



The benefit of EU action in health policy: The record to date

European Added Value
in Action

STUDY

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European Added Value in Action

This study provides a non-exhaustive overview of the added value achieved so far through European Union (EU) action in the field of health policy. The study, requested by the Coordinators of the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI), covers the benefits of EU action in the following sectors: the EU Health Programme, cross-border healthcare, pharmaceuticals regulation, medical devices, and prevention and vaccination. The study provides a brief overview of the EU legal framework, policy tools and best practice in each area.

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Executive summary

Health is one of the most relevant topics for European citizens, whether their personal health or that of their families and co-workers, health always ranks as a top priority in citizens' inquiries regarding EU policy. Interestingly, the majority of European citizens wish to see more European level measures. Health is also a major issue for European economies and the public financing of EU Member States.

The Coordinators of the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) requested a study on the 'Benefit of EU action in the area of health'. This study therefore provides a non-exhaustive overview of the European added value achieved so far in the area of health policy. Responding to the Coordinators' specific request, the study covers the benefits of EU action in the following sectors: EU Health Programme; cross-border healthcare; pharmaceuticals regulation; medical devices; prevention and vaccination.

This assessment builds on EPRS desk research and on specific expertise commissioned for the purpose of this analysis. For each topic, the study addresses the background, legal framework, policy tools, and provides examples of best practice. For the specific purpose of identifying the European added value, the main research questions posed were: 'Which actions have been taken by the EU so far?'; and 'What is the European added value concerning EU action in this field?'.

To ensure homogeneity within and comparability across topics, we analysed the EU added value achieved so far against eight criteria: 1. economies of scale; 2. free movement of persons; 3. cross-border threats; 4. promotion of best practices; 5. networking; 6. benchmarking for decision-making; 7. unlocking the potential of innovation; and 8. implementing EU legislation.

The analysis demonstrates that, within the limits set by the EU Treaties in health matters, the EU does acquit its responsibility and utilises its capacity to act on behalf of EU citizens in this policy area. The study furthermore concludes that EU health policy clearly achieves European added value and effectively addresses all eight criteria selected for analysis. European health policy measures taken to date are highly beneficial to and relevant for European citizens, economies and the Member States.

The study shows European added value resulting, for example, in:

- joint action, procurement and funding, as well as simplified procedures supporting Member States and pharmaceutical developers;
- patient access to health care in different EU Member States and harmonised patient rights;
- the facilitation of synchronised responses to pandemics/epidemics and simplification of the response to safety issues, as well as reduction of cross border threats;
- best practice portals and platforms as well as databases, development and diffusion of standards;
- public health official exchanges with scientists across Europe, e.g. as part of various activities and projects, and stronger national authority cooperation through networking;
- enabling of evidence based decision-making and consensus processes between national authorities and European players and stakeholders;
- enhanced pharmaceutical and treatment innovations, as well as teaching of innovation; and
- implementation of EU health legislation ensuring a safe and well-functioning internal market, the free movement of people, and protection of public health.

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1. Introduction

1.1. Setting

Health policy is of great interest to European citizens, whether their personal health or that of their families and co-workers, health always ranks as a top priority in citizens' inquiries regarding EU policy. Interestingly, the majority of European citizens wish to see more European level action. Moreover, this support grew from 63 % in 2016 to 69 % in 2018.¹ Health is also a major issue for European economies and the public financing of EU Member States. Suffice to mention that in 2017, overall Member State spending on health accounted for 9.6 % of EU GDP, up from 8.8 % in 2008. Nevertheless, it is argued that more than 1.2 million deaths could have been avoided in EU countries in 2015, through better public health policies or more effective and timely health care.²

The European Union's founding treaties did not specifically address health policy. It was only in the late 1980s that EU health policy began gradually to be introduced. In response to multiple health crises, such as 'mad cow' disease, occurring in Europe in the 1990s, a more coordinated health policy at EU level was established. In addition, with the deepening of EU integration, the social dimension of health grew in importance and a fully-fledged health policy was introduced in the EU Treaties.³

Today, however, the European Union still has no direct or shared competencies in the area of health. Many measures have nevertheless been taken since the early years of the European Community. Currently, EU action on health matters is much broader. One example of European added value achieved is the joint action in cross-border health care,⁴ which allows European citizens to travel to other European Member States free from the fear of being ineligible for treatment or having to pay huge medical fees in case of sickness in other EU countries.

To illustrate the European added value achieved so far in the area of health, the Coordinators of the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) requested a study on the benefit of EU action in health. The study should cover in particular the benefits of EU action in the following sectors: the EU Health Programme; cross-border healthcare; pharmaceuticals regulation; medical devices; prevention and vaccination.

1.2. Legal framework for EU health policies

As mentioned above, the European Union has a well-defined and limited set of competences in the area of health. The Union may neither define nor shape health policies, and moreover can neither organise nor provide health services and medical care. In that respect, the main responsibility lies with the Member States, whose duties are the definition of health policy, and the organisation, management and delivery of health services and medical care, as well as resource allocation.

Nevertheless, the Treaty on the Functioning of the European Union (TFEU) includes several articles addressing health and associated policy areas. The European Union shares competence with the

¹ N. Scholz, M. Kiss, A. Dobрева, EU policies – Delivering for citizens: [Health and social security](#), EPRS, European Parliament, November 2018.

² Both: [Health at a Glance, Europe 2018: State of Health in the EU Cycle](#), OECD and European Commission, OECD Publishing, Paris, 2018.

³ [European cross-border cooperation on health – Theory and practice](#), Consumers, Health, Agriculture and Food Executive Agency (Chafea), 2017.

⁴ [Cross-border health care](#), European Commission website, January 2019.

Member State provided for in Articles 4 and 168 (common safety concerns in public health matters) and Articles 4, 26 and 114 (the internal market).

Article 168 is key, as the EU can hereunder adopt health legislation. More precisely, Article 168(1) obliges the EU to ensure a high level of human health protection in the definition and implementation of its policies and activities. In the same spirit, Article 9 asks the Union to take requirements linked to the protection of human health into account, whilst Article 6 specifies the protection and improvement of public health as an area where the EU has (only) the competence to carry out action in support of, to coordinate or to supplement, action by the Member States. Further articles are Articles 114 (approximation of laws necessary to the establishment and functioning of the internal market) and 153 (social policy).

The Council and the European Parliament enact European Union legislation in the health field in accordance with the ordinary legislative procedure (Article 294 TFEU). The Council of the EU can itself also address recommendations on public health to EU countries.⁵

In general, the importance of EU measures is acknowledged in the TFEU ('a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities'). This shall be carried out by fostering cooperation with and support for Member States. Thereby EU action on health issues aims to improve public health, prevent diseases and threats to health (including those related to lifestyle), as well as to promote research. So far, the EU has adopted legislation in areas such as patients' rights in cross-border healthcare; pharmaceuticals and medical devices (pharmacovigilance, falsified medicines, and clinical trials); serious cross-border health threats; and tobacco; as well as organ donation, on standards of quality and safety of substances of human origin (blood, tissues and cells).

1.3. The European Union's role

The European Union supports Member State healthcare systems in tackling shared objectives and common challenges, such as how to increase life expectancy, or to tackle chronic diseases and pandemics. The EU supports the Member States by pooling resources, and coordinating and creating exchange of best practices, as well as by promoting joint health activities. Furthermore, the EU proposes legislation and provides funding. The Member States are encouraged to invest effectively in health, health care systems and health coverage.⁶

Co-financing is carried out through different instruments:⁷

- the EU Health Programme⁸ (health promotion, health security and health information);
- Horizon 2020 Programme (research projects in areas such as biotechnology and medical technologies);
- EU cohesion policy supports investments in health; and
- the European Fund for Strategic Investments.

The European Parliament is a decision-making body and as such has the capacity to shape European health policies, in particular through its Committee for Environment, Public Health, and Food Safety (ENVI). The Parliament furthermore promotes a coherent health policy approach through means

⁵ [EU Health Policy](#), European Commission website, January 2019.

⁶ Ibid.

⁷ Ibid.

⁸ Such programmes existed so far for the 2003-2007, 2008-2013 and 2014-2020 periods.

such as own-initiative reports, adoption of strategies, declarations, debates, and studies such as the present study on the benefits of EU health policy achieved to date.⁹

1.4. Approach

Because of the broad scope of health policy and the diversity of possible interventions, the present analysis provides an initial non-exhaustive overview of the European added value of the EU measures achieved so far on the six following topics: the EU Health Programme; cross-border healthcare; pharmaceuticals regulation; medical devices; prevention and vaccination. This assessment builds on the specific expertise commissioned for the purpose, as well as on EPRS desk research. The briefing notes were carried out by:¹⁰

- Prof. Dr Barbara Rath, Vienna Vaccine Safety Initiative (amongst others, Health Data Research, University of Nottingham School of Medicine; Research Director at the University of Bourgogne-Franche-Comté) on the European health programme and vaccination.
- Dr Anne-Laure Beaussier (CNRS Researcher at Sciences Po Paris) on cross-border health care and prevention.
- Prof. Christine Huttin (University Aix Marseille) on pharmaceuticals regulation and medical devices.

The study provides a short background to the EU legal framework and policy tools for each of the six topics mentioned above. Two to four examples of best practice are illustrated to map the benefits of current EU measures achieved so far. For the specific purpose of identifying the European added value, the main research questions were:

- 'Which actions have been taken by the EU so far?'
- 'What is the European added value concerning the action in this field?'

Where applicable, eight criteria, taken from the Ex-post evaluation of the health programme (2008-2013),¹¹ were used to measure the European added value achieved in the six identified topics, to ensure homogeneity within and comparability across topics.

Table 1 –European added value criteria

	European added value	
1.	Economies of scale	Use money more efficiently and provide citizens with better services
2.	Free movement of persons	Increase the movement of patients and healthcare personnel between EU Member States and ensure high quality public health across Member States
3.	Cross-border threats	Reduce risks and mitigate their consequences
4.	Promotion of best practices	Apply and promote best practices in all participating Member States so that EU citizens benefit from state of the art health care
5.	Networking	Disseminate results and/or share knowledge to build, support and sustain health capacity in the EU
6.	Benchmarking for decision making	Facilitate evidence based decision-making
7.	Unlocking the potential of innovation	Support the deployment of innovative solutions
8.	Implementing EU legislation	Ensure the correct implementation of EU legislation and/or the contribution of funded action for the development of EU legislation

⁹ [Public Health](#), Fact Sheet, European Parliament, 2018.

¹⁰ These briefing notes will be published in the form of annexes at a later stage.

¹¹ Ex-post evaluation of the health programme (2008-2013), [final report](#), European Commission, 2015.

2. EU Health Programme

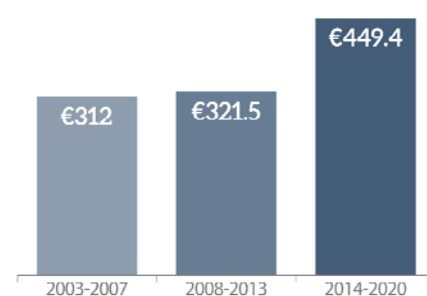
2.1. Background

The concept of an EU level health programme dates back to 1993, when the European Commission released a communication suggesting areas where coordinated and collective actions would strengthen Member States' public healthcare systems.¹² Based on this, eight programmes were carried out between 1996 and 2002. As their analysis identified a need for a more horizontal and interdisciplinary approach, three Health Programmes at EU level were implemented.¹³ Since then, EU health programmes have evolved from a 'disease-by-disease' approach to a comprehensive horizontal interdisciplinary policy instrument, which supports major European Commission priorities for the Europe 2020 strategy.¹⁴

The third health programme is the EU's main funding instrument for financing policy coordination in health. It has a budget of €449.4 million and covers the 2014-2020 period. Its four key objectives are: i) promote health, prevent disease and foster healthy lifestyles; ii) protect EU citizens from serious cross-border threats; iii) contribute to innovative, efficient and sustainable health systems; and iv) facilitate access to high quality, safe healthcare for EU citizens.¹⁵

Figure 1 – EU Health Programme budget

Financial envelopes for EU Health Programmes since 2003, in million €



Source: European Commission, [EU Health Programme](#), January 2019.

2.2. Legal framework

As mentioned in the introduction, Article 168 TFEU concerns incentive measures designed to protect and improve human health. Within the framework of Article 168, Regulation (EU) No 282/2014¹⁶ legally established the Third EU Health Programme for the 2014-2020 period. The previous health programmes (2003-2008) and (2008-2013) were adopted respectively by Decisions 1786/2002/EC¹⁷ and 1350/2007/EC.¹⁸

2.3. Policy tools

The EU has built an institutional multi-level architecture to support the efficient and effective implementation of the Third EU Health Programme. In particular, it consists of:¹⁹

- The European Commission Directorate-General for Health and Food Safety (DG SANTE), which is responsible for retrieving input and agreement from EU Member States, preparing

¹² [Public Health](#), Fact Sheets, European Parliament, 2018.

¹³ Ibid.

¹⁴ [EU Health Programme](#), European Commission website, January 2019.

¹⁵ Ibid.

¹⁶ Regulation of the European Parliament and the Council ([EU](#)) No 282/2014 on the establishment of a third programme for the Union's action in the field of health (2014-2020), 2014.

¹⁷ Decision of the European Parliament and of the Council [1786/2002/EC](#), adopting a programme of Community action in the field of public health (2003-2008), 2002.

¹⁸ Decision of the European Parliament and of the Council [1350/2007/EC](#), establishing a second programme of Community action in the field of health (2008-13), 2007.

¹⁹ [Health programme - DG SANTE & Chafea roles](#), European Commission website, January 2019.

and adopting annual work programmes according to the programme's priorities, and communicating with internal stakeholders, to issue reports and evaluate.

- The Consumers, Health, Agriculture and Food Executive Agency (Chafea), which issues grant agreements and payments, calls for proposals, monitors programme action and disseminates results.
- National focus points, which promote health programme opportunities, assist applicants, and contribute to the reporting, the evaluation and the dissemination of results at the national level.

At the same time, specialised agencies such as the European Centre for Disease Prevention and Control (ECDC) or the European Medicines Agency (EMA), coordinate and monitor the application of respective policies across Member States.

Finally, to facilitate and optimise the funding of health programme activities, a diversified ensemble of financial mechanisms, which covers either a part of, or the entire EU action, supports the Third EU Health Programme, including: project grants, operating grants, direct grants to international organisations, procurement contracts, and presidency conferences²⁰.

2.4. Benefits of current EU action

This section gives a short overview of the benefits of the EU Health Programme and a non-exhaustive summary of its European added value. Our analysis of the major Third EU Health Programme achievements uses the European Commission's mid-term evaluation report,²¹ published in late 2017 and attached as Annex I to this paper (forthcoming), as the main source of input.²²

This section on the benefit of the EU briefly addresses the four programme objectives: i) health promotion and disease prevention; ii) crisis preparedness and management; iii) innovation in health systems; and iv) access to better and safer healthcare. The section closes with v) a non-exhaustive overview of the European added value for the EU health programmes as identified in Annex I (forthcoming).²³ Moreover, in the following chapters, this paper analyses further fields for EU action in health, which are partly or fully addressed by the European health programmes.

Objective 1: Health promotion and disease prevention

The programme has focused on the generation, use, sharing and exchange of knowledge and best practices in order to contribute to the achievement of the UN Sustainable Development Goal to 'ensure healthy lives and promote well-being for all at all ages.'²⁴

Objective 2: Crisis preparedness and management

Action under the Third EU Health Programme has been decisive in strengthening Member States' capacity-building against health threats, by monitoring capabilities and gaps, delivering toolkits and guidelines at national level, and examining the preparedness and response mechanisms at EU level.

²⁰ [The Third Health Programme 2014-2020](#), European Commission presentation, January 2019.

²¹ [Mid-term evaluation of the Third Health Programme 2014 – 2020](#), final report, European Commission, 2017.

²² B. Rath, Annex I, Briefing note on EU Health Programme, 2019 (forthcoming).

²³ Ibid.

²⁴ [Sustainable Development Goal 3](#), Sustainable Development knowledge platform, United Nations website January 2019.

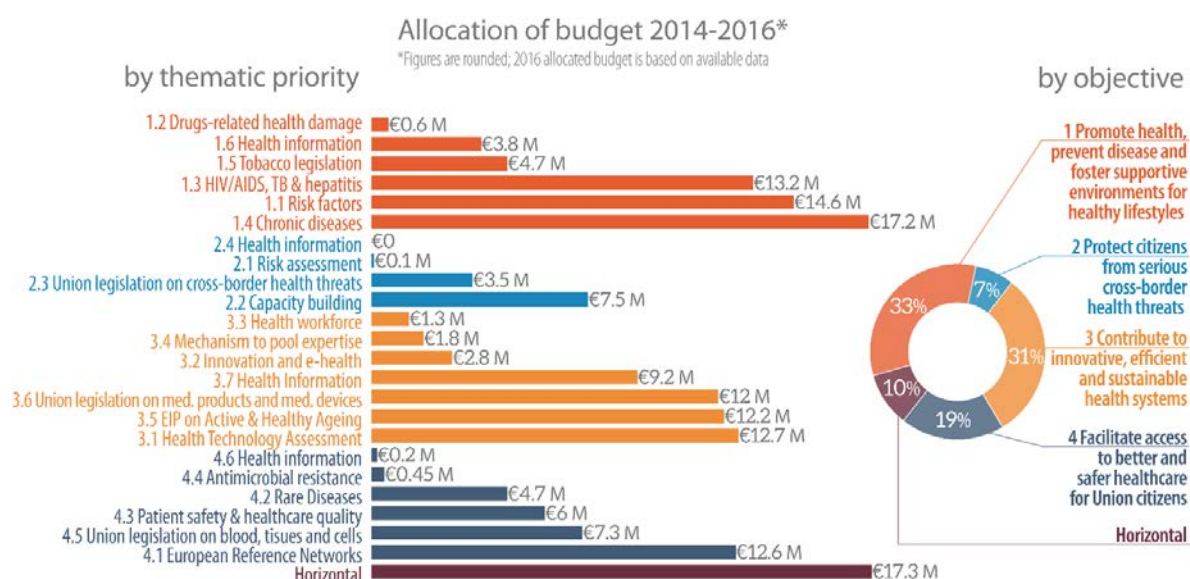
Objective 3: Innovation in health systems

Along with other EU programmes, the Third EU Health Programme implements policies favouring efficiency in EU expenditure and the maximisation of its impact.

Objective 4: Access to better and safer healthcare

Even during the early stages of implementation of the Third EU Health Programme, action has been taken at EU level aiming at facilitating communication between experts across Europe and increasing the quality and accessibility of healthcare systems.

Figure 2 – Priorities and objectives of the EU Health Programme 2014-2020



Source: European Commission, Mid-term evaluation, third health programme [SWD\(2017\) 331](#).

Examples of major achievements under the Third EU Health Programme are:²⁵

- The 'State of Health in the EU' cycle, a set of reports brought together by the European Commission, the OECD, and the European Observatory on Health Systems and Policies, which comprises the 'Health at a Glance: Europe report, 28 country profiles, a companion report and voluntary exchanges, which Member States can request. The objective of this cycle is to provide health officers and national governments with country-specific and EU-wide knowledge in health.
- The EU compass for action on mental health and wellbeing, a web platform collecting and exchanging best practices and monitoring policies at national and regional level concerning mental health.
- The European quality assurance scheme for breast cancer services, which is a collection of requirements and indicators seeking to guarantee the highest quality and most updated procedures for breast cancer screening in Europe; or the European breast cancer guidelines for screening and diagnosis, which are published on an annual basis.
- During the Ebola and Zika viral outbreaks, activities financed by the EU Health Programme and organised mainly through the Health Security Committee²⁶, limited the spread of the

²⁵ Impact Assessment, European Social Fund Plus (ESF+), [SWD/2018/0289](#), European Commission, 2018.

²⁶ The Health Security Committee is an informal advisory group set up by the Council of Health Ministers in 2001 and formalised in 2013. Its mandate includes the coordination of preparedness, response and international cooperation measures. For more see: Health Security Committee members, European Commission website, January 2019.

viruses, strengthened preparedness at national level and coordinated pan-European responses.

- 'Joint action to support the e-health network' contributed to the enhancement of the quality, efficiency and effectivity of healthcare services, through the standardisation and interoperability of cross-border health data.
- The European Network for Health Technology Assessment (EUnetHTA) contributed to the development of a common set of tools and standards, which strengthens European cooperation on creating, facilitating and promoting sustainable HTAs.
- Establishment of 24 European reference networks for rare diseases. As a result, more patients have now access to highly specialised knowledge and care, through a digital advisory board of medical experts.

Overview of the European added value of the Third EU Health Programme

Based on prior experiences, the European added value is a guiding principle for establishing the annual work programme (AWP) for the Third EU Health Programme.²⁷ Furthermore, to obtain funding, the applicants must explain the European added value to be created by their proposal.²⁸ Introducing the European added value criteria into the application process for funding was a further development based on the experience of implementing the Second EU Health Programme. The European Commission states that this pushed the majority of potential beneficiaries and assessment panels to consider the European added value aspect.²⁹

European added value with regard to the EU Health Programme

This analysis, as well as the mid-term evaluation, confirmed the European added value of the Third EU Health Programme and measures supported throughout all the criteria analysed in this paper, from the strong cross-border aspect to best practices and networking, from supporting the free movement of people to the creation of economies of scale. The consultation ran as part of the mid-term review underpins this conclusion. Summed up, stakeholders see European added value in addressing common challenges, e.g. health inequalities, migration, an ageing population, patient safety, high quality health care and tackling health threats. The mid-term review shows that the programme is highly relevant to Member State health needs.³⁰

Table 2 – EU Health Programme: Non-exhaustive list of European added value achieved

	Criteria	Resulting European added value
1.	Economies of scale	<ul style="list-style-type: none"> • Joint procurement mechanisms • Antibiotic stewardship programmes and implementation of best practice guidance • Facilitating the approval and use of generic medicines • Synchronised pharmacovigilance with regards to vaccines, medicines and (increasingly) medical devices • Effective and timely health messaging • Regulation of industry in areas of public health concern (such as nicotine/vaping) • Shared standards and validation mechanisms at EU level to alleviate the financial burdens on individual Member States
2.	Free movement of persons	<ul style="list-style-type: none"> • Movement of patients accessing health care in different EU Member States • EU-wide health insurance cards

²⁷ [Mid-term evaluation of the third health programme 2014-2020](#), Final Report, European Commission, 2017.

²⁸ Ibid.

²⁹ Ibid.

³⁰ Proposal for a regulation on the European Social Fund Plus (ESF+), [COM\(2018\) 382 final](#), European Commission, 2018.

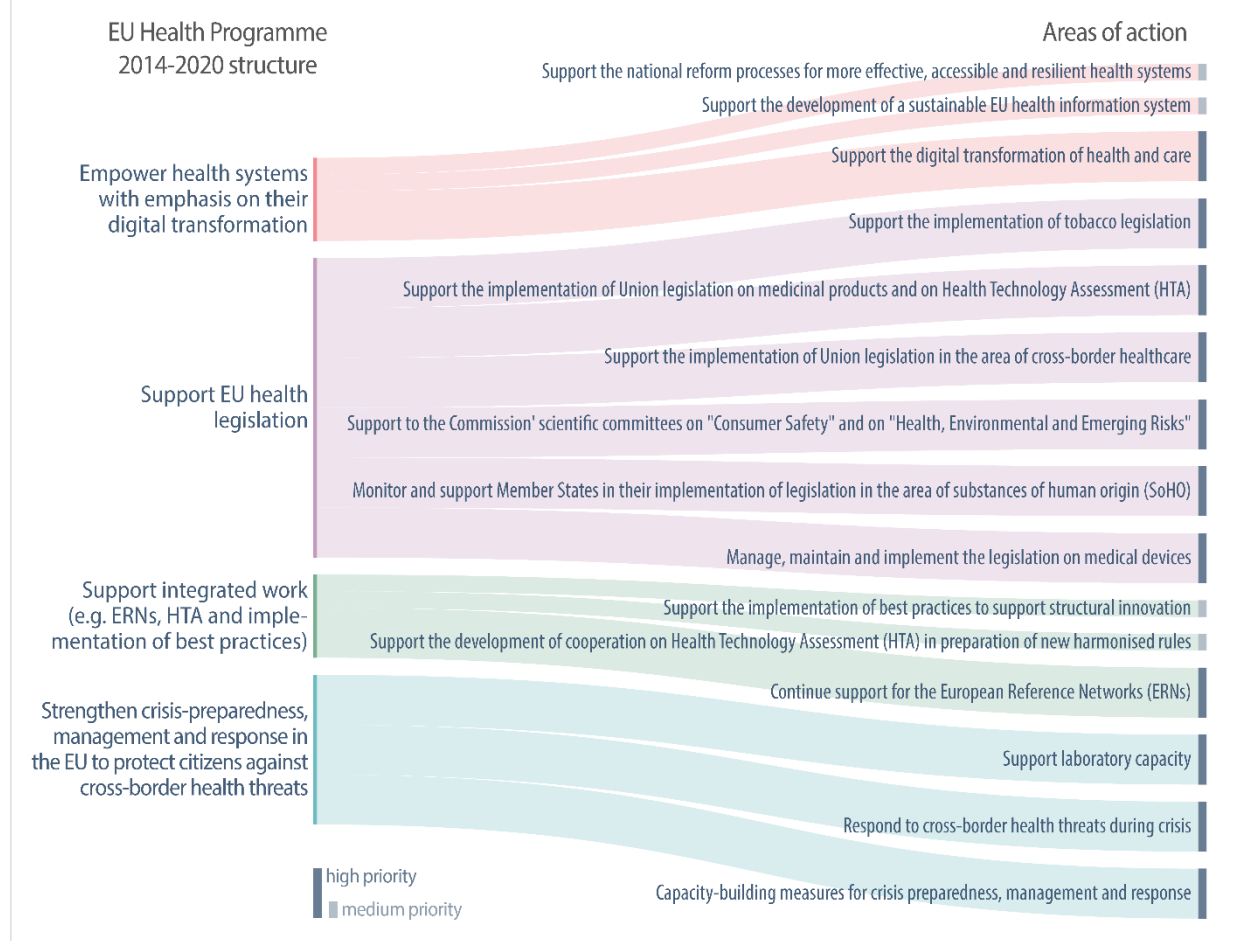
		<ul style="list-style-type: none"> • E-Prescriptions • Harmonisation and communication of patient rights across the EU • Coordination of/with patient advocacy and consumer groups • Pharmacy databases for controlled substances • Travel, displacement and migration • Better integration of the care provided to refugees and migrants across the EU • New educational pathways and guidance documents • Development of emergency protocols • Movement of healthcare personnel between EU Member States • Mutual recognition of medical/professional degrees in the EU • Addressing deficiencies in care (for example, doctor shortages) in rural areas • Uniform quality criteria (quality improvements, benefiting from efforts by stakeholders such as the Institute for Healthcare Improvement (IHI) Europe and others); certification
3.	Cross border threats	<ul style="list-style-type: none"> • Developing synchronised responses to pandemics/epidemics • Building capacity for EU-wide surveillance mechanisms/networks • Support for health screening and security at the border • Harmonisation of public health communication • Pharmacy database integration
4.	Promotion of best practices	<ul style="list-style-type: none"> • Best practice portal (linkage with government bodies and expert groups) • Chafea calls for proposal/tender to build capacity where it is most needed • Development of standard protocol for existing and emerging health priorities • Integration of data safety regulations in e-health procedures
5.	Networking	<ul style="list-style-type: none"> • Chafea calls and conferences • Public health official exchanges with scientists across the EU • NGO, 'citizen groups' and patient representative organisations' active involvement
6.	Benchmarking for decision-making	<ul style="list-style-type: none"> • Shared knowledge gateways • Linking the evidence and greater agreement and adoption sought across the EU • Consensus processes among public health agencies and other EU stakeholders
7.	Unlocking the potential of innovation	<ul style="list-style-type: none"> • Chafea/DG SANTE promotion of public health oriented funding fee from pharmaceutical organisations • Innovative payment models for innovative solutions • Innovation teaching in medical school
8.	Implementing EU legislation	<ul style="list-style-type: none"> • Protection of public health and promotion of health in all policies (Article 168 TFEU)

	<ul style="list-style-type: none"> • Support for implementation of EU health legislation for a safe and well-functioning internal market in areas such as cross-border healthcare and tobacco. • Support for the free movement of persons through cross-border health care legislation, e.g. by addressing patients' rights to cross-border health care and the use of e-health, which allows effective implementation of the 2011 Cross-border Healthcare Directive • Support for Member States for their implementation of EU health legislation, through the development of common tools.
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Source: EPRS, based on the Annexes to this study (forthcoming), staff working document SWD/2017/331 and final report of the mid-term evaluation of the third health programme, European Commission, 2017.³¹

A further approach to analysing the European added value was depicted in the impact assessment for a new European Social Fund Plus (ESF+) programme. A ranking of the top 15 areas of action identified by the European Commission, with higher European added value was used. (See figure 3.)

Figure 3 – Areas of action under the recent EU Health Programme with higher EU added value



Source: European Commission, ESF+ impact assessment, 2018.

³¹ B. Rath, Annex I, Briefing note on EU Health Programme, 2019 (forthcoming); Staff Working Document on the mid-term evaluation of the third health programme [SWD/2017/331](#), European Commission, 2017; and [mid-term evaluation of the Third Health Programme 2014-2020](#), final report, European Commission, 2017.

2.5. Showcasing EU measures in practice

This chapter gives three examples of EU action that impacts citizens' daily life. These showcases are depicted more extensively in Annex I of this paper (forthcoming). More details and further examples can be found in other EU publications on cross-border healthcare.³²

Best practice portal (BP Portal)

In conformity with the European added value criterion of promoting best practices, BP Portal³³ is a repository of examples of best practices that have been co-funded under the Third EU Health Programme, such as CHRODIS, JANPA and SCIROCCO. The main priorities of the BP Portal, as set out by DG SANTE, are to identify and disseminate best practices related to health promotion, non-communicable disease prevention and reduction of premature mortality due to non-communicable diseases, by one-third by 2030. Stakeholders are invited to submit evaluated practices to the BP Portal, which, once they are positively assessed, receive a certificate of recognition and are published on the Portal. To date, around 200 types of actions have been certified and published on BP Portal.

Health promotion and disease prevention knowledge gateway

The knowledge gateway³⁴ developed by the Joint Research Centre (JRC) and European Commission Directorate General for Health and Food Safety (DG SANTE) is an online reference point with structured and up-to-date, peer-reviewed information on a series of priority topics related to diets, physical activity, alcohol related harm and other fields related to prevention of non-communicable disease. The knowledge gateway was created to assist public health stakeholders in the communication of important health topics. It functions similar to a wiki platform, consisting of interlinked, and periodically updated, briefing notes, integrating expertise from different sources.

Economics of prevention study

Fulfilling the added value criterion of networking, a study³⁵ jointly produced between the European Commission, the World Health Organization (WHO) and the Organisation for Economic Cooperation and Development (OECD) represents a good example of the EU's determination to cooperate with international organisations to find solutions to EU issues. The Third EU Health Programme provided €600 000 in funding for a duration of two years (2015-2017), to launch the 'economics of prevention' action. The study aimed at supporting health officials to address the direct and indirect costs of non-communicable diseases, and especially, of obesity and harmful alcohol use. More specifically, the study estimated not only the healthcare and morbidity costs or the labour market impacts, but also assessed the negative welfare and positive economic impacts, such as higher revenues from alcohol taxes. It then concentrated and presented a set of government strategies, mechanisms and best practices for combating obesity and alcohol abuse.

³² [European cross-border cooperation on health – Theory and practice](#), Consumers, Health, Agriculture and Food Executive Agency (Chafea), 2017.

³³ Public Health, [Best practice portal](#), European Commission, January 2019

³⁴ [Health Promotion and Disease Prevention Knowledge Gateway](#), European Commission website, January 2019.

³⁵ [Sweeping changes to upgrade Europe's health systems](#), Consumers, Health, Agriculture and Food Executive Agency (Chafea), 2018.

Third EU Health Programme: facts & figures³⁶

- 16 Member States have integrated coherent approaches in the design of their preparedness plans in 2016, compared to none in 2014.
- 15 Health technology assessments (HTA) operated across the EU in 2014 and 2015.
- Joint HTA cooperation has grown to include 81 organisations from 29 countries, which constitute a network of strong partners across Europe working together for better access to health technologies for Europeans.
- Since March 2017, 24 thematic European reference networks, gathering over 900 highly specialised healthcare units from 26 countries, have begun working together on a wide range of diseases.
- Between 2014 and 2016, €165 6 million was allocated to the 23 thematic priorities set out by the Third EU Health Programme.
- To date, more than 245 projects have been funded under the Third EU Health Programme.
- Between 2014 and 2016, at least 11 cross-cutting actions for migrants and refugees were taken, with over €14 million allocated.
- In the 2014-2016 period, scientific committees supported by the Health Programme provided 87 opinions/provided scientific advice and risk assessment to the Commission.
- Between 2014 and 2016 33 % and 31 % of the funding under the of the EU Health Programme was allocated to objectives 1, on health promotion, and 3 on health systems; 19 % to objective 4, access to healthcare; 10 % to horizontal or cross-cutting activities; and 7 % to objective 2, cross-border health threats.

³⁶ Sources: Impact Assessment, European Social Fund Plus (ESF+), [SWD/2018/0289](#), European Commission, 2018, Staff Working Document on the mid-term evaluation of the third health programme [SWD/2017/331](#), European Commission, 2017; B. Rath, Annex I, Briefing note on EU Health Programme, 2019 (forthcoming)

3. Cross-border health care

3.1. Background

EU citizens have a right to free movement, and they use it. Whilst moving, staying healthy can be an issue, as is the question of the choice of treatment. The EU provides a right to access and reimbursement of healthcare in any EU Member State. This is a benefit for patients and may even help them to find appropriate treatment in a Member State other than their country of residence.³⁷ In addition, health professionals may profit from a greater variety of job opportunities, working together with colleagues to exchange knowledge and simply learning from each other to offer the best treatments for patients.

In this sense, cross-border healthcare can be defined as the movement of patients, health professionals and knowledge across the national borders of individual Member States.³⁸ As pointed out in Annex II (forthcoming), though in limited terms, patient and health professionals' mobility has significantly increased and more EU citizens are crossing EU borders.³⁹ With increased mobility, national health system boundaries become more permeable.⁴⁰

3.2. Legal framework

In 1971,⁴¹ the first regulations to ensure coverage of healthcare expenses for European workers traveling within the internal market came into play. The Court of Justice of the European Union (CJEU) ruled on several occasions on the issue, supporting European citizens' right to travel to another Member State to receive medical services.⁴² In that context, the two landmark cases were *Kohll* and *Decker* in 1998.⁴³ The CJEU stated that European citizens have the right to benefit from healthcare services in a different Member State, and to reimbursement in accordance with the tariffs of the Member State in which they are insured.⁴⁴

More recently, Directive 2011/24/EU⁴⁵ on patients' rights in cross-border healthcare consolidated these rulings and represented an important step toward patient empowerment and the recognition of the rights of European citizens to benefit from cross-border healthcare services.⁴⁶ The Directive addresses three main areas: reimbursement of the costs of cross-border healthcare; Member State

³⁷ [Cross-border healthcare in the EU](#), European Court of Auditors (ECA), 2018.

³⁸ [Evaluative study on the Cross-border Healthcare Directive \(2011/24/EU\)](#), Final report, European Commission, 2015.

³⁹ K. Footman et al., [Cross-border health care in Europe, Policy summary 14](#), WHO 2014 and A.-L. Beaussier, Annex II, Briefing note on cross-border healthcare, 2019 (forthcoming).

⁴⁰ H. Vollaard, *Solidarity, Territoriality, and Healthcare: Cross-National Policy Learning in Europe*. International Public Policy and Management, 2004, and A.-L. Beaussier, Annex II, Briefing note on cross-border healthcare, 2019 (forthcoming).

⁴¹ K. Footman et al., [Cross-border health care in Europe, Policy summary 14](#), WHO 2014, and, A.-L. Beaussier, Annex II Briefing note on cross-border healthcare, 2019 (forthcoming).

⁴² A.-L. Beaussier, Annex II, Briefing note on cross-border healthcare, 2019 (forthcoming), mentions the cases C-158/96 *Kohll* (1998); C-120/95 *Decker* (1998); C-157/99 *Geraets-Smits and Peerbooms* (2001); C-385/99 *Müller-Fauré and Van Riet* (2003); C-372/04 *Watts* (2006); C-444/05 *Stamatelaki* (2007).

⁴³ C-120/95 *Decker v Caisse de maladie des employés privés* (1998) and C-158/96 *Kohll v Union des caisses de maladie* (1998).

⁴⁴ For more information see: V. Léau, L. Marcelli, [European patients' rights in cross-border healthcare](#), EPRS, European Parliament, 2014.

⁴⁵ [Directive 2011/24/EU](#) on the application of patients' rights in cross-border healthcare, European Commission, 2011.

⁴⁶ A.-L. Beaussier, Annex II, Briefing note on cross-border healthcare, 2019 (forthcoming).

responsibilities with regard to cross-border healthcare; and cooperation between healthcare systems.⁴⁷ For further details, see Annex II to this paper (forthcoming).⁴⁸

3.3. Policy tools

As outlined in Annex II (forthcoming), EU actions and achievements in cross-border health care have lead to further developments, such as the creation of a European health insurance card in 2004. The investment in projects aimed at facilitating the circulation of patients, expertise, knowledge and information is another example. The creation of European reference networks (ENRs) for rare diseases; e-health projects increasing the interoperability of Member State IT management systems, facilitating the transmission of medical information and patient records; and support for the establishment of national contact points in Member States to help inform patients of their rights, are some of the most relevant outcomes.⁴⁹

The Second and Third EU Health Programmes 2008-2013 and 2014-2020 provided support for cross-border healthcare measures. The current Health Programme supports and encourages cooperation among Member States as a key objective.⁵⁰ Other EU funds are provided through programmes such as Horizon 2020 (H2020), the Connecting Europe Facility and EU Structural Funds. E-health projects that are relevant to the implementation of the Directive are funded through the European Union's Research and Innovation funding programme for 2007-2013 (FP7) and H2020 spending programmes.⁵¹

Activities are monitored and a Cross-border Healthcare Expert Group with experts from all EU countries assists the European Commission with the implementation of the Directive. It provides the Commission with advice and expertise, and national authorities with a forum to exchange their experience on implementing the Directive.⁵²

3.4. Benefits of current EU action

This section on the benefits of current EU healthcare measures is set up in five parts displaying aspects of i) patient mobility and patient rights; ii) the mobility of health professionals; iii) the European reference networks initiative on rare diseases; and vi) cross-border prescriptions. The section closes with v) a non-exhaustive overview of the European added value for cross-border health care identified in Annex II (forthcoming).

While Member States have exclusive competence on health matters, action at the European level has important added value in coordinating Member State policies and procedures, and in promoting more interoperability and exchange of data among national health systems. It also plays an important role in trying to tackle the practical obstacles to cross-border healthcare, such as administrative and cultural barriers.

⁴⁷ V. Léau, L. Marcelli, European patients' rights in cross-border healthcare, EPRS, European Parliament 2014.

⁴⁸ A.-L. Beaussier, Annex II, Cross-border healthcare, 2019 (forthcoming).

⁴⁹ Ibid.

⁵⁰ [Cross-border healthcare](#), Consumers, Health, Agriculture and Food Executive Agency (Chafea), 2018.

⁵¹ [Cross border healthcare in the EU](#), European Court of Auditors (ECA), 2018.

⁵² [Cross-border Healthcare Expert Group](#), European Commission website, January 2019.

i) Patient mobility and patient rights

EU healthcare measures on patient mobility and patient rights⁵³ aim to support individuals navigate the complex procedures involved in seeking health care abroad, and to promote better awareness of these rights.

European added value on patient mobility

The main European added value lies, amongst other things, in coordinating Member State policies and procedures, and in promoting more interoperability and exchange of data among national health systems.

ii) Mobility of health professionals

Based on EU freedoms of labour and movement and linked to cross-border healthcare, the EU is harmonising administrative requirements to support and facilitate professional mobility.⁵⁴

European added value with regard to mobility for health professionals

European added value with regard to mobility for health professionals⁵⁵ is linked to a coordination role in the recognition of professional qualifications of health professionals, which results in increased healthcare professionals' mobility across Member States. This creates stronger professional networks and encourages circulation of medical knowledge beyond national borders.

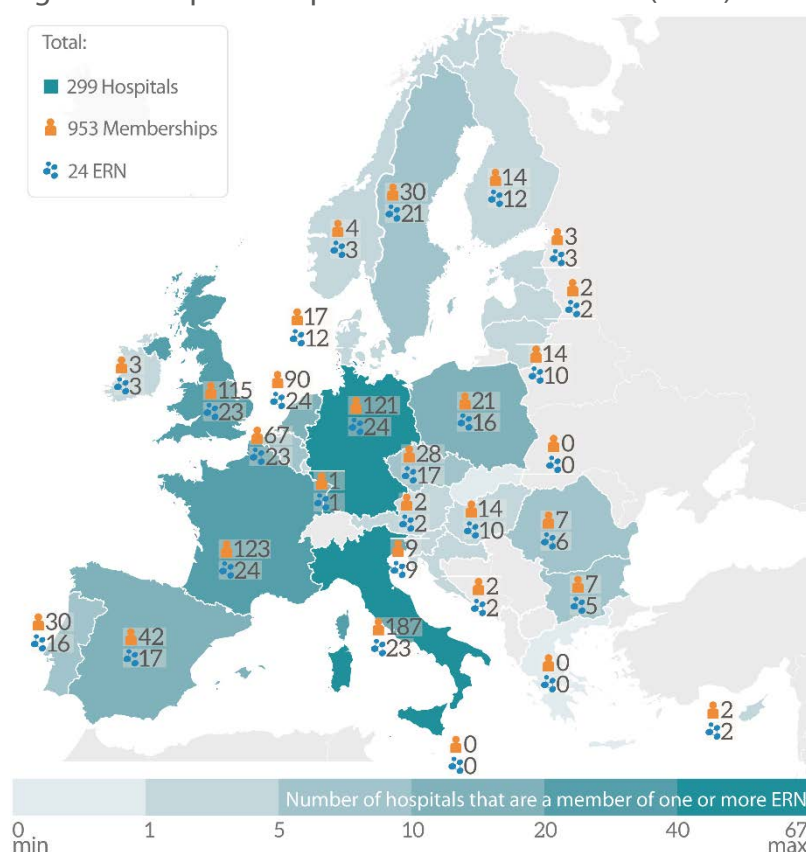
iii) European reference networks (ERNs) initiative on rare diseases

The ERN initiative⁵⁶ on rare diseases aims at improving diagnosis and treatment of patients with complex conditions and rare diseases. It addresses patient mobility and encourages the exchange of knowledge and expertise between health professionals and Member States.

European added value of the European Reference Networks initiative on rare diseases

The European added value of the European reference networks initiative

Figure 4 – Map of European reference networks (ERNs)



Data source: [European reference networks](#), European Commission website, February 2019.

⁵³ For more details, see A.-L. Beaussier, Annex II, Briefing note on Cross border Healthcare, 2019 (forthcoming).

⁵⁴ For more details, see A.-L. Beaussier, Annex II, Briefing note on Cross border Healthcare, 2019 (forthcoming).

⁵⁵ Ibid.

⁵⁶ Ibid.

on rare diseases⁵⁷ is achieved by encouraging the sharing of knowledge, connecting potential for innovation, and the possibilities offered by information technology (IT) services and technologies. It is highly cost-effective, as for example, it helps avoid expensive patient transport.

iv) Cross-border prescriptions

EU cross-border prescriptions⁵⁸ measures aim to simplify the recognition of medical prescriptions within the EU. That is to make it easier for patients to receive a prescribed medical product or medical device in another Member State than that in which the prescription originates.

European added value for cross-border prescriptions

Cross-border prescriptions relate to avoiding waste and additional visits to a local doctor to obtain a prescription. It helps to facilitate the free movement of patients and addresses the patients' rights to cross-border health care.

v) Overview of the European added value for cross-border healthcare

Cross border health care⁵⁹ measures, as well as the Directive itself, are said to have helped improve and strengthen legal certainty and clarity for patients regarding their rights. In addition, they support the national authorities responsible for their management.⁶⁰ Member States can now more easily join forces in voluntary cooperation and cohesion between border regions and in furthering cooperation in the field of e-health and ERNs for rare and complex diseases. ERNs help to improve the diagnosis, treatment and management of rare diseases through cooperation and pooling of knowledge. This can lead to results in innovations in research.⁶¹

Table 3 – Cross-border healthcare: Non-exhaustive list of European added value achieved

	Criteria	Resulting European added value
1.	Economies of scale	<ul style="list-style-type: none"> • Issues of medical shortages and waiting times in one country addressed by allowing treatment in another country • Coordination of Member States' policies and bilateral agreements • Standardisation of diplomas and EU-wide recognition of qualifications, simplified administrative procedures and improved efficiency by facilitating professional mobility • European reference networks (currently 24) on rare diseases allow sharing of scarce knowledge on rare diseases • E-health and e-prescriptions ensure better coordination of care, avoid duplications in care and inefficiencies by providing basic information on patient records to health professionals across the EU • Waste and additional visits to a local doctor to get a prescription (cost-effectiveness) avoided

⁵⁷ Ibid.

⁵⁸ Ibid.

⁵⁹ Ibid.

⁶⁰ [Public Health Newsletter 228](#), European Commission, January 2019.

⁶¹ Ibid.

2.	Free movement of persons	<ul style="list-style-type: none"> • Movement of patients increased by implementing simplified procedures for treatment and reimbursement for patients • Healthcare professional mobility increased across Member States by implementing easier recognition of diplomas for health professionals • ERNs facilitate cross border treatments for rare diseases • E-health facilitates and enhances the quality of cross border health care • Free movement of patients facilitated
3.	Cross-border threats	<ul style="list-style-type: none"> • N/A
4.	Promotion of best practices	<ul style="list-style-type: none"> • Examples of best practices at regional level disseminated to other EU Member states • European reference networks allow the diffusion of best practice guidelines on rare diseases • E-health solutions participate in the modernisation of health systems across the EU
5.	Networking	<ul style="list-style-type: none"> • EU acts as a platform allowing dialogue between Member States and health officials • Health professional mobility encourages stronger professional networks and the diffusion of medical knowledge beyond national borders • ERNs disseminate knowledge on best practices across the EU
6.	Benchmarking for decision-making	<ul style="list-style-type: none"> • Best practices and examples promoted at regional level • E-health voluntary network among Member States connects national authorities responsible for e-health and presents best practices in the development of interoperable applications to enhance the quality and continuity of care for patients
7.	Unlocking the potential of innovation	<ul style="list-style-type: none"> • Research projects funded • ERN on rare diseases allow for innovative collaboration and health professional networks • Innovation around e-prescriptions triggered through reforming the associated rules and necessary IT infrastructure.
8.	Implementing EU legislation	<ul style="list-style-type: none"> • Directive on Free Movement of Persons and Cross-border Healthcare • E-health allows effective and efficient implementation of the 2011 Cross-border Healthcare Directive • Patients' rights to cross-border healthcare and the free movement of persons

Source: EPRS and Annex II of this paper (forthcoming).

3.5. Showcasing EU measures in practice

This chapter illustrates four examples of the impact of EU action in citizens' daily life. The showcases are more extensively depicted in Annex II of this paper (forthcoming). More details and further examples can be found in other EU publications on cross-border healthcare.⁶²

Trinationales Kompetenzzentrum für Ihre Gesundheitsprojekte (TRISAN)

TRISAN is a tool for structuring and coordinating cross-border health located in the Upper Rhine (France Germany-Switzerland) region, which covers the Baden region and the Southern Palatinate (Germany), Alsace (France) and North-West Switzerland. It is a densely populated region focused around a number of urban centres and has a significant presence of cross-border workers. The tri-national cross-border centre project TRISAN aims to identify, coordinate and amplify the synergies born of several decades of cooperation on health in the Upper Rhine. It is intended to support administrations and healthcare providers on every side of the borders in order to best structure and develop partnerships and projects. The TRISAN project is run by the Euro-Institut at Kehl (Germany).

INTERSYC: Treating and protecting children together (Greece, Bulgaria)

The border between Greece and Bulgaria runs through a mountainous region distant from any urban centres. This remoteness causes significant challenges on both sides of the border in terms of public services, in particular in the area of health. The INTERSYC project (INTEgrated TERritorial SYnergies for Children, Health and Protection) was established between 2013 and 2015. It was set up by the organisation The Smile of the Child, in coordination with the Bulgarian non-profit association Chance, the Bulgarian Nadja Centre Foundation, the towns of Kavala and Paggaiou (Greece) and the Kardzali regional health inspectorate (Bulgaria). Bringing together these diverse skills and expertise made it possible to overcome regional isolation by measures such as seminars and training courses to improve protection, prevention and healthcare, particularly for children and their families and by developing activities to improve child health, particularly through prevention.

Joint action on rare cancers (JARC)

The JARC launched in October 2016 and gathers 34 partner organisations in 18 Member States; prioritises all rare cancers in EU and national cancer plans; harmonises practices and research funding. It targets European reference networks (three of which are devoted to rare cancers) to optimise the process of creation of the ERNs, by providing them with operational solutions and professional guidance in the areas of quality of care, epidemiology, research and innovation, education and state of the art definitions on prevention, diagnosis and treatment of rare cancers.

E-prescription

On 21 January 2019, the European Commission announced that the first EU patients, from Finland and Estonia, are now able to use digital prescriptions issued by their home doctor when visiting a pharmacy in another EU country. That is, Finnish patients are now able to go to a pharmacy in Estonia and retrieve medicine prescribed electronically by their doctor in Finland. The initiative applies to all e-prescriptions issued in Finland and to the Estonian pharmacies that have signed the agreement. The novelty of this initiative is that the e-prescriptions are visible electronically to participating pharmacists in the receiving country via the new e-health digital service infrastructure, without the patient having to provide a written prescription. This first step is in line with EU policy on digital health and care, and more countries are expected to follow soon.

⁶² [European cross-border cooperation on health – Theory and practice](#), Consumers, Health, Agriculture and Food Executive Agency (Chafea), 2017.

Cross-border health care: facts & figures⁶³

- In 2016 approximately €65 million was spent across all EU Member States collectively on cross-border health care. This is estimated as 0.004 % of the EU-wide annual healthcare budget.
- 50 % of patient mobility seems to be driven by proximity as well as collaborations between clinicians in border regions. A very significant part seems to reflect the patients' choice as where to receive healthcare.
- In 2017, a total of 74 589 enquiries were made at the 29 national contact points (NPs).
- 5 800 recognised rare diseases affect 6-8 % of the EU population (between 27 and 36 million people).
- 24 European reference networks have become a flagship initiative for cross-border health care. They connect 900 health care centres in 313 different hospitals across 26 Member States, affecting the lives of 30 million EU citizens.
- Between the launch of the ERNs in March 2017 and November 2018, 252 patients benefited from virtual consultations.
- The European rare diseases organisation (EURORDIS) established 24 European Patient Advocacy Groups (EPAGs) in 2016, mirroring the themes of the ERNs.
- Cross-border prescriptions are estimated to represent between 1.1-8 million prescriptions each year (0.02 % to 0.04 % of all medical prescriptions in the EU in 2012).
- Since January 2019, the first EU patients can use digital prescriptions in another Member State: Finnish patients may now go to a Estonian pharmacy to retrieve medicine prescribed electronically by their doctor in Finland.
- 22 Member States are part of the e-health digital service infrastructure expected to exchange e-prescriptions and patient summaries by the end of 2021.

Cross-border territories facts & figures

- In 2016 about 17 million EU citizens lived in a Member State other than that of their citizenship. Every year millions more make trips to other EU countries.
- Cross-border territories represent 40 % of the territory of the EU.
- More than 1 European in 3 lives in a border region.
- There are 2 million cross-border workers in the EU.
- There are 37 extended cross-border urban areas in Europe.

⁶³ Sources: A.-L. Beaussier; Annex II, Briefing note on cross-border healthcare, 2019 (forthcoming); N. Scholz, [Understanding European Reference Networks](#), EPRS, European Parliament, 2017; [First EU citizens using ePrescriptions in other EU country](#), press release, European Commission, 21 January 2019; [Care across borders](#), European Commission website, January 2019; [Rare diseases](#), European Commission website, January 2019; Report on the application of patients' rights in cross-border healthcare, [COM\(2018\) 651 final, European Commission](#), 2018; [People in the EU - statistics on origin of residents](#), Eurostat, 2017; [Fourth Conference on European Reference Networks](#), European Commission, 2018.

4. Pharmaceuticals regulation

4.1. Background

In the EU, all pharmaceuticals need authorisation prior to sale. The approval of pharmaceuticals in Europe is regulated through numerous procedures. Pharmaceuticals are mainly authorised in the Member States. Nevertheless, the European Union does have a responsibility to protect human health. The high quality and safety of human medicines is considered an essential measure to ensure public health. This idea dates back to the 1950s,⁶⁴ and the decision to progressively join forces between the EU and the Member State levels was built between 1965-1975.⁶⁵ On one hand, EU policies aim at ensuring public health, on the other, at allowing free movement of pharmaceuticals. Nowadays, there is a single EU-wide procedure managed by the European Medicines Agency (EMA), which pharmaceuticals have to pass in order to be released on the market. In practice, pharmaceuticals can be approved either at European level or through decentralised and mutual-recognition procedures in the Member States.⁶⁶

4.2. Legal framework

By laying down that 'a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities' in Article 168 of the Treaty on the Functioning of the European Union (TFEU), the legal basis for medicinal products is set. The European Parliament and the Council shall contribute to this objective by adopting 'measures setting high standards of quality and safety for medicinal products and devices for medical use'.⁶⁷

Since the introduction of Council Directive 65/65/EEC in 1965, as an outcome of the thalidomide disaster, legislation became more structured. The legal framework is constantly revised, and in 1975, this paved the way for joint EU marketing authorisation, and in 1995, the European Agency for the Evaluation of Medicinal Products (EMEA), which is now the European Medicines Agency (EMA) was created.⁶⁸

The regulation of pharmaceuticals in the EU is based on a quite complex regulatory framework. Topics such as manufacturing, clinical trials, marketing authorisation, pharmacovigilance and, patient information are addressed.⁶⁹ The definition of medicinal products is formulated in Article 1(2) of Directive 2001/83/EC. The common thread of the entire regulatory framework is the safeguarding of public health and the free movement of goods – respectively pharmaceuticals.⁷⁰

4.3. Policy tools

Today, the legal system for pharmaceuticals is based on the medicines regulatory authorities in the 31 Member States of the European Economic Area (EEA), the 'national competent authorities', NCAs,

⁶⁴ N. Scholz, [Legal framework governing medicinal products in the European Union](#), EPRS, European Parliament, 2015.

⁶⁵ C. Huttin, Annex III, Briefing note on Pharma regulation, 2019 (forthcoming).

⁶⁶ N. Scholz, [Legal framework governing medicinal products in the European Union](#), EPRS, European Parliament, 2015.

⁶⁷ For more see N. Scholz, [Legal framework governing medicinal products in the European Union](#), EPRS, European Parliament, 2015.

⁶⁸ N. Scholz, [Legal framework governing medicinal products in the European Union](#), EPRS, European Parliament, 2015.

⁶⁹ The whole body of European pharmaceuticals regulation, including guidelines, is compiled in [EudraLex](#) ('The Rules Governing Medicinal Products in the European Union').

⁷⁰ For a more detailed overview on the legal framework see N. Scholz, [Legal framework governing medicinal products in the European Union](#), EPRS, European Parliament, 2015 and C. Huttin, Annex III, Briefing note on Pharma regulation, 2019 (forthcoming).

the above-mentioned European Medicines Agency (EMA) and the European Commission (DG SANTE).⁷¹

In addition to the actions taken by these actors, the aim is to benefit from the actions taken and the knowledge gained in the Member States and to create efficiency gains, whilst not repeating challenges experienced and efforts already taken by other Member States. This is done through a network approach, which includes, amongst others, several voluntary meetings per year between the national authorities, the EMA and the Commission.⁷²

4.4. Benefits of current EU action

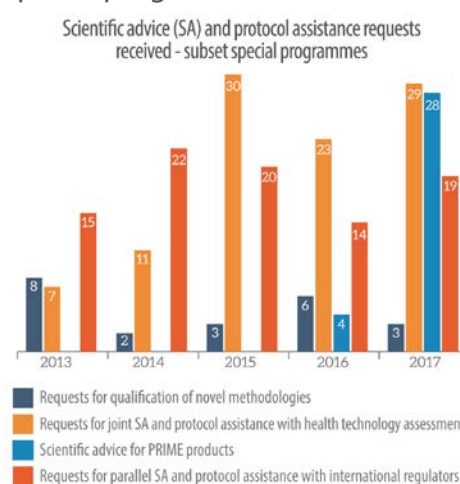
The European Medicines Agency (EMA) is at the centre of the control systems for pharmaceuticals in Europe. The EMA helps to guarantee the quality of pharmaceuticals through scientific assessments and recommendations as to whether pharmaceuticals are allowed to enter the market, as well as through monitoring their safety when marketed.⁷³

Besides the great majority of new pharmaceuticals passing through this system, pharmaceuticals also exist that were already available before this authorisation procedure existed. They follow another procedure, namely authorisation through the national level based on common EU data requirements and standards.⁷⁴

Besides the regulatory and authorisation approach, the EU also supports research and innovation funding programmes for new pharmaceuticals, e.g. the innovative medicines initiative, a public-private initiative to accelerate the development of clinical trials of new medicines and vaccines and the International Consortium for Personalised Medicine initiative.⁷⁵

Falsified pharmaceuticals is a highly sensitive issue, as it deals with individual citizens' health as well as with public health in general. The European Commission has addressed the phenomenon, for example, through a common logo for websites of legal online pharmacies/retailers.⁷⁶

Figure 5 – Requests received by the European Medicines Agency (EMA) – special programmes



Source: European Medicines Agency (EMA), [Annual Report 2017](#), 2018.

European added value with regard to pharmaceuticals regulation

Pharmaceuticals regulation's main added value lies in the economy of scale achieved through simplification and avoiding duplication and in the promotion of best practices and knowledge exchange through networking. Furthermore quality standards and thereby the safety and protection of individuals and public health are important. These latter are enhanced through, amongst other things, benchmarking, implementation of standards, as well as innovation.

⁷¹ N. Scholz, [Legal framework governing medicinal products in the European Union](#), EPRS, European Parliament, 2015.

⁷² Ibid.

⁷³ Ibid.

⁷⁴ Ibid.

⁷⁵ N. Scholz, What Europe does for me, My health, [People on prescription medication](#), EPRS, European Parliament, 2018.

⁷⁶ N. Scholz, [Legal framework governing medicinal products in the European Union](#), EPRS, European Parliament, 2015.

Table 4 – Pharmaceuticals regulation: Non-exhaustive list of European added value achieved

	Criteria	Resulting European added value
1.	Economies of scale	<ul style="list-style-type: none"> • Avoids duplication of documentation for market applications • Centralised procedure especially allows firms to access markets in the European Economic Area (EEA) • European Medical Agency (EMA) for orphan drugs provides incentives with reduced fees to companies with very limited markets concerning pharmaceuticals that address rare diseases
2.	Free movement of persons	<ul style="list-style-type: none"> • N/A
3.	Cross-border threats	<ul style="list-style-type: none"> • Easier to address safety issues • Risk reduction through the 'black triangle' on monitored pharmaceuticals that help identify the medicines concerned and report suspected side-effects
4.	Promotion of best practices	<ul style="list-style-type: none"> • Filing via the EMA⁷⁷ and/or other forms of cooperation of European experts provides various forms of simplification and may trigger scientific progress
5.	Networking	<ul style="list-style-type: none"> • Creation of the Network of Health Technology Assessment agencies: EUnetHTA,⁷⁸ leading to cooperation from the EU to evaluation and provide expertise on various technologies • European Medicines regulatory network coordinates national authorities in the Member States (EU) and the European Economic Area (EEA), collaboration with European Commission and EMA
6.	Benchmarking for decision-making	<ul style="list-style-type: none"> • Safety guidelines • Lists of criteria for prices and reimbursement • Technical tools for economic evaluation and shared expertise to be used by national authorities
7.	Unlocking the potential of innovation	<ul style="list-style-type: none"> • Very innovative drugs or breakthroughs receive fast access to market approval for the European market
8.	Implementing EU legislation	<ul style="list-style-type: none"> • ISO implementation standards in medicines

Source: EPRS and Annex III of this paper (forthcoming).⁷⁹

4.5. Showcasing EU measures in practice

Adaptive pathways – Initiatives for patient early access to medicines and their exploration with stakeholders

EMA conducted a pilot project on adaptive pathways between 2014 and 2016 to address patients' unmet medical needs with regard to development of medicines and data generation. In a first step, a small group of patients received pharmaceuticals addressing their specific needs. Based on the

⁷⁷ [European Medicines Agency](#) (EMA) website, January 2019.

⁷⁸ EUnetHTA is the [European network for HTA Joint Action](#).

⁷⁹ C. Huttin, Annex III, Briefing note on Pharma regulation, 2019 (forthcoming).

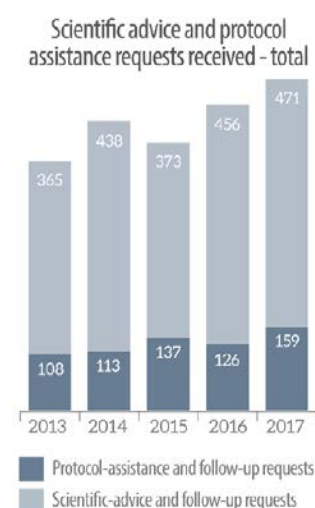
patients' experiences, the pharmaceutical was then authorised for use for wider groups of patients. A third of the 62 applications covered pharmaceuticals for cancer treatment. The final report found that adaptive pathways could support medicine development in areas of high-unmet medical needs. After the completion of the pilot project, EMA and the European Commission discussed the application of adaptive pathways in practice.⁸⁰

PRIME (PRiority MEDicines)

PRIME is a voluntary scheme, launched in March 2016, aiming at enhancing and improving innovation and development of pharmaceuticals addressing unmet medical needs and thereby accelerating their assessment. The focus lies on the most 'promising medicines' with the potential of major therapeutic benefits. Furthermore, early dialogue and scientific advice are an essential part

of the PRIME approach to improving clinical trial designs for the evaluation of marketing-authorisation application and protecting patients. Patients only take part in trials where necessary. Advanced therapies medicinal products (ATMPs), pharmaceuticals for human use based on genes, tissues or cells, take a share of up to 40 % of pharmaceuticals admitted to the scheme.⁸¹

Figure 6 – Requests received by the European Medicines Agency (EMA) in total



Source: European Medicines Agency (EMA), [Annual Report 2017](#), 2018.

Cooperation between EMA and HTA bodies

Providing scientific advice is one of the core EMA routines. In 2017, a joint platform for parallel consultation was created to provide medicine developers with advice on their development plans and to help them with the alignment of data required. This should ensure that new pharmaceuticals do not fail to be available or reimbursed for patients despite having market authorisation.⁸²

Patient registries

Patient registries are a highly relevant tool for post-authorisation evidence. The information collected on patients suffering from a specific disease with specific treatment, complements data from other sources. Risks and benefits can be better monitored. As in practice, however, there are challenges intertwined with these registries for regulators and developers. EMA therefore launched a patient registry initiative in 2015, aiming at evaluating pharmaceuticals in a more systematic way. In 2017, a strategy and a work plan for the patient registry initiative was developed. EMA also

initiated the registration of multinational disease registries in the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) resource database, which included 66 disease registries up to the end of 2017.⁸³

⁸⁰ N. Scholz, [Legal framework governing medicinal products in the European Union](#), EPRS, European Parliament, 2015 and [Annual Report 2016](#), European Medicines Agency (EMA), 2017.

⁸¹ N. Scholz, [European Medicines Agency, A look at its activities and the way ahead](#), EPRS, European Parliament, 2017 and [PRIME](#) (PRiority MEDicines).

⁸² [Annual Report 2017](#), European Medicines Agency (EMA), 2018.

⁸³ Ibid.

Pharmaceuticals regulation: facts & figures⁸⁴**European Medicines Agency (EMA) activities 2015-2019**

- 1 393 European public assessment reports (EPAR) operated, providing full scientific evaluations for medicines authorised at EU level.
- 64 Summaries of opinions published, examining the application of pharmaceutical companies for marketing authorisation through the centralised procedure.
- 1 780 Paediatric investigation plans (PIP) developed to ensure the necessary data are obtained to support a medicine's authorisation for use in children.
- EMA's Committee for Orphan Medical Products (COMP) approved 2 108 orphan designations to incentivise pharmaceutical companies to develop medicines for rare diseases.
- 512 Referrals published for human medicines, resolving concerns over the safety or the benefit-risk balance of a medicine.
- 1 227 Periodic safety update report single assessments (PSUR) conducted, informing EMA's scientific committees about potential benefits and risks changes.
- 22 Reports on medicine shortages issued, informing Member States about medicine scarcity reported in another Member State.
- From its launch in 2016 until January 2019 included, EMA received 193 applications for PRIME⁸⁵. Of these, 47 were accepted. With 13 pharmaceuticals for cancer therapy, oncology is the leading area.

European pharmaceuticals sector

- In 2017, the world pharmaceutical market was worth an estimated €755 billion ex-factory price. Of this, 22.2 % corresponds to Europe.
- The European pharmaceuticals industry employs around 750 000 people and 'generates three to four times more employment indirectly' (including Turkey).
- With exports amounting to €156.4 billion and imports to €76.7 billion, the EU was the largest world trader in medicinal and pharmaceutical products in 2017, with Switzerland (€65 billion) and the USA (€47 billion) following.
- In 2017, EU exports went mainly to the USA (31.1 %) and Switzerland (13.4 %) followed by China, Japan (6.1 % and 5.2 %), Russia (4.6 %) and Canada (3.0 %).
- Imports came from the USA (40.0 %), Switzerland (34.4 %), Israel (5.2 %), Singapore (4.5 %), China (4.1 %) and South Korea (2.5 %).
- The pharmaceutical industry in Europe spent approximately €35.200 billion on research and development (2017).
- The share of pharmaceuticals in health care costs is about 19.2 %. The share of outpatient care & other expenses accounts to 39.2 % and in-patient care (hospitals) to 40.6 %.

⁸⁴ Sources: [The EU – world's leading exporter of pharmaceutical products](#), Eurostat, 2017, [International trade in medicinal and pharmaceutical products](#), Eurostat, 2018; [The Pharmaceutical Industry in Figures - Key data](#), European Federation of Pharmaceutical Industries and Associations (EFPIA), 2018; [OECD Health Statistics](#) 2017, May 2018 – EFPIA calculations (non-weighted average for 25 EU & EFTA countries), OECD Health Policy Studies, [Pharmaceutical Innovation and Access to Medicines](#), 2018; [Annual Report 2016](#), European Medicines Agency (EMA), 2017; [Recommendations on eligibility to PRIME scheme](#) – Adopted at the CHMP meeting of 28-31 January 2019; N. Scholz, [European Medicines Agency. A look at its activities and the way ahead](#), EPRS, European Parliament, 2017; [Download medicine data](#), European Medicines Agency website, 18 February 2019.

⁸⁵ [PRIME](#) (PRiority MEDicines)

5. Medical devices

5.1. Background

Medical devices and in vitro diagnostic medical devices are highly important for diagnosing, treating and regaining health and for helping living a comfortable life and overcoming disabilities. They contribute to the EU citizens' health, EU healthcare, and to economic growth. Medical devices range from sticking plasters to X-ray scanners, dentures to hip joints and in vitro diagnostic devices from pregnancy self-tests, to blood-glucose meters, to state-of-the-art analytical laboratory equipment.⁸⁶ It is estimated that there are over 500 000 types of medical devices and in vitro diagnostic medical devices on the EU market.⁸⁷ The EU legal framework aims at guaranteeing high standards of quality and safety for medicinal products and medical devices.⁸⁸

5.2. Legal framework

The current EU legislation on medical devices is based on Article 114 TFEU. Accordingly, medical devices bearing the 'CE mark' (a certificate of conformity) can circulate freely in the EU. European legislation ensures the safety and efficacy of medical devices and facilitates patients' access to devices in the EU. Medical devices within the EU are currently regulated by three Directives: Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990), Directive 93/42/EEC on Medical Devices (MDD) (1993), and Directive 98/79/EC on In vitro Diagnostic Medical Devices (IVDMD) (1998).

To keep up with developments in science and technology as well as to ensure better protection of public health and patient safety, two new European Regulations (Regulation (EU) 2017/745 and Regulation (EU) 2017/746) are replacing the existing Directives.⁸⁹ They entered into force on 25 May 2017 and will progressively replace the existing directives. The new regulations will be fully applicable in 2020 for medical devices and in 2022 for in vitro diagnostic medical devices.

5.3. Policy tools

As previously mentioned, EU regulation dates back to the 1990s. A reform of the current regulation was needed due to problems with divergences in the interpretation and application of the rules, and technological progress, as well as incidents involving malfunctioning medical devices. Furthermore, in 2017, the European Commission started working on more structural and horizontal solutions for better market surveillance within the broader frame of a goods package reform.⁹⁰ A transition period of three years after publication of the Regulation on medical devices (MDs) and five years after publication for the Regulation on In vitro diagnostic medical devices (IVMDs) was included to allow manufacturers and authorities time to adjust.⁹¹

⁸⁶ N. Scholz, [Medical devices and in vitro diagnostic medical devices](#), EPRS, European Parliament, 2017.

⁸⁷ [New EU rules on medical devices to enhance patient safety and modernise public health](#), press release, European Commission, 5 April 2017.

⁸⁸ [Medical devices and pharmaceutical products](#), Consumers, Health, Agriculture and Food Executive Agency (Chafea), 2018.

⁸⁹ [Medical Devices](#), European Commission website, January 2019.

⁹⁰ [New EU rules on medical devices to enhance patient safety and modernise public health](#), press release, European Commission, 5 April 2017.

⁹¹ Ibid.

Other than medical products, MDs and IVMDs are subject to a conformity assessment. This is carried out by public third party organisations or private companies ('notified bodies') designated by the Member States. These bodies issue a 'CE' mark.⁹²

The new EU regulations on medical devices and on in vitro diagnostic medical devices provide a stronger mandate to the notified bodies, improve the availability of clinical data on devices and clearly set out manufacturers' responsibilities. They also improve the traceability of medical devices throughout the supply chain and set up a central database to provide comprehensive information on products. Tighter controls on high-risk devices, clinical investigations for medical devices, on performance studies for IVMDs and on the notified bodies are also part of the new regulation.⁹³

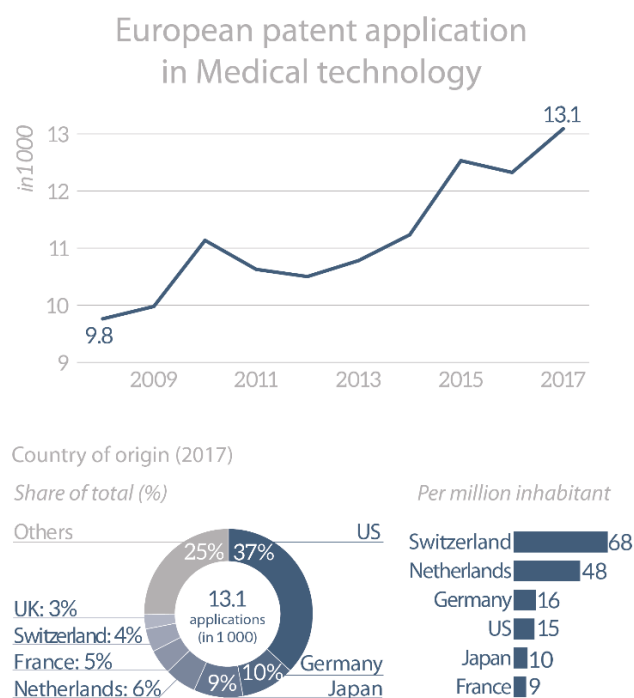
5.4. Benefits of current EU action

Since the introduction of EU rules on the safety and performance of medical devices, discrepancies have emerged in their interpretation and issues have arisen in some categories of medical devices.

To mention on example, in 2010 scandal broke regarding breast implants supplied by a French manufacturer (Poly Implant Prothèse, PIP), who had apparently used industrial silicone for the manufacture of breast implants for a number of years, potentially harming thousands of women worldwide.⁹⁴

As the EU has only recently revised the legal frameworks for MDs and for IVMDs and as they will only come into force in 2020 and in 2022, this analyses looks deeper at the European added value aimed to be achieved by the new Regulations ((EU) 2017/745 and (EU) 2017/746). They are expected to ensure better protection of public health and patient safety, functioning of the internal market, sharing of information and expertise between Member States, reduction of manufacturers' costs, more legal certainty and an innovation-friendly environment, as well as more transparency and patient empowerment and in general a more coherent European approach.⁹⁵

Figure 7 – Development of medical technology patents



Data source: European Patent Office (EPO), Statistics, [European patent applications 2008-2017 per field of technology](#), 2019.

⁹² These bodies issue a certificate of conformity ('CE' mark) for all but low-risk devices, the certification of which is handled by their manufacturers. The Medical Device Directive divides devices into four risk classes – from I (low) to III (high). N. Scholz, [Medical devices and in vitro diagnostic medical devices](#), EPRS, European Parliament, 2017.

⁹³ [Safer medical devices: Council adopts new EU rules](#), press release, European Council, 7 March 2019.

⁹⁴ N. Scholz, [Medical devices and in vitro diagnostic medical devices](#), EPRS, European Parliament, 2017.

⁹⁵ Staff working document on medical devices and on in vitro diagnostic medical devices [SWD/2012/0273 final](#), European Commission, 2017.

Overview of the European added value for medical devices

Table 5 – Medical devices: Non-exhaustive list of European added value partly achieved and aimed at under the new regulation

	Criteria	Resulting European added value
1.	Economies of scale	<ul style="list-style-type: none"> • EU database on medical devices (EUDAMED) with large part of information to be made publicly available • EU joint assessment - confirmed and strengthened procedure for notified bodies • Coordinated assessment of clinical investigations conducted in more than one Member State • Many aesthetic products subject to stricter controls due to the application of the same regulation as medical devices • Reduction of costs for manufacturers and Member States, e. g. due registration of devices and economic operators at the EU level • Reduced harm to consumers/patients through new obligations for manufacturers and authorised representatives
2.	Free movement of persons	<ul style="list-style-type: none"> • N/A
3.	Cross-border threats	<ul style="list-style-type: none"> • Reduced risks of medical devices leading to health threats • Easier to address safety issues and scandals on EU territory and quicker and more appropriate action • Further cooperation in health technology assessments (HTA) on medical devices
4.	Promotion of best practices	<ul style="list-style-type: none"> • European database with extensive information on medical devices, most of which is publicly available • Shared information and expertise between Member States and experts • EU helps with ISO/IS and similar framework standards to share the same knowledge base
5.	Networking	<ul style="list-style-type: none"> • Improved coordination in the fields of vigilance and market surveillance • Network of Health Technology Assessment agencies • Cooperation in expert opinion in partnership with academic networks
6.	Benchmarking for decision-making	<ul style="list-style-type: none"> • Strengthened designation and oversight processes of notified bodies • New classification system for IVMDs based on international guidance (notified body assesses about 80 %) • Observational study results shared within the regulatory framework of the notified bodies • Guides for studies and other forms of guidance and cooperation for the use of data in infrastructures are provided
7.	Unlocking the potential of innovation	<ul style="list-style-type: none"> • Innovation-friendly environment
8.	Implementing EU legislation	<ul style="list-style-type: none"> • EU regulations used as a regulatory tool

		<ul style="list-style-type: none"> • Scope for both MD and IVMDs clarified and the regime applied to devices manufactured and used in the same health institution • New dedicated rules for medical software and medical apps • Implementation of the two new regulations is critical to enforce the new regulatory framework.
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Source: EPRS⁹⁶

5.5. Showcasing EU measures in practice

As mentioned above, intervention at EU level was reviewed, and action was taken. This chapter illustrates two examples from the health programmes database.⁹⁷

Instructions for use of medical devices (COENJA2014)

Joint market surveillance on medical devices⁹⁸ intended for resterilisation focused on information in the instructions for use and the necessary validation data for resterilisation by the user. Eleven EU countries were involved. The programme was launched in November 2015, with a duration of 18 months. The lack of information on reprocessing medical devices, such as the information necessary for safe and adequate cleaning, disinfection and resterilisation, were addressed. Member States are reinforcing their market surveillance of medical devices, in particular by improving their coordination, i.e. for performing a joint market surveillance action including appropriate checks on the characteristics of products placed in the European Market. This joint action (JA) includes further development and expansion of the coordination between Member States, joint inspections by the competent authorities (CAs) shall be part of the project. The joint action assessed how much manufacturers and authorised representatives met legal requirements, improved joint market surveillance activities between Member States and helped to update EU requirements, providing guidelines for authorities, industry and the health care sector. It was funded with €199 999.

Market surveillance of medical devices (JAMS)

The EU joint action on market surveillance of medical devices⁹⁹ helps share best practices, training, knowledge and resources linked to the operation and use of medical devices, aiming to augment public health protection in the medical devices and in-vitro diagnostic medical devices sector. Nine EU countries are involved. The programme was launched in October 2016, with a duration of 36 months. The market surveillance action aims to reinforce market surveillance between competent authorities and to harmonise the approach taken across all Member States. It also aims to improve coordination and help competent authorities with fewer resources to develop skills and capacity through a European market surveillance network. It also helps to ensure a consistent and proportionate approach. It was funded with €849 487.

⁹⁶ Based on Communication on medical devices, [COM\(2017\)0129](#), European Commission, 2017; [New EU rules to ensure safety of medical devices - factsheet](#), European Commission, 2017; N. Scholz, [Medical devices and in vitro diagnostic medical devices](#), EPRS, European Parliament, 2017, and C. Huttin, Annex IV, Briefing note on Medical devices, 2019 (forthcoming).

⁹⁷ For more, see [Health Programmes Data Base](#), European Commission website, January 2019 and [Medical devices and pharmaceutical products](#), Consumers, Health, Agriculture and Food Executive Agency (Chafea), 2018.

⁹⁸ [Instructions for use of medical devices \(COENJA2014\)](#), Competent Authorities for Medical Devices website, January 2019.

⁹⁹ Market surveillance of medical devices (JAMS), Competent Authorities for Medical Devices website, January 2019.

Medical devices and in vitro diagnostic medical devices: facts & figures¹⁰⁰

- In Europe, the medical devices sector (including in vitro diagnostic medical devices) provided €110 billion in sales and 675 000 jobs in Europe in 2016.
- The EU sector is a global leader. It is estimated to make up to 29 % of the world market, behind the USA with about 43 % market share.
- With over 27 000 companies, it is also a major employer in Europe.
- 95 % of the companies are small and medium-sized companies (SMEs).
- In Europe, over 500 000 types of MDs and IVMDs are present on the market.
- In 2017, more than 13 090 patent applications for MDs and IVMDs reached the European Patent Office (EPO).
- The sector has applied in a higher amount than any other European sector (7.7 % of the total number of applications).
- The EU is a net exporter in this sector with an estimated trade surplus of €17.5 billion in 2016.
- Some 7.2 % of healthcare expenditure is on medical devices (0.7 % IVMDs and 6.5 % MDs).
- Expenditure on medical devices per capita in Europe is at around €203 (weighted average).
- Yearly reinvestment in research is about 6-10 % of medical device annual sales and 10 % of in vitro device annual sales.
- The importance of medical devices and in vitro diagnostic medical devices for public health will increase, as in 2060 it is estimated that twice as many Europeans will be aged 65 or older.

¹⁰⁰ Sources: [Medical Devices](#), European Commission website, January 2019; [New EU rules on medical devices to enhance patient safety and modernise public health](#), press release, European Commission, 5 April 2017; [New EU rules on medical devices to enhance patient safety and modernise public health](#), press release, European Commission, 5 April 2017; MedTech, [The European Medical technology industry in figures](#), 2018; [Modernising EU rules for medical device](#), European Council website, January 2019; [Modernising EU rules for medical device](#), European Council website, January 2019; [European patent applications 2008-2017 per field of technology](#), statistics, European Patent Office (EPO), 2019.

6. Prevention

6.1. Background

'Unhealthy diets and lack of physical activity are the leading causes of avoidable illness and premature death in Europe, and the rising prevalence of obesity across Europe is a major public health concern.' This quote from 2005 still holds true today.¹⁰¹ Prevention and health promotion are measures that help avoid disease, decrease risk factors and detect disease at an early stage. Based on the European Union's responsibility on public health and consumer protection and information, the EU has acted in this field since the 1980s.

6.2. Legal framework

Article 168 of the Treaty on the Functioning of the European Union (TFEU) sets the boundaries of EU legislative competences concerning public health, providing it with a supporting role, in so far as the EU is responsible for the facilitation of cooperation between the Member States. In particular, paragraph 1 underlines the responsibility of the EU to direct its actions towards 'preventing physical and mental illness and diseases', through 'promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health'.¹⁰² In addition, the EU may also adopt health legislation in specific areas.

EU action has taken many forms, from regulation of tobacco products¹⁰³ to directives on standards regarding the quality of water resources,¹⁰⁴ and internet platforms for the communication of best practices concerning mental health and wellbeing.¹⁰⁵ For more details on the directives addressing the areas covered by this analyses, see Annex V (forthcoming).¹⁰⁶

6.3. Policy tools

In addition to regulations and directives, the European Union has funded measures related to prevention and health promotion since the implementation of the first health programme (2003-2007). Currently, prevention falls mainly under the third health programme 2014-2020 (3HP).¹⁰⁷ It corresponds to the first core objective of the programme, covering a wide range of thematic priorities.

6.4. Benefits of current EU action

This section on the benefit of the EU is set up in nine parts: i) Tobacco; ii) Alcohol; iii) Nutrition and physical activity; iv) Mental health; v) Environmental health; vi) Cancer prevention; vii) Antimicrobial

¹⁰¹ Green Paper: Promoting healthy diets and physical activity: a European dimension for the prevention of overweight, obesity and chronic diseases. [COM\(2005\) 637 final](#), European Commission, 2005.

¹⁰² Consolidated version of the Treaty on the Functioning of the European Union – Part three: Union policies and internal actions – Title XIV: [Public health – Article 168](#).

¹⁰³ [Directive 2014/40/EU](#) of 3 April 2014 concerning the manufacture, presentation and sale of tobacco and related products.

¹⁰⁴ [Directive 2000/60/EC](#) of 23 October 2000 establishing a framework for Community action in the field of water policy.

¹⁰⁵ [EU-Compass for Action on Mental Health and Wellbeing](#), European Commission website, January 2019.

¹⁰⁶ A.-L. Beaussier, Annex V, Briefing note on Prevention, 2019 (forthcoming).

¹⁰⁷ [Regulation \(EU\) No 282/2014](#) on the establishment of a third Programme for the Union's action in the field of health (2014-2020).

Resistance and; viii) Infectious and transmissible diseases. The section closes with ix) a non-exhaustive overview of the European added value for prevention. The priorities, as well as the European added value, are identified in Annex V (forthcoming).¹⁰⁸ Non-communicable diseases, which represent 80 % of healthcare costs in the EU,¹⁰⁹ cover the greatest part of this analysis¹¹⁰ also addressing the estimation of the benefits from prevention of transmissible diseases.¹¹¹

As mentioned before, the EU's role is to complement and encourage Member States' actions through legislation and other initiatives on public health, health systems and environment related health problems.

i) Tobacco

Since 1987, when the European Union began its efforts to control and reduce tobacco consumption, a range of further measures have been taken, such as regulation (e.g. packaging, labelling, ingredients), advertising restrictions, the creation of smoke-free environments, and taxation measures and activities to counter illicit trade.

European added value with regard to tobacco

EU regulatory actions have brought concrete benefits mainly through the harmonisation of tobacco products and their taxation, the restrictions on the selling/advertising of tobacco products and on smoking in public spaces.

ii) Alcohol

EU action in this area aims to address alcohol related harm, as well as tackling cross-border challenges such as illicit trade. It is built upon promoting best practices to support the adoption of effective and innovative measures and coordinating Member States' policies.

European added value with regard to alcohol

The Committee on National Policy and Action (CNAPA) and the European Alcohol and Health Forum (EAHF) have both contributed to the harmonisation of national policies with regard to control and prevention of harmful drinking. In addition, the European Information System on Alcohol and Health (EUSAH) and other research projects financed by the third health programme have been pivotal for the sharing of best practices across Member States.

Figure 8 – Development of tobacco consumption

Smoking cigarettes daily in the EU-28
(2017)

Proportion (%) of people aged 15+



Variation in percentage point 2014 / 2017

Decrease

BE: -6	DE: -3	EE: -1
CY: -5	SE: -3	IE: -1
DK: -5	EL: -2	
NL: -4	ES: 2	
UK: -4	SI: -2	
HU: -3	LV: -1	

No Variation

PL: 0
PT: 0
LU: 0

Increase

RO: +1	MT: +3
FI: +1	FR: +4
BG: +2	LT: +4
HR: +2	IT: +4
AT: +2	SK: +5
CZ: +2	

Data source: Source: [Eurobarometer 458](#), 2017.

¹⁰⁸ For more details on section i) - ix), see A.-L. Beaussier, Annex V, Briefing note on Prevention, 2019 (forthcoming).

¹⁰⁹ [State of Health in the EU 2017](#), European Commission, 2018.

¹¹⁰ In order of appearance in the study: Tobacco, Alcohol, Nutrition and physical activity, Mental health, Environmental health, Cancer prevention and, Antimicrobial resistance.

¹¹¹ Infectious and transmissible diseases: HIV/AIDS, tuberculosis, hepatitis.

iii) Nutrition and physical activity

Keeping in mind that the European Union has restricted competences, the EU carries out its responsibilities in promoting a healthy lifestyle. Indeed, healthy eating and physical activity are essential to reducing chronic diseases. EU measures include action such as providing information on nutrition, food labelling, the promotion of a healthy diet and preventing child obesity.

European added value with regard to nutrition and physical activity

EU measures have an important impact in directing national policies towards healthier food and to implementing shared best practices at European level. In particular, EU policies focus on reducing childhood obesity, promoting restrictions on advertisement of unhealthy products, encouraging the application of measures related to a healthy start in life, ensuring comprehensive labelling on food product packaging, and imposing strict standards on food available in schools.

iv) Mental health

As a result, of the joint action on mental health and wellbeing, launched in 2013, and the European framework for action on mental health and wellbeing were developed. Within this framework, the Member States are supported in reviewing and improving their policies. The EU Compass for action on mental health and wellbeing is a platform that assists Member States in sharing policies and good practices.

European added value with regard to mental health

EU policies have been pivotal to the positioning of mental health at the top of national agendas. Through joint action, the EU Compass and the funding of innovative projects, a consensus has been built on evidence based policies, information is circulated more easily and best practices are shared among Member States.

v) Environmental health

Today, environmental health at European level is addressed by frameworks such as the Europe 2020 strategy¹¹² and the general EU environment action programme (the 7th EAP),¹¹³ touching topics such as air, water and noise, as well as risk management. Furthermore the EU Health Programme (2014-2020) also aims at supporting the prevention of diseases including environmental factors.

European added value with regard to environmental health

Thanks to the first environment and health action plan, measures have been introduced to support research and foster information systems across Europe.

vi) Cancer prevention

EU action on cancer prevention aims to foster research and knowledge and to encourage Member States in their activities in fighting cancer, such as introducing and implementing national plans. The Joint Research Centre (JRC) coordinated and funded several activities, such as the European partnership for action against cancer (2009-2013),¹¹⁴ and a joint action on cancer control (2014-2017).¹¹⁵

¹¹² Europe 2020, A European strategy for smart, sustainable and inclusive growth, [COM\(2010\) 2020](#), European Commission, 2010.

¹¹³ [Environment Action Programme to 2020](#), European Commission website, January 2019.

¹¹⁴ More on the [European Partnership for Action Against Cancer \(EPAAC\)](#), January 2019.

¹¹⁵ T. Albrecht et al., [European Guide on Quality Improvement in Comprehensive Cancer Control, CanCon Cancer Control Joint Action](#), 2017.

European added value with regard to cancer prevention

Raising awareness and triggering cancer prevention policies at the national level have been key achievements of EU policies so far. At the same time, activities have focused on the concentration of best practices, the development of knowledge on cancer and the promotion of screening programmes.

vii) Antimicrobial Resistance (AMR)

Antimicrobial resistance is a cross-border health threat and cannot therefore be addressed by a single Member State acting alone. This is why cooperation and coordination at EU level are of utmost relevance. In 2001, a community strategy against antimicrobial resistance started and was renewed in 2011. The strategy then included a five-year action plan to tackle the growing threat of antimicrobial resistance. A second European one health action plan against antimicrobial resistance was adopted in 2017.

European added value with regard to antimicrobial resistance

According to the evaluation of the first action plan on antimicrobial resistance, EU measures have been decisive in the stimulation of national policies against antimicrobial resistance, the strengthening of public-private collaborations for the development of new antibiotics and the promotion of activities on international level for cooperation, research and surveillance.

viii) Infectious and transmissible diseases

EU measures on infectious and transmissible diseases date back to the early 2000s. Still today, HIV/AIDS, tuberculosis and hepatitis (both B & C strains) are major threats to public health. Since 2003, over 72 actions have been funded under the EU Health Programme at a total of €46 million. The Third EU Health Programme has so far invested over €11.6 million in prevention, early detection and linkage to care, harm reduction and outreach to vulnerable groups.¹¹⁶

European added value with regard to infectious and transmissible diseases

Funded by the Third EU Health Programme, EU actions have contributed to implementing best practices, which aim at attaining international commitments to eradicating AIDS, viral hepatitis and tuberculosis epidemics in Europe. In addition, the EU has provided Member States and neighbouring countries with guidance and direct funding on fighting infectious diseases on the ground.

ix) Overview of the European added value in health prevention measures

According to the midterm evaluation of the third EU health programme, activities related to health promotion have attracted the greatest funding, in that 33 % of the total 2014-2016 budget (i.e. around €54.1 million) was allocated to health prevention and promotion. Furthermore, the projects and the respective measures supported have usually generated European added value through sharing of best practices.¹¹⁷

European action in the field of prevention clearly achieves European added value by increasing knowledge and information exchange, enhancing and promoting best practices, facilitating economies of potential scale and, unlocking innovation.

¹¹⁶ Ibid.

¹¹⁷ For a more detailed analysis of policy tools on all the different themes of this study see A.-L. Beaussier, Annex V, Briefing note on Prevention, 2019 (forthcoming).

Table 6 – Prevention: Non-exhaustive list of European added value achieved

	Criteria	Resulting European added value
1.	Economies of scale	<ul style="list-style-type: none"> • Standardisation of tobacco packaging and health warnings allow better consumer information (limit information asymmetry) • Harmonisation of the EU market so that Member States cannot gain a competitive advantage by undermining public health benefits • The CNAPA and the EAHF provide efficient ways to coordinate Member States and stakeholders on questions related to alcohol harm • The action plan on childhood obesity appears to be efficient • Harmonised ingredients and labelling for foodstuffs allows more efficient and safer trade across Member States • Development of a central system for monitoring air quality and pollution • European reference networks allow efficient diagnosis and medical protocols and, exchange of knowledge on rare cancers • The action plan provided a framework to guide and coordinate international activities on AMR, enabling economies of scale and greater effectiveness • The European Centre for Disease Prevention and Control (ECDC) allows sharing of knowledge about the prevalence of infectious diseases
2.	Free movement of persons	<ul style="list-style-type: none"> • N/A)
3.	Cross-border threats	<ul style="list-style-type: none"> • The European Anti-Fraud Office (OLAF) tax harmonisation and the future systems for traceability allow Member States to address cigarette smuggling • Reduced risks of cross-border environmental pollution • Reduced risk of contaminated food and products for chemical products and endocrine disruptors (food safety and consumer protection) • EU action provided a common framework to monitor and coordinate measures beyond national borders • Harmonisation, surveillance and coordination of responses through EU networks
4.	Promotion of best practices	<ul style="list-style-type: none"> • Joint action with Chrodis and partnership with World Health Organization (WHO) allow identification and dissemination of best practices • The CNAPA platform collects and spreads best practices among Member States • Best practices are efficiently identified and promoted by joint action • EU action allows the production of standardised definitions and recommendations on nutrition and health-enhancing physical activity • Production of a database (EU Compass) and brochures about best practices in mental health and wellbeing

		<ul style="list-style-type: none"> • Platforms created for exchanges of best practice on environmental health • EU guidelines on cancer prevention and screening • Production of national cancer plans • Member State activities stimulated through promotion of national campaigns on responsible antibiotic use • The European Centre for Disease Prevention and Control (ECDC) has published guidelines and best practices on prevention and early treatment of infectious diseases
5.	Networking	<ul style="list-style-type: none"> • Partnership with World Health Organization (WHO) Framework Convention on Tobacco Control • The CNAPA and the EAHF platforms aim at developing common positions and building networks among stakeholders and civil society actors • Cooperation with World Health Organization (WHO) and Organisation for Economic Cooperation and Development (OECD), EU platform for diet, integration of all stakeholders (such as food manufacturers, NGOs etc.), and the pooling of national research efforts, ensure the existence of an efficient and sustainable network • Comprehensive database, workshops and forum events on mental health and wellbeing • Knowledge on air pollution shared through an harmonised assessment system • Common platforms for exchanges of best practices and cutting edge medical procedures on cancer prevention • Monitoring and surveillance (for instance through joint analysis of animal and human consumption and resistance data and through full harmonisation in the veterinary field) • Forums and platforms for exchange and concerted action on infectious diseases
6.	Benchmarking for decision-making	<ul style="list-style-type: none"> • Projects such as the International Tobacco Control Policy funded • Evaluation project produced assessment and benchmarks • By highlighting best practices and increasing knowledge on alcohol consumption, EU measures encourage evidence based policy-making • Measuring childhood obesity across the EU in schools (COSI), country reports by CHRODIS PLUS and the Eurobarometer on sport and physical activity produce knowledge and foster evidence based policy-making • EU Compass centralises and updates best practices and Member State progress on mental health and wellbeing policies • Evidence based decision-making promoted through research and knowledge development on air pollution • Information and epidemiological knowledge provided on cancer prevalence and risk factors • Evidence based decision-making on antimicrobial resistance facilitated • The EU has gathered good practice examples on infectious diseases

7.	Unlocking the potential of innovation	<ul style="list-style-type: none"> • Best practices and innovative approaches shared • The identification and sharing of best practices allows innovative solutions implemented in some countries to emerge • Funding of pilot projects concerning obesity allows the identification of efficient and innovative local and national actions • National, regional or community initiatives on mental health gathered • Innovative projects and research projects funded • Best practices and innovative action on environmental health shared across all Member States • Research projects funded on environmental health • Research projects and European reference networks for rare cancers funded • Stronger international cooperation on R&D, increased public-private collaboration to boost the development of new antibiotics or alternative treatments • Research projects funded on prevention, treatment and vaccination
8.	Implementing EU legislation	<ul style="list-style-type: none"> • 2014 Tobacco Products Directive implemented • Public health protected (Article 168 TFEU) • Mental health promoted in all policies

Source: EPRS, based on Annex V of this paper (forthcoming).

6.5. Showcasing EU measures in practice

Joint action on reducing alcohol related harm (RARHA)

Funded with €1.5 million from the third EU health programme on a pan-European level, RARHA¹¹⁸ (2014 to 2017), aimed at mobilising Member States to carry out alcohol surveys using a common methodology and, to pool data for comparative assessment, to produce a baseline for comparative monitoring of drinking levels and patterns and alcohol related harms across the EU. The RARHA initiative combined scientific knowledge on the risks and experiences of the use of drinking guidelines to clarify their scientific basis and practical implications and to work towards consensus on good practice principles for the use of drinking guidelines as a public health measure. It also aimed to produce a toolkit of likely transferable interventions on which some evidence of effectiveness and cost estimates were available, to facilitate exchange between Member State public health bodies, and provide guidance for the use of evidence based approaches to reduce alcohol related harm.

Joint action on HIV and co-infection prevention and harm reduction (HA REACT)

In place until January 2019, HA REACT¹¹⁹ operated with a budget of €3.75 million co-funded under the Third EU Health Programme and 22 partners from 18 Member States. Its overall aim was to contribute to the elimination of HIV and to reduce the number of cases of tuberculosis and viral hepatitis in the EU by 2020. To carry out the activities, the project brought together partners working

¹¹⁸ See more on [JA RARHA](#) website, January 2019.

¹¹⁹ See more on [JA HA REACT](#) website, January 2019.

in the health, social affairs and security sectors. The HA REACT project was carried out in three focus countries: Latvia, Lithuania and Hungary. However, its achievements have benefited the entire EU.

Schools for Health in Europe (SHE)

Co-funded with an operating grant of €356 000 under the Third EU Health Programme and supported by WHO EURO, Schools for Health in Europe (SHE)¹²⁰ aims at improving the health of children and young people in Europe, including reducing health inequalities, through a specific focus on schools. It contributes mainly through the sharing of best practices, developing of European standards and indicators for health promotion and monitoring in schools and the strengthening of increased implementation activities on regional and local level within schools.

Prevention: facts and figures¹²¹

- Between 2008 and 2014, about 857 375 lives were saved in Europe thanks to the implementation of comprehensive tobacco control policies
- Between 2006 and 2016, alcohol consumption in the EU was reduced by 11 %
- Between 2005 and 2015, the average suicide rate in the EU decreased from 12.3 to 10.3 per 100 000 persons
- Health benefits linked to the Directive on the Registration, Evaluation, Authorisation and Restriction of Chemicals correspond to over €700 000 000 per year
- Between 2007 and 2016, access to colorectal cancer screening in the EU doubled, from 58 to 110 million people

Prevention need: facts and figures

- The total costs of mental health issues across the EU are estimated at more than 4 % of GDP (i.e. €600 billion)
- 1 in 6 adults are obese across the EU countries
- In 2016, about 790 000 people in the EU died prematurely due to unhealthy behavioural activities (alcohol, tobacco, malnutrition, lack of physical activity)
- In 2016, exposure to some serious air pollutants caused the death of 238 400 people across Europe
- In 2015, about 810 000 people were living with HIV in the EU
- 15 million life-years per year are estimated to be lost due to dietary risks alone

¹²⁰ See more [on Schools for Health in Europe](#) website, January 2019.

¹²¹ Sources: A.-L. Beaussier; Annex V, Briefing Note on Prevention, 2019 (forthcoming); OECD and [Health at a Glance: Europe 2018](#), European Commission, 2018; Data on [Suicide rates](#), OECD website, January 2019; [Initiatives on Nutrition and Physical Activity](#), European Commission website, January 2019.

7. Vaccination

7.1. Background

Estimates state that yearly 2.5 million deaths worldwide could be prevented by vaccination.¹²² Vaccination is one of the most efficient and cost-effective measures to fight disease, and the main tool for primary prevention of communicable diseases.¹²³ Due to widespread vaccinations, in Europe, smallpox has been eliminated, and Europe is polio-free.¹²⁴

Nonetheless, several EU countries are currently facing unprecedented outbreaks of vaccine-preventable diseases. The European Parliament,¹²⁵ European Commission and other experts¹²⁶ state that this is linked to insufficient vaccination coverage rates¹²⁷ and a fall in public confidence in vaccination.¹²⁸

7.2. Legal framework

Vaccination falls under Article 168 of the TFEU, which states that a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities. Furthermore, the Council may adopt recommendations on European Commission proposals to improve public health, in particular aiming at combating major health issues, early warning, monitoring and combating of serious cross-border threats to health. In this sense, vaccine-preventable diseases are considered major health concerns.¹²⁹

Further regulations and directives addressing the issue are:

- Regulation (EC) No 851/2004¹³⁰ mandating the European Centre for Disease Prevention and Control (ECDC),¹³¹
- Decision 1082/2013/EU¹³² on serious cross-border threats,¹³³
- Directive 2000/54/EC¹³⁴ on the protection of workers from risks related to biological agents,

¹²² [Vaccination](#), European Commission website January 2019.

¹²³ Council of the EU, Recommendation on strengthened cooperation against vaccine-preventable diseases, [2018/0115\(NLE\)](#), 2018.

¹²⁴ [Vaccination](#), European Commission website, January 2019.

¹²⁵ Resolution of 19 April 2018 on [vaccine hesitancy and the drop in vaccination rates in Europe](#), [2017/2951\(RSP\)](#), European Parliament, 2017.

¹²⁶ For example, European Academies Science Advisory Council (EASAC) and Federation of European Academies of Medicine (FEAM), [Vaccination in Europe. An EASAC and FEAM commentary on the EC Roadmap 'Strengthened cooperation against vaccine preventable diseases'](#), 2018.

¹²⁷ [Vaccination](#), European Commission website, January 2019.

¹²⁸ Ibid.

¹²⁹ Council of the EU, Recommendation on strengthened cooperation against vaccine-preventable diseases, [2018/0115\(NLE\)](#), 2018.

¹³⁰ Regulation (EC) No [851/2004](#) establishing a European Centre for Disease Prevention and Control, 2004.

¹³¹ Council recommendation on strengthened cooperation against vaccine-preventable diseases, [2018/0115\(NLE\)](#), 2018.

¹³² Decision [1082/2013/EU](#) on serious cross-border threats to health and repealing Decision No 2119/98/EC, 2013.

¹³³ Council recommendation on strengthened cooperation against vaccine-preventable diseases, [2018/0115\(NLE\)](#), 2018.

¹³⁴ [Directive 2000/54/EC](#) of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

- Directive 2010/32/EU implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector,¹³⁵
- Directive 2001/83/EC¹³⁶ on the Community code relating to medicinal products for human use, and
- Regulation (EU) No.726/2004¹³⁷ laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

7.3. Policy tools

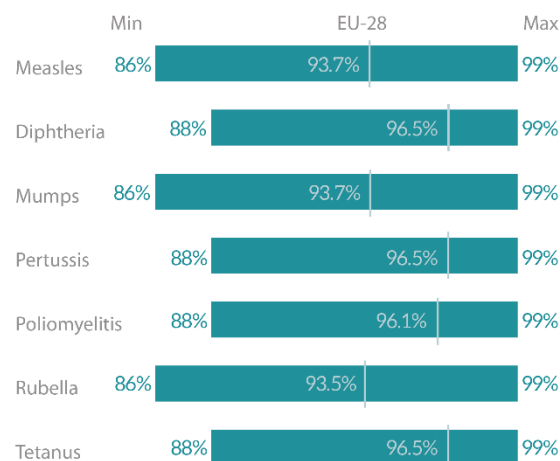
As enshrined in the TFEU, vaccination policy is a national competence and the European Commission supports EU countries in coordinating policies and programmes.¹³⁸ It thereby falls under one of the four objectives of the Third EU Health Programme (2014-2020), namely to 'Protect Union citizens from serious cross-border health threats'. This involves implementing EU legislation on communicable diseases, reinforcing risk assessment and strengthening health system capabilities in the EU countries to address health threats.¹³⁹

Besides the measures addressed in the directives and regulations mentioned under section 7.2, the Commission assists the Member States in guaranteeing immunisation for all children, promoting seasonal flu vaccination for at risk groups, authorising the use of two cervical cancer vaccines and assisting the Member States with strategies against pandemic influenza.¹⁴⁰

Due to an increase in measles cases and a decrease in vaccinations, the European Parliament¹⁴¹ passed a resolution on vaccine hesitancy and the fall in vaccination rates in Europe, in 2018. The same year, the European Commission¹⁴² adopted a communication and Council¹⁴³ agreed on recommendations aiming at tackling vaccine hesitancy, improving

Figure 9 – Vaccination coverage

Infants vaccinated in the EU-28
(%, 2014)



Data source: European Core Health Indicators (ECHI), [Vaccination coverage in children \(I\)](#), February 2019.

¹³⁵ Directive [2010/32/EU](#) implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU, 2010.

¹³⁶ Directive [2001/83/EC](#) on the Community code relating to medicinal products for human use, 2001.

¹³⁷ Regulation [726/2004](#) laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, 2004.

¹³⁸ [Vaccination](#), European Commission website, January 2019.

¹³⁹ Consumers, Health, Agriculture and Food Executive Agency (Chafea), [Medical countermeasures, vaccines and vaccination](#), 2018.

¹⁴⁰ [Vaccination](#), European Commission website, January 2019.

¹⁴¹ Resolution of 19 April 2018 on [vaccine hesitancy and the drop in vaccination rates in Europe](#), [2017/2951\(RSP\)](#), European Parliament, 2017.

¹⁴² Communication on Strengthened Cooperation against Vaccine Preventable Diseases, [COM \(2018\) 245 final](#), European Commission, 2018.

¹⁴³ Council recommendation on strengthened cooperation against vaccine-preventable diseases, [2018/0115\(NLE\)](#), 2018.

coordination on vaccine procurement, supporting research and innovation, and strengthening EU cooperation on vaccine-preventable diseases.

7.4. Benefits of current EU action

This section gives a short, non-exhaustive overview of the benefits of EU action on vaccination and a summary of European added value. More detailed information is available in Annex IV (forthcoming).¹⁴⁴

EU measures are currently based on strengthening coordination and cooperation among Member States by consolidation and sharing of information, ensuring access to vaccines, controlling vaccines to achieve the highest safety standards, exchange of ideas and development of joint strategies, as well as further research for the development of new vaccines.¹⁴⁵ To state one example, in September 2018, a joint action on vaccination (EU-JAV) was launched.¹⁴⁶

European added value from vaccination

This analysis, as well as that of the Council,¹⁴⁷ sees a clear added value in strengthening cooperation among Member States and all relevant sectors at EU level, such as the vaccine industry, research and innovation, and healthcare actors.¹⁴⁸ We identify economies of scale due to joint actions, procurement and funding; targeting cross-border health threats due to surveillance and coordination, as well as networking effects.

Overview of the European added value of vaccination

Table 7 – Vaccination: Non-exhaustive list of European added value achieved

	Criteria	Resulting European added value
1.	Economies of scale	<ul style="list-style-type: none"> • Joint procurement of vaccines and medical countermeasures • Resources saved with synchronised pharmacovigilance activities including vaccine pharmacovigilance • Consistent public health messaging in multiple EU languages • Shared guidance documents save resources at the Member State level • Joint funding for the validation and implementation of standards and guidance
2.	Free movement of persons	<ul style="list-style-type: none"> • EU-wide health insurance cards • E-prescriptions • Vaccine registries • Coordination and review of immunisation programmes and policies in Member States • Streamlined vaccine pharmaco-epidemiology and pharmacovigilance in the EU

¹⁴⁴ B. Rath, Briefing Annex VI, note on Prevention, 2019 (forthcoming).

¹⁴⁵ B. Rath, Annex VI, Briefing note on Prevention, 2019 (forthcoming) and [Protecting health, saving lives](#), factsheet, European Commission, 2018.

¹⁴⁶ For more, see section 7.5 Showcasing for examples.

¹⁴⁷ Council recommendations on Strengthened Cooperation against Vaccine Preventable Diseases [\[SWD \(2018\) 149 final\]](#) COM (2018) 244 final, 2018.

¹⁴⁸ Ibid.

		<ul style="list-style-type: none"> Streamlined reporting pathways for adverse events following immunisation Uniform criteria for the assessment of vaccine quality and safety
3.	Cross-border threats	<ul style="list-style-type: none"> Integration of vaccination and other measures for disease prevention measures offered to refugees and migrants across the EU EU-wide coordination of the surveillance of human and veterinary diseases with pandemic potential Emergency protocols with clear allocation of resources synchronised responses Integration of surveillance mechanisms for vaccine effectiveness and the burden of vaccine preventable diseases (Euro-Momo, iMove etc.) Efforts to strengthen public health communication and to counter vaccine disinformation
4.	Promotion of best practices	<ul style="list-style-type: none"> Development, coordination and monitoring of the implementation of best vaccination practices and policies in the EU at the ECDC and EMA. Development of new protocols and research methodologies through EU consortia funded by European Commission, DG Research Collaboration with European scientific associations, NGOs, industry, patient representatives and other stakeholder groups to develop uniform criteria, and methodologies for immunisation practice and policy
5.	Networking	<ul style="list-style-type: none"> Expert panels convened by the Commission, DG SANTE and Chafea¹⁴⁹ expert panels and consortia to address specific challenges Expert panels convened by ECDC and EMA to inform public health and regulatory decision-making Involvement of NGOs, citizen groups and patient representative organisations. Public review of policy processes for documents and decisions (as carried out for the call for action on immunisation) Connecting science in EU-wide research consortia on vaccines and immunisation
6.	Benchmarking for decision-making	<ul style="list-style-type: none"> Collation of data and know-how from EU Member States Evaluation of available evidence to harmonise vaccination schedules Formation of research and surveillance networks across the EU Developing consensus-building and decision-making capacity

¹⁴⁹ Chafea is the Consumers, Health, Agriculture and Food Executive Agency (Chafea).

7.	Unlocking the potential of innovation	<ul style="list-style-type: none"> • Funding programmes promote collaborative research, such as through clinical and public health research networks supported by Chafea¹⁵⁰/DG SANTE, Horizon 2020/DG Research and the Innovative Medicines Initiative • A special role is played by EMA, both concerning new vaccines and new immunisation platforms and devices. Innovation Task Force meetings are specifically designed to consult on early phase ideas and innovations • EMA, the Heads of Medicines Agencies in the EU and the innovation offices of national competent authorities (NCAs) have formed an innovation platform helping specifically with early phase development (EMA/HMA, 2016)
8.	Implementing EU legislation	<ul style="list-style-type: none"> • Joint action on immunisation • Joint procurement agreements • Legislative changes in some Member States towards making vaccination mandatory

Source: Annex VI of this paper (forthcoming).¹⁵¹

7.5. Showcasing examples

This chapter illustrates four examples of EU actions. More details and further examples can be found in Annex VI of this paper (forthcoming), as well as in an EU publication on vaccination and in the health programmes database.¹⁵²

EU JAV - European Union joint action on vaccination

European Union joint action on vaccination¹⁵³ aims at strengthening cooperation between European countries to fight vaccine-preventable diseases. The starting point was the European Commission's reinforcement of its support for national vaccination efforts. The EU JAV is funded through the Third EU Health Programme (2014-2020) with €3.55 million. Launched in 2018, the action will be carried out over 36 months. The EU JVA brings together the European Commission, national health ministries, international organisations, researchers and stakeholders from 20 countries. It addresses and works on vaccination hesitancy, the increase of vaccination coverage in the EU and the cooperation between national immunisation advisory groups, as well as increasing transparency and trust in decision-making concerning new vaccines.

Joint procurement of pandemic influenza vaccine (PIV)

This important EU action is built on the lessons learnt from the delays and difficulties experienced during the 2009/2010 influenza pandemic. The European Commission recognises that the average time between two influenza pandemics is 10-15 years, but the length of inter-pandemic periods

¹⁵⁰ Ibid.

¹⁵¹ B. Rath, Briefing note on Prevention, Annex VI, 2019 (forthcoming).

¹⁵² For more see European Commission, [Health Programmes Data Base](#), as at January 2019; [Medical countermeasures, vaccines and vaccination](#), Consumers, Health, Agriculture and Food Executive Agency (Chafea), 2018 and B. Rath, Annex VI, Briefing note on Prevention, 2019 (forthcoming).

¹⁵³ [European Joint Action on Vaccination \[EU-JAV\] \[801495\]](#), European Commission, health programmes database, January 2019 and European Union joint action on vaccination, [website](#), January 2019.

cannot be predicted. This is why the EU and Member States joined forces to be better prepared. The call for joint procurement of 'flu vaccines was launched accordingly in early 2019. Negotiations with the main producers of pandemic influenza vaccine are ongoing. Conditions for manufacturers' participation in the procurement procedure include a valid EU marketing authorisation, production capacity maintained for the duration of the contract, and the ability to submit an application within three months following the declaration of a pandemic by WHO and after receiving virus strain from the reference laboratory.¹⁵⁴

FluResp – Cost-effectiveness assessment of European influenza vaccine

The FluResp project¹⁵⁵ worked on renewing methodologies for assessing existing strategies to combat pandemic influenza by redefining pandemic scenarios. The EU supported the project with €699 220 in funding for a duration of 36 months. A driver of the project was the experience of the 2009 pandemic situation in Europe (H1N1/Swine 'flu outbreak). In response to influenza human pandemic alerts in Europe, FluResp assessed, compared and ranked different public health strategies. FluResp worked on modelling possible pandemic scenarios and control strategies. Based on the results of their research, guidelines for prioritising response strategies to influenza pandemics were developed. Overall, 18 public health measures and interventions were presented. These allow public authorities to adjust their ability to respond to threats.

Vaccination: facts & figures¹⁵⁶

- Every year, worldwide, vaccines prevent: 2.7 million measles cases, 2 million neonatal tetanus cases, 1 million pertussis cases.
- Each year, seasonal 'flu vaccination prevents around 2 million people in Europe from falling ill due to the 'flu.
- Vaccination prevents 2.5 million deaths worldwide each year and reduces disease-specific treatment costs, including antimicrobial treatments (prescribed for viral infections).
- Vaccination coverage rates for the first dose of the vaccine against measles vary in Europe from 85 % to 99 % with the average for the EU at 93.6 %.
- 24 Member States have signed the Joint Procurement Agreement covering now 447.8 million of the 5 082 million EU citizens.
- The European Commission has supported improving access to modern and essential vaccines in the 77 poorest countries around the world, through Vaccine Alliance ('Gavi'), since its inception in 2000.
- EU contribution to 'Gavi', €83 million by 2015, helped fully immunise 277 million children in the 2011-2015 period.
- The EU has among the lowest confidence in the safety and effectiveness of vaccination worldwide (safety 82.1 %, effectiveness 86.5 %, importance to EU citizens 90 %).
- In the cases of measles, diphtheria, tetanus and pertussis, a 95 % coverage rate is required to protect the whole community.
- Vaccination programmes led to the eradication of smallpox, the near eradication of polio, and an estimated 74 % reduction in measles deaths over the last 10 years.

¹⁵⁴ Ibid.

¹⁵⁵ [Cost-effectiveness assessment of European influenza human pandemic alert and response strategies \[FLURESP\] \[20101101\]](#), European Commission, health programmes database, January 2019.

¹⁵⁶ Source: [Protecting health, saving lives](#), Factsheet, European Commission, 2018; [EU cooperation on vaccine preventable diseases](#), Factsheet, Q&A, European Commission, 2018; [Vaccination](#), European Commission website, January 2019; B. Rechel et al., WHO, [The organization and delivery of vaccination services in the European Union](#), 2018; Resolution of 19 April 2018 on [vaccine hesitancy and the drop in vaccination rates in Europe](#), 2017/2951(RSP), European Parliament, 2017.; Council recommendation on strengthened cooperation against vaccine-preventable diseases, 2018/0115(NLE), 2018; [Vaccine confidence in the EU](#), Factsheet, European Commission, 2018; Consumers, Health, Agriculture and Food Executive Agency (Chafea), [Medical countermeasures, vaccines and vaccination](#), 2018.

8. Conclusion

Health is a highly relevant topic to Europeans for reasons of personal and public health, as well as for economic reasons such as job creation and economic stability and development. According to recent Eurobarometer surveys European citizens want the European Union to act and take on even more responsibility in this field. This study, requested by the Coordinators of the European Parliament Committee on the Environment, Public Health and Food Safety (ENVI) argues that European actions taken so far in the field of health have been highly beneficial to European citizens, economies and the Member States.

The specific focus of this study covers six areas: the EU Health Programme, cross-border healthcare, pharmaceuticals regulation, medical devices, prevention and vaccination. Criteria chosen to analyse the European added value: 1. economies of scale; 2. free movement of persons; 3. cross-border threats; 4. promotion of best practices; 5. networking; 6. benchmarking for decision-making; 7. unlocking the potential of innovation; and 8. implementing EU legislation, are all addressed by EU health policies.

8.1. Results of the European benefit achieved in the field of health policy to date

The analysis demonstrates, within the limits set by the EU Treaties in health matters, that European action is relevant and important. European added value is clearly achieved, for example in:

- joint action, procurement and funding, as well as simplified procedures supporting Member States and pharmaceutical developers;
- patient access to health care in different EU Member States and harmonised patient rights;
- the facilitation of synchronised responses to pandemics/epidemics and simplification of the response to safety issues, as well as reduction of cross border threats;
- best practice portals and platforms as well as databases, development and diffusion of standards;
- public health official exchanges with scientists across Europe, e.g. as part of various activities and projects, and stronger national authority cooperation through networking;
- enabling of evidence based decision-making and consensus processes between national authorities and European players and stakeholders;
- enhanced pharmaceutical and treatment innovations, as well as teaching of innovation; and
- implementation of EU health legislation ensuring a safe and well-functioning internal market, the free movement of people, and protection of public health.

8.2. Overview of the results of European benefit by area

Third EU Health Programme

The European added value of the Third EU Health Programme is achieved from the strong cross-border aspect to best practices and networking, from supporting the free movement of people to the creation of economies of scale. Stakeholders consider that European added value is achieved by addressing common challenges, e.g. health inequalities, migration, an ageing population, patient safety, high quality health care and tackling health threats. The programme is highly relevant to Member States' health needs.

Cross-border health care

Cross-border health care action and the directive itself improve and strengthen legal certainty and clarity for patients over their rights, and support the relevant national authorities. Member States

may more easily join forces in cooperation and cohesion between border regions and in furthering cooperation in the field of e-health and European reference networks (ERNs). ERNs help to improve diagnosis, treatment and management of rare diseases through cooperation and pooling knowledge and thereby facilitate innovations in research.

Pharmaceutical regulation

The European added value in pharmaceutical regulation lies in the economy of scale achieved through simplification and by avoiding duplication of procedures, as well as in promoting best practices and knowledge exchange through networking. Enhanced through benchmarking, implementation of standards, innovation, greater safety, and protection of European citizens and public health are also achieved.

Medical devices

The recently adopted regulations on medical devices and, in vitro diagnostic medical devices, which come into force in 2020 and 2022 respectively, are expected to ensure better protection of public health and patient safety. They will enhance the functioning of the internal market, sharing of information and expertise between Member States, reduce costs for manufacturers, deliver greater legal certainty, an innovation-friendly environment, transparency, patient empowerment and, in general a more coherent European approach.

Prevention

Greater exchange of knowledge and information, enhancing and promoting best practices, facilitating economies of scale and, unlocking the potential of innovation are possible through European actions in the field of prevention. This benefits European citizens and public health as it helps to avoid diseases, treat them sooner and more efficiently. The EU supports Member States and encourages them to join forces with other Member States to address challenges that do not stop at borders.

Vaccination

European added value in the area of vaccination is clearly achieved through strengthening the cooperation among Member States and all relevant sectors at EU level, such as the vaccine industry, research and innovation, and healthcare actors. Joint action, procurement and funding create economies of scale. Cross-border health threats are addressed through surveillance and coordination and networking effects are realised.

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This study provides a non-exhaustive overview of the added value achieved so far through European Union (EU) action in the field of health policy. The study, requested by the Coordinators of the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI), covers the benefits of EU action in the following sectors: the EU Health Programme, cross-border healthcare, pharmaceuticals regulation, medical devices, and prevention and vaccination. The study provides a brief overview of the EU legal framework, policy tools and best practice in each area.

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