicable diseases and key risk factors](#).

¹⁹¹ European Commission (2014) [The 2014 EU Summit on Chronic Diseases](#). Conference Conclusions.

¹⁹² OECD/EU (2016) [State of Health in the EU. Health at a Glance: Europe 2016](#).

¹⁹³ WHO/Europe (2016) [Action Plan for the Prevention and Control of Noncommunicable Diseases in the WHO European Region 2016–2025](#)

¹⁹⁴ Commission Communication (2009) [Action Against Cancer: European Partnership](#) COM/2009/0291 final.

¹⁹⁵ European Commission (2019) [Commission invites top experts to shape new research and innovation missions](#).

¹⁹⁶ Von der Leyen (2019) [A Union that strives for more. My Agenda for Europe](#): Political Guidelines for the Next European Commission 2019-2024.

¹⁹⁷ European Commission (2019) [President-elect von der Leyen’s Mission Letter to Stella Kyriakides](#).

¹⁹⁸ United Nations General Assembly (2018) Political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable diseases. [Time to deliver: accelerating our response to address non-communicable diseases for the health and well-being of present and future generations](#).

¹⁹⁹ “A risk factor is any attribute, characteristic or exposure of an individual that increases the likelihood of developing a disease or injury.” WHO, [Risk Factors](#).

²⁰⁰ WHO/Europe (2016) [Action Plan for the Prevention and Control of Non-communicable Diseases in the WHO European Region 2016–2025](#)

²⁰¹ WHO (2016) [Public health impact of chemicals: knowns and unknowns](#).

²⁰² There are additional main risk factors for mental ill-health. See for instance the [EU-Compass for Action on Mental Health and Well-being](#)

²⁰³ WHO, [Global Health Observatory \(GHO\) data: Non-communicable diseases](#).

²⁰⁴ United Nations General Assembly (2018) Political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable diseases. [Time to deliver: accelerating our response to address non-communicable diseases for the health and well-being of present and future generations](#).

²⁰⁵ European Commission, [Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases](#).

²⁰⁶ [CHRODIS+](#)

²⁰⁷ [Joint Action Mental Health and Well-being](#).

²⁰⁸ [Joint Action on Nutrition and Physical Activity](#).

²⁰⁹ European Commission (2019) [Flash Report: Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases](#).

²¹⁰ European Agency for Safety and Health at Work, [Future Campaigns](#), Focus on musculoskeletal disorders.

Draft Council Conclusions on the Economy of Well-being, to be adopted later in 2019, call for the introduction of a Mental Health Strategy for the EU. They also highlight the need for cross-sectoral policy cooperation to tackle the determinants of the burden of NCDs in order to promote people's well-being and address the growth in health expenditures.²¹¹ There appear to be opportunities to explore the pursuit of a synergistic approach for tackling cancer together with other NCDs.

4.2.4. Tobacco

Tobacco is the single largest avoidable health risk, responsible for nearly 700,000 deaths in the EU every year. Approximately half of smokers die prematurely.²¹²

Tobacco Products Directive. The WHO Framework Convention on Tobacco Control (FCTC) entered into force in 2005 and is the first legally binding international health treaty to which the EU and all Member States are party.²¹³ Signatories are required to implement a wide range of tobacco demand and supply reduction measures. In 2021, the Commission is due to publish a report on the implementation of the Tobacco Products Directive (TPD), which was adopted in 2014 and started applying from 2016.²¹⁴ This report presents an opportunity to discuss implementation and consider the need for any potential further measures.

Tobacco Tax Directive. In 2019, the Commission is due to publish a report on the EU Tobacco Tax Directive.²¹⁵ This report presents an opportunity to assess whether taxation, described as the single most effective tobacco control measure,²¹⁶ has been applied to its full potential within the EU.

Illicit tobacco trade. In 2018, the Commission published the second Action Plan to Fight Illicit Tobacco Trade until 2022.²¹⁷ The 2021 Commission report on the TPD, referred to above, is also meant to include an assessment of the EU's tracking and tracing system. In 2023, the global tracking and tracing regime under the Protocol to Eliminate Illicit Trade in Tobacco Products will come into effect.²¹⁸ By that date, the EU's system will need to be compliant and interoperable with the global level, which may require the introduction of a third action plan. In the context of these developments, also notable are the EU's ongoing agreements with three major tobacco manufacturers aimed at tackling contraband and counterfeiting of tobacco products.²¹⁹

4.2.5. Alcohol

The 2019 WHO status report on alcohol finds that despite some improvements in alcohol-related death rates, in 2016, over 290,000 people died in the EU, Norway and Switzerland from alcohol-attributable diseases. In the age group 20 to 24 years, almost a quarter of all deaths was caused by alcohol. The report highlights that previously observed reductions in heavy episodic drinking patterns seem to have come to a halt.²²⁰

²¹¹ Council of the European Union (2019) [Draft Council Conclusions: The Economy of Wellbeing](#).

²¹² European Commission, [Tobacco](#).

²¹³ [WHO Framework Convention on Tobacco Control](#).

²¹⁴ [Directive 2014/40/EU 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](#).

²¹⁵ [Council Directive 2011/64/EU on the structure and rates of excise duty applied to manufactured tobacco](#).

²¹⁶ WHO (2019) [WHO Report on the global tobacco epidemic 2019](#).

²¹⁷ Commission Communication, COM(2018) 846 final, [Fight the illicit tobacco trade 2018-2022. Second action plan](#).

²¹⁸ Conference of the Parties to the WHO FCTC (2013) [Protocol to Eliminate Illicit Trade in Tobacco Products](#).

²¹⁹ European Anti-Fraud Office, [Tobacco smuggling](#).

²²⁰ WHO/Europe (2019) [Status report on alcohol consumption, harm and policy responses in 30 European countries 2019](#).

EU alcohol strategy. The EU Alcohol Strategy was introduced in 2006 and expired in 2012.²²¹ It has not been updated, despite calls from the Council^{222 223} and Parliament²²⁴ for its renewal in 2015 and 2017. The effectiveness of the EU Alcohol and Health Forum²²⁵ is currently being evaluated.

In parallel, there have been increasing calls from health professionals for the development of a WHO Framework Convention on Alcohol, along the same lines as the FCTC.²²⁶ In 2017, the Swedish Government Commission on Equity in Health proposed initiating a European discussion on such a Convention.²²⁷ In its 2018 global report on alcohol and health the WHO noted that “alcohol remains the only psychoactive and dependence-producing substance with significant global impact on population health that is not controlled at the international level by legally-binding regulatory frameworks”.²²⁸

Nutrition and ingredient labelling. The Regulation on the Provision of Food Information to Consumers (FICR), adopted in 2011,²²⁹ exempts alcoholic beverages containing more than 1.2% by volume of alcohol from the mandatory listing of ingredients and the nutrition declaration. In 2017, the Commission adopted a report finding no “objective grounds” to justify the absence of such information on alcoholic drinks, and inviting the alcoholic beverages industry to present within one year a self-regulatory proposal that would cover the entire sector and would respond to consumers’ expectations.²³⁰ The industry has produced a joint self-regulatory proposal with specific annexes for different subsectors.²³¹ The Commission is currently evaluating these proposals.

Alcohol taxation and cross-border movement. In 2018, the Commission published two proposals on alcohol taxation: one concerning the Directive on General Arrangements for Excise Duties,²³² the other concerning the Directive on the Harmonisation of the Structures of Alcohol Excise Duties.²³³ The ENVI Committee was not invited to provide an opinion, and discussions are still ongoing in the Council. In 2019, the Commission launched a study into the rules for cross-border movements of alcohol and tobacco by travellers and distance buyers under the Directive on general arrangements for excise duties.²³⁴ Any potential legislative proposal from the study is likely to be referred to the Parliament and may warrant engagement of the ENVI Committee.

4.2.6. Nutrition

Eating well is a cornerstone of good health and well-being,²³⁵ however, today unhealthy diet is a leading risk factor for the entire burden of mortality and disease in the EU.²³⁶ The importance of tackling

²²¹ Commission Communication, COM/2006/0625 final, [An EU strategy to support Member States in reducing alcohol related harm](#).

²²² Council of the European Union, 2015/C 418/03, [Council Conclusions on an EU strategy on the reduction of alcohol-related harm](#).

²²³ Council of the European Union, 14082/17, [Council Conclusions: Cross-border aspects in alcohol policy](#).

²²⁴ [European Parliament resolution of 29 April 2015 on Alcohol Strategy](#) (2015/2543(RSP)).

²²⁵ European Commission, [Alcohol](#).

²²⁶ Yeung and Lam (2019) [Unite for a Framework Convention for Alcohol Control](#). Comment. The Lancet.

²²⁷ Slutbetänkande av Kommissionen för jämlik hälsa (2017) [Nästa steg på vägen mot en mer jämlik hälsa](#)

²²⁸ WHO (2018) [Global status report on alcohol and health 2018](#).

²²⁹ [Regulation \(EU\) No 1169/2011 on the provision of food information to consumers](#).

²³⁰ [Report from the Commission to the European Parliament and the Council regarding the mandatory labelling of the list of ingredients and the nutrition declaration of alcoholic beverages](#). European Commission. March 2011.

²³¹ European Commission, [Alcohol labelling](#).

²³² European Parliament Legislative Observatory [Procedure 2018/0176\(CNS\) General arrangements for excise duty. Recast](#).

²³³ European Parliament Legislative Observatory [Procedure 2018/0173\(CNS\) Alcohol and alcoholic beverages: harmonisation of the structures of excise duties](#).

²³⁴ European Commission (2018) [Third Programme for the Union’s action in the field of health \(2014–2020\): Work Programme for 2018](#)

²³⁵ WHO (2018) [Healthy diet. Factsheet No. 394](#).

²³⁶ Institute for Health Metrics and Evaluation. [Global Burden of Disease. EU, 2017, all ages, Risk factors for DALYs](#), based on the Global Burden of Disease study.

unhealthy food environments is widely discussed in the public health literature as a way to curb this trend.²³⁷

Nutrition and health claims. A REFIT procedure is ongoing on the Regulation on Nutrition and Health Claims, adopted in 2006.²³⁸ The procedure addresses whether or not to set nutrient profiles, which are mandatory under the Regulation but were never introduced. Nutrient profiles are meant to guide which foods can carry a claim so as not to mislead consumers. The procedure also addresses the establishment of an authorisation procedure for claims on plants and their preparations.

Front-of-pack nutrition labelling. The 2011 FICR²³⁹ required the Commission to deliver a report on ‘additional forms of expression’ used on food labels, such as front-of-pack (FOP) nutrition indications. The report is meant to address, among others, whether such additional forms of expression may need to be harmonised throughout the EU. The report is expected in 2019. Parallel developments, such as discussions in the Codex Alimentarius,²⁴⁰ the introduction of Nutriscore in France²⁴¹ and other countries, as well as a European Citizens’ Initiative²⁴² have increased the salience of the issue.

Foods for infants and young children. In 2020, new EU rules will apply prohibiting, among others, nutrition and health claims on infant formula and establishing general information requirements for young child feeding.²⁴³ In 2019 the WHO produced a report describing the European market situation for commercial foods for infants and young children, finding evidence of “widespread inappropriate promotion” of such foods.²⁴⁴ The 2018 European report on the national implementation of the International Code of Marketing of Breast-milk Substitutes, which also included a preliminary assessment of compliance with the 2016 WHO Guidance on Ending Inappropriate Promotion of Foods for Infants and Young Children,²⁴⁵ found there is much room for improvement in national policies to ensure child protection.²⁴⁶ An exploration of the needs, gaps and added value of further EU action to protect infants and young children from inappropriate marketing may be considered.

4.2.7. Chemicals

Chemicals are an integral part of every-day life, but some chemicals can severely damage human health or the environment.²⁴⁷ The health burden associated with endocrine disrupting chemicals (EDCs) has been found to be substantial, with an estimated monetary cost ranging from €46 to 288 billion per year.²⁴⁸

Non-toxic environment. The 2019 Commission reflection paper on the implementation of the SDGs towards 2030, prioritises a circular economy within a “toxic-free” environment as a strategic policy

²³⁷ [The Lancet Series on Obesity 2015.](#)

²³⁸ European Commission, [REFIT: Evaluation of the Regulation on nutrition and health claims.](#)

²³⁹ [Regulation \(EU\) No 1169/2011 on the provision of food information to consumers.](#)

²⁴⁰ European Commission (2019) [Codex Committee on Food Labelling \(CCFL\) 45th Session.](#)

²⁴¹ WHO/Europe (2017) [France becomes one of the first countries in Region to recommend colour-coded front-of-pack nutrition labelling system.](#)

²⁴² European Citizens’ Initiative, [Pro-Nutriscore.](#)

²⁴³ [Commission Delegated Regulation \(EU\) 2016/127 of 25 September 2015 supplementing Regulation \(EU\) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding.](#)

²⁴⁴ WHO/Europe (2019) [Commercial foods for infants and young children in the WHO European Region.](#)

²⁴⁵ WHO (2016) [Guidance on ending the inappropriate promotion of foods for infants and young children.](#)

²⁴⁶ World Health Organization, UNICEF, IBFAN (2018) [Marketing of breast-milk substitutes: National implementation of the international code Status Report.](#)

²⁴⁷ European Commission, [Chemicals are everywhere.](#)

²⁴⁸ Rijk et al. (2016) [Health costs that may be associated with Endocrine Disrupting Chemicals.](#) Institute for Risk Assessment Sciences. University of Utrecht.

foundation for a sustainable Europe.²⁴⁹ The Political Guidelines for the 2019-2024 Commission mention a “zero-pollution ambition,” including for hazardous chemicals.²⁵⁰

The EU’s 7th Environment Action Programme (7th EAP), adopted in 2013, commits the Commission to develop a Union strategy for a non-toxic environment by 2018. This strategy would have to prioritise, among others, the safety of nanomaterials, minimise the exposure to EDCs, address combination effects of chemicals and promote non-toxic material cycles.²⁵¹ In 2018, the Commission produced a Staff Working Document on options to address the interface between chemical, product and waste legislation.²⁵² A comprehensive strategy has not yet been produced. Council Conclusions from 2019 urge the Commission to “develop without further delay” a Union strategy for a non-toxic environment.²⁵³

Endocrine disrupting chemicals. In 2018, the Commission published a Communication on EDCs.²⁵⁴ The Parliament, in a 2019 Motion for Resolution, considered that this Communication does not deliver on the 7th EAP, which commits the Commission to take horizontal measures on EDCs by 2015 and to adopt a non-toxic environment strategy.²⁵⁵ It also notes about the need to revise the 1999 Community strategy on EDCs.²⁵⁶ In 2019, the Commission launched a Roadmap to review rules on EDCs, and a public consultation is upcoming.²⁵⁷ The future Commissioner for Health will contribute to the wider zero-pollution ambition by tackling the exposure to EDCs.²⁵⁸

REACH and other chemicals regulations. In 2018, the Commission published an evaluation report on the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).²⁵⁹ The next such report is due by 2022. In 2019, the Commission published a report on the Fitness Check of chemicals legislation excluding REACH.²⁶⁰ A REFIT procedure is ongoing on the evaluation of EU legislation on plant protection products and pesticides residues.²⁶¹ In 2019 the Commission published its Communication on Pharmaceuticals in the Environment.²⁶²

Environment Action Plan. The 7th EAP expires in 2020 and, apart from chemicals, covers health risks such as air pollution, noise, water pollution and climate change. Council Conclusions from 2019 call on the Commission to adopt an 8th Environment Action Plan at the latest in 2020.²⁶³

²⁴⁹ European Commission (2019) [A Sustainable Europe by 2030](#).

²⁵⁰ Von der Leyen (2019) [A Union that strives for more. My Agenda for Europe: Political Guidelines for the Next European Commission 2019-2024](#).

²⁵¹ [Decision No 1386/2013/EU on a General Union Environment Action Programme to 2020 ‘Living well, within the limits of our planet’](#).

²⁵² Commission Communication, COM/2018/032 final, [on the implementation of the circular economy package: options to address the interface between chemical, product and waste legislation](#).

²⁵³ Council of the European Union, 10713/19, [Council Conclusions: Towards a Sustainable Chemicals Policy Strategy of the Union](#).

²⁵⁴ Commission Communication, COM/2018/734 final, [Towards a comprehensive European Union framework on endocrine disruptors](#).

²⁵⁵ [European Parliament resolution of 18 April 2019 on a comprehensive European Union framework on endocrine disruptors \(2019/2683\(RSP\)\)](#).

²⁵⁶ Commission Communication, COM/99/0706 final, [Community strategy for endocrine disrupters - A range of substances suspected of interfering with the hormone systems of humans and wildlife](#).

²⁵⁷ European Commission, [Harmful chemicals – endocrine disruptors, review of EU rules](#).

²⁵⁸ European Commission (2019) [President-elect von der Leyen’s Mission Letter to Stella Kyriakides](#).

²⁵⁹ European Commission, [The REACH REFIT Evaluation \(REACH Review\)](#).

²⁶⁰ European Commission, [Chemicals: What the Commission is doing](#).

²⁶¹ European Commission, [REFIT - Evaluation of the EU legislation on plant protection products and pesticides residues](#).

²⁶² Commission Communication, COM/2019/128 final, [European Union Strategic Approach to Pharmaceuticals in the Environment](#).

²⁶³ Council of the European Union, 10713/19, [Council Conclusions: Towards a Sustainable Chemicals Policy Strategy of the Union](#).

4.2.8. Air quality

A 2018 WHO report launched at the United Nations Climate Change Conference in Katowice, underlines how climate change and air pollution are twin challenges, and how tackling both can produce considerable health benefits.²⁶⁴ Over 400,000 people die prematurely of air pollution in the EU each year, making air pollution the single largest environmental health threat.²⁶⁵

Ambient Air Quality Directives. The Political Guidelines for the 2019-2024 Commission mention tackling climate change as a major priority for the next five years.²⁶⁶ A 2018 special report by the European Court of Auditors on the Ambient Air Quality Directive concluded that EU's action to protect citizens from air pollution had not yet delivered the expected impact.²⁶⁷ In 2017, the Commission launched a REFIT procedure of the EU's two Ambient Air Quality Directives,²⁶⁸ with results expected to be published in late 2019. The Mission Letter to the Commissioner-designate for Environment and Oceans includes the priority of tackling air pollution as part of a wider "zero-pollution" ambition.²⁶⁹

National Emissions Ceiling Directive. The first National Air Pollution Control Programmes under the National Emissions Ceiling Directive,²⁷⁰ adopted in 2016, are due to be submitted in 2019.²⁷¹ These programmes should contain measures to ensure the emissions reduction commitments for 2020 and 2030 adopted under the Directive are met. The timely submission of these programmes and their quality are important considerations for the adequate implementation of the Directive.

Vehicle emissions. Several policy developments can be seen as a legacy of the 2015 "dieselgate" scandal, which brought to light how certain car manufacturers manipulated their vehicle emissions systems to produce lower nitrogen oxides (NOx) emissions during laboratory testing in order to ensure compliance with emissions standards.²⁷²

In 2019 the Commission presented a Roadmap towards clean vehicles,²⁷³ which provides an overview of already launched initiatives, such as the 2017 Europe on the Move package²⁷⁴ and the 2017 Clean Mobility Package,²⁷⁵ and focuses on several actions, including to deliver on dieselgate-related car recalls and to continue investigating the feasibility of new emissions standards, such as for Euro 7 vehicles.²⁷⁶

Urban planning and structural funds. Urban low emissions zones, which are city-specific measures to improve local air quality are increasingly being introduced across Europe and can help meet EU level mandatory air pollution limits. This development can be expected to continue, and a debate on this was held in the Parliament in 2019.²⁷⁷ Appropriate urban planning can also contribute to co-benefits for air quality and physical activity by promoting active and clean modes of transport.

²⁶⁴ WHO (2018) [COP24 special report: health and climate change](#).

²⁶⁵ European Environment Agency (2018) [Air quality in Europe – 2018 report](#).

²⁶⁶ Von der Leyen (2019) [A Union that strives for more. My Agenda for Europe](#): Political Guidelines for the Next European Commission 2019-2024.

²⁶⁷ European Court of Auditors (2019) [Special report no 07/2019: EU actions for cross-border healthcare](#).

²⁶⁸ European Commission, [Air Quality – AOD Fitness Check](#).

²⁶⁹ European Commission (2019) [President Von der Leyen's Mission Letter to Virginijus Sinkevičius](#).

²⁷⁰ [Directive \(EU\) 2016/2284 on the reduction of national emissions of certain atmospheric pollutants](#).

²⁷¹ European Commission, [Reduction of National Emissions - National Air Pollution Control Programmes](#).

²⁷² European Court of Auditors (2019) [Briefing Paper: The EU's response to the "dieselgate" scandal](#).

²⁷³ European Commission (2019) [Roadmap towards clean vehicles](#).

²⁷⁴ European Commission (2017) [Europe on the Move: Commission takes action for clean, competitive and connected mobility](#).

²⁷⁵ European Commission (2017) [Commission unveils clean mobility package to reinforce EU's leadership in clean vehicles](#).

²⁷⁶ Euractiv (2017) [Cities and Regions letter to European Council, MEPs, European Commission and National Experts](#).

²⁷⁷ European Parliament plenary debate (2019) [Clean air zone in EU cities](#).

The WHO Healthy Cities Network provides examples,²⁷⁸ and the topic is relevant for discussions on the distribution of resources through the EU structural and investment funds.²⁷⁹ The European Court of Auditors has launched an audit on the effectiveness of EU's action and funding on urban mobility.²⁸⁰

4.2.9. Healthy diets from sustainable food systems

The food system and public health are closely interlinked.²⁸¹ Various recent studies have found that a shift towards more sustainable dietary patterns can achieve nutritional and environmental co-benefits.^{282 283} A 2019 special report by the Intergovernmental Panel on Climate Change (IPCC) concludes that diets “featuring plant-based foods, such as those based on coarse grains, legumes, fruits and vegetables, nuts and seeds, and animal-sourced food produced in resilient, sustainable and low-GHG emission systems” represent major opportunities for climate adaptation and mitigation, and can generate important health co-benefits through improved nutrition.²⁸⁴ It also highlights the significant potential of public health policies in creating conducive food environments.

Strategy for sustainability from farm to fork. The 2019 Commission reflection paper on the implementation of the SDGs towards 2030 prioritises food system sustainability as a strategic policy foundation for a sustainable Europe.²⁸⁵ The Political Guidelines for the 2019-2024 Commission refer to the introduction of a “Farm to Fork Strategy” for sustainable food,²⁸⁶ and the Mission Letters entrust the future Commissioner on Health to lead this task.²⁸⁷ A Mission Board on soil health and food was established in 2019 to support the implementation of Horizon Europe, the next EU research and innovation programme.²⁸⁸ Food 2030 is an ongoing research policy initiative to support food system sustainability priorities, including on nutrition for sustainable and healthy diets.²⁸⁹

A paper produced for the 2018 Austrian EU Presidency reflects on the need and the ways to adopt policies, such as public procurement,^{290 291} that may deliver co-benefits for health, environmental and economic objectives.²⁹² In 2020, the Commission's Scientific Advice Mechanism (SAM) is expected to publish an opinion on moving towards a sustainable food system.²⁹³

²⁷⁸ WHO, [WHO Healthy Cities Network](#).

²⁷⁹ European Commission, [European structural and investment funds](#).

²⁸⁰ European court of Auditors (2019) [Audit preview: Urban mobility in the EU](#).

²⁸¹ See for instance: [FCRN Foodsource](#) for an evidence-based overview of food system-related challenges and opportunities. Hosted by the Food Climate Research Network and the University of Oxford Environmental Change Institute.

²⁸² Springmann et al. (2018) [Health and nutritional aspects of sustainable diet strategies and their association with environmental impacts: a global modelling analysis with country-level detail](#). The Lancet.

²⁸³ Willett et al. (2019) [Food in the Anthropocene: the EAT–Lancet Commission on healthy diets from sustainable food systems](#). The Lancet.

²⁸⁴ IPCC (2019) [Climate Change and Land: An IPCC special report on climate change, desertification, land degradation, sustainable land management, food security, and greenhouse gas fluxes in terrestrial ecosystems](#).

²⁸⁵ European Commission (2019) [A Sustainable Europe by 2030](#).

²⁸⁶ Von der Leyen (2019) [A Union that strives for more. My Agenda for Europe](#): Political Guidelines for the Next European Commission 2019-2024.

²⁸⁷ European Commission (2019) [President-elect von der Leyen's Mission Letter to Stella Kyriakides](#).

²⁸⁸ European Commission (2019) [Commission launches work on major research and innovation missions for cancer, climate, oceans and soil](#).

²⁸⁹ European Commission, [Food 2030](#).

²⁹⁰ De Almeida et al. (2016) [Revision of the EU Green Public Procurement Criteria for Food and Catering Services](#). European Commission Joint Research Centre.

²⁹¹ Caldeira et al. (2018) [Public procurement of food for health](#). European Commission Joint Research Centre and Maltese Presidency of the European Union.

²⁹² Parsons & Hawkes (2018) [Connecting food systems for co-benefits: how can food systems combine diet-related health with environmental and economic policy goals?](#) WHO European Observatory Health Systems and Policies.

²⁹³ European Commission Science Advisory Mechanism, [Towards an EU sustainable food system](#).

Several European Citizens' Initiatives (ECI) have been launched in this space,²⁹⁴ with a (likely) successful ECI on animal welfare recently closed.²⁹⁵ The challenges and opportunities related to this comprehensive agenda closely relate to the ENVI Committee's core mandate on environment, food safety and public health.

4.3. Cross-cutting issues

4.3.1. Health equity

In 2017, over 112 million people in the EU lived in households at risk of poverty or social exclusion, equivalent to between a fifth and a quarter of the entire population.²⁹⁶ People exposed to socio-economic vulnerabilities are disproportionately burdened by ill-health.²⁹⁷

Health equity in all policies. The 2019 Commission Reflection Paper on the Implementation of the SDGs towards 2030, prioritises a socially fair transition as a strategic policy foundation for a sustainable Europe.²⁹⁸ According to a 2019 WHO report, the policy areas affecting health equity are wide and cover action on multiple health determinants, including health services; income security and social protection; living conditions; social and human capital; and employment and working conditions.²⁹⁹ The 2019 draft Council Conclusions on the Economy of Well-being, describe how tackling (health) inequity contributes to fair and sustainable economic development.³⁰⁰

As highlighted in a 2009 Commission Communication on solidarity in health,³⁰¹ there is a strong health equity component to many actions addressing public health concerns; from action on mental health, to the creation of effective, accessible and resilient health systems,³⁰² from strengthening health promotion and diseases prevention capacities to tackle communicable and non-communicable diseases, to the development of inclusive digital health tools. A renewed assessment of the entry points for tackling health inequities through different policy and budgeting mechanisms may be considered.

European Semester and European Pillar of Social Rights. The Political Guidelines for the 2019-2024 Commission emphasise social fairness and a "just transition" as strategic priorities for the coming EU legislative mandate.³⁰³ The European Semester,³⁰⁴ a process that helps Member States coordinate their economic policies to address economic and social challenges, and the European Pillar of Social Rights (EPSR),³⁰⁵ which comprises 20 principles to improve social and economic well-being, are two key EU tools in this area.

The Political Guidelines for the 2019-2024 Commission include the introduction of a coordinated action plan to implement the EPSR and the integration of the SDGs into the European Semester among

²⁹⁴ European Commission, [The European Citizens' Initiative Official Registry](#).

²⁹⁵ European Citizens Initiative, [End the Cage Age](#).

²⁹⁶ Eurostat (2019) [People at risk of poverty or social exclusion](#).

²⁹⁷ [Health Inequalities in the EU - Final report of a consortium](#). Consortium lead: Sir Michael Marmot (2013) European Commission Directorate- General for Health and Consumers.

²⁹⁸ European Commission (2019) [A Sustainable Europe by 2030](#).

²⁹⁹ WHO/Europe (2019) [Health Equity Policy Tool. A framework to track policies for increasing health equity in the WHO European Region](#).

³⁰⁰ Council of the European Union, 11164/19, [Draft Council Conclusions: The Economy of Wellbeing](#).

³⁰¹ Commission Communication, COM/2009/0567 final, [Solidarity in Health: Reducing Health Inequalities in the EU](#).

³⁰² Commission Communication, COM(2014) 215 final, [On effective, accessible and resilient health systems](#).

³⁰³ Von der Leyen (2019) [A Union that strives for more. My Agenda for Europe](#): Political Guidelines for the Next European Commission 2019-2024.

³⁰⁴ European Commission, [The European Semester](#).

³⁰⁵ European Commission, [The European Pillar of Social Rights in 20 principles](#).

priorities.³⁰⁶ Consistent with previous years, the ENVI Committee can be expected to be invited to deliver opinions, among others, on the European Semester's Annual Growth Survey.³⁰⁷

Disability strategy. The 2010 European Disability Strategy will expire in 2020.³⁰⁸ In 2017, the Parliament adopted a Report calling for a new EU disability strategy 2020-2030.³⁰⁹ The report also contains various health-related recommendations, such as including a disability component in the transposition of the Cross-Border Healthcare Directive, increasing focus on mental health, ensuring accessibility of healthcare services, and pointing to the opportunities from the digital health agenda.

Roma integration strategies. The EU Framework for National Roma Integration Strategies, adopted in 2011, and which has healthcare as one of the main pillars, will expire in 2020.³¹⁰ A 2019 Parliament Resolution calls for a strengthened post-2020 framework with clear and binding targets.³¹¹

Migrants' health. In 2016, the Commission adopted an Action Plan to ensure a better integration of non-EU migrants.³¹² The action plan stresses that migrants experience a number of health-related disadvantages, including in access to health services, and contains several commitments for action. Different developments are ongoing under the European Agenda for Migration,³¹³ and a 2019 Commission Progress report on the Implementation of this agenda provides reference to health-related activities.³¹⁴ The Political Guidelines for the 2019-2024 Commission commit to proposing a New Pact on Migration and Asylum.³¹⁵ An assessment of further action to improve the health situation of migrants may be considered in this context.

Other developments on social determinants. The Political Guidelines for the 2019-2024 Commission mention as a priority the introduction of a European **Gender Strategy**, among others to ensure equal pay and tackle gender-based violence. In addition, they mention the introduction of a legal instrument to ensure a fair **minimum wage** for every worker in the EU, a European **unemployment benefit reinsurance scheme**, and the implementation of the **Work-life Balance Directive**.³¹⁶

4.3.2. Demographic transition

Demographic change, especially ageing, is highlighted as one of the mega-trends that will shape the EU's future.³¹⁷ In 2018, nearly one fifth of the EU population was aged 65 and over. The share of those aged 80 years or above is projected to increase by two and a half times between 2018 and 2100, to

³⁰⁶ Von der Leyen (2019) [A Union that strives for more. My Agenda for Europe](#): Political Guidelines for the Next European Commission 2019-2024.

³⁰⁷ European Parliament Legislative Observatory [Procedure file: 2018/2119\(INI\). European semester for economic policy coordination: annual growth survey 2019](#).

³⁰⁸ European Commission, [European disability strategy 2010-2020](#).

³⁰⁹ [Motion for a European Parliament Resolution on implementation of the European Disability Strategy \(2017/2127\(INI\)\)](#).

³¹⁰ Commission Communication, COM/2011/0173 final, [An EU Framework for National Roma Integration Strategies up to 2020](#).

³¹¹ [European Parliament resolution of 12 February 2019 on the need for a strengthened post-2020 Strategic EU Framework for National Roma Inclusion Strategies and stepping up the fight against anti-Gypsyism \(2019/2509\(RSP\)\)](#).

³¹² Commission Communication, COM(2016) 377 final, [Action Plan on the integration of third country nationals](#).

³¹³ European Commission, [European Agenda on Migration](#).

³¹⁴ European Commission, COM(2019) 126 final, [Progress report on the Implementation of the European Agenda on Migration](#).

³¹⁵ Von der Leyen (2019) [A Union that strives for more. My Agenda for Europe](#): Political Guidelines for the Next European Commission 2019-2024.

³¹⁶ Von der Leyen (2019) [A Union that strives for more. My Agenda for Europe](#): Political Guidelines for the Next European Commission 2019-2024.

³¹⁷ Gaub et al. (2019) [Global Trends to 2030. Challenges and Choices for Europe](#). European Strategy and Policy Analysis System.

almost 15% of the population.³¹⁸ Europe's age-related spending is also projected to increase, most of this not spent on pensions, but health services and long-term care.³¹⁹

At the same time, healthy ageing starts in childhood. Childhood obesity is a major public health issue with over a third of children overweight or obese in some EU countries.³²⁰

Childhood obesity is closely linked with inequalities and can have deleterious effects later in life.³²¹ In 2017, nearly a quarter of all children in the EU were at risk of poverty or social exclusion.³²²

Healthy ageing. In 2020, the WHO is launching the Decade of Healthy Ageing towards 2030.³²³ The WHO defines healthy ageing as “the process of developing and maintaining the functional ability that enables wellbeing in older age”.³²⁴ The Mission Letter to the Commissioner-designate on Democracy and Demography commits to the introduction of a Green Paper on ageing.³²⁵ There appears to be considerable scope to align these processes and explore entry points for EU policy action.

Childhood obesity. The EU Action Plan on Childhood Obesity, adopted in 2014, will expire in 2020.³²⁶ A 2018 study to support its evaluation, points to the added value of the existence of an EU action plan, and contains surveyed suggestions on ways the current plan could be strengthened.³²⁷ Council Conclusions from 2017 highlight that existing policies to tackle childhood obesity “have not been sufficiently effective” and call on the Commission and Member States to make tackling childhood obesity into an EU priority.³²⁸ The EU Platform for Action on Diet, Physical Activity and Health³²⁹ is currently being evaluated. The Strategy for Europe on Nutrition, Overweight and Obesity related health issues dates back to 2007.³³⁰

Child guarantee. In 2015, the Parliament adopted a Resolution on reducing childhood inequalities, including in health, calling for the introduction of a Child Guarantee in the framework of an integrated European plan to combat child poverty.³³¹ In 2018, the Commission commissioned a study on the feasibility of a child guarantee for vulnerable children. Following a consultation held in early 2019, the study is expected to be published in 2020.³³² The introduction of a Child Guarantee is included as an action in the Political Guidelines for the 2019-2024 Commission,³³³ and in the Mission Letter for the Commissioner-designate for Democracy and Demography.³³⁴ The European Court of Auditors has started an audit on the effectiveness of the Commission's support to Member States in reducing child poverty, including through EU funding.³³⁵

³¹⁸ Eurostat, [Population structure and ageing](#).

³¹⁹ Gaub et al. (2019) [Global Trends to 2030. Challenges and Choices for Europe](#). European Strategy and Policy Analysis System.

³²⁰ WHO (2018) Childhood Obesity Surveillance Initiative (COSI) Factsheet. Highlights 2015-17.

³²¹ Loring and Robertson (2014) [Obesity and inequities. Guidance for addressing inequities in overweight and obesity](#). WHO/Europe.

³²² Eurostat (2019) [Children at risk of poverty or social exclusion](#).

³²³ WHO, [Decade of Healthy Ageing \(2020-2030\)](#).

³²⁴ WHO, [What is healthy ageing?](#)

³²⁵ European Commission (2019) [President-elect von der Leyen's Mission Letter to Dubravka Šuica](#).

³²⁶ European Commission, [EU Action Plan on Childhood Obesity 2014-2020](#).

³²⁷ Boer et al. (2018) [Supporting the mid-term evaluation of the EU action plan on childhood obesity](#). The childhood obesity study – Study. Report for the European Commission.

³²⁸ Council of the European Union, 9977/17, [Council conclusions to contribute towards halting the rise in childhood overweight and obesity](#).

³²⁹ European Commission, [EU platform for action on diet, physical activity and health](#).

³³⁰ European Commission, COM(2007) 279 final, [A Strategy for Europe on Nutrition, Overweight and Obesity related health issues](#).

³³¹ [European Parliament resolution of 24 November 2015 on reducing inequalities with a special focus on child poverty \(2014/2237\(INI\)\)](#).

³³² European Commission, [Inception report of Child Guarantee feasibility study published](#).

³³³ Von der Leyen (2019) [A Union that strives for more. My Agenda for Europe: Political Guidelines for the Next European Commission 2019-2024](#).

³³⁴ European Commission (2019) [President-elect von der Leyen's Mission Letter to Dubravka Šuica](#).

³³⁵ European Court of Auditors (2019) [Audit preview: Child poverty](#).

4.3.3. Health in the digital age

The data and digitalisation revolution are well underway and have the capacity to significantly improve, or put in peril, the well-being of Europeans. The Political Guidelines for the 2019-2024 Commission refer to the “digital age” as a major priority.³³⁶ The Digital Single Market (DSM) was also one of the ten priorities of the outgoing Commission, with health as one of the sectors in which opportunities were identified.³³⁷

Digital health. The Mission Letter to the Health Commissioner-designate tasks the future Commissioner with creating a “European Health Data Space to promote health data exchange and support research on new preventive strategies, as well as treatments, medicines, medical devices and outcomes.”³³⁸ This follows on a wide range of initiatives undertaken during the previous legislature.

In 2018, the Commission published a Communication on the digital transformation of health and care in the Digital Single Market,³³⁹ focusing on three priorities: secure access to and sharing of health data across borders; better data to advance research, disease prevention and personalised health and care; and digital tools for citizen empowerment and person-centred care. The Communication follows a study on big data in public health published in 2016.³⁴⁰ It also responds to 2015 Council Conclusions on personalised medicines³⁴¹ and 2017 Council Conclusions on data in healthcare.³⁴²

Council Conclusions from 2019 call for more action on data and Artificial Intelligence, digital infrastructure and boosting digital skills, referring to “improved healthcare” as a key challenge.³⁴³ The Commission is currently planning the Digital Europe programme, a new funding instrument to boost the future development of the Digital Single Market, which is the subject of an ongoing public consultation.³⁴⁴

Ethics and privacy. The Political Guidelines for the 2019-2024 Commission refer to the importance of balancing the flow and wide use of data with “high privacy, security, safety and ethical standards”, and commit to putting forward legislation for a “coordinated European approach on the human and ethical implications of Artificial Intelligence”.³⁴⁵ They also state that this legislation should also look at the how big data can be used for innovations that create wealth for society and businesses.

In its 2018 report, the European Data Protection Supervisor highlighted the need to preserve human dignity in a digitalised world.³⁴⁶ In 2018, a High Level Expert Group on Artificial Intelligence (AI) was established which, among others, produced AI ethics guidelines.³⁴⁷

³³⁶ Von der Leyen (2019) [A Union that strives for more. My Agenda for Europe](#): Political Guidelines for the Next European Commission 2019-2024.

³³⁷ Commission Communication, COM(2015) 192 final, [A Digital Single Market Strategy for Europe](#).

³³⁸ European Commission (2019) [President-elect von der Leyen’s Mission Letter to Stella Kyriakides](#).

³³⁹ Commission Communication, COM/2018/233 final, [On enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society](#).

³⁴⁰ Habl et al. (2016) [Study on Big Data in Public Health, Telemedicine and Healthcare](#). Study for the European Commission.

³⁴¹ [Council Conclusions on personalised medicine for patients](#). EUR-Lex website. December 2015.

³⁴² Council of the European Union, 2015/C 421/03, [Council Conclusions on Health in the Digital Society — making progress in data-driven innovation in the field of health](#).

³⁴³ Council of the European Union, 10102/19, [Council Conclusions on the Future of a highly digitised Europe beyond 2020: “Boosting digital and economic competitiveness across the Union and digital cohesion”](#).

³⁴⁴ European Commission, [Have your say on the future of investment in Europe’s digital economy](#).

³⁴⁵ Von der Leyen (2019) [A Union that strives for more. My Agenda for Europe](#): Political Guidelines for the Next European Commission 2019-2024.

³⁴⁶ European Data Protection Supervisor (2018) [Annual Report 2018](#).

³⁴⁷ European Commission, [High-Level Expert Group on Artificial Intelligence](#).

In 2017, the Commission adopted a cybersecurity package,³⁴⁸ which includes a number of new initiatives to further improve EU cyber resilience and response, of relevance for sensitive health data. A Commission report on the evaluation and review of the General Data Protection Regulation (EU) 2016/279³⁴⁹ is expected for 2020, and the ongoing procedure on the draft e-Privacy Regulation³⁵⁰ present opportunities to build a robust EU data security framework for health.

E-Health. In 2012, the Commission released its eHealth Action Plan, which sets out a framework for taking advantage of the economic and social benefits promised by digital health until 2020.³⁵¹ The Action Plan's interim evaluation revealed great variations between Member States and concluded that further EU action would be desirable.³⁵² The future Health Commissioner will be tasked with making most e-health to contribute to high quality healthcare and reduce inequalities.³⁵³

M-Health. In response to the growing trend of smartphone apps and other mobile technologies, the Commission's Green Paper on Mobile Health (mHealth),³⁵⁴ issued in 2014, discussed, among others, the legal framework for health and wellbeing apps and led to a draft privacy code of conduct.³⁵⁵ This code, meant to provide practical guidance for app developers on data protection principles, is still awaiting approval.

Digitalisation and health risks. The Political Guidelines for the 2019-2024 Commission mention as an action point the establishment of joint standards for 5G networks.³⁵⁶ The Austrian Parliament has recently commissioned a study to evaluate the current state of knowledge on the health risks of cellular networks, in particular 5G, with results expected in 2020.³⁵⁷ The EU's Agency for Safety & Health at Work (OSHA) is running a foresight project on new and emerging occupational safety and health risks associated with information and communications technologies and work locations.³⁵⁸

Digital marketing and advertising. In 2017, two different Council Conclusions urged a response to the challenges posed by the marketing and advertising of alcohol³⁵⁹ and foods high in energy, fats, sugar and salt³⁶⁰ via online platforms and social media. Over the last several years, the WHO has published a number of reports on the practice of digital marketing of health-harming products, its negative effects on children and minors and on policies to tackle associated challenges.^{361 362 363}

³⁴⁸ European Commission, [Cybersecurity](#).

³⁴⁹ [Regulation \(EU\) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data](#)

³⁵⁰ European Parliament Legislative Observatory [Procedure 2017/0003\(COD\) Respect for private life and the protection of personal data in electronic communications](#)

³⁵¹ Commission Communication, COM(2012) 736 final, [eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century](#)

³⁵² Wauters et al. (2014) [Interim evaluation of the eHealth Action Plan 2012-2020](#). Report for the European Commission

³⁵³ European Commission (2019) [President-elect von der Leyen's Mission Letter to Stella Kyriakides](#)

³⁵⁴ European Commission, COM(2014) 219 final, [Green Paper on mobile Health \("mhealth"\)](#)

³⁵⁵ European Commission, [Privacy Code of Conduct on mobile health apps](#)

³⁵⁶ Von der Leyen (2019) [A Union that strives for more. My Agenda for Europe](#): Political Guidelines for the Next European Commission 2019-2024

³⁵⁷ Institute of Technology Assessment of the Austrian Academy of Sciences, [5G and health: Evaluation of the current state of knowledge on the health risks of cellular networks](#)

³⁵⁸ European Agency for Safety and Health at Work, [Developments in ICT and digitalisation of work](#)

³⁵⁹ Council of the European Union, 14082/17, [Council Conclusions: Cross-border aspects in alcohol policy](#)

³⁶⁰ Council of the European Union, 9977/17, [Council conclusions to contribute towards halting the rise in childhood overweight and obesity](#)

³⁶¹ WHO/Europe (2019) [Monitoring and restricting digital marketing of unhealthy products to children and adolescents](#)

³⁶² WHO/Europe (2018) [Evaluating implementation of the WHO set of recommendations on the marketing of foods and non-alcoholic beverages to children. Progress, challenges and guidance for next steps in the WHO European Region](#)

³⁶³ WHO/Europe (2016) [Tackling food marketing to children in a digital world: trans-disciplinary perspectives. Children's rights, evidence of impact, methodological challenges, regulatory options and policy implications for the WHO European Region](#)

A reform of the Audiovisual Media Services Directive (AVMSD) was adopted in 2018 and the new rules will apply from 2020.³⁶⁴ The AVMSD contains provisions setting certain standards for audiovisual commercial communications.³⁶⁵ The Directive prohibits commercial communications for tobacco products and electronic cigarettes, restricts those for prescription-only medicinal products and medical treatments, and to a limited extent addresses the exposure of minors to commercial communications for alcoholic beverages and nutritionally unbalanced foods. The rules for commercial communications on food and alcohol only extend marginally to online platforms.

4.3.4. International trade

Trade and investment agreements. EU trade and investment agreements have moved beyond discussions of tariffs to focus more on eliminating or reducing non-tariff barriers and into the space of investment protection and regulatory cooperation. As the breadth of trade discussions has grown, so have the potential impacts on public health.³⁶⁶ The EU includes a non-binding Trade and Sustainability Chapter in its agreements, covering environmental and labour issues but no further health concerns.³⁶⁷

The EU holds exclusive competence for trade policy, negotiating trade agreements on behalf of Member States. The Parliament is a co-legislator in this area, and the Plenary votes to approve or reject finalised deals.³⁶⁸ Further, the ENVI Committee may influence ongoing negotiations by adopting opinions to Parliament Resolutions, as it has done previously, for example, on the Transatlantic Trade and Investment Partnership (TTIP) with the United States.³⁶⁹ Currently, the European Commission lists 11 active trade negotiations as being updated or negotiated in its current state of play overview. A further 18 deals are listed as pending, or partly in place.³⁷⁰

4.3.5. Global health

In 2018, the WHO adopted its Thirteenth General Programme of Work 2019-2023, with three strands of strategic priorities to ensure that: 1 billion more people benefit from universal health coverage (UHC); 1 billion more people are better protected from health emergencies; and 1 billion more people enjoy better health and well-being.³⁷¹

Global health and SDGs. In 2018, 11 of the world's leading health and development organisations, coordinated by the WHO, launched a Global Action Plan with the aim to accelerate progress towards the health-related SDGs.³⁷² In 2018, the Commission proposed that the EU's external action should be implemented by a Neighbourhood, Development and International Cooperation Instrument 2021–2027,³⁷³ and the same year a Roadmap was launched on protecting citizens against health threats, with

³⁶⁴ [Directive 2010/13/EU on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services \(Audiovisual Media Services Directive\)](#)

³⁶⁵ Article 1(1)(h) Directive 2010/13/EU defines “audiovisual commercial communication” as “images with or without sound which are designed to promote, directly or indirectly, the goods, services or image of a natural or legal person pursuing an economic activity”. Forms of audiovisual commercial communication include, inter alia, advertising, sponsorship, teleshopping and product placement.

³⁶⁶ Khan et al. (2015) [The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems, and Public Health](#). The London School of Economics and Political Science

³⁶⁷ European Commission, [Sustainable Development](#)

³⁶⁸ European Parliament (2019) [Making the most of globalisation: EU trade policy explained](#)

³⁶⁹ [Opinion of the Committee on the Environment, Public Health and Food Safety for the Committee on International Trade on recommendations to the European Commission on the negotiations for the Transatlantic Trade and Investment Partnership \(TTIP\) \(2014/2228\(INI\)\)](#)

³⁷⁰ European Commission, [Negotiations and Agreements](#)

³⁷¹ WHO (2018) [Thirteenth general programme of work 2019–2023](#)

³⁷² WHO (2018) [Global Action Plan for healthy lives and well-being for all](#)

³⁷³ European Parliament Legislative Observatory [Procedure 2018/0243\(COD\): Neighbourhood, development and international cooperation instrument 2021–2027](#)

special focus on epidemics such as Ebola and Zika.³⁷⁴ In 2019, the Commission launched a Roadmap for an EU-Africa global health partnership.³⁷⁵

The latest EU strategic documents addressing global health as a comprehensive topic date back to 2010, when the Commission published a Communication on the EU Role in Global Health³⁷⁶ and the Council adopted similarly named Conclusions.³⁷⁷ These documents predate the adoption of the SDGs. 2019 Council Conclusion on supporting the SDGs across the world, note that progress needs to be accelerated in particular in integrating SDGs more closely into existing frameworks.³⁷⁸ A discussion on strengthening the role of the EU in global health cooperation is on the agenda for a 2019 meeting of the Council Working Party on Public Health at Senior Level.³⁷⁹ The development of a comprehensive EU post-SDG global health agenda may be considered.

4.3.6. Funding for public health

Public health funding mechanisms. EU funding mechanisms central to the pursuit of health and health equity will start new programming periods in 2021. Processes related to the setting of priorities and budget allocations for these instruments are closely linked to the overall negotiations on the next Multiannual Financial Framework (MFF) and the annual budgets of the EU. The ENVI Committee acts as an opinion-giving committee in budgetary procedures and can consider the appropriateness of proposed funding allocations in light of public health priorities, and monitor the effectiveness and efficiency of expenditures.

The most notable development is the upcoming merging of the current EU Health Programme into a new **European Social Fund Plus**, which will further include the current European Social Fund (ESF), the Youth Employment Initiative (YEI), the Fund for Aid to the Most Deprived (FEAD) and the EU Programme for Employment and Social Innovation.³⁸⁰

Due to the cross-cutting nature of health policy, other financial instruments could be used to address public health priorities and strengthen health systems infrastructure, including the **Cohesion Fund** and **European Regional Development Fund (ERDF)**,³⁸¹ **Horizon Europe**,³⁸² the **Civil Protection Mechanism**,³⁸³ the **LIFE Programme**,³⁸⁴ the **European Agricultural Guarantee Fund (EAGF)**, the **European Agricultural Fund for Rural Development (EAFRD)**,³⁸⁵ the **European Maritime and Fisheries Fund (EMFF)**,³⁸⁶ **InvestEU**,³⁸⁷ the **Structural Reform Support Programme (SRSP)**,³⁸⁸ and the **Neighbourhood, Development and International Cooperation Instrument**.³⁸⁹ Furthermore, the

³⁷⁴ European Commission, [Protecting citizens against health threats](#)

³⁷⁵ European Commission, [EU-Africa Global Health Partnership \(Horizon Europe programme\)](#)

³⁷⁶ Commission Communication, COM(2010)128 final, [The EU Role in Global Health](#)

³⁷⁷ Council of the European Union, 9644/10, [Council Conclusions on the EU role in Global Health](#)

³⁷⁸ Council of the European Union, 10997/19, [Council Conclusions on Supporting the Sustainable Development Goals across the world: The 2019 Joint Synthesis Report of the European Union and its Member States](#)

³⁷⁹ Council of the European Union, Notice of Meeting and Provisional Agenda, 13 September 2019, [Working Party on Public Health at Senior Level](#)

³⁸⁰ European Commission, [Health policies in the future EU budget \(2021-2027\)](#)

³⁸¹ European Commission, [New Cohesion Policy](#)

³⁸² European Commission, [Developing Horizon Europe](#)

³⁸³ European Commission, [EU Civil Protection Mechanism](#)

³⁸⁴ European Commission, [LIFE programme](#)

³⁸⁵ European Commission, [Financing the Common Agricultural Policy](#)

³⁸⁶ European Commission, [European Maritime and Fisheries Fund \(EMFF\)](#)

³⁸⁷ European Commission, [InvestEU](#)

³⁸⁸ European Commission, [Structural Reform Support Programme \(SRSP\)](#)

³⁸⁹ European Parliament Legislative Observatory [Procedure 2018/0243\(COD\): Neighbourhood, development and international cooperation instrument 2021-2027](#)

Political Guidelines for the 2019-2024 Commission include as a priority action the establishment of a **Just Transition Fund**.³⁹⁰

4.3.7. Inclusive and transparent policy-making

Inclusive policy-making. A 2019 special report by the European Court of Auditors assessed whether the Commission’s public consultations are effective at reaching out to citizens and making use of their contributions.³⁹¹ It found that the Commission’s framework for public consultations was generally of a high standard, but that outreach activities to citizens could be further improved. The Political Guidelines for the 2019-2024 Commission seek to ensure a greater say for Europeans in setting EU policy priorities.³⁹²

Over the last period a number of committees and expert groups under the Directorate General for Public Health and Food Safety have been disbanded and their work brought under the purview of the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases (SGPP).³⁹³ At the same time, the EU Health Policy Platform³⁹⁴ is increasingly employed as a central mechanism for organising the engagement of civil society organisations and citizens in health policy. Additional mechanisms and funding opportunities may need to be explored to increase dialogue between the EU institutions and the general public on health policy.

Transparency and integrity in policy-making. In 2015, the European Ombudsman delivered a recommendation on the EU’s compliance with Article 5.3 of the Framework Convention on Tobacco Control,³⁹⁵ which, together with accompanying guidelines,³⁹⁶ establishes an obligation and provides a guide for policy-makers to protect public health policy-making from tobacco industry vested interests. The Ombudsman considered that the EU rules and procedures in place were “not sufficient” to ensure transparency and avoid undue influence, and recommended several actions.³⁹⁷

In 2018, the Parliament adopted a report urging the Commission to implement the Ombudsman’s recommendations.³⁹⁸ The Political Guidelines for the 2019-2024 Commission refer to the need to ensure that EU institutions are “beyond reproach on ethics, transparency and integrity”, and put forward the idea to create an independent ethics body to this end.³⁹⁹ Enhancing the transparency and integrity in public health policy-making is important to address the commercial determinants of health.

³⁹⁰ Von der Leyen (2019) [A Union that strives for more. My Agenda for Europe](#): Political Guidelines for the Next European Commission 2019-2024

³⁹¹ European Court of Auditors (2019) [Special report no 14/2019: ‘Have your say!’: Commission’s public consultations engage citizens, but fall short of outreach activities](#)

³⁹² Von der Leyen (2019) [A Union that strives for more. My Agenda for Europe](#): Political Guidelines for the Next European Commission 2019-2024

³⁹³ European Commission, [Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases](#)

³⁹⁴ European Commission, [EU Health Policy Platform](#)

³⁹⁵ [WHO Framework Convention on Tobacco Control](#)

³⁹⁶ [Guidelines for implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control](#)

³⁹⁷ European Ombudsman, Case 852/2014/LP, [Improving tobacco lobbying transparency](#)

³⁹⁸ [European Parliament resolution of 13 December 2018 on the annual report on the activities of the European Ombudsman in 2017 \(2018/2105\(INI\)\)](#)

³⁹⁹ Von der Leyen (2019) [A Union that strives for more. My Agenda for Europe](#): Political Guidelines for the Next European Commission 2019-2024

4.3.8. Brexit

Potential health risks of Brexit. Brexit poses significant risks of negative health implications, both in the United Kingdom (UK) and the remaining EU Member States. This is particularly true for a “No-deal” Brexit. While dependent on further details and developments, areas of concern include:

- Withdrawal of the UK from the European Centre for Disease Prevention and Control (ECDC), could reduce the EU’s **early warning surveillance and monitoring capacity** in communicable disease outbreaks. The UK plays an active role in various surveillance and reporting systems established by the ECDC, such as the Early Warning Response System (EWRS)⁴⁰⁰ and the Epidemic Intelligence Information System (EPIS).⁴⁰¹
- There is a significant movement of medicines between the UK and the continent. “Operation Yellowhammer”,⁴⁰² the UK Government’s no deal planning scenario document, identifies **medicines shortages** in the UK as a key concern. This may however also affect the rest of the EU if, for instance, supplies are held up at Dover or Calais and key ingredients or packaging materials cannot reach the EU in time.
- **Batch testing** for all medicines marketed in the EU must be carried out in an EU Member State. Pharmaceutical companies have been making arrangements to relocate batch testing to EU27 countries but it is unlikely that this will be possible for all medicines before 31 October 2019.⁴⁰³ Unless temporary batch testing in the UK is accepted, there could be shortages of certain medicines across EU countries.
- The UK Medicines and Healthcare Products Regulatory Agency (MHRA) plays a major role in the **approval of medicines** across the EU.⁴⁰⁴ Normally, the MHRA would also have continued to be the responsible agency for the lifetime of the medication on the EU market. The UK’s withdrawal may put pressure on the capacity of other Member States’ medicines agencies, and the process of transferring dossiers may not be completed before an eventual withdrawal.
- Following withdrawal from the EU, the UK will also lose access to EudraVigilance,⁴⁰⁵ which is an EU monitoring and reporting system to identify suspected adverse medicines reactions after they have been placed on the EU market. This will have implications for the EU27’s action on **pharmacovigilance**.
- Almost 50% of medical devices on the EU market were certified in the UK.⁴⁰⁶ Certified in the EU (CE) certificates issued by a UK-registered institution may no longer be valid within the remaining EU27 after Brexit. Manufacturers of **medical devices** would then have to apply for a new CE certificate via an approved institution in one of the 27 EU Member States.

⁴⁰⁰ European Centre for Disease Prevention and Control, [Early Warning and Response System of the European Union \(EWRS\)](#)

⁴⁰¹ European Centre for Disease Prevention and Control, [Epidemic Intelligence Information System \(EPIS\)](#)

⁴⁰² UK Government (2019) [Operation Yellowhammer. HMG Reasonable Worst Case Planning Assumptions. As of 2 August 2019](#)

⁴⁰³ European Commission (2019) [Withdrawal of the United Kingdom and EU rules for batch testing of medicinal products](#). Ref. Ares(2019)1073098 - 21/02/20

⁴⁰⁴ UK Parliament, [The impact of Brexit on the pharmaceutical sector](#)

⁴⁰⁵ European Medicines Agency, [EudraVigilance](#)

⁴⁰⁶ British Standards Institution, [BSI Medical Devices and Brexit](#)

ANNEX 1 KEY INSTITUTIONS AND AGENCIES

Knowledge institutions

World Health Organization (WHO) Regional Office for Europe	http://www.euro.who.int/en/home
Organisation for Economic Co-operation and Development (OECD) Health division	https://www.oecd.org/health/
European Observatory on Health Systems and Policies	http://www.euro.who.int/en/about-us/partners/observatory
International Agency for Research on Cancer (IARC)	https://www.iarc.fr/
UN Food and Agricultural Organization (FAO)	http://www.fao.org/home/en/
Intergovernmental Panel on Climate Change (IPCC)	https://www.ipcc.ch/

EU Agencies & structures

European Commission Joint Research Centre (JRC)	https://ec.europa.eu/jrc/en
European Centre for Disease Prevention and Control (ECDC)	https://ecdc.europa.eu/en/home
European Chemicals Agency (ECHA)	https://echa.europa.eu/home
European Environment Agency (EEA)	https://www.eea.europa.eu/
European Food Safety Authority (EFSA)	http://www.efsa.europa.eu/
European Medicines Agency (EMA)	https://www.ema.europa.eu/en
European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)	http://www.emcdda.europa.eu/
European Agency for Safety and Health at Work (EU-OSHA)	https://osha.europa.eu/en
European Union Agency for Fundamental Rights (FRA)	https://fra.europa.eu/en
European Labour Authority (ELA)	https://ela.europa.eu/
Consumers, Health, Agriculture and Food Executive Agency (CHAFEA)	https://ec.europa.eu/chafea/index_en.htm

This in-depth analysis provides an outlook on the topics that may shape the ENVI Committee's public health agenda during the new legislature. It describes key public health definitions, principles and concepts, discusses the EU's powers to act on health, and presents an overview of health policy developments and challenges.

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