



TAIEX application form - IPA, ENI

1. Request

Project Type*:

☐ Workshop

☐ Expert
Mission

☐ Study
Visit

☐ Series of
Events

Project title*:

Harmonization of the national legislation on organ transplantation with the EU directives under the Association Agreement between the European Union and Georgia

Beneficiary country*:

Georgia

Beneficiary Ministry/Service*:

Ministry of Health, Labour and Social Affairs of Georgia

Date of submission*:

16/05/2018

Objective of the request*:

Please include a list of the workshops, expert missions and study visits that you would like to request within the above-mentioned project and the relevant Chapter/Sub-chapter of EU Legislation cited later. (Participant information will be required later in relation to study visits)*:

The main objective of the project to support of harmonization national legislation on organ transplantation with the respective EU Directives under the Association Agreement between the European Union and Georgia.

Contact Point*:

near-taiex@ec.europa.eu

2. Applicant

	Person submitting the Application	Authorisation from your administration
Title (Ms,Mr)*:	Ms	Ms
First Name *:	Mariam	Maia
Family Name *:	Darakhvelidze	Lagvilava
Ministry or Institution*:	Ministry of Health, Labour and Social Affairs of Georgia	Ministry of Health, Labour and Social Affairs of Georgia
Function:	Head of Healthcare department	Deputy Minister of Labor, Health and Social of Georgia
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Postcode:	0119	0119
City :	Tbilisi	Tbilisi
Country*:	Georgia	Georgia
Office phone:	(032) 2 51 00 26	(032) 2 51 00 26
E-mail *:	gvantsa.phanjikidze@gmail.com	mlagvilava@moh.gov.ge

3. Content

3.1 What will the Member State Expert(s) focus on during the visit?*

☐ Legislation
 ☐ Implementation
 ☐ Institutional development

Target audience*:

(Specify if officials from Ministries, institutions, regulatory authorities, professional associations or other)

Minister of Labor, Health and Social Affairs of Georgia;
 Transplantation Council of Georgia;
 Georgian Association of Transplantologists;
 Transplantation services providers.

3.2 EU legislation concerned

Experience in Acquis Chapters

28 Consumer and health protection (Partial), 28.30 Health protection [15.30] (Complete)

Keywords

Please give reference to EU regulations, directives etc.

1. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;
2. Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells;
3. Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells;
4. Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation.

3.3 Additional information

Event 1

☐ Workshop

☐ Expert Mission

☐ Study Visit

Proposed indicative date of the exchange/event:

23/07/2018

Duration (days):

5

Expected number of participants:

20

Main topics/content

Please list in details the issues you would like to discuss with the Member States expert(s), such as legislation, infrastructure, strategies, training and any other elements of relevance. Please include the aim as well as the expected impact/outcome of the requested assistance*

- 1) Evaluation of existing regulatory legislation with respect to EU directives;
- 2) Develop an Action Plan;

Event 2

☐ Workshop

☐ Expert Mission

☐ Study Visit

Proposed indicative date of the exchange/event:

24/09/2018

Duration (days):

5

Expected number of participants:

3

Main topics/content

Please list in details the issues you would like to discuss with the Member States expert(s), such as legislation, infrastructure, strategies, training and any other elements of relevance. Please include the aim as well as the expected impact/outcome of the requested assistance*

Event 3

☐ Workshop

☐ Expert Mission

☐ Study Visit

Proposed indicative date of the exchange/event:

10/12/2018

Duration (days):

5

Expected number of participants:

20

Main topics/content

Please list in details the issues you would like to discuss with the Member States expert(s), such as legislation, infrastructure, strategies, training and any other elements of relevance. Please include the aim as well as the expected impact/outcome of the requested assistance*

- 1) Assessment of primary projects regarding transplantation, according to the EU directives;
- 2) Recommendations.

Event 4

☐ Workshop

☐ Expert Mission

☐ Study Visit

Proposed indicative date of the exchange/event:

04/02/2019

Duration (days):

3

Expected number of participants:

30

Main topics/content

Please list in details the issues you would like to discuss with the Member States expert(s), such as legislation, infrastructure, strategies, training and any other elements of relevance. Please include the aim as well as the expected impact/outcome of the requested assistance*

Review of prepared projects with the involvement of national stakeholders and international experts.

3.4 Current situation/justification*

Please describe briefly the current situation related to the sector of legislation concerned and provide all information that can contribute to the evaluation of your application

Organ transplant/ transplantation services in Georgia have evolved over the past 20 years: the first kidney transplant operation was conducted in 1995, the first liver transplantation - in 2014 and corneal transplantation has been also

operation was conducted in 1995, the first liver transplantation - in 2014 and corneal transplantation has been also performed in the country as part of ophthalmologic services. In Georgia, organ transplants from living donors are used, with the exception of corneal transplants, when imported cadaver material is applied. As for the transplants from dead donors, despite the fact that the legislation regulates some aspects of this kind of donation, it is not performed in Georgia due to the lack of respective infrastructure, as well as of the willingness on the part of the population.

Since 1995, Georgia has performed a total of 294 kidney and 28 liver transplants. In 2016, 24 kidney and 13 liver transplants and in 2017, 21 kidney and 10 liver transplantations were performed.

The Ministry of Labor, Health and Social Affairs has launched the program of dialysis development since 1996 and the state program of kidney transplantation - since 1999. The number of dialysis program users is increasing: in 1996, 20 patients underwent hemodialysis in three medical facilities, currently 2,200 patients are benefiting from hemodialysis services in 21 medical institutions, 97 patients undergo peritoneal dialysis in 2 medical institutions, and 244 patients with kidney transplants receive immunosuppressive therapy under the same program. Liver transplantation is mainly covered by the state program of "Referral Service", in case of patient application. At this stage the renal transplantation services are provided by 4 medical facilities (all in Tbilisi) and liver transplantation services - by 4 medical establishments (1 in Batumi and 3 in Tbilisi).

In 2000 Transplantation Council was created at the Ministry of Labour, Health and Social Affairs, which is a consultative body of the Ministry, among the functions of which is the preparation of recommendations on the main directions of state policy in the field of transplantation.

It is noteworthy that transplantation services have developed since 2000, however, important changes in the legal acts operating in the field have not been made. The exception is the charter of the Transplantation Council, updated in 2017 and the revision of the "Rules on Human Organ Export and Import" in 2016. The requirements for donation, testing, processing, conservation, storage and distribution of human tissues and cells, rules on traceability, undesirable reactions and the standards for the quality and safety of the organs and cells have not been yet established (despite that under the Law of Georgia on Transplantation of Human Organs there is the obligation to approve the standards of organ search, procurement, storage and transplantation, as well as of approving quality standards).

Consequently, upgrading of the legal base on the organ transplantation is very urgent, furthermore, Georgia-EU Association Agreement envisages the implementation of the current EU directives under Association Agreement on organ transplantation, by 2019.

3.5 Previous TAIEX and Twinning assistance*

☐ Yes ☐ No

If yes, please provide details thereof:

3.6 Is there any planned or currently running project financed by EU funds and/or other international programmes dealing with the issues covered by the request? Has any such project been implemented in the last two years?*

☐ Yes ☐ No

If yes, please provide details thereof:

4. Logistics

4.1 Member State administration(s) from which you wish to receive the expertise

Preferred Member State (The choice cannot be always guaranteed), Optional

Italy

Member State Authority/Institution (if known)

Istituto Superiore di Sanità (ISS) (National Institute of Health)

4.2 Do you know the Member State expert from whom you wish to receive expertise (Optional)?

Title (Ms,Mr)*:

First Name *:

Family Name *:

Ministry or Institution*:

Function:

Office address:

Office number :

Postcode:

City :

Country*:

Office phone:

E-mail *:

Additional information (if required)

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4.3 Beneficiary contact person for administrative questions and practical matters related to this event

Title (Ms,Mr)*:

Ms

First Name *:

Natia

Family Name *:

Nogaideli

Ministry or Institution*:

Ministry of Labor, Health and Social Affairs of Georgia

Function:

Head of Regulation Division in Healthcare department

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0119

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E-mail *:

nnogaideli@moh.gov.ge

4.4 Is interpretation required?

☐ Yes

☐ No

4.5 Contact person for the evaluation of the impact of TAIEX assistance

E-mail *:

nnogaideli@moh.gov.ge

Please Note:

The information contained in this form will be made available on-line to the Permanent Representation, or Mission of your country in Brussels. All applications received directly from administrations of beneficiaries will be forwarded to the EU Delegation / Office concerned for a preliminary evaluation. This application form has a validity period of two years from the date that it was submitted; TAIEX reserves the right to cancel any event that has not been implemented within the two year period. Personal data contained in this document will be processed in accordance with the privacy statement of the TAIEX instrument (See <https://webgate.ec.europa.eu/TMSWebRestrict/publicDocument?id=149>) and in compliance with the Regulation (EC) N° 45/2001.



In coherence with the EU Gender Action Plan 2016-2020 TAIEX strives to promote gender equality by aiming at equal participation of women and men in its events and by engaging both women and men as experts.