



# Health for the EU

A selection of actions funded under the Third EU Health Programme

Special edition for the EU Health Programme  
Conference 30 September 2019



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## FOREWORD

*Vytenis Andriukaitis*  
European Commissioner for  
Health and Food Safety

*I am pleased to introduce you to this overview of some of the achievements of the EU health programme. This is a specific EU funding instrument designed to support policy development and implementation to protect citizens health, and to promote ways of keeping healthy through the life course. The programme also encourages innovative ways to organise health services to provide the highest quality care for EU citizens. During the last few years, we have all witnessed significant societal changes that have had an impact in the field of public health:*

*we have been shifting from care to wellbeing, from cure to prevention, from fragmented services to integrated systems. Although there have been many significant changes, one thing remains the same: health is something that matters to every single EU citizen. Thanks to continual research and innovation, we are making improvements in how we deal with rare and complex diseases and discovering less known aspects of illnesses and viruses. Progress made in developing treatments for HIV and for Human Papilloma virus are two striking examples. It is undeniable that healthy citizens make for a healthy economy. In a society where prosperity also leads to longevity, it is in the interest of all policy makers to address existing and emerging issues that impact public health. In a European Union where health is a fundamental concern of all citizens, we strive through our EU activities to reduce inequalities in health, both within and between our EU countries, paying particular attention to vulnerable and excluded populations. The framework of the sustainable development goals provides a common objective for our policies.*

*In this context, the EU Health Programme has been working since 2003 to make a real difference in the life of citizens and will continue to make an important contribution. I warmly encourage readers who are interested in health issues to delve into the pages of this brochure to discover a number of success stories in various fields such as diseases prevention, health systems, health threats and health information, all of them co-financed by the 3rd Health Programme (2014-2020). Positive, tangible results have been achieved in many areas, some of which touch your daily lives.*

*I am delighted to acknowledge work being done to make sure medical devices like wheel chairs, dental implants and cardiac pace makers are safe throughout their periods of use, or the EU-Joint Action on Vaccination that is helping to strengthen cooperation to fight vaccine-preventable diseases. Vaccine hesitancy, as you may know, was ranked*

*as one of the top 10 health threats by the World Health Organization in 2019. And then there is the Joint Action on Tobacco Control that is helping to combat the number one cause of preventable death, the use of tobacco. These are only a few examples of the type of work supported through the Health Programme. Find out more about them, and other success stories, in the pages that await you in this brochure.*

*As European Commissioner for Health, I am working hard to make sure that there is a strong health dimension in the future 2021-2027 EU budget. We need to keep investing in people and promoting equal opportunities, social protection and inclusion. Doing so we will contribute to health in many ways, from improving crisis preparedness and the response against cross-border health threats to strengthening health systems and supporting EU legislation in the fields of medicine, tobacco and cross-border care. We will also continue to strengthen the support for the European Reference Networks and to identify and implement best practices for health promotion and disease prevention. No matter what the future brings, we can meet it full on in confidence only if we are in good health. Good health for all EU citizens must be the basis on which everything else, including our economies and our security, must be built. Learning from the past while looking to the future, the new EU health budget plays a vital role in that and will continue improving the lives of millions of European citizens.*

*Now, enjoy this brochure in good health and be inspired!*



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# The third EU Health Programme Overview

These success stories are just a selection of the hundreds of projects and actions that were made possible through the third EU Health Programme, which has been working since 2014 to improve public health in Europe.

The Health Programme gives the European Commission the opportunity to substantiate its strong commitment to invest available funds in ways that get real results and ensures that each euro invested from the EU budget adds value and has a positive impact on people's health and daily lives.

The third EU Health Programme was established in 2014 with an overall budget of € 449.4 m . Its major aim is to support and add value to the policies of the EU countries to improve the health of Union citizens and to reduce health inequalities.

The third EU Health Programme is the successor of eight Public Health action programmes carried out between 1998 and 2003, the first Public Health Programme (2003-2008) and the second EU Health Programme (2008-2013), which partly share topic areas and priorities. Therefore, many priority areas in the current Programme constitute a 20-year long commitment of the European Commission and a complementary development of actions under those priorities. A database with descriptions of all the projects funded under the three Health Programmes, including their major outputs, is available at the CHAFAEA website.

## Four objectives

The third EU Health Programme is structured around 4 objectives:

- 1. to promote health, prevent diseases, and foster supportive environments for healthy lifestyles;
- 2. to protect citizens from serious cross-border health threats;
- 3. to contribute to innovative, efficient and sustainable health systems;
- 4. to facilitate access to better and safer healthcare for Union citizens.

The Programme has entailed the increased use of evidence-based practices in EU countries, integrated coherent approaches in preparedness plans, improved surveillance and response to cross-border health threats, increased sustainability of health systems, and the creation of European Reference Networks on specific rare diseases.

Another valued output is the exchange and implementation of best practices among European countries.

## Who can participate?

The Programme is open to organisations in all EU countries, plus the EEA countries Norway and Iceland. In addition, Serbia, Bosnia Herzegovina and Moldova have signed a Memoranda of Understanding to be able to participate in the Programme.

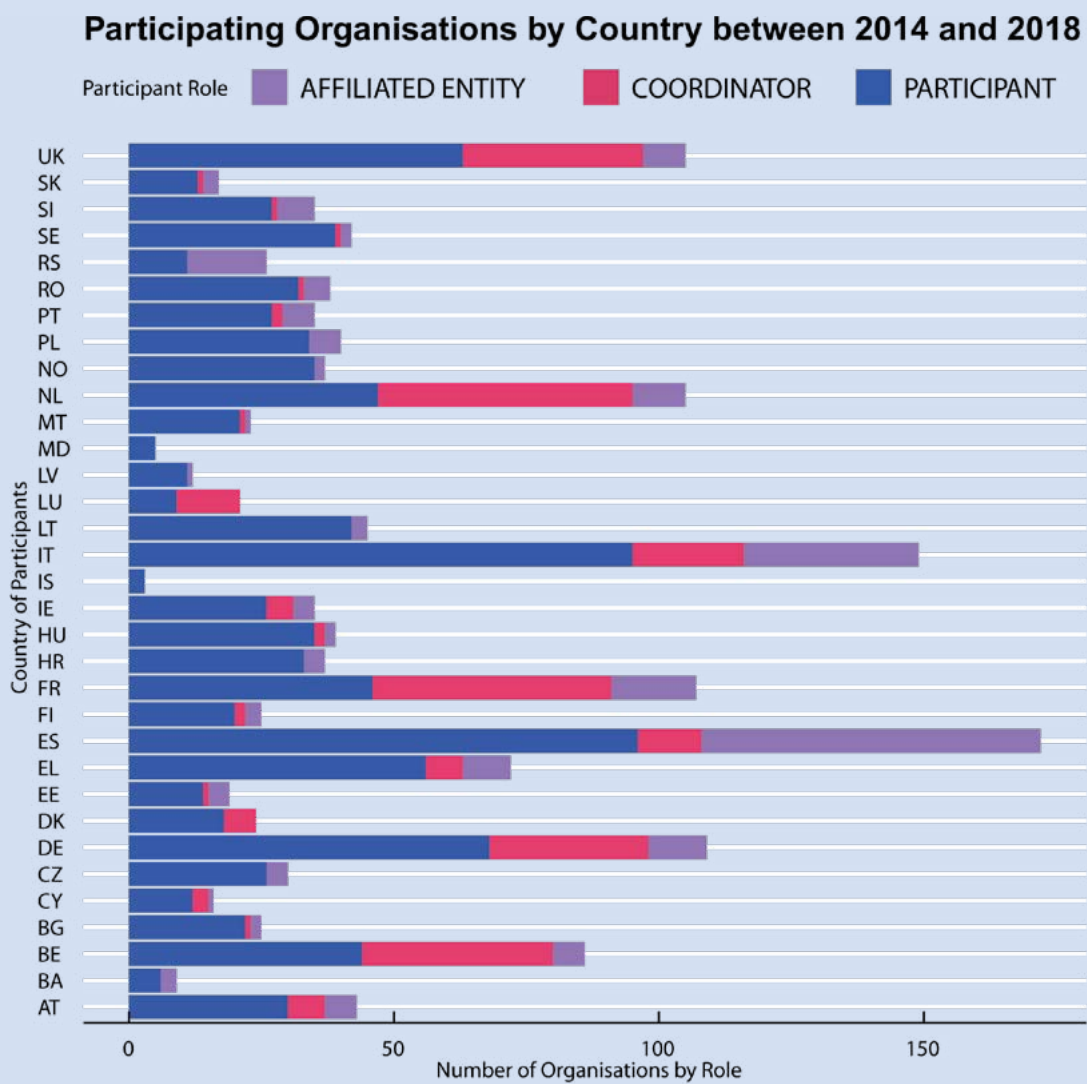


Figure: Participating organisation by country and by role within the grant, 2014-2018 data

## Chafea

The implementation of large parts of the EU Health Programmes was successfully outsourced to the Consumers, Health, Food and Agriculture Executive Agency (Chafea) in 2006. The agency is one of six Executive Agencies created by the European Commission to specialise in programme implementation, such as the organisation of calls for proposals, proposal evaluations, grant monitoring, procurement procedures and payments of the EU contributions.

## Funded actions

Currently, the Programme has funded more than 350 actions, which involve over 7322 organisations across Europe. Actions can have the form of project grants, or can be Joint Actions with European country authorities, operating grants for Non-governmental organisations in the field of Public Health or grants to European Reference Networks or grants to international organisations such as the OECD, WHO, UNICEF and IOM. In addition to grants, numerous service contracts have been signed under the Programme, which deliver specific health reports, databases, training services to health professionals and feasibility assessments of future policies.

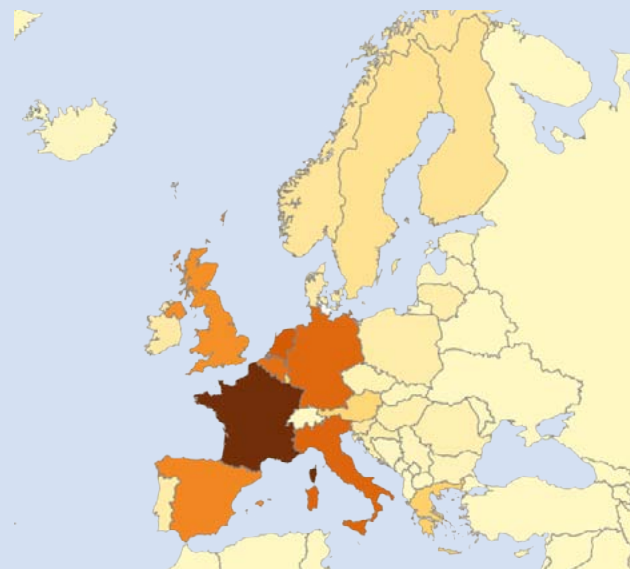
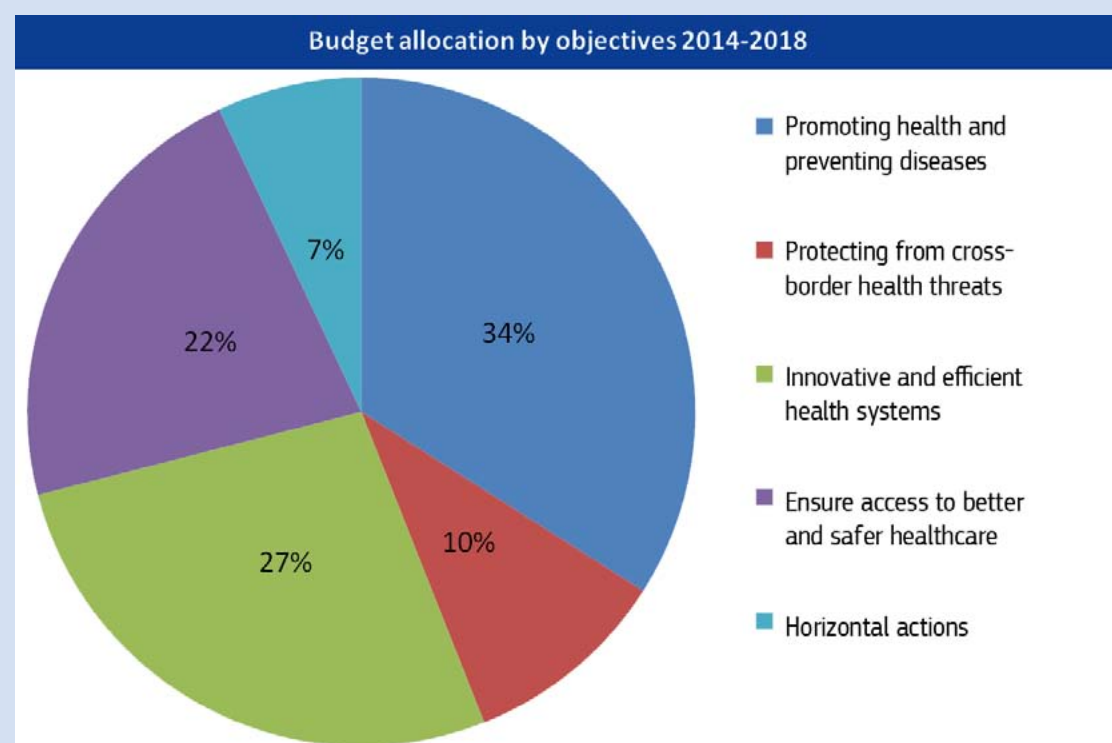
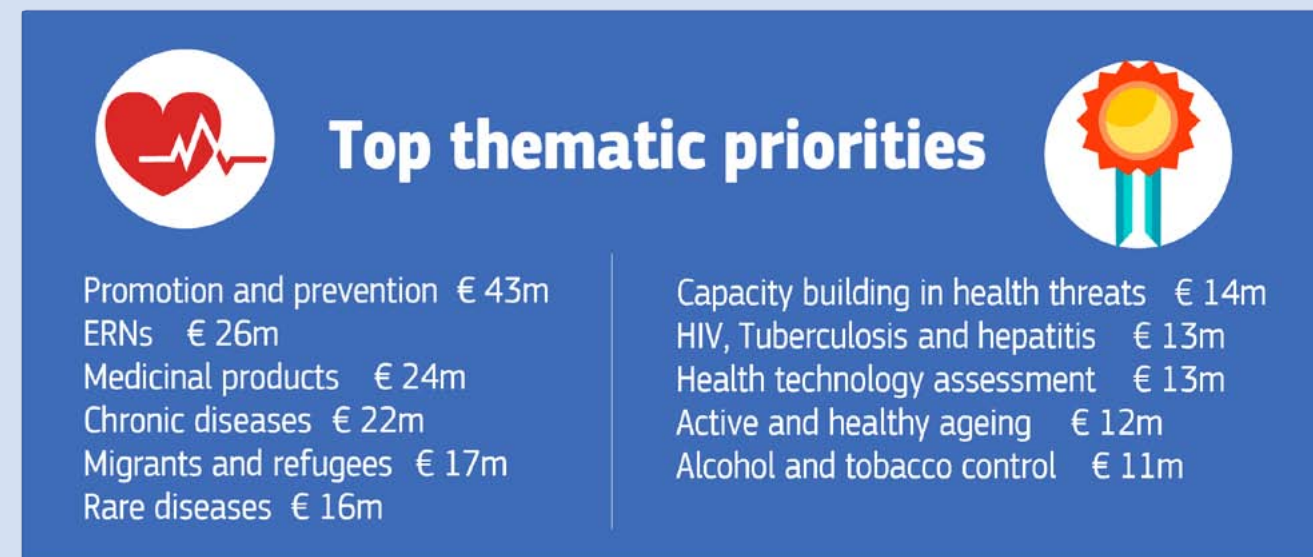


Figure: Funds allocated by country and by role 2014-2018 (Proportional to the darkness of the color)

All EU countries are participating in the Programme. Nevertheless, there are still major differences in the number of organisations that participate from the various countries, and in the frequency of their participation. Organisations in some countries are more active than in others.



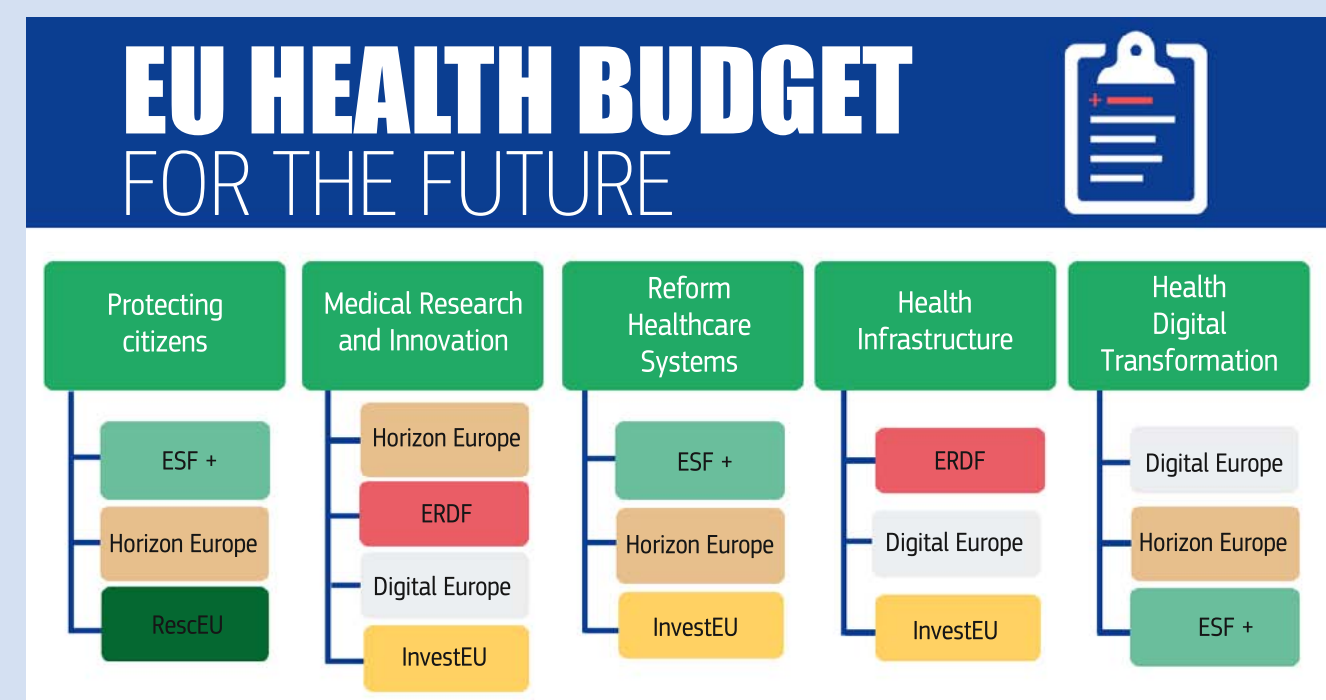
Data commitments 2014-2018



Budget allocation by top priorities 2014-2018

## The future of health in the EU

Due to the assessed relevance of the actions undertaken by the third Health Programme and the leverage effect that they can have on health policies at European, national and regional level, the European Commission keep including health in the Multiannual Financial Framework of the European Union which will start in 2021. Therein, the EU Health Programme will be integrated into the European Social Fund Plus (ESF+), and its priorities will be in line with the principle of public health policies under the European Pillar of Social Rights.







# JANPA

## Joint Action on Nutrition and Physical Activity

**Start date - end date:** 01/09/2015 to 30/11/2017

**Project Coordination:** The Agency for Food, Environmental and Occupational Health & Safety - ANSES (France).

The Joint Action consortium was composed of 39 associated partners from 24 European countries as well as Norway. The Consortium could count on a broad and diverse expertise in the European and national health, nutrition and physical activity programmes.

**EC Contribution:** € 1 200 000

**Website:** <http://www.janpa.eu>



## Eating healthy and being active from an early stage: kids on the right track for life!

According to the WHO, over 60% of children who are overweight before puberty will be overweight in early adulthood. Childhood obesity has also been strongly associated with risk factors for cardiovascular disease, type 2 diabetes, orthopaedic problems, mental disorders, underachievement in school and lower self-esteem.

Therefore, it is urgent to start action to help children and young people enjoy their youth and set them on the right track to live long and healthy lives, free of avoidable non-communicable diseases and physical and mental burdens.

**The “Joint Action on Nutrition and Physical Activity” was designed to help do just that, aiming to halt the rise of overweight and obesity in children and adolescents by 2020, in alignment with the goals of the EU action plan on childhood obesity 2014-2020, explains JANPA coordinator Michael Chauliac.**

This Joint Action is an example of successful collaboration: 25 EU countries and Norway worked together with commitment and enthusiasm. Information is essential to shape measures to improve the nutritional balance and quality of our food. We need to know, for example, do different children's cereals on the same shelf vary greatly in sugar content? Does the sugar content in the same product vary from country to country? And since our supermarkets are stocked by suppliers from all over Europe, improving the nutrition of foods by reformulating the recipes can only be effective if we work together.

This Joint Action has contributed significantly to this effort by testing a methodology in three countries to collect nutritional information on food products. We now have a way to easily and regularly compare how much salt, sugar and fat there is in the food in our supermarkets. Within and across categories, within and across countries.

This is an achievement that can help citizens make more informed choices. It can support innovative companies that create choice and jobs by launching healthier food options. And it can help authorities engaged in supporting food reformulation.

Another important deliverable of the Joint Action is the study of the economic cost of obesity and inactivity. This Joint Action assessed the effect of specific reductions in the prevalence of childhood overweight.

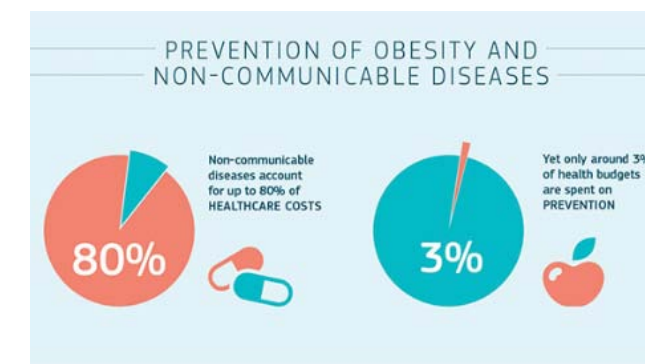
One in three children in the EU aged 6-9 years is overweight or obese. These children are more likely to suffer from bullying, self-confidence issues, depression

and underachievement in school. Obesity in children is strongly related to the socio-economic status of their parents and is likely to be passed on to subsequent generations.

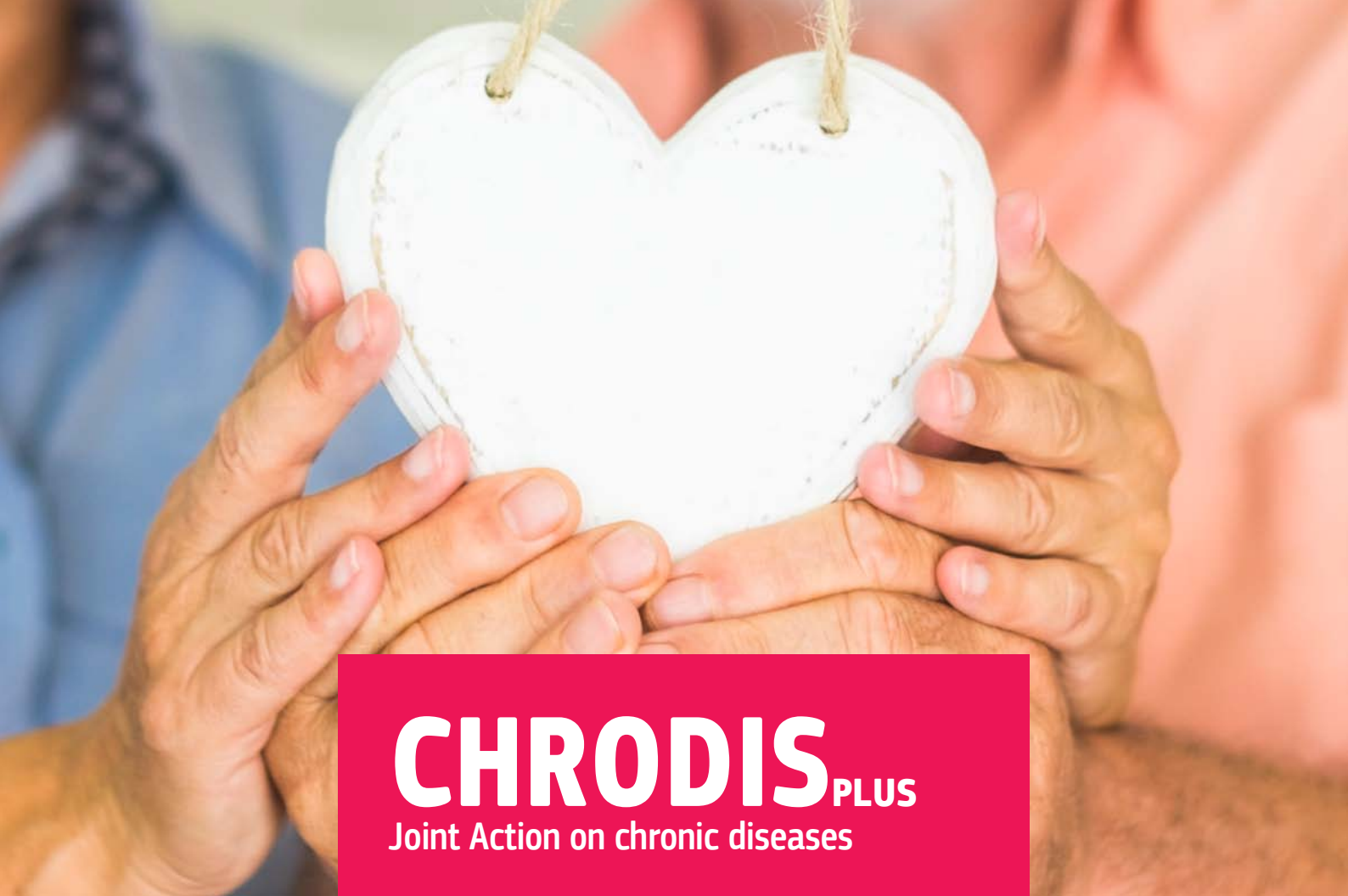
Nutritional problems and physical inactivity directly affect life expectancy and the quality of life of millions of citizens, as well as the efficiency and sustainability of health systems. Unhealthy diets translate directly into a huge health and budgetary burden. Obesity alone is reducing life expectancy by up to 4 years, removing up to 4,5pp of GDP growth in the EU, and consuming up to 7% of health budgets. Additional costs result from loss of productivity due to health problems and premature death (2.8 million deaths per year from causes associated with overweight and obesity). And its prevalence among children and adults continues to increase in several countries.

The Joint Action further identified best practices to foster healthy habits in the areas of integrated interventions for pregnant women and families, and in school settings, working across health and education policies. Intervening at an early age in schools and via reformulation have proven effective at not only reducing overweight and obesity, but also at reducing inequalities. It is particularly important to support the most vulnerable: children and the less fortunate.

This is particularly important because the European Commission is directly supporting EU countries (via the Steering Group on Prevention and Promotion) in a three-step approach: i) asking EU countries about their priorities for reducing non-communicable diseases; ii) collecting validated best practices in those areas, and iii) making support available for countries to roll out those practices. This effectively promotes the replication of best-in-class approaches in Europe.







# CHRODIS<sub>PLUS</sub>

## Joint Action on chronic diseases

**Start date - end date:** 01/09/2017 to 31/08/2020

**Project Coordination:** Instituto de Salud, Carlos III, ISCIII, Spain.

The Joint Action is run by 42 partners from Belgium, Bulgaria, Croatia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Serbia, Slovakia, Slovenia, Spain as well as an important number of stakeholders.

**EC Contribution:** € 4 999 999

**Website:** <http://chrodis.eu>



## Working together to alleviate the burden of chronic diseases!

In order to raise awareness for a Europe free of preventable chronic diseases, premature deaths and avoidable disabilities, CHRODIS PLUS is putting forward initiatives built on four cornerstones:

- health promotion and primary prevention as a way to reduce the burden of chronic diseases
- patient empowerment
- tackling functional decline and quality of life as the main consequences of chronic diseases
- making health systems sustainable and responsive to the ageing of our populations associated with the epidemiological transition

The three-year Joint Action CHRODIS PLUS is working to help reduce this burden by promoting the implementation of policies and practices that have been proven to work. As identified by CHRODIS PLUS' predecessor, the Joint Action CHRODIS, EU countries have a wealth of knowledge on effective and efficient ways to promote health and prevent and manage Non Communicable Diseases (NCDs) and there is great potential in using this knowledge more effectively.

"Europe has never been more fragile and projects like these bring the community together through common goals, directed to actual gains for our citizens" says Dr Rokas Navickas, scientific coordinator of the Joint Action.

**"As part of this European collaboration, thousands of EU citizens are directly benefiting from the joint action, and tens of thousands will be within a year or two, with national policies, already scaling up the work, being done by CHRODIS PLUS."**

Critical situations require a complex and unified response. CHRODIS PLUS envisions a Europe free of preventable diseases, premature deaths and avoidable disabilities. That's why it carries out more than 20 pilot actions implementing the findings of the CHRODIS Joint Action

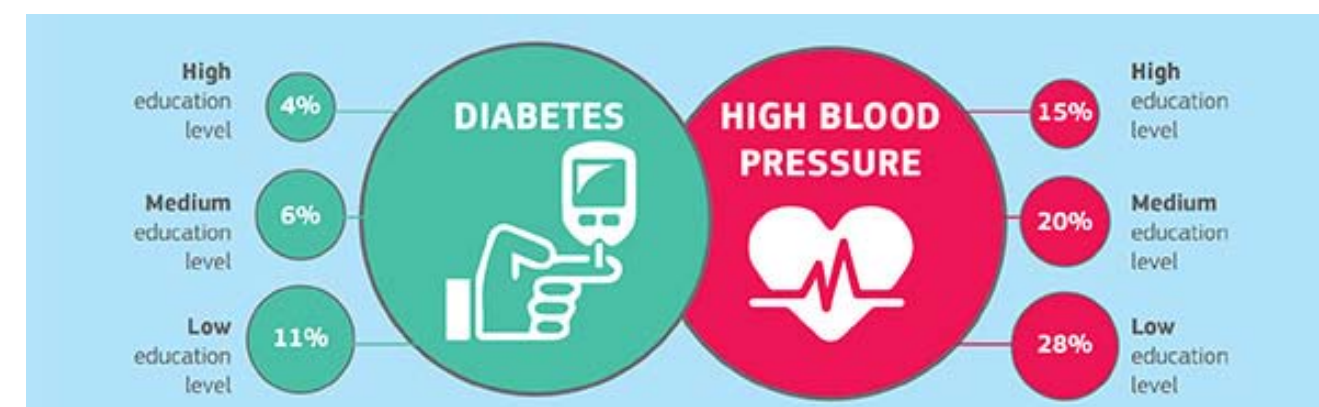
in local contexts to make a difference on the ground and aims to find practical and sustainable solutions. One of the key objectives is to show how identified good practices can be really put into use in another country and directly benefit patients.

"When so much is known, it becomes a matter of prioritisation of what we do and where do we start," says Dr Navickas. The lessons learned from pilot experiences will help to refine these interventions and give useful insight for further scaling-up. The pilot projects range from promoting physical activity in schools and promoting health at the work place to helping to provide quality insurance for hospital patients and improve care for multi-morbid patients."

CHRODIS PLUS is governed by an Executive Board made up of leaders of its 8 different work packages. It is also supported by a Governing Board comprised of representatives from all European countries participating in the 3rd Health Programme.

"Now is the time each country needs to prepare in order to maximise the benefits of CHRODIS PLUS outcomes in their country, and I invite everyone who is in a position to stimulate changes in their country to keep track of CHRODIS PLUS activities," urges Dr Navickas. "This group has the motivation and dedication to overcome any obstacle to implementing actions that will greatly benefit EU citizens.

We have a high energy vibe that comes from knowing that we are making a difference. This feeling drove us forward and the idea that we are writing Europe's healthcare history keeps us motivated," says Dr Navickas. "I truly believe that the activities conducted during CHRODIS PLUS can yield long-term results, that the implementers' efforts will be converted into powerful and effective responses to the burden of non-communicable diseases."







# ORAMMA

## Operational Refugee and Migrant Maternal Approach

**Start date - end date:** 01/01/2017 to 31/03/2019

**Project Coordination:** The University of West Attica in Athens supported by organisations based in Belgium, Greece, the Netherlands and the United Kingdom.

**EC Contribution:** € 477 015

**Website:** <http://oramma.eu>



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PHOTO BY ROWAN DURRANT.

## Response for migrant and refugee pregnant women and lactating women with new-born babies

"Operational Refugee and Migrant Maternal Approach" (ORAMMA), was designed to inform an integrated perinatal care model sensitive to the needs of migrant women and their families to reduce perinatal health inequalities for migrant women in Europe.

Implementation of ORAMMA's work is based on a team approach, including: health workers, social care providers and locally recruited cultural maternity peer supporters (MPS).

The planning and delivery of health and social care services should be informed by the needs of migrant mothers and local communities, ultimately leading to greater integration.

There is a commonality across all needs-based assessments indicating that knowledge and awareness regarding rights and entitlements is key for the integrated healthcare provision of migrant and refugee mothers. Thus specific sessions have to be incorporated in the training of the health and social care providers, with quality control, ensuring that the planning and delivery of services not only take into account the aforementioned rights, but strive to improve communication with migrant and refugee mothers.

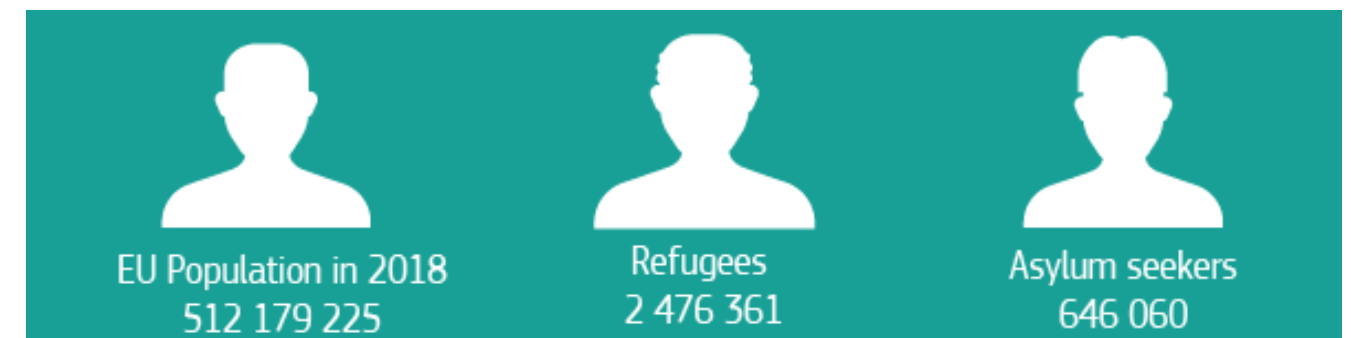
The ORAMMA project provided just that type of support to help migrant and refugee women and women seeking asylum to have a positive experience of pregnancy. Here is what some of the women who received support had to say about the help they received through ORAMMA: **"Earlier I felt totally alone. I could not talk with anyone about my pregnancy. But now I can call her. She will answer me or help me". "She knows how everything works here. Without her, we are in a difficult situation and we don't know where to go". "I had someone who understood me, standing next to me all the time. [...] I could share all my thoughts. She was a mother too and knew a lot about baby care."**

ORAMMA conducted an assessment among refugees and asylum seekers about their health and social care

needs. Results showed that many refugees felt they had a good understanding of the range of health and social care services available to them, but there was limited knowledge on multiple topics, as well as a certain degree of confusion on how to use services, for instance, the use of emergency services during the perinatal period. Registration with a midwifery-led team was high among migrant mothers in the study, and experiences of accessing health services were good. The provision of continuous care from a midwifery-led multidisciplinary team of HCPs and support by the Maternity Peer Supporters (MPS) empower women in their access to health care services, according to the evidence coming from migrant women involved in the ORAMMA project.

MPS could potentially help migrant mothers by making sure they receive health information and building up their confidence. Mentoring can provide opportunities for integration and support for all women, not just migrant mothers or other 'at risk' women and can occur in the social and health context or within the community. At the community level, MPS with a migrant background work with migrant mothers in a relationship that is considered to be mutually beneficial, enabling the migrant mothers to gain experience in the process. Another example of MPS contributing to mentoring practices could be homework centres where migrant or marginalised mothers are aided during the perinatal period (prenatal and postnatal) by MPS or volunteers. This would be particularly suited to a context where migrant mothers cannot easily access information or health services.

Migrant mothers should be supported so that they fully understand their rights and entitlements. Service providers should be increasingly aware of how to meet their needs, workforce should be trained and empowered, and MPS should be given new roles in existing structures.





# ECIBC

## European Commission Initiative on Breast Cancer

**Start date - end date:** 01/04/2015 to 31/12/2020

**Project Coordination:** The European Commission Directorate-General Health and Food Safety (DG SANTE) has the policy leadership on the EU health related policies aiming to protect and improve public health. There two working groups active on ECIBC, the Guidelines Development Group (GDG) and the Quality Assurance Scheme Development Group (QASDG). They are composed by experts selected through public open calls. They represent a very wide range of expertise with the aim to be as inclusive as possible, which comprises as well women and patient advocates to ensure to have their views properly considered.

ECIBC is taken forward in close coordination with experts from 35 European countries.

These countries also nominated a national contact as a focal point to provide feedback and advice as appropriate based on their expertise on their national context.

**EC Contribution:** approx. 1.500.000 EUR/year 2014-2019

**Website:** <https://ecibc.jrc.ec.europa.eu>



## A person-centred initiative to improve breast cancer care

It's shattering to get a diagnosis of breast cancer. And when life suddenly feels fragmented and broken, the last thing anyone needs is more fragmentation and uncertainty. Yet breast cancer patients have not always been guided and cared for in a comprehensive way to address all the challenges that the cancer implies. Women have often been left to figure out things for themselves, to put their trust in several different health providers who may have conflicting opinions, to be handled as a 'case' instead of a person with fears, families, hopes and dreams.

The European Commission Initiative on Breast Cancer (ECIBC) wants to change all that, to focus on the whole person and their needs and wants, their physical health but also their emotional well-being. In short, it strives to improve breast cancer care from prevention to diagnosis to recovery or palliative care, helping every patient to get the very best care possible in a very personalised, caring way. To accomplish this, the European Commission's Joint Research Centre (JRC) is developing the most up-to-date, evidence-based recommendations on screening and diagnosis and providing a platform of trustworthy guidelines for the whole care pathway. The project maintains close interactions with several relevant international associations, as well as with other complementary Commission projects, such as the innovative Partnership for Action Against Cancer (iPAAC), and in particular with Work Package 10 further developing the Governance of Integrated and Comprehensive Cancer Care at EU level.

**"It's remarkable that it is 2019 and this is still not being done," says Ciarán Nicholl, Health in Society Unit in the JRC, who heads the initiative.** "Women, who constitute the vast majority of patients affected by breast cancer, often feel very alone and unsure if they are making the right decisions. They may just consult with one physician who prescribes chemotherapy or radical surgery and decide to follow that route, whereas JRC recommends that a group of experts look at each patient's entire situation individually and confer with each other, and together, with the patient fully on board and informed, choose a pathway of care that feels like the very best option.

"We've created a rich resource for medical professionals and patients alike. For health professionals working in Breast Cancer Services, the ECIBC - Quality Assurance Scheme provides the vehicle to facilitate implementation of these European Guidelines, thus fostering the roll out of updated, evidence-based procedures for breast cancer screening, diagnosis and care.

"And for professionals and patients, the European Breast Cancer Guidelines are another component. These are evidence-based recommendations for the screening and the diagnosis of breast cancer, which are written clearly and presented in a modular format online, making them easy to access and use," says Nicholl.

For example, a woman can indicate her age bracket and see how strongly mammography is recommended, and at what frequency. A 50-year-old whose close relatives have had breast cancer, for example, will see that it is very strongly recommended that she get annual mammography tests. Patients can go through the modular webpages and use them interactively, looking at their own particular situation and finding out what the leading experts recommend.

"It's empowering. It really gives patients the confidence to benefit from the multidisciplinary advice they want when trying to decide how they should best fight breast cancer. They can easily inform themselves about the latest evidence and recommendations, and they can discuss their treatment plan and options with their physicians as an empowered partner, and jointly take the best informed decision," says Nicholl.

In May 2019, the JRC released 10 new evidence-based recommendations on how mammogram results and follow-up appointments should be communicated to women within screening programmes. The way that this information is given to women can have a strong impact on their quality of life and general well-being, especially in terms of the levels of stress and anxiety they experience. It can also influence their future participation and trust in breast cancer screening initiatives.

That very much reflects the philosophy behind the ECIBC. It's all about being there for the patient, helping them on this journey starting with quality screening that allows for early diagnosis which gives patients the time to receive often live-saving treatment, followed by affordable and high quality post-therapy and, at the same time, reassuring them that they are not alone. The ECIBC gives them clear guidance and leading expertise, right at their fingertips.

*European women's probability of developing breast cancer over a lifetime is 1 in 8. A woman's individual risk of breast cancer may be higher or lower than this average, depending on a number of factors, including, age, family, reproducing history, race, ethnicity and others.*



# JATC

## Joint Action on Tobacco Control

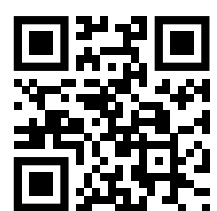
**Start date - end date:** 16/10/2017 to 15/10/2020

**Project Coordination:** Hellenic Cancer Society, HCS, Greece.

The Joint Action is run by 30 partners from Austria, Belgium, Bulgaria, Cyprus, Denmark, Estonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, Moldova, the Netherlands, Norway, Portugal, Serbia, Slovenia, Spain, Sweden, the United Kingdom as well as supported by 13 international collaborating partners.

**EC Contribution:** € 1 995 334

**Website:** <http://jaotc.eu>



## Supporting the implementation of Tobacco products EU legislation

What can help prevent the largest preventable cause of death and disability worldwide? Efforts to reduce the use of tobacco products! The use of tobacco products kills more people globally than anything else that can be voluntarily avoided. The EU Tobacco Products Directive, which went into force in 2014, progressively rolls out legislative actions to help make tobacco use less attractive and to inform consumers of just what it is they are consuming – including harmful additives. If you've seen the graphic visual warnings on cigarette packaging, you've seen the TPD in action.

It also introduces tracking and tracing measures for all tobacco products and mandates manufacturers and importers to report, through the EU Common Entry Gate (EU-CEG), on the ingredients used in tobacco and related products. In order to provide support for the implementation of the TPD, a Joint Action on Tobacco Control has been launched throughout the EU countries. The JA aims to have impact in three areas: preventing tobacco use, preventing non-communicable disease and strengthening cross-EU countries collaboration. The JATC involves, in fact, the majority of EU countries as well as non-EU countries, such as Norway, Iceland, Moldova and Serbia.

**" Effective TPD implementation is considered of crucial importance in terms of changing public health in Europe," says Prof Panagiotis Behrakis, JATC Coordinator, "and that is what we aim to achieve within the 36 months of the JATC. At the current "half time", we can already see the impact of the actions, like enhanced communication and the solutions to key issues that the JATC has tackled."** One of the most important achievements of JATC so far was the creation of a Data Sharing Agreement. This legal agreement sets out the rules and regulations for the sharing and handling of data between EU countries, both for JATC partners and non-JATC partners. A total of 19 EU countries and Norway have currently signed the data sharing agreement and are now able to share data with other JATC members.

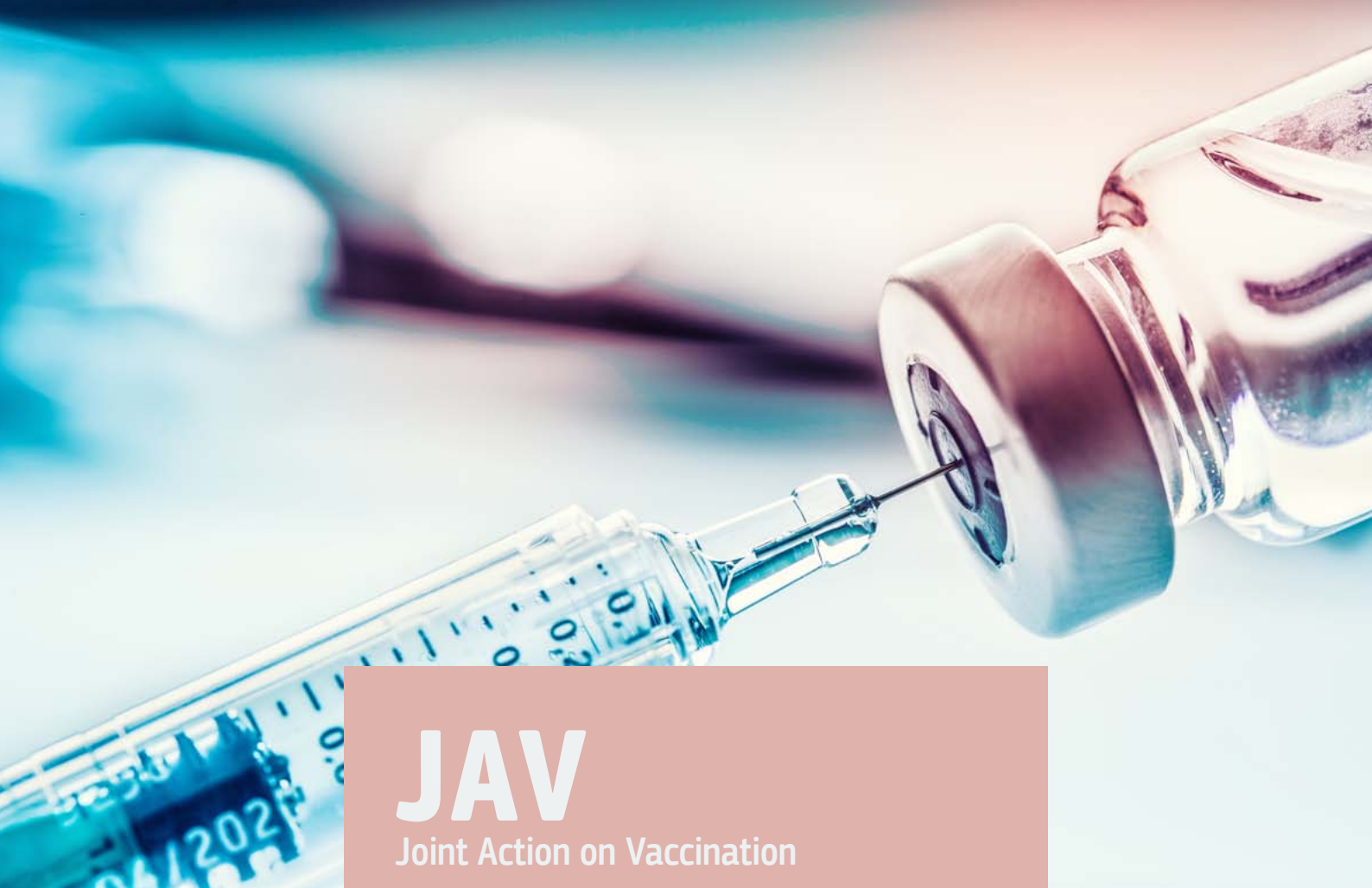
"Another achievement during the first period of JATC was the creation of a Data Sharing Protocol, which established a guideline for requesting, sharing and handling data from the EU-CEG. This procedure also sets out the legal and technical framework of data sharing. "Yet another simple but useful action which has been delivered is the

Common Needs Assessment, which aimed to identify potential areas of prioritisation that could address the needs of EU MS regulators in implementing the TPD. In brief, it provides a baseline understanding of the issues, barriers and potential gaps across European countries with regards to areas that are under the scope of the JATC activities. Both national and international barriers to the implementation of the TPD have been reported, with a specific emphasis on the difficulties faced to regulate and monitor products via the EU-CEG.

"Additionally, the checklist of e-cigarette product compliance, in order to facilitate the monitoring to the TPD both for manufacturers and regulators of e-cigarettes, has been met with enthusiasm and has already been adopted by some EU countries. "Finally, International and National Tobacco Control stakeholders benefit from the information that they receive within the context of JATC dissemination activities and will also potentially benefit significantly from the public release of data on tobacco product developments and tobacco ingredient reporting," says Prof Behrakis.

Citizens will also benefit from the implementation of this Joint Action as it will not only support the implementation of the TPD across the EU, but will also address issues that will ensure a high level of public health through the appropriate regulation of tobacco products. They will also be able to obtain accurate information on tobacco product descriptions and ingredients and increase their knowledge about how these products impact their health.





# JAV

## Joint Action on Vaccination

**Start date - end date:** 01/08/2018 to 31/07/2021

**Project Coordination:** Institut National de la Santé et de la recherche médicale (Inserm), France.

A total of 20 partners from 20 countries, 3 from Non EU countries and 17 from EU countries participate to the Joint Action consortium.

**EC Contribution:** € 3 530 232

**Website:** <https://eu-jav.com>



## Saving lives and preventing infectious diseases through vaccination

Infectious diseases don't need passports or any other authorisation to travel. They cross national borders whenever they can. That's why close collaboration and coordination at EU level is critical to prevent cross-border health threats and epidemics, even though EU countries decide themselves on immunization programmes at national level.

The EU Joint Action on Vaccination (EU-JAV) was set up to deliver and share concrete tools to help strengthen national responses to vaccination challenges. EU-JAV brings together organisations and universities from 20 countries (17 EU countries and 3 non-EU countries) and a wide range of stakeholders, including civil society and manufacturers' representatives working on vaccination policy and health services. Promoting vaccination is urgent at a time when coverage is insufficient and vaccine-preventable diseases are on the rise.

For example, a large measles epidemic has affected the EU/EEA EU countries in the past three years, according to the European Centre for Disease Prevention and Control, with 44,074 cases reported by 30 EU countries between 1 January 2016 and 31 March 2019.

**"This project identifies technical requirements, operational structures and mechanisms for cooperation to bridge gaps and even maximize synergies between experts and policy makers," explains Geneviève Chêne, coordinator of the EU-JAV on behalf of INSERM** (The French National Institute of Health and Medical Research) professor of medicine in public health and director of the Bordeaux school of public health (ISPED) at the University of Bordeaux. "The goal is not to provide new scientific insight, but to increase the

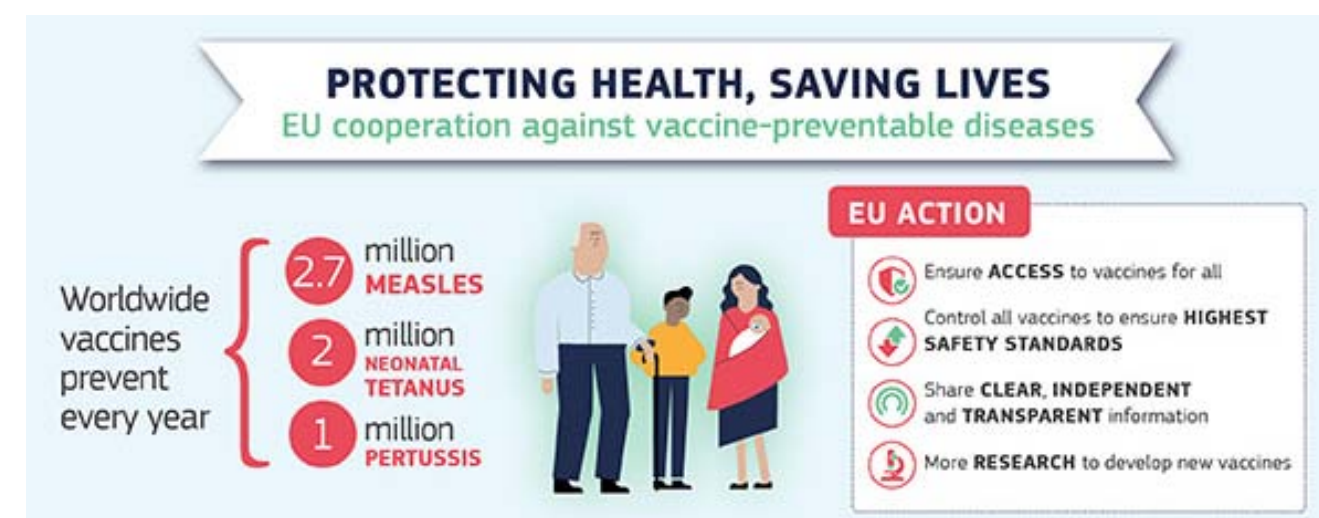
efficiency of the policies and interventions implemented in the field of immunization, based on the best evidence, tools and practices."

Since the start of the joint action in September 2018, the different working groups have been working in five main targeted areas, strengthening vaccine surveillance capabilities based on digitalised data, developing a concept of a data warehouse on demand and supply of vaccines, developing tools and methods for setting priorities for vaccine research, identifying interventions to build confidence in vaccinations and gathering scientific evidence of national immunisation programmes.

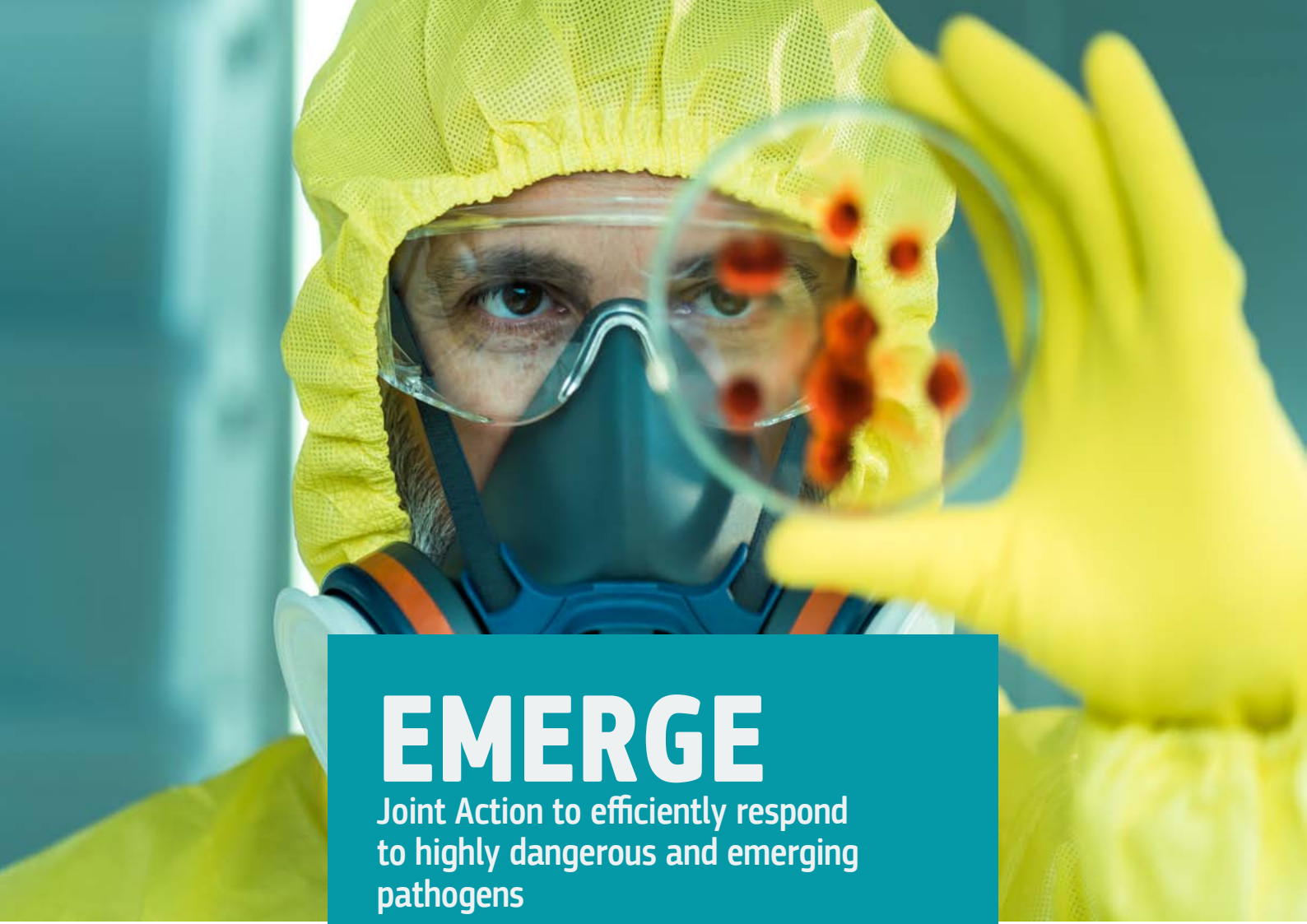
Part of EU-JAV's legacy will be the creation of a sustainable mechanism of cooperation and communication between EU and non EU countries for the implementation of best practices on vaccine policy.

"Thanks to a strong political support at the European Commission's level, this project has the potential to accelerate the adoption of innovative tools and best practices at the national level while strengthening European cooperation to fight against vaccine-preventable diseases and therefore to help shape a healthier future for the European population," says Chêne.

"The commitment of all partners and stakeholders to the work programme is enormous. It deserves respect and brings hope for the future."







# EMERGE

Joint Action to efficiently respond to highly dangerous and emerging pathogens

**Start date - end date:** 01/06/2015 to 31/03/2019

**Project Coordination:** Robert Koch Institute, Germany.

A total of 33 Associated Partners and 4 Collaborating Partners from 25 European countries participated to the action.

**EC Contribution:** € 3 499 873

**Website:** [https://www.emerge.rki.eu/Emerge/EN/Home/Homepage\\_node.html](https://www.emerge.rki.eu/Emerge/EN/Home/Homepage_node.html)



## Halting emerging health threats before they go viral!

The preparation that goes into protecting the public from emerging infectious diseases poses particular difficulties - laboratories and public health systems must be ready to identify and contain rare and dangerous pathogens that they might not ever have to contend with. But how can they know they're ready to handle a crisis when and if it ever starts hitting the population?

The Joint Action EMERGE was set up to help make sure that when and if an emerging infectious disease poses a health threat in the EU to respond rapidly, efficiently, and in a coordinated way. EMERGE is a network of more than 40 diagnostic laboratories focused on different groups of bacteria and viruses that are of special concern. When notified by the Health Security Committee of a potential crisis, this network will spring into outbreak response mode.

As well as providing an integrated infrastructure and strategy for diagnostic laboratories, EMERGE provided a platform to unite other laboratory networks, institutions and agencies who are working in this field.

With the ultimate goal to help ensure that the EU can respond quickly to cross-border outbreaks, the Joint Action focused on improving laboratory preparedness, developing synergies, establishing protocol and guidelines, sharing knowledge and best practices, and conducting training exercises and external quality controls.

**"You need to do emergency exercises if you are going to be ready to respond in real emergencies. We don't often have the possibility to test our response because these agents are fortunately rare.** We have to prepare for something that is not happening, but which might occur, we have to be able to identify and control viruses that cause Ebola or West Nile Fever, or bacteria like Brucella species that cause Malta fever or Bacillus anthracis that causes Anthrax.

There is a list of rare pathogens that we manage. In general, countries are working with one or two pathogens, in order to develop their knowledge and skills. But we need to be sure that almost the same quality of detection is developed across different European countries or at least to improve the detection possibility of the countries where it isn't good enough.

"How has this been done? We send a sample to the labs, they have to test it and we compare the results to be sure they get the same results as at other labs.

There are different methods, different approaches, and different results. Working with these standardisation samples is dangerous. People working in the labs have to be careful that they don't get infected, so they must adhere to common rules about biological safety and security," he says. EMERGE produced agreed diagnostic protocols and guidelines for outbreak management, to improve response and avoid duplicating efforts.

"We are also working to develop training to further raise the capability in certain EU countries, to improve the expertise of the laboratories performing the tests. In addition we are also developing a bio bank of dangerous pathogens, to have a collection of rare diseases samples that can be used as a reference for diagnostic and for research."

EMERGE ended in March 2019, but is being followed by SHARP JA with a work package for laboratories, that is developing a legislated international regulation application. It is not exactly the same type of work, but it does represent a continuation and it builds on the work of EMERGE.

### Examples of previous outbreaks:

*Escherichia coli outbreak in 2011 was linked to sprouted seeds originating from Germany. It caused almost 4,000 cases of severe gastrointestinal disease, and at least 55 deaths.*

*Chemical outbreaks and spills can lead to transboundary pollution and thus affect public health. In 2010, Ajka aluminum plant waste spill into the Danube and in 1986 the Sandoz chemical spill lead to polluted the Rhine, both accidents affecting multiple countries.*

*Ebola epidemic in 2014-15 in West Africa demonstrated that the world was ill-prepared to detect, prevent and respond to emerging infectious disease outbreaks. More than 14,000 cases and 9,000 deaths in the main three affected countries, and EU-level preparation was also needed.*





# EU HEALTHY GATEWAYS

Joint Action on preparedness and action at points of entry  
(air, maritime and ground crossing)

**Start date - end date:** 01/05/2018 to 30/04/2021

**Project Coordination:** University of Thessaly, Greece.

A total of 37 authorities (17 partners, 3 affiliated entities, 17 collaborating stakeholders) from 29 European countries and Taiwan participate to the HEALTHY GATEWAYS Joint Action consortium.

**EC Contribution:** € 3 000 000

**Website:** <https://www.healthygateways.eu>



## Preventing and eradicating health threats at points of entry

Passengers aren't the only ones entering different countries through airports, ports and ground crossings. Infectious diseases, chemicals and environmental hazards can also be transported across borders and sometimes present a serious threat to human health. The Joint Action Preparedness and action at points of entry, known as EU HEALTHY GATEWAYS, is designed to help EU countries be prepared to detect and respond to all health threats affecting or inherently coming from the transport sector, therefore contributing to a high level of public health protection in the EU.

EU HEALTHY GATEWAYS builds upon the work of two consortiums that preceded it, SHIPSAN and AIRSAN. Best practices for management of public health events at Points of Entry were identified through the Joint Action, and these best practices are catalogued, shared and put into use. The Joint Action also produces guidelines and supports the EU countries in validating contingency plans. But even the best laid plans will not be effective if they cannot be put into use immediately when needed.

EU HEALTHY GATEWAYS supports the rapid exchange of information between authorities, using electronic means via an established communication network for points of entry. And because an ounce of prevention is worth a pound of cure, it also supports hygiene inspections on ships and airplanes. In the event of future public health emergencies of international concern, the Joint Action will be able to spring into emergency mode to help EU countries respond in a coherent manner and to implement any temporary recommendations issued by the WHO according to International Health Regulations (IHR, 2005) and Decision 1082/2013/EU on serious cross border threats to health.

Under the framework of EU HEALTHY GATEWAYS, the Joint Action also ensures that inspections on passenger ships are conducted by inspectors working at the competent authorities of EU countries, following the procedures described in the European Manual for Hygiene Standards and Communicable Disease Surveillance on Passenger Ships and in the deliverables of the EU SHIPSAN ACT Joint Action ([www.shipsan.eu](http://www.shipsan.eu)), as updated during the EU HEALTHY GATEWAYS Joint Action.

The aim of inspection activities is to make it easier to implement best practices for coordinating and executing hygiene inspections on conveyances at national level, in order to prevent cross border disease spread and improve compliance with European legislation standards. A common inspection schedule based on target factors (considering historical inspection results and giving priority to ferries and inland navigation vessels) at

EU level is composed annually and agreed to by all participating authorities, to avoid duplicate inspections in EU ports. The inspection team consists of one or more inspectors fulfilling the criteria and conducting an inspection according to the European Manual for Hygiene Standards and Communicable Disease Surveillance on Passenger Ships. The inspection team prepares the inspection report including findings and corrective actions, with each inspection site being given a grade ranging from "A" to "D". An inspection grading system methodology was designed and pilot tested, and has been applied as of June 2019. The inspection grades of cruise ships and ferries and further information on the inspection grading system can be found here: <https://www.healthygateways.eu/Inspection-Grading-System>.

Both public health preparedness planning and response measures need to be addressed and require cooperation at a European level. Cross-border health threats at points of entry cannot be effectively addressed by EU countries individually. Through its activities, this joint action supports this type of preparedness planning in a coordinated way at EU level.

**The value of the Joint Action is also in its ability to support the EU countries and participating countries to improve the implementation of core capacities required under International Health Regulations at points of entry.**

Through its activities, EU HEALTHY GATEWAYS will support EU countries in this area by identifying, promoting and facilitating the uptake of best practices, implementing sustainable training programmes and table-top/simulation exercises, and running the European Inspection Programme for ships.

At the end of the joint action, we expect that competent authorities will be able to better implement the requirements of Article 4 on preparedness and response planning of Decision No 1082/2013/EU and that countries participating in the consortium will improve core capacities evaluation results under the IHR. The knowledge and skills of the personnel working for the competent authorities will also be improved.

*An outbreak of acute gastroenteritis (AGE) due to Norovirus, which is the most common cause of AGE on cruise ships, took place between end of August and mid- September 2018: a total of 104 cases of AGE were recorded by the local authorities. The knowledge of the guidelines in SHIPSAN manual for prevention and control of AGE on passenger ship was acknowledged to be very useful.*





# INTEGRATE

Joint Action on HIV, viral hepatitis, tuberculosis and sexually transmitted infections

**Start date - end date:** 01/09/2017 to 31/08/2020

**Project Coordination:** Centre of Excellence for Health, Immunity and Infections – CHIP, Denmark. The INTEGRATE Joint Action harmonizes 29 partners from public health institutions, hospitals (infectious disease and research departments), NGOs and universities from 16 countries, namely Croatia, Denmark, Estonia, Greece, Hungary, Ireland, Italy, Lithuania, Malta, Poland, Romania, Serbia Slovakia, Slovenia, Spain and UK.

**EC Contribution:** € 1 999 877

**Website:** <https://integrateja.eu>



## Integrating early diagnosis and linking prevention and care

The concept of people-centred and integrated HIV and co-infections health services is part of the strategic action 2016-2021. It focuses on HIV and co-infections sensitive universal health coverage, addressing the needs of people living with, at risk of and affected by HIV and improving access to integrated services, including for HIV, tuberculosis, hepatitis and drug dependence, especially at the community level. This concept is also at the core of the Joint Action INTEGRATE that works to unite the efforts of healthcare specialists working in four different areas where there are overlaps and scope for synergies – HIV, viral hepatitis, tuberculosis and sexually-transmitted infections.

“INTEGRATE is an ambitious project with an important objective,” says the Coordinator of the Joint Action Dorthe Raben, Director of Research Coordination at Center of Excellence for Health, Immunity and Infections, at Rigshospitalet, Denmark. **“The diseases it is dealing with have long been treated in silos in most countries, which often doesn’t make sense because of the many overlaps and synergies that could be created and missed opportunities for better diagnosis and care. The project is building more evidence that this is the case and is outlining the barriers that exist on national levels to achieve better integration.”**

“A large pool of experts are involved in INTEGRATE’s activities”, explains Lella Cosmaro, from the NGO Fondazione LILA Milano ONLUS, one of the project partners and head of one of the work packages. “The overall objective is to find ways to increase integrated early diagnosis and linkage to prevention and care of these four diseases across Europe. INTEGRATE has brought together 29 partners from different organizations in 16 EU countries: hospitals, public health institutions, research institutions, civil society and academia. We also have a large advisory group made of other relevant stakeholders, including DG SANTE, ECDC, EMCDDA, WHO, UNAIDS, Civil Society Forum, European health professionals associations, etc...”.

The project makes use of existing work, shares it and builds on it. Cosmaro says that what sets INTEGRATE apart is that its partners have worked to optimise existing resources without necessarily trying to “reinvent the wheel”. “There have already been many big projects on HIV, hepatitis and TB that have achieved important results, but they concentrated only on one of the diseases,” she says. “In addition, each European country has many years of practice and expertise in each of these sectors that can be shared and extended to other countries so that people in Europe will in the future be

able to access similar health services.

“The change that Europe is undergoing is that of integrating the four diseases areas to optimise prevention, testing and treatment/care investments and solutions, starting from the best practices that have already been documented for HIV and in some cases, also for other infections. It is a difficult but exciting objective and this project is really working to find ways to achieve it.”

Integration cannot happen without the involvement of stakeholders from different disciplines: policy, health care and community, says Raben. “It’s very rewarding to see how project partners, advisory board members to the project and other stakeholders get involved and share experiences and support this important project.”

Cosmaro agrees, saying that having helped shift the mentality from competition to one of cooperation is one of the project’s greatest achievements: “We are now at the end of the second year of activities and many of the specific objectives have been reached. But in my opinion, the biggest achievement so far has been that of succeeding in changing our minds and working methods/procedures, opening to the idea of integrating, combining and incorporating different prevention tools, testing services, models of care, disease units. We have started to think differently and to switch from an old, traditional approach to the new integrated one; we can see it in the way we are proceeding.”

Many of the projects’ good practices pilot’ activities are still running and will be concluded by 2020. “A lot of work is still on-going, so we will only be able to understand the real impact of the actions a few months from now,” says Cosmaro. “But the glow of positive change is already being felt.”

*2016 HIV surveillance data from EU/EEA countries indicates that:*

*-sex between men accounted for the largest proportion of cases diagnosed in 2016 (40%).*

*-there is evidence of a decline in the rate of new HIV diagnoses in the region as a whole.*

# SCHEER

The European Commission's Scientific Committee on health, environmental and emerging risks

The European Commission mandates the SCHEER to conduct risk assessments on non-food subjects having a potential impact on human health and the environment and related issues not covered by other European Union risk assessment bodies.

**Website:** [https://ec.europa.eu/health/scientific\\_committees/stub-for-40f3c994716e9f2fe01806a558d99197aa1760164044950cb1d98dcc\\_en](https://ec.europa.eu/health/scientific_committees/stub-for-40f3c994716e9f2fe01806a558d99197aa1760164044950cb1d98dcc_en)



Ensuring the highest level of health and environmental protection that European citizens expect from the European Union institutions

Is it safe to use sunbeds? Does aluminium in toys pose a risk for children? Do Light Emitting Diodes (LEDs) lights present any risk to the eyes or disturb sleep patterns? And are additives in tobacco products safe or do they pose an added risk for people who use cigarettes, e-cigarettes and other tobacco products?

Did you know world-renowned scientists are working to safeguard your health by looking into questions like these? The European Commission's Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) looks at emerging risks and conducts risk assessments, examining all the latest, scientifically sound data on the subjects. The European Commission mandates the SCHEER to conduct these risk assessments on non-food subjects that Committee members have identified as having a potential impact on human health and/or the environment in the future. The Commission services can also request the SCHEER to do a risk assessment regarding questions about broad, complex or multidisciplinary issues that require a comprehensive assessment of risks to public health and/or the environment, and related issues not covered by other European Union risk assessment bodies

**Recently, for example, the SCHEER has provided risk assessments, called Opinions, on subjects including medical devices such as metal hip replacements and breast implants, risks related to nanotechnology and synthetic biology, and risks related to pollutants in the environmental media.**

These Opinions are based on the latest scientifically sound research, which the 17 committee members study at length and discuss in working groups. If necessary, they can call upon other independent experts who are listed in a reserve list and in a database and make themselves available for this purpose. The SCHEER working group then writes a draft Opinion and posts it online for public consultation, and then that input is taken into consideration for writing the final Opinion. All of these Opinions are available on the Scientific Committee website, as well as the comments submitted during the drafting process. Summaries of the Opinions are often published on renowned scientific journals. Some of them with direct relevance to the public are also produced and can be found online, explaining complicated science in easily understandable terms.

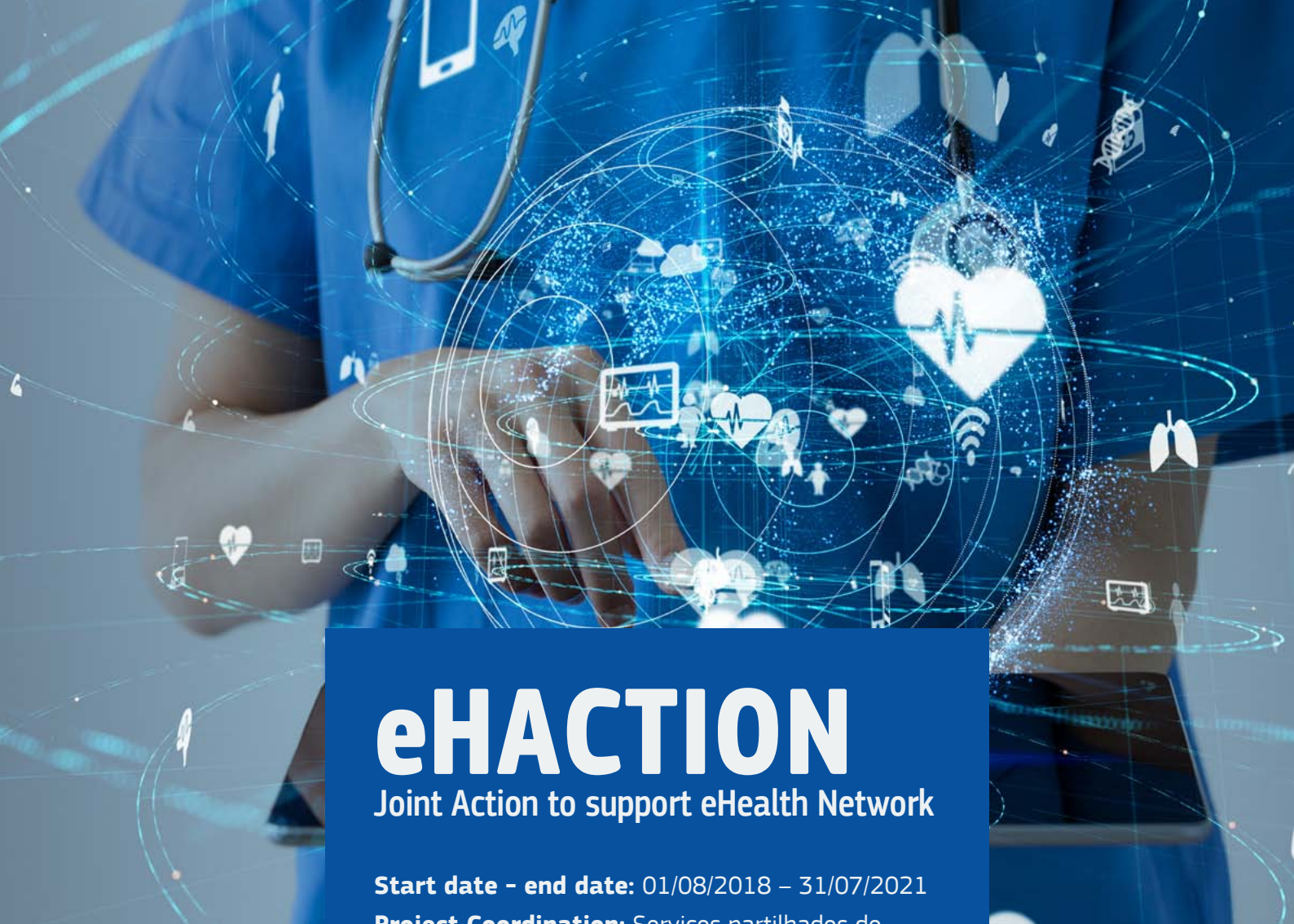
The SCHEER is one of two Scientific Committees managed by the Directorate-General for Health and Food Safety, the other is the Scientific Committee on Consumer Safety (SCCS). Over the decades, the SCHEER and the SCCS, and their predecessors, have adopted more than a thousand scientific Opinions, most of which served as a basis for regulation of consumer risk, contributing to a more evidence-based EU policy-making.

Both the SCHEER and the SCCS work in the area of risk assessment, which ascertains if there is problem. This should not be confused with risk management, which deals with how to solve it. "It is our task to review all the recent and relevant literature on a particular topic and to draw conclusions based on the scientific merit of studies conducted by reputable scientists," says the Chair of the SCHEER, Dr Theo Vermeire.

"Although our work can be highly technical and our members include top scientific experts carefully selected from around the world, our work isn't meant to be academic and of interest only to our fellow scientists, but to be used to help protect the health and safety of European citizens. Transparency and independence are our most important standards," says Dr Vermeire. Documents on the SCHEER process of risk assessment and on how SCHEER weighs all the scientific evidence to arrive at its conclusions are also available online.

*The ultimate goal of the scientific advice provided by the SCHEER is to guarantee European citizens a high level of health and environmental protection and, at the same time, allow science and innovation to play a key part in encouraging competitiveness, sustainability and economic growth in Europe.*





# eHACTION

## Joint Action to support eHealth Network

**Start date - end date:** 01/08/2018 – 31/07/2021

**Project Coordination:** Servicos partilhados do Ministerio da saúde Epe (SPMS), Portugal.

The Ehealth Network (EHN) is a voluntary network, set-up under article 14 of the Directive 2011/24/EU. It provides a platform of EU countries' competent authorities dealing with eHealth. The Joint action supports eHealth Network scientifically and technically. 21 organisations from EU and non EU countries contribute to the implementation of the Joint action from Autrsia, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Portugal, Serbia, Slovenia and Spain.

**EC Contribution:** € 2 699 990

**Website:** <http://ehaction.eu>



## Promoting and strengthening the use of eHealth as a resource for health services and citizens

It's very likely that you can see the future. Or maybe that you are even helping to create it. If you are using your phone as pedometers or to measure your sleep, keep track of your calories, workout or meditate, you're using m-Health, which is a branch of eHealth. If you have ever asked for your health records to be sent electronically, filled a prescription sent by email, or paid for a virtual consultation with an online doctor, you've used eHealth. And if you can imagine patients in even the remotest villages getting virtual health assistance, or patients with anxiety, depression, diabetes or Alzheimers using mobile phone apps as part of their treatment plans, you can picture how eHealth can make things easier for patients and save time, money and lives.

eHealth is already providing support to patients around the world, from helping patients and doctors stay in contact for diagnosis and continued care to making it possible for rare disease patients to get the expert help they need through the European Reference Networks.

The EU had the foresight to actively lay the groundwork, looking carefully at all its potential but also its challenges, like protecting citizens' data and privacy. The eHealth Network, a network of EU competent eHealth authorities, was set up in 2011. It is supported by the Joint Action eHAction, which provides EU countries with technical and scientific advice to promote political discussion and further alliances in the use of information and communication technology (ITC) for health development.

**"Both citizens and health professionals will benefit from eHAction as far as being able to use health apps, mHealth and tele Health safely and to be duly informed so that they can increase their eSkills and eHealth literacy and save time by using easier and automated processes," says Henrique Martins, coordinator of the Joint Action.**

"I believe that since the European Union is characterised as a Market that is not only single but digital, citizens must be empowered with the possibility of accessing their own health information anywhere, which makes ICT interoperability between EU countries crucial.

"It is also important to consider each EU country's particularities and to respect data protection. With this in mind, by working interdependently through cultural diversity, each of them can contribute significantly to this commitment.

"eHAction is particularly focused on engaging citizens as users, and to encourage them to take an active role in this action by raising their skills to access and control their health data alongside their health professionals. But the

joint action also intends to benefit society by helping to analyse large volumes of health data generated across the healthcare sector," says Martin.

This will help prepare healthcare systems and providers to adopt and implement interoperable cross-border solutions, which will ensure progress in eHealth. And because the sustainability of cross-border healthcare must be addressed and guaranteed under EU projects and post-Horizon 2020, it is important to converge efforts on common strategies to develop a single market that is a real pioneer in Europe and I would say, in the world."

The Joint Action is working with the Commission towards harmonising the format to exchange Electronic Health Records and a Common Semantic Strategy for Europe. It has produced various reports and guidelines, including the Policy framework on People Empowerment; the Report on Cross-Border use cases and the Report on eSkills for Professionals and Best Practices in Data Protection. So far, 15 workshops have been promoted and involved experts in distinct focus areas, for example the WP8 Kick-off in Paris, February 2019, on international eHealth strategies and more recently, in Thessaloniki in July 2019, on Interoperability for Hospital CIOs and CEOs.

"We have two years ahead and many goals yet to accomplish," says Martins. "Among others, to ensure that countries' approach to patient access to health data and health professionals eSkills regarding cross-border needs and re-use of data are synergistic and supportive.

"We also hope to improve awareness on cybersecurity and to increase the applicability of big data by mobilising knowledge across Europe and frame post 2021 scenarios for eHealth policy cooperation and practical implementation," says Martins.





## MEDICAL DEVICES IN VITRO DIAGNOSTIC MEDICAL DEVICES GET READY FOR THE NEW REGULATIONS



What you  
need to know !

# JAMS

Joint Action on Market surveillance of  
medical devices

**Start date - end date:** 17/10/2016 to 16/10/2019

**Project Coordination:** Agence nationale de  
sécurité du médicament et des produits de santé  
(ANSM).

A number of partners has joined from Austria,  
Croatia, Cyprus, Czech Republic, Denmark, Estonia,  
France, Ireland, Italy, Latvia, the Netherlands,  
Norway, Portugal, Spain, Sweden, UK.

**EC Contribution:** € 849 488

**Website:** <https://www.camd-europe.eu/joint-action-projects/market-surveillance-of-medical-devices-jams>



## Paving the way for the new EU legislation on medical devices

Medical devices range from wheelchairs and glasses to dental implants and cardiac pacemakers, and EU citizens who rely on them also rely on these devices being safe and meeting the highest standards. The new EU medical devices regulation (MDR) came into force on 25 May 2017 to provide this assurance and it will be fully implemented by May 2020. The Joint Action on Market Surveillance of Medical Devices (JAMS) helps build the good cooperation and mutual understanding between EU countries required to smoothly transition to full compliance with this new regulation.

JAMS reinforce the market surveillance system for medical devices by improving the coordination of EU countries of the European Union and ensuring adequate communications and cooperation.

More than 15 EU countries are involved in this EU-funded project, working towards achieving the highest level of safety for medical devices in Europe. The JAMS project has developed a harmonised, proportionate and risk-based approach for joint inspections of manufacturers, as well as European guidance, best practices and training on clinical evaluation throughout the device life cycle. In very practical ways, it promotes and creates the increased cooperation between authorities called for in the new regulations for medical devices.

"The project can seem really technical at first sight but once you understand it, you can see its consequences for people, even in your own everyday life," said Lara Lainé-Lemarchand, project coordinator and a member of the French Medicines Agency Inspection directorate (ANSM). **"Market surveillance is crucial in the health products regulation because it guarantees the safety of the products bought, consumed and/or used by European citizens.** As a European citizen, I am relieved to know that EU countries put efforts into ensuring the best level of safety for their citizens. In

improving the European market surveillance system by preventing safety risks due to non-compliant products, robust proactive market surveillance will afford better protection of public health, more confidence and stability in the regulatory system."

JAMS established a communication platform for clinical experts to facilitate better and rapid cooperation on clinical assessments and to make it easy to share best practices. Common specifications prioritisation procedures and processes were also developed and an overview of national practices was taken to help find a consistent and proactive way to develop joint inspections of medical device manufacturers in Europe. As a consequence of the good work already achieved, an increasing number of countries and organisations have shown interest in the work done within the JAMS.

"We still have a couple of outputs to achieve by the end of the year 2019," said Lainé-Lemarchand. "First of its kind, a training for inspectors on joint inspection of manufacturers will take place in Lisbon this November.

"Several guidance documents are also being developed to consolidate this new joint inspection process. Clinical training materials will also be issued to harmonise clinical data assessment methods. But we don't want to stop there. We intend to pursue the work on market surveillance by exploring new areas of cooperation.

"Establishing a coordination mechanism and building cooperation amongst EU countries on clinical data assessment and the inspection of manufacturers can be the basis for broader coordination and cooperation and this could be expanded to all areas of market surveillance in the future."







# SEPEN

Support for the health workforce planning and forecasting expert network

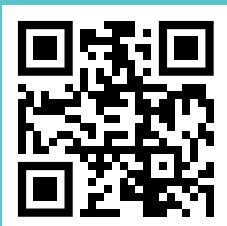
**Start date - end date:** 05/09/2017 to 04/09/2020

**Joint tender leader:** Semmelweis University, Budapest, Hungary.

Partners: the University of Leuven (Katholieke Universiteit Leuven), the Italian Ministry of Health (Ministero della Salute), the Italian National Agency for Regional Health Services (AGENAS), and the Standing Committee of European Doctors (CPME).

**EC Funding:** € 876 730

**Website:** <http://healthworkforce.eu>



## Establishing an expert network on health workforce planning and forecasting

Freedom of movement is one of the cornerstones of the EU. Yet, because it gives medical graduates, physicians and nurses the freedom to move where they have more opportunities and better pay, it can also create a challenge. Romania, for example, lost half its doctors between 2009 and 2015.

But while the brain drain generally flows from the poorer countries to the richer, “it’s important to realise that rich countries that strongly rely on foreign workforce can also be in trouble if mobility patterns change, for instance because of events like Brexit and the financial crisis of 2008,” says Dr Eszter Kovacs, coordinator of the project better known by its acronym SEPEN, which stands for ‘Support for the health workforce planning and forecasting expert network.’

SEPEN was set up by the European Commission to sustain cross-country cooperation and provide support to EU countries to increase their knowledge, improve their tools and succeed in achieving a higher effectiveness in health workforce planning processes and policy.

It builds upon the work of the European Health Workforce Planning and Forecasting Joint Action, which left a wealth of resources like handbooks, toolkits and best practices for SEPEN to take forward and for anyone interested in health workforce planning to use freely.

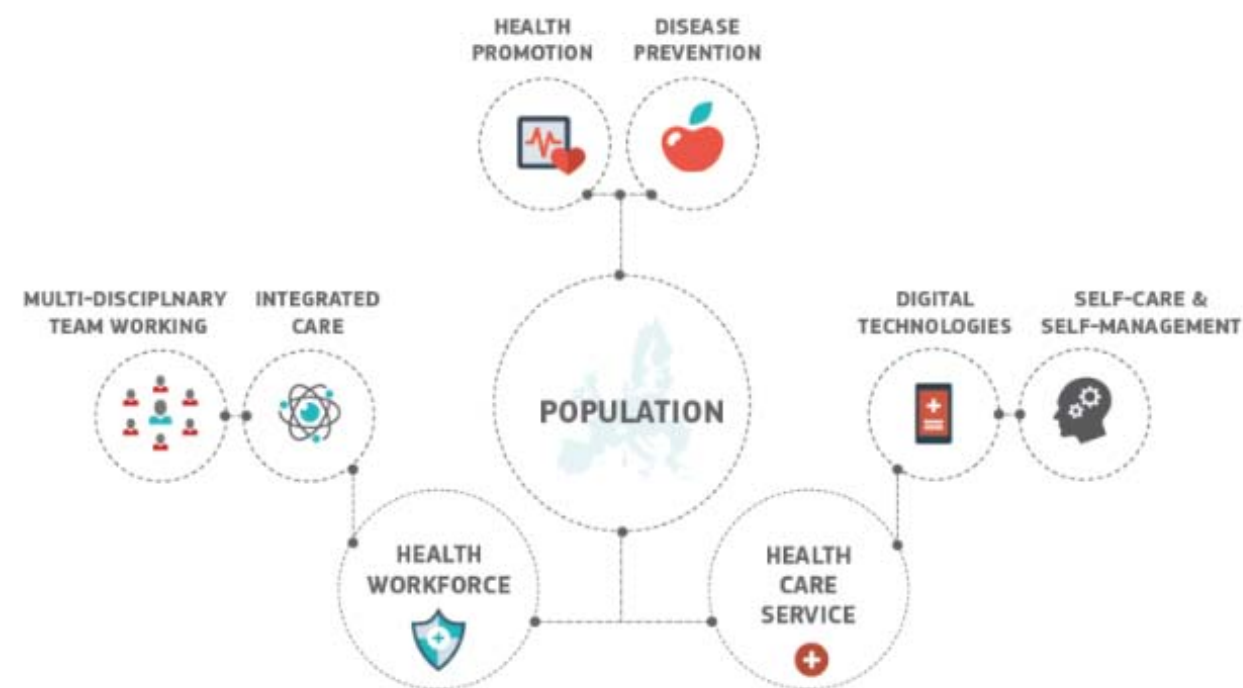
“The internal market facilitates mobility and the one and only thing to be strengthened is the collaboration

between countries regarding health workforce planning,” says Kovacs, an assistant professor at the Semmelweis University Health Services Management Training Centre in Budapest.

**“Each country has its own issues concerning health workforce, like education, ageing, unequal distribution, recruitment or retention,” says Kovacs, “but the facilitated information exchange and knowledge sharing can help health systems in the EU operate more effectively. This is why SEPEN is a crucial activity because it brings experts and interested parties closer and fosters the exchange.”**

SEPEN provides insight on relevant issues and tailor-made support “on demand” for EU countries willing to improve their health workforce planning capacities at national and regional level.

The joint action’s work is divided into five areas, namely providing these exchanges as well as networking, mapping national health workforce policies, transferring knowledge and good practices, and publicising and documenting the result of all of this work online on the dedicated website.









# EDQM

## European Directorate for the Quality of Medicines

The Commission of the European Union and the Council of Europe created a network of official medicines control laboratories which boosted a new collaboration in the area of quality control of marketed medicinal products for human and veterinary use. In 1995, the EDQM took upon itself this new responsibility and subsequently set it up. The activities of the network are co-funded by the European Commission.

**Website:** <https://www.edqm.eu/en/general-european-omcl-network-geon>



## Working with the Council of Europe to keep medicines safe and available for people and animals in Europe

We take medicine – with or without a spoonful of sugar to get it down – with complete confidence, certain that it is going to help make us feel better or stay well, not cause us harm. And we can be confident, partly thanks to the work of the Official Medicines Control Laboratories (OMCL) Network and the Biological Standardisation Programme (BSP) of the European Directorate for the Quality of Medicines & HealthCare (EDQM), a director of the COUNCIL of Europe. The medicines they keep under watch include biologicals (vaccines, blood-derived medicinal products, bio-therapeutics) and “classical” (chemically-defined/ small-molecule pharmaceuticals) medicines for human and veterinary use, independent of whether they are innovative or generic. The goal is two-fold – first that all the medicines are of good quality and second, that they are accessible to every person and every animal who needs them.

The OMCL Network, with its market surveillance programmes and related activities, is not a short-term ‘project’, but a network established in 1994, based on the long-term cooperation of all EU/EEA countries. All countries either participate directly or benefit from the results. The work is based on the principles of work sharing, information exchange and mutual recognition of test results and the network continually adapts to be in line with scientific progress and evolving needs.

“EU legislation requires, in addition to quality control by manufacturers during the production and release of medicines, manufacturer-independent surveillance testing is carried out by public laboratories in the EU countries (OMCLs)”, explains project coordinator, Michael Wierer. “It makes sense that someone beside the manufacturer – someone unbiased and independent – is keeping guard. Public labs may test medicines during their pre- or post-authorisation phase as part of programmed activity and will also react if alerted to any specific signals/problems. The EDQM coordinates the OMCLs’ activities and acts as its secretariat to optimise the use of resources and save costs.”

The Biological Standardisation Programme is a collaborative initiative. Its aim is to develop reference standards and common testing methods as tools for the standardisation of biologicals. This is done with a focus on supporting the sometimes challenging EU requirement to reduce, refine and replace the testing on

animals. These tools are critical for manufacturers to conduct quality controls and for public labs to carry out reliable surveillance testing of these complex molecules.

The European OMCL Network and the Biological Standardisation Programme optimise and streamline the surveillance of medicines and avoid duplication of work.

Recent successes include the validation of an animal-free test that will be used to assess the quality of every batch of acellular Pertussis vaccine used in patients. The European OMCLs also recently successfully contributed to managing an incident concerning potential carcinogenic contamination of certain medicines for the treatment of hypertension.

**“The network is the perfect example of how European countries can work together in a progressive and productive way with each contributing for the benefit of all,” says Wierer.** “The sharing of know-how and resources makes for a strong and independent expertise at the service of EU citizens. The access to good quality medicines is a basic human right and something that every citizen should be able to take for granted. Through the coordination of the European OMCL Network and the Biological Standardisation Programme, the EDQM contributes to making this happen.”

*In 2017, more than 1400 product-testing projects were added to the OMCL Network’s work programme for the market surveillance of medicinal products authorised in the European Economic Area (EEA) via the Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP) system. As of December 2017, the MRP/DCP database was holding some 9900 product testing records, with contribution from 34 different OMCLs. Some 70 individual counterfeit/illegal products testing report were issued by the network in 2017 via the OMCL’s Know-X database, which contained 3700 OMCL reports as from July 2018.*



# EXPH

## The Expert Panel on effective ways of investing in health

The Commission needs expert evidence-based advice to help EU countries to develop, maintain or improve their health systems. Therefore, the Expert Panel on effective ways of investing in health was then established by Commission Decision in 2012. It consists of 14 experts selected as members for a 3 year period.

**Website:** [https://ec.europa.eu/health/expert\\_Panel/home\\_en](https://ec.europa.eu/health/expert_Panel/home_en)



## Health is wealth: the expert panel helps strengthening EU health systems!

Clarifying terms of reference is partly what the independent Expert Panel on Effective Ways of Investing in Health strives to do. How can you solve a problem if you don't know exactly what it is? How can you make sure people are in agreement about the meaning of more slippery terms like 'value', as in value-based healthcare?

The Expert Panel on Effective Ways of Investing in Health is called upon by the Commission to define terms, pinpoint problems and knowledge gaps and point the way to possible solutions. The Panel has been chaired since the beginning by Prof. Jan De Maeseneer, who is also the Head of Department of Family Medicine and Primary Health Care at Ghent University.

"The Panel includes high-level experts from different countries and different backgrounds. Health systems analysts, economists, and people like myself from a medical background have formed a strong bond and work together for the common good. Our mandates come from the Commission, mainly from the Directorate General for Health and Food Safety, but also from other Directorate Generals like agriculture that deal with issues that directly or indirectly impact health. The Expert Panel can also make suggestions for studies on its own."

The Panel is involved in the areas of health planning and budget prioritisation; health services research; hospital and healthcare management; healthcare provision and health education and promotion. Given the specific nature of the mandates, the Panel might be supported by external experts selected from a Commission database or directly if additional particular expertise is needed. "The roughly 60-page documents we produce are called Opinions," says De Maeseneer, "and they often lead to EU countries taking action on various issues. We've published 15 or 16 Opinions so far, looking at a wide range of problems and also looking ahead at new challenges such as shifting demography and the digitalisation of the health sector.

"When we saw how the financial crisis in Greece challenged access to care, we came together to discuss how to better protect citizens and assure them access to health care no matter what the economic and political situation. We suggested a model identifying policy levers which are crucial to providing security and better access to healthcare", said De Maeseneer. "Very often our Opinions have a cross-directorate application, touching upon broader societal considerations, because health is something that is impacted by many different

factors including environmental, political and economic realities."

Recent topics the Expert Panel has examined include 'Defining 'Value' in value-based healthcare' as well as 'Assessing the impact of digital transformation of health services. And last year, it delivered a very timely Opinion that examined obstacles to vaccination uptake, in face of declining vaccination coverage, growing hesitancy and the rise of vaccine-preventable diseases like measles. **"We are increasingly looking at themes within a European framework, like equality and patient-centred perspectives and European values," says De Maeseneer.**

How does it work in practice? On the basis of studying the recent literature, the experts produce a preliminary report or Opinion, which is posted online. Then a meeting is held in Brussels to provide stakeholders with an opportunity to share their views and comment on draft Opinions. "This leads to very constructive discussions and we sometimes discover certain issues that we might have overlooked," says De Maeseneer. All the finalised Opinions are published online, along with their factsheets that present the key messages in an easy-to-read way.

"We also receive requests from the Council and the European Parliament, and from other groups including NGOs to attend meetings and present the Opinions, which often become reference documents in their subjects. Besides prompting useful debates, they have also added to the knowledge base for decision-makers to draw upon when making policies and legislation."

### How to define value according to EXPH

*ALLOCATIVE VALUE: Equitable distribution of resources across all patient groups.*

*TECHNICAL VALUE: Achievement of best possible outcomes with available resources.*

*PERSONAL VALUE: Appropriate care to achieve patients' personal goals.*

*SOCIETAL VALUE: Contribution of healthcare to social participation and connectedness*

*This comprehensive meaning of 'value' offers a wider perspective than the interpretation of 'value' as purely monetary in the context of cost-effectiveness.*





# STATE OF HEALTH IN THE EU

**Start date - end date:** 01/12/2017 to 30/06/2020

**Project Coordination:** The State of Health in the EU is an initiative undertaken by the European Commission that provides policy makers, interest groups, and health practitioners with factual, comparative data and insights into health and health systems in EU countries. The continuous cycle is developed in cooperation with the Organisation for Economic Co-operation and Development (OECD) and the European Observatory on Health Systems and Policies.

**EC Contribution:** € 1 500 000

**Website:** [https://ec.europa.eu/health/state/summary\\_en](https://ec.europa.eu/health/state/summary_en)



## Factual and comparative data and insights into health and health systems in EU countries

The State of Health in the EU initiative provides national policymakers with much-needed analysis and cross-country insights to help improve their health systems and boost the health of their populations. The recurring, two-year cycle tracks the evolution of EU health systems in terms of their effectiveness, accessibility and resilience.

The Health at a Glance: Europe report is produced every other year as part of this cycle, and its findings can help shape policy by pinpointing weaknesses and needs. The Health at a Glance: Europe 2018 report, for example, stated that mental health problems, such as depression, anxiety disorders and addiction, affect more than one in six people across the European Union in any given year. Besides the impact on people's well-being, the report estimated the total costs of mental ill health at over EUR 600 billion – or more than 4% of GDP – across the 28 EU countries.

That is the kind of information policymakers need, but in addition to this report on Europe as a whole, the State of Health in the EU cycle also produces Country Health Profiles, which really take an in-depth look at each country's context, factoring in both strengths and weaknesses. These profiles, alternating every other year with the Health at a Glance: Europe reports, can assist national policymakers by focusing on key issues of particular relevance to them.

Once they have this information, national health authorities may take advantage of another product of the State of Health in the EU cycle – the voluntary exchanges. They are invited to meet face to face with the experts who compiled the reports and to talk about strategies and solutions. Experts are from the Organisation for Economic Cooperation and Development (OECD) and the European Observatory on Health Systems and Policies (Observatory), who, together with the European Commission's Directorate for Health and Food Safety, are the collaborative partners in the State of Health in the EU cycle.

"This strengthened cooperation between the OECD and the Observatory under the State of Health in the EU cycle was initiated by the European Commission in 2016 and helps to achieve greater alignment and coherence in the "diagnostic" that is provided to countries. It also provides them with greater support for mutual learning, supporting improvements in the health of populations and the performance of health systems," said Gaetan Lafortune of the OECD.

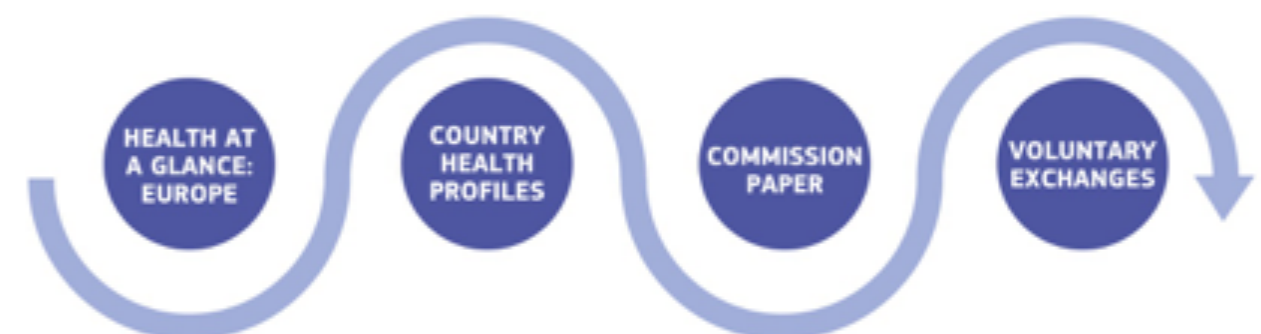
"The OECD is pleased to work closely with the European Commission and the Observatory in the on-going implementation of the key steps in this cycle."

"Together with the European Commission, the OECD prepares Health at a Glance: Europe as a starting point of each cycle. The OECD then works together with the Observatory on the individual Country Health Profiles, which is a process closely overseen by the European Commission as well. These profiles assess the strengths and challenges of each country in prevention policies and in making health systems more effective, accessible and resilient."

The European Commission presents a Companion Report alongside the Country Health Profiles, drawing some cross-cutting conclusions and exploring opportunities for both mutual learning and EU support.

**"At the close of the two-year cycle, the OECD and the Observatory offer health authorities in EU countries the opportunity to hold tailor-made dialogues to discuss selected policy priorities with international experts who can bring in the experience of other countries in tackling these issues," says Lafortune.**

The State of Health in the EU cycle has received positive feedback from both EU countries and stakeholders. Particularly appreciated are the conciseness and balanced approach in assessing the strengths and weaknesses of each country, and the opportunity to discuss findings and policy options with experts.





# EURORDIS

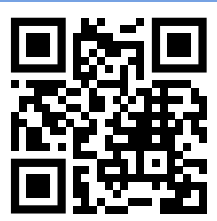
European Organisation for Rare Diseases Association

**Start date - end date:** 01/01/2019 to 31/12/2019

**Project Coordination:** The European Organisation for Rare Diseases (EURORDIS – Rare Diseases Europe) was granted for the first time within the framework of the Work Plan 2008 of the EU Health Programme. Over the years the operating grants have significantly contributed to the implementation of EURORDIS' long term strategies and its annual key objectives.

**EC Contribution:** € 1 029 456 in 2019

**Website:** <https://www.eurordis.org>



## Giving a voice, ending isolation and improving lives for families and patients affected by rare diseases

Some 6% of the total EU population are rare disease patients, which is equivalent to the combined populations of the Netherlands, Belgium and Luxembourg. According to EURORDIS – Rare Diseases Europe, 1 in 20 people will live with a rare disease at some point in their lives, yet despite this, there is no cure for the majority of rare diseases and many go undiagnosed.

EURORDIS is a non-profit alliance of 862 rare disease patient organisations from 70 countries that work together to improve the lives of the 30 million people living with a rare disease in Europe. Its mission is to build a strong pan-European community of patient organisations and people living with rare diseases and to be their voice at the European level. "Cross-border EU action in the field of rare diseases is the only way forward to tackle this public health need," says Yann le Cam, Chief Executive Officer of EURORDIS.

A big part of EURORDIS's work is to help increase awareness about rare diseases and advocate for rare disease patients, and one important way it does this is through Rare Disease Day. Since this international annual event was launched in 2008, thousands of events have taken place worldwide, reaching hundreds of thousands of people and resulting in extensive media coverage and impact on policy makers.

This initiative is part of the wider advocacy effort by EURORDIS, Rare Diseases International and the NGO Committee for Rare Diseases to build a rare disease movement globally, with rare diseases now on the agenda of the World Health Organisation as well as included in the High Commissioner for Human Rights annual report on Universal Health Coverage.

These are extremely visible achievements, but are only a few of EURORDIS's long list of successes. EURORDIS helps promote and maintain rare diseases as a EU Public Health Policy priority, and has promoted National Plans and Strategies on Rare Diseases in all 28 EU countries and other European countries. It has contributed to the designation of over 1100 orphan drugs and organises the European Conferences on Rare Diseases & Orphan Products. And it provides training through its Open Academy to rare disease patient advocates in therapeutic development, research and leadership so that they can engage meaningfully across the spectrum with clinicians, researchers, policy makers, regulators and industry.

EURORDIS also played an instrumental role in getting the patient community involved in the European Reference Networks (ERNs), which are virtual networks involving

healthcare providers across Europe. There are 24 ERNs, each focusing on a particular disease area, involving more than 900 highly-specialised healthcare units in 26 EU countries. EURORDIS created 24 European Patient Advocacy Groups, each corresponding to the scope of one of the 24 ERNs, and today there are over 200 patient advocates are working with clinicians and researchers in these ERNs to improve patients' access to high quality diagnosis, care and treatment of complex or rare medical diseases.

Although great strides have been made, rare disease patients needs continue to go unmet. In May 2019, EURORDIS and its member organisations launched a new position calling for the provision of holistic care for the 30 million Europeans living with a rare disease and their families by 2030.

Over the years the support from the EU Public Health Programme has significantly helped to implement of all these activities. **"Importantly, it has allowed the organisation to maintain an independent voice when elevating the needs of rare disease patients, one of the most vulnerable stakeholders in society," says Le Cam.** "This is the only publicly funded programme that addresses cross-border and concerted action in healthcare also covering operational expenses, and as such it has been a major force to address the public health needs of people living with a rare disease in the EU.

"While EURORDIS' work has had a positive impact on thousands of rare disease patients in the EU, our vision extends beyond any borders. Rare diseases know no borders, the challenges that rare disease patients face day after day, remain an unmet public health need that is common and ever present regardless of where they live. EURORDIS has strived to push for international concerted action, and work across borders and diseases to improve the lives of people living with a rare disease."

- *More than 30 million people in the EU are affected by rare diseases*
- *More than 600 different registries across Europe at national, regional and local level*





# ERNs

## European Reference Networks

The European Reference Networks (ERNs) were created under the 2011 Directive on Patient Rights' in Cross-Border Healthcare and are aiming to increase patients' accessibility to the best advice for diagnosis and treatment.

**EC Contribution:** : The EU is supporting the ERNs trough several funding sources and programmes. Each ERN is receiving over a 5-year period a total EUR 1 million. In addition, the EU is supporting the Networks organisational work, the transversal networking and coordination activities and the capacity building actions with other funding actions coming from the Public Health programme.

**Website:** [https://ec.europa.eu/health/ern\\_en](https://ec.europa.eu/health/ern_en)



## Working for patients with rare, low-prevalence and complex diseases

For many patients with rare or complex diseases, this is not something they have to imagine, it's their reality. On average, it takes between 7 and 10 years for a rare disease patient to get the right diagnosis. A decade or nearly a decade of suffering without hope of help. The rare or low prevalence (infrequent) and complex diseases and conditions (rare or complex diseases / conditions) they have may be something their local doctors have never seen and do not know about. Yet the expertise they need to get a diagnosis or a proper treatment might be just a few hours away or available in another EU country.

"No one doctor or even country has the knowledge and capacity to treat all rare and complex conditions, but through European Reference Networks, set up by the European Commission in 2017, doctors have access to a highly-specialised pool of colleagues from all over Europe," says Dr Irene M. J. Mathijssen, chair of the ERN coordinators group and Head of the Department of plastic and reconstructive surgery at Erasmus MC. **"By exchanging knowledge at EU-level, doctors can provide the best treatment and give the best advice to their patients with rare and complex conditions. And that means that tens of thousands of people will have the chance to live longer and healthier lives."**

"On the European Reference Networks website, you can hear from some of the patients suffering from rare or complex diseases that are the focus of the ERNs. The lives of patients facing similar issues may be turned around in the future thanks to the advice on the proper diagnosis and treatment that was provided by the ERNs. You can watch the video featuring Elisa in Italy, who had rare bone disease all of her life and was only diagnosed at the age of 30. And the video featuring Jasper, a young Dutch patient with a rare heart problem who was able to get help and now looks forward to watching his daughter grow up. Or of Paula, a young patient from Barcelona who needed a transplantation and further pre- and post-operative care.

Patient organisations, with EURORDIS as one of the main drivers, were the real force behind setting up these networks. In this first phase, over 900 healthcare units are collaborating in 24 thematic networks, ranging from childhood cancer to immunodeficiency. International experts in these different specialised areas hold virtual panels on patient cases, exchange information and expertise among themselves and help the doctors in charge of the patient to get an accurate diagnosis or proper care.

It all starts with the primary or secondary healthcare

providers. "When they realise that they may be dealing with a rare or complex disease that requires specialists, they can refer the patient to their regional or national network of specialists or contact the national ERN contact point on their behalf," says Dr Mathijssen. That is, if they have these types of regional and national networks in their Member State – not every country yet does.

In fact, countries with the greatest needs are often the ones with the least access to the assistance that ERNs can provide. Local, regional and national healthcare providers need to be encouraged to make use of this unique resource. One reason they might be reluctant to do is that they are concerned about the expense. But ERNs can actually save them money, explains Dr Mathijssen. ERN experts hold consultations online, saving the patient the expense and burden of travelling, saving public resources, and keeping healthcare funds in the home countries. It's also worth mentioning that experts working for the ERNs volunteer their time – they are currently not paid for their services.

"ERNs are still in their infancy, and we are working hard to make them more accessible. Digital health technology might assist in that and could also be used to monitor and follow up patients as well. But already over the past two years we have seen lives changed and patients getting the help they need, for example, patients who have rare forms of epilepsy, who finally got the right diagnosis and care. That's extremely gratifying," says Dr Mathijssen. There is more to be done, but ERNs are part of a broader strategy to make the European health systems more efficient, accessible and resilient. And they are working!

- More than 300 hospitals
- More than 900 healthcare units
- Thousands of patients helped by 2020



**Share. Care. Cure.**



# VISTART

Joint Action on Vigilance and Inspection  
for the Safety of Transfusion, Assisted  
Reproduction and Transplantation

**Start date - end date:** 10/10/2015 to 09/02/2019

**Project Coordination:** Istituto Superiore di Sanità,  
ISS., Italy.

A total of 17 partners from 14 EU countries  
participate to the Joint Action, namely Austria,  
Belgium, Bulgaria, Croatia, France, Greece, Ireland,  
Italy, Hungary, Lithuania, Portugal, Norway, Poland  
and Romania.

**EC Contribution:** € 2 328 664

**Website:** <https://vistart-ja.eu>



## Keeping organs, blood, tissues and cells available and safe for patients in need

Say 'SoHo' and people think of well-known districts in Manhattan and London. But say SoHO to someone on a waiting list for a kidney or in urgent need of a blood transfusion and they'll immediately think of 'substances of human origin' (SoHO). Blood, tissues, cells and organs are used in a variety of medical therapies that can save lives (e.g. blood transfusion in case of trauma), improve the quality of life (e.g. kidney transplants), and even help create life (gametes for in vitro fertilisation).

And yet, the use of SoHO presents risks, in particular the transmission of diseases or other unexpected reactions in the patient. The European Union sets high legal standards of quality and safety of SoHO, and vigilance activities are in place to protect citizens.

That said, EU countries are responsible for their own healthcare systems and decisions on authorised practices for SoHO, particularly those concerning ethics, are taken at national level. The Commission does not intervene in these decisions, which can vary between countries. Nevertheless, once practices are allowed and authorised by EU countries, they need to meet the EU legal requirements on safety and quality. National authorities may however choose to add local, more stringent, requirements, for example an additional lab-test in response to a local epidemiological outbreak of a highly infectious disease.

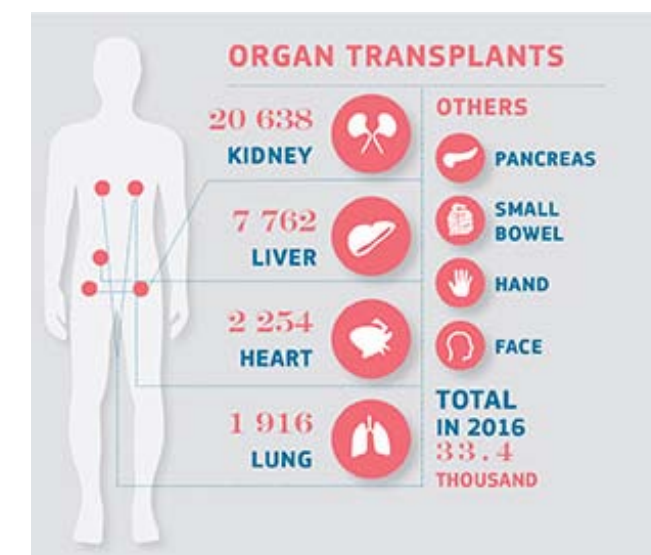
The European Commission funds actions in the area of SoHO through the EU Health Programme mainly in the form of projects and/or joint actions with national authorities. Actions aim at supporting the EU mandate on safety and quality; but also at improving the availability of SoHO or increasing the efficiency of the health systems that support donation and supply.

Some recent examples of these types of joint actions are VISTART and GAPP, which were coordinated jointly by the Italian National Transplant Centre (CNT) and the Italian National Blood Centre (CNS). "VISTART deserves the credit of bringing together for the first time ever the Competent Authorities of blood, tissues and cells," says the project manager for both VISTART and GAPP, Paola Di Ciaccio, Head of Foreign Affairs Division, Italian National Transplant Centre, Italian National Institute of Health. "And it was able to foster fruitful discussions on how to carry out inspections of establishments, how to increase vigilance on serious adverse events and reactions, and how to authorise new blood, tissue and cell preparations in a harmonised way. VISTART brought successful cross-fertilisation that yielded shared guidelines, procedures and training, helping to keep European patients safer.

"GAPP's purview is vast, to say the least," says Di Ciaccio. "The participating authorities are here confronted with the challenge of tackling change and novelty, namely how a new product is processed or a process is modified. Such changes require careful consideration, a conservative approach is needed on the one hand to provide optimum safety of the patients, while innovation and progress must also be encouraged in order to improve or increase available therapies that could bring significant benefits for patients.

"GAPP is midway through and promises to supply an unprecedented framework for authorising product processing; countless high level experts have been involved from the different fields as well as a large number of national and international organizations. **The final product of the action is expected to be a useful common IT tool that will allow in-the-field EU authorities to share common knowledge for leading-edge processes and how to ensure that they are safe and effective,"** says Di Ciaccio.

It sounds complicated, and it is, but that's why it requires experts working behind the scenes to ensure that everything regarding substances of human origin meets the highest of standards. When patients need a medical intervention, they have enough on their minds without worrying about the safety of the procedure meant to save their lives. If they receive substances of human origin in the EU, they can rest assured and put their energies into regaining their health.







# JAMRAI

Joint Action on Antimicrobial Resistance and Health care Associated infections

**Start date - end date:** 01/09/2017 to 31/08/2020

**Project Coordination:** Institut National de la Santé et de la recherche médicale (Inserm), France.

The Joint Action is run by 44 partners from 20 countries : Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, France, Germany, Greece, Italy, Latvia, Lithuania, the Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Spain and Sweden as well as more than 40 participants.

**EC Contribution:** € 4 178 163

**Website:** <https://eu-jamrai.eu>



## Working to halt one of the world biggest health threats!

Antibiotics brought many changes to our daily lives. They cured previously deadly diseases and made surgery, cancer treatments, neonatal care and organ transplants safer, saving millions of lives. But too much of a good thing is a bad thing –the overuse and inappropriate use of antibiotics have given rise to bacteria resistant to multiple antibiotics, also known as super bugs. Super bugs may take us back to pre-antibiotic days when people died of infections; Antimicrobial resistance (AMR) is one of the biggest public health threats today and may become the world's greatest killer by 2050 if proper actions are not taken now.

EU-JAMRAI – the Joint Action on Antimicrobial Resistance and Healthcare Associated Infections, brings EU countries and stakeholders together to find solutions to keep antibiotics working. **"We are the first European Joint Action in the field," says EU-JAMRAI coordinator, Professor Marie-Cecile Ploy. "And we have a clear objective: to bridge the gap between declarations and actions and make Europe a best practice region identifying and implementing evidence based measures to tackle AMR."**

EU-JAMRAI involves universities, hospitals, regulatory agencies, governments and public health institutes. Its stakeholder forum, made up of more than 40 organisations, ensures that the Joint Action is strategically connected to the global challenges and developments in the AMR field. "If we want to tackle antimicrobial resistance, we have to stop working in silos, says Prof Ploy." EU-JAMRAI is a unique place where EU countries and all key actors work together to find and implement concrete actions at operational level under the 'One Health' approach".

In its first two years, EU-JAMRAI has achieved results in several key areas: one of the first steps was to map the national actions being taken on AMR. "After this mapping effort, we undertook a self-assessment that was carried out by 18 EU countries. The results showed several common issues such as the need to get or keep the issue on the political agenda, lack of resources, difficulties in translating surveillance data into actions and the challenge of working with a 'One Health' approach," says Prof Ploy. "We followed this up with a series of 'peer reviews' – exchange visits between two countries to exchange experiences.

"We believe that peer reviews can help transform European action on AMR. We have done seven country-to-country visits so far to evaluate each other's interventions and discuss policy options. This translates into a very useful exchange of good practices. In the field of Healthcare-Associated Infections we have carried out two surveys with more than 2,500 respondents to help inform our efforts to improve prevention. It is important to recognize that AMR and infection control are tightly linked," says Prof Ploy. "We cannot fight against AMR efficiently without tackling infection control issues."

Another priority is to reduce the use of antibiotics. "Antibiotic misuse is accelerating AMR at a very fast pace. Getting doctors, dentists, vets and farmers to change their behaviour and use fewer antibiotics in a more targeted and effective way is a challenge that cannot be underestimated," says Prof Ploy. EU-JAMRAI has published guidelines, reports and other tools for health professionals and has led AMR awareness campaigns to promote appropriate antibiotic use. Active on social media, their latest video campaign, #DontLeaveItHalfway, was translated into 18 languages and was seen by 2.7 million people in a single month".

They've also helped to identify key areas where more AMR research needs to be done, namely within the environmental field, within the food chain sector and on how to improve clinical trials efficiency. "We are also visiting countries in order to better design incentives for the development of antibiotics and diagnostic tools aligned with each country's need," says Prof Ploy.

### Why is AMR a serious threat to public health?

- 25.000 patients die annually in the EU alone as a result of infections caused by resistant bacteria
- Globally this number could be as high as 700.000
- 10 million deaths per year are projected between 2015 and 2050 if current infection and resistance trends are not reversed. Only 0,7 million of these additional deaths would occur in North America or Europe, with the largest numbers in Africa and Asia.

# References

As to the terminology used, please note that throughout the text "EU countries" include EU Member States and participating countries to the Third Health programme 2014/2020.

Page 13 - JANPA: chart on prevention of obesity and non-communicable diseases is from [https://ec.europa.eu/newsroom/sante/newsletter-specific-archive-issue-frame.cfm?newsletter\\_service\\_id=261&newsletter\\_issue\\_id=15967&pdf=true&fullDate=Thu%2020%20Jun%202019&lang=en#newslettertop](https://ec.europa.eu/newsroom/sante/newsletter-specific-archive-issue-frame.cfm?newsletter_service_id=261&newsletter_issue_id=15967&pdf=true&fullDate=Thu%2020%20Jun%202019&lang=en#newslettertop)

Page 15 - Chrodis Plus: chart on % of people with diabetes and high blood pressure is from [https://ec.europa.eu/newsroom/sante/newsletter-specific-archive-issue.cfm?archtype=specific&newsletter\\_service\\_id=261&newsletter\\_issue\\_id=13890&page=1&fullDate=Wed%2003%20Jul%202019&lang=en](https://ec.europa.eu/newsroom/sante/newsletter-specific-archive-issue.cfm?archtype=specific&newsletter_service_id=261&newsletter_issue_id=13890&page=1&fullDate=Wed%2003%20Jul%202019&lang=en)

Page 17- ORAMMA: Chart on % of refugees and asylum seekers is from [https://www.europarl.europa.eu/infographic/welcoming-europe/index\\_en.html#filter=2018](https://www.europarl.europa.eu/infographic/welcoming-europe/index_en.html#filter=2018)  
As to the picture, the ORAMMA team encountered many powerful and, often, painful images. Therefore, they opted to include that one which refers to the work of Kalliopi Lemos, instead. They believe this is a powerful yet respectful manner to safeguard the dignity of these vulnerable people pledges.

Page 19 – European Commission Initiative on Breast Cancer: Percentage of women that may be affected by a breast cancer is from <https://ecibc.jrc.ec.europa.eu/recommendations/>

Page 21 – Joint Action on Tobacco Control: Chart percentage of smokers in the EU is from the Special Eurobarometer 458 on Attitudes of European towards tobacco and electronic cigarettes surveys run in March 2017 <https://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2146>

Page 23 – Joint Action on Vaccination: Data regarding vaccines are from the info-graphic on Protecting health, saving lives: EU cooperation against vaccine – preventable diseases [https://ec.europa.eu/health/sites/health/files/vaccination/docs/2018\\_factsheet\\_en.pdf](https://ec.europa.eu/health/sites/health/files/vaccination/docs/2018_factsheet_en.pdf)

Page 25 – Joint Action to efficiently respond to highly dangerous and emerging pathogens:  
The data have been gathered through the implementation of the Joint Action. For further information please consult the following website:  
[https://www.emerge.rki.eu/Emerge/EN/Home/Homepage\\_node.html](https://www.emerge.rki.eu/Emerge/EN/Home/Homepage_node.html)

Page 27 – Joint Action on preparedness and action at points of entry: The example provided was described in the 04 June 2019 newsletter under the thematic session, Maritime transport, available at: <https://www.healthygateways.eu/Newsletters/newsletter-issue-4-june-2019>

Page 29 – Joint Action on HIV, viral hepatitis, tuberculosis and sexually transmitted infections: Data from the Surveillance report, Annual Epidemiological Report for 2017, ECDC: <https://ecdc.europa.eu/en/news-events/new-hiv-diagnoses-alarmingly-high-levels-european-region-despite-progress-eueea>

Page 33 - Joint Action to support eHealth Network: the data is from the Eurobarometer 460, Attitudes towards the impact of digitisation and automation on daily life available at: <https://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2160>

Page 35 - Joint Action on Medical devices. The chart is from the Transition Timelines from the Directives to the Regulations - Medical Devices and in vitro Diagnostic Medical Devices available at <https://ec.europa.eu/docsroom/documents/34907>

Page 37 – Support for the health workforce planning and forecasting expert network – The chart on the driving forces influencing future skills and competences is from [https://ec.europa.eu/health/workforce/overview\\_en](https://ec.europa.eu/health/workforce/overview_en)

Page 39 - Joint action on Health Technology Assessment – the e-health glossary is available at: [https://ec.europa.eu/health/ehealth/overview\\_en](https://ec.europa.eu/health/ehealth/overview_en)

Page 41 - European Directorate for the Quality of Medicines: data is from the factsheet OMCL Network 2018, available at the following link: <https://www.edqm.eu/sites/default/files/factsheet-omcl-network-2018.pdf>

Page 43 – Expert Panel on effective ways of investing in health: The definition of value is taken from the report "Defining value in "value based healthcare" available at [https://ec.europa.eu/health/expert\\_panel/sites/expertpanel/files/docsdir/024\\_defining-value-vbhc\\_en.pdf](https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/docsdir/024_defining-value-vbhc_en.pdf)

Page 47 - European Organisation for Rare Diseases Association data from the website of the organisation: <https://www.eurordis.org/about-rare-diseases>

Page 49 - European Reference Networks data from the flyer "European Reference Networks Helping patients with low-prevalence rare or complex diseases" available at: [https://ec.europa.eu/health/sites/health/files/ern/docs/2018\\_patientsflyer\\_en.pdf](https://ec.europa.eu/health/sites/health/files/ern/docs/2018_patientsflyer_en.pdf)

Page 51 - Joint Action on Vigilance and Inspection for the Safety of Transfusion, Assisted Reproduction and Transplantation data are from the infographic Organs, blood, tissues & cells in the EU available at: [https://ec.europa.eu/health/sites/health/files/blood\\_tissues\\_organs/docs/infographic\\_obtc\\_en.pdf](https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/infographic_obtc_en.pdf)

Page 53: Joint Action on Antimicrobial Resistance and Health care associated infections data are from the factsheet "The new EU One health Action plan against AMR" available at: [https://ec.europa.eu/health/amr/sites/amr/files/amr\\_summary\\_action\\_plan\\_2017\\_en.pdf](https://ec.europa.eu/health/amr/sites/amr/files/amr_summary_action_plan_2017_en.pdf)

# Useful links

**European Commission Directorate-General for Health and Food Safety (SANTE) website**  
[https://ec.europa.eu/health/home\\_en](https://ec.europa.eu/health/home_en)

**Consumers, Health, Agriculture and Food Executive Agency (Chafea) website**  
[https://ec.europa.eu/chafea/index\\_en.htm](https://ec.europa.eu/chafea/index_en.htm)

**Chafea Programmes Data Base (PDB)**  
[https://webgate.ec.europa.eu/chafea\\_pdb/](https://webgate.ec.europa.eu/chafea_pdb/)

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