



European activities in the field of Organ donation and transplantation

5th Journalist Workshop on Organ donation and transplantation
26 November 2014, Brussels

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■ 1) European landscape

- Organ donation
 - deceased donation
 - living donation
 - donation over time
- Transplantation

■ 2) EU action

- EU legislation
- EU Action Plan
- EU-funded projects

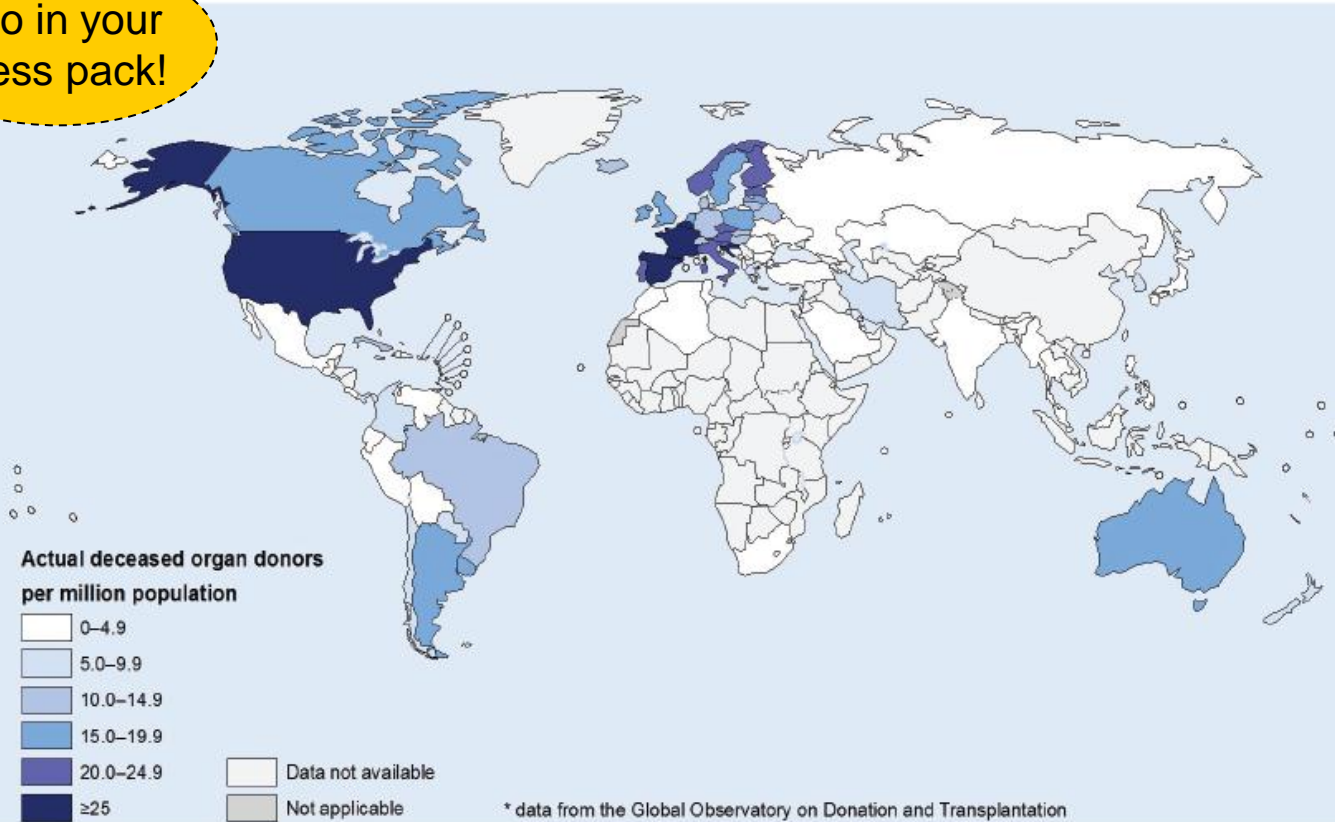
■ 3) **Communicating** about organ donation & transplantation

1) European landscape

Deceased donation (2012)

Actual donors from deceased persons, 2012*

Also in your press pack!



Thanks to Eurobarometers, we also know that **European citizens are in favour of donating their organs after death** (EU average: 55% say "yes, I would be willing to donate organs immediately after my death")

Eurobarometer 333a, October 2009

See also Eurobarometers 183.5 (Dec. 2002) and 272.d (Nov. 2006)

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: Global Observatory on Donation & Transplantation. Map Production: Health Statistics and Information Systems (HSI), World Health Organization

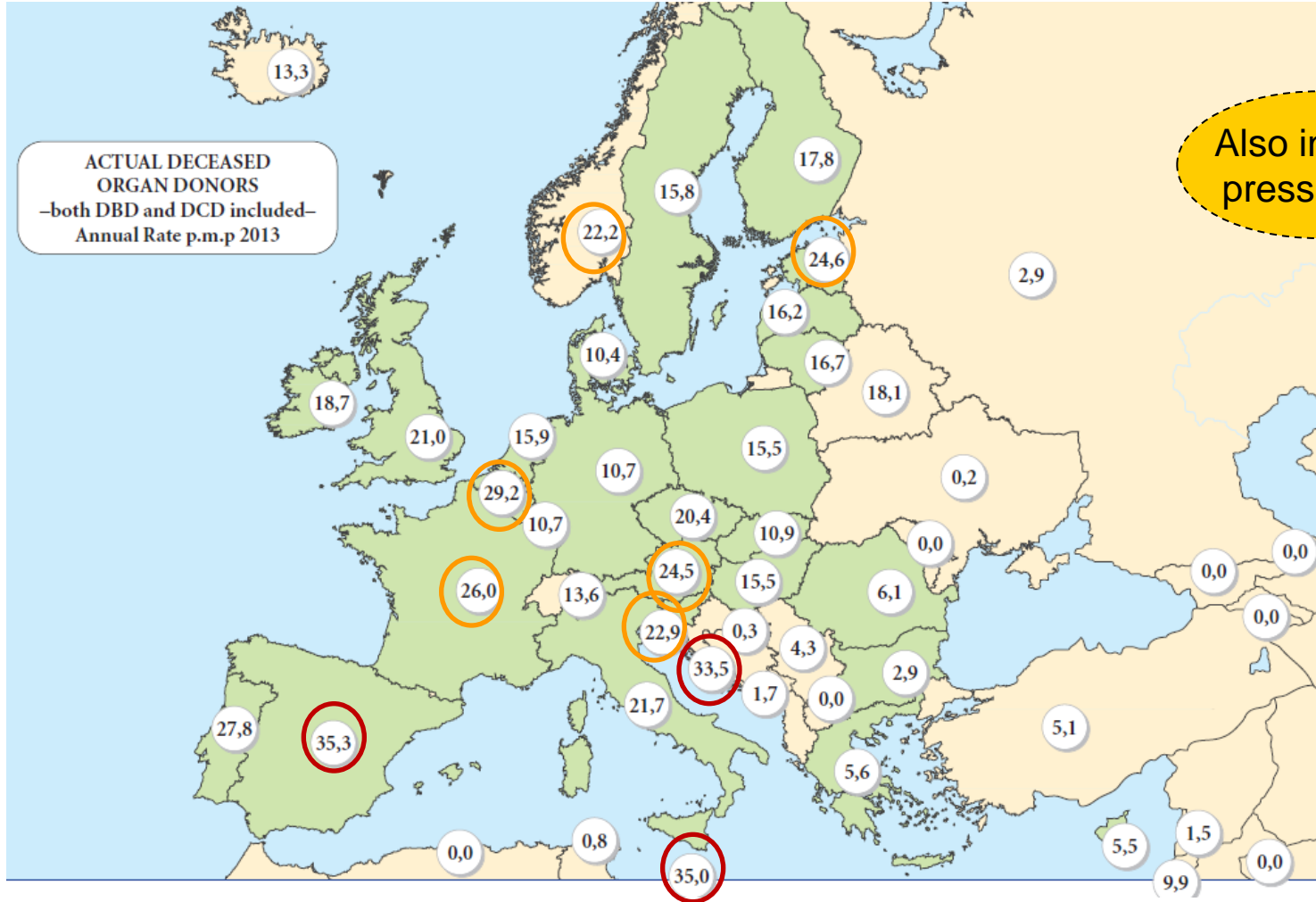
World Health Organization
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■ high deceased donation rates in Europe

Eurobarometers:

1) European landscape

Deceased donation (2013)



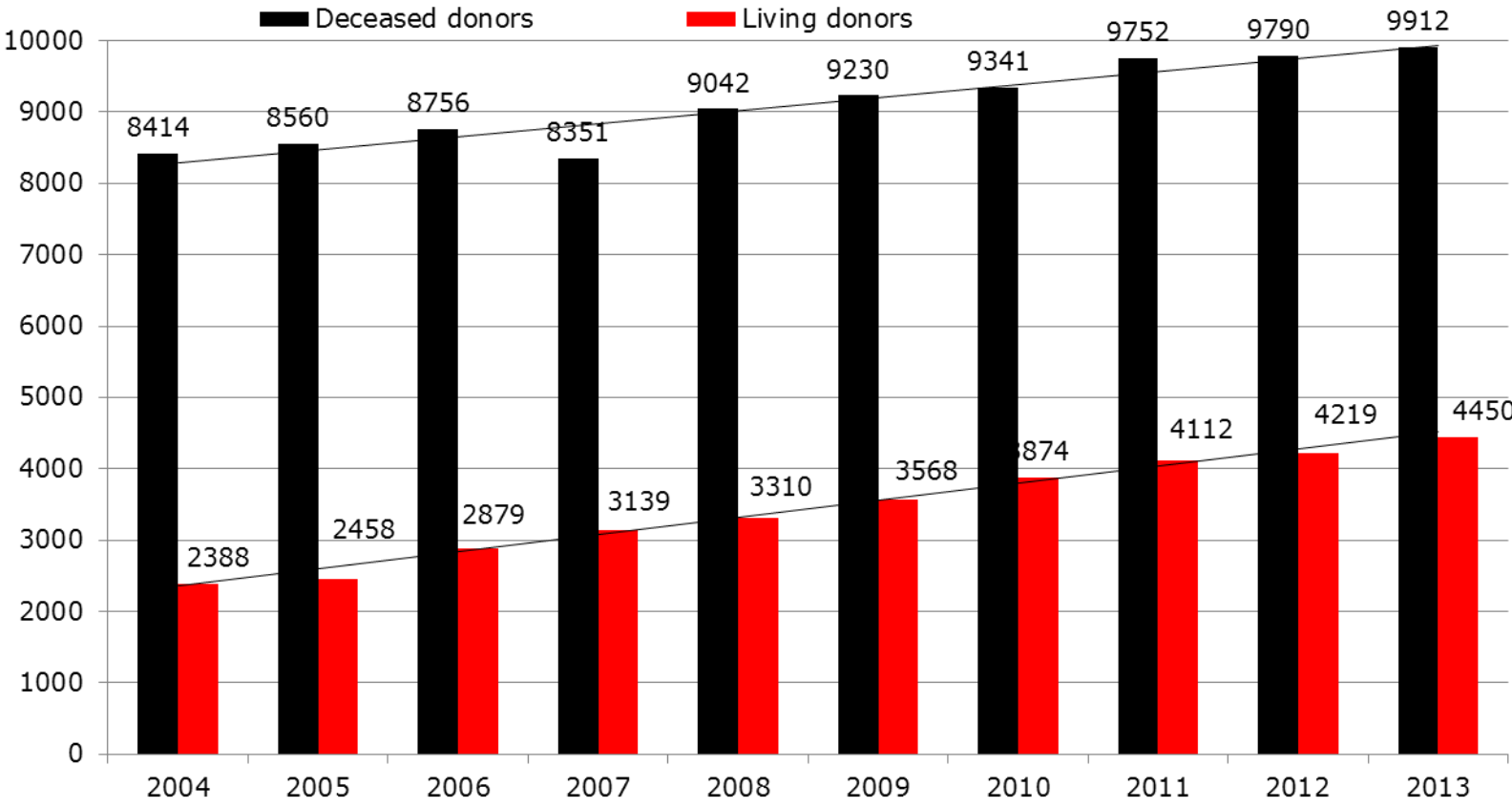
■ Highest rates of deceased donation (> 30 pmp) in the South of Europe



1) European landscape Donation over 10 years (EU, 2004 -2013)

Deceased and living donors in the European Union, 2004 to 2013

(All 28 EU Member States in 2013 are captured for all years in this graph, even if they joined the EU after 2004)



increase in deceased donation + 18 %

increase in living donation + 86 %

→ total increase in donation: + 33 %

Also in your press pack!

■ Constant increase in the EU in the last 10 years, thanks to living donation

1) European landscape Donation & Transplants



2013 data

EUROPEAN UNION DATA

TRANSPLANTS:

DONATION:

- living donors →

Kidney Transplants	Liver Transplants	Heart Transplants	Lung Transplants	Pancreas Transplants	Small Bowel Transplants	Patients Transplanted
19227 (21,8% LD)	7173 (3,6% LD)	2037	1825	865	38	31165

- Deceased donors →

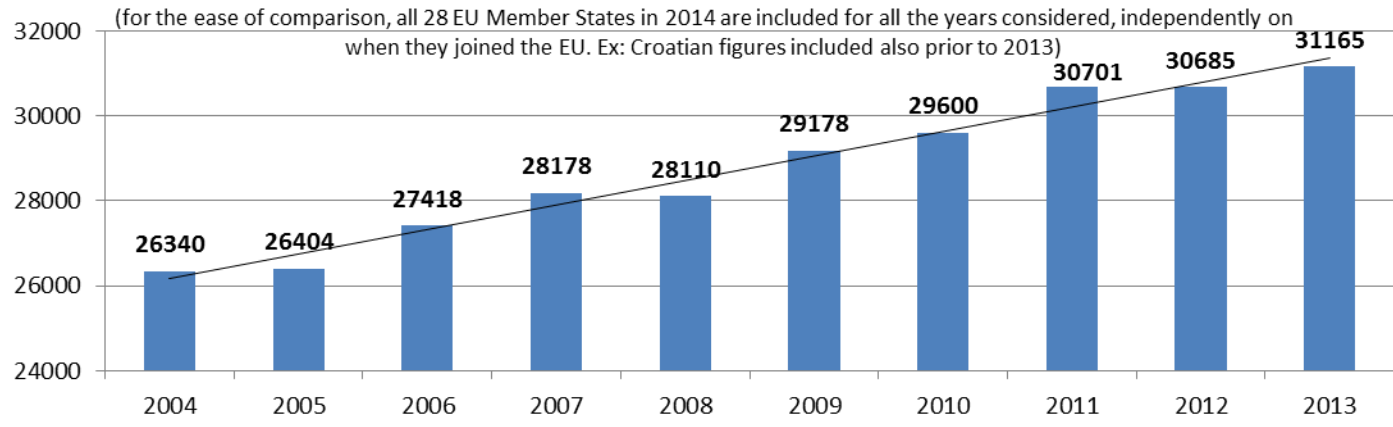
9912 ACTUAL DECEASED ORGAN DONORS (both DBD and DCD included)

*2013 data

N= 28 COUNTRIES (508,7 million inhabitants)

2004 to 2013

Organs transplanted in the European Union



Also in your press pack!

- Totally 31165 patients transplanted in the EU in 2013 (62 % kidney tx)
- 9912 deceased donors and 4450 living donors in 2013
- A constant increase since 2004**



1) European landscape

Transplants: Europe in the world

Also in your press pack!

European activities compared to global activity in organ transplantation

Source: 2013 and 2014 Transplant Newsletters, Global Observatory on Donation & Transplantation

2012 transplants	Kidney	Liver	Heart	Lung	Pancreas	Small bowel	Organs transplanted
Global activity (% living donation)	77818 (42,3%)	23986 (18,2%)	5935	4359	2423	169	114690
EU (with Croatia) (% living donation)	19085 (20,8%)	6973 (3,7%)	2004	1756	833	34	30685
% of global activity	24,5%	29,1%	33,8%	40,3%	34,4%	20,1%	26,8%
EU incl. HR + Iceland, Norway, Turkey (% LD)	22295 (32,2%)	8074 (16,8%)	2099	1809	867	39	35183
% of global activity	28,7%	33,7%	35,4%	41,5%	35,8%	23,1%	30,7%

→ **more than 25 % of transplants worldwide** took place in the **European Union in 2012** (one third for EU + Turkey, Norway, Iceland)

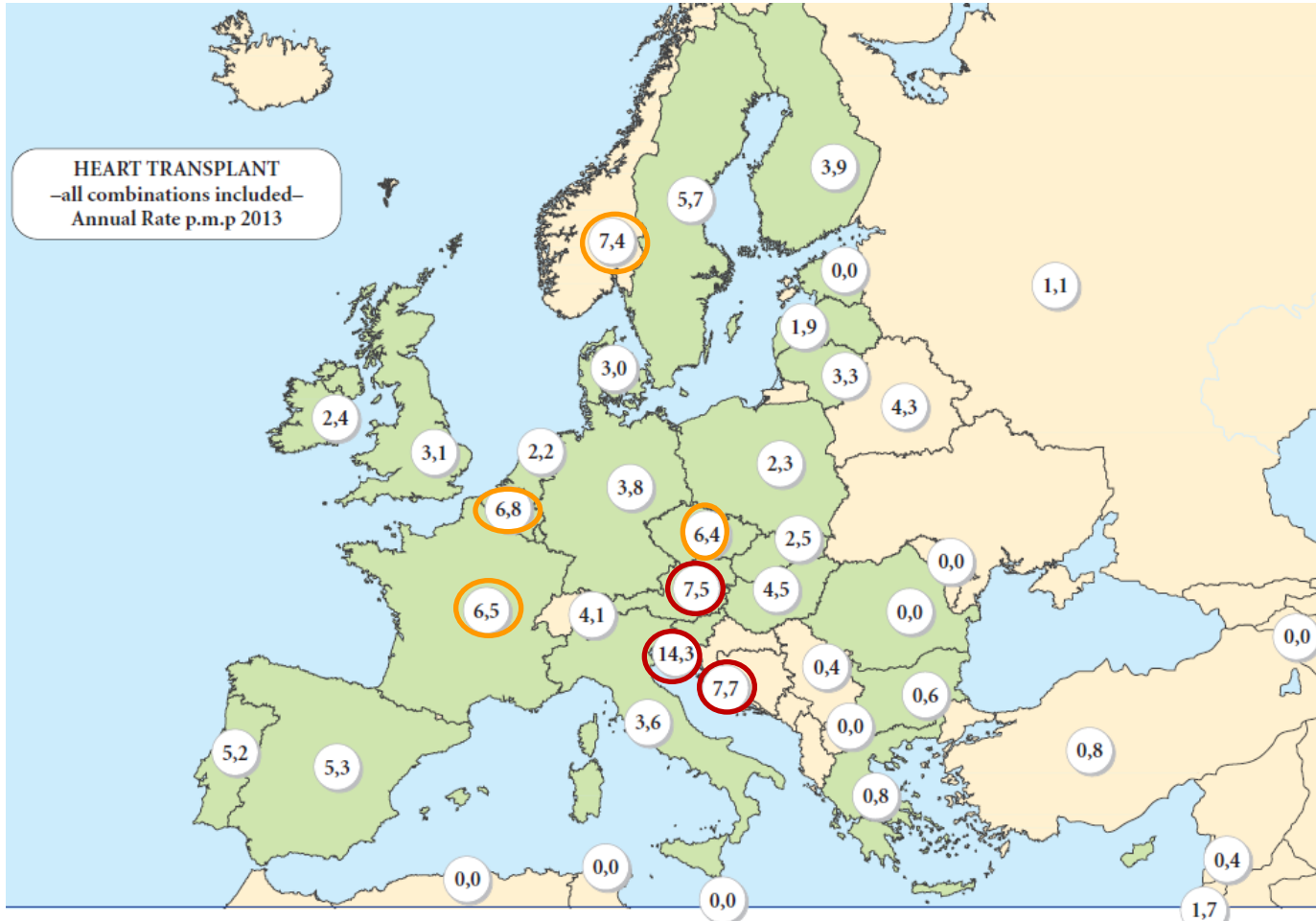
→ the rate of **kidney transplants from living donors** worldwide (42%) is twice higher than the rate for the European Union (21%)

→ for EU + Turkey, Norway, Iceland: 32 % due to high living donation rates in Turkey



1) European landscape

Heart transplants



- Heart transplants rates lower than kidney or liver transplant rates
- Some countries have no heart transplant programmes → high added value of cooperation/agreements with other countries, to propose solutions to their patients



1) European landscape Cooperation

More information
in your press pack!

- Many countries are members of "**European Organ Exchange Organisations**" (EOEOs)
 - Eurotransplant: 8 EU Member States (Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands, Slovenia)
 - Scandiarttransplant: 3 EU Member States (Denmark, Finland, Sweden) + Iceland and Norway
 - South Alliance for Transplant: Now 5 partner countries: 4 EU Member States (France, Italy, Portugal, Spain) plus Switzerland and 1 observer: Czech Republic
- Many EU Member States have **bilateral agreements and/or fixed collaborations** with neighbouring countries, for example:
 - Spain - Portugal
 - Italy - Malta
 - Ireland - United Kingdom
 - etc.



■ 2) Action at the level of the European Union (EU)

- EU legislation:
 - Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation

- EU "Action Plan on organ donation and transplantation (2009-2015): Strengthened Cooperation between Member States"
(a Communication from the Commission)

- EU-funded projects
 - Research projects (see press pack)
 - Public Health projects

2) EU Action

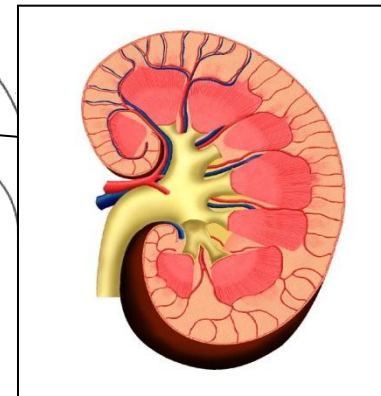
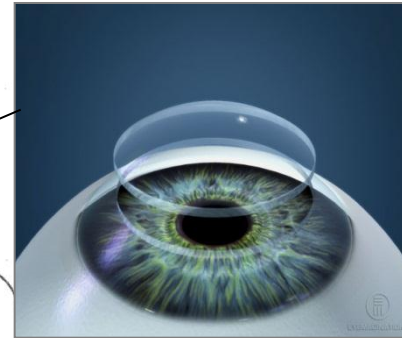
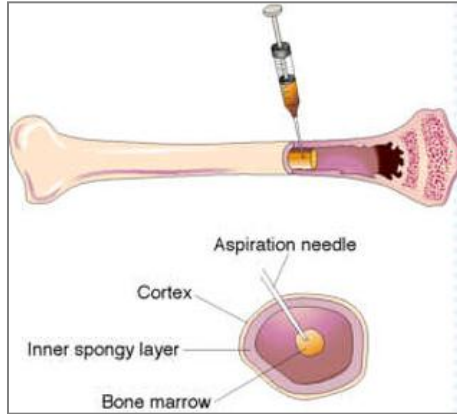
Legal basis for "substances of human origin" (SoHO)



European
Commission

Legal basis:
Article 168 of
the Treaty on
the Func-
tioning of the
European
Union:

"setting **high
standards
of quality
and safety
of organs**
and
substances of
human
origin, blood
and blood
derivatives"



**3 sectors
explicitly
mentioned in
the Treaty:**

→ **Blood and
blood
derivatives**

→ **Tissues and
cells**

→ **Organs**

Cover (even if not
explicitly listed):

- kidneys
- livers
- hearts
- lungs
- pancreas
- small bowel
- vascularised
composite
allografts



2) EU Action Legislation for human organs

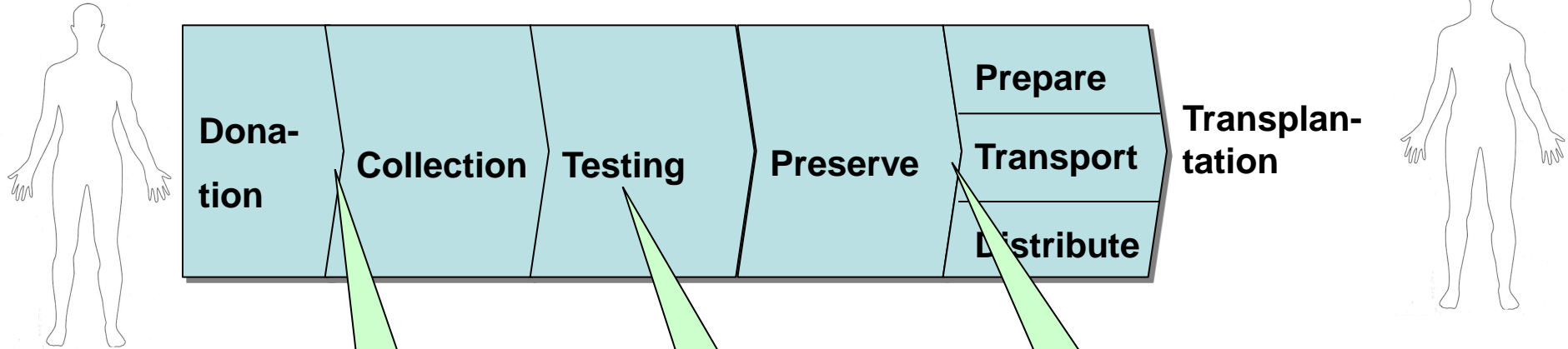
■ **Directive 2010/53/EU** of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation

- Adopted on 7 July 2010
- To be transposed by into national laws by 27 August 2012
- → EU network of National Competent Authorities meet and exchange twice a year
- Currently:
 - "transposition check" to verify if Directive correctly transposed
 - "implementing survey" to understand how the Directive is implemented in EU Member States

■ **Commission Implementing Directive** laying down information procedures for the exchange, between Member States, of human organs intended for transplantation

- Aligns communications on organ characterisation (offering), traceability and alerts
- Adopted on 9 October 2012, to be transposed by into national laws until 9 April 2014

- Chain from donation to transplantation, from donor to recipient



■ 3 levels:

- Procurement/transplant centres**
 Selection, consent...
 HIV, Hepatitis B, Hepatitis C...
 Processing Quality requirements
- National Competent Authorities**
 Oversight: vigilance, traceability, authorisation, inspection...
- European Commission**
 Support tools: traceability, rapid alert system system...



2) EU Action

Scope, key principles

- **Quality and safety of organs** (chapter II, Articles 4 to 12)
 - Framework for quality and safety
 - Procurement and procurement organisations
 - Organ and donor characterisation
 - Reporting system, management of serious adverse events & reactions
 - Healthcare personnel
 - Transport of organs
 - Transplantation centres
 - Traceability
- **Donor and recipient protection, donor selection and evaluation** (III)
 - Principles: voluntary and unpaid donation
 - Consent requirements
 - Quality and safety of living donation, protection of living donors
 - Protection of personal data, confidentiality and security of processing
- **Obligations of competent authorities, exchange of information** (IV)
 - Designations and tasks of CAs (autorisation, control/audit etc.)
- **Organ exchange with third countries and European Organ Exchange Organisations** (V)
- **General provisions** (VI): reports, penalties, transposition etc.



2) EU Action Outside the scope

- The following areas are **outside of the scope of the Directive**:
 - Consent systems (opt-in / opt-out)
 - Management of waiting lists
 - Allocation criteria
 - Ethical aspects, legislation around brain death
 - But internationally: medical consensus on when & how to determine brain death
 - Health systems and resources
 - Including decision to start/stop specific donation/transplantation programmes
- The areas remain **national competence**
- However, the Commission can encourage Member States to **share experiences through collaboration under the Action Plan** (voluntary tool)



2) EU Action

Non legal activities,
international cooperation

- with the **World Health Organisation** (WHO)
 - Mutual information
 - Ethical issues (non commercialisation etc.)
 - Declaration of Istanbul on Organ Trafficking and Transplant Tourism

WHO Guiding principles on transplantation (11):

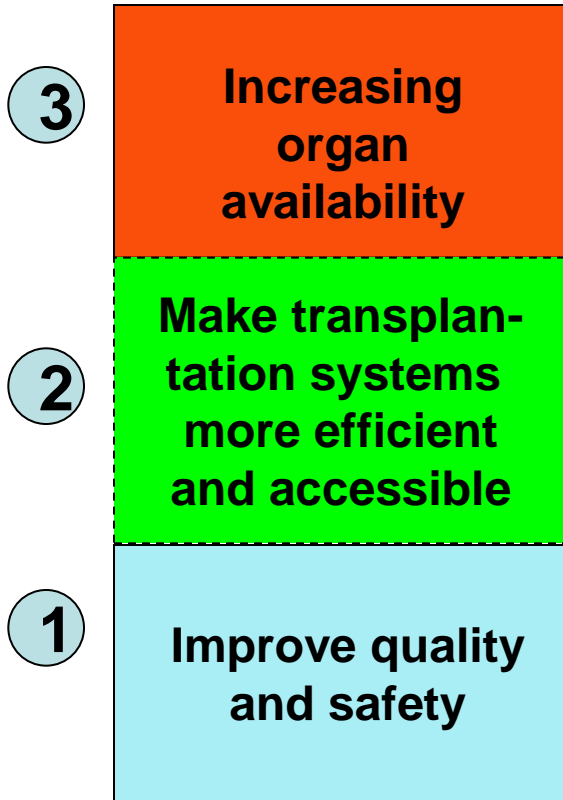
- 1: « Organs may be removed from the bodies of deceased persons for the purpose of transplantation if (a) any consent required by law is obtained, and (b) there is no reason to believe that the deceased person objected to such removal »
- 2: « physicians determining that a potential donor has died should not be directly involved in organ removal from the donor or subsequent transplantation... »
- 3: « Donation from deceased persons should be developed to its maximum therapeutic potential, but adult living persons may donate organs as permitted by domestic regulations. In general living donors should be genetically, legally or emotionally related to their recipients. » Other principles (no donation by living minor except narrow exceptions allowed under national law, no payment, allocation to be guided by clinical criteria and ethical norms etc.)

- with the **Council of Europe** (47 members, including EU Member States): for consistent transplant policies at European level
 - Guide on the quality and safety of organs → for healthcare professionals at hospital level (transplant coordinators for ex.)
 - Resolutions on transplant donor coordinators, living donation etc.
 - **Convention against Trafficking in Human Organs** (July 2014): complementary to EU legislation against trafficking in human beings (including for the purpose of organ removal)



2) EU Action The Action Plan

Communication from the Commission: « **Action Plan on Organ Donation & Transplantation (2009-2015): Strengthened Cooperation between Member States** » (December 2008)

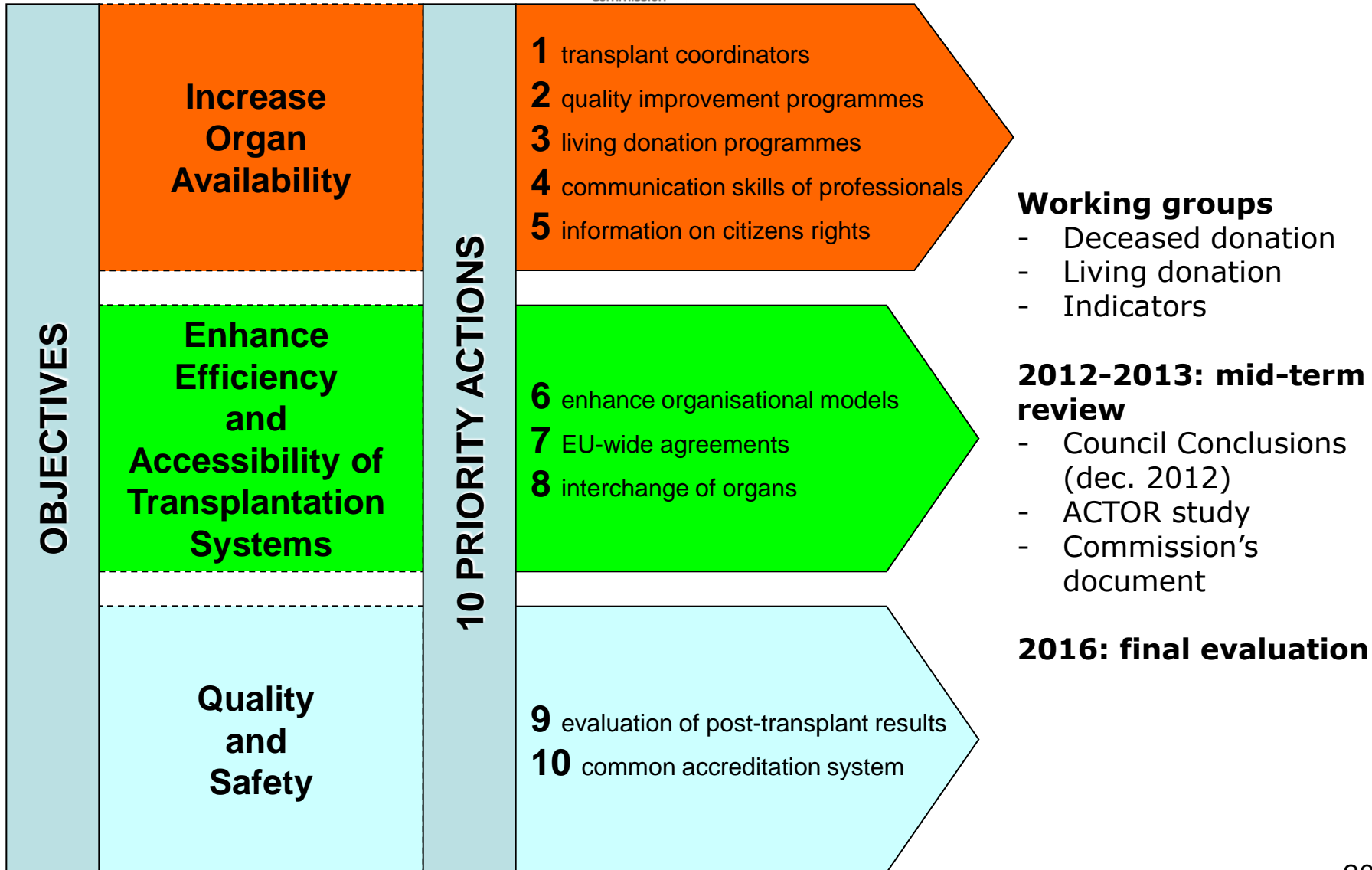


EU LEGAL FRAMEWORK
= Directive (July 2010)

10 PRIORITY ACTIONS
(2009-2015) = Action Plan
(Dec. 2008)



2) EU Action The Action Plan

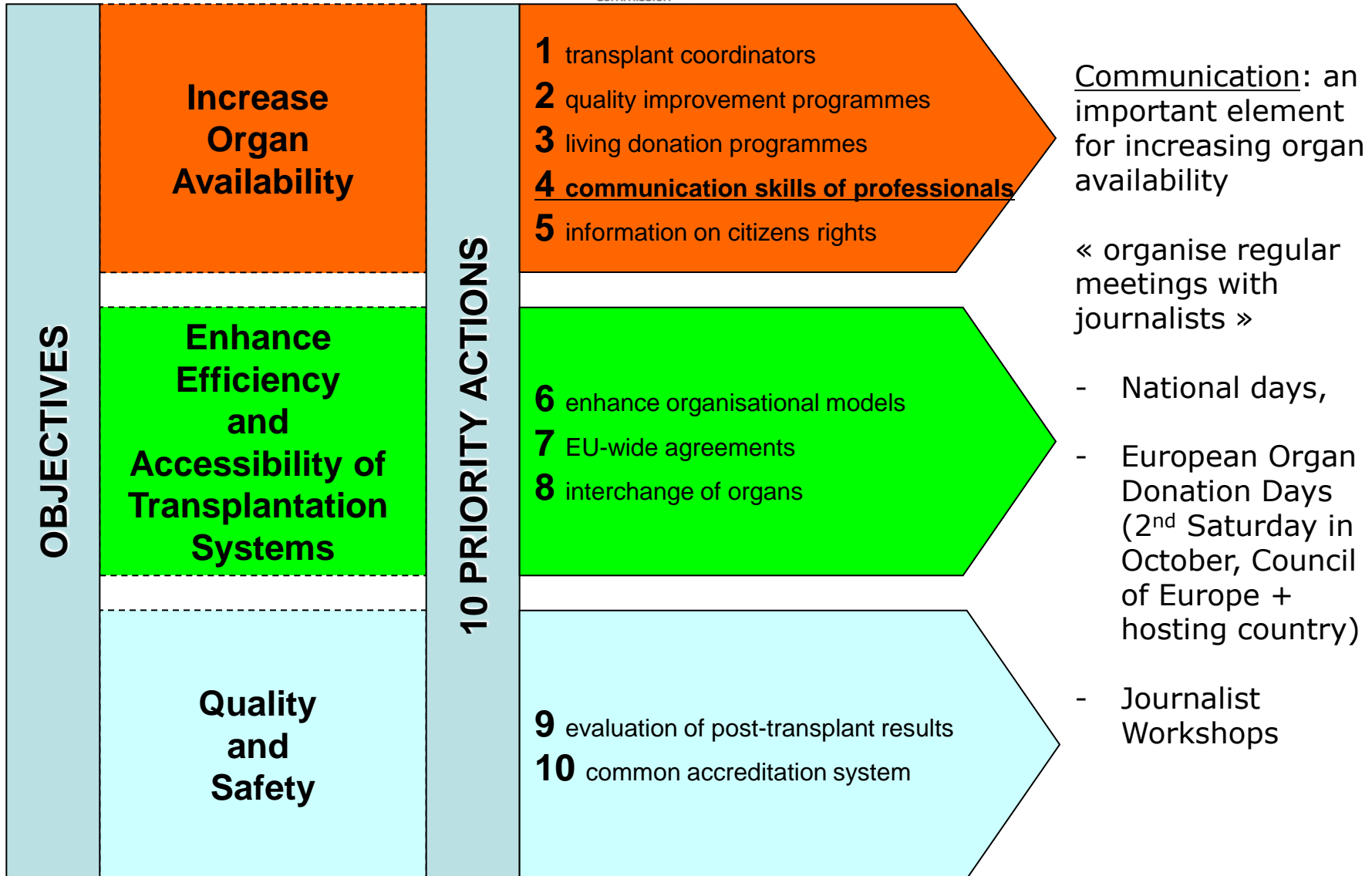




2) EU Action EU-funded projects some examples

- Research projects: on organ preservation, immuno-suppression, xenotransplantation etc.
- Public health projects:
- Project: “**Train the trainers in transplant donor coordination**” (2011)
 - for national/regional/local trainers (80 participants from all Europe)
 - to increase organ availability
- Joint action **ACCORD – Assisting Member States in reaching the full potential of deceased and living donation (2012-2015)**
 - Collaboration between transplant coordinators and intensive care units
 - Registers for living donors
 - Twinning programmes
- Joint Action **FOEDUS – Facilitating the Exchange of Organ Donated in EU Member States (2013-2016)**, to support cross-border exchanges
 - develop an IT tool to offer cross-border organs which cannot be used at national level
 - identify barriers to organ exchanges and encourage cross-border agreements to facilitate organ exchanges
 - agree on communication strategies

More information
in your press pack!





3) Communicating about organ donation and transplantation

■ **Communication - a topic for several EU-funded projects:**

- Train the trainers in transplant donor coordination (train coordinators)
- European Donation Days (toolkit for event organisers)

<http://www.europeandonationday.org/>

- FOEDUS (support Competent authorities developing their communication capacities: optimise initiatives to improve public awareness)

■ **European Organ Donation Days:** Council of Europe event, each year hosted in a different country (hosted in Belgium in 2012, in Italy in 2013, Portugal in 2014)

<http://www.eodd2014.it/eodd-2014-eng/>

<http://eodd2013.be/en>

■ **Personal stories / celebrities**

- famous persons in the country (donor, transplanted patient, opinion leaders, including religious leaders)
- human stories (not necessarily famous persons)

3) Communicating about organ donation



■ At the occasion of the 2014 European Organ Donation Day in Rome (Italy), the Pope Francis made a declaration in favor of organ donation at the end of the Holy celebration: **donation of organs after death is "a distinctive witness of love for others" and "abuses and trafficking (of organs) should be avoided"** (8 Oct. 2014)

http://w2.vatican.va/content/francesco/it/audiences/2014/documents/papa-francesco_20141008_udienza-generale.html (in Italian only)

■ Already on 19 September 2014, Representatives from the (WHO) Declaration of Istanbul Custodian Group (DICG) had an audience with the Pope Francis, who declared: **"Organ trafficking and commercialization are immoral - DICG is at liberty to convey this message on my behalf"**



■ President of Turkish Religious Affairs (Mehmet Görmez, 2013) at the conference which held by the Ministry of Health and the Turkish Transplant Foundation **"all religions totally support the donation, there is no difference between Christian and Muslim world about this issue. Giving life to a person means giving life the whole humanity"**.



3) Communicating about organ donation Journalist Workshops



Comisarul european pentru sănătate, Tonio Borg, face o declarație în urma unei conferințe la un pacient transplantat. Fotografii de la al 4-lea workshop despre donarea și transplantul de organe (7 octombrie Bruxelles).



Interviu cu mama unui donator de organe decedat, RTL Croatia, în timpul celui de-al 4-lea workshop al jurnaliștilor despre donarea și transplantul de organe (7 octombrie, Bruxelles).

Organised in Brussels
by Commission in 2010,
2011, 2012, 2013... and
today



Voluntatea activității de transplant, în aplicarea recomandărilor din Planul de Acțiune UE, cum ar fi o prezentă creștere a coordonatorilor in-house în spitale (acțiunea prioritară nr. 1 a Planului de Acțiune). Aceste eforturi urfăse, conduse în mod activ de către coordonatorul național Victor Zota, arată de deja rezultate esențiale: cu 114 donatori decedați între 1 ianuarie și 30 octombrie 2013, România aproape că și-a dublat numărul de donatori decedați, comparativ cu întregul an 2012 (65 de donatori). În 2012, au avut loc aproximativ 250 de proceduri de transplant în România, față de peste 350 doar în primele 10 luni ale anului 2013.

ROMÂNIA APROAPE CĂ ȘI-A DOBLAT NUMĂRUL DE DONATORI DECEDAȚI COMPARATIV CU ÎNTREGUL AN 2012 (65 DE DONATORI). ÎN 2012, AU AVUT LOC APROXIMATIV 250 DE PROCEDURI DE TRANSPLANT ÎN ROMÂNIA, FAȚĂ DE PESTE 350 DOAR ÎN PRIMELE 10 LUNI ALE ANULUI 2013.

DONATORI DECEDAȚI VERSUS DONATORI ÎN VIAȚĂ
ȚĂRILE SUD-EUROPENE SUNT MULT MAI „SPECIALIZATE” ÎN DONĂRILE PROVENITE DE LA DONATORI DECEDAȚI, în timp ce în țările nordice există programe bine dezvoltate privind donarea de la donatori în viață. Criteriile de alocare a unui organ depind și de timpul de conservare pe unu respectiv tip de organ. Prin urmare, distanța și logistica joacă în totdeauna un rol important.

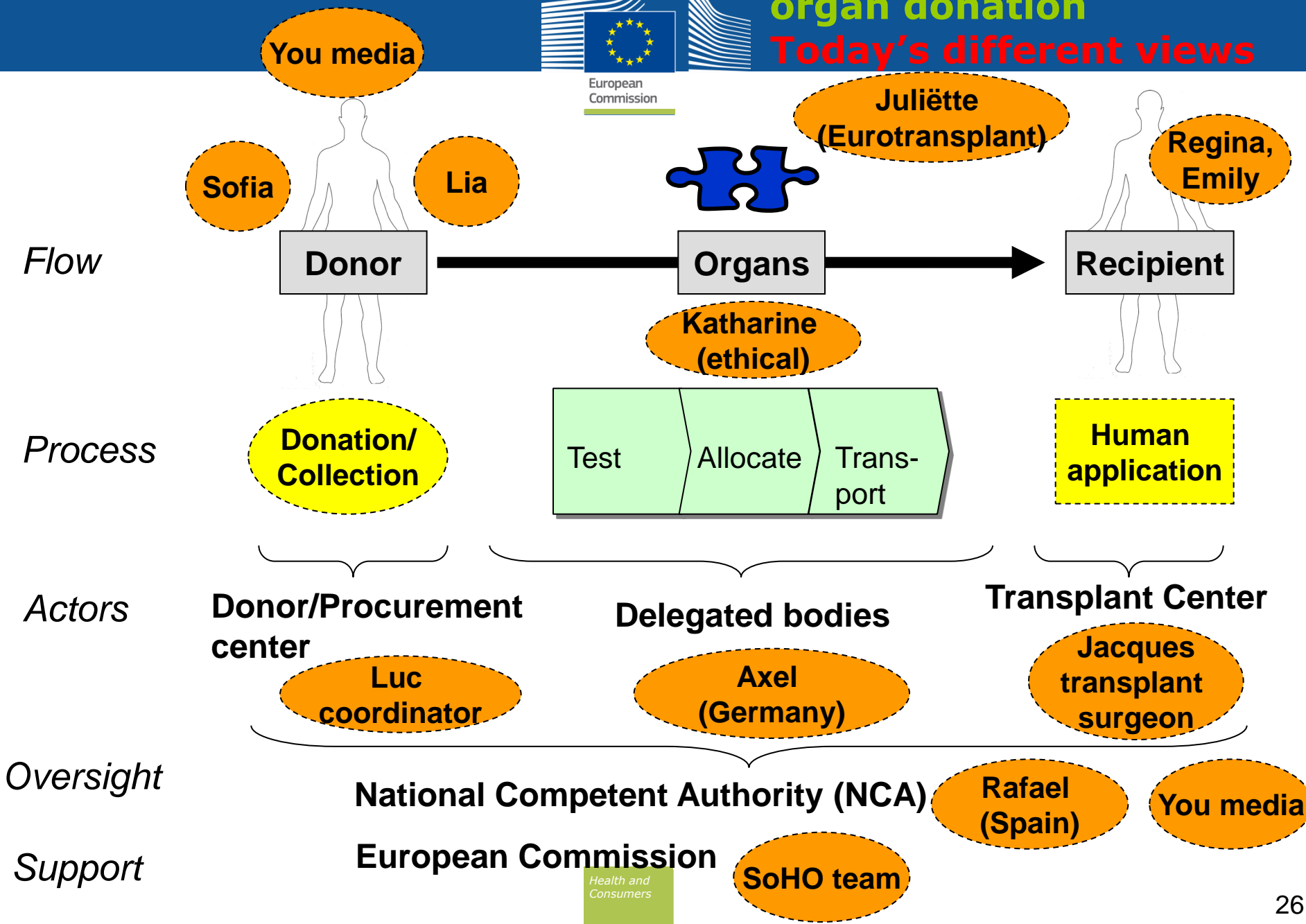
- Objective:** increase public awareness
- Participation:** totally 150 journalists from 30 countries, specialised & general media
- In press pack: also national contact points
- When shared with us by authors, **articles/press releases/videos** published on our website (and translated) after all editions

http://ec.europa.eu/health/blood_tissues_organs/events/journalist_workshops_organ_en.htm#fragment0



3) Communicating about organ donation

Today's different views



http://ec.europa.eu/health/blood_tissues_organs/policy/index_en.htm

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SoHO, support
Trainees*

THANK YOU FOR YOUR ATTENTION !