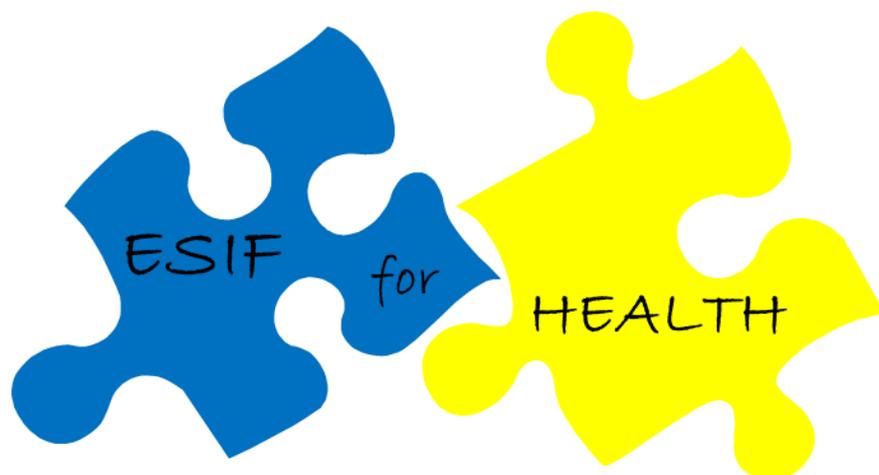


TECHNICAL TOOLKIT:

CATEGORIZATION OF THE 2014-2020 ESI FUNDS INSTRUMENTS AND MECHANISMS

Developed under the project “Provision of support for the effective use of European Structural and Investment (ESI) Funds for health investments”



31 January 2015



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List of abbreviations

| | |
|-----------------------|--|
| BEPA | Bureau of European Policy Advisors |
| CEF | Connecting Europe Facility |
| CF | Cohesion Fund |
| CHAFEA | Consumers, Health and Food Executive Agency |
| CIP | Competitiveness and Innovation Framework Programme |
| COSME | Competitiveness of Enterprises and Small and Medium-sized Enterprises |
| CLLD | Community-led Local Development |
| CPR | Common Provision Regulation |
| DEA | Digital Agenda for Europe |
| DG EMPL | Directorate-General for Employment, Social Affairs and Equal Opportunities |
| DG REGIO | Directorate General for Regional and Urban Policy |
| DG SANCO | Directorate General for Health and Consumers |
| EARDF | European Agricultural Fund for Rural Development |
| EC | European Commission |
| EU | European Union |
| EMFF | European Maritime and Fisheries Fund |
| ERDF | European Regional Development Fund |
| ESF | European Social Fund |
| ESIF/ESI Funds | European Structural and Investment Funds |
| ETC | European Territorial Cooperation |
| GDP | Gross domestic product |
| ICT | Information and communication technologies |
| ITI | Integrated Territorial Investment |
| JASMINE | Joint Action to Support Micro-finance Institutions in Europe |
| JASPERS | Joint Assistance to Support Projects in European Regions |
| JEREMIE | Joint European Resources for Micro to medium Enterprises |
| JESSICA | Joint European Support for Sustainable Investment in City Areas |
| NGOs | Non-governmental organizations |
| OP | Operational Programme |
| PA | Partnership Agreement |
| R&D | Research and development |
| SME | Small and medium enterprises |
| TEN | Trans-European Networks |
| TNC | Transnational cooperation |
| TO | Thematic Objective |
| WP | Work Package |



Introduction

This document “Categorization of the 2014-2020 ESI Funds instruments and mechanisms” forming a part of the Technical toolkit supporting the Guide for effective investments in health under ESI Funds (hereinafter “the Guide”) is developed in the framework of a tender action on the provision of support for the effective implementation of European Structural and Investment Funds (hereinafter “ESIF”) for health investments, managed by the Consumers, Health and Food Executive Agency (CHAFAEA) on behalf of the Directorate General for Health and Consumer (DG SANCO), being delivered by EY.

The Guide and its supporting documents (see the list of project outputs below) are based on broad analyses of collected case studies and EY expert opinion and do not represent official European Commission documents.

The project outputs developed within the framework of the tender action are as follows:

- ▶ WP 1 MAPPING REPORT ON THE USE OF EUROPEAN STRUCTURAL AND INVESTMENT FUNDS IN HEALTH IN THE 2007-2013 AND 2014-2020 PROGRAMMING PERIODS
- ▶ WP 2 GUIDE FOR EFFECTIVE INVESTMENTS IN HEALTH UNDER ESI FUNDS
- ▶ WP 3 TECHNICAL TOOLKIT FOR EFFECTIVE INVESTMENTS IN HEALTH UNDER ESI FUNDS *with the following documents under the toolkit:*

- ▶ **WP 3 (1) CATEGORIZATION OF THE 2014-2020 ESI FUNDS INSTRUMENTS AND MECHANISMS**

- ▶ WP 3 (2) REFERENCE CHECKLIST: ESSENTIAL AND SUCCESS FACTORS FOR CALLS FOR PROPOSALS AND FOR THE ASSESSMENT OF PROJECT APPLICATIONS
- ▶ WP 3 (3) SET OF INDICATORS USEFUL FOR THE FINAL EVALUATION OF ACTIONS
- ▶ WP 3 (4) COMPENDIUM OF (NEW) CONCEPTS AND MODELS FOR INNOVATIVE, EFFECTIVE AND SUSTAINABLE HEALTH CARE
- ▶ WP 3 (5) MANUAL ON HOW TO PLAN, IMPLEMENT AND SUSTAIN CAPITAL INVESTMENT IN HEALTH AND HEALTH CARE
- ▶ WP 3 (6) REFERENCE DOCUMENT ON THE APPRAISAL OF INVESTMENT
- ▶ WP 3 (7) REFLECTION OF ADDITIONAL ISSUES RAISED BY MEMBER STATES

This part of the toolkit aims to set out the different instruments and mechanisms of the Cohesion Policy in the 2014-2020 programming period, to clarify what the conditions for their use are and to assess their relevance for financing priorities in the area of health.

The document covers the following topics:

- ▶ Chapter one addresses various **forms of support and tools for funding**.
- ▶ Chapter two focuses on **ESIF mechanisms and principles**.



1. ESI Funds instruments

ESIF instruments mean various forms of support and tools for funding. In the text below, the following instruments are examined:

- ▶ **Forms of support under ESIF:**
 - ▶ Grants & prizes
 - ▶ Repayable financial instruments
- ▶ **Specific approaches under ESIF:**
 - **Integrated territorial and urban development instruments**
 - ▶ Integrated Territorial Investment (ITI)
 - ▶ Community-led Local Development (CLLD)
 - ▶ Integrated Sustainable Urban Development
 - **European Territorial Cooperation instruments**
 - ▶ Cross-border programmes
 - ▶ Transnational programmes
 - ▶ Interregional programmes
 - **Connecting Europe Facility**
 - **Social Innovation tool**

For the years 2014-2020, funding is possible through five ESI Funds, i.e. European Regional and Development Fund (ERDF), European Social Fund (ESF), Cohesion Fund (CF), European Maritime and Fisheries Fund (EMFF), and European Agricultural Fund for Rural Development (EARDF). Health and health care will be primarily funded under ERDF and ESF.

In addition to the ESI Funds, which represent a delivery tool for the Cohesion Policy, this document also briefly introduces the following Community programmes:

- ▶ Horizon 2020
- ▶ Third Health Programme
- ▶ Competitiveness of Enterprises and Small and Medium-sized Enterprises (COSME)



1.1. Forms of support under ESIF

According to Article 66 of the Common Provisions Regulation, the ESI Funds shall be implemented to provide support in the following forms:¹

▶ Non-repayable means of funding

- ▶ Grants
- ▶ Prizes

▶ Returnable means of funding

- ▶ Repayable assistance
- ▶ Financial instruments

1.1.1. Grants and prizes

Most of the EU funding will be distributed through grants, which, together with prizes, provide **non-repayable public funding**. In the form of grants, a wide variety of actions as specified by the investment priorities will be available for financing.

Grants will represent the main form of ESIF investment in health, as health is a public service, which does not primarily generate profits. The use of repayable forms of investment is, therefore, limited as a means of investment in most of the health actions.

As the rules governing the use of grants are widely known and are not specifically limited in any way other than imposed by the regulations,² this instrument is not developed further in this document. Mechanisms and principles described in further detail in this paper shall nevertheless be considered in case of any implementation of ESIF, including grants.

With respect to the fact that grants will be used as the main form of support in all funds and within all thematic objectives, their use in the area of health is extensive.

1.1.2. Financial instruments³

Repayable assistance and **financial instruments** represent a returnable means of funding.

Financial instruments provide support for investments by way of **loans, guarantees, equity** and other risk-bearing mechanisms including policy-based guarantees for the ESF, possibly combined with interest rate subsidies or guarantee fee subsidies within the same operation.

¹ Common Provision Regulation (EU) No 1303/2013.

² Common Provisions Regulation No 1303/2013, ERDF Regulation No 1301/2013 and ESF Regulation No 1304/2013.

³ EC: Cohesion Policy 2014-2020 factsheet on Financial Instruments in Cohesion Policy 2014-2020. Available at: http://ec.europa.eu/regional_policy/sources/docgener/informat/2014/financial_instruments_en.pdf; for further information, please visit Regional Policy – Inforegio on The Funds at: http://ec.europa.eu/regional_policy/thefunds/fin_inst/index_en.cfm.



In the past, these instruments have only been used for 1-1.2% of actions, but in the programming period 2014-2020, it is planned to use these instruments for 10% of actions. Due to their high relevance, and in order to allow better understanding of their functioning, the following text focuses on financial instruments in detail.

During the 2007-2013 programming period, the **financial instruments were managed by JASPERS, JEREMIE, JESSICA and JASMINE joint initiatives**. Funding through these specific instruments was **highly prescriptive** with regard to sectors, beneficiaries, types of projects and activities that were supported. JASPERS concentrated on major infrastructure projects implemented in the twelve EU countries which joined the EU in 2004 and 2007 with costs of over €50 million (infrastructure, water, waste and energy oriented projects). JASMINE offered technical assistance to non-bank microcredit providers. JEREMIE supported SMEs and JESSICA funded projects focused on sustainable urban development.

In contrast to the 2007-2013 programming period, the rules proposed for the 2014-2020 period state that Member States and Managing Authorities may use financial instruments in relation to **all thematic objectives** covered by Operational Programmes (OPs), and for all funds, **where it is efficient and effective to do so**.

The new framework also contains clear rules to enable a better **combination of financial instruments** with other forms of support, in particular with grants, as this further stimulates the design of well-tailored assistance schemes that meet the specific needs of Member States or regions.

Implementation of financial instruments is ruled by Title IV of the Common Provisions Regulation and Annex IV to the Common Provisions Regulation.⁴ This title sets out complex rules for use, implementation and management of the financial instruments.

As stated in Article 37, financial instruments shall be implemented to support investments which are expected to be financially viable and do not give rise to sufficient funding from market sources.

Loans

According to the EC definition, loans are **non-derivative financial assets with fixed or determinable payments** that are not quoted in an active market other than:

- ▶ Those that the entity intends to sell immediately or in the near term, which shall be classified as held for trading.
- ▶ Those that the entity upon initial recognition designates as available for sale.
- ▶ Those for which the holder may not recover substantially all of its initial investment, other than because of credit deterioration, which shall be classified as available for sale.

Loans can be used for a limited number of projects within the area of health due to the rule that projects with a positive socio-economic impact but no direct economic return will not be approved. However, this instrument might be suitable for SMEs working in the field of health.

⁴ Common Provision Regulation (EU) No 1303/2013.



Guarantees

A financial guarantee is a contract that helps to **ensure that a creditor or lender is reimbursed for any losses** that result from the failure of a debtor to make payments on the outstanding debt in accordance with the provisions of the agreement that governs the business relationship. One of the benefits of the financial guarantee is that it can **help the debtor to secure a more attractive interest rate** on the loan or other debt instrument. This is because the guarantee helps to lower the degree of risk that the lender is taking on in order to approve the loan.

Guarantees, similarly to loans described in the previous chapter, can only be used for a limited number of projects within the area of health due to the rule that projects with no direct economic return will not be approved. However, this instrument might also be used to support SMEs working in the field of health.

Equity

Venture capital financing is an appropriate tool for funding innovative projects and companies with a potential for rapid growth. The term “private equity” refers to medium to long-term financing provided in exchange for acquiring a stake in the owners’ equity of enterprises whose shares are not traded on any stock exchange.

The potential use of equity in the area of health can be foreseen as a **funding instrument for start-ups or high-tech companies** doing their business in the health care sector.

In the area of health, the potential use of financial instruments is limited. Their use can be envisaged in projects in the field of:

- ▶ SMEs doing business in the health care sector
- ▶ Start-ups or high-tech companies doing business in the health care sector (i.e. eHealth)
- ▶ Wellness and prevention services (i.e. physiotherapy) with clients’ financial participation
- ▶ Complex care for the elderly (i.e. senior residences)

1.2. Specific approaches to development under ESIF

1.2.1. Integrated approach to territorial development

The integrated approach to territorial development is tightly linked to the new Cohesion Policy. According to the Common Strategic Framework, annexed to the Common Provisions Regulation,⁵ Member States are greatly encouraged to approach territorial development in an integrated manner, i.e. to combine the ESI Funds with integrated packages at a local, regional or national level, so that they address specific territorial challenges and needs. This requires higher cooperation and coordination from different levels of government. Community-led Local Development (CLLD), Integrated Territorial Investments (ITI) and Integrated Sustainable Urban Development are the main approaches to territorial development promoted in the 2014-2020 period.

⁵ Common Provision Regulation (EU) No 1303/2013.



Community-led Local Development (CLLD)⁶

Community-led Local Development represents a specific bottom-up approach which is designed for use at a sub-regional level, complementary to other development support at a local level. Its purpose is to meet local objectives and needs, and to contribute to smart, sustainable and inclusive growth. Community-led local development is designed and implemented by a local action group⁷ so that it enables involvement not only of representatives of local public authorities, but mainly citizens, communities and organizations at a local level in finding responses to the social, environmental and economic challenges while taking into consideration specific local needs.

The main principles for CLLD are stated in Article 32 of the Common Provisions Regulation.⁸ According to Article 32, in order to facilitate a manageable approach to its integration into the programming process, CLLD should be carried out under a single thematic objective, either to promote TO 8 – Employment & supporting labour mobility or to promote TO 9 – Social inclusion & combating poverty; in spite of the fact that actions financed as part of Community-led Local Development could contribute to all other thematic objectives.

Implementation of CLLD is ruled by Articles 33-35 of the Common Provisions Regulation. It includes complex rules for setting up strategies, defining local action groups and the coverage of the support from ESI Funds as well as implementation and management regulations.

In the area of health, the potential use of Community-led Local Development can be envisaged in relation to the following actions:

- ▶ Community-led Local Development will be part of either thematic objective No. 8 – Employment & supporting labor mobility or thematic objective No. 9 – Social inclusion & combating poverty, both of which contain various health eligible areas.
- ▶ Local actors have a better knowledge of local challenges in health that need to be addressed.
- ▶ Increased access to health care in a region is a part of its territorial development strategy.
- ▶ Can be applicable especially to set up or improve / make more accessible local health care services in rural areas.
- ▶ Can be used where health and social care are linked (to support regional strategy planning).
- ▶ Can be used in deprived urban areas to improve public health, health care or to strengthen prevention to reduce drug abuse.

⁶ EC: Guidance on Community-Led Local Development for Local Actors – European Structural and Investment Funds Guidance for Member States and Programme Authorities, Guidance for Beneficiaries, May 2014. Available at:

http://enrd.ec.europa.eu/app_templates/enrd_assets/pdf/clld/Policy-guidance/guidance-clld-local-actors_en.pdf;

EC: Common Guidance of the European Commission's Directorates-General AGRI, EMPL, MARE and REGIO on Community-led Local Development in European Structural and Investment Funds, April 29, 2013. Available at:

http://ec.europa.eu/regional_policy/what/future/pdf/preparation/clld_guidance_2013_04_29.pdf ;

EC: Cohesion Policy 2014-2020 factsheet on Community-led Local Development, March 2014. Available at:

http://ec.europa.eu/regional_policy/sources/docgener/informat/2014/community_en.pdf

⁷ Neither public authorities nor any single interest group at the decision-making level can represent more than 49% of the voting rights.

⁸ Common Provision Regulation (EU) No 1303/2013.



Integrated Territorial Investment (ITI)⁹

Integrated Territorial Investment is a territorial development tool that enables the implementation of a territorial strategy in an integrated manner while drawing funds from at least two different priority axes in the same or different programmes.

Provisions relevant to integrated territorial development are stated in the Common Provisions Regulation¹⁰ under Article 36.

Where an urban development strategy or other territorial strategy, or a territorial pact referred to in Article 12(1) of the ESF Regulation,¹¹ requires an integrated approach involving investments from the ESF, ERDF or Cohesion Fund under more than one priority axis of one or more Operational Programmes, actions may be carried out as an Integrated Territorial Investment.

Implementation of ITI must be based on a territorial development strategy. Where implementation does not reflect a territorial development strategy, or the investment is to be financed from only one priority axis, it does not constitute an ITI.

ITI may cover any type of territory at a sub-national level – a region, a functional area, an urban or a rural municipality or a neighbourhood. An ITI can also be used in the context of European Territorial Cooperation programmes (ETC).

Member States have a choice whether to use ITIs. In the case of Sustainable Integrated Urban Development under Article 7 of the ERDF Regulation,¹² Member States may envisage a dedicated priority axis or a specific Operational Programme for sustainable urban development as an alternative to ITIs or in addition to ITIs.

ITI can be a **mono-fund** as well as **multi-fund** instrument. Therefore, it is useful to finance actions with both soft and investment-like expenditure.

In the area of health, the potential use of ITI can be envisaged in relation to the following actions:

- ▶ Health investment is a part of a cross-sectorial territorial strategy.
- ▶ Increased access to health care in a region is part of its territorial development strategy.
- ▶ It requires funding in more than one area, i.e. it requires both an increase in the number of ambulatory health care facilities as well as training of medical staff.
- ▶ Can be applicable especially to remote regions with an underdeveloped health infrastructure.
- ▶ Can be applicable in regions with a local economy focus on health services, i.e. regions with specialized research centers or specialized health care facilities.

⁹ EC: Cohesion Policy 2014-2020 factsheet on Integrated territorial investment, March 2014. Available at: http://ec.europa.eu/regional_policy/sources/docgener/informat/2014/iti_en.pdf

¹⁰ Common Provision Regulation (EU) No 1303/2013.

¹¹ Regulation (EU) No 1304/2013 of the European Parliament and of the Council of 17 December 2013 on the European Social Fund and repealing Council Regulation (EC) No 1081/2006.

¹² Regulation (EU) No 1301/2013 of the European Parliament and of the Council of 17 December 2013 on the European Regional Development Fund and on specific provisions concerning the Investment for growth and jobs goal and repealing Regulation (EC) No 1080/2006.



Integrated Sustainable Urban Development¹³

Integrated Sustainable Urban Development represents an instrument designed to tackle the economic, environmental, climate and social challenges of urban areas. Its development is mainly funded from ERDF based on Articles 7 to 9 of the ERDF Regulation.¹⁴ It involves investment under more than one priority axis in the same or different Operational Programmes. The role of cities in the Member States should be strengthened by giving them the opportunity to design and implement fully integrated strategies.

Based on the fact that the Integrated Sustainable Urban Development instrument is mainly focused on economic, environmental, climate or social sectors, its **use in health investment** is limited. Its potential use can be envisaged in relation to:

- ▶ Physical urban renewal combined with measures promoting social inclusion in urban areas (e.g. social / medical centers for the elderly population)

1.2.2. European Territorial Cooperation (ETC)¹⁵

During the 2014-2020 programming period, European Territorial Cooperation remains a separate objective of the ERDF Cohesion Policy. Three types of territorial cooperation programmes will be supported by the fund:

- ▶ Cross-border programmes
- ▶ Transnational programmes
- ▶ Interregional programme

Transnational programmes will be partially supported by the ESF as well.

Cross-border programmes

The Cohesion Policy encourages regions and cities from different EU Member States to create cross-border programmes. Member States and regions shall seek to make use of cooperation to achieve synergies and to resolve common challenges identified jointly in the border regions (such as poor accessibility, lack of research and innovation cooperation) according to the Common Strategic Framework, annexed to the Common Provisions Regulation.¹⁶ The cross-border cooperation will be funded under ERDF.

¹³ EC: Cohesion Policy 2014-2020 factsheet on Integrated Sustainable Urban Development. Available at: http://ec.europa.eu/regional_policy/sources/docgener/informat/themes2012/urban_en.pdf

¹⁴ Regulation (EU) No 1301/2013 of the European Parliament and of the Council of 17 December 2013 on the European Regional Development Fund and on specific provisions concerning the Investment for growth and jobs goal and repealing Regulation (EC) No 1080/2006.

¹⁵ DG REGIO: European Territorial Cooperation – Building bridges between people, September 2011. Available at: http://ec.europa.eu/regional_policy/information/pdf/brochures/etc_book_lr.pdf

¹⁶ Common Provision Regulation (EU) No 1303/2013.



In the area of health, there is wide potential for the use of cross-border programmes, especially in the following areas:

- ▶ R&D collaboration (HIV / AIDS, cancer and others), including cooperation between clusters and other organizations
- ▶ Cooperation between medical practitioners, hospitals, polyclinics and health insurance companies on both sides of the border in order to have accessible but specialized health care, e.g.:
 - ▶ Emergency medical assistance (ambulance)
 - ▶ Cross-border transplant and blood transfusion cooperation
- ▶ Development of health tourism (health resorts)
- ▶ Medical staff mobility to increase the share of knowledge
- ▶ Mobility of medical technology
- ▶ Development of infrastructure and training in order to be able to prepare and respond to health threats such as influenza outbreaks.

Transnational programmes

Several transnational cooperation programmes will be supported by the ERDF (the programmes will be successors of the 13 INTERREG IVB programmes). The programmes are set for projects that allow cooperation between national, regional and local entities in larger geographical areas – the areas of the new programmes will be similar to the current programmes. The new Operational Programmes will only be allowed to select four out of the 11 thematic objectives highlighted in the Common Provisions Regulation.¹⁷

In the area of health, the funding from transnational programmes **will depend on the specific thematic objectives supported by individual Operational Programmes**. Its potential use can be envisaged in the following areas:

- ▶ Transnational research clusters and collaboration initiatives active in R&D in health care and well-being
- ▶ Knowledge sharing of national best practices in the area of health care

There will be the transnational cooperation programmes under the ESF as well. The main purpose of transnational cooperation between the Member States under the ESF is to contribute to the quality and effectiveness of employment policy and delivering reforms. A transnational dimension has an important multiplier effect: it can strengthen the capacities to innovate, modernise and adapt to new social and economic challenges as well as identify issues and suggest solutions for reforms which can shape and deliver the relevant policy related targets. It can also help to improve the quality of governance.

¹⁷ Common Provision Regulation (EU) No 1303/2013.



For transnational cooperation (TNC), different programming options are available:¹⁸

- ▶ **Specific approach – development of a specific priority axis dedicated to TNC (for which the ESF contribution will be increased by 10%) in an Operational Programme.**

In the region of Veneto in Italy, Axis 5 of the ESF Operational Programme is dedicated to inter-regional activity and transnational cooperation, providing a budget of approximately 11 million EUR. Under this Priority, **Veneto has launched specific calls for transnational projects, focusing on the key ESF regional priority areas:** human capital, social inclusion and the employment of disadvantaged people.

- ▶ **Horizontal / cross-cutting approach – integration of TNC within all or some thematic priorities of an OP.**

In Poland, **transnational cooperation can be implemented within all priorities of the Polish ESF Operational Programme**, which covers a wide range of areas such as employment, social integration, adaptability of employees and enterprises, education, higher education, good governance and **health**. The only exception concerns small projects in rural areas which cannot be implemented in cooperation with transnational partners. **Transnational projects can be implemented at both regional and national level**, and transnational components can also be added to projects during their implementation.

- ▶ **Dual Approach – combination of the dedicated priority with the horizontal / cross-cutting approach.**

In Sweden, **any ESF project can apply for funding for transnational cooperation, but there are also specific calls for projects for which transnational cooperation is obligatory**. There are calls at both national and regional level, and the regions play a very important role. The proposition of projects including transnational cooperation has increased from 7% in January 2010 to 32% in January 2012. The total TNC budget in projects is approximately 15 million EUR, 2.1% of all ESF funding.

Interregional programme

One interregional cooperation programme (INTERREG EUROPE) will be implemented in the 2014-2020 period (as the successor of INTERREG IVC). The program will cover the entire EU and will support projects focused on the following thematic objectives:

- ▶ Research & Innovation (TO 1)
- ▶ Competitiveness of SMEs (TO 3)
- ▶ Shift towards a low-carbon economy in all sectors (TO 4)
- ▶ Environmental protection and promotion of resource efficiency (TO 6)

¹⁸ DG EMPL: Guidance on Transnational cooperation under the European Social Fund.



In the area of health, the potential implementation of the Interregional programme can be envisaged in the following areas which are **linked to thematic objectives 1 and 3**:

- ▶ Exchange of experience among regional actors to improve policies in support of innovation addressing the key societal challenges in the field of health, demographic change and well-being.
- ▶ Cooperation of SMEs and research institutes in the field of eHealth development and other products and services connected with the ageing population, care and health.

1.2.3. Connecting Europe Facility (CEF)

The Connecting Europe Facility or CEF is an instrument extending previously mentioned territorial programs. The concept is fairly new as the plan was adopted in October 2011 and the regulation followed in December 2013. As for its use, CEF is the funding instrument for the Trans-European Networks (TEN) in the fields of transport, energy and digital networks. The CEF aims to fill the missing links in Europe's energy, transport and digital backbone, helping to complete the European single market.

Relevant for the health investments, CEF Digital is anchored to the Europe 2020 strategy, which puts digital infrastructure at the forefront with the Digital Agenda for Europe (DEA) initiative. The biggest asset of ICT in health is that it provides Europeans with better and cheaper tools to improve the quality and delivery of social care, health monitoring and electronic health records. CEF will secure that digital service infrastructures exist and facilitate the use of actual digital services. Therefore, it aims to achieve a better quality of life for European citizens, innovation and growth for a competitive EU industry and more sustainable health care systems for society through an interconnected digital backbone.¹⁹

1.2.4. Social Innovation Tool

Social innovation means developing new ideas, services and models to better address social issues. It invites input from public and private actors, including civil society, to improve social services.²⁰ It is part of the social investment package, and must be embedded in policy making and connected to social priorities. The social innovation concept is described in detail in the Guide on Social Innovation released by DG REGIO and DG EMPL.²¹

The Bureau of European Policy Advisors (BEPA) identified three key approaches to social innovation:²²

- ▶ Social demand innovations which respond to social demands that are traditionally not addressed by the market or existing institutions and are directed towards vulnerable groups in society. They have developed

¹⁹ More information in EC: Digital Agenda for Europe – A Europe 2020 Initiative – Connecting Europe Facility. Available at: <http://ec.europa.eu/digital-agenda/en/connecting-europe-facility>

²⁰ Definition of Social innovation according to DG EMPL: Social innovation. Available at: <http://ec.europa.eu/social/main.jsp?catId=1022&langId=en>

²¹ EC: Guide to Social Innovation, February 2013. Available at: http://ec.europa.eu/regional_policy/sources/docgener/presenta/social_innovation/social_innovation_2013.pdf

²² Bureau of European Policy Advisors: Empowering people, driving change – Social Innovation in the European Union, 2011. Available at: http://ec.europa.eu/bepa/pdf/publications_pdf/social_innovation.pdf



new approaches to tackling problems affecting youth, migrants, the elderly, socially excluded etc. The European Social Fund and initiatives like PROGRESS traditionally link to this.

- ▶ The societal challenge perspective focuses on innovations for society as a whole through the integration of the social, the economic and the environmental. Many of the integrated approaches seen in the ERDF's URBAN programmes as well as the URBACT programme fall into this societal challenge approach.
- ▶ The systemic change focus, the most ambitious of the three and to an extent encompassing the other two, is achieved through a process of organizational development and changes in relations between institutions and stakeholders. Many EU approaches that involve 'stakeholders' are attempting to move in this direction such as the EQUAL programme (driven by the idea of changing the balance of power between users and providers) and LEADER.

The social innovation concept is relevant for the health and ageing issues, as new types of services are being developed to deal with the ageing population. These services tend to be more community-based and deploy social networks. Example of Finland (below in the textbox) shows, how ESI Funds can be implemented for social innovation purpose.²³

Finland has used the ERDF to co-finance a living lab focused on health and welfare services. **It combines technological advances with social innovations involving the user group plus all relevant stakeholders, bringing together public services and private enterprises.**

1.3. Community programmes (non-Cohesion Policy funding)

It is vital that Member States ensure coordination of the use of different funding sources, and especially that they coordinate the implementation of ESIF with the possibility of using other funding sources such as Community programmes. Community programmes relevant to health and health care in 2014-2020 are the programmes Horizon 2020 and the 3rd Health Programme. Additionally, the programme COSME might be also mentioned as its support of SMEs would possibly be interesting for many health care entities such as researches or services' providers.

Horizon 2020²⁴

Horizon 2020 is the EU's biggest research and innovation programme, an instrument implementing the "Innovation Union", which represents one of the main strategic goals in Europe 2020 to secure smart, sustainable and inclusive growth. The main aims of Horizon 2020 are to secure Europe's long-term global competitiveness through innovative world-class science and to facilitate the cooperation of public and private bodies in research and innovation and to share knowledge between them.

Provisions relevant to Horizon 2020 are stated in Regulation no. 1291/2013.²⁵ According to the regulation, Horizon 2020 should closely cooperate with ESI Funds in research and innovation to create synergies.

²³ Details available in EC: Guide to Social Innovation, February 2013, page 38. Available at: http://ec.europa.eu/regional_policy/sources/docgener/presenta/social_innovation/social_innovation_2013.pdf

²⁴ DG Research and Innovation: Health – Moving towards Horizon 2020. Available at: http://ec.europa.eu/research/health/policy-issues-horizon2020_en.html ; and EC: Horizon 2020 – The EU Framework Programme for Research and Innovation. Available at: <http://ec.europa.eu/programmes/horizon2020/en/>.



Horizon 2020 sets out three main funding priorities. **Health and health care** is funded from the priority “**Societal challenges**” where health, demographic change and well-being represent one of the specific funding objectives.

The programme sets out two-year work programmes specifying which areas will be funded. For the years 2014 and 2015, Horizon 2020 announced **two main areas for health care, demographic change and well-being**: “**Personalising health and care**” and “**Coordination activities**”.

Various projects in the field of health related research and innovation can be funded through this programme, for example:

- ▶ Independent living with cognitive impairments
- ▶ Promoting mental wellbeing in the ageing population
- ▶ Prevention and health promotion
- ▶ Control of infectious epidemics through rapid pathogen identification
- ▶ Vaccine platforms for TB and HIV
- ▶ Personalized medicine in health and care systems
- ▶ Self-management of health and disease
- ▶ Citizen engagement and mHealth for disease management
- ▶ Patient empowerment supported by ICT
- ▶ Digital representation of health data to improve diagnosis and treatment
- ▶ eHealth and others

Health programme²⁶

The goal of the 3rd Health Programme is to support actions that will have a positive impact on people’s health and will reduce health disparities. The programme is set up completely in accordance with the Europe 2020 strategic goals focused on intelligent, sustainable and inclusive growth. Provisions relevant to the Health programme are stated in Regulation no. 282/2014.²⁷ Funding under this programme will complement health-related measures funded through ESI Funds and Horizon 2020. Grants for co-financing projects will be provided to public authorities, private sector, international institutions and NGOs.

²⁵ Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC.

²⁶ DG SANCO: Health Programme 2014-2020 – presentation, February 2014. Available at: http://ec.europa.eu/health/programme/docs/healthpgm_pres_nov2013_en.pdf

²⁷ Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union’s action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC.



Projects that can be funded within the Health Programme should support health in the following areas:

- ▶ Create efficient, innovative and sustainable health systems (eHealth)
- ▶ Promote good health (health information, promotion of a healthy lifestyle)
- ▶ Encourage innovation in health (eHealth)
- ▶ Increase citizens' accessibility to better and safer health care
- ▶ Protect citizens from serious cross-border health threats (preparedness planning, vaccination)

Competitiveness of Enterprises and Small and Medium-sized Enterprises (COSME)²⁸

COSME is a new programme for the competitiveness of SMEs, running from 2014 to 2020 with a planned budget of EUR 2.3 billion, which continues the actions of the 2007-2013 Entrepreneurship and Innovation Programme (EIP) under the Competitiveness and Innovation Framework Programme (CIP). It aims at strengthening the competitiveness and sustainability of the business. Specifically, COSME will support SMEs with a series of horizontal measures aimed at improving access to finance for SMEs, improving access to markets, improving the framework conditions for business creation and growth, and supporting and promoting entrepreneurship and entrepreneurial culture.

This programme is likely to represent an interesting tool for health entities since there are many SMEs in the health care sector across the Member States. Various health researches or health services' providers would be possible concerned about any tools available for and relevant to SMEs and R&D, regardless if they are particularly oriented to the care and clinical development or the industrial one. Moreover, getting involved in R&D actions might contribute to the professional recognition and financial motivation of a medical staff.

Provisions relevant to COSME are stated in Regulation no. 1287/2013²⁹. According to the regulation, the EU's actions should be coherent, consistent and complementary to the Member States' financial instruments for SMEs, provide a leverage effect and avoid creating market distortion. The entities entrusted with the implementation of the actions should ensure additionality and avoid double financing through the Union resources (the same applies to other programmes as well). With the aim of achieving added value and substantial impact of the Union funding, close synergies should be developed between the COSME programme and the Horizon 2020 programme.

COSME will facilitate and improve access to finance for SMEs through two different financial instruments, available from 2014:

- ▶ The Loan Guarantee Facility
- ▶ The Equity Facility for Growth

²⁸ DG Enterprise and Industry: Programme for the Competitiveness of Enterprises and Small and Medium-sized Enterprises (COSME). Available at: http://ec.europa.eu/enterprise/initiatives/cosme/index_en.htm

²⁹ Regulation (EU) No 1287/2013 of the European Parliament and of the Council of 11 December 2013 establishing a Programme for the Competitiveness of Enterprises and Small and Medium-sized Enterprises (COSME) (2014-2020) and repealing Decision No 1639/2006/EC.



The COSME programme should also give a high priority to the simplification agenda. COSME focuses on **lightening the administrative burden on businesses** by removing unnecessary reporting and information requirements. **SMEs are disproportionately affected by regulation.** A special focus is thus needed to create more favourable conditions for them.

All businesses have access to the services of the Enterprise Europe Network and can freely approach the local partner in their region. Over 600 partner organizations in 54 countries have built a capacity to reach out to more than 2 million SMEs.

The services linked with the access to market, offered by COSME, include:

- ▶ Information on EU legislation and participation in EU programmes (Horizon 2020, regional funds)
- ▶ Assistance to find a business partner abroad: in the EU or worldwide
- ▶ Advice on EU access to finance
- ▶ Support for innovation and technology transfer
- ▶ Obtaining SME's opinion on EU legislation

In the area of health, SMEs doing business in the health care sector might benefit from COSME programme.

Specific measures shall aim to facilitate SME access to markets outside the Union. Such measures may include providing information on existing barriers to market entry and business opportunities, public procurement and customs procedures, and improving support services in terms of standards and intellectual property rights in priority third countries.



2. ESI Funds mechanisms

2.1. Funding mechanisms

The principal ESI Funding mechanisms for 2014-2020 are defined below:

- ▶ Delivering the Europe 2020 strategy goals, contribution to thematic objectives
- ▶ Synergies, coordination and complementarities
- ▶ Ex-ante conditionalities
- ▶ Thematic concentration
- ▶ Strong result orientation
- ▶ Performance reserve based approach

2.1.1. Delivering the Europe 2020 strategy goals

According to the Europe 2020 strategy goals, the supported investments shall support intelligent, sustainable and inclusive growth and contribute to fulfilling the following targets:

- ▶ Creating growth and jobs
- ▶ Higher investment in R&D / innovation
- ▶ Tackling climate change and energy dependence
- ▶ Better education
- ▶ Reduction in poverty and social exclusion

The actions shall support the **thematic objectives** listed in Article 9 of the Common Provision Regulation. Investments in health are eligible under seven of the eleven TOs:

- ▶ Research & Innovation (TO 1)
- ▶ Information and communication technologies (TO 2)
- ▶ Competitiveness of SMEs (TO 3)
- ▶ Employment & supporting labor mobility (TO 8)
- ▶ Social inclusion & combating poverty (TO 9)
- ▶ Education, skills & lifelong learning (TO 10)
- ▶ Institutional capacity building & efficient public administration (TO 11)

The remaining thematic objectives are:

- ▶ Supporting the shift towards a low-carbon economy in all sectors (TO 4)
- ▶ Promoting climate change adaptation, risk prevention and management (TO 5)
- ▶ Preserving and protecting the environment and promoting resource efficiency (TO 6)
- ▶ Promoting sustainable transport and removing bottlenecks in key network infrastructures (TO 7)

Although being not dedicated to address health issues, health subjects usually might apply for funding from them.



For more details about possible health actions supported under 2014-2020 thematic objectives, please refer to chapter 2.2. in the Guide for effective investments in health under ESI Funds.

2.1.2. Synergies, coordination and complementarities

Synergy, coordination and complementarity mechanisms are set out in the Common Strategic Framework, annexed to the Common Provisions Regulation.³⁰ According to the framework, Member States should conform to the following principles:

- ▶ Combine ESI Funds in a complementary manner to achieve the set thematic objectives.
- ▶ Ensure the effective coordination of ESI Funds (where appropriate, through the implementation of multi-fund programmes) in order to increase the impact and effectiveness of the Funds.
- ▶ Establish mechanisms to ensure coordination and synergies to avoid overlaps.
- ▶ Use integrated approaches (ITIs, Community-led Local Development, Sustainable urban development).
- ▶ Coordinate joint financing between ESI Funds and other Union policies and instruments (Horizon 2020, Health Programme and others) especially in areas of research infrastructures, exchange of good practice and training throughout regions.

Acting in accordance with these mechanisms is crucial for the effective implementation of funds in health and the health care sector. In this area, the Member States should primarily focus on coordination of the public health infrastructure, investments and human capacity in the health care sector.

2.1.3. Ex-ante conditionalities

In order to ensure the effective implementation of ESI Funds, the Common Provision Regulation has set up the mechanism of ex-ante conditionalities. These represent the minimum requirements which need to be fulfilled ex ante, that is prior to the funding is started. The preconditions have to be fulfilled at the time of the submission of Partnership Agreements (PA) between a Member State and the European Union; for those not fulfilled at the date of submission of the Partnership Agreement, the PA has to set out actions to be taken, the bodies responsible and the timetable for the implementation of those actions (Article 19 of the CPR).

Member States are obliged to fulfil only applicable ex-ante conditionalities. As defined in Article 2, point 33 of the CPR, 'applicable ex-ante conditionality' means a concrete and precisely pre-defined critical factor, which is a prerequisite for and has a direct and genuine link to, and direct impact on, the effective and efficient achievement of a specific objective for an investment priority or a Union priority.

Ex-ante conditionalities are of two types:

- ▶ Thematic ex-ante conditionalities defined for areas of action based on the investment priorities under individual thematic objectives. Thematic ex-ante conditionalities have to be fulfilled if a Member State is planning to allocate funding to the concrete investment priority. The list of thematic ex-ante conditionalities is defined in annex to the Common Provisions Regulation.

³⁰ Common Provision Regulation (EU) No 1303/2013.



- ▶ General ex-ante conditionalities, also defined in the annex to the Common Provisions Regulation.

More guidance on general ex-ante conditionalities and assessment of their fulfilment can be found in the European Commission Guidance on ex-ante conditionalities.³¹

Health is also one of the areas of actions for which **thematic ex-ante conditionality** is set. This ex-ante conditionality is to be fulfilled if the Member State is planning to allocate funding under the TO 9, investment priority “Investing in health and social infrastructure which contributes to national, regional and local development, reducing inequalities in terms of health status, promoting social inclusion through improved access to social, cultural and recreational services and the transition from institutional to community-based services.”

The ex-ante conditionality is defined as follows: “**The existence of a national or regional strategic policy framework for health** within the limits of Article 168 Treaty of Functioning of the European Union ensuring economic sustainability.”

Criteria for fulfilment:

- ▶ A national or regional strategic policy framework contains:
 - ▶ Coordinated measures to improve access to quality health services
 - ▶ Measures to stimulate efficiency in the health sector through deployment of effective innovative technologies, service delivery models and infrastructure
 - ▶ Monitoring and review system
- ▶ A Member State or region has adopted a framework outlining available budgetary resources on an indicative basis and a cost-effective concentration of resources on prioritized needs for health care.

Rationale:³²

- ▶ Programming period 2007-2013 lacked overall strategic thinking and budgetary planning, therefore some investments have failed to achieve the intended objectives and impacts. The health ex-ante conditionality is a prerequisite for the early and efficient definition of the areas in need of financing and the type of investments required. The strategy should explain how infrastructure needs have been appraised and how this exercise has been translated into decision mapping out the long-term infrastructure network.

Moreover, other thematic ex-ante conditionalities have to be fulfilled when health investment is planned under other thematic objectives and investment priorities. For example, if active and healthy ageing under TO 8 are to be supported, the ex-ante conditionality “Active ageing policies are designed in the light of the Employment Guidelines” has to be fulfilled. Similarly, there are ex-ante conditionalities for other investment priorities under which health investment can be foreseen.

³¹ EC: Guidance on ex-ante conditionalities for the European and Investment Funds, Part II, February 13, 2014. Available at: http://ec.europa.eu/regional_policy/what/future/pdf/preparation/part2_guidance_ex-ante_conditionalities_guidance.pdf

³² As given in the European Commission Guidance on ex-ante conditionalities.



2.1.4. Thematic concentration

In order to ensure the effective implementation of funds, which will contribute to the strategy of smart, inclusive and sustainable growth, the Member States should, according to the Common Strategic Framework,³³ target the implementation of funds at their key priorities based on their national, regional and local context.

ERDF

According to the **ERDF Regulation**,³⁴ the degree of thematic concentration should take into account the level of development of the region, the contribution of the Cohesion Fund resources where applicable, as well as the specific needs of regions whose GDP per capita used as an eligibility criterion for the 2007-2013 programming period was less than 75% of the average GDP.

The support from the ERDF under the *Investment for growth and jobs* goal should be concentrated on research and innovation, information and communication technologies (ICT), small and medium-sized enterprises (SMEs) and promoting a low-carbon economy (depending on which category of regions is supported).

The thematic objectives set out in the first paragraph of Article 9 of the Common Provisions Regulation (*described in chapter 2.1. of the Guide*) to which the ERDF may contribute under the *Investment for growth and jobs* goal, shall be concentrated as follows:

▶ **In more developed regions:**

- ▶ At least 80% of the total ERDF resources at a national level shall be allocated to two or more of the thematic objectives 1, 2, 3 and 4.
- ▶ At least 20% of the total ERDF resources at a national level shall be allocated to the thematic objective 4.

▶ **In transition regions:**

- ▶ At least 60% of the total ERDF resources at a national level shall be allocated to two or more of the thematic objectives 1, 2, 3 and 4.
- ▶ At least 15% of the total ERDF resources at a national level shall be allocated to the thematic objective 4.

▶ **In less developed regions:**

- ▶ At least 50% of the total ERDF resources at a national level shall be allocated to two or more of the thematic objectives 1, 2, 3 and 4.
- ▶ At least 12% of the total ERDF resources at a national level shall be allocated to the thematic objective 4.

³³ Common Provision Regulation (EU) No 1303/2013.

³⁴ Regulation (EU) No 1301/2013 of the European Parliament and of the Council of 17 December 2013 on the European Regional Development Fund and on specific provisions concerning the Investment for growth and jobs goal and repealing Regulation (EC) No 1080/2006.



ESF

As stated in the **ESF Regulation**,³⁵ the Member States should ensure that Operational Programmes respond to their national challenges and aim to fight unemployment, poverty and social exclusion. The thematic objectives set out in the first paragraph of Article 9 of the Common Provisions Regulation³⁶ (*described in chapter 2.1 of the Guide*) should be that at least 20% of the total ESF resources in each Member State shall be allocated to the thematic objective 9.

- ▶ **In more developed regions:** Member States shall concentrate at least 80% of the ESF allocation to each Operational Programme on up to five of the investment priorities set out in Article 3(1).
- ▶ **In transition regions:** For transition regions, Member States shall concentrate at least 70% of the ESF allocation to each Operational Programme on up to five of the investment priorities set out in Article 3(1).
- ▶ **In less developed regions:** Member States should concentrate at least 60% of the ESF allocation to each Operational Programme on up to five of the investment priorities set out in Article 3(1).

2.1.5. Strong result orientation

Investments funded from ESI Funds need to be result-oriented rather than only focusing on the financial means in order to ensure that the Cohesion Policy will significantly contribute to the reduction in economic and social inequalities between Member States and to achieving the strategic Europe 2020 goals.

The result-oriented approach implies that for each programme area the desired improvement in the situation should be identified. The expected results should be supported by a limited number of indicators which indicate what the target of the programme intervention is. It is vital that the Member States concentrate primarily on creating results that will have a significant impact on Europe rather than just on achieving the set up output indicators.



*For more details on indicators relevant for health, see **WP 3 (3) Set of indicators useful for final evaluation of actions.***

2.1.6. Performance reserve based approach

The performance reserve based approach is set out in the Common Provisions Regulation, Articles 20 to 22. According to Article 20, a total amount of 6% of the resources allocated to all ESI Funds should constitute a performance reserve which shall be established in the Partnership Agreement and programmes and allocated to specific priorities.

The performance reserve should have between 5-7% of the allocation to each priority within a programme, with the exception of priorities dedicated to technical assistance and programmes dedicated to financial instruments.

³⁵ Regulation (EU) No 1304/2013 of the European Parliament and of the Council of 17 December 2013 on the European Social Fund and repealing Council Regulation (EC) No 1081/2006.

³⁶ Common Provision Regulation (EU) No 1303/2013.



In 2018, the Member States will submit performance reviews, on accomplishing their milestones, to the Commission; the following year, the Commission will decide which programmes and priorities have accomplished their milestones and the performance reserves will then be allocated only to those programmes and priorities which have achieved them. In the case of not reaching the milestones, the Member State shall propose the reallocation of the corresponding amount of the performance reserve to priorities set out in the Commission's decision.

2.2. Cohesion Policy principles

Along with the above-described mechanisms, the four key principles of the Cohesion Policy³⁷ shall also be taken into account when planning and delivering investments with the implementation of ESIF:

- ▶ Concentration
- ▶ Programming
- ▶ Partnership
- ▶ Additionality

Concentration principle

The first principle corresponds to one of the mechanisms described above. The thematic concentration is, however, only one of the three dimensions in which concentration should take place. These three dimensions are:

- ▶ **Concentration of effort** (thematic concentration), which consists of targeting investment on key growth priorities, represented by the thematic objectives No. 1-4 for ERDF and on a limited number of up to five investment priorities for the ESF thematic objectives No. 8-11.
- ▶ **Concentration of resources**, which consists of concentration of 70% of the ESIF resources in the poorest regions and countries.
- ▶ **Concentration of spending**, which means that at the beginning of each programming period, annual funding is allocated to each programme and these funds must be spent by the end of the second year after their allocation (the n+2 rule).

Programming principle

The programming principle expresses the rule that ESIF support multi-annual programmes aligned with EU objectives and priorities.



More on Cohesion Policy programming with relation to health investment can be found in the Guide for effective investments in health under ESI Funds in chapter 2.

³⁷ DG REGIO: Cohesion Policy principles. Available at: http://ec.europa.eu/regional_policy/how/principles/index_en.cfm.



Partnership principle

This principle states that each programme shall be developed through a collective process involving authorities at all levels, i.e. at a European, regional and local level, and other stakeholders including social partners and organizations from civil society. The partnership should be present throughout the whole lifecycle of the programming process, from design through management and implementation to monitoring and evaluation.



Specific advice on how to involve partners and health experts in the process of the health investment lifecycle can be found in the Guide in Parts 2 and 3, which link the programming of ESIF Operational Programmes with health investment.

Additionality principle

In line with the additionality principle, the financing from the ESI Funds shall not replace national spending by a Member State, but shall be additional to it. In other words, this principle stipulates that contributions from the Structural Funds must not replace public or equivalent structural expenditure by a Member State, i.e. the availability of ESIF may not result in a reduction in national structural expenditure.

The Commission agrees with each country upon the level of eligible public (or equivalent) spending to be maintained throughout the programming period, and checks on compliance in the middle of the programming period, in 2018, and at the end, in 2022.



Sources

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