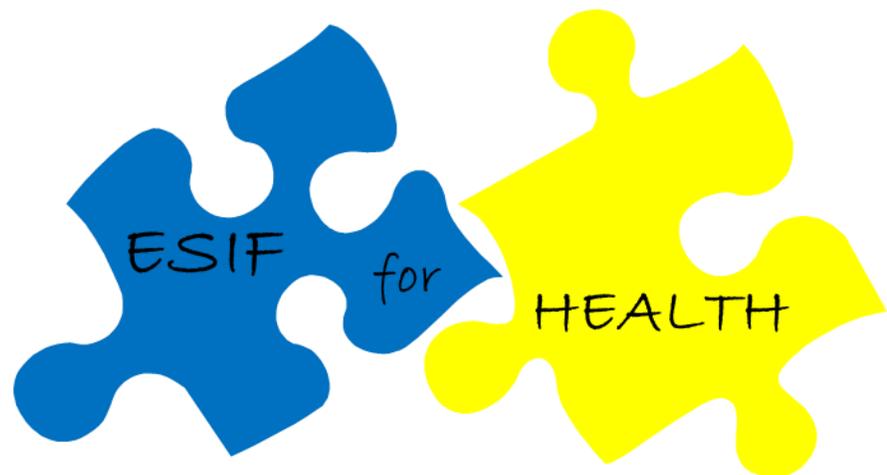


TECHNICAL TOOLKIT:

REFLECTION OF ADDITIONAL ISSUES RAISED BY MEMBER STATES

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

CHAFEA	Consumers, Health and Food Executive Agency
DG SANCO	Directorate General for Health and Consumers
EC	European Commission
ECJ	European Court of Justice
ECR	European Court Report
EEA	European Economic Area
ESIF / ESI Funds	European Structural and Investment Funds
EU	European Union
No.	Number
SAMO	State Aid Monitoring Office in Hungary
SGEI	Service of general economic interest
WP	Work Package

Introduction

The document “Reflection of additional issues raised during national visits” forming a part of the Technical toolkit supporting the Guide for effective investments in health under ESI Funds 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 Consumers (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 document reflects issues raised by workshop participants during national visits in selected Member States in the course of the project roll-out phase. As the document reacts to specific requirements of Member States involved in the dissemination phase, it covers various topics which do not necessarily have to follow one another.

The document addresses the following topics:

- ▶ Chapter 1 focuses on **State aid and its application in health** care system funding and support.
- ▶ Chapter 2 focuses on public strategies and **principles of public strategies development and implementation.**

1. State aid

This chapter aims to set out EU State aid rules and outline their impact on investments made in the area of health and health care.

When planning the implementation of health investments through ESIF Funds it is vital to assess their compliance with State aid rules. Generally, provision of State aid is, according to the Treaty on the Functioning of the European Union (hereinafter “Treaty”), prohibited. To determine whether an investment represents State aid or not, Article 107 (1) of the Treaty defines four criteria. To be State aid, a measure needs to have these features:

- ▶ Transfer of state or public resources
- ▶ Economic advantage of a certain undertaking or sector
- ▶ Impact on trade between Member States
- ▶ Distortion or threat of distorting competition

If all four features are met, the assistance is almost certainly State aid. Aid measures can only be implemented after **approval by the Commission**. Moreover, the Commission has the power to **recover incompatible State aid**.¹

1.1. State aid rules in the area of health

Certain health and medical services are, based on rulings of the European Court of Justice², considered as economic activity and, therefore, their funding through ESIF might be perceived as State aid.³ In general, the more integrated into the national health system a health care provider is, the less likely it is to be considered as an undertaking subject to the rules on State aid.⁴

However, some health and health care services exist that are exempted from economic activities because they fulfil public service functions. Their financing is possible through a concept of **services of general economic interest** (hereinafter “SGEI”). According to the EC, services of general economic interest represent economic activities that public authorities identify as being of particular importance to citizens and that would not be supplied if there were no public intervention.

The State aid for services of general economic interest is regulated by the Commission Decision of 20 December 2011 on the application of Article 106.2 of the Treaty on the Functioning of the European Union to State aid in the form of **public service compensation** granted to certain undertakings entrusted with the operation of services of general economic interest (hereinafter “Commission Decision”) and by Communication from the Commission on

¹ More information about procedures that need to be followed if the intervention meets features of a State aid could be found at the EC website: http://ec.europa.eu/competition/state_aid/overview/index_en.html

² ECJ, Case C-157/99, *Smits and Peerbooms*, 2001, ECR I – 5473, Art. 53 and others mentioned below.

³ For example, the ECJ has considered that certain hospital services, even though provided free of charge, under the applicable health insurance scheme could constitute an economic activity.

⁴ Greer, Scott L.: *The Politics of European Union Health Policies*. Open University Press, 2010.

the application of the European Union State aid rules to compensation granted for the provision of services of general economic interest.⁵

The SGEI concept may apply to various situations and terms. EU law, in accordance with subsidiarity and proportionality principles, does not oblige public authorities to formally introduce this concept into their domestic law. Nevertheless, some countries have clearly defined which tasks and services are considered of general economic interest.

In Slovakia, the definition of health care as SGEI is regulated by the law (Act No. 576/2004 Coll. on Health Care, services related to health care and on amendments to certain laws). Based on the Act, providing health care in the outpatient care and inpatient care is a service of general economic interest.

According to the Commission Decision, **public service compensation does not constitute State aid** when the following criteria are met⁶:

- ▶ The beneficiary must actually have public service obligations to discharge, and the obligations must be clearly assigned. The entrustment of the obligations should be done through the following acts:
 - ▶ Law
 - ▶ Acts
 - ▶ Concession contract
 - ▶ Municipal decisions
 - ▶ Public service contract
 - ▶ Other regulatory decision
- ▶ The parameters on the basis of which the compensation is calculated must be established in advance in an objective and transparent manner.
- ▶ The compensation must not exceed the necessary costs to cover the public service obligations, taking into account the relevant receipts and reasonable profit.
- ▶ In case the undertaking is not chosen by the public procurement procedure, the level of compensation must be determined on the basis of an analysis of the costs that a typical well-run undertaking would have incurred.

In case the above-mentioned criteria are not fulfilled, the compensation of health activities (hospitals providing medical care, including, where applicable, emergency services and ancillary services directly related to their main activities) can still be provided if it is considered as compatible with the internal market according to the Commission Decision.

⁵ Other European Commission documents related to SGEI include Commission Communication on a European Union framework for State aid in the form of public service compensation (2011) and the Commission Regulation of 25 April 2012 on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to de minimis aid granted to undertakings providing services of general economic interest.

⁶ Based on Altmark decision, ECJ, Case C-280/00, 2003. More about the Altmark case available at: <http://curia.europa.eu/juris/liste.jsf?language=en&num=C-280/00>.

1.2. Economic and non-economic health activities

Furthermore, State aid rules apply only to “undertakings”. An undertaking is an entity engaged in an economic activity, regardless of the entity’s legal status or the way in which it is financed. In the text below, **examples of economic and non-economic activities** related to the area of health and health care based on European Court of Justice Judgments⁷ are described:

► Economic activities

- ▶ Emergency transport services and patient transport services.
(Case C-475/99 *Glöckner* [2001] ECR I-8089)
- ▶ Medical services provided either in a hospital environment or elsewhere. However, public hospitals can also exercise non-economic activity.
(Case C-157/99, *Smits and Peerbooms*, 2001, ECR I – 5473)
- ▶ Hospitals and other health care providers that offer their services for remuneration, directly from patients or from their insurance.
(Case C-244/94 *FFSA*, Case C-67/96 *Albany*, *Joined Cases C-115/97, C-116/97 and C-117/97 Brentjens, and Case C-219/97 Drijvende Bokken*)
- ▶ Health care services provided by independent doctors and other private practitioners for remuneration at their own risk. The same principle applies to independent pharmacies.
(*Joined Cases C-180 to C-184/98 Pavlov and Others*, paragraphs 75 and 77)

► Non-economic activities

- ▶ The organization of public hospitals which are an integral part of a national health service and are almost entirely based on the principle of solidarity, funded directly from social security contributions and other State resources, and which provide their services free of charge to affiliated persons on the basis of universal coverage.
(Case T-319/99 *FENIN* [2003] ECR II-357, paragraph 39)
- ▶ Activities that in themselves could be of an economic nature, but are carried out merely for the purpose of providing another non-economic service.
(Case T-319/99 *FENIN*, paragraph 40)

*The text above has been developed based on analysis of the interpretation of Community law by relevant European institutions, i.e. mainly the General Court and the European Court of Justice. However, **ensuring and assessing compliance with the Community law is primarily the responsibility of individual Member States** and contentious issues are first assessed by national judicial authorities in Member States. The examples and interpretation of the case law introduced above shall therefore not be considered as generally valid and binding, but national judicial authorities shall consider them when deciding on cases of State aid. **In case of any uncertainty, prior consultation with a competent body responsible for State aid issues in your country shall be recommended.** Such a body shall exist in every Member State (for example in Hungary, the responsible body is the State Aid Monitoring Office (SAMO) under the Ministry of Finance).*

⁷

Communication from the Commission on the application of the European Union State aid rules to compensation granted for the provision of services of general economic interest, 2012. Available at: <[http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52012XC0111\(02\)#ntr41-C_2012008EN.01000401-E0041](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52012XC0111(02)#ntr41-C_2012008EN.01000401-E0041)>.

2. Public strategies development and implementation

This chapter reviews the entire public strategy development process in order to provide a basic guide on how to properly set up, develop and implement a public strategy. The principles and information presented below build mostly on the methodology for development of public strategies developed by EY for the Czech Ministry of Finance, summarized in the Methodology for public authorities for effective preparation of public strategies.⁸ The EY approach has been piloted and successfully implemented at various government levels and we believe that the principles introduced below are worth sharing with others.

2.1. Principles

When preparing public strategies, certain fundamental principles should be observed. Then, with these, key questions within the strategy development should be able to be answered. The main questions asked are:

- ▶ Why is a given strategy being created?
- ▶ What is its purpose (which issue will be solved)?
- ▶ How will the issue be solved?
- ▶ When will the issue be solved?
- ▶ Who will solve the issue?
- ▶ How long is the strategy valid for?
- ▶ How much will a given solution cost?

The fundamental principles of public strategies preparation are listed below. All these should be observed within the process. **In case of violating any of them, reasons have to be defined and sufficiently clarified.**

The principles of public strategies preparation are as follows:⁹

- ▶ **Strategies have to be prepared transparently and objectively.** In order to achieve this, as wide a range of stakeholders as possible should be involved in the preparation process.
- ▶ **All strategic materials have to be prepared in adequate form and appropriate quality.** On the basis of this, the government (or an approval authority) has to be able to make responsible decisions.
- ▶ **Merely specific issues have to be solved.** That is, strategies should aim at solving specific and significant problems, not vague and marginal ones.
- ▶ **Strategic projects have to be coordinated,** i.e. particular strategies should not be prepared separately. They should be coordinated both horizontally and vertically and according to their time continuity and consistency.

⁸ EY: Methodology for preparation of public strategies, Ministry of Finance Czech Republic, 2011.

⁹ Ibid.

- ▶ **Standard procedures and a project management approach should be employed.** All of the mandatory requirements on strategic documents quality stated in the methodology documents have to be met and the process structure has to be compliant with the standard practice of project management.
- ▶ **Source of financing has to be absolutely clear.** Thus the implementation financing has to be clearly defined and the implementation of the approved strategies should be reflected in budgeting on a regular basis so that the highest feasible level of efficiency is sought and any negative unintended effects are minimized.
- ▶ **Strategies have to be in compliance with real needs.** In order to achieve this, strategy development should be evidence-based. Thus, both the intended and real impacts of strategy implementation should be monitored and evaluated.
- ▶ **Strategies have to include particular measures and the implementation structure has to be well-defined.** For this reason, responsibility for objectives accomplishment should be clearly defined and the indicators and metrics of success, as well as the process of implementation should be sufficiently specified.
- ▶ **The strategy owner has to be defined** so that the overall responsibility is assigned.
- ▶ **The effectiveness of implemented measures should be evaluated on a regular basis** and if necessary, corrective mechanisms can be proposed in time.

2.2. Strategy development process

After the initial strategy set-up, the strategy development process itself takes place. This should follow a certain sequence of actions which is described in detail later.

The strategy development process as such can be divided into the seven following phases. If one is able to match each own action with a given phase, it can **simplify the project management and process control, and make strategy development more transparent.**

The phases of a strategy development process ensue as follows; and all of the fundamental actions within a phase are listed below each of them:¹⁰

1. Identification of strategy creation need

- ▶ Organization of strategy creation preparation
- ▶ Data collection
- ▶ Current state analysis and future development forecast
- ▶ Preliminary vision analysis
- ▶ Input report preparation and approval

¹⁰ EY: Methodology for preparation of public strategies, Ministry of Finance Czech Republic, 2011.

2. Project set-up

- ▶ Organizational structure staffing
- ▶ Project plan of strategy creation preparation
- ▶ Plan of cooperation and communication preparation
- ▶ Risk management plan for strategy creation preparation

3. Analytics and forecasting phase (on a regular basis)

- ▶ Data sources identification and primary analyses elaboration
- ▶ Existing solutions analysis including international practice
- ▶ Current state analysis
- ▶ Future development forecast
- ▶ Analytical part of strategic document compilation

4. Strategic direction, priorities and variants determination

- ▶ Vision verification and options of objectives definition
- ▶ Options selection for further elaboration

5. Strategy elaboration

- ▶ Strategic objectives elaboration
- ▶ Set of indicators set-up
- ▶ Variant measures identification
- ▶ Measures assessment and selection
- ▶ Draft strategy finalization

6. Implementation financing and evaluation set-up

- ▶ Work breakdown structure creation
- ▶ Managing structure of strategy implementation set-up
- ▶ Change management plan set-up
- ▶ Risk management plan set-up and assumption determination for successful strategy implementation
- ▶ Monitoring system of objectives attainment set-up
- ▶ Strategy evaluation set-up
- ▶ Communication plan of strategy implementation creation
- ▶ Strategy implementation budget creation
- ▶ Strategy implementation schedule creation

7. Strategy approval

- ▶ Strategy approval plan revision and finalization
- ▶ Internal strategy revising and approval
- ▶ External strategy revising and approval
- ▶ Project closing

2.3. Strategy implementation

Once properly planned and approved, the strategy is being implemented. Even at this stage some essential practices and recommendations should be stressed.

Strategy implementation has several features with regard to which one should proceed when implementing a public strategy. Strategy implementation manages forces during the action, it focuses on efficiency, it is primarily an operational process, it requires special motivation and leadership skills, and finally, it requires coordination among many stakeholders.

According to the above mentioned, there is an essential condition for successful strategy implementation – **all relevant stakeholders should be involved as much as possible in strategy formulation and strategists should be involved as much as possible in strategy implementation.** This can significantly diminish the impacts of the fact that subjects and organizations involved in implementation are motivated more by their perceived self-interests than by general public interests.

Strategy implementation should directly follow all preliminary actions within the phases of project set-up, and implementation financing and evaluation set-up, as listed in the previous subchapter. However, conditions might change during the time strategy is effective. Therefore, validity of key investment aspects and assumptions shall be revived over the time and if relevant, change of the strategy shall be managed.

To review proper implementation management, several particular issues of strategy implementation should be enumerated. Basic actions to be undertaken are:¹¹

▶ Develop the procedures and tools for monitoring and evaluation

- ▶ Regular objectives / indicators serve as guidelines for action, and standards of performance.
- ▶ They should state quantity, quality, cost, and time—and also be verifiable. Terms and phrases such as maximize, minimize, as soon as possible, or adequate should be avoided.
- ▶ They should be measurable, consistent, reasonable, challenging, clear, communicated throughout the organization, characterized by an appropriate time dimension, and accompanied by commensurate rewards and sanctions.
- ▶ There are three types of indicators: output indicators (monitoring particular activity), outcome indicators (assessing objectives achievement) and impact indicators (related to broader strategic objectives).

¹¹ List is formed in order to meet criteria for fulfillment of the ex-ante conditionality: Regulation (EU) No 1303/2013 of the European Parliament and of the Council of 17 December 2013, laying down common provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund, the European Agricultural Fund for Rural Development and the European Maritime and Fisheries Funds and laying down general provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund, and the European Maritime and Fisheries Funds and repealing Council Regulation (EC) No 1083/2006 (“Common Provisions Regulation”).

- ▶ **Devise policies**
 - ▶ Policies clarify what work is to be done and by whom
 - ▶ They facilitate the solving of recurring problems and guide the implementation of strategy
 - ▶ They should be stated in writing whenever possible
- ▶ **Allocate resources**
 - ▶ There are at least four types of resources that can be used to achieve the desired objectives: financial resources, physical resources, human resources, and technological resources.
 - ▶ Strategic management enables resources to be allocated according to the priorities established by the objectives.
- ▶ **Alter an existing organizational structure**
 - ▶ Structure should be designed to facilitate the strategic pursuit and therefore follow strategy.
 - ▶ Changes in strategy often require changes in structure since the structure dictates how resources will be allocated. Unless new or revised strategies place emphasis in the same areas as former strategies, structural reorientation commonly becomes a part of strategy implementation.
- ▶ **Minimize resistance to change**
 - ▶ Resistance to change can be considered a huge threat to successful strategy implementation.
 - ▶ People often resist strategy implementation because they do not understand what is happening or why changes are taking place.
 - ▶ Change must be viewed as an opportunity rather than as a threat.
- ▶ **Develop a strategy-supportive culture**
 - ▶ Strategists should strive to preserve, emphasize, and build upon aspects of an existing culture that support proposed new strategies.
 - ▶ Aspects of an existing culture that are antagonistic to a proposed strategy should be identified and changed.
- ▶ **Develop a human resources strategies and policies covering the main gaps identified in this field**
 - ▶ Disruption of social and political structures supplementing strategy execution must be anticipated and considered during strategy formulation and managed during strategy implementation.
 - ▶ Formal statements about the importance of strategic management must be consistent with actual support and rewards given for activities completed and objectives reached.
 - ▶ As mentioned as fundamental, the best method for preventing and overcoming human resource problems in strategic management is to actively involve as many relevant stakeholders as possible in the process.

After the implementation itself, a strategy evaluation is vital. Evaluations can alert relevant authorities to a (potential) problem in time. **Adequate and timely feedback is the cornerstone of effective strategy implementation.**

Strategy evaluation activities should be performed on a continuing basis, rather than merely at the end of specified periods or just after problems occur. Inappropriate waiting can result in a late reaction. As critical success factors

change, stakeholders should be involved in determining appropriate corrective actions. If assumptions and expectations deviate significantly from forecasts, then the strategy formulation activities should be renewed.

To conclude, the phase of strategy review, **evaluation and control includes:**

- ▶ **Examination of the underlying bases of strategy**
- ▶ **Comparison of expected results with actual results**
- ▶ **Taking corrective actions to ensure that performance conforms to plans**

2.4. Barriers and measures

Finally, it is vital to become conscious of possible barriers of a strategy development and general key measures of public strategies.

The essential barriers are constituted by a **lack of general coordination** and **insufficient political support**.

Coordination deficiencies can appear in various forms. Namely, absence of unanimous methodology of strategic documents making can represent a big issue just as missing hierarchy of strategies or absence of compact strategic management system and planning. Moreover, it is also important to be aware of a possible problem of budgeting not directly connected to the government's priorities or a lack of personal and central capacities (departments) for strategic work. Lastly, the establishment of unmeasurable objectives can pose a significant barrier since it evolves into insufficient implementation and strategy monitoring.

On the other hand, insufficient political support can arise from the absence of a strong political assignment or an unstable political environment.

The **key measures for barrier removal** are as such:¹²

- ▶ Creation and approval of a **public strategies preparation methodology**
- ▶ Assembly of the **public administration, workers having adequate knowledge of and experience with strategic work**
- ▶ Development of **strategic management on central level and closer connection of strategic management with budgeting**
 - ▶ Coordination of strategic management on government level
 - ▶ Setting of a prioritization process of strategic objectives on central level of public administration
 - ▶ Seeking broader political agreement, or at least cooperation, in order to ensure the process continuity
- ▶ **Independence and transparency** of a strategy preparation

Elimination of the barriers through these measures represents a prerequisite for the proper employment of strategy preparation principles, strategy development process procedures and strategy implementation. Requirements summarized in this last subchapter should be completely fulfilled and subsequently supplemented by all recommendations listed in the previous subchapters.

¹² EY: Methodology for preparation of public strategies, Ministry of Finance Czech Republic, 2011.

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- ▶ Communication from the Commission on the application of the European Union State aid rules to compensation granted for the provision of services of general economic interest Text with EEA relevance, 2012. Available at: [http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52012XC0111\(02\)#ntr41-C_2012008EN.01000401-E0041](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52012XC0111(02)#ntr41-C_2012008EN.01000401-E0041)
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