



Brussels, 4.1.2017
COM(2016) 809 final

**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE
COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE
COMMITTEE OF THE REGIONS**

**on the implementation of 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**

{SWD(2016) 451 final}

1. Introduction

Article 22 of Directive 2010/53/EU¹ requires Member States to report to the European Commission, before 27 August 2013 and every three years thereafter, on the activities carried out in relation to the provisions of the Directive. The Commission is required to transmit a report on the implementation of this Directive to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

In 2013, several Member States were still in process of implementation; hence the Commission sent questionnaires to Member States in 2014 (implementation survey). This Report draws from the replies to this implementation survey, which was answered by 29 countries, all Member States and Norway. The analysis of these countries' replies to the 2014 implementation survey is included in the Staff Working Document accompanying this Report. Where appropriate, data gathered through other channels were also taken into account (e.g. exchanges with the national organ competent authorities during the bi-annual meetings with the Commission, Council of Europe annual Transplant Newsletters², Eurobarometer surveys³ and outputs of EU-funded projects).

This implementation report focuses on the institutional set-up in Member States, and in particular on the identification of the authorities in charge of the different tasks listed in Article 17 of Directive 2010/53/EU. The Annex to the Staff Working Document accompanying this Report sets out all authorities and their tasks.

This report also makes some references to the Action Plan on Organ Donation and Transplantation⁴, which complements Directive 2010/53/EU in improving quality and safety, and also focused on increasing organ availability and enhancing efficiency and accessibility of transplantation systems.

2. Transposition of Directive 2010/53/EU

Pursuant to Article 32 Directive 2010/53/EU, the deadline for its transposition elapsed on 27 August 2012. The verification of the adequate transposition of Directive 2010/53/EU (also referred to as EU organ legislation in this document) into national legislation is ongoing.

3. Implementation of Directive 2010/53/EU

Overall, from what appears in this first survey, the implementation of the EU organ legislation by Member States is considered adequate. The legislation has resulted in the establishment of competent authorities that oversee the activities from donation to transplantation in each country. The authorities apply a framework for quality and safety including authorisation, inspection and vigilance. However, some difficulties in interpretation, implementation and enforcement of the legislation were also identified.

¹ Directive in the Official Journal: <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32010L0053>
Corrigendum to the Directive: [http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32010L0053R\(01\)](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32010L0053R(01))

² <https://www.edqm.eu/en/organ-transplantation-reports-73.html>
<http://www.ont.es/publicaciones/Paginas/Publicaciones.aspx>

³ 2002-3 Eurobarometer: http://ec.europa.eu/health/ph_threats/human_substance/documents/ebs_183.5_fr.pdf
2006-7 Eurobarometer: http://ec.europa.eu/health/ph_threats/human_substance/documents/ebs272d_en.pdf
2009-10 Eurobarometer: http://ec.europa.eu/public_opinion/archives/ebs/ebs_333a_en.pdf

⁴ Action Plan on Organ Donation and Transplantation (2009-2015): strengthened cooperation between Member States, COM(2008) 819/3

It is important to underline that the legislation in question does not provide a basis for full harmonisation and accordingly many differences exist in the national approaches. Whilst this is fully legitimate, in some cases it may limit comparability of national transplant systems and mutual acceptance of authorisations and inspections, with consequences for potential cross-border movement of organs.

3.1. Designation and tasks of the competent authorities and overall set-up

Article 17 of Directive 2010/53/EU foresees that Member States shall designate one or more competent authorities (or delegated bodies) to take a series of measures:

- (a) establishing and keeping updated a framework for quality and safety,
- (b) ensuring the regular control or audit of procurement organisations and transplantation centres,
- (c) grant, suspend or withdraw the authorisations of procurement organisations or transplantation centres,
- (d) put in place a reporting system and management procedure for serious adverse events and reactions,
- (e) issue appropriate guidance to healthcare establishments, professionals and other parties involved in all stages of the chain from donation to transplantation or disposal,
- (f) participate in the network of competent authorities and coordinate at national level input to the activities of that network,
- (g) supervise organ exchange with other Member States and with third countries,
- (h) ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ transplantation activities.

All Member States have appointed competent authorities at national level to ensure oversight. Competent authorities can also be appointed at infra-national level (regional or local) or at the supra-national level (European Organ Exchange Organisations, EOEOs). Fourteen countries only have authorities at national level (BG, CY, CZ, EE, EL, IE, LT, LV, MT, PL, PT, RO, SK, UK), while others also report to have authorities at regional level and/or supra-national level. The total number of competent authorities at national level is 68 (an average of 2.3 authorities declared per country). This includes 21 delegated bodies.

Ministries of Health often play a key role in the implementation of Directive 2010/53/EU. In five countries, delegated bodies include hospitals. Eurotransplant and Scandiatransplant, two EOEOs, were reported by respectively eight and four countries as delegated bodies.

Key tasks under Article 17 of Directive 2010/53/EU which are typically performed at national level include (a) *framework for quality and safety*, (d) *SARE (Serious Adverse Reaction and Events)/biovigilance*, (e) *issue guidance*, (f) *attend meetings of the network of competent authorities*, and (h) *personal data protection*. Unless the countries have regions with important responsibilities (see next section), the tasks (b) *control and audit*, and (c) *authorisation* are also mainly implemented at national level.

Authorities at regional level can be administrative entities which have decentralised powers or specific responsibilities/task allocation. For instance, Sweden reported four hospitals having a coordination role for a whole region, thus de facto being delegated bodies at regional level. Among the nine Member States which report a role for regional competent authorities, the

most common tasks are (b) *control and audit* (in six countries) and (c) *authorisation* (in seven countries). The total number of tasks assigned to the regional competent authorities varies according to the countries from a single task (Finland) to six tasks (Denmark and Spain).

Two EOEOs exist at the European level which were entrusted with a task pursuant to Article 17 of Directive 2010/53/EU. The EOEOs are Eurotransplant (AT, BE, DE, HR, HU, LU, NL and SI), and Scandiatransplant (DK, FI, NO, SE)⁵. Also the South Alliance for Transplantation (SAT) is an EOEO created in 2012. SAT is however not reported to be directly involved in the tasks of Article 17. Where a country is member of an EOEO, task (g) *supervision of cross-border exchange* is indeed implemented by or with the support of this EOEO. Often the EOEO is also associated for task (a) *framework for quality and safety*. The other most commonly performed tasks by EOEOs include (d) *reporting and management of (SARE)*, (f) *participation in network of competent authorities*, and (h) *personal data protection*. It needs however to be noted that even within the same EOEO, members do not report exactly the same tasks, thus showing that different approaches or agreements might be in place between each country and the EOEO. It is important to note that some countries concluded bilateral agreements (for exchanging organs or transplant patients) with other countries or partners (healthcare establishments): CY with AT (for lungs), MT with IT. Three countries (CY, IE and LV) report exchanging organs with or sending/receiving patients to/from other countries on a bilateral case-by-case basis outside any agreement.

To conclude, three types of organisational “models” can be defined: i) countries operating with authorities only at national level (14 countries), ii) countries operating with authorities at national and regional levels (3 countries) and iii) countries operating with EOEOs (12 countries). In all three settings, multiple authorities and bodies can be involved to implement the tasks, in line with size, healthcare organisation and capacities of each country concerned.

Member States with a unique authority or a limited number of bodies and levels allow for a clearer identification of authorities in charge of the tasks under Article 17, as well as for other tasks outside the scope of this Directive such as consent systems, managements of waiting lists or allocation of organs, and for accountability in general.

Wherever different oversight activities (authorisation, inspection, vigilance) are undertaken by different authorities, communication and coordination needs to be ensured. A well-informed and strong national coordinating contact point is therefore essential, in particular where competent authority responsibilities are shared among multiple organisations and levels. Irrespective of the organisational set-up, it is important that authorities have appropriate resources at their disposal to carry out the required duties, as well as to ensure their independence from economic operators in the sector and from other undue influences.

3.2.Organ donation and procurement

To ensure quality and safety in the donation, procurement organisations play a key role.

3.2.1. Authorisation of procurement organisations

Articles 5, 6 and 17 of Directive 2010/53/EU require that procurement organisations are duly authorised and have at their disposal adequate personnel, material and equipment. In view of the wide concepts of "procurement organisation" and "authorisation" provided for in Article 3

⁵ Iceland is also member of Scandiatranplant but is not captured in the present report (not EU Member State).

of Directive 2010/53/EU, a wide range of entities can fulfil the requirements. Authorisations for procurement organisations are granted at the level of the healthcare establishment in the majority of countries (27/29). Additionally, they are granted to the team or unit of the hospital (9/29); to any authorised body which coordinates the procurement of organs (8/29); or to any authorised body which undertakes the procurement of organs (4/29). Such authorisations are also granted to individual healthcare professionals (7/29).

All countries reported having an authorising scheme in place for procurement organisations, and 26 reported that all the existing procurement organisations had effectively been granted an authorisation. Three Member States are still in the process of granting authorisations. Additionally, some Member States combine authorisations for procurement organisations and transplantation centres.

In 11 EU Member States (DK, EL, ES, FR, HR, IT, LT, MT, PL, RO, SI), authorisations of procurement organisations are limited in time: for fixed periods, ranging from two to five years, in eight countries or for variable periods in three other (for details see Figure 7 in the Staff Working Document). Where durations of authorisations are variable, validity terms are set according to different criteria. Often, the scheme for renewal of authorisation requires that the criteria applied to grant the initial authorisation are met again. A few countries report having withdrawn authorisations, usually temporarily, because the initial conditions for granting the authorisation were no longer fulfilled (e.g. due to the departure of key health professionals).

3.2.2. Procurement teams coming from abroad to procure organs

It is current practice in Europe that procurement teams from partner countries come over, within established cooperations, to procure organs usually to be transplanted in this partner country. This avoids loss of organs (from existing donors) that would otherwise not be procured. For example, a heart or lung procurement team might go over to a country with only renal or hepatic transplant programmes where hearts or lungs would not be transplanted.

26 Member States reported that procurement teams come from abroad on a regular or on an ad-hoc basis. In 21 of them, such activities are performed within the framework of a fixed collaboration, most frequently with or within Eurotransplant or Scandiatransplant. Five Member States also report to receive procurement teams outside fixed collaborations, while several countries have (also⁶) bilateral collaborations with other, often neighbouring countries (e.g. FI and EE, LU and FR, MT and IT, PT and ES, SK and CZ, CY and IT or UK).

3.2.3. Ensuring procurement organisations' compliance with the Directive

To secure a framework for the quality and safety of procurement activities, Member States must establish oversight, using several means, often combined: mainly by control, audit or inspection of procurement centres (conducting on-site inspections) or by desk-based analysis of the mandatory documentation.

22 countries reported on-site controls, audits or inspections of procurement centres. Desk-based analysis of the mandatory documentation is also a frequently used in 20 Member States. 16 countries report to use both control/audit of procurement organisations and desk-based analysis. These figures suggest that the combination of different measures may be the most successful way to ensure that the requirements of the Directive are fully met.

⁶ One country can be involved in different types of collaborations.

Among the 22 countries implementing inspections, 12 have defined inspection schemes at national level. The frequency ranges from every year to every three or five years, with a two-year interval being most common (occurring in seven countries). In some Member States, schemes for inspections of procurement organisations are set at regional level and therefore vary between regions (Germany, Italy, Spain). Three countries reported risk-based inspection schemes (Denmark, Estonia, Finland), which is also used in other sectors, such as the blood and tissues and cells sector. Rules for inspection and control have not been fixed so far in three countries (Belgium, Portugal, Norway).

3.2.4. Personnel involved in the procurement

Different approaches are used to assess the competency of healthcare personnel: verifying the qualifications at the moment of recruitment (23 countries), completion of regular training programmes (24 countries) or additional certification (11 countries). All Member States reported at least one of these three measures. Most Member States combine different methods, which may be a comprehensive way to meet this requirement.

Different kinds of healthcare personnel are involved in procurement and donation activities (often, but not only, so-called “transplant donor coordinators” or “key donation personnel”, nurses/doctors, different specialties etc.). The profiles also depend upon the healthcare and educational systems of the Member States concerned.

Training can be provided at the international level through congresses organised by professional societies or sessions organised by EU-funded projects (for example ETPOD, the *European Training Program on Organ Donation* or the pilot project on training and social awareness, see also section 3.5.). Continuous training programmes are also offered at national, regional and even local (hospital) level. Few Member States offer training at all levels. Training is provided by specialised bodies including foundations, healthcare establishments, professional associations and societies.

3.2.5. Consent system for organ donation

Three Eurobarometers⁷ carried out at EU level since 2002 reveal that EU citizens are largely supportive of organ donation, independently of the consent system in their country.

Two main consent systems exist in Europe: an “opt-in” system under which donors are required to explicitly give their consent for organ donation, and an “opt-out” system, where consent is presumed unless a declaration to the contrary is made before death. Regardless of the consent system applied in the country, it is standard practice to approach family members of the deceased prior to any procurement decision.

Figure 3 presents national consent systems as reported (note that consent systems are not subject to Directive 2010/53/EU). Sixteen Member States and Norway have adopted an opt-out system at national level for organ donation. Seven Member States have an opt-in system in place while four countries have a mixed system (e.g., where different regions have different systems).

3.2.6. The selection and protection of living donors

For some organs such as kidneys and livers (and very experimentally lungs), living donation is possible. This allows for a complementary source of organs. However, removing an organ from a healthy person is an invasive measure and can have medical, psychological, social and

⁷ See footnote 5 page 1, last Eurobarometer: http://ec.europa.eu/public_opinion/archives/ebs/ebs_333a_en.pdf

economic consequences. Hence, living donors must be carefully screened, selected and followed up, as laid down in Article 15 of the Directive.

Most countries have introduced registers or records for living donors (23/29). 17 countries reported having already initiated a register before the adoption of the Directive, while others have launched such records in 2014 or 2015. In most of these Member States, record keeping is set at national level (16/23). Four Member States reported that a record is kept at the international level, their national data on living donors being included in the relevant record hosted by their EOEO (Belgium with Eurotransplant; Denmark, Sweden and Norway with Scandiatransplant). A few Member States specified that a record is locally kept by each transplantation centre. Significant differences are noted between Member States in the content and type of data captured in the register. Six countries reported not to have a register in place, but three of them plan to establish one soon (Croatia, Portugal, Slovenia).

Over the last years, the European Commission co-financed several projects (see section 3.5.) to support Member States in these efforts. The ACCORD guidelines and standards for the set-up and implementation of such registers are considered to be a benchmark, and the development of a model for a (European) Register of (national/local) Registries, aimed at collecting living donor follow-up data in an international database, was tested. A recent Council of Europe Resolution explicitly mentions ACCORD deliverables as a key reference⁸, confirming and expanding the recognition of their value also to non-EU countries.

The majority of countries (27/29) provide a follow-up to living donors after donation. Some countries have set fixed periods for conducting medical follow-ups, which occur on a regular basis varying from a week after donation and two weeks after donation, to monthly or yearly medical evaluations. 16 countries provide lifelong medical attention, while seven have defined fixed terms for their follow-up, ranging from one year to thirty years. In all 27 countries where a medical follow-up is provided to donors, such follow-up includes a review of the general health status of the donor, evaluation of any complication and functioning of the remaining organ. The medical treatment provided is assessed and blood pressure or blood status are considered in 26 countries. Psychological aspects are considered in 21 countries.

Overall, the follow-up of living donors and the development of registers to document this follow-up are important aspects in the implementation of the organ legislation and still areas where Member States need to make progress. The Commission intends to continue to support Member States.

3.2.7. The follow-up of transplanted patients

While the follow-up of living donors is a requirement of Directive 2010/53/EU, the follow-up of transplanted patients is left to Member States' decisions^{9 10}. To support Member States, the

⁸ Resolution CM/Res(2015)11 on establishing harmonised national living donor registries with a view to facilitating international data sharing and its Explanatory Memorandum - See more at: https://www.edqm.eu/sites/default/files/resolution_on_establishing_harmonised_national_living_donor_registries_with_a_view_to_facilitating_international_data_sharing_2015_11.pdf
<https://www.edqm.eu/en/organ-transplantation-recommendations-resolutions-74.html>

⁹ Recital 24 of the Directive recognises that the competent authorities should have a key role to play also in this matter: "The competent authorities [...] should have a key role to play in ensuring the quality and safety of organs during the entire chain from donation to transplantation and in evaluating their quality and safety throughout patients' recovery and during the subsequent follow-up. For that purpose, besides the system for reporting serious adverse events and reactions, the collection of post-transplantation data is needed for a more comprehensive evaluation of the quality and safety of organs intended for transplantation. Sharing such

European Commission co-funded the EFRETOS project which aimed at establishing common definitions for the evaluation of the results of transplantation, and at promoting a model for a registry of registries with follow-up data. In addition, registers developed and held by transplant professionals and societies - such as ERA-EDTA¹¹ for kidneys or ELTR¹² for livers - play a key role. Several competent authorities do already collaborate with these professional associations and the European Commission encourages such cooperation by inviting them to meetings with authorities.

3.3. Authorisation of transplantation centres and personnel

The results of the survey regarding transplantation activities are very similar to the results on organ donation and procurement (section 3.2.). Also here, the Directive 2010/53/EU provides for a broad definition of transplantation centres (different levels possible) and the definition of “authorisation” encapsulates different concepts. Authorisations for transplantation centres are granted at the level of the healthcare establishment in the majority of Member States and Norway (26/29). Additionally, they are granted to the team or unit of the hospital (11/29) or to any authorised body which undertakes the transplantation of organs (2/29).

All Member States mentioned to have authorisation schemes in place for transplantation centres (in six Member States the regional level in charge of authorising), and 25 countries confirmed that all transplant centres had effectively been authorised, while four countries are still granting (or renewing) authorisations to (some of) their centres (delays relate to late transposition of the Directive 2010/53/EU, to adoption of secondary legislation and/or to practical implementation issues).

14 Member States and Norway reported non time-limited authorisations. The other countries authorise for fixed (one, two, three, four or five years) or variable periods.

In most countries (27/29), compliance with the Directive 2010/53/EU is verified through on-site controls, audits or inspections of the transplantation centres. Many Member States (19/28) perform desk-based analysis of mandatory documentation. More than half use both methods (17/29).

23 countries ensure qualification of staff by verifying this at the time of recruitment. Regular training programmes are foreseen in 24 countries. Several countries also report to rely on trainings organised by professional societies or organisations for example via the Section of Surgery and the European Board of Surgery of the European Union of Medical Specialists operating in close collaboration with the European Society of Organ Transplantation.

3.4. Framework for quality and safety

information between Member States would facilitate further improvement of donation and transplantation across the Union.”

¹⁰ Task (e) foreseen for competent authorities under Article 17 also includes this aspect: “issue appropriate guidance to healthcare establishments, professionals and other parties involved in all stages of the chain from donation to transplantation or disposal, which may include guidance for the collection of relevant post-transplantation information to evaluate the quality and safety of the organs transplanted.”

¹¹ Register of the European Renal Association - European Dialysis and Transplant Association:

<http://www.era-edta.org/>

¹² European Liver Transplant Registry: <http://www.eltr.org/>

While the authorisation and inspection of procurement organisations and transplantation centres are important oversight elements, other measures also contribute to quality and safety of donation and transplantation activities. For example the adoption of operating procedures for different actions (listed in the Directive) contributes to a framework for quality and safety from donation to transplantation or disposal.

All 29 countries reported having implemented operating procedures to verify the completion of the organ and donor characterisation Article 4 2. (c) (in accordance with Article 7 of the Directive 2010/53/EU). However, three countries reported not to have any operating procedures in place at present for the other areas in Article 4 (2), such as the verification of donor identify, verification of consent or ensuring traceability.

Countries seem to be at different stages in the adoption and implementation of operating procedures. Some have completed the process and a framework for quality and safety is fully in place, while others have partially adopted a framework and the adoption process and/or implementation for the remaining operating procedures is ongoing. Some countries declared having operating procedures in place but also mentioned that these might vary between hospitals or regions. Only a few countries seem to have national operating procedures in place. Also in this area, the European Commission supports Member States via EU-funded projects and by sharing documents made available.

In conclusion, operating procedures seem to be in place and implemented for most donation and transplantation activities in Member States, however there is still room for improvement and for learning from each other's experiences in this area.

3.5. EU support for the implementation of the EU Organs Directive and of the “EU Action Plan on Organ Donation and Transplantation (2009-2015)”

The European Commission has been supporting the national implementation of the legislation by a variety of means ranging from regular expert meetings to EU-funded projects. The meetings of the expert sub-group on organ donation and transplantation (which is part of the Competent Authorities on Substances of Human Origin Expert Group - CASoHO E01718) allow for sharing of best practices and discussing common problems.

Since 2008, a number of projects have been funded under the multi-annual programmes for Union action in the field of health, providing support to Member States when implementing requirements of Directive 2010/53/EU and of the EU Action Plan, with a particular focus on:

- training of transplant donor coordinators with the European Training Programme on Organ Donation (ETPOD)¹³ or with the “train the trainers” dedicated course¹⁴;
- improving quality systems with ODEQUS¹⁵;
- developing living donation with EULID, ELIPSY, EULOD, ACCORD¹⁶ or the Toolbox¹⁷ prepared within the Living donation Working group;
- supporting the follow-up of transplanted patients with EFRETOS¹⁸;

¹³ ETPOD: <http://etpod.il3.ub.edu/> See also: <http://ec.europa.eu/chafea/projects/database.html?prjno=2005205>

¹⁴ European Training Course in Transplant Donor Coordination in the European Union

¹⁵ European Quality System Indicators and Methodology on Organ Donation (ODEQUS): <http://ec.europa.eu/chafea/projects/database.html?prjno=20091108>

¹⁶ <http://www.accord-ja.eu/>

¹⁷ http://ec.europa.eu/health/blood_tissues_organ/docs/eutoolbox_living_kidney_donation_en.pdf

¹⁸ European Framework for the Evaluation of Organ Transplants: <http://www.efretos.org/>

- facilitating cross-border organ exchange with COORENOR, MODE and FOEDUS;
- improving awareness-raising with EDD, FOEDUS and the Commission's Journalist Workshops¹⁹;
- investigating organ trafficking with HOTT²⁰ (Combatting trafficking in persons for the purpose of organ removal);
- supporting non EU countries with dedicated workshops and a direct grant to the Council of Europe;
- increasing deceased donation rates thanks to dedicated strategies;
- addressing specific national issues with twinning activities within ACCORD,
- as well as mapping efforts under the EU Action Plan via the ACTOR²¹ (mid-term review) and FACTOR studies (final review).

Two projects²² will also start by the end of 2016 to further support Member States in the field.

4. Conclusion

Overall, national authorities and oversight mechanisms seem to be established in all Member States and Norway to ensure safety and quality standards of human organs. However, in line with the quite general legal requirements in EU legislation, the set-up of the national organisations can be fragmented and vary significantly between countries, which increases the importance of a good coordination within and between countries.

Some work might still be needed to improve MS follow-up, both of recipients and of living donors, and on some aspects of the framework for quality and safety, for example for operating procedures or for authorisations. Some of this work is already being developed through Commission funded work. Future implementation surveys and reports will be able to demonstrate Member States' progress.

¹⁹ http://ec.europa.eu/health/blood_tissues_organ/events/journalist_workshops_organ_en.htm

²⁰ <http://hottproject.com/>

²¹ http://ec.europa.eu/health/blood_tissues_organ/docs/organs_actor_study_2013_en.pdf

²² See two Financing decisions and annexes adopted on 10 July 2015 : http://ec.europa.eu/health/blood_tissues_organ/key_documents/index_en.htm#anchor3